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by

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Introduction

Good morning, Chairman Wyden, Ranking Member Crapo, and Members of the Committee. Thank you for inviting me to address the role of PBMs in the prescription drug supply chain. My name is Robert Burns and I am a management & strategy professor specializing in health care at the University of Pennsylvania's Wharton School. My research and teaching examine how the entire U.S. healthcare ecosystem operates; I have taught an Introductory Course on this material for nearly four decades at three business schools. I have also recently written a textbook on the topic.[1] Another part of my research agenda examines how the institutional and retail supply chains work in the healthcare ecosystem; I have examined these supply chains since the mid-1990s and written two books on them.[2] [3]

To paraphrase Mark Antony in Shakespeare's *Julius Caesar,*[4] I come here today not to *praise* PBMs but to *bury* some concerns about them. My testimony covers three topics. Part I explains the operations of intermediaries (i.e., "middlemen") in healthcare supply chains and demystify their role. Part II explains why pharmacy benefit managers (PBMs) are not the drivers of the rising prices of brand drugs, as many allege. Part III explains the growing trend of vertical integration in the retail pharmaceutical supply chain and explores its possible impacts.

My conclusions and opinions are based on my own research, teaching, and first-hand experience with the healthcare ecosystem since my doctoral training in late 1970s. They do not necessarily represent the views of the Wharton School.

Part I : Dark Territory: Lifting the Veil on PBMs[5]

"Dark Territory" describes a section of railroad track not controlled by any signals. There are safety concerns due to the absence of train detection. There is a lessened ability to detect mis-alignment in track switches, broken rails, or runaway rail cars. It is dark and mysterious.

Healthcare's version of dark territory consists of intermediaries that connect buyers and sellers. Often, these intermediaries are widely mistrusted and vilified. They seem out of control, lack transparency and federal regulation, act in ways that reportedly threaten patient safety, make a lot of money without making anything, and are viewed with suspicion. During the 1990s, health maintenance organizations (HMOs) constituted the dark territory. The criticisms of the HMOs back then pale in comparison with the invective leveled over the past two decades at two other intermediaries: group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs). Like the late comedian Rodney Dangerfield, "they get no respect". Worse yet, they serve as the 'whipping boys' of healthcare who take the rap for others.[6]

Last year, I published a 650-page volume that takes readers through this dark territory.[7] Here, I focus my remarks on the PBMs. The allegations against PBMs include: monopoly power, anticompetitive behavior, collusion with manufacturers, exclusive contracts, financial ties with suppliers that mitigate search for the best products at the lowest cost, reduced provider discretion and patient access to needed medicines, conflicts of interest, preoccupation with growing revenues, excessive fees and profits, kickbacks, secret rebates, lack of full disclosure, harms to patient quality, and higher consumer costs. Most of these allegations can usually be found in just a single newspaper story, book chapter, or industry report. Needless to say, the authors of such stories rarely "go deep" into any of these allegations.

I approach these issues through the lens of "critical thinking". I teach my undergraduate courses at Wharton using the Socratic Method: I show students an argument that someone has proposed, and then get them to first ask the question, "Is What I Just Heard Really True?" I then spend the course training students to evaluate such proposed arguments using published research evidence (both pro and con) to thereby answer the question.

My book evaluates the claims advanced by GPO critics against several bodies of evidence. These include (1) the historical PBM chronicle, (2) the agency role that PBMs play on behalf of insurers, (3) the documented tradeoffs that PBMs make regarding access, cost, and quality while serving their insurer clients, (4) the growing concentration in US healthcare, and (5) the existential threat of supplier consolidation. I conclude that PBMs are nowhere near the villains their critics have painted them to be. They perhaps deserve a bit more thanks for the roles they perform. One should remember that the Kaiser Permanente health plans of today that policy-makers laud as solutions to population health and the triple aim were the whipping boys in earlier decades.[8]

Some History Lessons

PBM critics rarely bother to examine their history. The narrative has (until now) never been pulled together from archival and eyewitness sources, which requires a lot of homework. As former President Harry Truman said, "the only thing new in the world is the history you don't know." My recent book devotes two chapters and 115 pages to this chronicle. The lessons from this narrative do not support the allegations and conclusions of the critics.

<u>Like GPOs, PBMs Have Historically Served the Interests of Local Providers and Health Plans</u>

The early PBMs began as local cooperatives providing medical and pharmaceutical services to community members through prepaid groups on a capitated basis. They were less healthcare insurance and more healthcare assurance providers. They were typically organized around HMOs that provided both medical and pharmacy benefits to cover the total health care needs

of their enrollees under an affordable budget. The early PBMs were thus tied to health insurers, just like they are today.

Today, following the decline of HMOs, PBMs serve insurers and providers of health services but neither supply these services nor charge for them. They are at least one or more degrees of separation from where healthcare costs and quality are rendered. Efforts by critics to lay the responsibility for rising healthcare costs or harms to patient quality at the feet of the PBMs are misguided.

PBM Leverage Over Product Suppliers

PBMs sought to amass purchasing volume to negotiate lower prices from product manufacturers. HMO-PBMs combined the prescription orders of scores (and then hundreds) of physicians on their medical staffs. Both routed these orders through a centralized negotiating hub to contract as "one" with manufacturers. The game has always been one of "leverage" over suppliers to exchange higher buyer volume for lower unit price. This game became more important for survival and customer service with intensification of input cost pressures and/or reimbursement pressures. When squeezed downstream, PBMs sought to squeeze drug manufacturers upstream.

PBMs Subject to Considerable Federal Oversight

Both GPO and PBM intermediaries have been subjected to considerable scrutiny by the U.S. Congress (House and Senate hearings), the Congressional Budget Office, and various Federal Agencies such as the Federal Trade Commission (FTC) and the Office of The Inspector General (OIG). Such scrutiny led to the development of 'codes of conduct' for both intermediaries during 2004 to 2005. None of this scrutiny has since resulted in any subsequent change in legislation or regulatory oversight of either intermediary. This latter point suggests that the codes of conduct may have served their purpose, as some research suggests.

PBMs Have Utilized Many of the Same Contracting Tools for Decades

Certain PBM (and GPO) practices have irritated their critics in the new millennium. For PBMs, they include drug formularies, contract administration fees (CAFs) paid by manufacturers, discounts and rebates from manufacturers, narrow pharmacy networks, and spread pricing.

What critics fail to realize is that most of these contracting tools have long been in place without causing an uproar. That is likely because these tools served the economic interests of their sponsoring organizations downstream (health plans), who developed them to deal with competitive and reimbursement pressures. Just like many contracts between buyers and sellers

in the private sector, PBM contracts are never publicly disclosed in order to encourage price discounting by manufacturers (and inhibit any collusion among them).

PBM Business Models Have Changed Over Time

Finally, the historical narrative demonstrates that the business models and revenue sources of these intermediaries have changed over time. PBMs are now heavily focused on the dispensing of specialty drugs, as are other players in the healthcare ecosystem. Yet, PBM critics continue to attack them regarding strategies heavily pursued in the past, particularly manufacturer rebates and pharmacy network management. Although still a sizeable portion of their revenues, such strategies and revenue sources are on the wane.

PBMs' Agency Role in Serving Health Plans

PBMs seek to exert leverage over suppliers, not over their health plan sponsors. Their actions are thus consistent with being 'agents'. Surveys of health plans confirm this agency role via high satisfaction levels and a concordance in their goals and interests. As further evidence of this agency role:

- suppliers have been historically skeptical of intermediaries like PBMs
- suppliers have sought to render them ineffective
- suppliers do not contract with PBMs when they do not have to (due to lack of competition)
- the relationships between suppliers and these intermediaries are characterized as "adversarial", and
- suppliers raise prices unilaterally 'because they can', which the PBM intermediaries seek to counteract.
- PBMs believe that supplier competition is always in their interest

Tradeoffs: The Name of The Game

Economics and the entire healthcare ecosystem are all about tradeoffs.[9] For example, when one examines the different health plans that employers offer workers, those plans that offer a wider choice of providers (more open-network models such as preferred provider organizations, or PPOs) come with higher premiums - that is, PPOs trade off wider access for higher cost.

The same tradeoffs factor into the strategies employed by PBMs. PBMs (in partnership with health plans) have developed formulary tiers that allow plan participants to access the drug(s) they prefer at the cost they can afford. PBMs do not dictate the choice to their plan enrollees.

Product quality is, nevertheless, evident in the decisions made by health plan pharmacy and therapeutics committees. Such committees are heavily comprised of clinicians (physicians, nurses, pharmacists) who focus primarily on product quality, not on product cost. In other words, these committee mechanisms represent local-level decisions by clinicians on the types of products they want. PBMs are not in the business of telling doctors what they can or cannot order or prescribe. To the extent the product choice set is limited, it usually reflects committee (peer) assessments of what are comparable, therapeutically-equivalent products with no evidence-base to differentiate them.

Another area where strategic tradeoffs are evident is national versus local. The GPOs began as local cooperatives and developed contracts for local membership. The proximity and small membership size made it fairly easy to decide upon products and manufacturers to contract with. As they grew, however, the regional and (then) national GPOs faced increasing difficulty in developing contracts that all of their members wanted. The GPOs therefore embarked on several strategies that allowed members to customize contracts to suit local needs and clinician preferences, including regional GPO affiliates, assistance with custom contracting, contracting tiers, etc. The goal was to balance the economic leverage of centralized buying with access to desired products at the local level. PBMs have engaged in similar tradeoffs. They, along with their health plan sponsors, have developed national drug formularies than can be tailored or disregarded by health plans at the local level.

Consolidation

PBMs have come under fire for being concentrated sectors in which a small number of intermediaries manage the vast bulk of sales. This observation is correct. But then critics extrapolate to conclude that these huge oligopolies raise costs, harm their own members, and engage in anti-competitive practices that harm the public's welfare.

The evidence base refutes all of these charges. First, PBMs help their health plan clients by negotiating lower input prices and serve as their agents. Second, there has been no federal antitrust enforcement activity brought against these parties since the early 2000s. There has also been a vastly reduced number of lawsuits filed against them since they adopted codes of conduct in the mid-2000s. Third, the entire healthcare ecosystem and nearly all the intermediaries in the supply chain have grown more concentrated. For some reason, however, critics do not usually complain about the oligopolies among pharmacies, pharmaceutical wholesalers, and specialty distributors. If one really wants to start pointing fingers at the biggest culprits in consolidation and rising cost, one does not have to look very far: large hospital systems ("Big Med").[10] [11]

Existential Threat of Supplier Consolidation, Concentration, And Pricing

The greatest existential threat to intermediaries such as PBMs is consolidation and/or concentration among the manufacturers upstream with whom they contract. The immediate impact is (1) a reduction in the number of suppliers available for customers to contract with, and (2) the reduction in the competitive rivalry among these suppliers.

Research suggests that pharmaceutical mergers and acquisitions (M&A) are sometimes motivated by the desire to limit competition. Researchers have found that a company is 5-7% less likely to complete the drug development project in its acquisition's pipeline if those drugs would compete with the acquirer's existing product line (i.e., "killer acquisition").[12] Other research shows that M&A can result in reduced R&D spending and patenting for several years;[13] conversely, higher competition spurs R&D spending by firms.[14] [15]

The threat of supplier concentration particularly resides in the availability of specialty pharmaceuticals, many of which are off patent. There are higher entry barriers in the biologics space due to (among other reasons) the complexity of the science, uncertainty regarding the regulatory process for biosimilars, and the guidelines for 'interchangeability'. The result is fewer competitors and little generic threat to these newer biological products. Biologics as a percentage of drug spending doubled between 2006 and 2016, from 13% to 27%. The wholesale acquisition cost of biologics is a multiple of the cost of small molecules. The approval of biologic license applications (BLAs) for new biological products has recently overtaken the approval of new molecular entities (NMEs) for traditional drugs. The threat facing payers is containing the cost of these drugs. At the same time, the distribution of specialty pharmaceuticals has become a major revenue driver for the PBMs and others.

Moreover, specialty drugs are more buffered from the effects of drug formularies and tiers. Formulary position is driven by competition within the therapeutic area. Such competition is greater in some areas (e.g., metabolic, cardiovascular, central nervous system, gastrointestinal) than in others (oncology, infectious disease, immunology, and respiratory). In the former areas, there is less clinical differentiation among drug classes and more variation in tiering; in the latter areas, there is more clinical differentiation among drug classes and much less dispersion of formulary drugs across price tiers. This reflects the considerable unmet clinical need and variation in patient response to specialty (e.g., oncologic) drugs, making it harder to restrict and/or channel physician choice among products. Finally, drugs that treat widely prevalent conditions (e.g., diabetes) and thus incur high aggregate spending are more likely to be targeted by formulary tiers than are specialty drugs that incur lower aggregate spending which are more likely to attract payer strategies such as step therapy.

Summary

GPOs and PBMs occupy parallel roles in the institutional and retail channels of the health care value chain. There are multiple similarities in their historical origin, product selection bodies, role in the value chain, role as agents for downstream buyers, business model, operating guidelines, transparency, rebates earned, cost management efforts, tradeoffs managed, and directional influence in the supply chain. These similarities are counter-balanced by their differences in channel served (institutional vs. retail), products contracted for, customer served (hospital vs. health plan), founding period, owner/sponsor, number of firms, and industry financials.

Finally, they are both intermediaries. They do not buy, sell, or price products conveyed through the supply chain. They are also not providers of health care services. Their impact on the cost and quality of care rendered to patients is thus removed from the parties who play the major roles here. The remarkable finding here is that these intermediaries may nevertheless serve the public's welfare by controlling the rise in healthcare costs.

Part II : The Brouhaha over Rebates and the Gross-to-Net Price Disparity[16]

Over the past few years, observers have noted not only the rise in drug list prices but also the growing disparity between gross and net prices for pharmaceutical products. As a percent of drug price growth, rebates accounted for only 6-9% during 2011-2012 but then accounted for 57-77% during 2013-2015.[17] The disparity has continued. More recent data published by IQVIA show that between 2015-2018 branded drug invoice price grew between 5.5% and 11.2%, while branded drug net price grew between 0.3% and 2.9%; between 2018-2021, branded drug invoice price grew between 4.3% and 6.6%, while net price either fell or grew only modestly (-2.9% to +1.7%).[18] The latter data indicate that net brand prices are growing less than the annual average growth in the consumer price index, and that manufacturer rebates are partly responsible. Some health economists argue that rebates roughly constitute the difference between list price and net price.[19]

Indeed, a recent report by a small, provider-owned PBM (Navitus Health Solutions) shows that per-member-per-month (PMPM) drug spending for its plan sponsor clients grew only 1.5% during 2021. This (low) growth rate was driven by higher utilization (9.1% for specialty drugs, 1.3% for nonspecialty drugs) and not by unit cost (-4.8% for specialty drugs, -2.2% for nonspecialty drugs).[20] Another recent report by Milliman estimates that manufacturer rebates reduced total per-capita healthcare costs by 6% ($397) in 2022.[21]

Some observers allege that the rise in list prices is partly caused by the higher rebates (and other payments made by manufacturers to PBMs), which are represented by the gap between

gross and net price. In their view, the facts that (1) higher rebates and other fees account for a higher percentage of the drug's list price increase and (2) the rebate size increases with list price are evidence of causation. The *theory* behind this presumed causality is that the PBMs benefit from higher rebates, and that this may encourage manufacturers to hike their list prices which leads to a win-win situation: the PBM earns more rebates, and the higher rebates earn the manufacturer a more favorable position on the formulary where they can achieve higher sales volume. These observers nevertheless admit that the lack of granular data on PBM rebates and drug prices (due to confidentialty clauses) renders this causal assertion uncertain. As the great 'philosopher' Yogi Berra once said, "In theory, theory and practice are the same. In practice, they are not."

The flaw in this causal logic is shown by several pieces of evidence. Drug manufacturers raise prices several times a year, whereas PBMs negotiate contracts and rebates every two to three years, with the rebates remaining constant during the duration of each contract. Moreover, drug manufacturers raise prices in anticipation of losing patent protection (and thus market share), in the event of filing patent lawsuits against competitors (potentially gaining share), in anticipation of a generic product entering the market (losing market share), in anticipation of new competitors entering the market (and thus losing market share), or in the event that an existing competitor pulls their product from the market (gaining market share). In general, drug manufacturers raise prices because they can - - e.g., when they enjoy more of a monopoly position in their therapeutic category, when they have superior marketing, when their product is a physician preference item (PPI), and when their product has brand preference among patients. Most health economists acknowledge that drug manufacturers control list price.

Multiple factors have contributed to the growing spread between gross and net drug prices (known as the gross-to-net disparity). *First* is the growing consolidation of the PBM sector. PBM consolidation was legitimated by the Federal Trade Commission's (FTC) sign-off on Express Scripts' (ESI) acquisition of WellPoint's Next Rx in-house PBM in 2009, and the market valuation placed on Next Rx's business.[22] This consolidation accelerated in the 2012-2015 period, led by ESI's acquisition of Medco (2012), Catamaran's acquisition of ReStat and TPG's acquisition of EnvisionRx (both in 2013), and then Optum's acquisition of Catamaran (2015).[23] By 2017, the top three PBMs commanded 71% of the market (measured in scrips): CVS (25%) ESI (24%), and Optum (22%). The top 7 PBMs controlled 95% of the market. This market concentration of buyers allows PBMs and health insurers to extract large discounts in price from manufacturers in exchange for a drug's position on the formulary. This is a major driver of drug rebates (discounts on list price) paid to the PBMs.

Second, complementing the growing *concentration* on the buyer side (PBM market), there can be growing *competition* on the supplier side in the form of competing pharmaceutical products. This is also referred to as "crowded therapeutic categories." Such product competition gives PBMs and health insurers leverage over manufacturers by virtue of playing one manufacturer off another and threatening to move market share to the manufacturer who offers better terms (including higher rebates).

Third, beginning around 2012, but picking up around 2014, PBMs began to utilize the strategy of "formulary exclusion" whereby manufacturers are threatened with product removal from the PBM's national formulary.[24] CVS/Caremark removed 34 brand-name drugs from its standard national formulary in January 2012, and added another 17 drugs to the exclusion list in 2013; ESI followed CVS' example in 2014. Both PBMs have added more drugs to the list over time. Optum, Prime Therapeutics, Aetna, and Cigna embraced drug exclusions by 2016.

Such a strategy works in the presence of therapeutically comparable brand-name drugs. In 2016, more than 50% of the commercial market was covered by plans with formulary exclusions. Note that exclusions block access to specific products on a PBM's recommended national formulary; they are, thus, suggestions rather than mandates. ERISA Plan Sponsors and health insurers can ignore the PBM's national formulary, but then face reduced rebates and/or higher plan costs. They, thus, tradeoff higher access to drugs for higher costs incurred - - much in the way that formularies financially reward patients for selecting generic and lower-tier drugs with lower costs, while allowing access to additional drugs on higher tiers but requiring patients to face higher costs via higher copays or coinsurance. Nevertheless, the prospect of exclusion leads manufacturers to offer larger rebates. A precipitating event here was the introduction of AbbVie's Hepatitis-C drug *Viekira Pak* to compete with Gilead's *Sovaldi* and *Harvoni*. The number of products on the formulary exclusion lists for two PBMs (CVS and ESI) has grown steadily since 2012.[25]

Fourth, statutory rebates are another large driver of gross-to-net discounts. The Patient Protection and Affordable Care Act (PPACA 2010) increased the mandatory rebates that pharmaceutical manufacturers must pay under the Medicaid program. For single-source (non-generic) drugs, the Unit Rebate Amount (URA) increased from 15.1% of a product's average manufacturer price (AMP) to 23.1% of AMP. It also required manufacturers to provide rebates in the Medicare Part D coverage gap. The Bipartisan Budget Act, signed into law in February 2018, increased these discounts. Rebates and other channel discounts to PBMs and pharmacies constitute "Direct and Indirect Remuneration" (DIR) payments made to Part D Plan Sponsors. These payments were stable from 2010-2012 but began to accelerate beginning in 2013. DIRs help to create a gap between list and net prices.

Fifth, the pharmaceutical industry experienced steep patent cliffs in 2012 and 2015, and much higher level of patent expiries in the period 2013-2019 compared to earlier levels (e.g., 2010).[26] Attending these patent expiries was a wave of new generic drugs entering the market. The advent of biosimilars in the biotechnology market constituted a parallel development, but on a smaller scale. Research documents that drug prices decrease markedly after patent expiration.[27] In 2017, the generic dispensing rate - - the percentage of drug prescriptions dispensed with a generic drug instead of a branded drug - - was 90%. The rise in generics and generic dispensing rates occasioned a slowdown in the price growth of branded drugs.

Sixth, the same increase in rebates has been observed in Medicare Part D. Between 2006 and 2020, Part D drug rebates as a percentage of total drug costs rose from 8.6% to 27.0%.[28] This is relevant since PBMs, which administer the drug benefit, retain less than 1% of these rebates and thus do not benefit. Instead, analysts point out that the growing Part D rebates are tied to competition among manufacturers within a given drug class to get on the formulary.[29] Research by Milliman shows that, among drugs with rebates covered under Part D, rebates as a percentage of gross drug costs reached 39% in the presence of direct brand competition. Rebates reached 34% when there were 3+ competitors including a direct generic substitute, 27% when there were 1-2 competitors with a direct generic substitute, and only 23% in the absence of direct brand competition or a generic substitute.[30]

Seventh, the growth in the gross-to-net difference observed over time has been driven not by commercial rebates but instead by Medicare Part D rebates and 340B discounts.[31] According to Adam Fein, the gross-to-net difference in the price of branded drugs reflects a declining share in commercial rebates (22% of difference in 2021, down from 27% in 2017), a rising share in Part D rebates (23% of difference in 2021, up from 19% in 2017), and a sharply rising share in 340B discounts (20% in 2021, up from 10% in 2019).

Considering the Arguments of GPO Critics: Critical Thinking Exercise

PBM critics counter by asserting that PBMs are not the only drug channel parties with an incentive for higher prices under Medicare Part D. Since 99%+ of the manufacturer rebates flow to the health plans, there may be an incentive for the health plan sponsors to favor higher list prices. The prescription drug plans (PDPs) which administer the Part D benefit earn a portion of their profits from DIR payments. Manufacturer rebates comprise the vast majority (92%) of DIR payments, which are paid to plans get favorable placement on their formularies.[32] Critics have expressed concern that this remuneration structure may lead

health plans to favor higher-priced brand drugs (which come with rebates) on their formularies over lower-cost generics (which do not come with rebates).

As evidence, researchers examined 57 unique drug formularies across all 750 stand-alone PDPs in 2016, focusing on 935 drugs that were "multi-source" (brand and generic both available).[33] They found that 12.8% of multi-source drugs did not have generics covered in any formulary; they also found that 72% of formularies placed at least one branded product in a lower cost-sharing tier than the generic. When they examined 222 multi-source drugs covered in all formularies that had both brand and generic products covered in at least one formulary, they found that brand products were placed in a lower cost-sharing tier than the generic for only 5% of these drugs. If there is a problem, the low percentages suggest it is limited in scope. Additional evidence from other researchers confirms this.[34] A recent analysis of Medicare Part D plans with matched pairs of brand and generic drugs found that branded drugs are rarely covered when generics are available. Most of the time (84%), only generics were covered; some plans might cover both brand and generic products (15%). In the few instances were branded drugs had preferential formulary placement, beneficiary and Medicare prices were generally low for both products.[35]

Eighth, there is correlational evidence of an association between rebates and list prices, and an association between increases in rebates and increases in list prices. However, the evidence here is not consistent, and can oftentimes suggest no relationship at all.[36] Moreover, the researchers who report these findings are somewhat circumspect in their conclusions, arguing that to the degree that PBMs retain rebates (rather then pass them along to health plans) "a higher list price *might* generate more revenue for PBMs" [italics added].[37] Some of my researcher friends similarly hedge their bets, stating that rebates are "*probably at least partially* responsible for the faster increase in list prices than in the amounts received by drug manufacturers (net prices)" [italics added].[38] They are also quite clear in stating that rebates have moderated the growth in drug prices.[39]

Ninth, and finally, there is growing research evidence that a main driver in the list prices of brand drugs is not PBM rebates but rather federal reimbursement policies. Economists suggest that Medicare Part D dynamics encourage growth in list prices and thus in rebates. These dynamics include Part D benefit design and beneficiary cost-sharing. The Federal Government is at greatest financial risk for high drug spending in Part D by virtue of shouldering 80% of costs in the catastrophic coverage phase, thereby encouraging higher list prices. Via this mechanism, Part D cost-sharing and beneficiary out-of-pocket costs are tied to list price.[40]

In a similar vein, the Congressional Budget Office (CBO) recently concluded that Medicaid's statutory rebates provide incentives to manufacturers to negotiate higher prices with commercial insurers as well as employ higher market-wide launch prices. The CBO's causal argument is as follows: more people covered by public insurance (such as Medicaid) leads to more third-party (public) coverage of drug spending which, in turn, means more patients less exposed to high drug prices and more willing to buy high-priced drugs - - all of which alleviates pressure on manufacturers to restrain their price hikes.[41] The cause is not PBM rebates, but rather moral hazard resulting from public insurance coverage. This last point suggests that - - to paraphrase the old comic strip *Pogo* - - we have met the enemy and the enemy is us. Rising prices and out-of-pocket of costs may have been unwittingly induced by Federal payment policy.[42]

All of these factors contribute to gross-to-net discounts. These discounts accelerated from 2014 through 2019.[43] The majority of these gross-to-net discounts were not realized by PBMs and other drug channel participants such as wholesalers and pharmacies, but rather were realized by public and private payers (62%). Researchers estimate that pharmacies capture the bulk (15%) of the remainder, with PBMs (5%) and wholesalers (2%) capturing much less.[44] [45]

This means that ERISA Plan Sponsors and the health insurers they contract with realized large discounts off of drug list prices, which accounts for the majority of the growing gross-to-net disparity. This is reflected in data for both small and large employers that capture the rebates flowing back to the ERISA Plan Sponsors in 2021.[46] The data indicate that a growing percentage of both smaller and larger employers are receiving 100% of the rebates negotiated by their PBMs. Among larger employers, the 100% pass-through is by far the most common rebate arrangement; a majority of smaller employers also received 100% pass-throughs, but nearly one-quarter receive a percentage share of rebates.

The question is what did ERISA Plan Sponsors and health insurers do with the rebates (savings)? The rebates can be used in a number of ways, according to insurance executives.[47] First, they can be used to offset the healthcare costs generated by employees (or plan members) and thereby reduce their insurance premiums; this approach benefits everyone. Second, they can be used to fund employer wellness programs, which also benefits all members. Third, they can be used to finance patient engagement programs which extend enhanced benefits to those choosing more cost-effective plans or those more compliant with their medications. Alternatively, the rebates can be used to lower patient copays for members using specific drugs or reduce the prices paid at point-of-sale; this benefits specific members.

PBMI survey data suggest that the vast majority of employers (68%) use the rebates to offset the overall plan costs to the employer, especially their own spending on drugs.[48] By contrast, a smaller percentage of employers (11%) use the discounts to reduce the premiums of their employees (11%), a strategy that benefits all workers. A small percentage of employers (15%) split the savings with employees, or reduce employee out-of-pocket costs at the point-of-sale (4%). This means that employers use the discounts generated by their employees with more severe illnesses that require expensive drugs (which earn higher rebates) to cover their overall health expenditures rather than benefit the employees who generate the rebates. The irony, according to industry analysts, is that the employees' actual out-of-pocket costs are set by their insurer and ERISA Plan Sponsor. It is not the PBMs, but rather the Plan Sponsors and health insurers who elect not to share the rebates directly with employees.[49]

Over time, employers' drug benefit designs have shifted out-of-pocket spending from flat co-payments to deductibles and coinsurance arrangements. By 2019, more than half of all consumer out-of-pocket spending on prescription drugs was for coinsurance or deductibles, both of which are tied to list price.[50] Evidence shows the decline in cost-sharing using co-payments, the rise in cost-sharing using coinsurance when employer plans include high deductibles, by drug tier, and the dollar amount of cost-sharing by drug tier for both co-payment and coinsurance. Moreover, over time, the percentage of ERISA Sponsor Plans with pharmacy benefit deductibles has risen. These deductibles can be separate from or combined with the medical deductible.[51]

A recent survey of large employers by the National Business Group on Health suggests some change in employer sentiment here. In 2019, 18% of employers reported having a point-of-sale rebate program in place; 2% said they were implementing a program in 2020, and another 40% were considering such a program for 2012-2022.[52] Such programs pass the rebates directly to the employee at point of purchase. Such point-of-sale programs are most appropriate when the employee is filling a prescription during the deductible phase of coverage or when paying a coinsurance. As industry analysts make clear, this decision about point-of-sale programs is at the discretion of ERISA Plan Sponsors and the health insurers they contract with. These two parties choose the overall prescription drug benefit that is offered to plan participants, which can include: which drugs are covered, the different levels of cost-sharing, the number of pharmacies available to participants, and the incentives for using certain network pharmacies.

These choices reflect the tradeoffs that ERISA Plan Sponsors and health insurers make between access, quality, and cost. These two parties then contract with PBMs to <u>administer</u> their prescription drug plans and <u>implement</u> the choices made by Plan Sponsors.

Part III : Vertical Integration Along the Retail Pharmaceutical Supply Chain[53]

Adam Fein at Drug Channels has continued to update researchers and policy-makers on the growing consolidation of diverse players operating in the retail pharmaceutical supply chain. The latest version from Adam's 2023 report is reproduced below (with his permission).

Exhibit 234: Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023

1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail and specialty pharmacy services. On Dec. 31, 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was rebranded as AllianceRx Walgreens Pharmacy.
2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit subsidiary as Centene Pharmacy Sevrices.
3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
5. Previously known as Evernorth Care Group and Cigna Medical Group.
6. In 2021, Cigna's Evernorth business acquired MDLive.
7. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions are expected to close in 2023.
10. Previously known as IngenioRx.
10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations.
Source: Drug Channels Institute research. Companies are listed alphabetically by corporate name.

We do not know whether the vertical chains in the Figure above are pro- or anti-competitive. There are no data on the costs, prices, or other performance metrics resulting from these combinations. Researchers acknowledge that "it is well known in antitrust economics that assessing policies in industries with important vertical relationships is challenging … Even in the presence of reliable data, how vertical relationships affect consumer welfare is generally theoretically ambiguous, and under various models of supplier behavior, stronger vertical relationships can greatly improve consumer welfare or greatly harm it."[54]

Some observers look at this chart and quickly conclude that the emergence of such behemoth, bureaucratic intermediaries may not be good for the public. Even a seasoned analyst such as Adam Fein suggests, "These organizations are poised to exert greater control over patient access, sites of care/dispensing, and pricing."[55] At the same time, Fein argues that whether they do or can exercise such control is pure speculation. Other researchers go further, concluding that competing value chains such as those depicted above might serve as the new basis of competition in an ecosystem that is quickly consolidating.[56] This sounds like a great topic for critical thinking.

The Key Issue in Vertical Integration: Make versus Buy

The type of combinations depicted in the Figure above are known as "vertical integration". Management researchers often argue that the central decision in corporate strategy concerns "make versus buy": i.e., make it in house or buy it in the marketplace. The choices are also known as "insource versus outsource". There are advantages to each approach such as: use the company's managerial hierarchy versus market forces to coordinate the two parties' behaviors, seek the advantages of collaboration versus the benefits of specialization, diversify versus focus, etc. With regard to pharmaceutical benefits, the two approaches are known as "carve-in" versus "carve-out".[57] There is no clearly-defined calculus regarding which option to take in the make-vs-buy decision. One has to calculate the costs and benefits of each option - - and be satisfied with the tradeoffs. In the absence of data on costs and prices, no one that I know of has made these calculations for the vertically integrated firms depicted here.

It is important to note that, historically, the players in the retail pharmaceutical supply chain have taken both approaches. For example, the PBM sector began using a carve-in approach when staff model HMOs served as their own pharmacy benefit managers working under a capitated budget constraint.[58] The objective was to provide comprehensive coverage of both inpatient and outpatient services, including prescription drugs, at an affordable cost ("assurance" rather than insurance). Standalone PBMs that originally developed as staff-model HMOs waxed and waned in popularity. Later PBMs evolved a different set of benefits and services that attracted both employers and health plans as clients; while some PBMs could be carved in, many were carved out of the health plan. United's acquisition of Pacificare in 2005 marked the beginning of the current trend to the carved-in approach (a return to the roots). United's move was motivated by its desire to acquire Pacificare's health plan operations; the PBM came with the deal. By virtue of acquiring Pacificare's 3.3 million enrollees, United increased its enrollment stature (25.7 million lives) relative to its larger competitor Wellpoint (27.7 million lives), diversified geographically into the West (where Pacificare was located), gained traction in the Medicare risk market, and helped it to prepare for the coming Medicare drug benefit. The deal was also part of the M&A frenzy among health plans in the 2005-2006 era.[59] Thus, the sector has experimented with both approaches over time, oftentimes based on historical circumstances, opportunities, or rationales specific to that point in time - - but not necessarily to get into the PBM business.

Adversarial Relationships

The historical lesson here is that the relationships between PBMs and health plans can vary. It is also important to note that the relationships between PBMs and their health plan clients are

not always cordial and productive but could instead be unwieldy and rather adversarial. They can both wind and unwind.

Anthem – Express Scripts Litigation

In 2009, Express Scripts entered a 10-year contract with Anthem to provide exclusive pharmacy benefits. In 2016, Anthem filed a lawsuit arguing that its contract with Express Scripts guaranteed it competitive prices for prescription drugs. Anthem or a third-party consultant it retained would conduct a market analysis every three years to determine how competitive the PBM's pricing was; if the pricing was not competitive, then Anthem could renegotiate pricing terms with its PBM. In 2011-2012, Anthem commenced the first round of these renegotiations, which lasted for nearly one year and strained the relationship between the two parties, before they reached an agreement. However, Anthem concluded it was overcharged $3 Billion a year for several years. Anthem began a second round of renegotiations in 2014 by demanding $15 Billion in price concessions from its PBM, and then notified it of breach of contract. Express Scripts countered that the insurer was responsible to produce a market analysis of drug prices that would serve as the basis of negotiations. It also stated that it earned well below than $3 Billion annually from the PBM agreement and thus could not meet Anthem's demand.

In 2017, Anthem announced it would not new its contract with Express Scripts. This meant a loss of 20% of the PBM's revenue. In early 2018, a U.S. District Court Judge dismissed Anthem's suit, stating that its contract did not explicitly state that its PBM would ensure competitive pricing; Express Scripts' only obligation was to negotiate based on data the insurer provided.

Downstream Effects of the Litigation

The litigation had several downstream effects - - for both insurers and PBMs. First, Anthem had to replace its big-three PBM. In October 2017, Anthem announced its plan to launch its own in-house PBM, IngenioRx, in collaboration with CVS Health; the latter would provide Anthem with claims processing, point-of-sale engagement, and prescription fulfillment services. In 2019, Anthem launched IngenioRx, which reportedly accounted for one-fifth of Anthem's revenue, and served as the insurer's PBM vehicle to target self-insured employers.

Second, Express Scripts faced the loss of its largest health plan client (Anthem) and questions about its future as a stand-alone PBM in an era of consolidation. In April 2017, Express Scripts reported in its quarterly earnings announcement that it did not expect Anthem to renew its contract; indeed, in January 2019, Anthem terminated the contract a year earlier than scheduled. Express Scripts was soon courted by another insurer, Cigna. Cigna was rebounding from its failed horizontal merger with Anthem: on February 8th of 2017, the District Court for the District of Columbia sided with the Department of Justice in blocking the horizontal merger

of Cigna and Anthem. In March of 2018, Cigna announced its plan to acquire Express Scripts for $67 Billion and pursue a vertical merger instead. The deal closed in early December.

The February 2017 District Court ruling also blocked the proposed merger of Aetna and Humana. Within months of the decision, Aetna likewise pursued a vertical merger with CVS Health. CVS Health executives presented the merger to investors as a strategy to develop health hubs for Aetna enrollees at CVS drugstores.

Historical Rationales for Vertical Integration

The combinations of (1) Cigna with Express Scripts and (2) Aetna with CVS Health meant that all three major PBMs now had health plan partners. UnitedHealth had previously formed Optum in 2011 by combining its existing pharmacy benefit and care delivery services within the company. Its PBM operations stemmed from its 2005 acquisition of PacifiCare, a health plan which had a pharmacy benefit manager.

Indeed, there have been many rationales for such vertical integration offered over the past decade. These rationales reflect the period's *Zeitgeist* (spirit of the times): care coordination, manage the continuum of care, disease management and chronic disease management, use big data and data analytics to (a) stratify enrollees by their risk level and then (b) identify and intervene for those at high risk. Providers have offered similar rationales for the vertical integration mergers they have undertaken.

Vertical integration has also been partly motivated by the growth in spending on specialty drugs. Such spending is split between the pharmacy benefit and the medical benefit. Patients taking specialty medications tend to have more expensive conditions that health plans need to manage. Health plans have argued that spending under both benefits is large and roughly equal in level, thus requiring close management of both. While there is some overlap, specialty drug spend for different disease categories tends to dominate one benefit over the other (e.g., multiple sclerosis on the pharmaceutical benefit side, oncology on the medical benefit side).

The vertical integration strategies were also partly motivated by Department of Justice's move to block Aetna's and Cigna's prior horizontal merger efforts (with Humana and Anthem, respectively). The latter observation suggests that, at least initially, one underlying rationale for vertical integration was simply growth, not necessarily the specific merger partner.

Current Rationales for Vertical Integration

Adam Fein (at Drug Channels) and Eric Percher (at Nephron Research) have done perhaps the best job of articulating the current vertical integration movement in the pharmaceutical supply

chain. As noted above, Fein suggests that the issue may be control over the drug channel: "vertically-integrated payers/PBMs/providers are poised to restructure U.S. drug channels by exerting greater control over patient access, sites of care/dispensing, and pricing. If they can effectively coordinate their sprawling business operations, they will pose a substantial threat of disruption to the existing commercial strategies of pharma companies."[60] Such control could result from (1) channeling of enrollees to the specialty pharmacies and providers inside these vertical firms, (2) rewarding providers for formulary compliance, and (3) greater management and utilization control over provider-administered drugs and the buy-and-bill practices of in-house physicians.[61]

In his 2022 Report,[62] Fein summarized some additional specific goals of vertical integration that are mentioned by Percher:[63]

- Because healthcare services (e.g., pharmacy) are not subject to the same risk-based capital requirements or profitability regulations as insurers, integration can allow them to retain a greater share of revenues.

- Patients who are on expensive specialty medications have high overall medical spending which can benefit from the combined pharmacy and medical benefit.

- Vertical integration enables insurers to tap into the growing market for specialty pharmaceuticals and perhaps control downstream pharmacy assets.

Challenges to Vertical Integration

In his 2022 and 2023 reports, Fein is also careful to point out the challenges facing the strategy of vertical integrating insurers with PBMs and pharmacies.

- There is no guarantee that an insurer which owns its own PBM and pharmacy operations is assured that prescribing physicians are aware of any pharmacy network restrictions and can direct their drug dispensing.

- Employers may be skeptical about whether the savings from combining the pharmaceutical and medical benefit will accrue to them. This may slow down their adoption of such plans. Not all health plan sponsors seem to be beating a path to such integrated offerings. According to Drug Channels, 77% of small employers (< 1,000 workers) contracted with a combined health plan/PBM in 2021. By contrast, only 53% of mid-sized employers (1,000 – 5,000 workers) and only 33% of large employers (> 5,000 workers) did so; the latter two categories were more likely to carve out the PBM.[64]

- Hospitals have been entering the specialty pharmaceutical business and acquiring oncologist practices. The market for physician-administered drugs is thus shifting from physician offices to hospital outpatient departments. Alternate sites of care such as home infusion account for a portion of the medical benefit spend as well as Medicare Part B spend. Hospitals may enjoy a competitive advantage over integrated insurers in this fragmented market.

- Some prior insurer/PBM/pharmacy/provider joint ventures (e.g., those involving Humana, Prime Therapeutics, Centene) and prior insurer-PBM acquisitions (UnitedHealth and DPS) have unwound.[65] Humana has retrenched to focus on its core Medicare business. In 2021, it began sourcing formulary rebates for its commercial health plans via Cigna's Ascent Health Services business; in 2022, it announced it would divest its majority interest in Kindred at Home and Personal Care Divisions. Prime Therapeutics sold its 49% stake in the AllianceRx Walgreens Prime pharmacy; it also outsourced significant portions of its PBM operations to Cigna's Evernorth, including retail pharmacy network contracting, formulary rebates, and mail and specialty pharmacy dispensing. Centene announced plans to outsource PBM operations to Express Scripts and has already sold other businesses (e.g., Magellan Rx PBM, Rare specialty pharmacy). These vertical integration formations are thus quite fluid.

The overall goal of vertical integration may be the magic word, "synergy". Like Helen of Troy, synergy may be the strategy that launched a thousand mergers.[66] Synergy results when the whole is greater than the sum of the parts (i.e., 1 + 1 = 3). There are two types of synergies: cost synergies and revenue synergies. Following Fein and Percher, revenue synergies seem to be front of mind in combining the component parts depicted in the Figure above,. All of this is speculative and theoretical at the moment. We have yet to see whether these combinations can figure out how to coordinate the various parts they acquire. Success will largely hinge on getting physicians and patients to follow directives and "do the right thing": e.g., use in-house pharmacies and providers (stay in network) when they are part of different organizations. Success may be challenged by having to rely on those outside, non-contracted organizations to attract needed volume. As a result, each vertical integration combination may need business from other similar combinations, who are their competitors.

Consequences of Vertical Integration

Vertical integration may have important, positive consequences for competition. According to analysts, one outcome of this vertical integration will be more aggressive price competition among health plans and PBMs.[67] This could come about by the merging parties' bundling of

medical and pharmacy benefits, which would entail a diminution of carve-out contracts between employers and PBMs for just the pharmacy benefit. This would put pressure on the margins of the freestanding PBMs, because vertically integrated insurers would discount their in-house PBM's services to win the combined business. Any stand-alone PBM contracts would need to lower prices to remain competitive.

Such integration might also reduce heterogeneity in health plans' approaches to strategic alignment with PBMs (which used to vary along an outsourcing-insourcing continuum). Greater homogeneity in strategic alignment across dyads of health plans and PBMs would increase their competitive rivalry since downstream buyers discern fewer distinctive features of one vertical integration combination.

Such integration also potentially signals that PBMs may focus increasingly more on the specialty pharmacy business for their profitability and, conversely, focus increasingly less on retained rebates. PBMs have passed along a much greater share of these rebates to health plan sponsors over the past decade, from 75% in 2013 to 90% in 2018. According to some PBM industry presentations, rebates apply to 70% of their branded pharmacy scripts, which in turn account for only 10% of total scripts. Rebates have also diminished in importance due to Medicare's growing share of retail prescription drug spending (from 18% in 2006 to 30% in 2017) and the low amount of rebates retained by PBMs in Part D PDPs.

Finally, growing vertical integration between health plans and PBMs will likely reduce the transparency of freestanding PBMs' financial results.[68] We have already confronted the opacity issue in trying to assess the performance of vertical integration efforts by hospitals to develop physician and health plan divisions.[69]

Vertical Integration: Ride into the Danger Zone?

Vertical integration has become a popular strategy in the healthcare ecosystem. Many of the recent vertical integration efforts depicted in the Figure above include providers (e.g., physicians, ambulatory surgery centers or ASCs, retail clinics) as well as insurers, pharmacies, and PBMs. A prominent illustration is UnitedHealth Group which includes the insurer UnitedHealth, its in-house PBM (OptumRx), and its Optum Health division, which employs or contracts with roughly 70,000 physicians and owns a chain of ASCs and urgent care centers. Another is CVS Health, which encompasses Aetna, CVS pharmacies, and their retail clinics. Such provider markets are typically more fragmented than the core pharmacy and PBM businesses, offer another possible revenue stream, and can involve the key prescriber.

The healthcare sector is in the midst of its second or third iteration of vertical integration involving hospitals, physicians, insurers, and alternate care sites. The historical evidence among

this different set of players has already been published, weighed in the balance, and found wanting.[70] It is not a pretty picture. Most of the vertical combinations fall into one of three categories - - physicians with insurers, hospitals with insurers, physicians with hospitals. They have all suffered from disappointing financial performance and, sometimes, huge losses. There are an estimated fifty different reasons why combinations of providers with insurers do not work; worse yet, it may only take one of those reasons to sink the deal.[71]

How should one evaluate vertical integration between firms in adjacent stages in the healthcare value chain? According to strategy researchers, vertical integration (insourcing) makes more sense than using the market (outsourcing) when the following general conditions hold:

- There are few firms in the adjacent stage
- There is need to make transaction-specific investment in an upstream/downstream firm
- The integration ensures access to needed inputs
- There is a need for coordination between the firms in the adjacent stages
- The adjacent stages are similar in their optimal scale
- The two stages are strategically similar
- There is high certainty in market demand
- There is low risk in the reliability of the trading partner
- There is low need to continually upgrade capabilities

Moreover, the following specific conditions must also be met **if** the vertical integration is to confer competitive advantage over rivals:

- The integration achieves coordination & collaboration not open to other firms
- The integration improves the joint performance of value chain activities under one roof
- The integration leverages resources and capabilities across the combined firm
- Ownership is needed to capture all of this value
- Culture clashes between the two firms can be avoided
- Executives can get the two firms to work together

The bar is pretty high. Many firms may be challenged to clear it. It is unclear whether executives consider the general market and specific firm conditions needed to make vertical integration succeed. Vertical integration is a specific type of corporate diversification. The evidence base for the performance of diversified firms is not much better than that for vertically-integrated firms. Related diversification outperforms unrelated diversification; but, focus may outperform related diversification. The key question is how big is the overlap between the value chains of the firms that are integrating; the secondary question is whether the overlap occurs in the most important stages of their value chains. This requires a comparison of the health plan's value

chain and the PBM's value chain.[72] Another key issue is that such an analysis needs to be conducted for each pair of components in the vertical chain. A final issue which most strategists fail to consider is this: given the popularity of vertical integration and the large number of firms adopting this strategy, just where is the competitive advantage?

Conclusion Regarding Vertical Integration

In sum, vertical integration is not a guaranteed success. When pursued by hospitals and physicians, there has been a lot of red ink and unwinding of the combinations. This is all documented evidence. At the same time, hospitals have utilized vertical integration with physicians to increase the prices they charge insurers in local markets; this serves to increase their costs and total spending. This, too, is well documented. Regulators need to closely monitor what effects the combinations depicted in the Figure above exert on pricing and costs. At this point, we simply do not know.

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[1] Lawton Robert Burns. *The U.S. Healthcare Ecosystem* (New York: McGraw-Hill, 2021).

[2] Lawton Robert Burns. *The Health Care Value Chain* (San Francisco, CA: Jossey-Bass, 2002).

[3] Lawton Robert Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[4] Act III, Scene 2. Just to be clear, we are not talking here about Mark Anthony, J Lo's third husband. Their last names are spelled differently. My students always get them confused.

[5] This section draws on Chapter 14 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022). It also draws on an article I recently wrote in *The Hill*, "What History Tells Us About Your Prescription Costs and the New 'Bad Boys' of Health Care," (March 22, 2023).

[6] 'Whipping Boys' is not a derogatory term. It refers to the use of stand-ins who were punished for the wrongdoings of the princes that were heir to the throne of the Tudor and Stuart kings of England. It was bad optics to whip the heirs, so childhood friends who were educated alongside them served as the substitutes. A synonym for whipping boy is scapegoat.

[7] Lawton Robert Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[8] For a positive view of Kaiser today, see: Donald Berwick, Thomas Nolan, and John Whittington. "The Triple Aim: Care, Health, and Cost," *Health Affairs* 27(3) (2008): 759-769. Less than 100 years ago, however, Kaiser and other prepaid health plans were viewed as "dangerous deviations from accepted forms of practice". See Patricia Spain Ward. "United States versus American Medical Association et al.: The Medical Antitrust Case of 1938-1943," *American Studies* 30(2) (1989): 123-153.

[9] Lawton Robert Burns. *The U.S. Healthcare Ecosystem* (New York: McGraw-Hill, 2021): Chapter 2.

[10] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Health Care in America*. (Chicago, IL: University of Chicago Press, 2021).

[11] Lawton Robert Burns and Mark V. Pauly. "Big Med's Spread," *Milbank Quarterly* (Spring 2023, forthcoming).

[12] Colleen Cunningham, Florian Ederer, and Song Ma. "Killer Acquisitions," *Journal of Political Economy* 129(3) (2021): 649-702.

[13] Government Accountability Office. *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals* GAO-18-40 (Washington, D.C.: GAO, November 2017).

[14] Richard Thakor and Andrew Lo. "Competition and R&D Financing: Evidence from the Biopharmaceutical Industry," *Journal of Financial and Quantitative Analysis* (2021).

[15] However, the threat is not always due to supplier mergers. M&A activity among large pharmaceutical manufacturers has not resulted in a more concentrated sector. In 2006, the top ten firms accounted for 46% of total sales; ten years later they accounted for only 41% of sales.[15] Instead, in recent years, the threat has sometimes come from generic drugs where either market demand is too small to support more than one firm and/or all other suppliers have withdrawn for various reasons. The result is a monopoly and egregious pricing behavior. Two prominent examples are Turing Pharmaceuticals and its drug Daraprim, and Mylan Pharmaceuticals and its EpiPen - firms which continually hiked their prices because they could.

[16] This section draws on Chapter 9 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[17] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Figure 9.9.

[18] IQVIA Institute. *The Use of Medicines in the U.S.* 2022. Available online at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf. Accessed on July 12, 2022.

[19] Gerard Anderson. Remarks to "Understanding the Role of Rebates in Presciption Drug Pricing," Conference sponsored by Alliance for Health Policy (December 28, 2018). Available online at: https://www.allhealthpolicy.org/11282018-publicbriefing-transcript/. Accesssed on July 12, 2022.

[20] Adam Fein. "Drug Channels News Roundup," Drug Channels (June 2022). Available online at: https://www.drugchannels.net/2022/06/drug-channels-news-roundup-june-2022.html. Accessed on July 12, 2022.

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[23] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Figure 9.10.

[24] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Figure 9.11.

[25] Drug Channels. The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Exhibit 85: 127.

[26] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Figure 9.12.

[27] Gerard Vondeling, Qi Cao, Maarten Postma et al. "The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review," *Applied Health Economics and Health Policy* 16 (2018): 653-660.

[28] *The 2022 Annual Report of The Boards of Trustees of The Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. June 2022. Table IV.B8.

[29] Jack Hoadley. Remarks to "Understanding the Role of Rebates in Presciption Drug Pricing," Conference sponsored by Alliance for Health Policy (December 28, 2018). Available online at: https://www.allhealthpolicy.org/11282018-publicbriefing-transcript/. Accesssed on July 12, 2022.

[30] Nicholas Johnson, Charles Mill, and Matthew Kidgen. *Prescription Drug Rebates and Part D Drug Costs*. Milliman Research Report (July 16,2018).

[31] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Chapter 11.

[32] William Feldman, Benjamin Rome, Veronique Raimond et al. 'Estimating Rebates and Other Discounts Revieved by Medicare Part D," *JAMA Health Forum* 2(6) (2021): e210626.

[33] Mariana Socal, Ge Bai, and Gerard Anderson. "Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available," *JAMA Internal Medicine* 179(6) (2019): 832-833.

[34] Stacie Dusetzina, Juliette Cubanski, Leonce Nshuti et al. "Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available," *Health Affairs* 39(8) (2020): 1326-1333.

[35] I am not sure which side is right and which is wrong. Maybe I have missed something. My colleagues are welcome to point out the error in my ways. As Jalen Hurts, the quarterback of the Philadelphia Eagles said after losing this year's Super Bowl, "you either win or you learn". Wise words to live by.

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[39] Erin Trish. *Drug Rebates in Medicare Part D* (Los Angeles: University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, July 27, 2021).
[40] Erin Trish. *Drug Rebates in Medicare Part D* (Los Angeles: University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, July 27, 2021).
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[45] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs*, 2022: Figure 9.15.
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[54] Zarek Brot-Goldberg, Catherine Che, and Benjamin Handel. "Pharmacy Benefit Managers and Vertical Relationships in Drug Supply: State of Current Research," NBER Working Paper Series (April 2022).
[55] Drug Channels. *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Philadelphia, PA: Drug Channels Institute): p. 366.
[56] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Health Care in America* (University of Chicago Press, 2021): Chapter 10.
[57] This is covered in Chapter 9 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).
[58] This is covered in Chapter 10 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).
[59] The historical M&A trend among PBMs is depicted in Chapter 11 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).
[60] Adam Fein. "Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?" Drug Channels (December 12, 2019).
[61] Here is what Adam Fein has to say. With regard to *buy-and-bill utilization management:* Ownership of clinics enables much greater control over provider-administered drugs—including opportunities to tighten utilization management, negotiate greater rebates from manufacturers, and drive greater biosimilar adoption. For example, Optum's MedExpress clinics currently offer infusion therapy in select Florida and Indiana locations for people with UnitedHealthcare or Humana insurance…commercial health plans try to move infusions to lower-cost sites of care. This is typically achieved with utilization management strategies that guide patients to lower-cost and/or better-performing sites of care. But employed physicians and in-house clinics make site-of-care management much easier. With regard to *buy-and-bill channel management*, A physician office or clinic that is

owned by a vertically integrated organization can be required to obtain provider-administered specialty pharmaceuticals from the company's own specialty pharmacy. This practice is called white bagging. It has displaced buy-and-bill for a significant share of provider-administered drugs in commercial health plans. By owning the infusion site, the insurer bypasses the challenge of getting hospitals to accept white bagging. Adam Fein. "Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?" Drug Channels (December 12, 2019).

[62] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Section 12.3.

[63] Eric Percher. *Optum Launches 'Emisar' Contracting Entity; Navitus Aligns with Ascent via Prime* (Nephron Research, July 26, 2021). Eric Percher. *A Closer Look: Cigna/ESI Makes Waves with Ascent Contracting & Econdisc Sourcing GPOs* (Nephron Research, January 23, 2020).

[64] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Exhibit 80.

[65] This section is taken from Drug Channels. *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Philadelphia, PA: Drug Channels Institute): pp. 367-368.

[66] In his play, *The Tragical History of the Life and Death of Doctor Faustus*, the sixteenth century English playwright Christopher Marlowe refers to Helen of Troy as "the face that launched a thousand ships". Helen was the queen of Sparta and the wife of the king, Menelaus. When Paris, son of the king of Troy, abducts Helen, Menelaus enlists the help of his older brother Agamemnon, King of Athens, to launch the Greek fleet (the 1,000 ships) to attack Troy. This is the start of the Trojan Wat as depicted in Homer's *The Iliad*. I have to explain all of this to my Penn students who (somehow, somewhere) neither read the book nor took a course on Greek history. They do not know what face launched a thousand ships, let alone who Menelaeus and Agamemnon were. When, in disbelief, I push further to ask them what they know about the Trojan War, I continue to get blank faces. Out of a class of 55 students one year, only one raised his hand, answering in a questioning voice, "Brad Pitt?". Our educational system is in trouble.

[67] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*.

[68] Growing vertical integration between health plans and PBMs will likely reduce the transparency of freestanding PBMs' financial results. Consider UnitedHealth Group, which had revenues of $226.2 Billion in 2018. For 2018, revenues at its OptumRx subsidiary were $69.5 Billion. Interpreting the OptumRx figure is challenging, because: (1) it includes a combination of prescription revenues from its own mail/specialty pharmacies plus external retail network pharmacies, (2) it is reported net of rebates, (3) it *excludes* the value of members' out-of-pocket payments from revenues from retail network dispensed prescriptions, but *includes* the value of these member payments from prescriptions dispensed by its in-house pharmacies, and (4) it includes revenues of $39.4 Billion (57%) from services provided to other subsidiaries, e.g. UnitedHealthcare. Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*.

United's 10-K statement from 2021 includes a depiction of the conglomerate's total revenues. The data indicate huge growth between 2018 and 2021 in the revenues of OptumRx (from $69.5 Billion to $91.3 Billion) and Optum Health (from $24.1 Billion to $54.0 Billion); they appear to be the growth drivers in UnitedHealth's total revenues (from $226.2 Billion to $287.6 Billion). United's biggest revenue source (60%) is the company's Medical and Retirement insurance segment. OptumRx may become increasingly more or less dependent on enrollees outside the parent company. It is difficult to determine the sources of United's profits coming from internal versus external sources given the conglomerate structure and the mix of customers.

[69] Jeff Goldsmith, Lawton R. Burns, Aditi Sen, and Trevor Goldsmith. *Integrated Delivery Networks: In Search of Benefits and Market Effects*. (Washington, D.C.: National Academy of Social Insurance, 2015).

[70] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Healthcare in America*. (Chicago, IL: University of Chicago Press, 2021). Jeff Goldsmith, Lawton R. Burns, Aditi Sen, and Trevor Goldsmith. *Integrated Delivery Networks: In Search of Benefits and Market Effects*. (Washington, D.C.: National Academy of Social Insurance, 2015). Lawton R. Burns, David Asch, and Ralph Muller. "Vertical Integration of Physicians and Hospitals: Three Decades of Futility?" in Mark V. Pauly (Ed.), *Seemed Like a Good Idea: Alchemy versus Evidence-Based Approaches to Healthcare Management Innovation* (Cambridge, UK: Cambridge University Press, 2022). Lawton R. Burns and Darrell P. Thorpe. "Why Provider-Sponsored Health Plans Don't Work." *Healthcare Financial Management: 2001 Resource Guide*: 12-16. 2001.

[71] Lawton R. Burns and Darrell P. Thorpe. "Why Provider-Sponsored Health Plans Don't Work." *Healthcare Financial Management: 2001 Resource Guide*: 12-16. 2001.
[72] Compare Figures 11.14 and 13.5 in *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs.*