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Designing Disruption in Pharmaceuticals

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ARTICLE

DESIGNING DISRUPTION IN PHARMACEUTICALS

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CONTENTS

INTRODUCTION

Almost two millennia ago, Archimedes explained that the shortest distance between two points is a straight line.[1] That fundamental principle has been lost in the strange, meandering design of the nation's pharmaceutical supply system. The result, as Archimedes would have predicted, is disastrous for the system's efficiency—not to mention for patients, payors, and taxpayers alike.

Rather than a straight line, the flow of products and payments for prescription drugs more closely resembles a Rube Goldberg machine,[2] in which payment

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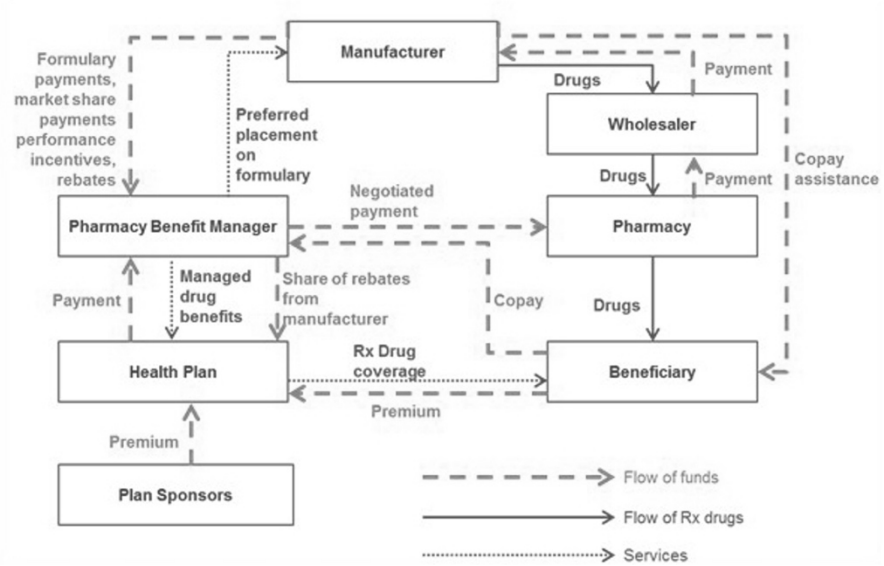
[1] *See* ARCHIMEDES, ON THE SPHERE AND CYLINDER bk. 1, at 3 (Thomas L. Heath ed., trans., Cambridge Univ. Press 1897) (c. 225 B.C.E.); *see also* THOMAS L. HEATH, ARCHIMEDES 36 (London, MacMillan & Co. 1920).

[2] Rube Goldberg was a cartoonist who drew overly complex machines intended to perform a simple task. *See* David Olsen & Mark J. Nelson, *The Narrative Logic of Rube Goldberg Machines*, 10 INT'L CONF. ON INTERACTIVE DIGI. STORYTELLING (Nov. 14–17, 2017), *in* 10690

flows in multiple directions, product flows in different directions, and all of it looks like the pathway of a drunken sailor, dropping money from his pocket along the way.

Figure 1: Pharmaceutical Supply Chain[3]



Systems emerge for a reason. Some develop in response to genuine economic efficiencies. Some blossom in response to legal or regulatory imperatives. Others emerge for more perverse reasons, when incentives within the system encourage distortions—deviations in the pathway so that a clever participant can amble over and pluck a tasty morsel from a neighboring field. Each of these has played a role, at various times, in the development of the pharmaceutical system.

With a structure as entrenched and complex as this, a key question emerges: Is it possible to reorder the system once it has ossified into place? This article contemplates disrupting the pathways that have grown up across time—that is, designing disruption for pharmaceuticals. If one could design a system with a much more direct and coherent path from those who manufacture prescription medicine to the patients who take them, what would that pathway look like, and what key barriers would need to be moved out of the way, either practical, legislative, or regulatory? Part I of this article describes the twisted drug supply chain in the United States. Part II presents a snapshot of profits and prices in the

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LECTURE NOTES IN COMPUTER SCIENCE 104 (Nuno Nunes, Ian Oakley &Valentina Nisi eds., 2017).

[3] Neeraj Sood, Tiffany Shih, Karen Van Nuys & Dana Goldman, *Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System*, HEALTH AFF. BLOG (June 13, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/ [https://perma.cc/DA48-3SBR].

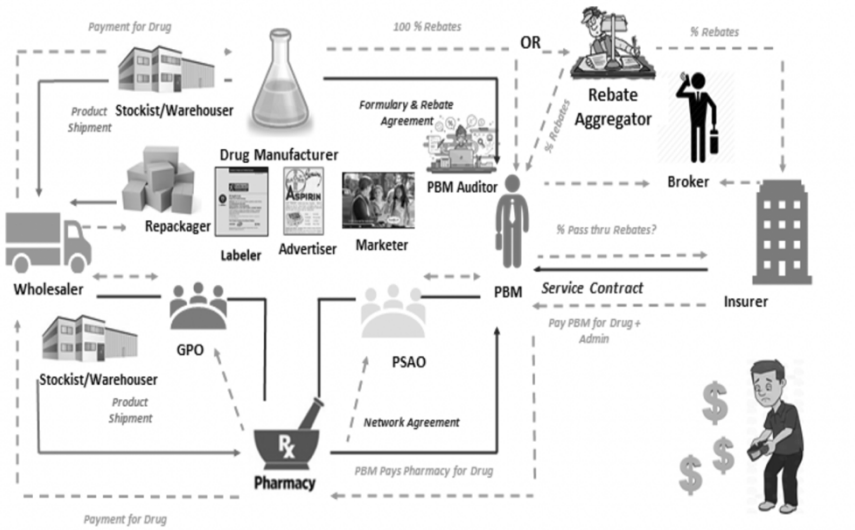
pharmaceutical industry. Part III describes the dynamics of pricing for medicine, particularly explaining the ways in which buy-side constraints that limit price in more typical markets are dampened in the healthcare market. Part IV traces the historic development of the various players and distortions in the pharmaceutical market, describing the context of their emergence and the interests served. Part V sets out a proposal that individual states—as the laboratories of democracy—could pilot to bypass many of the contortions that are strangling the industry. This section also describes the legal changes that would be needed to allow such initiatives to flourish, including changes that could be accomplished through expansion of existing legal doctrine or passage of new legislation.

I. TODAY'S SUPPLY CHAIN

The path a prescription drug takes from the drug company to a patient's medicine cabinet is labyrinthine, to say the least, populated with a host of intermediaries throughout. To give readers a glimpse into the topic, the introduction to this article presented a graphic of the drug supply chain. The current section uses an additional graphic, which includes even more players and complexities. As this second graphic—displayed below—demonstrates, the process of transmitting a drug from its manufacturer to its user supports an ecosystem of different players, many of whom—such as wholesale distributors and rebate aggregators—largely escape notoriety.[4]

[4] For instance, three of the six largest healthcare companies (by 2020 revenue) are wholesale distributors. *See* Eric Oliver, *10 Biggest Healthcare Companies by Revenue*, BECKER'S ASC REV. (Jan. 6, 2021), https://www.beckersasc.com/benchmarking/10-biggest-healthcare-companies-by-revenue.html [https://perma.cc/BRD4-D3PT] (noting that wholesale distributors McKesson, AmerisourceBergen, Cardinal Health rank third, fourth, and sixth, respectively).

Figure 2: Pharmaceutical Intermediaries[5]



In highly simplified form, the disjointed journey of a prescription drug[6] begins at the drug company's manufacturing facility, where the drug is produced.

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[5] Diagram courtesy of Marilyn Bartlett. It is worth emphasizing that this chart describes the flow of prescription drugs through pharmacies, not hospitals. The hospital pharmaceutical supply chain has its own kinks, including the 340B Drug Pricing Program, which secures protected drug costs (based on average manufacturer costs, before mark-ups from wholesalers and pharmacies) for low-income "safety net hospitals." *See* 340B HEALTH, *Overview of the 340B Drug Pricing Program*, https://www.340bhealth.org/members/340b-program/overview/ [https://perma.cc/6XSE-TDBL]. The Supreme Court will consider a challenge to Trump-era reductions to the reimbursements government pays to safety net hospitals for such discount drug purchases made under the 340B Program later this term. *See* Rachel Cohrs, *Supreme Court to Take Up Hospitals' Challenge to Medicare Pay Cuts*, STAT NEWS (July 2, 2021), https://www.statnews.com/2021/07/02/supreme-court-hospitals-challenge-to-medicare-drug-pay-cuts/?utm_source=STAT+Newsletters&utm_campaign=bc5adacc25-dc_diagnosis_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-bc5adacc25-152947498 [https://perma.cc/AJJ8-U6NA]. In addition to 340B, hospitals across the board demonstrate more irregular pricing than the supply chain for retail pharmacies overall. Indeed, with the HHS requirement that hospitals post their drug costs, data collected from those hospitals in compliance indicates a remarkable pricing disparity. *See* Aaron Gal, Lance Wilkes, Lee Hambright, Amy Xiong, Betty Huang, Sally Fernandes, Ben Weissman & John Rogers, ALLIANCE BERNSTEIN, *U.S. Healthcare: As Hospitals Are Forced to Release Real Prices, We Learn Their Drug Markups Average 250%; Will Dynamics Change?,* BERNSTEIN RSCH. REP.: U.S. BIOPHARM., Jan. 15, 2021, at 7.

[6] This graphic visualizes the journey of branded prescription drugs, which, unlike generic drugs, tend to elicit rebates from brand drug companies via Pharmacy Benefit Managers

The manufacturing process may itself be fragmented across multiple parties. For instance, a significant portion of drug manufacturing by American firms is outsourced overseas.[7] Contract manufacturing organizations (CMOs) are also increasingly used in various stages of drug production, so much so that one industry report estimates that only one-third of drug manufacturing occurs in-house.[8]

From the manufacturer, the product may be routed through a warehouse before acquisition by a wholesale distributor. Drugs may again be outsourced for repackaging[9] or relabeling.[10] Many manufacturers also rely on external advertising or marketing agencies to direct the promotion of their drugs to consumers.[11]

(PBMs) to health plans. Generic drug supply chains are similar from a supply standpoint, although they lack some of the payment middlemen that handle brand drug rebates, for instance. Moreover, payment flows are also weighted differently. For example, wholesalers and pharmacies capture a significantly greater portion of revenue from generic—as opposed to branded—drugs. *See* Sood, *supra* note 3.

[7] *See generally* Lisa Walkush, Yvette Jansen, Ashley Johnson & Corine Whitttick, *The Growing Benefits to Reshoring Pharma Operations*, PHARMA MFG. (Aug. 17, 2020), https://www.pharmamanufacturing.com/articles/2020/the-growing-benefits-to-reshoring-pharma-operations/ [https://perma.cc/C64C-BUYC].

[8] *See* DATEX CORP., *Warehouse Basics: What Is Pharmaceutical Contract Manufacturing?*, https://www.datexcorp.com/what-is-pharmaceutical-contract-manufacturing/ [https://perma.cc/AA8D-YTZ6]. Also relevant are licensing agreements between two or more drug companies to distribute or market a drug in foreign markets. *See, e.g.*, Rahul Khetan, *Biopharma Licensing and M&A Trends in the 21st-Century Landscape*, 25 J. COMM. BIOTECH. 37, 39 (2020).

[9] Medication may be repackaged to help patients stay on a dosage schedule or deliver a specific quantity of medication. *See* PROFICIENTRX, *What Is Repackaging Medication?*, (Oct. 14, 2020), https://proficientrx.com/repackaging-medication-how/ [https://perma.cc/8VC9-CKY2].

[10] Drugs manufactured abroad may be re-labeled upon importation to comply with U.S. regulations and standards. *See* Importation of Prescription Drugs, 85 Fed. Reg. 62,094, 62,095 (Nov. 30, 2020) (to be codified at 21 C.F.R. pt. 1, 251).

[11] The aggressive marketing of prescription drugs directly to consumers—a practice allowed only in the United States and New Zealand—can be traced back decades to medical advertising agencies led by the likes of Arthur Sackler (of Oxycontin infamy). For a history of the Sackler family and their contributions to modern medical marketing, *see generally* GERALD POSNER, PHARMA: GREED, LIES AND THE POISONING OF AMERICA (2020) [hereinafter POSNER]; *see also* Aiken, *infra* note 73 (describing how direct-to-consumer advertising induces unnecessary or additional prescriptions); *cf.* Robin Feldman, *Physicians Treating Alzheimer's Disease Patients Should Be Aware That Televised Direct-to-Consumer Advertising Links More Strongly to Drug Utilization in Older Patients*, 81 J. ALZHEIMER'S DISEASE 1169, 1174 (2021) (finding that advertising spending for high-spending drugs is associated with increased drug utilization).

Wholesale distributors sell and ship prescription drugs to pharmacies,[12] many of which are large, consolidated chains with significant purchasing power.[13] In contrast, independent pharmacies can benefit from "group purchasing organizations" allowing many smaller outlets to band together for securing better deals from wholesalers,[14] often by contracting in bulk.[15] Only after a drug reaches a pharmacy is it then dispensed to patients.

If it takes a village to move a prescription drug from the assembly line to the pharmacy counter, the corresponding flow of payments from patient back to drug company is no less involved. In return for filling a prescription at the pharmacy, an insured patient, instead of directly compensating the pharmacy, usually pays a co-pay or co-insurance amount to the pharmacist, an amount that is determined by the plan's formularies. Unless the patient purchases the same medication regularly, the patient most likely will not know what the prescription will cost until the purchase is rung up at the cash register. The health plan foots the remaining bill, and the resulting transaction, known as a claim, is processed by intermediaries called Pharmacy Benefit Managers (PBMs).[16] The health plan

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[12] As with the purchases they make from drug companies, wholesalers (as the name suggests) tend to sell large quantities of drugs at once, an arrangement that favors consolidated pharmacy chains. *See* Russ Britt, *Growing Share of 'Big Three' Gets Federal Attention*, MARKETWATCH (May 30, 2007), https://www.marketwatch.com/story/growing-share-of-big-three-drug-wholesalers-gets-attention [https://perma.cc/6ULC-8PXZ]. Although the supply chain is disintegrated, vertical partnerships between pharmacies and wholesalers may create a more integrated pipeline. *See* Adam J. Fein, *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, DRUG CHANNELS (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html [https://perma.cc/QK34-7Q7E] [hereinafter Fein, *Wholesalers*] (attributing increase in wholesaler AmerisourceBergen's market share to partnerships with Express Scripts and Walgreens Boots Alliance, a major PBM and pharmacy chain, respectively).

[13] *See* Adam J. Fein, *The Top 15 U.S. Pharmacies of 2020: Market Shares and Revenues at the Biggest Companies*, DRUG CHANNELS (Mar. 9, 2021), https://www.drugchannels.net/2021/03/the-top-15-us-pharmacies-of-2020-market.html [https://perma.cc/D8GB-4GBN] [hereinafter Fein, *Pharmacies*] (noting that three largest pharmacies held more than 50% of U.S. market in 2020).

[14] *See* TERRY HISEY, MATT HEIM, ROB JACOBY & JEREMY MANCKE, DELOITTE, THE ROLE OF DISTRIBUTORS IN THE U.S. HEALTH CARE INDUSTRY 7 (2019). GPOs are also important for smaller hospitals and medical clinics acquiring prescription drugs. *See* Todd Ebert, Healthcare Supply Chain Assoc., U.S. Federal Trade Commission Workshop Presentation Slides: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics 136 (Nov. 8, 2017) (available at 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/WLW2-WEC3]) [hereinafter FTC Workshop Slides].

[15] *See* Britt, *supra* note 12.

[16] *See generally* Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 9, 2019), https://time.com/5564547/drug-prices-medicine/

pays the PBM not only to process claims and serve as the intermediary with the pharmacy, but also to design its formularies[17] and negotiate rebates from drug companies. The PBM retains a negotiated portion of these drug company rebates, passing through the remaining percentage to health plans.[18] These rebates, which will cover purchases by large numbers of patients and possibly of multiple drugs, are paid out long after the patient has made the purchase.

Rebates, although touted as a cost-savings measure,[19] confuse the flow of payments considerably. Paid back to health plans in the form of a lump sum, rebates camouflage the price a health plan ultimately pays for a single prescription.[20] To

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[https://perma.cc/T4K3-UKCC]; *see also* Sood, *supra* note 3. The co-pay or co-insurance amount can vary considerably depending on the plan and the patient's status within the plan. For example, Medicare Part D has four stages of coverage in any given year. These range from full coverage to the "donut hole" period. During the "donut hole" period, the patient must pay 25% of all drug costs. Price-sensitivity of patients may be greater during the "donut hole" period than during the "catastrophic coverage" period, when the patient's contribution is lower. *See The Four Coverage Stages of Medicare's Part D Program*, BLUE MEDICARERX (Oct. 1, 2020), https://www.rxmedicareplans.com/Learn/Stages [https://perma.cc/A3DE-LJCE].

[17] Many health plans utilize a formulary as a cost-saving method of organizing the drugs they cover, placing expensive drugs on higher tiers (with a higher co-pay) and cheaper drugs on lower, more accessible tiers. A properly designed formulary should incentivize patients to choose cheaper, generic options when available, because they will be found on lower tiers, with lower co-pays. *But see* Robin Feldman, *The Devil in the Tiers,* 8 J.L. & BIOSCIENCES 1, 19 (2021) [hereinafter Feldman, *Devil*] (analysis of Medicare claims between 2010 and 2017 found that drugs are increasingly "mis-tiered", with 74% of drugs placed on inappropriate tiers).

[18] *See* Response Letter from Eric R. Slusser, Exec. Vice President/CFO, Express Scripts, to Sec. Exch. Comm'n (June 26, 2017) (on file with author) (noting that some clients prefer to keep greater percentage of rebates); *see also* ROBIN FELDMAN, DRUGS, MONEY AND SECRET HANDSHAKES 30–31 (2019) [hereinafter HANDSHAKES] (noting that PBMs may respond to mandatory rebate pass-throughs by simply shifting rebate dollars to inflation payments or administrative fees they also receive from brand drug companies). Similarly, some insurers have promised to begin passing drug company rebates through to patients, but such an initiative may be toothless if premiums or co-pays become simultaneously more expensive. *See* Entis, *supra* note 16.

[19] As drug companies are eager to point out, rebates are not the only means of reducing list prices. Manufacturer coupons and co-pay assistance are paid out to patients by drug companies or their affiliated charities. This outlay does not reflect an unexpected altruism from drug companies and can instead be understood as another payment stream in the complex pharmaceutical web—issuing coupons helps retain a larger user base (whose health plans still pay their full cost allotment) and contributions made through a charitable organization are tax-deductible. *See generally* SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R44264, PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS (PAPS) (2017).

[20] Maintaining the opacity of drug prices enables PBMs to capture a greater share of revenue, sometimes resulting in higher drug prices. *See generally* Robin Feldman, *Perverse*

further complicate matters, although drug companies may issue rebates directly to PBMs, these payments may first be collected by rebate aggregators before reaching the PBM.[21] Rebate aggregators, however, may be affiliated with the PBMs to which they pay out the rebates compiled from drug companies; this arrangement enables the PBM to capture a greater cut of drug company rebates, in turn passing fewer rebates through to health plans.[22]

Still other intermediaries can pose between drug companies and patients, further diverting and re-allocating payment flows. Just as group purchasing organizations help independent pharmacies secure drug supply from wholesalers, pharmacy services administration organizations (PSAOs) act as umbrella groups for many smaller, independent pharmacies, collectively leveraging their market share to negotiate contracts with PBMs and health plans.[23] Similarly, pharmacy brokers can connect health plans with PBMs, especially in the case of smaller, self-insured employers.[24] Third-party administrators may also act as liaisons between health plans and PBMs, helping to design formularies in line with the specifications of a health plan.[25] Finally, auditors may examine contracts between PBMs and other actors—such as health plans and pharmacies—creating

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Incentives: Why Everyone Prefers Higher Drug Prices—Except for Those Who Pay the Bills, 57 HARV. J. ON LEGIS. 303 (2020) [hereinafter Feldman, *Perverse Incentives*]. PBMs do not just passively benefit from the secrecy of rebate and net price amounts; rather, they spuriously assert that their contracts with drug companies constitute trade secrets. *See* Robin Feldman & Charles Tait Graves, *Naked Price & Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 63–80 (2020).

[21] *See* Rose McNulty, *In Drug Pricing, PBMs Called the "Arsonist and Firefighter in One"*, 26 EVIDENCE-BASED ONCOLOGY 315, 315 (2020), https://www.ajmc.com/view/in-drug-pricing-pbms-called-the-arsonist-and-the-firefighter-in-one- [https://perma.cc/X9AQ-P3T8] (noting that PBMs sometimes contract rebate aggregator to collect from drug companies on their behalf).

[22] *See id*. (observing that rebate aggregator affiliated with PBMs can help PBMs circumvent contractual requirement to pass rebates through to health plan by retaining some percentage of rebates that aggregator collects and delivers to PBMs and that health plans may be unaware that rebate aggregators are affiliated with or owned by PBMs that use them).

[23] *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-176, PRESCRIPTION DRUGS: THE NUMBER, ROLE, AND OWNERSHIP OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (2013) [hereinafter GAO PSAO REPORT]; HISEY, *supra* note 14, at 7.

[24] *See* Bob Meyer, *Getting the Most Out of a Prescription Benefit Plan*, BROKER WORLD MAG. (Aug. 1, 2018), https://brokerworldmag.com/getting-the-most-out-of-a-prescription-benefit-plan/ [https://perma.cc/9R4V-RVGR]. There are, however, generally few PBM options from which a health plan may select, with three firms controlling more than 85% of the market—a fact that has already attracted legislative attention. *See Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Fin.*, 116th Cong. 240 (2019); *see also* HANDSHAKES, *supra* note 18, at 14.

[25] *See* Kev Coleman, *What is a Third-Party Administrator (TPA)?*, ASS'N HEALTH PLANS (Nov. 18, 2020), https://www.associationhealthplans.com/group-health/what-is-tpa/#:~:text=TPAs%20help%20with%20the%20design,participate%20in%20its%20ongoing%20administration [https://perma.cc/ZM6Y-GDB6].

yet another niche in the drug supply ecosystem.[26] Audits may be performed in both directions: health plans can audit their PBM contracts,[27] and PBMs may audit pharmacy claims to ensure that pharmacies are not falsifying claims or over-dispensing medications.[28]

Although the intermediaries of the pharmaceutical ecosystem seem to crowd a large room, the same organizations may in fact fill many of its niches. Cardinal Health, for example, commands more than a quarter of the wholesale distribution market,[29] but also operates in practically every other node of the supply chain. Cardinal—the sixth-largest healthcare company in the world[30] —advertises services ranging from contract manufacturing[31] to group purchasing[32] and from pharmacy services administration organizations[33] to pharmacy

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[26] *See, e.g.*, PILLARRX, *4 Financial Benefits to Having a PBM Audit*, https://pillarrx.com/4-financial-benefits-to-pbm-audit/ [https://perma.cc/P6WL-S4XX].

[27] *See, e.g.*, *The Health Plan's Guide to Auditing your Pharmacy Benefit Manager Contract from A to Z*, THE BURCHFIELD GRP. 21–22 (2017), https://cdn2.hubspot.net/hubfs/139847/BFG-Health_Care_Guide-052317.pdf?t=1502895470217 [https://perma.cc/6Q5U-Q4HP]. *But see* Feldman & Graves, *supra* note 20, at 72 (noting that health plan auditors may be precluded from analyzing details of PBM contracts with brand drug companies on basis of trade secrecy claims).

[28] *Cf.* Press Release, U.S. Attorney's Office, S.D.N.Y., Manhattan U.S. Attorney Announces $269.2 Million Recovery from Walgreens in Two Civil Healthcare Fraud Settlements (Jan. 22, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civilhealthcare#:~:text=Crotty%20and%20unsealed%20today%2C%20requires,who%20did%20not%20need%20them [https://perma.cc/68PW-78G4] (reporting $200 million settlement following allegations that Walgreens over-dispensed insulin pens to Medicaid patients).

[29] As of 2018, Cardinal wholesale revenue exceeded $100 billion annually. *See* Fein, *Wholesalers*, *supra* note 12.

[30] Oliver, *supra* note 4.

[31] *Contract Manufacturing & Pharmacy Solutions*, CARDINAL HEALTH, https://www.cardinalhealth.com/en/services/manufacturer/contract-manufacturing-organization.html [https://perma.cc/3XMF-C327] (displaying specific advertisement of radiopharmaceuticals, a targeted therapy with radioactive molecules increasingly used in oncology); *see Radiopharmaceuticals: Radiation Therapy Enters the Modern Age*, NAT'L CANCER INST. (Oct. 26, 2020), https://www.cancer.gov/news-events/cancer-currents-blog/2020/radiopharmaceuticals-cancer-radiation-therapy [https://perma.cc/8XT3-4SWV].

[32] *Group Purchasing Organizations*, CARDINAL HEALTH, https://www.cardinalhealth.com/en/services/specialty-physician-practice/our-gpos.html [https://perma.cc/UCJ7-27JJ].

[33] *Pharmacy Services Administration Organization (PSAO)*, CARDINAL HEALTH, https://www.cardinalhealth.com/en/services/retail-pharmacy/managing-care/psao-services.html [https://perma.cc/7XHE-NQJM. Nine of the twenty-two PSAOs identified in a government report were owned by wholesaler. The "Big Three" wholesalers—Cardinal, AmerisourceBergen, and McKesson—own three of the five largest PSAOs. *See* GAO PSAO REPORT, *supra* note 23, at 25.

management.[34] Consequently, a company like Cardinal has a chance to profit from nearly every transaction involved in moving a drug from manufacturer to patient.[35] Cardinal, predictably, is not the only player to switch uniforms: CVS Health includes CVS, one of the largest retail pharmacy chains, Caremark, one of the "Big Three" PBMs, and Aetna, a major health insurer[36]—a fact that has raised conflict of interest concerns.[37] Although at first glance the supply chain is remarkably disaggregated, with distinct intermediaries for each task, the same consolidated actors often don many hats.

Parsing the functions of various agents is not the only challenge posed by the pharmaceutical supply chain. The price attached to a prescription drug shifts at each stop on this winding road, generating a tongue-twisting series of acronyms that mirrors the convolution of the supply chain itself. When a wholesaler purchases a drug directly from the manufacturer, it pays a wholesale acquisition cost (WAC),[38] which, by the statutory definition, does not include any rebates or discounts.[39] In contrast, the average manufacturer price (AMP)—what wholesalers pay manufacturers for a drug—is derived from sales transactions, including discounts in the price wholesalers pay manufacturers; to participate in Medicaid, drug companies must report AMPs to the Center for Medicaid & Medicare Services quarterly.[40]

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[34] *Ordering and Inventory*, CARDINAL HEALTH, https://www.cardinalhealth.com/en/services/retail-pharmacy/ordering-and-inventory.html [https://perma.cc/LRQ3-EPMP.

[35] For more on the various stakeholders that benefit from this tangled supply chain, *see infra* Section IV.

[36] *See* Stacy Mitchell & Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, PROMARKET (Feb. 19, 2021), https://promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/ [https://perma.cc/EQL3-AGKA] (describing how the FTC enabled remarkable vertical consolidation in healthcare sector in addition to horizontal mergers, exemplified by the Caremark-CVS-Aetna triumvirate).

[37] HANDSHAKES, *supra* note 18, at 47–48 & 148 n.19; Mark J. Botti, C. Fairley Spillman & Diana L. Gillis, *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/82QA-2RDM] (noting that FTC investigated CVS-Caremark merger but found no antitrust wrongdoing).

[38] For a primer on the alphabet soup of drug pricing acronyms, *see generally* Joey Mattingly, *Understanding Drug Pricing*, U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/understanding-drug-pricing [https://perma.cc/2LWS-MN3D].

[39] *See* 42 U.S.C. § 1396r–8(k)(5) (2021). WAC is not based on actual sales data, limiting its utility as a policy tool. *See* U.S. DEP'T. OF HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., OEI-05-05-00240, MEDICAID DRUG PRICE COMPARISONS: AVERAGE MANUFACTURED PRICE TO PUBLISHED PRICES i (2005) [hereinafter HHS OIG REPORT].

[40] HHS OIG REPORT, *supra* note 39. Average manufacturer price is the touchstone for some federal initiatives, such as the 340B program. *See* 340B HEALTH, *supra* note 5.

At the next stage, average wholesale price (AWP) measures what retail pharmacies pay to acquire drugs from wholesalers.[41] Like the WAC, AWP does not reflect discounts, leading some to dub it as shorthand for "Ain't What's Paid."[42] Rather than drawing from actual sales data, AWP is based on pricing information that drug companies provide to third-party databases.[43] Commonly referred to as a drug's "list price", the AWP is significantly higher than AMP.[44] The inflation of AWP matters because most states use it to calculate Medicaid reimbursement.[45]

Crucially, however, not one of these acronyms describes what a drug eventually costs from the pharmacy.[46] Although the out-of-pocket amount a patient pays to dispense a drug (in the form of a co-pay or co-insurance) may be discernible (at least to the patient), far more elusive is the "net price" that the health plan pays the drug company via a PBM.[47] With the identity of a prescription drug's price changing from node to node, the supply chain functions ultimately as a cipher, confusing rather than clarifying what a drug costs.

II. A SNAPSHOT OF PRICES & PROFITS

The system certainly has not proven a boon for society. The pharmaceutical industry today is beset by a staggering growth in prescription drug prices. In the United States—where some brand-name drugs cost more than triple what they

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[41] Dawn M. Gencarelli, *One Pill, Many Prices: Variation in Prescription Drug Prices in Selected Government Programs, in* NAT'L HEALTH POLICY FORUM ISSUE BRIEF NO. 807 1, 3 (2005), https://www.ncbi.nlm.nih.gov/books/NBK561171 [https://perma.cc/3X5E-KJ7P]; *see generally* Mattingly, *supra* note 38.

[42] HANDSHAKES, *supra* note 18, at 12.

[43] *Id*.; Gencarelli, *supra* note 41.

[44] *See* HHS OIG REPORT, *supra* note 39, at 11 (stating that AMP is an average of 70% lower than AWP for generic drugs and 23% lower for brands).

[45] *See id*. at 11–12 (noting that to determine reimbursement amounts, forty-nine states use estimated acquisition cost (EAC), which reduces AWP by a percentage generally larger for generic drugs).

[46] Another measure—the usual & customary price (U&C)—expresses the cash or retail cost of a drug at the pharmacy but excludes the rebates and discounts from which insured patients benefit. In theory, a drug's U&C cost should be higher than its AWP, on account of the pharmacy taking its cut. *See generally* Mattingly, *supra* note 38; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-306R, PRESCRIPTION DRUGS: TRENDS IN USUAL & CUSTOMARY PRICES FOR COMMONLY-USED DRUGS 8 (2011) (finding that U&C prices rose faster than AMPs & AWPs for same basket of drugs between 2006 and 2010).

[47] *See* HANDSHAKES, *supra* note 18, at 13–14 (explaining when health plans receive a rebate check from PBMs, amount reflects many transactions over course of quarter or year, rendering per-unit cost of single prescription inscrutable); *see also* Feldman & Graves, *supra* note 20, at 72 (discussing how opacity of net prices is upheld by trade secrecy claims, mutual interest of drug companies, and PBMs to maintain secret net prices).

do in other countries[48]—the average price of brand-name drugs increased 313% between 2010 and 2017.[49] Even commercially insured patients are now saddled with higher out-of-pocket drug costs compared to previous years,[50] a plight that the uninsured suffer more acutely still.[51] As a result, many who depend on life-saving medication regularly skip or ration their dosages,[52] making access to medicine a serious national concern.

Industry intermediaries, by contrast, have enjoyed healthy revenue growth during this period. PBM revenue grew nearly 50% between 2014 and 2016 alone, fueled by an increase in administrative fees.[53] Moreover, a lack of transparency means that PBMs' profit margins may be significantly understated.[54] At

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[48] *See* Andrew W. Mulcahy, *Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries,* RAND CORP. (Jan. 28, 2021), https://www.rand.org/news/press/2021/01/28.html [https://perma.cc/Z8KK-EJRM] (finding that price of "brand-name originator drugs" in U.S. was 344% of thirty-two OECD countries' average price in 2018).

[49] Feldman, *Devil*, *supra* note 17, at 1 (examining Medicare claims for cohort of roughly one million patients from 2010 to 2017 and measuring prices of brand name drugs after accounting for rebates).

[50] *See* Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, JAMA NETWORK OPEN (May 31, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2734804 [https://perma.cc/SX3C-XJ6A] (stating that 78% of top-selling drugs have carried 50% or greater increase in insurer and out-of-pocket costs since 2012).

[51] List price increases especially impact uninsured patients, who do not benefit from rebates paid out to insurers. Such prices reliably rise several percentage points each year. *See* Juliette Cubanski & Tricia Neumann, *Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs*, KAISER FAM. FOUND. (Feb. 4, 2021), https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/#:~:text=Among%20the%20drugs%20with%20list,times%20the%20rate%20of%20inflation [https://perma.cc/FY8J-P2SH] (noting that between 2018 and 2019, median list prices rose 6.5%, with many drugs' price gains exceeding 10%).

[52] *See, e.g.*, H.B. 19-1216, 73rd Gen. Assemb. 2 (Colo. 2019) (observing that 40% of Coloradans using insulin reported having to skip or ration doses at least once a year).

[53] Robert Zirkelbach, *The PBM Story You Haven't Heard: Hidden Fees Quadrupled in Two Years*, PHRMA (Mar. 20, 2019), https://catalyst.phrma.org/the-pbm-story-you-havent-heard-hidden-fees-quadrupled-in-two-years [https://perma.cc/P66D-G4GR] (noting that PBM industry revenue increased from approximately $15 billion in 2014 to more than $22 billion in 2016, with "hidden" administrative and service fees charged to drug companies nearly quadrupling).

[54] PBMs neglect to include the transactional fees they earn from passing through rebates—when such "pass-through" revenue is accounted for, PBMs are the most profitable entity in the pharmaceutical industry. *See* Laurie Toich, *Are PBMs Downplaying Their Profits?*, PHARMACY TIMES (Apr. 5, 2017), https://www.pharmacytimes.com/view/are-pbms-downplaying-their-profits [https://perma.cc/S79T-NZEU].

the same time, wholesaler distributor[55] and pharmacy[56] revenues have also displayed consistent growth as the supply chain has become increasingly tangled.

The pharmaceutical industry itself reports robust profits, too. In fact, drug company profit margins rank among the highest of any publicly traded corporations.[57] Much of this stems from raising prices on existing drugs. One source reports that 80% of the growth in profits from the 20 largest drug companies resulted from raising prices on existing drugs.[58] In other words, increasing profits are not due to introducing new drugs or increasing sales, just increasing prices on existing drugs.[59]

As things stand, there is little incentive to impel the transformation of the system from within. Although various parties often pin the plight of rising drug prices on one another,[60] all benefit from the system that produces them. When the PBMs' slice of the pie grows over time, the slice that belongs to drug companies or pharmacies does not necessarily shrink. Rather, overall prescription drug spending continues to grow, with government payors and patients left holding the tab.[61]

III. HOW CAN A PIE KEEP GROWING?

Any discussion of price and efficiency in the context of healthcare requires a tour of certain overarching characteristics of the industry. The most important

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[55] *See* Fein, *Wholesalers*, *supra* note 12 (discussing that wholesale distributors experienced annual revenue growth of 4–14% between 2015 and 2019, according to their increased consolidation).

[56] *See* Fein, *Pharmacies*, *supra* note 13 (noting that fourteen of fifteen largest U.S. pharmacies saw their prescription revenue increase between 2019 and 2020).

[57] Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan & Ekaterina Galkina Cleary, *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 JAMA 834, 837 (2020), https://jamanetwork.com/journals/jama/fullarticle/2762308 [https://perma.cc/6HCW-RVNK] (stating that net income comprised 13.8% of large pharmaceutical firms' total revenue between 2000 and 2018, compared to other S&P 500 companies' average of 7.7%).

[58] Joseph Walker, *For Prescription Drug Makers, Price Increases Drive Revenue,* WALL. ST. J. (Oct. 5, 2015, 9:59 PM), www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750 [https://perma.cc/8QY5-95T5].

[59] *See id*.

[60] Trade groups that represent one sector of the supply chain routinely disseminate hit pieces targeting another set of firms. *See, e.g*., Alicia Caramenico, *With Rebates, Everyone Pays Except for Drug Companies*, AHIP (May 9, 2018), https://www.ahip.org/with-rebates-everyone-pays-except-for-drug-companies/ [https://perma.cc/24JG-S9DD] (citing research to assert that drug company rebates do not lower prices for consumers).

[61] Prescription drug spending has generally accelerated in recent years, highlighted by a 5.7% increase in 2019, up from 3.8% in 2018. *See National Health Expenditure Fact Sheet,* U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/965J-Z762] (last visited Oct. 16, 2021).

characteristic is the following: buy-side constraints that limit price in more typical markets are dampened in the health-care market. Spending on healthcare—whether on treatments or on insurance premiums—is not nearly so responsive to budgetary pressures as is spending on other kinds of products and services.[62] This price inelasticity is particularly strong in the market for prescription drugs, where price increases do not readily prompt a drop in demand. Several factors contribute to this well-documented irrationality in health-care spending.

Price increases do not dull patients' demand for healthcare because patients do not actually pay the full cost of healthcare. Much of the cost is paid by insurance, public and private payors. For those who do not obtain health insurance through their employers, the government is the payor through programs like Medicare and Medicaid. Otherwise, employer-provided health insurance is the payor.[63] Either way, the patient is relieved from paying the full cost of healthcare because that cost is spread over a pool of covered individuals and over a period of time.[64] Even when the cost to a particular patient is staggering, health insurance often bears the brunt, if not the entirety, of the financial burden.[65] In addition, some drug companies have payment assistance programs that absorb patient costs through rebates and coupons.[66] Where a drug has no therapeutic

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[62] HANDSHAKES, *supra* note 18, at 6–7, 36 & 119–122 nn.11–20; *see also* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 14 (2017) [hereinafter DRUG WARS] ("Many drugs are necessities for the patients who use them, especially those for rare disorders. The price is quite *inelastic*, meaning that demand is not responsive to price—people will pay whatever they need to secure the good.").

[63] Even employer-provided health insurance is partially funded by either federal or local government through tax benefits for employers and employees. HANDSHAKES, *supra* note 18, at 6 & 119 n.13; *see* Nicholas Drew, *Two Federally Subsidized Health Insurance Programs Are One Too Many: Reconsidering the Federal Income Tax Inclusion for Employer-Provided Health Insurance in Light of the Patient Protection and Affordable Care Act*, 54 B.C. L. REV. 2047, 2056–57 (2013) (describing government subsidy for employer-provided healthcare created by section 106 of Internal Revenue Code); Yair Listokin, *Equity, Efficiency, and Stability: The Importance of Macroeconomics for Evaluating Income Tax Policy*, 29 YALE J. ON REG. 45, 48–49 (2012) (noting government subsidy excluding "employer-provided health insurance from income tax"); Max Huffman, *Competition Policy in Health Care in an Era of Reform*, 7 IND. HEALTH L. REV. 225, 261 (2010) (observing that healthcare costs are paid with "before tax dollars").

[64] HANDSHAKES, *supra* note 18, at 6 & 119 n.12*; see* Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 7 (Hutchins Ctr. on Fiscal & Monetary Policy at Brookings, Working Paper No. 30, 2017), www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf [https://perma.cc/GN9V-VCZN] (observing that externalities, *inter alia*, prevent optimal substitution by consumers because consumers do not bear full costs).

[65] Robin Feldman, Incentivizing Failure 28 & n.63 (Aug. 2, 2021) (unpublished manuscript) (on file with author); *see* discussion *supra* note 16, and accompanying text.

[66] DRUG WARS, *supra* note 62, at 17 & n.69; Feldman, *supra* note 65, at 28; HANDSHAKES, *supra* note 18, at 51, 53–54; Scott Morton & Boller, *supra* note 64, at 27; William G.

alternative, health insurers are sometimes required by government or patient demand to include the drug in the applicable formulary (the list of covered prescription drugs), no matter the price.[67] It may be that insulating patients from the full cost of care is by design, to prevent "sticker shock" among patients and doctors.[68]

The irrationality of health-care spending is also due to informational deficiencies experienced by patients *qua* consumers.[69] Patients must rely on their

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Schiffbauer, *Let's Talk About Prescription Drug Copay Coupons: Do They Operate as Unregulated Secondary Insurance?*, BLOOMBERG L. NEWS (Apr. 18, 2018, 12:02 PM), https://news.bloomberglaw.com/health-law-and-business/lets-talk-about-prescription-drug-copay-coupons-do-they-operate-as-unregulated-secondary-insurance [https://perma.cc/GG4R-FQFE] (suggesting that coupon plans constitute unregulated insurance, in which drug company handing out coupon indemnifies patient for any higher cost-sharing that may result from using branded drug); Carolyn Y. Johnson, *Secret Rebates, Coupons, and Exclusions: How the Battle Over High Drug Prices Is Really Being Fought*, WASH. POST (May 12, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/05/12/the-drug-price-arms-race-that-leaves-patients-caught-in-the-middle/ [https://perma.cc/75AX-7PUJ]; David Schultz, *Drug Coupons: A Good Deal for the Patient, But Not the Insurer*, KAISER HEALTH NEWS (Oct. 1, 2012), https://khn.org/news/drug-coupons/ [https://perma.cc/5LW4-7YS3] (noting laws preventing those covered by federal health insurance from using coupons and detailing debate over co-pay rebates); Karen Weintraub, *Mass., 50th State, Now Allows Drug Coupons: What You Need to Know*, WBUR (July 16, 2012), https://www.wbur.org/news/2012/07/16/drug-coupons-massachusetts [https://perma.cc/HP2D-KGS7] (covering repeal of Massachusetts's law banning drug coupons); *see also* Charles Ornstein, *Are Copay Coupons Actually Making Drugs More Expensive?,* PROPUBLICA (June 30, 2016, 10:59 AM), https://www.propublica.org/article/are-copay-coupons-actually-making-drugs-more-expensive [https://perma.cc/DK2H-S36M].

[67] Medicare requires a drug from certain therapeutic groups to be included in the formulary as well. *See* U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *What Medicare Part D Plans Cover*, MEDICARE.GOV, https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover#:~:text= All%20Medicare%20drug%20plans%20generally,similar%20drug%20should%20be%20available [https://perma.cc/K9RT-YRSL] (last visited Oct. 17, 2021). Insurers may risk losing customers if they fail to include a certain drug on their formulary, giving the drug company leverage to charge more for a drug in demand. If a generic or cheaper competitor is not a perfect substitute, a patient's refusal to switch is validated by laws that require health plans to continue coverage for drugs under some circumstances. *See* Feldman, *supra* note 65, at 27 & n.65.

[68] DRUG WARS, *supra* note 62, at 86 ("The brunt of the costs of these schemes falls on insurers and not patients, perhaps intentionally so that patients and doctors do not feel the sticker shock of high prices.").

[69] *Id*. at 17 ("Patients require drugs, have little idea about cost, and will only pay a small percentage of it anyway, sharply affecting their ability to respond to price."); HANDSHAKES, *supra* note 18, at 6–7 & 119 n.12; Scott Morton & Boller, *supra* note 64, at 2 (noting that information asymmetries, *inter alia*, prevent optimal substitution by consumers because consumers lack medical expertise or reliable information with which to identify therapeutic equivalents).

healthcare professionals.[70] The professional, not the patient, determines what medication must be prescribed, and, hence, what drug must be purchased.[71] However, the professional's determination may be subject to economic factors, such as the availability of insurance reimbursement for the drug, or factors distant from the merits, such as the wooing of physicians by drug companies.[72] In some cases, direct-to-consumer advertising can induce patients to purchase, or request prescription of, a particular drug.[73] While patients could benefit greatly if companies provided them with reliable information on price and quality, the provision of such information in a comprehensible form can be difficult, even absent the distracting seductions of advertising.[74]

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[70] HANDSHAKES, *supra* note 18, at 7.

[71] *Id*.

[72] *Id*. at 7 & 120 n.15; *see Open Payments*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., www.cms.gov/openpayments/ [https://perma.cc/6NLZ-G6R3] (identifying value and nature of companies' payments to physicians).

[73] HANDSHAKES, *supra* note 18, at 7 & 120 n.14; DRUG WARS, *supra* note 62, at 15 & nn. 60–61; Kathryn J. Aiken, John L. Swasy & Amie C. Braman, U.S. FOOD & DRUG ADMIN., *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results* 2, 26–27 (2004), https://www.fda.gov/files/drugs/published/Patient-and-Physician-Attitudes-and-Behaviors-Associated-With-DTC-Promotion-of-Prescription-Drugs-Final-Report.pdf [https://perma.cc/C9HJ-46B6] (demonstrating that advertising dramatically increases number of patient requests or inquiries about specific drugs). Only two industrialized nations allow direct-to-consumer advertising (DTCA) for prescription medication: the United States and New Zealand. Bruce Patsner, *Problems Associated with Direct-to-Consumer Advertising (DTCA) of Restricted, Implantable Medical Devices: Should the Current Regulatory Approach Be Changed?*, 64 FOOD & DRUG L.J. 1, 3 (2009) (stating that "aside from New Zealand, DTCA is banned in every other Western industrialized nation except the United States"); *Keeping Watch Over Direct-to-Consumer Ads*, U.S. FOOD & DRUG ADMIN., https://web.archive.org/web/20171213072240/ [https://perma.cc/YL3L-5BMC]; Erin J. Asher, *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.").

[74] HANDSHAKES, *supra* note 18, at 7 & 120–121 nn.16-17; Letter from Marina Lao, Deborah L. Feinstein & Francine Lafontaine, Fed. Trade Comm'n Staff, to Rep. Joe Hoppe & Rep. Melissa Hortman, Minn. House of Reps. 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/150702minnhealthcare.pdf [https://perma.cc/G36A-6B9H]. *See* Christopher Whaley, Jennifer Schneider Chafen, Sophie Pinkard, Gabriella Kellerman, Dena Bravata, Robert Kocher & Neeraj Sood, *Association Between Availability of Health Service Prices and Payments for These Services*, 312 JAMA 1670, 1670–1676 (2014); U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-791, HEALTH CARE PRICE TRANSPARENCY: MEANINGFUL PRICE INFORMATION IS DIFFICULT FOR CONSUMERS TO OBTAIN PRIOR TO RECEIVING CARE 1–2 (2011), www.gao.gov/assets/590/585400.pdf [https://perma.cc/9HVG-RCD3]; Fed. Trade Comm'n, Examining Health Care Competition

Most importantly, the ordinary budget limitations of the consumer, while reining in the prices of other monopolists, do not rein in the prices of health-care monopolists.[75] Outside of the health-care context, the consumer may be willing to pay high prices set by a monopolistic seller of good X, but there are limits to how high the monopolist can raise the price of X. The consumer has a finite budget and a list of items on which money *must* be spent, whether they are necessities like food, clothing, and housing, or desirables like the occasional movie out with the family.[76] The portion of the consumer's budget that can be spent paying the price charged by the non-health-care monopolist is necessarily limited by the consumer's must-spend list.[77] But in the health-care context, those ordinary budget limitations do not prevent the monopolist from charging prices (and obtaining payments) that would not otherwise be possible. To take a simple real-world example, healthcare is often a matter of life and death; since the consumer's life is infinitely valuable to the consumer, the consumer will pay colossal sums of money for a health-care product—say, a novel chemotherapy—that will prolong the consumer's life, often for only a short period.[78] The consumer's payment of such sums, for minimal extension of life, earns the health-care monopolist profits beyond what the non-health-care monopolist will make.

Webcast (Feb. 24, 2015) (transcript available at www.ftc.gov/news-events/events-calendar/2015/02/examining-health-care-competition); *High Prices, Low Transparency: The Bitter Pill of Health Care Costs: Hearing Before the S. Comm. on Fin.*, 113th Cong. 8–9 (2013) (statement of Paul B. Ginsburg, President, Center for Studying Health System Change), https://www.finance.senate.gov/hearings/high-prices-low-transparency-the-bitter-pill-of-health-care-costs [https://perma.cc/M2Y8-7LXL].

[75] HANDSHAKES, *supra* note 18, at 6 & 119 n.10; Brian A. Hearn, Nicola Amendola & Giovanni Vecchi, *On Historical Household Budgets*, (Inst. for New Econ. Thinking, Working Paper No. 45, 2016), https://www.ineteconomics.org/research/research-papers/on-historical-household-budgets [https://perma.cc/C2FC-HUJ5]; Thomas J. Campbell, *Labor Law and Economics*, 38 STAN. L. REV. 991, 1005 & n.82 (1986) (citing EDWIN MANSFIELD, MICROECONOMICS 251 (4th ed. 1982)); Kenneth M. Casebeer, *Unemployment Insurance: American Social Wage, Labor Organization and Legal Ideology*, 35 B.C. L. REV. 259, 298 (1994).

[76] HANDSHAKES, *supra* note 18, at 6.

[77] HANDSHAKES, *supra* note 18, at 6 & 119 n.10; Hearn, *supra* note 75, at 4–5; Campbell, *supra* note 75; Casebeer, *supra* note 75.

[78] HANDSHAKES, *supra* note 18, at 7 & 121 n.19. Of total healthcare spending in the United States, 8.5% is for individuals in their last year of life. *See* Alan R. Weil, *Advanced Illness and End-of-Life Care*, 36 HEALTH AFF. 1167, 1167 (2017); Courtney Davis, Huseyin Naci, Evrim Gurpinar, Elita Poplavska, Ashlyn Pinto & Ajay Aggarwal, *Availability of Evidence of Benefits on Overall Survival and Quality of Life of Cancer Drugs Approved by European Medicines Agency: Retrospective Cohort Study of Drug Approvals 2009–13*, 359 BMJ 4530 (2017),
https://www.bmj.com/content/359/bmj.j4530 [https://perma.cc/LDC4-F3XB]
("The magnitude of the benefit on overall survival ranged from 1.0 to 5.8 months (median 2.7 months).").

In short, irrationality in healthcare markets leads to decisions that would be considered irrational in other budgetary contexts.[79] The irrationality is even more marked when the consumer understands that someone else—the health insurer—is footing the bill.[80] Although every health-care decision is not a life-and-death matter, the difference is frequently a matter of degree: for the consumer, today's non-emergency treatment could prevent tomorrow's life-threatening impairment. The bottom line is that the gravity of health-related issues leads to a market that is typified by distorted purchasing decisions[81] and that can only be described as irrational.[82]

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[79] *See* HANDSHAKES, *supra* note 18, at 7 & 121 n.18; Wendy Netter Epstein, *Revisiting Incentive-Based Contracts*, 17 YALE J. HEALTH POL'Y L. & ETHICS 1, 11–14 (2017) (describing skewed economic incentives in healthcare); Clive Crook, *The Slippery Economics of Health Care*, THE ATLANTIC (Oct. 2005), www.theatlantic.com/magazine/archive/2005/10/the-slippery-economics-of-health-care/304394/ [https://perma.cc/ZHL9-DEZE] (describing lack of consumer incentives in healthcare decision making); DAVID GRATZER, THE CURE: HOW CAPITALISM CAN SAVE AMERICAN HEALTH CARE 42 (2006); ARNOLD S. KLING, CRISIS OF ABUNDANCE: RETHINKING HOW WE PAY FOR HEALTH CARE 53–54 (2006); William P. Kratzke, *Tax Subsidiaries, Third-Party-Payments, and Cross-Subsidization: America's Distorted Health Care Markets*, 40 U. MEM. L. REV. 279, 282 (2009) (citing E. Haavi Morreim, *Diverse and Perverse Incentives of Managed Care: Bringing Patients into Alignment*, 1 WIDENER L. SYMP. J. 89, 95, 139 (1996)); Uwe E. Reinhardt, *Reorganizing the Financial Flows in American Health Care*, 12 HEALTH AFF. 172, 176 (Supp. 1993); 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 co-payment schemes to help healthcare purchases mimic typical economic rationales); *see also* Marie McCullough, *Breakthrough Cancer Therapy Raises Tough Questions about Drug Costs, Value*, THE PHILADELPHIA INQUIRER (Feb. 6, 2018), https://www.inquirer.com/philly/health/breakthrough-cancer-therapy-raises-tough-questions-about-drug-costs-and-value-20180207.html [https://perma.cc/Y5ZQ-2X2K] (quoting one commentator's assertion that the "key question is not: What's it worth to save a child's life… If that was [sic] 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").

[80] HANDSHAKES, *supra* note 18, at 7.

[81] *Id*. at 6 & 119 n.11. Buying distortions in the healthcare market are described more fully in DRUG WARS, *supra* note 62, at 13 (noting that "pharmaceutical market does not operate much like a standard market at all"); Clifford D. Stromberg, *Health Law Comes of Age: Economics and Ethics in a Changing Industry*, 92 YALE L.J. 203, 209–11 (1982) (reviewing WILLIAM J. CURRAN & E. DONALD SHAPIRO, LAW, MEDICINE AND FORENSIC SCIENCE (3rd ed. 1982)); Abigail Moncrieff, *Understanding the Failure of Health-Care Exceptionalism in the Supreme Court's Obamacare Decision*, 142 CHEST 559, 559 (2012) (observing that in constitutional challenge to Patient Protection and Affordable Care Act, Supreme Court's failure to employ healthcare exceptionalism was "odd" holding that disregards uniqueness of healthcare market).

[82] HANDSHAKES, *supra* note 18, at 6–7 & 121 n.18.

IV. INTERESTS SERVED

Obviously, profits are an interest. But the profit motive alone does not explain the baroque arrangement of the pharmaceutical supply chain. Habits and pathways develop for a reason. This section will trace the factors that shaped the emergence of various intermediaries and their interactions.

A. The Emergence of Pharmacy Benefit Managers (PBMs)

As described in Section I, pharmacy benefit managers, or PBMs, play a crucial role in directing the flow of payments between patients, health plans, drug companies, wholesalers, distributors, and other members of the pharmaceutical supply chain.[83] But as much as PBMs' oversized role may seem like a fixture of the system, it is in fact the product of relatively recent historical circumstances.

The precursor to the PBM was a company called Pharmaceutical Card System (PCS), which opened its doors in 1969.[84] PCS handled prescription processing for medical insurance companies, formulary lists, and pharmacy reimbursements, collecting a fee for every claim processed.[85] McKesson, then the largest drug distributor in the U.S.,[86] bought PCS in 1970 in order to develop additional businesses—pharmacy benefit managers—that would operate under a similar model.[87] The timing was fortuitous: rising drug prices and a stagnant economy were stirring bipartisan anxiety over healthcare costs. In 1973, the Nixon administration passed the Health Maintenance Organization (HMO) Act,[88] which heralded a shift from the private healthcare policies of the postwar period to "managed care,"[89] wherein patients pay less to access a more restrictive set of services within a delineated network of hospitals and providers.[90] To control the cost of the prescription drug benefit, insurers developed outpatient drug formularies, or lists of the medications they covered.[91] At the same time, HMOs and other insurance companies outsourced their claims to PBMs for processing in order to

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[83] *See generally* Feldman, *Devil*, *supra* note 17; HANDSHAKES, *supra* note 18; Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed*, WASH. POST (Nov. 26, 2018) [hereinafter Feldman, WASH. POST], https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/ [https://perma.cc/V4FH-WLWF].

[84] POSNER, *supra* note 11, at 392.

[85] *Id*.

[86] McKesson remains one of the largest drug wholesale distributors in the U.S. *See* Fein, *Wholesalers*, *supra* note 12.

[87] POSNER, *supra* note 11, at 392.

[88] *See* Health Maint. Org. Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (1973).

[89] POSNER, *supra* note 11, at 390.

[90] *See, e.g.*, *Appendix B. A Brief History of Managed Care*, NAT'L COUNCIL ON DISABILITY, https://www.ncd.gov/policy/appendix-b-brief-history-managed-care [https://perma.cc/WZ7A-QFJH].

[91] Feldman, *Devil*, *supra* note 17, at 12.

reduce their own bureaucratic labor. Riding on this wave, PBMs acquired tens of millions of customers over the next decade.[92]

Between the 1980s and early 2000s, PBMs took on a more involved role in the pharmaceutical supply chain.[93] By introducing mail order drug delivery programs, PBMs edged out corner drugstores; by developing computer software that made it easier and faster to process prescriptions, PBMs inserted themselves into retail pharmacy chains as in-house service providers.[94] PBMs' expanding middleman function quickly entrenched PBMs in the system as a source of drug history information for the patients they served.[95] But it wasn't until the 2006 enactment of Medicare Part D—the Voluntary Prescription Drug Benefit Program—that PBMs' position in the pharmaceutical supply chain took on the dimensions it has today.[96] A component of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare Part D incorporated prescription drug coverage into Medicare.[97] The resulting wave of new patients with prescription drug coverage prompted health plans to give PBMs two new and significant responsibilities: designing formularies for health plans and extracting rebates from drug companies.[98]

Since the 1984 passage of the Hatch–Waxman Act, which facilitated the entry of generic drugs to market, brand-name drug companies had been looking to lay

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[92] POSNER, *supra* note 11, at 392.

[93] Throughout the 1990s, drug companies—following the lead of Merck, which bought Medco in 1993—began to acquire PBMs in recognition of their ability to assert control over drug pricing, which was previously the domain of the companies. Once the FTC caused drug companies to divest from PBMs, PBMs began to acquire other PBMs instead. The market consolidated to the point that, by 2015, just three companies—CVS Caremark, Express Scripts, and UnitedHealth Optum—controlled 73% of the market. *See* MENTAL HEALTH AM. OF CAL., *Fact Sheet: Pharmacy Benefit Managers*, CONNECTION COAL., http://www.mhac.org/wp-content/uploads/2018/03/Fact-Sheet-PBMs-Final.pdf [https://perma.cc/X747-V8EJ] ("It was during the mid to late 1990's that drug manufacturers purchased PBMs (e.g., Merck purchased Medco in 1993). Yet, the FTC considered these relationships a conflict of interest and required the manufacturers to divest themselves of the PBMs. Subsequently, between 1998 and 2003 the manufacturers severed ownership of their PBM."); *see also* Matan C. Dabora, Namrata Turaga, Kevin A. Schulman, *Financing and Distribution of Pharmaceuticals in the United States*, 318 JAMA 21, 21 (2017) [hereinafter Dabora, *Financing and Distribution*] ("PBMs developed in the 1980s as employers added outpatient prescription drug coverage to their health insurance plans. By 2015, industry consolidation had resulted in 3 PBMs—CVS Caremark, Express Scripts, and UnitedHealth's Optum—controlling a 73% share of the PBM market.").

[94] POSNER, *supra* note 11, at 393.

[95] *Id*.

[96] Feldman, WASH. POST, *supra* note 83; *see also* Feldman, *Devil*, *supra* note 17, at 10.

[97] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

[98] *See* Feldman, *Devil*, *supra* note 17.

bulwarks against the erosion of their dominance.[99] To offset the flood of cheaper options generic companies presented patients, brand drug companies began vying for favorable placement in insurers' formularies by offering rebates to insurance companies.[100] The enactment of Medicare Part D put both ends of this process in the hands of PBMs. Insurers pay PBMs a portion of the rebate that PBMs negotiate, which is supposed to incentivize PBMs to push for larger discounts.[101] Similarly, the formulary structure is supposed to incentivize patients to choose cheaper drugs by placing these drugs on lower "tiers" and providing that lower tiers have lower out-of-pocket payments for patients.[102] These incentives theoretically work together to keep healthcare costs down for insurers and patients alike.[103]

Instead, PBMs and drug companies treat the former as a means of securing the latter. Rather than tendering greater discounts, pharmaceutical companies simply raise their list prices, which enables them to grant PBMs a steeper rebate without offsetting any costs[104]—a move that PBMs encourage without oversight[105]—by offering companies better or worse formulary placement, or even the exclusion of a competitor from the formulary, depending on the amount they can earn from the deal.[106] To exacerbate matters, the prices around which these negotiations revolve are hidden.[107] Contracts between PBMs and health plans are based on the size of the rebate the signatories believe the PBM can negotiate, but the health plan never learns how big the rebate actually is, meaning the PBM

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[99] *See generally* DRUG WARS, *supra* note 62.

[100] *See id*. at 70; *see also* HANDSHAKES, *supra* note 18, at 20.

[101] *See* Feldman, *Devil*, *supra* note 17, at 12; HANDSHAKES, *supra* note 18, at 17 (describing how incentives are intended to work along pharmaceutical supply chain).

[102] *See* Feldman, *Devil*, *supra* note 17, at 3.

[103] *See generally* Feldman, *Devil*, *supra* note 17.

[104] *See* HANDSHAKES, *supra* note 18, at 18–19; *see also* Feldman, WASH. POST, *supra* note 83.

[105] *See* POSNER, *supra* note 11, at 495 ("PBMs are the only unregulated part of the pharmaceutical supply chain. [For PBMs,] [t]here are no requirements for public transparency. [And PBMs] have [no] legal obligation to disclose to anyone the rebates they received from pharma companies.").

[106] *See* HANDSHAKES, *supra* note 18, at 18–19; Feldman, *Devil, supra* note 17, at 15–16 (summarizing lawsuits concerning Johnson & Johnson, Sanofi Pasteur, and Allergan); *see also* Complaint at 1, Pfizer, Inc. v. Johnson & Johnson, 2018 U.S. Dist. LEXIS 31690 (E.D. Pa. 2017) (No. 17-CV-4180) (E.D. Pa. dismissed per stipulation July 20, 2021); Complaint at 3, Castro v. Sanofi Pasteur, Inc., 2017 U.S. Dist. LEXIS 174708 (D.N.J. 2011) (No. 11-CV-7178) (D.N.J. dismissed Oct. 20, 2017); Complaint at 6, Shire U.S., Inc. v. Allergan, Inc., 375 F. Supp. 3d 538 (D.N.J. 2017) (No. 17-CV-7716).

[107] *See* Feldman & Graves, *supra* note 20, at 72; *see also supra* text accompanying notes 45, 46.

keeps the difference if the rebate is larger than anticipated.[108] The "black box" nature of this process is by design: as the Medicare Prescription Drug, Improvement, and Modernization Act made its way through Congress, pharmaceutical companies lobbied to make sure the Act explicitly barred Medicare from negotiating drug prices.[109] In so doing, the industry set up PBMs to take on the expansive and domineering role they play today. The 2010 Affordable Care Act includes a similar provision.[110]

B. The Emergence of Volume Rebating

PBMs do not act alone. Drug companies exploit PBMs' intermediary role in the pharmaceutical supply chain to hoard market share and keep out competitors. One significant way in which this happens is through the practice of volume rebating.

Volume rebating can take several forms. At the most basic level, an entrenched drug company takes advantage of its established position in the market by promising a PBM a bigger profit if the PBM sells more of the drug company's product.[111] The drug company does so by offering to pay the PBM a certain amount of money per unit of product sold. Given that the entrenched drug company can offer more units of the product, a new competitor that does not have the resources or market share to sell as many units simply cannot pay the PBM the same level of compensation, no matter how cheaply the new competitor prices its drug. The entrenched drug company thereby prevents the new competitor from gaining a foothold in the market, padding PBM pockets along the way.

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[108] *See* Feldman, *Perverse Incentives*, *supra* note 20, at 327 ("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.").

[109] *See, e.g.*, Dabora, *Financing and Distribution*, *supra* note 93; *Fact Sheet: How Much Money Could Medicare Save By Negotiating Prescription Drug Prices?* COMM. FOR A RESPONSIBLE FED. BUDGET (Apr. 11, 2016), https://www.crfb.org/press-releases/fact-sheet-how-much-money-could-medicare-save-negotiating-prescription-drug-prices [https://perma.cc/U3DJ-486M] ("Federal law currently prohibits the Secretary of Health and Human Services from negotiating prescription drug prices. Only Congress has the power to change this law."); POSNER, *supra* note 11, at 495 ("The pharmaceutical industry lobbied to ensure that the legislation [the Medicare Prescription Drug, Improvement, and Modernization Act] explicitly prevented the government from negotiating drug prices.").

[110] *See* Brett Norman & Sarah Karlin-Smith, *The One That Got Away: Obamacare and the Drug Industry*, POLITICO (July 13, 2016, 5:32 AM), https://www.politico.com/story/2016/07/obamacare-prescription-drugs-pharma-225444 [https://perma.cc/KH89-8752] ("No government negotiations of drug price—although both Donald Trump and Hillary Clinton have endorsed Medicare negotiations.").

[111] *See* HANDSHAKES, *supra* note 18, at 21–22 (walking through the incentives underlying the practice of volume rebating).

The situation may be analogized as follows.[112] Imagine a major alcohol company approaching a bar owner with a proposal: if the bar owner sells 50,000 bottles of the company's beer, the company will pay her fifty cents per bottle. If the bar owner sells 50,000 bottles of the company's beer *and* refuses to put a certain competing microbrewery's beer on the menu, the company will pay her a dollar per bottle. The microbrewery cannot compete if it can only make a limited number of bottles of beer; the alcohol company's proposal essentially squeezes the microbrewery out of a deal with the bar and preserves for the company a larger share of the bar's beer sales.

To be clear, volume rebating is neither unique to the pharmaceutical industry nor inherently anticompetitive.[113] For example, a manufacturer of computer chips may attempt to attract a technology company's business by offering a volume discount on its chips.[114] Neither the manufacturer's success in attracting the technology company's business, nor even the technology company's decision to purchase all of its chips from the single manufacturer, would necessarily herald anticompetitive behavior.[115] But context is key. In the pharmaceutical industry, volume rebating enables drug companies to prolong the monopoly rewards of a patent that had been granted by the government with the understanding that those rewards would be finite. Moreover, volume rebating determines which drugs a PBM includes in the health plan's formulary.[116] While a consumer can elect to buy a computer from a different technology company, a patient cannot always choose to forego a drug or to switch to a different drug because the one they need is too expensive.[117] Yet these are the options left open to patients when drug companies engage in volume rebating.

Volume rebates become even less surmountable when multiplied across drug classes. In this situation, also known as "bundled," "packaged," or "loyalty" rebating, a drug company tells the PBM that in order to receive the best rebate, the

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[112] The following analogy is adapted from *id*.

[113] *See* Fiona Scott Morton, Deputy Assistant Att'y Gen., Antitrust Div., Speech at the Georgetown University Law Center Antitrust Seminar: Contracts that Reference Rivals 2 (Apr. 5, 2012), (transcript available at https://www.justice.gov/atr/file/518971/download [https://perma.cc/4TYH-K4LK]).

[114] This example is adapted from HANDSHAKES, *supra* note 18, at 28.

[115] Scott Morton, *supra* note 113, at 5 ("For instance, observing that a buyer has bought exclusively from one seller is not necessarily a problem: sellers may bid for a buyer's business, and a particular buyer may choose to extract all surplus by buying from one seller.").

[116] *See* HANDSHAKES, *supra* note 18, at 28 (describing unique consequences of volume rebating in drug industry).

[117] Alternately, the patient could choose to enroll in a different health plan. However, these choices are often limited not only by the patient's employer or geographic region, but by numerous other considerations, including cost and the coverage of other needed drugs or services. *See id*. at 29.

PBM must sell a certain quantity of each of several drugs in a portfolio.[118] To put that in terms of the bar analogy, the alcohol company tells the bar owner it will offer her a better discount if, in addition to selling a certain number of bottles of beer, she also sells a certain amount of the company's whiskey and vodka. Even if the microbrewery could compete with the company's beer proposal, it would nevertheless be edged out of the market due to its inability to manufacture equivalent quantities of whiskey and vodka *and* offer a similarly high discount across the same range of drinks. With this method, drug companies can leverage dominant products in its portfolio—for example, a major drug still under patent protection that has no branded therapeutic or generic alternatives—to protect its market share in products that are under threat from competitors by bundling the therapeutic or generic products with the dominant portfolio products. Because health plans must offer at least one drug in each therapeutic class, such bundled rebates are particularly attractive to PBMs.[119]

Volume rebates block smaller drug companies and generic drug companies from gaining traction in the market. They also enable brand drug companies to extend their patent-driven monopolies well beyond the expiration of those patents. Brand drug companies may sweeten the deal by paying PBMs extra money under labels such as "data management fees" or "administrative fees."[120] While the rebate payment scheme at least nominally encourages PBMs to seek out larger discounts, these extra fees are untethered from any such obligation. With these discounts, drug companies sway PBMs even further from the supposed mission of lowering costs.

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[118] *See* HANDSHAKES, *supra* note 18, at 21; *see also* Robin Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2080, 2104–05 (1999) (describing similar notion of defensive leveraging in which firm uses monopoly on one product to help preserve its monopoly in another market). As an example, Eli Lilly, an antibiotic monopolist in the 1970s, required hospitals to purchase three of its five antibiotic products to receive a rebate. The program impeded new competitor SmithKline from entering with its two new antibiotic products because the collective rebate amount across the five drugs was too high for SmithKline to match on a single drug. *See* SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1060, 1062 (3d Cir. 1978).

[119] *See* U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 67 (explaining mandate to include drug from each therapeutic group).

[120] HANDSHAKES, *supra* note 18, at 15 & 131–32 n.84; *see also* Response Letter from Eric R. Slusser, Exec. Vice President/CFO, Express Scripts Holding Co., to Div. Corp. Fin., U.S. Sec. & Exch. Comm'n (Jun. 26, 2017) (available at https://www.sec.gov/Archives/edgar/data/0001532063/000119312517213574/filename1.htm [https://perma.cc/YSV6-EZXY]) (responding to SEC request for more information on rebate program: "We administer a rebate program through which we receive rebates and administrative fees from pharmaceutical manufacturers."); Linda Cahn, *Don't Get Trapped By PBMs' Rebate Labeling Games*, MANAGED CARE MAG., www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games [https://perma.cc/JMW9-VG6C]. PBM fee amounts are on the rise in recent years, nearly quadrupling between 2014 and 2016. *See* Zirkelbach, *supra* note 53.

Most insidious of all is the fact that the details of these payments and prices—from the pre-rebate price of the drug to the size of the rebate itself to the existence and quantity of any fees—are obscured from other supply chain entities as well as from regulators and the public.[121] The health plan sees only the price a patient pays when purchasing a drug and the total rebate the PBM has secured after it has deducted its portion, a lack of transparency that PBMs and drug companies justify with spurious trade secrecy claims.[122] This arrangement allows PBMs to continue to mine for profits under a cloak of obfuscation that hides the dollar flow along with the very workings of the pharmaceutical supply chain itself.

C. The Emergence of Wholesale Distributors

Wholesale distributors have been part of the pharmaceutical supply chain for much longer than PBMs, though wholesale distributors' role in driving up prices is likewise a relatively recent development.

Drug companies have sold their products wholesale to intermediaries who distribute them to retailers since the 1800s, a century before the pharmaceutical industry as we know it grew out of World War II–era research initiatives.[123] McKesson and AmerisourceBergen, two of the "Big Three" drug wholesale distributors operating in the United States today, were established in 1833[124] and 1871,[125] respectively. The third largest wholesale distributor, Cardinal Health, was originally founded in 1971 as a food distributor.[126] Over the long history of their existence, wholesale distributors' place in the pharmaceutical supply chain has not gone uncontested. In the 1940s, following in the vertically integrated Squibb's lead, some drug companies underwent corporate restructuring to try and eliminate their need to deal with a middleman.[127] These decisions were made

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[121] *See* Feldman & Graves, *supra* note 20, at 72 (describing how trade secrecy claims serve to guard contract information from parties—including health plans and auditors).

[122] *Id.*

[123] *See generally* POSNER, *supra* note 11.

[124] *Our History: Advancing Healthcare*, MCKESSON, https://www.mckesson.com/About-McKesson/Our-History/ [https://perma.cc/HR5S-NC2P].

[125] *Our History*, AMERISOURCEBERGEN, https://www.amerisourcebergen.com/about-us/our-history [https://perma.cc/8Q25-WHNQ].

[126] *Executive Interview: Bob Walter*, J. HEALTHCARE CONTRACTING, https://www.jhconline.com/executive-interview-bob-walter.html [https://perma.cc/4CSQ-XHPG].

[127] *See* POSNER, *supra* note 11, at 49 ("Despite the intense competition, Squibb's penicillin profit margins were 10 percent better than the average of its top four rivals. That was because it was the only vertically integrated firm, not only manufacturing the drug, but packaging it before selling it to hospitals, clinics, and physicians. Competitors only made it and then relied on packages and wholesale distributors. Starting in the late 1940s, Pfizer, Merck, Lilly, and Parke-Davis created internal divisions to eliminate the middlemen.").

in an effort to bolster profits on penicillin, then a newly invented wonder drug.[128] But drug companies and wholesale distributors have since come to work in tandem to extract profits from the system.

Unusually for a product distributor, drug wholesale distributors make most of their profits from the buy-side rather than the sell-side, partly due to cost pressure on providers by Medicare, Medicaid, insurance companies, and other third-party payers.[129] Throughout the 1990s, drug wholesale distributors capitalized on drug companies' annual price increases—which regularly averaged one percent above inflation—via investment buying: wholesale distributors purchased large quantities of drugs in anticipation of the increase, then sold their inventory at a small markup.[130] Investment buying was a boon for drug companies, too, who found in wholesale distributors a receptive partner for channel stuffing, a process through which companies inflate their sales figures by pushing extra product through a distributor.[131] In 2002, however, the U.S. Securities and Exchange Commission (SEC) launched a probe into Bristol-Myers Squibb for this practice.[132] Though the SEC did not end up finding Bristol-Myers guilty (the company settled for $150 million instead[133]) the anxiety the probe provoked among wholesale distributors prompted them to inaugurate the payment model in place today.[134]

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[128] *Id*.

[129] *See* Leroy B. Schwarz & Hui Zhao, *The Unexpected Impact of Information Sharing on U.S. Pharmaceutical Supply Chains*, 41 INTERFACES 354, 355 (2011) ("Indeed, unlike distributors of most other products who earn money on the 'sell side,' pharmaceutical distributors earn most of their gross margin from the *manufacturers* whose products they distribute.… Distributors earn their margin on the buy side for many reasons; these include the buying power of large retail pharmaceutical chains that dispense the majority of pharmaceuticals, and cost pressure on providers (e.g., hospitals) by third-party payers (e.g., Medicare, Medicaid, and insurance companies). This cost pressure encouraged the development of healthcare group-purchasing organizations, which negotiate the prices that their (otherwise unaffiliated) provider members pay for pharmaceuticals and other supplies.").

[130] *See id*. at 355–56.

[131] *See id*. at 356.

[132] *SEC Eyes Bristol-Myers*, CNN MONEY (July 11, 2002, 4:36 PM), https://money.cnn.com/2002/07/11/news/companies/bristolmyers/index.htm [https://perma.cc/B4R4-J7ES] ("The company made so many sales to wholesalers last year that inventories built up too much, causing the company to have to restate its revenue and earnings expectations for 2002. The SEC wants to know if the company inflated sales purposefully by offering incentives to wholesalers—including warnings that it planned to raise prices on some of its products—in order to meet last year's revenue targets. Analysts have said the company's sales practices may have boosted revenue by as much as $1 billion").

[133] Press Release, U.S. Sec. & Exch. Comm'n, Bristol-Myers Squibb Company Agrees to Pay $150 Million to Settle Fraud Charges (Aug. 4, 2004) (available at https://www.sec.gov/news/press/2004-105.htm [https://perma.cc/3SJQ-T5GS]).

[134] *See* Schwarz & Zhao, *supra* note 129, at 357; *see also* Adam J. Fein, *Drive the Right Supply Chain Behaviors*, HARV. BUS. REV. (Aug. 2005),

Under this model, wholesale distributors and brand drug companies come to terms known by any of several acronyms: "distribution service agreements" (DSA), "fee for service agreements" (FFS), "inventory management agreements" (IMA), or "distribution performance agreements" (DPA).[135] In what is essentially a safeguard against the appearance of channel stuffing, drug companies offer wholesale distributors a discount on their products if wholesale distributors keep their inventories low.[136] Drug companies also pay wholesale distributors a percentage of the brand drug's list price, also called the "wholesale acquisition cost" (WAC), as compensation for distributing the drugs as well as for taking on financial responsibility for them.[137] By purchasing and taking legal ownership of the drug company's products, the wholesale distributor absorbs credit risk for holding and reselling inventory.[138]

Of course, this compensation scheme means that wholesale distributors' profits grow whenever drug companies raise the list price; when the list price rises, the fee earned by wholesale distributors rises because the fee is a percentage of list price.[139] How the scheme incentivizes wholesale distributors to rely on price

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http://www.pembrokeconsulting.com/pdfs/Drive~the~Right~Behaviors-Fein-August2005.pdf [https://perma.cc/E5MYA6KT].

[135] *See* Adam J. Fein, *How Wholesalers Profit from Brand-Name Drug Inflation (But Probably Not as Much as You Think)*, DRUG CHANNELS (Oct. 22, 2015), https://www.drugchannels.net/2015/10/how-wholesalers-profit-from-brand-name.html [https://perma.cc/GY42-WBRT] [hereinafter Fein, *Inflation*].

[136] *See* Schwarz & Zhao, *supra* note 129, at 357–58.

[137] *See id*.; Fein, *Inflation*, *supra* note 135 ("DSA fees are generally computed as a percentage of a brand-name drug's list price. Therefore, the dollar value of a wholesaler's fee payment from the manufacturer rises whenever a manufacturer increases a drug's list price—the Wholesale Acquisition Cost (WAC). Gross profits increase because the wholesaler's fees are computed based on the new, higher price. The wholesaler could also benefit by selling inventory purchased at the older price at the new higher price.").

[138] *See The High Cost of Access: Fact or Fiction?*, AMERISOURCEBERGEN, https://www.amerisourcebergen.com/brand-stories/mythbusting-the-high-cost-of-access [https://perma.cc/9ZXP-WVUV] [hereinafter AMERISOURCEBERGEN, *High Cost*] ("[Perhaps] most importantly, distributors take on financial risk by taking title to and carrying inventory. We also extend credit for the products we buy from manufacturers and sell to customers. Distributors infuse critical cash into manufacturers' areas of core competency (like R&D) and ensure critical products are on pharmacy shelves for the customers who need them."); Adam J. Fein, *Building a New Drug Wholesaler Compensation Model: What Happens as Brand Inflation Slows?*, DRUG CHANNELS (July 24, 2018), https://www.drugchannels.net/2018/07/building-new-drug-wholesaler.html [https://perma.cc/9BRK-MXTV] [hereinafter Fein, *New Compensation Model*] ("[Wholesalers] also play a crucial role in the financial transactions within the drug distribution system. They purchase and take title (legal ownership) to a manufacturer's product and absorb credit risk when reselling a manufacturer's products. As a result of this channel role, the two biggest components of wholesalers' current assets are (1) the product inventories purchased from manufacturers and owned by the wholesaler, and (2) the accounts receivables that customers owe to wholesalers.").

[139] *See e.g.*, Fein, *Inflation*, *supra* note 135.

hikes, however, is less straightforward than it may first appear. Although wholesale distributors are occasionally able to bolster their margins by selling inventory purchased at a pre-hike price at the new post-hike price, drug companies tend to guard against this possibility by including recapture and revaluation clauses in their service agreements.[140] Under these clauses, the wholesale distributor must return to the drug company the difference between the value of the inventory before and after a price increase.[141] The wholesale distributor's profits still increase because the WAC, and therefore the WAC fee, has increased, but its gross margins stay the same.[142] As a result, the wholesale distributor becomes dependent on regular price hikes in order to maintain its margins and satisfy its stakeholders—even though it may continue to make a more-than-healthy profit from its WAC fee.[143]

Meanwhile, drug companies do not have to report the amount the wholesale distributor pays them following each revaluation,[144] contributing to the confusion over the price paid for a drug by any given entity in the pharmaceutical

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[140] *See* Adam J. Fein, *McKesson's Profit Shortfall: How Wholesalers Benefit from Rising Drug List Prices*, DRUG CHANNELS (Jan. 26, 2017), https://www.drugchannels.net/2017/01/mckessons-profit-shortfall-how.html [https://perma.cc/24UD-3J48] [hereinafter Fein, *Shortfall*] (describing recapture and revaluation clauses).

[141] *See id*.

[142] *See id*.; Adam J. Fein, *What McKesson's Profit Warning Means for Manufacturers and Pharmacies*, DRUG CHANNELS (Oct. 31, 2016), https://www.drugchannels.net/2016/10/what-mckessons-profit-warning-means-for.html [https://perma.cc/CX9T-P8A9] [hereinafter Fein, *Profit Warning*].

[143] *See* Fein, *Profit Warning*, *supra* note 142. Fein quotes from an interview with John Hammergren, Chairman, President, and CEO of McKesson:

[W]here a manufacturer's behavior has changed dramatically from its previous behavior and we had come to depend on those mechanisms as part of our funding source with that manufacturer, I think we have every right to go back to those manufacturers and say, listen, we need to open the dialog again because by your unilateral decision, you have significantly impacted our profitability on your particular product lines and we don't think that's fair and we want to recover that lost margin.

Id. Fein glosses the statement as follows: "Here, a 'manufacturer's behavior' means its list price increases. Hammergren's statement implies that McKesson will go after manufacturers that make a 'unilateral decision' not to increase WAC list prices." *Id*. *See also* AMERISOURCEBERGEN, *High Cost*, *supra* note 138 ("Myth: Distributors benefit from—and encourage—high drug prices. Fact: Wholesalers' fees are in direct correlation to the amount of risk they take on for a product."). Note that AmerisourceBergen does not explicitly rebut wholesale distributors' role in driving up drug prices—it only explains why they are justified for receiving them.

[144] Fein, *Shortfall*, *supra* note 140 ("The manufacturer gains the value of price increase on product that has been purchased by wholesaler but not yet sold to wholesaler's customer.... [These] sums therefore have important implications for government pricing and manufacturer's channel compensation approaches. Revaluation amounts can be substantial, although manufacturers do not typically report the value of inventory revaluation received from wholesalers.").

supply chain.[145] Because state governments use these prices to calculate the amount they reimburse pharmacies for prescription drugs dispensed via Medicaid,[146] the consequences of hidden transactions extend not only to patients but to taxpayers. A 2005 report from the Department of Health and Human Services put it frankly:

[State] Medicaid agencies generally use AWP [average wholesale price] and/or WAC to estimate pharmacy acquisition costs for drug reimbursement. However, studies, investigations, and audits by OIG [Office of Inspector General], the Department of Justice, and others have found that these published prices, particularly AWP, substantially overstate the actual prices pharmacies pay for drugs.[147]

Consequently: "because States lack accurate drug pricing data, Medicaid drug reimbursements exceed pharmacies' actual acquisition costs."[148]

D. The Emergence of "Hidden Brokers"

The byzantine structure of the pharmaceutical supply chain has also given rise to hidden brokers like Pharmacy Services Administrative Organizations (PSAOs) and Group Purchasing Organizations (GPOs), acronyms tucked between pharmacies and other intermediaries.[149] Although these brokers may

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[145] *See generally* Gencarelli, *supra* note 41 (describing problems with use of average wholesale price (AWP) for reimbursement by Medicaid, Medicare, and other government drug purchasing programs); Leigh Ann Anderson, *Average Wholesale Price (AWP) as a Pricing Benchmark*, DRUGS.COM (Sept. 23, 2020), https://www.drugs.com/article/average-wholesale-price-awp.html [https://perma.cc/8GCZ-227J] ("Reimbursements from insurance companies (including. [sic] pharmacy benefit managers—PBMs) may be based on AWPs. However, pharmacies purchase drugs based on the WAC. The difference between the WAC (what the pharmacy actually paid for the drug) and the reimbursement from insurance (based on AWP) is known as the spread and equates to the profit that the pharmacy receives. Market pricing on brand name drugs tends to be roughly 15% less than the AWP. However, the relation of AWP to generic pricing is not clear. Older generics tend to have a large spread between the AWP and WAC, which in turn gives a large spread and higher profit margins for the pharmacy or other provider of the drug…. Collusion between AWP publishers and wholesalers to artificially inflate the AWP (a 25% markup instead of a 20% markup), and in turn increase the spread (the profit that the pharmacy receives), led to court cases in the U.S."); *Drug Pricing and Reimbursement 101: RJ Health—Methodologies & Drug Claims—AWP, WAC, ASP, APC Explained*, RJ HEALTH, https://rjhealth.com/2019/07/31/drug-pricing-101-reimbursement-rj-health-methodologies-drug-claims-code-level-unit-level-hcpcs-ndc/ [https://perma.cc/SUG7-J7NY] (describing how each kind of drug pricing is determined, frequently with built-in markups).

[146] *See e.g.*, Gencarelli, *supra* note 41, at 4–8.

[147] HHS OIG REPORT, *supra* note 39, at 3.

[148] *Id.* at 1.

[149] To visualize where PSAOs and GPOs stand in relation to the larger supply chain, *see* Oliver, *supra* note 4*; see also supra* text and chart accompanying note 5. Other "hidden"

facilitate competition by helping smaller, independent pharmacies and hospitals compete against their consolidated peers,[150] they also burden the system with another intermediary layer, further complicating the pathway of pharmaceuticals.[151]

PSAOs have developed to assist pharmacies—particularly smaller, independent pharmacies—as they negotiate contracts with PBMs and health plans.[152] The emergence of PSAOs represents a response to the extensive and convoluted agreements that underpin pharmacies' business with other players in the supply chain; many independent pharmacies lack the resources or wherewithal to handle these contracts on their own.[153] PSAOs, representing a cohort of many pharmacies at once, can thus empower smaller firms within a consolidated pharmacy landscape.[154]

Viewed another way, however, PSAOs exemplify how complexity in a system begets additional complexity. The demand for PSAO services, after all, is a reaction to the powerful inscrutability of PBMs, another intermediary in the supply chain.[155] Moreover, although supportive of smaller firms, PSAOs may also help entrench other consolidated intermediaries: 75% of independent

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agents operate discreetly in the supply chain, including rebate aggregators & pharmacy brokers. Like other intermediaries in the supply chain, PSAOs primarily operate under a veil of secrecy, although some states recently passed state laws intended to bolster reporting requirements. *See, e.g.*, H.B. 978, 2020 Leg., 441st Sess. (Md. 2020); *see also* PHARM. CARE MGMT. ASS'N, PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (PSAOS) AND THEIR LITTLE-KNOWN CONNECTIONS TO INDEPENDENT PHARMACIES 10 (2021) [hereinafter LITTLE-KNOWN CONNECTIONS] (other states like West Virginia and Wisconsin have also considered measures requiring PSAOs to report pharmacies they contract with—along with their fee structures).

[150] *See* GAO PSAO REPORT, *supra* note 23, at 22 (describing how PSAOs create efficiencies for independent pharmacies).

[151] *But see id.* at 23 (noting that PSAOs generally charge monthly fee to members for their services, which may avoid some of spread pricing concerns that plague PBM or GPO sectors). *See supra* Section IV, Part A (describing how PBM compensation structure may motivate PBMs to pursue higher drug prices).

[152] *See generally* GAO PSAO REPORT, *supra* note 23; *see also* LITTLE-KNOWN CONNECTIONS, *supra* note 149, at 8 (noting that 83% of independent pharmacies are represented by PSAO as of 2019—marginal increase from 80% described in 2012 GAO Report).

[153] GAO PSAO REPORT, *supra* note 23, at 15–16.

[154] *See* Patrick M. Kelly, Matthew J. DiLoreto & Elyse Petroni, *Pharmacy Services Administrative Organizations (PSAOs)*, HEALTHCARE DISTRIBUTION ALL., https://www.hda.org/issues/pharmacy-services-administrative-organizations [https://perma.cc/TKW8-HSFL] (noting that independent pharmacies comprise about 35% of U.S. pharmacy market); *see also* Fein, *Pharmacies*, *supra* note 13 (reporting collective market share of independent pharmacies pales compared to that of three largest pharmacy chains, which together account for more than half of market).

[155] *See* GAO PSAO REPORT, *supra* note 23, at 15–16 ("Independent pharmacies generally lack the legal expertise and time to adequately review and negotiate third-party payer or PBM contracts, which can be lengthy and complex.").

pharmacies use PSAOs that are owned by the three dominant wholesale distributors.[156] Wholesale distributors can leverage their PSAO services to not only retain their pharmacy clients, but also benefit their distribution business by increasing the drug volume that an independent pharmacy requires as an outcome of their negotiated PBM contract.[157] In this way, PSAOs and wholesale distributors may mutually reinforce one another's market position, helping to solidify the complexity of the system.

Group purchasing organizations (GPOs) occupy an analogous niche between independent pharmacies or hospital clinics and wholesale distributors. A GPO, like a PSAO, bands together many individual actors—small pharmacies, in addition to hospitals and health clinics—to obtain drugs from wholesalers at a discounted rate.[158] The first GPO—a group of New York hospitals—formed in 1910;[159] there are now more than 600 organizations of this kind, although the GPO market for prescription drugs is dominated by an increasingly consolidated few.[160]

Spurring the rise of GPOs was first the inception of Medicare and Medicaid,[161] and then, in 1986, the passage of a "safe harbor" provision to the Anti-Kickback Statute clarifying that GPOs could receive administrative fees from suppliers.[162] A 2012 Government Accountability Office study found, consequently, that large GPOs are funded almost entirely by supplier or vendor fees, which are determined by applying a percentage—ranging from less than one percent to more than three percent for generic prescription drugs—to the

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[156] *See* LITTLE-KNOWN CONNECTIONS, *supra* note 149, at 1 (noting that Cardinal Health, AmerisourceBergen, and McKesson own PSAOs used by vast majority of independent pharmacies).

[157] *See* GAO PSAO REPORT, *supra* note 23, at 27.

[158] *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-13, GROUP PURCHASING ORGANIZATIONS: FUNDING STRUCTURE HAS POTENTIAL IMPLICATIONS FOR MEDICARE COSTS (2014) [hereinafter GAO GPO REPORT] (discussing how GPOs help pharmacies and healthcare providers purchase medical devices and services, in addition to prescription drugs); *see generally* DAN O'BRIEN, JON LEIBOWITZ & RUSSELL ANELLO, GROUP PURCHASING ORGANIZATIONS: HOW GPOS REDUCE HEALTHCARE COSTS AND WHY CHANGING THEIR FUNDING MECHANISM WOULD RAISE COSTS (2017) (funded by Healthcare Supply Chain Association (HSCA) trade & lobbying group that advocates for GPOs).

[159] *The Evolution of Group Purchasing Organizations*, DRUG TOPICS (Oct. 10, 2016), https://www.drugtopics.com/view/evolution-group-purchasing-organizations [https://perma.cc/GGA3-CT7E].

[160] *See* GAO GPO REPORT, *supra* note 158, at 5.

[161] *See* DRUG TOPICS, *supra* note 159 (following the launch of Medicare and Medicaid, the number of GPOs grew to around forty by 1974).

[162] Omnibus Budget Reconciliation Act of 1986, 42 U.S.C. §§ 1320a-7b(b)(3)(C) (1986); 42 C.F.R. § 1001.952(j) (1991); *see* GAO GPO REPORT, *supra* note 158, at 6–7 (clarifying 1991 HHS qualification requirements for GPOs to qualify for safe harbor); *see also* O'BRIEN, *supra* note 158, at 5 (noting that no previous court found that vendor fees paid to GPOs constituted kickback).

negotiated price of a given product.[163] Although proponents of GPOs tout their ability to reduce supply and transaction costs for their members,[164] their fee-based compensation structure, like that of PBMs,[165] may act to discourage GPOs from fighting for lower prices.[166] Pharmacies or small clinics that choose to go it alone, however, may not be able to marshal sufficient volume to deal attractively with wholesaler distributors.[167]

To keep afloat in the flood of paperwork and contracts that is the prescription drug supply chain, independent pharmacies have increasingly turned to PSAOs and GPOs. However, the consequent growth of PSAOs and GPOs has ironically saddled the supply chain with another layer of transactions and negotiations, requiring drugs to pass through more hands—and empty more pockets—before reaching patients. Patterns of horizontal[168] and vertical[169] consolidation, meanwhile, empower intermediary firms to remain entrenched between drug companies and payors. In other words, we should not expect these hidden brokers to truly disappear.

Concentration at various levels of the industry also discourages disruption of the supply chain as a whole. Only three major PBMs control most of the market.[170] As noted above, the wholesale distributor level also exhibits a high level

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[163] GAO GPO REPORT, *supra* note 158, at 16.

[164] *See e.g.*, O'BRIEN, *supra* note 158, at 3 (asserting that GPOs improve competition for healthcare procurement and lower prices for patients).

[165] *See supra* text accompanying notes 104–107 (describing how PBM compensation structure fuels higher prices); *see also* HANDSHAKES, *supra* note 18, at 18–21; Feldman, *Perverse Incentives*, *supra* note 20.

[166] GPOs are paid mainly by the suppliers with whom they contract, not the hospitals and pharmacies on whose *behalf* they contract, which may lessen the incentive to negotiate lower prices. Lower prices translate to lower vendor fees. *See* FTC Workshop Slides, *supra* note 14, at 169; *cf.* Robert E. Litan, Hal J. Singer & Anna Birkenbach, *An Empirical Analysis of Aftermarket Transactions by Hospitals*, 28 J. CONTEMP. HEALTH L. & POL'Y 23, 23 (2011) (finding that hospitals saved 10–14% when using purchasing agent *not* compensated by its suppliers).

[167] *See* Britt, *supra* note 12 (describing anecdotal accounts of independent pharmacies and small medical clinics cut off by major wholesalers for failing to meet minimum purchasing thresholds, forcing them to purchase from other pharmacies at significant markup).

[168] Pharmacies, PBMs, and wholesale distributors all exhibit remarkable horizontal consolidation, with the top three firms in each sector commanding more than 50%, 85% and 95% of their respective markets. *See* Fein, *Pharmacies*, *supra* note 13 (calculating 2020 pharmacy market); HANDSHAKES, *supra* note 18, at 14 (describing PBM market share in commercial insurance space); Fein, *Wholesalers*, *supra* note 12 (calculating 2019 wholesale distribution market).

[169] Several healthcare giants transcend one niche of the pharmaceutical supply chain, as increased vertical integration enables firms like Cardinal Health to capture revenue at every stage from contract manufacturing to pharmacy services administration. *See supra* text accompanying notes 29–37.

[170] The three largest PBMs control 85% of the commercial insurance market. *See* HANDSHAKES, *supra* note 18, at 14.

of concentration, with three large players dominating the industry.[171] This encourages conscious parallelism, in which companies that should be competing with one another offer similar prices and terms, often moving in lockstep.[172] Conscious parallelism is not illegal,[173] but it is undesirable from society's perspective. When everyone moves together, no one competes, and the result is a massive monolith of an industry, rather than one full of nimble, varied, and creative competitors.

Competitive opportunities are further weakened by those who play more than one role on the field—for example, a PBM running a chain pharmacy or an insurance company running a mail-order pharmacy. Vertically combined functions, in the proper circumstances, can provide opportunities to block competition. Although a half-century ago, the conservative Chicago School of Law and Economics posited that firms cannot extract additional monopoly rents through vertical integration, post-Chicago scholarship has demonstrated that such a strategy can be effective, particularly as a method of monopoly maintenance in the face of disruptive technologies.[174]

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[171] 95% of all prescription drugs move through the three largest wholesale distributors. *See* Fein, *Wholesalers*, *supra* note 12.

[172] *See* HANDSHAKES, *supra* note 18, at 102 & 174–175 n.57 (describing how major PBMs can tacitly coordinate contract terms and pricing by using services of PBM consultants, who share access to same databases of drug prices and formulary costs); 6 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW 1402 (3d ed. 2010) (describing hub-and-spoke conspiracies, in which middle player can facilitate collusion between market competitors without direct communication between competitors to each other); *see generally* U.S. v. Apple, Inc., 791 F.3d 290 (2d. Cir. 2015) (ruling against Apple and e-book publishers where Apple served as hub for the publishers).

[173] *See, e.g.*, Brooke Grp., Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 227 (1993) ("Tacit collusion, sometimes called oligopolistic price coordination or conscious parallelism, describes the process, not in itself unlawful, by which firms in a concentrated market might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by recognizing their shared economic interests and their interdependence with respect to price and output decisions."); Valspar Corp. v. E.I. Du Pont De Nemours & Co., 873 F.3d 185, 191 (3d Cir. 2017) ("Even though such interdependence or 'conscious parallelism' harms consumers just as a monopoly does, it is beyond the reach of antitrust laws[.]").

[174] *See, e.g.*, Feldman, *Defensive Leveraging*, *supra* note 118, at 2085 (challenging one-monopoly-profit rule); Hans-Theo Normann, *Vertical Integration, Raising Rivals' Costs and Upstream Collusion* 10–11 (Max Planck Inst. for Rsch. on Collective Goods, Working Paper No. 2008/30, 2008) (finding that equilibrium needed to sustain joint-profit maximum of certain colluding firms is unambiguously lower with vertical integration than that needed for collusion in separated industry); Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 ANTITRUST L. J. 513, 515 (1995) (explaining that post-Chicago theorists, employing newer methodologies of modern industrial organization, have identified circumstances in which vertical mergers and vertical restraints can raise significant competitive concerns). U.S. competition agency views on the topic, particularly

In short, there must be a better way to run a railroad. The myriad twists and turns of the pharmaceutical supply chain, combined with high levels of concentration at various levels, ensure that patients and payors will be burdened by excessive costs. The results are visible in the soaring costs of prescription medication, particularly in comparison to the same drugs across time and in other industrialized nations.[175]

V. FROM HERE TO THERE

Trees grow in strange and twisted ways to adapt to the environment. Branches will bend and weave to reach the open sun; trunks will embed themselves in chain-link fencing; roots will spread to a neighboring yard when a swimming pool blocks their path. And so it is with the pharmaceutical supply system. The system has sprouted in winding ways as participants try to avoid obstacles and reach for additional nourishment. The result, however, is not necessary, nor is it inevitable.

Even operating within current constraints, one could imagine and design effective disruptions to the system. The ingredients could include a direct pipeline, storage, and delivery components, and perhaps a dash of regulatory nourishment. And where is the best place for such a new system to sprout? An excellent location would be in the laboratories of democracy themselves: the states.

As Justice Brandeis explained in a legendary dissent: "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[176] A state's right to engage in this

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related to a vertical merger's capacity to raise rivals' costs, have evolved over time from a Chicago-School perspective to a post-Chicago perspective. *Compare* Malcolm Coate & Andrew N. Kleit, *Exclusion, Collusion, and Confusion: The Limits of Raising Rivals Cost* (Fed. Trade Comm'n, Bureau of Econ., Working Paper No. 179, 1990) (George H.W. Bush Administration publication asserting that "while 'Raising Rivals Costs' is a theoretically valid method of achieving an anticompetitive effect on price, its practical uses are extremely limited") *with* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, VERTICAL MERGER GUIDELINES 4 (2020) (Trump Administration publication asserting that "[a] vertical merger may diminish competition by allowing the merged firm to profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market").

[175] Wineinger, *supra* note 50 (describing increase in brand-name prescription drug prices since 2012); Mulcahy, *supra* note 48 (finding that brand-name prescription drugs in U.S. cost over triple their average cost in 32 other OECD countries).

[176] New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). The phrase "laboratories of democracy" has become ubiquitous in describing the role of the states, from academic works to federal government sources. *See, e.g.*, U.S. DEP'T OF STATE, *State and Local Governments: Laboratories of Democracy*, AMERICA.GOV (Dec. 16, 2007), https://web.archive.org/web/20091113070938/http://www.america.gov/st/pubs-english/2007/December/20071216153045esnamfuak0.6855432.html [https://perma.cc/FTH2-

experimentation flows from the Tenth Amendment's decree that powers which the Constitution does not delegate to the federal government or prohibit to the states are reserved to the states or to the people.[177] Those powers reserved to the states are described by the vague and amorphous term "police powers,"[178] through which a state may protect the general welfare of its citizens,[179] even if the definition of the welfare of the state's citizens might differ from the definition its next door neighbor derives for its own citizens. A state's core police powers include the ability to regulate health and safety for its citizens.[180] Moreover, in modern context, the notion of a state's police powers has expanded to broadly include economic issues, rather than only health, safety, and morals.[181]

Thus, the states are well equipped to experiment with different approaches to the pharmaceutical supply system, depending on the necessary business and legal environments. A state with a large population might have the volume flow to make such an experiment attractive to the necessary players—and, of course, the goal would be to drastically reduce the number of players, along with the concomitant monetary leakage.

Within this construct, a closed environment such as a state penal system provides a potential environment for a pilot program. Such a system would be accustomed to sourcing a wide variety of medications and could have the capacity

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3ADB]; G. Alan Tarr, *Laboratories of Democracy? Brandeis, Federalism, and Scientific Management*, 31 PUBLIUS: J. FEDERALISM 37 (2001) (describing Brandeis' metaphor but arguing that it would be better to abandon it).

[177] *See* U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

[178] *See, e.g.*, Berman v. Parker, 348 U.S. 26, 32 (1954) ("An attempt to define [the police power's] reach or trace its outer limits is fruitless, for each case must turn on its own facts. The definition is essentially the product of legislative determinations addressed to the purposes of government, purposes neither abstractly nor historically capable of complete definition."); 1 JAMES BRADLEY THAYER, CASES ON CONSTITUTIONAL LAW 693 n.1 (1895) ("Discussions of what is called the 'police power' are often uninstructive . . . ."); *see also* Reuel E. Schiller, *Regulation's Hidden History,* 25 REVS. AM. HIST. 416, 418 (1997) (describing shifts in contours of state's police powers and noting that in 19th century, "the police power was above even the Constitution. Individual rights bowed before it. In a well-regulated society, personal property and liberty existed only to the extent that they did not interfere with the felt necessities of public power").

[179] *See, e.g.*, Webber v. Virginia, 103 U.S. 344, 347–348 (1880) (defining "police powers of the states" as "those powers by which the health, good order, peace, and general welfare of the community are promoted").

[180] *See, e.g.*, City of Hillsborough v. Automated Med. Labs., Inc., 471 U.S. 707, 714 (1985) (explaining that statutes regulating health and safety are part of state's general police power); *Webber*, 103 U.S. at 348 (listing health as within state's police powers).

[181] *See* Santiago Legarre, *The Historical Background of the Police Power,* 9 J. CONST. L. 745, 792–93 (2007) (noting that history of notion of police power from 16th century onward and describing Supreme Court's repudiation of *Lochner*-era restrictions on state's ability to regulate in economic sphere).

to handle storage and inventory. Each of these components would be essential in establishing an effective structure, and thereby convincing other public, and even private, health systems that disruption is possible. I will refer to the program as the "state pilot."

The state pilot would negotiate directly with drug companies for the purchase of medications. Drug companies have complained mightily, in forums ranging from Congressional hearings to press notices, about the profits that are siphoned out of the healthcare system by the PBM intermediaries.[182] Thus, one could expect that drug companies would view these direct pathways as a useful opportunity, both from a profit and public relations standpoint.

Initiating the program would not require waiting until all drug companies agree to participate. Starting with a few large players, or even one, could be enough to begin breaking the system. As with the entire notion of starting with a demonstration project, getting the camel's nose under the tent can be very effective in toppling a structure.

Although not essential for the state pilot, one could imagine replacing wholesale distributors as well as PBMs. Other private delivery services, including Amazon, FedEx, UPS, etc., might provide effective alternatives, thereby injecting competition at the wholesale distributor level of the supply chain.

Providing an environment where the state pilot could flourish would require certain legal changes at the state level. Conversations with industry insiders suggest that PBMs currently use their market power to interfere with any attempt to purchase directly from drug companies. Consider the following potential threat from a PBM: if employers and drug companies negotiate directly with each other, rather than going through the PBM, the PBM will claw back past rebate amounts from the employer and retaliate against the drug company by placing the company's drugs on less favorable formulary tiers on other health plans throughout the state.

States have the power to dampen these threats. As noted above, states can regulate commercial behavior within their own borders in the interests of the health and welfare of their citizens.[183] Thus, a state could pass legislation providing that any business practice that forbids or discourages companies from interacting with the state pilot is void as a matter of being against public policy. Moreover, the statute could provide that if PBMs retaliate through other contracts in the state, the drug company has a cause of action under state law to recover the consequent business losses. The goal would be to forbid commercial

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[182] *See, e.g.*, *Drug Pricing in America: A Prescription for Change, Pt. II: Hearing Before the S. Comm. on Fin.*, 116th Cong. 15 (2019) (statement of Olivier Brandicourt, CEO, Sanofi-Aventis U.S., LLC) ("I appreciate the confusion as to why patient costs continue to rise, even when the amount that PBMs and health plans pay declines. This situation is unacceptable and unsustainable for too many patients."); Zirkelbach, *supra* note 53 (PhRMA blog post highlighting the increase in PBM revenue).

[183] *See* Legarre, *supra* note 181.

behaviors that are not in the public interest as drug companies and other intermediaries seek to prevent improvements in the healthcare supply chain.

Even without legislation, state courts could determine that these PBM practices violate state antitrust law as anticompetitive, state tort law as an interference with a prospective business relationship, or state consumer protection laws—depending on the practice.[184] Once again, the language is chosen to begin in a narrow fashion, although the state could easily choose to craft the legislation as applying more broadly to other health plans within the state.

If state pilot programs such as these were successfully implemented, additional steps could help ensure that similar systems did not emerge. Ideally, one would want to confirm that pharmaceutical companies could not shift the current practice of providing rebates and side payments to PBMs (in exchange for disadvantaging competitors) to a new practice of providing those payments to insurers. Insurers should have greater incentives to resist such an approach, but other work has noted the potential for a confluence of incentives that could prompt insurers and drug companies to act outside the interests of consumers and competition.[185] And, of course, no state pilot program such as this could solve all aspects of the problems plaguing modern pharmaceutical markets. For example, even going directly from here to there and eliminating all of the monetary leakage in the system would not solve the problem of trying to finance expensive new specialty drugs that launch at an annual cost of seven figures.[186] Nevertheless, unwinding the twisted pathways of the pharmaceutical industry would go a long way in reducing the costs to patients and payors alike.

CONCLUSION

The ostensibly simple task of moving a prescription drug from manufacturer to medicine cabinet has steadily devolved into a morass of intermediaries and contract negotiations, with every step incurring an additional transaction. Payers have suffered rising drug prices during this period, but the complexity has, for others, bred opportunity. Intermediaries comfortably populate the many niches that have emerged throughout the supply chain. With more mouths to feed, the eventual cost to consumers and payors continues to mount.

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[184] *Cf.* Paul R. Gugliuzza, *Patent Trolls and Preemption*, 101 VA. L. REV. 1579, 1599–1600 (2015) (describing state efforts to prosecute patent trolling with existing consumer protection and deceptive trade practices statutes); Pennsylvania v. Tap Pharm. Prod., Inc., 415 F. Supp. 2d 516 (E.D. Pa. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 20074).

[185] For an in-depth discussion of these issues, see HANDSHAKES, *supra* note 18, at 32–44, 93–95.

[186] The two most expensive specialty drugs—Zolgensma & Zokinvy—command list prices of more than one million dollars for an annual treatment course. Many others near the same mark. *See* Hannah McQueen, *The 10 Most Expensive Drugs in the U.S., Period*, GOODRX (Sept. 7, 2021, 2:38 PM), https://www.goodrx.com/blog/most-expensive-drugs-period/ [https://perma.cc/9UM7-TJ95].

Ossified and highly profitable, the pharmaceutical supply chain has little incentive to simplify itself; rather, several factors help perpetuate its convoluted status quo. Many of these firms operate in the recesses of the pharmaceutical landscape, largely exempt from disclosure requirements or regulatory scrutiny. Other intermediary firms have entrenched themselves through extensive consolidation, owning formidable market power, and lobbying clout as a result. Instead of stumbling around this labyrinth, it is time to cut a straighter path. Enabling states and other large payors to source drugs directly from manufacturers would disrupt the expensive and elaborate rituals that have developed in the space between them. A disruptive alternative does not need to be a destructive one. A low-stakes pilot program at the state level can offer a model for states and other payers to take on price negotiation and inventory responsibilities without compromising patient access to medication. Other solutions may also suffice, such as leveraging existing shipping channels to transport drugs more efficiently. In any case, without a simpler set of directions to follow, society will have no choice but to continue enduring expensive detours.