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Non-Transparent PBM Cash Flows: Balancing Market Forces Under a Reluctant Legislative Regime

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NON-TRANSPARENT PBM CASH FLOWS: BALANCING MARKET FORCES UNDER A RELUCTANT LEGISLATIVE REGIME

JOHN McGuinness*

ABSTRACT

In recent years, Pharmacy Benefit Managers (PBMs) have been subject to increasing regulation in efforts to protect consumers from rising drug prices. Although regulation is needed to control PBMs' unique market position, the pharmaceutical industry continues to suffer at the expense of consumer choice. Legislation varies between jurisdictions and fails to account for market realities. Recent state proposals attempting to weaponize free market ideals have either failed to obtain the requisite vote or are falsely accused of government overreach hiding behind the veil of market-based propositions.

This Note will examine the PBM transaction and explain why a regulatory regime aimed to restore consumer choice and industry transparency will produce optimal market conditions without stifling competition.

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INTRODUCTION

Attempting to benefit from economies of scale, the pharmaceutical industry took a good idea, pharmacy benefit managers (PBMs), and turned it into a complex series of transactions at the expense of market transparency and consumer choice. PBMs are the middlemen of the prescription drug industry, contracted by health plans, employers, and government entities to manage prescription drug programs on behalf of health plan beneficiaries.² Specifically, PBMs are contracted to administer prescription drug plans because they are vested with negotiating power to secure rebates and discounts from drug manufacturers.3 Under these bilateral market conditions, middlemen narrow the available sets of buyers and sellers, which improves consumer welfare if the market search is costly and inefficient.⁴ However, in the case of prescription drugs, PBMs conceal information and raise consumer costs as a consequence of the market's "extensive ... contract negotiation, cost-benefit analysis, corporate haggling, manufacturer rebates, and the artful salesmanship of pharmacy benefit managers."5

Although some scholars argue PBM deficiencies are systematic and therefore require direct regulation, this Note posits significant federal initiatives will only dirty the already murky water of the complex pharmaceutical market.⁶ These regulations overlook market realities and fail to acknowledge that PBMs are merely one cog in the wheel of the prescription drug industry.⁷ Accordingly, this Note examines the pharmacy benefit management industry, identifies unfair trading practices in concealment

¹ Economy of scale, ENCYCLOPEDIA BRITANNICA (2011).

² Mark Meador, Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation, 20 ANNALS. HEALTH L. 77, 77–78 (2011) (explaining PBMs role in "coordinat[ing] the sale and reimbursement of prescription drugs between health insurance plan sponsors or employers, drug manufacturers, and local and national pharmacies").

³ Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323, 328 (2002).

 $^{^4}$ Abdullah Yavaş, *Middlemen in Bilateral Search Markets*, 12 J. of Lab. Econ. 406, 408 (1994).

⁵ Meador, *supra* note 2, at 77.

⁶ But see Meador, supra note 2, at 78; see also infra Part III.

⁷ Allison Dabbs Garrett & Robert Garis, Leveling the Playing Field in the Pharmacy Benefit Management Industry, 42 VAL. U.L. REV. 33, 78 (2007).

of information, and reevaluates the necessary levels of intervention in creating efficient market inputs and outputs, enabling parties to arrive at an economically efficient solution.⁸ In conclusion, this Note will explain how restructured contract incentives support both transactional efficiency and market morality.⁹

I. PHARMACY BENEFIT MANAGER INDUSTRY

A. Industry Structure and Composition

According to the Office of Policy Planning, roughly 95 percent of insured Americans have prescription drug coverage administered through a PBM. ¹⁰ Specifically, three large PBMs control approximately 80 percent of the PBM market, consisting of at least 180 million lives in the United States. ¹¹ At its inception, PBM transactions were arranged to "negotiat[e] discounts with pharmacies and manufacturers, substitut[e] less expensive drug alternatives ... and fill[] prescriptions for chronic conditions by mail" ¹² Nevertheless, PBMs leveraged their negotiating power and market control at the expense of consumer choice and market transparency. ¹³

⁸ See generally Sherwin Rosen, Transaction Costs and Internal Labor Markets, in The Nature of the Firm: Origins, Evolution, and Development 82–84 (Williamson et al., ed., 1993); Ronald H. Coase, The Nature of the Firm (1937).

⁹ See infra Part V.

¹⁰ Letter from Maureen K. Ohlhausen, Acting Dir., Office of Policy Planning, Fed. Trade Comm's et al. to Senator Richard L. Brown, North Dakota Senate 4 (Mar. 8, 2005), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota -h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-manag ers-and-covered-entities/050311northdakotacomnts.pdf [https://perma.cc/KM P2-X5MY].

¹¹ THE STATE OF COMPETITION IN THE PHARMACY BENEFITS MANAGER AND PHARMACY MARKETPLACES: HEARING BEFORE THE H. JUDICIARY SUBCOMM. ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW (2016) (statement of David Balto, private antitrust attorney and antitrust enforcer for the Department of Justice and the Federal Trade Commission), https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf [https://perma.cc/88DE-AHYN].

¹² Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NW. J.L. & Soc. Pol'y 1, 2 (2013) (citing Cong. Budget Office, Issues in Designing A Prescription Drug Benefit for Medicare 14, 40 tbl. 6 (2002)).

¹³ See infra Part II.

B. PBM Profit Optimization

PBM business models are built around different pricing mechanisms.¹⁴ "There are three price measures that are important in understanding the payment system for prescription drugs in the retail pharmacy market: the average manufacturer price (AMP), the wholesale acquisition cost (WAC), and the average wholesale price (AWP)."¹⁵ The AMP is the price paid by PBMs to either the manufacturer or retail pharmacies that buy directly from the manufacturers,¹⁶ whereas, the WAC denotes the manufacturer's price list for sales of a specific drug.¹⁷ Lastly, the AWP is an illustrative pricing list for a drug sold by wholesalers to retail pharmacies or nonretail providers.¹⁸ To aid our understanding of the entire transaction, the Congressional Budget Office has published the following diagram¹⁹:

¹⁴ Meador, *supra* note 2, at 79.

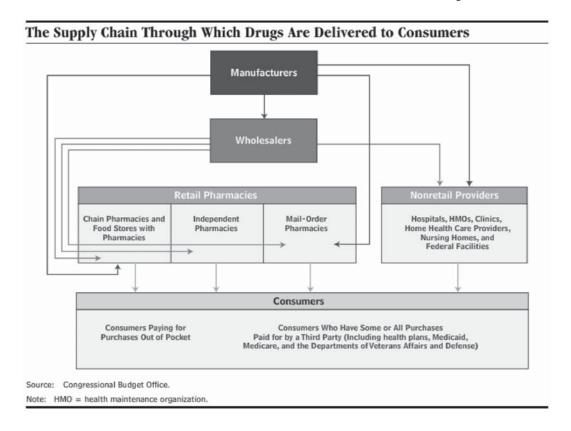
¹⁵ CONGRESSIONAL BUDGET OFFICE, PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR 3 (2007), Pub. No. 2703, https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf [https://perma.cc/F3JT-TZX2].

 $^{^{16}}$ *Id*.

 $^{^{17}}$ *Id*.

¹⁸ *Id*.

¹⁹ *Id*. at 5.



Before departing from the mechanics of PBM pricing models, it is necessary to address the consequences of spread pricing. Generally, spread pricing is where PBMs mark up the difference between the amount they reimburse pharmacies for a drug and the amount charged to its clients.²⁰ According to Bloomberg, "[s]pread pricing is a practice that's most common with generic drugs, which make up almost 90 percent of all prescriptions dispensed in the U.S."²¹ As a practical matter, PBMs negotiate with manufacturers using a lower-quoted price, while setting reimbursement rates with plan sponsors using higher price listings, and therefore entrench sizable profits.²²

In a subsequent Bloomberg study of ninety generic drugs, "PBMs and pharmacies siphoned off \$1.3 billion of the \$4.2 billion Medicaid insurers spent on the drugs in 2017."²³ Generally,

²⁰ Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/ [https://perma.cc/5CJA-2FGA].

 $^{^{21}}$ *Id*.

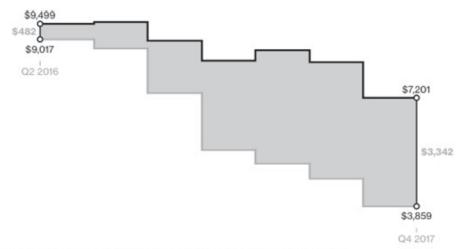
²² Garrett & Garis, *supra* note 7, at 40.

²³ Langreth et al., *supra* note 20.

the highest markups follow the introduction of new generic drugs.²⁴ Illustrated in the chart below, Ohio's Medicaid plan providing for generic versions of the Novartis AG's leukemia pill, Gleevec, saw as much as \$3,000 in spread pricing fees.²⁵



Combined pharmacy and PBM spread and fees



Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding

While the Gleevec spread does not "distinguish between how much of the [spread] markup is going to the pharmacies and how much is retained by PBMs," independent pharmacists claim the additional revenue is not returned to the pharmacy.²⁶ Furthermore, "four out of five Medicaid managed-care plans" are controlled by CVS, which contracts with private insurers and "cover[s] roughly 90 percent of the state's 2.8 million ... Medicaid beneficiaries."²⁷

In other words, CVS's statewide control has enabled them to keep their spread pricing a trade secret.²⁸ According to CVS, "revealing pricing details would keep it from getting the best rates, and that money it makes on spreads pays for other services the company provides."²⁹ However, in response to repeated state contests concerning CVS's industry practice, Ohio obtained the

²⁴ *Id*.

²⁵ *Id*.

²⁶ Langreth et al., *supra* note 20.

 $^{^{27}}$ *Id*.

 $^{^{28}}$ *Id*.

²⁹ *Id*.

spread statistics and determined the hidden fees paid by the state "amounted to \$223.7 million in a 12-month period." Immediately following this report, the Ohio legislature mandated the managed-care plans to terminate spread pricing contracts for 2019. In conclusion, Bloomberg suggests "that PBMs, not pharmacies, have been getting most of the markups on generic drugs in Ohio." Despite legislative efforts to eliminate spread pricing, PBMs are still utilizing similar pricing strategies and secretly exploiting drug costs to their advantage. 33

More recently, President Donald Trump signed the Know the Lowest Price Act and the Patients' Right to Know Drug Prices Act.³⁴ While these legislative initiatives will be discussed in Part III,³⁵ this subsection will briefly discuss their effect on PBMs' pricing strategies. Specifically, the legislation invalidated PBM "gag" clauses, which "prevent pharmacists from informing patients if a prescription would be cheaper if purchased out-of-pocket."³⁶ For purposes of this section, the legislation is a step in the right direction as it restores market power to the consumer.³⁷ The legislation also cuts against the negative externalities of PBM "take-it-or-leave-it contracts."³⁸ The legislation rearranges contract incentives and encourages negotiation between pharmacists and PBMs.³⁹ Nonetheless, these rearrangements are rendered

³⁰ *Id*.

 $^{^{31}}$ *Id*.

 $^{^{32}}$ *Id*.

 $^{^{33}}$ *Id*.

³⁴ See Brittany Shoot, Trump Signs 2 Drug Pricing Bills, HHS Secretary Promises 'More to Come,' FORTUNE (Oct. 11, 2018), http://fortune.com/2018/10/11/trump-administration-gag-clause-compare-prescription-prices/ [https://perma.cc/3P3Y-MH53].

³⁵ See infra Part III.

³⁶ Shoot, *supra* note 34.

³⁷ Your pharmacist's hands may be tied when it comes to telling you drug prices, DIABETES PATIENT ADVOCACY COALITION (May 4, 2018), http://diabetes pac.org/pbm-gag-clauses-tie-pharmacists-hands/ [https://perma.cc/8YYC-PTGC] ("When the patient goes to the pharmacy to purchase their prescription medicine, they pay their copay price, believing that they are getting a good deal through their insurance ... [when] in actuality, they may be better off skipping their insurance and paying the listed price.").

³⁸ *Id.* (explaining if "pharmacists refuse[] to sign the contract because it includes a gag order, the PBM will simply take its business to the next pharmacy in town.").

³⁹ Shoot, *supra* note 34.

useless if PBMs continue to exploit other contract techniques in negotiations.⁴⁰

C. Inefficient Bilateral Market Conditions

PBMs negotiating power and in-house pricing schemes have allowed them to position themselves upon two sides of an intermediate market bilateral oligopoly. In simplistic terms, a bilateral oligopoly is a market game with two commodities, allowing strategic behavior on both sides of the market ... [and] when the number of buyers is large, ... [the] oligopoly[, the PBM,] approximates a game of quantity. In PBM markets, the concentrated buyers and sellers are not equally equipped to reach bilateral efficiency. Moreover, some economists argue bilateral oligopolies promote market efficiency because "downstream firms" demand is met on a reoccurring basis. However, this is not the case as applied to PBMs market negotiations. The PBM industry is not composed of the assumed set of buyer-seller pairs enabled to negotiate, as Part II will explain its inefficiencies.

Under ideal market conditions, buyers and sellers are properly equipped to negotiate and exchange rights under mutually agreeable terms for a specified period of time.⁴⁷ Presuming the bilateral nature of PBM contracts, they must "consist[] of mutual promises to do some future act, and the consideration of the promise of one party is a promise on the part of the other."⁴⁸ Part II will identify concerns, beyond the scope of contract negotiations,

⁴⁰ DIABETES PATIENT ADVOCACY COALITION, *supra* note 37.

⁴¹ Henry Waxman, Competition and Consumer Protection in the 21st Century Hearings, F.T.C. 1 (Aug. 20, 2018), https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0053-d-0016-154973.pdf [https://perma.cc/2CVH-7W3G].

⁴² Alex Dickson et al., *Bilateral oligopoly and quantity competition*, 52 ECONOMIC THEORY 979, 979 (2013).

⁴³ Johan Stennek et al., *Bilateral oligopoly: WZB Discussion Paper No. FS IV 01-08*, ECONSTOR 1, 3 (2001) (defining bilateral efficiency as a contract which "maximizes the sum of the two firms' profits").

⁴⁴ *Id*. at 4.

⁴⁵ See infra Part II.

 $^{^{46}}$ *Id*.

⁴⁷ Stennek et al., *supra* note 43, at 4.

⁴⁸ 17A Am. Jur. 2D Contracts § 8 (2018).

regarding PBMs' industry practices and discuss the need for limited intervention utilizing the Coase Theorem.

II. RELATED INDUSTRY CONCERNS

A. Formulary Control

In addition to their pricing mechanisms, "PBMs ... amplify the benefits of rebate concealment and spread profits through the careful construction of formularies."⁴⁹ A formulary is created by the PBM and enumerates which drugs are covered and their corresponding co-pay costs.⁵⁰ This arrangement restructures incentives and encourages PBMs to provide the drugs that offer greater yields from rebates and profits.⁵¹ As illustrated using basic economics, "assume drug A costs \$50 and the PBM will keep \$5 of the rebate from the manufacturer, while drug B costs \$100 and the PBM will keep \$6 of the rebate."⁵² Consequently, despite drug A being more cost efficient for the plan sponsor, the PBM has an incentive to sell drug B in order to optimize rebates contributing to its own profits.⁵³

PBM manipulation of formularies reaches even farther than rudimentary economics. PBMs have concocted their own incentive programs to ensure formulary compliance.⁵⁴ For example, PBMs may pay pharmacists bonus fees whenever they convince a physician to prescribe a formulary drug.⁵⁵ Consequently, incentives become even more intertwined and pushed down the supply chain as some pharmacists might be incentivized to act in their own self-interest. Specifically, a pharmacist might notify a physician that the drug he or she prescribed is

⁴⁹ Meador, *supra* note 2, at 83.

⁵⁰ Garrett & Garis, *supra* note 7, at 44.

⁵¹ Pharmacy Benefit Mgmt. Inst., *Prescription Drug Benefit Cost and Plan Design Report* 20 (2008–09) (on file with author) (explaining the effects of formulary design, and suggesting the mistrust between pharmacies and PBMs make it easier for PBMs to exploit their financial relationship and possess nearly complete control of formulary list).

⁵² Meador, *supra* note 2, at 83.

⁵³ Id

Andrew S. Krulwich, The Response to Health Care Reform by the Pharmaceutical Industry, 50 FOOD & DRUG L.J. 1, 2 (1995).
 Id.

not on the formulary and subsequently convince the physician to prescribe the formulary drug instead.⁵⁶ Furthering this line of logic, drug manufacturers are also incentivized to "have their products placed on a formulary."⁵⁷ As a result, manufacturers are more inclined to offer generous rebates to a PBM in exchange for formulary placement or offer the PBM volume discounts when purchasing certain drugs.⁵⁸ Therefore, the logic is circular, and no entity has an incentive to provide oversight of PBM activity.

As a result of PBMs murky dealings and unequal negotiating power, they have control over such formulary lists when trading with pharmacies.⁵⁹ Notably, legislation has not attempted to address this issue.⁶⁰ As described in Part III, this matter is best addressed using a market-based approach, provided formularies are determined through a series of negotiations, and cannot be addressed through aggressive price regulation.⁶¹

B. Undercutting Pharmacies: Mail-Order Production

Mail-order pharmacies are controlled by PBMs and promise consumers lower co-pays and convenient service.⁶² However,

⁵⁶ Bruce N. Kuhlik, The FDA's Regulation of Pharmaceutical Communications in the Context of Managed Care: A Suggested Approach, 50 FOOD & DRUG L.J. 23, 30 (1995).

⁵⁷ Ruth B. Timm, The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding, 31 VAL. U. L. REV. 309, 318 (1996).

⁵⁸ *Id.* (citing Kuhlik, *supra* note 56, at 31; Robert Marks, *Managed Care Perspectives*, MANAGED CARE WK. 3 (Dec. 5, 1994)).

⁵⁹ *Id.* at 319–20.

⁶⁰ Shoot, *supra* note 34 (Trump's executive orders address pricing discrimination *after* the contract has been created).

⁶¹ Id.; see generally Marcelle Arak et al., There is a better way to fix our broken 'free market' for drugs than negotiating prices, MARKETWATCH (Jan 31, 2017), https://www.marketwatch.com/story/there-is-a-better-way-to-fix-our-broken-free-market-for-drugs-than-negotiating-prices-2017-01-20 [https://perma.cc/D4 LH-K8ST] (explaining why market-based solutions are better suited for negotiating parties).

⁶² F.T.C., PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf [https://perma.cc/3FMU-CM3K] [hereinafter F.T.C., PHARMACY BENEFIT MANAGERS].

mail-order pharmacies merely functioned as another profitproducing utility exploited by PBMs.⁶³ Perhaps even more troubling, mail-order pharmacies enable a PBM to control the supply of drugs to its own pharmacies, thereby cutting out competitors and optimizing its profits under higher spreads and rebates from drug manufacturers.⁶⁴ Mail-order pharmacies have even gone so far as to contact doctors and persuade them to switch patients to an alternative drug which has a higher spread price.⁶⁵ According to the FTC, mail-order pharmacies could be manipulated by PBMs to "increase costs and generate additional profits"⁶⁶ Federal agencies have not correctly analyzed PBM mail-order pharmacies, and without proper market constraints, it is unclear whether PBMs are favoring mail-order pharmacies in ways contrary to the plan sponsor's interest.⁶⁷

C. Judicial Challenges to Unfair Trading Practices

It is not a new concept that PBMs are in a dangerous position, as PBMs have been alleged to make illegal attempts to monopolize in violation of federal antitrust legislation.⁶⁸ In 2006, the Eastern District of Pennsylvania consolidated six antitrust challenges alleging PBMs conspired to fix prices and monopolize the insurance-covered drug industry.⁶⁹ The Judicial Panel Multidistrict Litigation found the "actions in th[e] litigation involve common questions of fact, and that centralization ... will serve the convenience of the parties" Specifically, in one of the consolidated cases, an independent pharmacy alleged the PBMs

⁶³ See Jeffrey S. Baird, What to Know About Working with PBMs, PHARMACY TIMES (Feb. 20, 2018), https://www.pharmacytimes.com/news/what-to-know-about-working-with-pbms [https://perma.cc/T9AX-DTAS].

⁶⁴ Garret & Garis, *supra* note 7, at 67 (noting PBMs' competition-eliminating activity is at the expense of the consumer because they redirect product to their own pharmacies, even if the competitor could provide it at a lower cost).

⁶⁵ Johnson, supra note 3, at 332; see also Meador, supra note 2, at 84.

 $^{^{66}}$ F.T.C., Pharmacy Benefit Managers, supra note 62, at i.

⁶⁷ *Id*.

⁶⁸ See 15 U.S.C. §§ 1, 2 (2006) (Sherman Antitrust Act prohibits contracting or conspiring in ways that restrict trade).

 $^{^{69}}$ See In re Pharm. Benefit Managers Antitrust Litig., 452 F. Supp. 2d. 1352, 1352–54 (J.P.M.L. 2006).

 $^{^{70}}$ *Id*.

were involved in illegal "parallel behavior."⁷¹ Plaintiffs contend that "plan sponsors share, and are aware that they share, a common strategy ... utiliz[ing] a PBM to combine purchasing power and drive down pharmacy costs."⁷² Underpinning the concerns in this Note, the complaint states the following:

PBMs ... remov[e] the need and existence for any market whereby they must compete in order to secure the services of pharmacist[s] to service their insured ... [thus,] removal of this market and conferring of the aggregate power to negotiate these services upon ... PBMs amounts to horizontal price fixing as it allows for the stabilization and repression of the fees pharmacists would be able to charge in a free and open market.⁷³

The U.S. District Court for the Northern District of Alabama, Northeastern Division, denied the PBMs motion to dismiss and the case is pending upon grant of Plaintiff's motion to certify the action as a class action.⁷⁴ However, Judge Hopkins noted, "by conspiring to hold down prices paid to independent pharmacies (among other alleged actions), PBMs [would] bankrupt those pharmacies, thereby capturing a larger segment of the insurance-paid prescription market for the PBMs' own prescription-dispensing business and allowing the PBMs to charge higher prices for that service."⁷⁵

The court's conclusions later appeared in the House Judiciary Subcommittee on Courts and Competition Policy Hearing, regarding antitrust effects on healthcare providers. According to the Committee, "PBMs have substantial monopsony or oligopsony power and are able to use this power to reduce compensation which harms the ability of community pharmacies to provide adequate services." While *N. Jackson* did not result in direct punitive

N. Jackson Pharm., Inc. v. Express Scripts, Inc., 345 F. Supp. 2d. 1279,
 1284 (N.D. Ala. 2004) (citing SAC Compl. at 53).

⁷² *Id.* at 1294.

 $^{^{73}}$ *Id*.

⁷⁴ N. Jackson Pharm., Inc. v. Express Scripts, Inc., Nos. CV-03-2696-VEH, CV-03-2697-VEH, 2006 U.S. Dist. LEXIS 98774, at *36 (N.D. Ala. Mar. 3, 2006).

⁷⁵ N. Jackson Pharm., Inc., 345 F. Supp. 2d. at 1292.

⁷⁶ Antitrust Laws and Their Effects on Health Care Providers, Insurers and Patients: Hearing before the H. Judiciary Subcomm. on Courts and Competition Policy, 111th Cong. 127–28 (2010) (statement of David Balto, Senior Fellow, Ctr. for Am. Progress Action Fund) [hereinafter Antitrust Laws and Their Effects on Health Care Providers, Insurers and Patients].

⁷⁷ *Id*.

damages, it shed light on the unclear PBM market and coercive concentration of market power. As discussed above, *N. Jackson* triggered the Committee's recognition of the "critical link" pharmacists have in effective healthcare management. However, the Healthcare Guidelines do not address collaboration by pharmacies, and consequently raise antitrust obstacles to pharmacists. In fact, the Committee noted the "FTC has approved ... [three] pharmacy joint ventures to provide health care services under the Guidelines [but] none in the past decade. Consequently, pharmacists' unique connection with consumers is untapped and under-utilized to restore consumer purchasing power.

In addition to these consolidated cases, the patchwork of various state and federal laws have left the industry to its own correcting mechanics. Part III⁸² will discuss specific regulatory initiatives. However, Congress has established anti-kickback rules, targeted fraudulent PBM activity under the False Claims Act (FCA), and attempted to apply a liability regime under ERISA. Intertwined with federal initiatives, lies state regulatory attempts to control the PBM market. For example, Kansas and "[n]umerous other states have passed statutes ... requiring PBMs to register with the state's insurance commissioner." Maine went so far as to mandate that "PBMs are fiduciaries and must act with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of like character and with like aims." ⁸⁵

These mixed federal and state efforts resulted in frequent litigation and ultimately produced "slow and inconsistent approaches" to major anticompetitive behavior. 86 Accordingly, while these cases highlight major market deficiencies, at their best,

⁷⁸ Antitrust Laws and Their Effects on Health Care Providers, Insurers and Patients, supra note 76, at 127.

⁷⁹ *Id.* (explaining since pharmacies only dispense and do not prescribe, they are unable to meet the threshold to help providers integrate to help control utilization).

⁸⁰ *Id*.

⁸¹ See Garrett & Garis, supra note 7, at 47.

⁸² See infra Part III.

⁸³ See Garrett & Garis, supra note 7, at 51–53.

 $^{^{84}}$ Id. at 59.

⁸⁵ Id. at 60. (citing Me. Rev. Stat. Ann. Tit. 22, § 2699 (2007)).

⁸⁶ Id. at 47.

judicial remedies fail to uniformly address underlying market concerns and burden retail pharmacies to pursue costly litigation.⁸⁷

III. FEDERAL AND STATE INITIATIVES

A. Federal

The Federal government has taken notice of PBMs' unequal bargaining power and has invested considerable resources in addressing market deficiencies.⁸⁸ Notably, Congress passed the Medicare Modernization Act, which mandates that the Federal Trade Commission (FTC) analyze the PBM mail-order system.⁸⁹ However, the FTC's report found that PBMs' self-dealing had no causal connection to higher prices.⁹⁰ The FTC's conclusion was challenged, and critics of the report stated that the Commission failed to understand the underlying economic issues of the PBM industry and only analyzed whether plan sponsors were overpaying PBMs.⁹¹

The FCA has some *bite*, as its intention was to target PBM practices which may be fraudulent.⁹² In addition, the Anti-Kickback Act of 1986 (AKA) prevents parties from contracting for preferential treatment.⁹³ Even under the Medicaid rebate program, the PBM may be liable if it "overstate[s] the price offered to it by the manufacturer[, and] the PBM fails to take into account 'certain payments for benefits provided to PBMs by the pharmaceutical manufacturers"⁹⁴ Another source of liability is based

⁸⁷ *Id*.

⁸⁸ See Peri Iz, Study of Pharmaceutical Benefit Management Industry, HEALTH CARE FINANCING ADMINISTRATION 41 (June 2001), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/cms_2001_4.pdf [https://perma.cc/8CNB-97KL].

⁸⁹ Social Security Act of 1935, Pub. L. No. 108-173, 117 Stat. 2174 (2004) (provision required the FTC study to analyze whether PBMs were engaged in self-dealing).

⁹⁰ See F.T.C., PHARMACY BENEFIT MANAGERS, supra note 62, at xi-xiv.

⁹¹ See id. at iii–vi (the report had also failed to analyze the effectiveness of anti-kickback laws).

⁹² False Claims Act, 31 U.S.C. § 3729(a) (2000).

⁹³ Anti-Kickback Act of 1986, 41 U.S.C. § 53 (2010).

⁹⁴ Garrett & Garis, *supra* note 7, at 52 (quoting Sheehan, *Prescription Drug Plans, Fraud Schemes, and the False Claims Act*, 17 TAXPAYERS AGAINST FRAUD 18, 21 (1999)).

in the Racketeering Influenced and Corrupt Organization Act (RICO) where an Illinois U.S. District Court entertained a multifraud challenge against a PBM.95 In Morse, the employer contracted with a PBM which established a system "whereby the policyholder's pharmacy, before releasing the prescription drug to the policyholder, accesses [the PBMs] system and finds out whether [the PBM] will provide 100 [percent] of the cost or whether the policyholder must copay 20 [percent] before receiving the prescription."96 In other words, the pharmacy can profit immediately upon the exchange so long as the policyholder is filling a brand name drug. Additionally, the employer is saving the PBM money, as it is not responsible for 20 percent of the drug expense. There, the court determined the employer and its contracted PBM entered into a scheme to "administer their prescription" drug program in a manner which deprives policyholders of a benefit to which they are entitled and does so knowingly."97 In conclusion, the court denied defendant's motions and granted plaintiffs' petition to proceed as a class action matter.98

Despite occasional judicial enforcement,⁹⁹ these federal directives are inadequate unless fiduciary duties are applied to PBMs. Fiduciary responsibilities, as applied to PBMs, have been challenged under ERISA. According to the statute, "a fiduciary shall discharge his duties with respect to the plan solely in the interest of the participants and beneficiaries." ¹⁰⁰ ERISA defines fiduciary as:

[A] person ... with respect to a plan to the extent (i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, (ii) he renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to

 $^{^{95}}$ Morse v. Bankers Life & Cas. Co., No. 99-C-0193, 2000 WL 246245, at *1 (N.D. Ill. Feb. 24, 2000).

⁹⁶ *Id.* at *1.

⁹⁷ *Id.* at *3.

⁹⁸ *Id.* at *6.

⁹⁹ See *id*.

¹⁰⁰ 29 U.S.C. § 1104(a)(1) (2002).

do so, or (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan¹⁰¹

PBMs have strongly contested their functions fall outside ERISA statutory interpretation because any alternative finding would subject them to a heightened degree of scrutiny. 102 The Supreme Court explained the test for whether an entity is a fiduciary as one that depends on the entity's control and authority over the plan. 103 Attempts to litigate PBMs as fiduciaries have been explored by the courts. 104 For example, in Caremark, *Inc.*, the Seventh Circuit denied ERISA liability. ¹⁰⁵ Specifically, the Seventh Circuit had to reconcile the following contract provision with that of ERISA's fiduciary standard: "Caremark will use its best commercially reasonable efforts to negotiate these rates with existing pharmacies in [Carpenters'] network."106 However, even with the provision, Caremark could not negotiate AWP pricing, nor did the contract contain any mechanism for a pass-through of any additional savings Caremark managed to negotiate with retailers. 107 Caremark was still "free to negotiate with retailers to pay less than the amount Carpenters would later reimburse it, allowing Caremark to pocket the difference."108 Ultimately, because Caremark's bargain with the Carpenters was at arm's length, Caremark owed no fiduciary duty. 109 The court furthered its analysis and interpreted "commercially reasonable efforts" to carry little weight as Caremark was still equipped to

¹⁰¹ 29 U.S.C. § 1002(21)(A) (2000).

¹⁰² Thomas O'Donnell & Mark Fendler, Prescription or Proscription? The General Failure of Attempts to Litigate and Legislate Against PBMs as "Fiduciaries," and the Role of Market Forces Allowing PBMs to Contain Private-Sector Prescription Drug Prices, 40 J. HEALTH L. 205, 205–06 (2007).

¹⁰³ Mertens v. Hewitt Assocs., 508 U.S. 248, 262 (1993).

¹⁰⁴ See generally Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 467 (7th Cir. 2007); Bickley v. Caremark RX, Inc., 461 F.3d 1325 (11th Cir. 2006) Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C., 433 F.3d 181 (2nd Cir. 2005).

¹⁰⁵ Caremark, Inc., 474 F.3d at 477.

¹⁰⁶ *Id.* at 473.

¹⁰⁷ Id.

¹⁰⁸ *Id.* (noting that this was the very conduct the plaintiff was alleging as breach of fiduciary duties).

¹⁰⁹ *Id.* at 474.

"negotiate better prices with the retailers than a single client could negotiate." ¹¹⁰

PBMs have defensively relied on language within their plan sponsor contracts, which explicitly disclaim fiduciary status. 111 Part III will analyze whether PBMs' contract defense is dispositive upon the question. However, courts have generally held PBMs' activity falls short of the "discretionary authority or discretionary control over the management of the plan because the PBM was contractually prohibited from unilaterally changing negotiated drug prices with respect to the plan and was not contractually obligated to pass along to the plan the savings that the PBM negotiated with drug retailers."112 Similarly, the Seventh Circuit concluded that "[b]y agreeing to pay a fixed amount to Caremark, Carpenters forwent its opportunity to garner any additional savings that Caremark could extract from retailers."113 There was no provision in the contract that required specific dealings of rebates, and without fiduciary duties, there is no nexus to Carpenters' claim for savings which the PBM managed to acquire. 114

Subjecting PBMs as fiduciaries would protect against controversial business practices, such as concealing spread cost, and structuring incentives to promote high cost formulary drugs. 115 Generally, the PBM would owe duties to plan sponsors and thereby beneficiaries of private health plans. 116 As noted above, state jurisdictions have passed statutes requiring the PBM to operate as a fiduciary. 117 Notwithstanding judicial shortcomings, presuming PBMs operate as fiduciaries "raises a second issue: are state laws preempted by ERISA?" 118 In re Express Scripts, Inc. PBM Litigation v. Local 153 Health Fund addressed the preemption issues and posited "whether the plan had standing to sue under ERISA section

 $^{^{110}}$ *Id*.

 $^{^{111}}$ Garrett & Garis, supra note 7, at 50–51 (citing Glanton v. ALCOA Prescription Drug Plan, 465 F.3d 1123 (9th Cir. 2005)).

¹¹² Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 467, 470, 473 (7th Cir. 2007).

 $^{^{113}}$ *Id*.

¹¹⁴ *Id.* at 470,475–76.

¹¹⁵ See id. at 472, 477.

¹¹⁶ See generally id.

¹¹⁷ Meador, supra note 2, at 95–96.

¹¹⁸ See id. at 101 (citing David Slade, ERISA Preemption and the Question of Pharmacy Benefit Managers' Fiduciary Duty, 30 J. LEGAL MED. 409, 411 (2009)).

1132 and whether Express Scripts was acting as a plan fiduciary."¹¹⁹ In *In re Express Scripts*, "[t]he plaintiff's only assertion that might establish fiduciary status was that plaintiff was [functioning as] a trustee."¹²⁰ Specifically, *In re Express Scripts* "considered whether a plan may bring an action for breach of fiduciary duty if it is not an enumerated party under section 1132(a)(2)."¹²¹ The court sidestepped this issue and ruled on procedural grounds that "subject matter jurisdiction was not proper under ERISA."¹²² There, "the Eight Circuit [essentially] decided that a plan generally does not have standing as an entity to bring a cause of action under ERISA ... [but a]n exception to this rule may exist when the plan can establish that it is a fiduciary of itself."¹²³

The U.S. District Court for the Eastern District of Missouri squared 1132(d)—which expressly granted plans a cause of action—with 1132(a), concluding plans could exercise that right only when jurisdiction is proper. The plaintiff contended it was a trustee and thus established fiduciary status; however, the court held this assertion was unsubstantiated. The District Court went on to clarify that fiduciary duty actions could be entertained when brought by the proper party as a named fiduciary in the plan documents. Court for the District of Columbia and the First Circuit, had differing conclusions in similar actions. Consequently, litigation efforts under ERISA will have to be determined on a circuit-by-circuit basis due to the lack of clear and effective market regulation.

Although a notable procedural hurdle, "in most cases a plaintiff need not worry about this, because there will be a named fiduciary in the plan documents." Thus, the named fiduciary

¹¹⁹ David Slade, Commentary, ERISA Preemption and the Question of Pharmacy Benefits Managers' Fiduciary Duty, 30 J. LEGAL MED. 409, 415 (2009).

¹²⁰ *Id.* at 417.

¹²¹ *Id*. at 416.

 $^{^{122}}$ *Id*.

¹²³ *Id.* at 417.

¹²⁴ See Local 153 Health Fund v. Express Scripts, Inc., No. 4:05-MD-016 72-SNL, 2007 U.S. Dist. LEXIS 90470, at *24–25 (E.D. Mo. Dec. 7, 2007).

¹²⁵ *Id.* at *27.

¹²⁶ See id. at *28.

¹²⁷ See Pharm. Care Mgmt. Ass'n v. D.C., 605 F. Supp. 2d 77, 87–88 (D.D.C. 2009); Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 305 (1st Cir. 2005).

¹²⁸ Meador, *supra* note 2, at 103.

¹²⁹ Slade, *supra* note 119, at 418.

could "amend the complaint to name a proper plaintiff" via a plan trustee. ¹³⁰ Upon resolving questions of standing, the courts are still left with unresolved substantive matters: "whether the state law claims raised by the plaintiff were preempted and whether the PBM could be considered a fiduciary under ERISA." ¹³¹ Under the Supreme Court holding in *Aetna Health Inc. v. Davila*, state laws are preempted, however, the Court omitted "[t]he question of whether a PBM is a fiduciary." ¹³²

In 2007, the Seventh Circuit did not apply fiduciary standards to a PBM as applied to its negotiation with retailers. ¹³³ The Circuit "reasoned that nothing in the contract between the plan and the PBM required the PBM to pass ... all savings obtained through its bargaining." ¹³⁴ The Seventh Circuit's holding, in conjunction with the Eight Circuit's reasoning in *In re Express Scripts*, indicates that a prudent contract between the PBM and the plan could create fiduciary status. ¹³⁵ Consequently, the current precedent remains a question of contract interpretation.

Some scholars argue, "subject[ing] a PBM to excessive fiduciary duties would not be fair, as the PBM is a business and does not exist solely to reduce costs to the plan." This proposition suggests courts should "consider the existing ERISA provisions in light of applicable public policy" in order to balance the PBMs self-interest with its owed duty. This argument sets a dangerous invitation for the courts. Not only would it likely further inconsistent enforcement, but it encourages courts to engage in duties traditionally reserved to the legislature. At best, courts are left to judicial precedent as applied to "cases involving managed care organizations (MCOs) ... [which] favor[s] an MCO's freedom to reduce health care costs by making determinations about how

 $^{^{130}}$ *Id*.

¹³¹ *Id*.

¹³² *Id.*; see also Aetna Health Inc. v. Davila, 542 U.S. 200, 208–09 (2004) (holding that "[t]he purpose of ERISA is provide uniform regulatory regime [regarding] employee benefit plans.").

 $^{^{133}}$ See Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 463, 464 (7th Cir. 2007).

¹³⁴ Slade, *supra* note 119, at 419–20.

¹³⁵ See id. at 420.

¹³⁶ *Id.* at 423.

¹³⁷ Id. at 424.

 $^{^{138}}$ See id.

much, and what kind of, care should be provided."¹³⁹ Without statutory framework, the courts are not yet equipped to assert authority in efforts to correct an unaccountable industry.¹⁴⁰

B. State

Various state agencies have also made attempts to regulate PBMs, including, "boards of pharmacy, state insurance commissioners, and state Medicaid agencies."141 These agencies are often limited in jurisdictional scope and have thus been ineffective in addressing the macroeconomic concerns raised herein. Although, legislatures have made direct attempts to regulate PBMs. 142 For example, the District of Columbia passed a law requiring "[A PBM] to act as a fiduciary [,] ... [p]erform its duties with care, skill, prudence, and diligence[,] ... notify the covered entity ... of any activity, policy or practice ... that directly or indirectly presents any conflict of interest[,]" and require various disclosures upon request of a covered entity. 143 While research regarding these laws effectiveness is limited, "in South Dakota ... well over \$800,000 was saved in state health insurance costs in a single year as the direct result of the more transparent business model" akin to Maine's and the District of Columbia's regulation. 144 These legislative efforts are effective as they reveal PBMs' pricing strategies and require a heightened degree of protection to plan sponsors. 145 Nonetheless, as this Note will conclude, these solutions can be broadened naturally upon restoring transparent negotiations and consumer choice. Without these market considerations in mind. similar state legislative action alone will incentivize forum shopping and cause health plans to transfer their suits to jurisdictions with favorable legislation. 146

As mentioned in Section I.B, President Trump's executive orders are not effective, and substantively been enforced by states

¹³⁹ *Id*.

¹⁴⁰ See id. at 424–25.

¹⁴¹ Garrett & Garis, *supra* note 7, at 55.

¹⁴² See id. at 59–61.

¹⁴³ D.C. CODE § 48-832.01 (Westlaw 2019).

¹⁴⁴ Prescription Policy Choices, PBM Fiduciary Duty and Transparency (2005), https://fliphtml5.com/gzdm/qltz [https://perma.cc/T75G-3U3C].

¹⁴⁵ See Garrett & Garis, supra note 7, at 58, 76.

¹⁴⁶ See id. at 73–74.

prior to October 2018.¹⁴⁷ According to the National Conference of State Legislation, thirty-three states enacted laws prohibiting PBM "gag clauses" as of May 2019.¹⁴⁸ Additionally, some states have mandated transparency in their efforts to reduce rising drug cost.¹⁴⁹ Specifically, South Dakota's statute mandates PBMs to release rebate information and enforce audit rights.¹⁵⁰ Although states are better suited for experimental legislation, inconsistent approaches are not conducive to addressing market deficiencies and produce costly state litigation.¹⁵¹

The Virginia legislature has been proactive in its attempts to regulate PBMs commercial activity. 152 As early as 2015, Virginia required "contracts between health insurance carriers and their intermediaries to contain provisions that allow the parties to update every seven days the maximum allowable cost list."153 In addition, the 2015 legislation protects the participating pharmacy from PBM retaliation should it invoke its rights under any contractual provision. ¹⁵⁴ Neighboring jurisdictions, such as Maryland, have also been active in attempts to promulgate legislation authorizing the State Insurance Commissioner to require specific disclosures from PBMs, and "provides that a [contract] provision prohibiting reimbursements of a certain amount does not apply to reimbursements for certain drugs or to chain pharmacies."155 Maryland's legislation goes so far as to regulating "how PBMs ... negotiate their contracts with pharmacies, including what must be disclosed as well as the timing for specific actions like audits."156

Maryland's legislative initiatives are unique in that they achieve regulation through means of negotiation and disclosure

 $^{^{147}}$ Colleen Becker, States Regulating Pharmaceutical Benefit Managers, National Conference of State Legislatures (Oct. 11, 2018), http://www.ncsl.org/research/health/pbm-state-legislation.aspx [https://perma.cc/JKV5-7GZC].

¹⁴⁸ See *id*.

¹⁴⁹ See *id*.

¹⁵⁰ S.D. Codified Laws § 58-29E-4 (2007); see § 58-29E-7.

¹⁵¹ See Garrett & Garis, supra note 7, at 47.

¹⁵² See PBM WATCH, Pharmacy Benefit Manager Legislation, http://www.pbmwatch.com/pbm-legislation.html [https://perma.cc/68PD-L8SU].

¹⁵³ *Id.*; see also VA. CODE ANN. § 38.2-3407.15:2 (2015).

¹⁵⁴ See id. § 38.2-3407.15:2(B).

¹⁵⁵ PBM WATCH, supra note 152; see also MD. CODE ANN., INS. § 15-1642 (2018).

 $^{^{156}}$ PBM Watch, supra note 152; see generally Md. Code Ann., Insurance \S 15-1601 (2018).

requirements, rather than mandatory pricing review. 157 Specifically, § 15-1601(k) directly addresses Pharmacy and Therapeutics Committees (P&T) as "a committee established by a [PBM] to: (1) objectively appraise and evaluate prescription drugs; and (2) make recommendations to a purchaser regarding the selection of drugs for the purchaser's formulary."158 The use of P&T's is commonly used in private industry.¹⁵⁹ For example, Blue Shield of California's P&T is "made up of independent community physicians and pharmacists, who are not Blue Shield of California employees."160 Similar to concepts of corporate law, P&Ts attempted to remove bias and presented an opportunity for state intervention while balancing efficient market considerations. 161 Nonetheless, P&Ts are not being utilized as its members often lack an understanding of "health care system contracts and reimbursement strategies."162 In other words, P&Ts must uniformly consider "pharmacy's role in the total episode of care and the impact of pharmaceuticals on value-based reimbursement strategies"163 in response to furthering "total clinical outcomes in designing costeffective formularies."164

While the effects of these state initiatives are difficult to measure, the Virginia legislature has continued to enforce principles of market transparency and PBM regulation. Virginia Senator Dunnavant and Delegate Pillion introduced budget amendments aimed to increase PBM accountability, ensure state oversight of Medicaid Managed Care Organizations (MCOs), and

¹⁵⁷ See PBM WATCH, supra note 152.

¹⁵⁸ § 15-1601(k).

¹⁵⁹ See Linda S. Tyler et al., ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, 65 Am. J. HEALTH-SYS. PHARMACY 1272, 1273 (2008).

¹⁶⁰ BLUE SHIELD OF CALIFORNIA: PHARMACY AND THERAPEUTICS COMMITTEE, What is the Pharmacy and Therapeutics Committee?, https://www.blueshieldca.com/bsca/pharmacy/faqs/pharmacy-therapeutics-committee.sp [https://perma.cc/J8X4-3R2P].

¹⁶¹ Tyler et al., *supra* note 159, at 1273–74.

¹⁶² David Shulkin, Reinventing the Pharmacy and Therapeutics Committee, 37 PHARMACY THERAPEUTICS 623, 624 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498992/ [https://perma.cc/FTA4-KJRG].

 $^{^{163}}$ *Id*.

 $^{^{164}}$ *Id*.

¹⁶⁵ See generally Memorandum from the American Pharmacists Association to the VCU School of Pharmacy (Jan. 25, 2019) (on file with author).

mandate that pharmacies are fairly reimbursed. ¹⁶⁶ According to the American Pharmacists Association, Iowa, Kansas, Louisiana, Mississippi, and North Carolina, state programs have the authority to ensure reasonable contract terms between MCOs, PBMs, and community pharmacies. ¹⁶⁷ Specifically, the contract terms enable states to track expenditures of its tax dollars because they establish reimbursement rates for pharmacy services under the feefor-service program. ¹⁶⁸

While Virginia's legislative proposals do not go so far as to require contract provisions, they are aimed at protecting consumer choice of pharmacy providers and requiring fair treatment of community retail pharmacies. ¹⁶⁹ For example, Virginia H.B. 2223 "allow[s] a covered individual to fill their prescription at any mail order or networking participating retail pharmacy if the retail pharmacy agrees to a comparable price to the mail order." ¹⁷⁰ The Bill also prohibits PBMs from charging differential co-payment or additional fees for a covered individual that chooses to fill their prescription at an in-network retail pharmacy instead of the mail order pharmacy. ¹⁷¹ In accordance with the premise behind this Note, H.B. 2223 aims at restoring consumer choice to best regulate the market through state regulation of transparent transactions.

Critics of Virginia H.B. 2223 posit the bill undercuts law-makers' duty to "preserve the right of private contract." Critics argue enabling "government overreach would restrict some of the practices and tools PBMs use to reach optimal deals, potentially resulting in higher insurance premiums." Adversaries of

¹⁶⁶ See *id*.

¹⁶⁷ *Id*.

 $^{^{168}}$ *Id*.

¹⁶⁹ See *id*.

¹⁷⁰ *Id.*; see also H.B. 2223, 2019 Gen. Assem., Reg. Sess. (Va. 2019) (a bill to amend and reenact § 54.1-3420.2 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3407.15:5, relating to pharmacy services; mail order and delivery; pharmacy benefit managers).

¹⁷¹ Memorandum from the American Pharmacists Association to the VCU School of Pharmacy (Jan. 25, 2019) (on file with author).

¹⁷² Americans for Tax Reform, *HB2223 Could Result in Higher Insurance Rates for Medicines* (Feb. 8, 2019), https://www.atr.org/hb2223-could-result-higher-insurance-rates-medicines [https://perma.cc/F66J-X2CQ].

 $^{^{173}}$ *Id*.

H.B. 2223 counter, claiming "[t]he best way to lower the price of healthcare is to embrace free market solutions, which allow for competition that improves quality, increases the number of choices available, and naturally lowers prices." ¹⁷⁴

Although the H.B. 2223 critics are correct in some of their general conclusions, they wrongly identify issues and falsely believe government intervention and free market principles are mutually exclusive. Provided the PBM market is operating under manipulated incentives and inequitable bargaining powers, further removal of oversight will only lessen marketplace competition. Without the proper market infrastructure, as instituted through targeted government intervention, PBMs will operate under the smoke screen of free market protections while exploiting its unilateral bargaining power.

Ultimately, Virginia was reluctant to involve itself with the PBM market and H.B. 2223 failed the requisite vote to pass the Senate. ¹⁷⁵ In the wake of Virginia's recent rejection of market oversight, retail pharmacies continue to face impracticable market pressures under a regime of pricing instruments designed to punish customers that elect to fill a prescription via in-network retail community pharmacy. ¹⁷⁶ Moreover, as discussed in Section II.C, contract disputes will continue to be litigated and further produce inconsistent standards and PBM forum shopping.

IV. MARKET SOLUTIONS

As a result of inconsistent state legislative approaches, and under a federal regime hesitant to consider comprehensive legislation, this Note posits private industry mechanics and market-based approaches will produce optimal consumer conditions. These approaches are grounded in contract to "give health plan managers guidance regarding the tools they need to equip themselves to negotiate more effectively with PBMs." According to fundamental Coasean economics:

 $^{^{174}}$ Id.

¹⁷⁵ See Virginia Legislative Services: H.B 2223 Pharmacies; delivery of prescription drugs, pharmacy benefit managers (Feb. 14, 2019) (Senate Subcommittee of Education and Health passed indefinitely).

¹⁷⁶ See Memorandum from the American Pharmacists Association to the VCU School of Pharmacy (January 25, 2019) (on file with author).

¹⁷⁷ Garrett & Garis, *supra* note 7, at 78.

Direct government regulation will not necessarily give better results than leaving the problem to be solved by the market or the firm. But equally there is no reason why, on occasion, such governmental administrative regulation should not lead to an improvement in economic efficiency. This would seem particularly likely when, as is normally the case with the smoke nuisance, a large number of people are involved, and in which therefore the costs of handling the problem through the market or the firm may be high.¹⁷⁸

These economic concepts are applicable to government allocation just as they are to market resources. 179 Similar to the political market, PBMs face lower transaction costs and are equipped for coercive bargaining, while pharmacies and consumers face higher transaction costs and thereby are disincentivized from market negotiations. 180 As illustrated in Parts I and II, costs are imposed on those in the high-transaction-cost group, who cannot bargain to mitigate them.¹⁸¹ Applied in this Note, "[t]he Coase theorem implies that resources are being allocated efficiently if constraints are taken as given but also implies that resources could be allocated more efficiently if constraints can be modified to lower transaction costs by changing institutions." ¹⁸² Moreover, Coase's solution in "The Problem of Social Cost" requires government intervention to allocate resources and enforce market optimization. 183 Academics believe, "if government does the job properly of pricing the externalities—neither society nor business need suffer under a regulatory regime compared to the theoretical optimal outcome."184

¹⁷⁸ John Cassidy, *Ronald Coase and the Misuse of Economics*, NEW YORKER (Sept. 3, 2013), https://www.newyorker.com/news/john-cassidy/ronald-coase-and-the-misuse-of-economics [https://perma.cc/T5XU-8AAY].

¹⁷⁹ See Randall G. Holcombe, The Coase Theorem, Applied to Markets and Government, 23 INDEP. REV. 249, 250–52 (2018).

¹⁸⁰ *Id.* at 252.

 $^{^{181}}$ *Id*.

¹⁸² *Id.* at 256–57 (citing Francesco Parisi, *Political Coase Theorem*, 115 PUBLIC CHOICE 1-2: 1-36 (2003)).

¹⁸³ See Clapton Munongerwa, Coase Theorem: Is there need for Government Intervention? 3–4, https://www.slideshare.net/claptonmunongerwa/coasian-ar guments [https://perma.cc/2DPB-E2NC] (explaining when government intervention is necessary under Coase economic assumptions).

¹⁸⁴ Eric Schnurer, A Map for Making Government Useful 3, U.S. NEWS (Sept. 4, 2013), https://www.usnews.com/opinion/blogs/eric-schnurer/2013/09

According to a *U.S. News* report, "the prescription drug debate in recent years ... centered on using government not to mandate that drug manufacturers cut prices, but to aggregate consumer purchasing to drive prices down." In conclusion, regulation can be productive if its regulatory bodies conceive healthcare initiatives within the same economic considerations as businesses. Targeted government regulation is necessary to internalize externalities, and thereby restore efficient market structures and negotiations to PBMs transactions and contribute to lower drug costs. 187

A. Free-Market Myth and Private Industry Concerns

The common myth that the pharmaceutical industry is *free* because its prices are not regulated is flawed in its reasoning. As articulated in the subsequent discussion, aggressive federal regulation is a culprit of high prescription drug cost.¹⁸⁸

1. Artificial Monopolies, Innovative Drugs, and "Off-Patent Drugs" 189

The Constitution has long recognized the importance of rewarding, incentivizing, and protecting innovation through the use of patents.¹⁹⁰ As applied to pharmaceuticals, these protections are especially necessary presuming the high costs and risks of drug development.¹⁹¹ "But monopolies are not markets, especially

/04/ronald-coase-and-how-government-can-operate-like-corporations [https://perma.cc/HU8H-WSS2].

¹⁸⁶ Id.; see Garrett & Garis, supra note 7, at 78.

 $^{^{185}}$ *Id*.

¹⁸⁷ Schnurer, *supra* note 184, at 3.

¹⁸⁸ See generally Avik S. A. Roy, The Competition Prescription: A Market-Based Plan for Making Innovative Medicines Affordable, The Found. For Research on Equal Opportunity (2017), https://freopp.docsend.com/view/cf agar8 [https://perma.cc/F7L6-8YBF].

¹⁸⁹ *Id.* (article discusses an unusual class of drugs which patents have expired, yet federal regulation continues to freeze competition and effectively raise drug costs for plan sponsors and consumers).

¹⁹⁰ See generally U.S. CONST. art. I, § 8, cl. 8; Karl B. Lutz, Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution, 32 J. PAT. OFF. SOC'Y 83, 86–87 (1950).

¹⁹¹ Roy, *supra* note 188, at 10.

in the dozens of disease areas where therapeutic alternatives are not available."¹⁹² Despite sunset provisions to certain patents, "[t]here are a number of old drugs whose patents have long expired for which prices are unusually high, because unwise [] FDA regulations effectively guarantee monopolies and prohibit competition."¹⁹³ Specifically, four categories of *off-patent drugs* have been the target of price inflation: (1) drugs used to treat rare disease; (2) preexisting drugs that were marketed before the FDA's inception; (3) drugs delivered using specialized devices; and (4) drugs associated with significant health and/or safety issues.¹⁹⁴

For purposes of this Note, analysis into the complex grants of *off-patent* or *orphan* drugs is unnecessary. Essentially, the federal government has manufactured competitive barriers to entry as many manufacturers have manipulated the federal regulations to insulate themselves from competition. ¹⁹⁵

This begs the question: are there available remedies vested in existing antitrust regulations? The answer is limited, as "insurers are prevented by federal and state antitrust laws from jointly negotiating reimbursement rates for innovative drugs [within] [] a given region." Therefore, federal regulations, as applied to innovative drugs, secure monopolies to drug manufacturers, while simultaneously prohibiting insurers from collectively negotiating with its suppliers. 197

Eliminating market barriers to promote competition and lower consumer costs is not radical and has been effective in comparative industries.¹⁹⁸ While subsequent sections will expound upon market-based solutions, it is worthy to discuss the restructuring of the FDA Modernization Act of 1997 ("FDA Act").¹⁹⁹ The FDA Act was designed to expedite drug products to life-threatening medical demand.²⁰⁰ Avik Roy, President of the Foundation for

 $^{^{192}}$ *Id*.

 $^{^{193}}$ *Id.* at 10–11.

¹⁹⁴ *Id*. at 11.

¹⁹⁵ *Id.* at 13–14.

¹⁹⁶ *Id.* at 15.

 $^{^{197}}$ *Id*.

¹⁹⁸ *Id.* at 15–16 (explaining how price competition has controlled Apple's manipulation of the information-technology market, contributing to higher quality products within reasonable consumer price expectations).

 $^{^{199}}$ See id. at 14–17; see generally FDA Modernization Act of 1997, 21 U.S.C. \S 301 (2018).

²⁰⁰ 21 U.S.C. § 301.

Research on Equal Opportunity, suggests Congress could amend the FDA Act to expand its expedited provision "to drugs being developed for diseases where only one or two FDA-approved drugs can be considered to represent the standard of care."²⁰¹ According to Roy, restructuring the FDA Act would "advance the public's interest in mitigating the adverse impact of monopolies and duopolies."²⁰² Notwithstanding Roy's competition-based approach, the underlying problem persists, that is, patients' lack of control over assets expended on their behalf, and prevailing opaque market conditions.²⁰³

2. PCMA's Market-Based Solution

The House Committee on Oversight and Government Reform arranged hearings examining "methods and reasoning behind recent drug price increases." Responding to these concerns, Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA), "outlined market-based policy solutions to help increase competition and lower prescription drug costs." While this Note approaches Merritt's statements with skepticism, he correctly articulated "[t]he pricing tactics discussed today are just one piece of a much larger puzzle." Specifically, Merritt outlined the following as viable market-based solutions: (1) accelerating FDA approvals of me-too drug brands against drugs facing no competition; (2) accelerating FDA approval of generics to compete with off-patent brands facing no competition; (3) generate a government "watch list" of all off-patent brands, thereby putting acquirers on alert that policymakers can monitor these situations;

²⁰¹ Roy, *supra* note 188, at 17.

 $^{^{202}}$ *Id*.

²⁰³ *Id*.

²⁰⁴ Press Release, PCMA, PBMs Provide Policy Solutions to Increase Competition, Reduce Rx Costs (Feb. 4, 2016), https://www.pcmanet.org/pbms-provide-policy-solutions-to-increase-competition-reduce-rx-costs/ [https://perma.cc/V32R-5AE6] [hereinafter Press Release, PCMA]; see also Developments in the Prescription Drug Market: Hearing Before the House Committee on Oversight and Gov't Reform, 2154 RHOB 114th Cong. 1 (2016), https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104374 [https://perma.cc/6RF5-8TXA].

²⁰⁵ Press Release, PCMA, *supra* note 204, at 1.

²⁰⁶ *Id.* (PARA what pricing tactics were discussed and implications of his statements); see also Developments in the Prescription Drug Market: Hearing Before the House Committee on Oversight and Gov't Reform, supra note 204, at 7–8.

and (4) mandating co-pay coupons as illegal kickbacks for all insurance companies that receive federal subsidy.²⁰⁷

In theory, the PCMA's argument purports to increase competition through broader consumer choice. However, it fails to address market transparency. This is likely due to PBMs fear of transparency litigation. In fact, It he PBM industry argues that legislation mandating disclosure will harm the PBM industry and reduce the discounts that the PBMs are able to negotiate on behalf of health plans. Tormer policy director for the Federal Trade Commission (FTC), David Balto, responded to PCMA's transparency concerns, calling them inconsistent with economic theory, antitrust law and common sense. Tonsequently, PCMA's argument falls short of its purported market-based solution. Under this proposal, PBMs would still be encouraged to weaponize pricing strategies, reap benefits from spread pricing, and ultimately, consumers would remain uninformed and powerless.

B. Transparent Markets and Contracting Tenants

Market transparency has long been a concern of regulatory agencies. According to the Securities Exchange Commission (SEC), transparency "plays a fundamental role in the fairness and efficiency of the secondary markets" and "transparency [helps] to link dispersed markets and improves the price discovery, fairness, competitiveness and attractiveness of U.S. markets." As applied to PBMs, its market power is derived from streams of market share but also "from the paucity of information available to those who deal with the PBMs." Naturally, transparency contributes to efficient dealings and discourages controversial industry practices. 215

²⁰⁷ Press Release, PCMA, *supra* note 204, at 2.

²⁰⁸ *Id*. at 1.

²⁰⁹ *Id*.

²¹⁰ Garett & Garis, *supra* note 7, at 61.

²¹¹ Id. at 62–63 (citing Rob Eder, Nothing More 'transparent' than PBM Posturing—Prescription Benefit Management, DRUG STORE NEWS (Sept. 22, 2003)). ²¹² Id. at 61.

²¹³ SEC Market 2000 Study, Chapter IV-1 (Jan. 1994).

²¹⁴ Garrett & Garis, *supra* note 7, at 63 (citing Bates v. State Bar of Ariz., 433 U.S. 350, 377–78 (1977) (noting restrictions on pricing transparency "increases the difficulty of discovering the lowest cost seller")).

²¹⁵ See SEC Market 2000 Study, supra note 213, at Chapter IV-1.

For example, attorneys general from twenty states settled claims under deceptive trade practices actions against Medco Health Solutions, Inc.²¹⁶ According to the New York Attorney General, "[t]his case show[ed] how [PBMs] previously hid from consumers, doctors and health plans that they were switching prescriptions to promote their own profits."²¹⁷ Garrett & Garis articulate that these practices are readily prevented when negotiating parties are equipped with transparent negotiating power backed by statutory enforcement.²¹⁸ Furthermore, Garrett's article posits a plausible market-based solution, utilizing nonprofit pass through PBMs that provide complete transparency to plans.²¹⁹

According to Garrett's nonprofit concept, setting up the "PBM could be [done] through a joint venture arrangement among the plans, the system could be licensed, or the plans could simply pay a processing fee calculated on a per-covered life or per-transaction basis."²²⁰ These independent, or transparent PBMs, pledge to conduct business in accordance with a set of guiding principles by the NCPA that align the interests of patients, employers, and community pharmacies.²²¹ Ideally, these entities would focus on formulary management.²²² According to Bestie's Employee Benefit Review, "transparent model PBMs focus on evidence-based formulary development, objective clinical review, and lowest net costs."²²³ Some transparent PBM models even open its committee meetings to clients, and make available all minutes for client review.²²⁴ Bestie concludes, under transparent PBMs models, "the results are clearly visible, and clients can feel very

²¹⁶ Press Release, New York Attorney General, 19 States Settle Deceptive Trade Practices Claims Against Medco Health Solutions (Apr. 26, 2004).

 $^{^{217}}$ *Id*.

²¹⁸ Garrett & Garis, *supra* note 7, at 65, 72–73.

²¹⁹ *Id.* at 72, 74.

²²⁰ Id. at 74

²²¹ National Community Pharmacists Association, *Transparent PBM Listing*, https://www.ncpanet.org/pdf/Independent-Transparent-PBMs-Listing.pdf [https://perma.cc/9GZW-F2QJ].

 $^{^{222}}$ Navitus, $Employee\ Benefit\ Plan\ Review$, https://m.navitus.com/getattach ment/7262cce1-fbea-4ab3-9ef2-c4d0f4838c86/The-Transparent-PBM-Pass-Through-Model-Managing-Dr.aspx [https://perma.cc/DC73-TZQ6].

 $^{^{223}}$ *Id*.

²²⁴ *Id*.

comfortable in a pay-for-performance setting."²²⁵ Furthermore, because transparent PBM incentives are aligned with that of its clients, retained discounts are passed directly back to its clients.²²⁶ However, even a transparent PBM may not disclose all of its contracts nor eliminate self-serving incentives.²²⁷ Therefore, statutes should encourage transparent entity formation while enforcing fiduciary duties in negotiation efforts.

Standardized contracting has also been suggested to reduce transactional costs and empower consumer choice.²²⁸ Standardized contracts mitigate administrative obstacles associated with collaborative health plans negotiating with a large number of sponsors.²²⁹ Thus, subject to the limitations in Part V, these contracts would shorten the negotiation process, increase parties' familiarity with contract terms, restrict room for deviation, and aid in establishing a uniform body of common law.

C. Role of Pharmacists

Pharmacists play a significant role within any healthcare regime. The House Judiciary Subcommittee on Courts and Competition suggests pharmacists critical nexus to effective management "result[s] [from their] face-to-face service and personal relationships" which enable them to "help patients manage lifestyle choices, [and] monitor and improve drug adherence." Under this Note's market-based approach, in conjunction with federal gag-clause prohibition, pharmacists can empower consumers and send signals

 $^{^{225}}$ *Id*.

²²⁶ *Id*.

²²⁷ *Id.* (explaining even a PBM which guarantees 80 percent of rebates returned while retaining 20 percent will still be inclined to maximize its 20 percent earning potential).

²²⁸ Garret & Garis, *supra* note 7, at 74.

²²⁹ *Id.* at 74–75 (explaining Rx Collaborative which was run by Towers Perrin, contracted with 50 Fortune 500 companies that all insisted on completed disclosure of revenue sources and negotiating pricing with manufactures. Because the contracts were not standardized, this approach was infeasible given the unusually high transactional and informational costs associated with company requests).

²³⁰ Antitrust Laws and Their Effect on Healthcare Providers, Insurers and Patients: Hearing Before the Subcomm. On Courts and Competition Policy of the H. Comm. On the Judiciary, 111th Cong. 157 (2010).

to the market via product choice.²³¹ Community pharmacies rely on transparent information exchanges, which "provid[es] them [with] the important groundwork to have access to patients medical records which will help them coordinate care with other providers."²³² However, unlike some community pharmacies, pharmacists are not charged with the duty to negotiate with customers and provide cheaper drug alternatives.²³³ In other words, the federal executive orders that grant pharmacists the ability to fully inform customer choice, do not place the onus on pharmacist for every transaction.²³⁴ Consequently, pharmacists' unique nexus to consumer choice continues to be under-utilized and dilutes the effect of legislative initiatives.²³⁵

V. CONTRACT AND MARKET MORALITY

Collectively applying these considerations, it's important to revisit the instrument at the apex of all PBM market debates. That is, the contract between plan sponsors and PBMs contracted pharmacies. Examining these contracts, and their formation, is critical as contract law's purpose has been linked to supporting robust markets. Moreover, Professor Nathan Oman, William & Mary Law Professor and Co-Chair of the Center for the Study of Law and Markets, suggests even agreements not connected to well-functioning markets should be enforced, if only to develop new well-functioning markets. Oman's approach to boilerplate contracts, while correctly focused on market behavior, should not be applied to the PBM market until some degree of correction occurs.

Despite Oman's well-reasoned support of boilerplate or standardized contracts, when applied to the current PBM market, the logic conflicts. The use of these contracts in murky, abused,

²³¹ *Id.* at 128.

 $^{^{232}}$ *Id*.

²³³ DIABETES PATIENT ADVOCACY COALITION, supra note 37.

²³⁴ See Linette Lopez, Trump just sold us all out on drug pricing, BUSINESS INSIDER (June 21, 2017), https://www.businessinsider.com/donald-trump-drug-pric ing-executive-order-2017-6 [https://perma.cc/VR8G-CLUS].

 $^{^{235}} Id$

²³⁶ NATHAN B. OMAN, THE DIGNITY OF COMMERCE: MARKETS AND THE MORAL FOUNDATIONS OF CONTRACT LAW 102 (2016).

²³⁷ *Id.* at 102–03.

and opaque markets is far more costly than the implied fear of transaction costs when obtaining consent.²³⁸ Similar to the fiduciary context of an expert and lay person, PBMs are sophisticated and enter contract negotiations with unmatched negotiating power.²³⁹ Accordingly, while I agree with Oman's thesis, the PBM industry must first become educated regarding the complex exchanges through transparency legislation, coupled with increased competition, compulsory pharmacist interaction, independent pass through entities, and sufficient negotiation structures. Upon balancing these interests, the PBM market will become vested with the necessary prerequisites for efficient laissez-faire exchanges, aimed to reach the economically desired outcome. Once achieved, Oman's argument should then be applied to boilerplate contracts to lower transaction costs and support the new well-functioning market. In summation, contract law, under the proper conditions, is correlated with positive cultivation of transparency values.

CONCLUSION

Until recently, PBMs have evaded examination because most consumers are unaware of their existence and fail to understand the complex transactional process. While there still rests a heavy educational burden upon PBM market players, one thing remains, mere legislative efforts, without market considerations, are insufficient to correcting the imbalance. The PBM market remains a small piece within the larger healthcare industry. However, PBM market regulation is functionally necessary when addressing prescription drug costs. Legislative efforts continue to fall short of effective business-reasoned policy and undermine the markets ability to facilitate efficient results when under corrected incentives. Competition within the PBM market, underpinned through the discussed transparency solutions, will lower drug costs and restore consumer purchasing power without clouding the market with burdensome legislation.

²³⁸ Garrett & Garis, *supra* note 7, at 61.

²³⁹ Johnson, *supra* note 3, at 328.

²⁴⁰ Garrett & Garis. *supra* note 7, at 78.

²⁴¹ *Id.* at 36.

²⁴² *Id.* at 78.