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Pharmacy Benefit Managers and Pricing in the Pharmaceutical Supply Chain

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Before the

Subcommittee on the Administrative State, Regulatory Reform, and Antitrust
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SUMMARY OF REMARKS

Chairman Massie, Ranking Member Correa, and members of the Subcommittee, thank you for this opportunity to discuss the role of Pharmacy Benefit Managers (PBMs) in the pharmaceutical supply chain and the potential impact these entities have on drug prices for Americans.

My name is Joey Mattingly and I am a pharmacist and PhD-trained health economist on the faculty at the University of Utah College of Pharmacy. I study drug pricing policy, pharmacy supply chain dynamics, and ways to improve our health care system. I also support the University's human resources team responsible for the benefits of approximately 30,000 beneficiaries. I have worked in this field for more than 20 years, from pharmacy technician in my hometown (Bardstown, Kentucky) to pharmacist and district manager of a large pharmacy chain. For the past 10 years, my academic research has specifically focused on the topics we will discuss today.

While the increased interest in regulating PBMs allows us to have a rich discussion on how we pay for pharmaceuticals, my fear is that advocacy efforts by all stakeholders who stand to win or lose with new regulation can distract our attention from facts.

I have had the pleasure of working with all of the stakeholders involved in these policy fights and I genuinely empathize with the arguments made by all sides. In my written testimony, I have detailed several key issues in the same way I would teach these issues to my students – which I would like to thank my students for helping me prepare for this testimony.

To kick things off, I would like to highlight 3 issues I believe the Subcommittee should consider:

1. We need a process to balance Individual Patient Goals vs. Population Goals.

When I get sick, I can talk with my doctor about a variety of treatment strategies. If that strategy involves a medication, I am also free to pick whatever pharmacy I want. However, as an employee of the University of Utah, if I want to use my prescription insurance to pay for that medication, this decision is no longer a patient-doctor decision because I am essentially asking ALL of my coworkers and the taxpayers of Utah to contribute to my care. Now my health care goals must be aligned with my employer's goals. We need to work to develop a fair process to find a win-win for the patient and the employer and we need a process to settle disagreements.

2. If you remove the PBM from the equation today, who or what steps in to fill that void? (And who benefits from a weakened or completely eliminated PBM scenario?)

PBMs have been around in the US since the 1960s and while they have evolved substantially, many of their core functions have remained constant over the past 60 years. PBMs typically gain customers through a relatively transparent process, responding to a competitive bid process developed by plan sponsors (e.g., employers, governments) who are requesting their help with things like developing and managing a formulary or managing the pharmacy network for the plan. When we remove the PBM, who will be best to fulfill these services? And who stands to gain from this new environment.

3. Our pharmaceutical supply chain is riddled with anticompetitive business practices, mostly by design. How will the actions that focus solely on PBMs impact the other actors in the supply chain?

We have to grapple with the reality that we made a tradeoff in the 1960s. Essentially, to incentivize the development of new pharmaceuticals, we decided that we would grant innovative pharmaceutical companies a temporary monopoly to reward the successful companies for all their research investments.[1] The US would get a massive investment in this innovation from the business sector, but we would need to

[1] Conti RM, Frank RG, Cutler DM. The Myth of the Free Market for Pharmaceuticals. *N Engl J Med*. 2024;390:1448-1450. DOI: 10.1056/NEJMp2313400

pay higher prices initially. PBMs have evolved to leverage large populations to gain price concessions from pharmaceutical manufacturers with this government-approved monopoly power. Additionally, PBMs have used their size and scale to capture price concessions from pharmacies. On one hand, this is good for health plans, assuming the savings are passed on. On the other hand, these price concessions from pharmacies could make "once profitable pharmacies" no longer sustainable.

As this Subcommittee deliberates whether PBM practices require additional regulation, I simply ask that the Members work through the same mental exercises I would ask my students to walk through. Remove the PBM from the equation and then play out a scenario for each of the following stakeholders: the patient, health plan sponsor, pharmacy, and drug manufacturer.

FULL WRITTEN TESTIMONY

SECTION I: PAYING FOR PHARMACY SERVICES

In the United States (US), hypothetically speaking, every patient has the freedom to purchase any medication prescribed by his or her doctor and that patient can go to any pharmacy of his or her choosing to purchase that medication. This, of course, assumes that the patient can pay for these services without using health insurance. The moment the patient elects to use insurance for the purchase of these services, the patient is asking all the members of a larger population to help with this purchase. This fundamentally changes this health care decision from a "patient-focused" one to a decision that impacts an entire group of people. The concept of having insurance pay for prescription drugs did not develop in the US until the 1960s, but by 1980 more than 30% of the prescriptions in the US were covered by a third-party insurance.[2] Today, the US Department of Health and Human Services (DHHS) Office of Disease Prevention and Health Promotion estimates that more than 84% of patients under age 65 have prescription drug insurance[3] and the Centers for Medicare and Medicaid Services (CMS) estimates more than 80% of Medicare enrollees are also enrolled in Medicare Part D (Medicare's outpatient prescription drug benefit).[4] In other words, prescription drug benefits are now the norm in the US and patients using their benefits must consider how their decisions impact all other beneficiaries of their health plan.

Any discussion of prescription benefits begins with the ***Insurance Premium Equation*** (**Eq. 1**) that is a fundamental concept in health economics.

Equation 1. The "Insurance Premium Equation" in health economics.[5]

$$\boldsymbol{Premium = (1 + L_D)(1 - c)px}$$

The pharmacy benefit premium (e.g., monthly or annual payment amount to enroll and maintain the benefit) is a function of other important variables including the price of drugs (p), the total utilization or prescriptions covered over the period (x), the coinsurance rate (c), and the loading factor or costs to administer the plan including any return on investment (L_D). When I teach this equation, I ask my

[2] Mattingly TJ, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum*. 2023;4(11):e233804. doi:10.1001/jamahealthforum.2023.3804
[3] Office of Disease Prevention and Health Promotion. Healthy People 2023. Accessed September 2, 2024. Available at: https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-care-access-and-quality/increase-proportion-people-prescription-drug-insurance-ahs-03
[4] Centers for Medicaid & Medicare Services. Medicare Monthly Enrollment. Accessed September 2, 2024. Available at: https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment
[5] Sloan FA, Hsieh CR. Health Economics. 2012. MIT Press: Cambridge, MA.

students to focus on the direction of the relationship in the equation and imaging holding all other variables constant – then consider what happens to the premium.

So, why does the premium equation matter for this Congressional Hearing? Nearly, everything we discuss today will come back to this equation and how different entities in the pharmaceutical supply chain influence each variable.

SECTION II: EVOLUTION OF THE PHARMACY BENEFIT MANAGER (PBM)

2.1. Early PBMs and Pharmacy Owner Opposition

As the pharmaceutical industry evolved midway through the 20th century, a new demand for prescription monitoring and "prepaid" health insurance plans that included drug expenses. In 1958, a group of pharmacists in Ontario, Canada established Prescription Services, Incorporated (PSI) which offered a prepayment plan for drugs.[6] By 1964, PAID Prescriptions (originally "California Pharmaceutical Services, Inc."), emerged thanks to pharmacists and was viewed as a pharmacy "Blue Shield" (drawing comparisons to the growing Blue Cross and Blue Shield health insurance plans).[7] By 1968, PAID Prescriptions began setting reimbursement rates for pharmacies wishing to enter its pharmacy network. In addition to these new reimbursement rate limits, pharmacists were upset about these newly formed pharmacy benefit manager (PBM) entities because of recordkeeping provisions, variability in coverage, and the methods in which these reimbursement rates were to be calculated.[8] ***Sound familiar?*** In 1969, Nick Avellone, former Chairman of the National Association of Retail Druggists (Now called the National Community Pharmacists Association or NCPA) called third-party payment for prescription drugs "the number one concern in pharmacy today."[9]

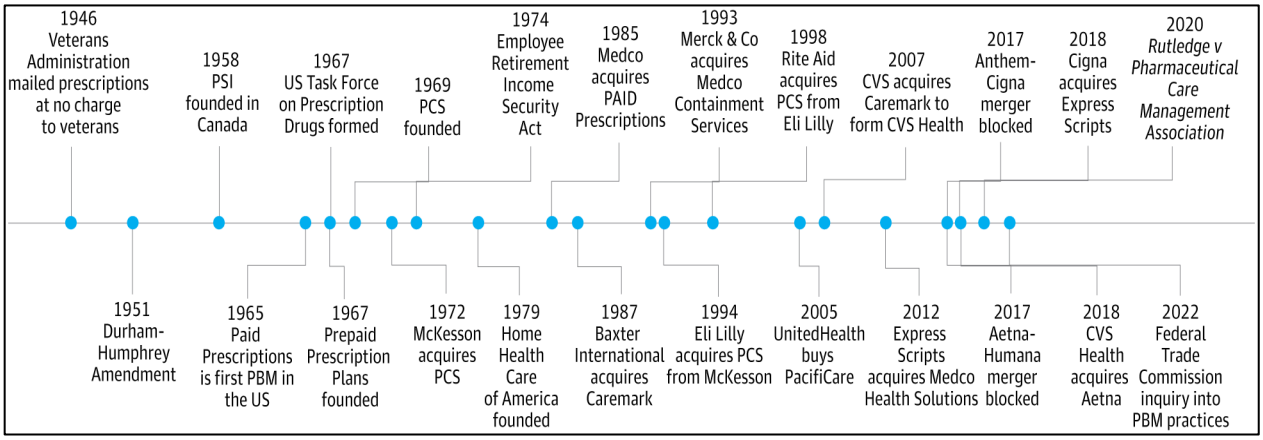
2.2. Vertical and Horizontal Integration of PBMs

The newly formed PBM entities were ripe for integration with other entities in the pharmaceutical supply chain. Beginning in the 1970s, McKesson (one of the largest wholesale distributers of drugs) acquired Pharmaceutical Card System (PCS), becoming one of the first instances of "vertical integration"

[6] Morgan JP. Watching the monitors: "PAID" prescriptions, fiscal intermediaries and drug-utilization review. *N Engl J Med*. 1977;296(5):251-256. doi:10.1056/NEJM197702032960505
[7] Ibid.
[8] Campbell NA, Hammel RW. Development of the third-party payment concept for medical and pharmaceutical services. *Pharm Hist*. 1973;15(3):117-123.
[9] Ibid.

of the pharmaceutical supply chain.[10] A few years later, a large home infusion company entered the PBM market, was renamed "Caremark" and subsequently sold to Baxter International – one of the largest manufacturers of hospital supplies in the US.[11] The strategic mergers and acquisitions (M&As) of PBMs with other supply chain entities has continued for fifty years (**Figure 1**), but not all have been welcomed and some have been stopped by the US Department of Justice.

Figure 1. Key Events in the Evolution of the Pharmacy Benefit Manager (PBM) Industry by Mattingly et al., published in *JAMA Health Forum* in 2023.[12]



2.3. Modern Functions of a PBM

While the PBM industry has evolved substantially since the 1960s, the business still revolves around core functions that ultimately focus on managing the variables in our "premium equation" discussed previously. At a high level, modern PBMs focus on key activities that include: 1) ***formulary development***; 2) ***utilization management***; 3) ***drug price negotiation***; 4) establishing and managing a ***pharmacy network***; and 5) providing ***mail order pharmacy*** services.[13]

The formulary specifies which drugs will be covered and how much patients will pay "out-of-pocket" (OOP) when they purchase these drugs, often discussed as different "Tier" levels (e.g., lower OOP for generic drugs or preferred brand drugs, higher OOP for non-preferred brands or specialty).[14] Formularies are typically developed by a committee that is made up of clinicians, often called a pharmacy

[10] Mattingly TJ, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum*. 2023;4(11):e233804. doi:10.1001/jamahealthforum.2023.3804
[11] Ibid.
[12] Ibid.
[13] Ibid.
[14] Grabowski H, Mullins CD. Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions. *Soc Sci Med*. 1997;45(4):535-544. doi:10.1016/S0277-9536(96)00394-2

and therapeutics (P&T) committee, who will review the clinical evidence to determine the appropriateness of formulary inclusion.[15]

Utilization management encompasses all the actions that typically frustrate patients and clinicians, because as the name implies, it puts limitations on the types of therapies approved, quantities approved, or additional clinical evidence documentation prior to approval. Actions include prior authorization, step therapy requirements (sometimes referred to as "fail first"), day supply or dosage limits, and various financial incentives to encourage the patient to change therapies or steer patients to preferred network providers.[16] Prior authorization policies are widely used in managed care, however there may be some variation or inconsistency across health plans and across plan sponsor types (e.g., private vs. government).[17] The expansion of utilization management policies has caused some concern, especially for patients and clinicians who experience the increased burdens of these policies.[18]

One of the more controversial roles in recent years has been the PBM's role in drug price negotiation. A PBM negotiates on behalf of a health plan with two very important groups: 1) brand pharmaceutical manufacturers and 2) pharmacies. When a pharmaceutical manufacturer launches a new drug onto the market, it may offer a rebate to PBMs as part of the negotiation to obtain a preferred placement on the PBM's formulary in relation to its competitors.[19] This rebate offer can distort the actual price, or "net price", that is ultimately paid for drug utilization, but there are some pricing benchmarks that have been used to estimate this net price such as the Veterans Affairs Federal Supply Schedule (FSS)[20] and net prices reported by SSR Health.[21] On the other end, PBMs negotiate with pharmacies for the price they are willing to accept in order to be included in the PBM's pharmacy network (a strategy dating back to the 1960s). Because of these private negotiations, commonly used compendium prices such as Wholesale Acquisition Cost (WAC) or Average Wholesale Price (AWP) are almost useless in cost analyses for prescriptions.

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[15] Goldberg RB. Managing the pharmacy benefit: the formulary system. *J Manag Care Spec Pharm*. 1997;3(5):565-573. doi:10.18553/jmcp.1997.3.5.565

[16] Howell S, Yin PT, Robinson JC. Quantifying the economic burden of drug utilization management on payers, manufacturers, physicians, and patients. *Health Aff (Millwood)*. 2021;40(8):1206-1214. doi:10.1377/hlthaff.2021.00036

[17] Gupta R, Fein J, Newhouse J, Schwartz AL. Comparison of prior authorization across insurers: cross sectional evidence from Medicare Advantage. *BMJ* 2024;384:e077797. DOI: 10.1136/bmj-2023-077797

[18] Resneck JS. Refocusing Medication Prior Authorization on Its Intended Purpose. *JAMA.* 2020;323(8):703–704. doi:10.1001/jama.2019.21428

[19] Dusetzina SB, Bach PB. Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle. *JAMA.* 2019;321(16):1563–1564. doi:10.1001/jama.2019.2445

[20] Mattingly TJ, Levy JF, Slejko JF. *et al.* Estimating Drug Costs: How do Manufacturer Net Prices Compare with Other Common US Price References? *PharmacoEconomics*. 2018;36:1093–1099.

[21] Ippolito B, Levy J. Best Practices Using SSR Health Net Drug Pricing Data. *Health Affairs Forefront.* March 10, 2022. DOI: 10.1377/forefront.20220308.712815

Finally, the PBM also develops and manages an extensive network of community pharmacies along with mail-order and specialty pharmacy access for health plan members. The US is home to more than 60,000 outpatient pharmacies, including a mix of large national retail chains, mass merchandiser stores, regional chains, and independently owned small businesses.[22] One area of concern that has been raised by policymakers and pharmacy advocates is the business relationship between PBMs and pharmacies within the preferred pharmacy network.[23]

2.4. How PBMs get their customers

In recent months, two high profile examinations of PBMs were published (by the *New York Times*[24] and the Federal Trade Commission or FTC[25]) that both claimed to be based on significant investigation and examination of these entities – but both failed to explain how PBMs actually earn business or acquire customers. The process by which PBMs gain business is relatively simple. A plan sponsor (e.g., self-funded employers, insurers, managed care organizations, state and federal governments) begins by determining whether or not they wish to offer pharmacy benefits to their employees. If they do wish to offer pharmacy benefits to plan members, then the sponsor needs to determine whether or not they have the expertise to manage these benefits or whether they need to contract out these services to a PBM. If a plan sponsor determines it needs to contract out, then it will typically begin a formal **request for proposals (RFP)** process to seek bids from PBMs.[26] In this structured process, PBMs competitively bid on business from the plan sponsor by addressing specific points outlined in the RFP. In many cases, these bids are private, but for municipal governments these RFP documents are publicly available and can be used to help us understand what services plan sponsors typically request from PBMs. In the case below, you can see that a city government explicitly asks PBMs to submit proposals that meet several minimum requirements.

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[22] Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *JAPhA*. 2022;62(6):1816-22.
[23] Federal Trade Commission. Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. July 2024. Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-report
[24] Robbins R, Abelson R. The Middlemen: The opaque industry secretly inflating prices for prescription drugs. *New York Times*. June 21, 2024. Available at: https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html
[25] Federal Trade Commission. Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. July 2024. Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-report
[26] Johnson A, Anderson BN. PBM Best Practices Series: RFP process. *Milliman White Paper Series.* September 2016. Available at: https://www.milliman.com/-/media/milliman/pdfs/articles/best-practices-pbm-rfp-process.ashx

Case Study: City of Buffalo, New York (RFP Issued March 1, 2023)

In spring 2023, the Department of Human Resources for the City of Buffalo published an RFP for PBM services.[27] At the time of this RFP, the City of Buffalo served approximately 12,045 plan members.

As part of this RFP, the City of Buffalo outlined minimal proposal requirements including:

1. Member Copay - Members will pay the lowest of the following: plan copay, plan price plus dispensing fee, usual & customary (U&C), or retail cash price.
2. Rebates - Compensation or remuneration of any kind received or recovered from a pharmaceutical manufacturer attributable to the purchase or utilization of covered drugs by eligible persons. Rebates should be proposed with a percentage share of the total rebate paid by the manufacturer along ***with a minimum floor guarantee***.
3. Rebates are guarantees on the greater of, percentage of the total rebates paid by the manufacturer to the PBM based on the City utilization or minimum floor guarantees (i.e., not fixed) basis whichever is greater.
4. If your claim payment to pharmacies is other than a percent off AWP, please describe your approach and estimate what the expected savings off AWP will be.
5. Please provide a specific, concise line by line listing of ALL available formulary options, Utilizations Management options, and/or clinical programs or tools and their associated fee. Be sure to specify fees if there are various levels or tiers of a program. Be sure to specify fees for both a la carte and bundle/package options.

The selected items above were chosen to demonstrate how an employer can write in specific requests to PBMs and clearly state that if the PBM submitting a bid for the contract doesn't include these items that they will likely not be selected. This context is important because many of the items under scrutiny (e.g., rebates, spread pricing, fees) can be laid out in a very transparent way in the contracting process. For example, if an employer wants to work with a PBM without "spread pricing" they can simply request all proposals include that language.

[27] Department of Human Resources, City of Buffalo. Request for Proposals for: Pharmacy Benefit Management Services. March 1, 2023. Available at: https://www.buffalony.gov/DocumentCenter/View/11585/2023-Pharmacy-Benefit-Management-Services-RFP?bidId=

2.5. Rebate Guarantees and Role of Employer Benefit Consultants

Recently, a survey of 110 organizations with self-insured pharmacy benefits highlighted a few important issues that should be considered in our discussion of how PBMs earn customers and responds to these RFPs. Specifically, the researchers found that 62.7% of employers reported having rebate agreements with rebate guarantees for specialty drugs.[28] Even more concerning, employers reported a high reliance on benefits consultants and a process (referred to as "spreadsheeting") where consultants present employers with models comparing the rebate guarantees across the received proposals in an aggregated form, potentially obscuring the net prices paid for specific drugs or other fees.[29] These findings call into question all the interactions and relationships of expert consultants who contract with employers to facilitate the RFP process or help an employer evaluate the performance of the winning PBM. Especially if these consultants receive any other benefits or have any potential conflicts of interest with existing PBMs.[30]

SECTION III: PBM IMPACTS ON DRUG PRICING

3.1. Which "drug price" are we referring to?

All drug pricing policy discussions must be very clear when defining which price is the focus of the conversation. This is often the most confusing, but it critical for our ability to assess how PBMs impact drug pricing. Often when you read a newspaper article referring to a drug price, they are using a "list price" from the manufacturer – not considering the final net price paid for insured patients or considering any markups along the supply chain after the manufacturer. Additionally, most news and academic journal articles on "patient affordability" only focus on out-of-pocket costs for the patient being treated and fail to account for the annual premiums paid by all beneficiaries for the plan.

In the case of prescription drugs, the complexity of the pharmaceutical supply introduces many new terms and when we write new policy using different price definitions there is the potential for unintended consequences (**Table 1**).

[28] Henderson R, Patterson J, O'Brien JM. Prescription Rebate Guarantees: Employer Insights. *Am J Manag Care*. 2024;30(11). In Press. Available at: https://www.ajmc.com/view/prescription-rebate-guarantees-employer-insights
[29] Ibid.
[30] Herman B. 'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits. *STAT News*. June 20, 2023. Available at: https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/

Table 1. Select drug pricing terms with additional context and commentary.

Drug Price Term	Place in Supply Chain	Expert Commentary
Wholesale Acquisition Cost (WAC)	The manufacturer's list price and meant to serve as a proxy for the price a wholesale company pays to acquire the drug.	This is a compendium price listed in databases such as MediSpan and Redbook. This price is commonly used in news articles as it is easily accessible, but it is incredibly misleading.
Average Wholesale Price (AWP)	This is a compendium price meant to be a proxy for the price a pharmacy pays to acquire the drug from a wholesale distributor.	This is a compendium price listed in databases such as MediSpan and Redbook. For brand name drugs, the AWP is typically around 20-23% higher than WAC. However, for generic drugs this AWP has substantial variation and is not reliable.
Usual & Customary (U&C)	This represents a pharmacy's "cash price" without insurance. It is a common term in retail businesses.	Pharmacies have advertised low U&C prices to gain market share for decades. Famous cash-based pricing schemes for generic drugs include things like the Walmart "$4 list" or other pharmacies advertising a low price without the use of insurance.
Out-of-Pocket (OOP) Cost	This represents the patient's amount owed to the pharmacy at the time of dispensing. It can include obligations such as a deductible and/or copayment based on benefit design.	This is the amount most important to an individual patient trying to make a decision at the pharmacy counter. While OOP costs limits have become more popular in policy circles, all OOP discussions should include total cost and premium cost impacts.
National Average Drug Acquisition Cost (NADAC)	This is a pharmacy cost estimate based on a national "Retail Price Survey" conducted by Myers & Stauffer, LC through a contract with CMS.	The NADAC has grown in popularity to more accurately represent pharmacy acquisition costs, however survey methods create potential reporting biases and does not include any off-invoice price discounts or rebates from wholesalers to pharmacies.
Dispensing Fee	This represents a flat prescription-level fee for the pharmacy's professional services.	Dispensing fees are meant to account for the cost to dispense the drug without any relationship to the actual price of the drug itself. Dispensing fees have traditionally been minimal (e.g., <$1) in most contracts, but have increasingly become more common in "cost+" benefit designs.
Net Price	This is meant to represent the final price paid by a health plan or PBM after all rebates or discounts are accounted for.	While we have more sophisticated ways to estimate the size of rebates for some brand name drugs, there are still substantial challenges with the full accounting for all price concessions at a prescription-level.

3.2. How drug price definitions can impact prices paid

The definitions listed above are critical when we want to understand the impacts of certain policies or how these prices are actually implemented into PBM contracts. For example,

when the FTC released its interim staff report on PBMs, it selected 2 drugs (imatinib mesylate and abiraterone acetate) for a case study to compare reimbursement rates for unaffiliated pharmacies, PBM-affiliated pharmacies, and with the prices found in the NADAC survey.[31] They concluded that both unaffiliated and PBM-affiliated pharmacies were reimbursed significantly more than NADAC and that PBM-affiliated pharmacies were paid more than pharmacies not affiliated with the PBM – concluding that vertically integrated PBMs have an incentive to prefer their own pharmacies and increase prescription drug costs.1 Unfortunately, the FTC failed to explore possible explanations of how this phenomenon could occur regardless of the PBM, which could be more informative for policy solutions. For example, in August 2024 these 2 drugs had AWP prices published in Redbook that varied from 20% markups over AWP to more than 5,000% for abiraterone acetate and over 8,000% for imatinib (**Table 2**).

Table 2. Selected imatinib and abiraterone acetate drug prices in Redbook 2024.

Product	Manufacturer	WAC (per unit)	AWP (per unit)	Suggested Markup (%)
Abiraterone Acetate, 250mg tablets, 120-count bottle				
	Wockhardt USA	1.88	97.21	5,084
	5 different manufacturers	1.88	97.08	5,077
	Northstar Rx	1.88	93.53	4,888
	Hikma Pharmaceuticals	5.00	92.09	1,742
	Apotex	8.33	92.09	1,005
	Mylan Pharmaceuticals	14.17	97.21	586
	Teva Pharmaceuticals	29.16	97.21	233
	Patriot Pharmaceuticals[a]	76.57	91.88	20
	CivicaScript[b]	1.33	1.60	20
Imatinib mesylate, 400mg tablets, 30-count bottle				
	Upsher-Smith Laboratories	4.17	364.41	8,646
	3 different manufacturers	4.33	364.41	8,309
	2 different manufacturers	5.04	394.66	7,731
	Teva Pharmaceuticals	14.57	364.41	2,401
	Chartwell Rx	18.00	394.66	2,093
	Apotex	19.18	364.40	1,800
	Hikma Pharmaceuticals	45.61	364.41	699
	Northstar Rx	78.52	376.95	380
	Mylan Institutional[c]	11.70	14.04	20
	Major Pharmaceuticals	66.67	80.00	20

a) Patriot Pharmaceuticals is a wholly owned subsidiary of Janssen Pharmaceuticals, the brand manufacturer for Zytiga® (abiraterone acetate)
b) CivicaScript is a sister company to CivicaRx, formed in partnership with Blue Cross Blue Shield organizations
c) Mylan & Mylan Institutional are subsidiaries of Viatris, formed in 2020 through the merger of Pfizer's Upjohn division and Mylan. They produce imatinib products with different prices for institutional use.

3.3. Concept of Spread Pricing

Pricing differentials established by a PBM between the contract established with a health plan and the actual price paid to a pharmacy for the service has also garnered recent attention from policy makers

[31] Federal Trade Commission. Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. July 2024. Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-report

with spread pricing prohibitions introduced in bills such as the PBM Transparency Act or PBM Reform Act.[32] This differential price, also referred to as "risk mitigation pricing" by the Pharmaceutical Care Management Association (PCMA)[33], has been offered by PBMs to employers where the PBM guarantees the price at the initiation of the contract and takes on any risk associated with price inflation or benefits with price deflation.

Table 3. Example of spread differences on two manufacturers of Atorvastatin 10mg.

Drug Name & Strength	NDC	Manufacturer	NADAC	WAC	AWP	AWP – 70% (PBM-Plan)	AWP – 80% (PBM-Pharmacy)	PBM "Spread"	Pharmacy "Spread"
Atorvastatin 10mg	43598-0830-90	Dr. Reddy's Laboratories	0.96	2.49	115.52	34.66	23.10	11.55	22.14
	00093-5056-10	Teva Pharmaceuticals	0.96	3.82	225.00	67.50	45.00	22.50	44.04

AWP-based contracts create major incentives for both PBM and pharmacies to strategically purchase specific NDCs

In the case example of Atorvastatin 10mg, when you model hypothetical contracting scenarios between the PBM and the health plan (e.g., "AWP – 70%") and the pharmacy (e.g., "AWP – 80%"), you can see that in some cases an AWP-based formula could create disincentives to use the lowest price generic. PBMs have understood this phenomenon for many years and for many common generic drugs, they have created a "maximum allowable cost" (MAC) list that functions as a price ceiling for these drugs – preventing pharmacies from being incentivized toward the higher AWP product. However, to my knowledge, health plans do not have an equivalent MAC list for PBMs.

In any case, the concept of spread pricing has some benefits for employers, particularly those who may be price sensitive to potential price inflation throughout the year. Additionally, allowing PBMs to profit from spread pricing creates an incentive to put downward pressure on pharmacy costs in its network, which could be disastrous for small businesses with little negotiating power. However, it does create weird incentives that may be difficult for any single health plan to manage.

3.4. National Average Drug Acquisition Cost (NADAC) Plus Pricing Models

In recent years, the "NADAC plus a dispensing fee" pharmacy price model has gained in popularity with several states implementing this approach and with support from the largest independent

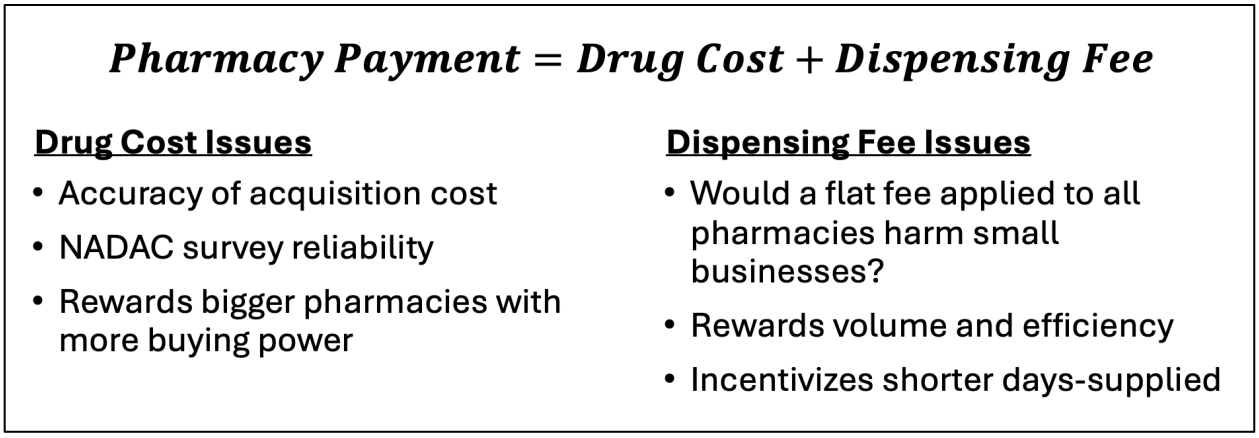
[32] Mattingly TJ, Ben-Umeh KC, Bai G, Anderson GF. Pharmacy Benefit Manager Pricing and Spread Pricing for High-Utilization Generic Drugs. *JAMA Health Forum.* 2023;4(10):e233660. doi:10.1001/jamahealthforum.2023.3660

[33] Pharmaceutical Care Management Association. Small And Mid-Sized Employers Rely On Spread Pricing For Predictable, Fixed Pricing. PCMA Blog. May 31, 2023. Available at: https://www.pcmanet.org/pcma-blog/small-and-mid-sized-employers-rely-on-spread-pricing-for-predictable-fixed-pricing/05/31/2023/

pharmacy organization.[34] While on its face, this approach seems pretty straightforward and offers a much better solution when compared to using an AWP- or WAC-based pricing methodology, there are still issues when using NADAC that members of Congress should consider.

First, NADAC is based on a monthly survey of a relatively small number of outpatient pharmacies in the US conducted by a national accounting firm contracted by CMS.[35] The survey is voluntary and focuses on independent and chain pharmacies – excluding closed door pharmacies such as mail order or specialty pharmacies.[36] In April 2024, generic drug prices in the NADAC survey dropped by approximately 19% and the NCPA reported that the drop was not related to the updated survey methods but that CMS reported the changes were due "to a meaningful increase in pharmacy participation"[37] – in other words, a large number of pharmacies with substantial pricing discounts reported low enough prices to bring the national average down. This raises significant concerns regarding the acquisition cost data collection and analysis process.

Figure 1. Summary of key issues with "Cost-Plus" or "NADAC-Plus" pricing models.



Second, a cost-plus model requires a professional "dispensing fee" to be applied to all prescriptions. While this sounds simple, setting an appropriate dispensing fee rate can actually be challenging. If the fee is uniformly applied to all prescriptions regardless of day supply quantities, pharmacy type, or medication type, then the fee will likely "overpay" for relatively simple prescriptions,

[34] National Community Pharmacists Association. News around the states. Published February 26, 2024. Accessed September 6, 2024. Available at: https://ncpa.org/newsroom/qam/2024/02/26/news-around-states
[35] Levy J, Rosenberg M, Vanness D. A Transparent and Consistent Approach to Assess US Outpatient Drug Costs for Use in Cost-Effectiveness Analyses. *Value in Health*. 2024;21(6):677-684.
[36] Centers for Medicare & Medicaid Services. Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs. February 2024. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf
[37] National Community Pharmacists Association. What's going on with NADAC? June 5, 2024. Available at: https://ncpa.org/newsroom/qam/2024/06/05/whats-going-nadac

shorter durations, and for high-volume pharmacies. A flat rate would also "underpay" for more complex prescriptions that require more pharmacy staff time or for small pharmacies that have a very low volume of prescriptions. Additionally, we would need a plan to adjust the fee annually with inflation to account for pharmacy operation cost increases over time. We would also need to prevent pharmacies from switching patients from longer durations (e.g., "90-day-supply") to shorter durations to increase total prescription volume.

3.5. Insurance coverage influences demand for prescription drugs

Most US consumers have health insurance that includes some form of pharmacy benefit as part of the insurance design. When a drug is covered by insurance, the patient is not exposed to the full cost of the drug – distorting our classical supply-demand models taught in introductory economics courses. Health care providers (e.g., doctors, clinics, hospitals) may be rewarded for using more expensive drugs[38] if they are compensated based on the drugs sales price or if they are 340B covered entities.[39] Additionally, PBMs and insurers may have incentives to cover higher priced drugs based on rebate arrangements.[40] All of these factors influence the demand for pharmaceuticals – particularly the demand for high cost drugs.

SECTION IV: DRUG PRICINGS ISSUES UNRELATED TO THE PBM

4.1. Temporary Monopoly Power – The Tradeoff for Innovation

In the late 1950s / early 1960s, the Senate Subcommittee on Antitrust and Monopoly conducted several months of hearings on the administered prices for prescriptions. Led by Senator Estes Kefauver, these hearings ultimately led to draft legislation called the "Drug Industry Antitrust Act" in 1961 which focused on amending the Food, Drug, and Cosmetic Act (FDCA), Sherman Antitrust Act, and existing patent laws.[41] Senator Kefauver specifically wanted to reform the intellectual property rights for pharmaceutical companies – however, his bill did not have the votes. Around that same time, the thalidomide scare increased the priority for President Kennedy's administration to get a bill through Congress and Kefauver's bill was essentially overhauled to focus on "safety, effectiveness, and reliability" of drugs and stripped the bill of Kefauver's drug pricing components.[42] Despite the bill being

[38] Conti RM, Frank RG, Cutler DM. The Myth of the Free Market for Pharmaceuticals. *N Engl J Med*. 2024;390:1448-1450. DOI: 10.1056/NEJMp2313400
[39] Conti RM, Bach PB. Cost Consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156
[40] Mattingly TJ, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum*. 2023;4(11):e233804. doi:10.1001/jamahealthforum.2023.3804
[41] Mattingly TJ. Kennedy, Kefauver, and Castro: A historical lesson on the politics of drug pricing reform. *Health Affairs Forefront*.
[42] Ibid.

named for him and receiving the first ink pen President Kennedy used to sign the bill into law, Senator Kefauver was furious about the Senate politics involved and even described the event as the "first time in my 23 years in Congress that an administration has emasculated a bill without letting its sponsor and chairman know."[43] What ultimately resulted from the 1962 Kefauver-Harris Amendments to the FDCA was a more robust regulatory system for new drugs to enter the market that would require more clinical trial testing prior to approval. While this was arguably one of the most impactful pieces of legislation in terms of efficacy and safety for our drugs, it would increase the costs for manufacturers to bring drugs to market. In exchange for these increased costs, pharmaceutical manufacturers would maintain the monopoly powers granted through their patents that would enable the companies to both recoup their costs and make a substantial return on investment for shareholders.

To this day, the value of the intellectual property for pharmaceuticals has provided an enormous incentive for the research, development, and commercialization of drugs. When comparing to other S&P 500 companies outside of the pharmaceutical industry, pharmaceutical company profitability from 2000 to 2018 was 13.8% compared to nonpharmaceutical company earnings of 7.7%.[44] And as part of this tradeoff for monopoly power and increased profitability, a patient who contracts the Hepatitis C virus (HCV) can now be cured, a newborn child with Cystic Fibrosis (CF) can expect to live more than 20 years longer than that same child born in the 1990s[45], and we may be closer to slowing down the progression of Alzheimer's disease than ever before.

4.2. Pros and Cons of Out-of-Pocket Limits

One policy solution that has gained favor in recent years has been "out-of-pocket caps" for patients. This policy type is great to limit the risk exposure for people when they become sick and need to use their insurance to pay for health services, however these caps simply shift the cost to the monthly premium everyone in the health plan must pay (see Insurance Premium Equation in Section I). Historically, different out-of-pocket costs have been used at the pharmacy counter to encourage patients to use preferred drug products on the pharmacy formulary. The PBM works with each health plan to establish different price levels or tiers, with the most preferred (often lowest cost, like generic drugs) drugs placed with a very small or no copayment. For many medications, these lower tiers are typically affordable for most families and research on recent insulin out-of-pocket caps in Colorado demonstrated that the caps did not change insulin utilization for Type 1 and Type 2 diabetics using insulin, likely

[43] McFadyen RE. Estest Kefauver and the Drug Industry. Emory University ProQuest Dissertations & Theses. 1973. Available at: https://www.proquest.com/docview/302719773?pq-origsite=gscholar&fromopenview=true&sourcetype=Dissertations%20&%20Theses

[44] Ledley FD, McCoy SS, Vaughan G, Cleary EG. Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies. *JAMA.* 2020;323(9):834–843. doi:10.1001/jama.2020.0442

[45] Ong T, Ramsey BW. Cystic Fibrosis: A review. *JAMA*. 2023;329(21):1859-1871. doi:10.1001/jama.2023.8120

because many commercial plans already had out-of-pocket copayments lower than the state-mandated cap.[46] When Congress evaluates proposals seeking to cap spending on prescriptions, it must evaluate both the current level of out-of-pocket spending and the potential impact on insurance premiums that would increase costs for all beneficiaries.

4.3. Understanding Drug Price Inflation and the Value of Innovation

One of the issues that arises when policy discussions center around drug pricing is that typically focus on an unadjusted "price" that fails to adequately account for the underlying value of all the technological advancements that have been achieved to make that drug and what benefits the drug offers. This concept of adjusting for quality improvements when we calculate price inflation is not new. What does this mean?

For most goods and services (e.g., televisions, computers, automobiles), quality adjustments are made for the Consumer Price Index (CPI) to ensure any price differential attributed to a change in product quality is removed from the equation.[47] Unfortunately for drug prices, we make no such adjustments to take into consideration the innovation occurring in the drug market. Additionally, current drug price indexes fail to account for new launches of drugs that may have a much higher price than other drugs currently on the market for the same condition. Last year, we demonstrated that for Hepatitis C virus (HCV) drug therapies, a product-level approach for measuring inflation likely underestimated price increases because they failed to capture the significant jump in price for the whole class of medications and that prescription-level analyses did not consider the innovations that allowed for shorter treatment durations (3-month vs. 12-month) actually overestimated price increases.[48] In other words, our current methods for comparing prices of pharmaceuticals over time are not actually helpful for consumers.

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[46] Anderson KE, Chaiyakunapruk N, Gutierrez EJ, et al. State Out-Of-Pocket Caps On Insulin Costs: No Significant Increase In Claims Or Utilization. *Health Affairs*. 2024 43:8, 1137-1146.

[47] US Bureau of Labor Statistics. Consumer Price Index: Quality Adjustment in the CPI. Accessed September 6, 2024. Available at: https://www.bls.gov/cpi/quality-adjustment/home.htm

[48] Mattingly TJ, Anderson GF, Levy JF. Comparison of Price Index Methods and Drug Price Inflation Estimates for Hepatitis C Virus Medications. *JAMA Health Forum*. 2023;4(6):e231317. doi:10.1001/jamahealthforum.2023.1317