

Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation

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I. INTRODUCTION

The purchase of prescription medicine for the average consumer is often a simple process—and in some cases, an expensive one.¹ For businesses in the healthcare industry, it is complex and highly profitable.² To patients, it appears they are purchasing medication from a pharmacy—with their doctor’s permission—and are simultaneously or subsequently reimbursed for their expense by their insurance company. In reality, their purchase is the end result of an extensive process of contract negotiation, cost-benefit analysis, corporate haggling, manufacturer rebates, and the artful salesmanship of pharmacy benefit managers. While simplified transactions are ordinarily beneficial to consumers, in the case of prescription drugs they conceal unnecessarily inflated prices.

At a time when the political winds are driving the sails of healthcare reform, transparency is essential to determining how and where to lower costs in the industry.³ While many look to health insurers, a more worthy

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1. *OECD in Figures 2009*, ORG. FOR ECON. CO-OPERATION & DEV., http://www.oecd-library.org/economics/oecd-in-figures-2009_oif-2009-en (“Health spending and resources” hyperlink) (last visited Dec. 19, 2010) (calculating that Americans spent \$7,290 per capita on health care in 2007).

2. Allison Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 36-37 (2007) (“In 2006, Express Scripts had a net income of \$474 million on revenues of \$17.7 billion, Medco Health Solutions, Inc. made \$630 million on revenues of \$42.5 billion during the same period, and Caremark RX, Inc. made \$1.1 billion on revenues of \$36.8 billion in 2006”). I am greatly indebted to the authors of this piece for their thorough survey of the PBM industry and its inner workings. As will be seen below, however, additional information concerning the legal issues involved in the industry leads to the conclusion that their concluding prescription is woefully inadequate.

3. Mark J. Botti, Chief, Litig. I Section U.S. Dep’t of Justice, Antitrust Div., Competition in Healthcare and Certificates of Need, Prepared Testimony Before the General Assembly of the State of Georgia (Feb. 23, 2007), in 6 HEALTH CARE & ANTITRUST L. app.

starting point would be the sale and distribution of prescription drugs.⁴ This paper examines the pharmacy benefit management industry by describing its operation, analyzing potential antitrust and other legal concerns involved in its ties to health plan sponsors, prescription drug manufacturers, and pharmacies, and evaluating existing proposals for regulating the industry to lower costs for health plan sponsors and consumers. These topics have been the subject of frequent litigation and investigation for the past several years, on both the state and federal levels. This paper argues that the problems discussed herein are systemic and thus require direct regulation, rather than remedial litigation, in order to curb abuses in the industry.

To that end, this paper concludes with a proposal for legislation requiring pricing limitations and manufacturer rebate transparency designed to lower prescription drug costs and place restrictions on pharmacy benefit management behavior that will not rely on risky statutory interpretation. While these proposals may not address any latent inefficiencies in the research and manufacturing sector of the prescription drug industry, they would represent significant steps towards cutting costs and eliminating waste in the American healthcare system.

II. THE PHARMACY BENEFIT MANAGEMENT INDUSTRY

Pharmacy benefit management companies (PBMs) are, in essence, the middlemen of the prescription drug industry.⁵ They coordinate the sale and reimbursement of prescription drugs between health insurance plan sponsors or employers, drug manufacturers, and local and national pharmacies.⁶ Plan sponsors and employers hire PBMs to design and administer plans for prescription drug benefits for their members or

E145 (2010).

4. *OECD in Figures 2009*, *supra* note 1 (Pharmaceuticals comprise twelve percent of healthcare spending in the United States); Calvin Woodward, *FACT CHECK: Health Insurer Profits Not So Fat*, ASSOCIATED PRESS, Oct. 25, 2009, available at <http://www.foxnews.com/politics/2009/10/26/fact-check-health-insurers-profits-fat/> (explaining that, contrary to popular belief, health insurance companies have not been seeing large profits.); *see, e.g.*, Russ Britt, *Health care's healthy decade*, MARKETWATCH (Nov. 19, 2009, 7:34 p.m. EST), available at <http://www.marketwatch.com/story/health-care-ends-bonanza-decade-on-bright-note-2009-11-19?link=kiosk> (attributing part of the economic growth to far greater profits realized in the pharmaceuticals industry); Barbara Martinez et al., *As Health Middlemen Thrive, Employers Try to Tame Them*, WALL ST. J., Dec. 29, 2006, at A1 (noting that, in 2005, "[t]he three largest pharmaceutical benefit managers, for instance, had net income of \$1.9 billion").

5. Christy Rentmeester & Robert Garis, *Commentary—Reply to Malley*, 33 J. HEALTH POL. POL'Y & L. 975, 976 (2008).

6. Garrett & Garis, *supra* note 2, at 34; Regina Sharlow Johnson, *PBMs: Ripe For Regulation*, 57 FOOD & DRUG L. J. 323, 327 (2002).

employees.⁷ In return, PBMs provide industry-specific knowledge not found in most human resources departments, as well as negotiating power (because of their large patient base) to secure rebates and discounts from drug manufacturers and pharmacies.⁸ Most PBMs also offer various administrative services on a fee basis, and many run their own mail-order pharmacies.⁹ Overall, in selecting a PBM to manage its members' health benefits, "[t]he primary concerns of the health plan typically include pricing, customer service, and pharmacy plan design."¹⁰

A. Pricing

As is to be expected, the PBM business model centers largely on pricing mechanisms. While PBMs once operated primarily on a fee basis, recent decades have seen a shift to a more complex, and more profitable, business model.¹¹ This model revolves around three important pricing measures for brand name prescription drugs: Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), and Average Manufacturer Price (AMP).¹² The WAC is the industry equivalent to a manufacturer suggested retail price or catalog price and is only occasionally relevant to pricing prescription drugs.¹³ The AWP is an industry-wide published list of prices, ostensibly for wholesalers selling to pharmacies.¹⁴ Pharmacies do not actually pay this rate, however, and instead use the AWP as the basis for the price they charge to PBMs, health plans, and government programs, all of which typically negotiate a percentage discount.¹⁵ Lastly, the AMP is the average price actually paid to manufacturers by wholesalers and pharmacies, including any rebates or discounts (but not rebates to PBMs).¹⁶

7. Johnson, *supra* note 6, at 327.

8. *See infra* Part II.B.

9. Johnson, *supra* note 6, at 327 (explaining that the administrative services include drug utilization reviews and data mining); Garrett & Garis, *supra* note 2 at 37. Because this paper focuses primarily on prescription drug coverage, however, it will not actively discuss administrative services.

10. Garrett & Garis, *supra* note 2, at 39.

11. Christy Rentmeester & Robert Garis, *Rebates and Spreads: Pharmacy Benefit Management Practices and Corporate Citizenship*, 33 J. HEALTH POL. POL'Y & L. 943, 946 (2008) [hereinafter *Rebates & Spreads*].

12. CONG. BUDGET OFFICE, *PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR* 3 (Jan. 2007) [hereinafter *CBO REPORT*].

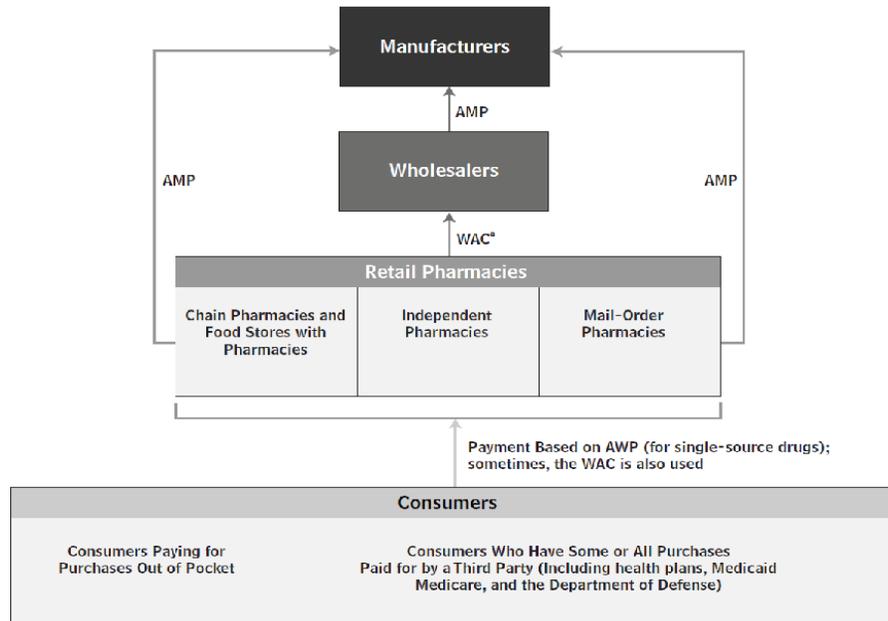
13. *Id.* (stating that the WAC is useful primarily when single-source drugs are involved and the price approximates AWP).

14. *Id.*; Garrett & Garis, *supra* note 2, at 39.

15. *CBO REPORT*, *supra* note 12, at 3; PHARMACY BENEFIT MGMT. INST., *PRESCRIPTION DRUG BENEFIT COST AND PLAN DESIGN REPORT 20 (2008-09)*, available at http://www.pbmi.com/2008_report/index.html [hereinafter *2008 PBMI Report*].

16. *CBO REPORT*, *supra* note 12, at 3; PHARMACY BENEFIT MGMT INST., *PRESCRIPTION*

The Congressional Budget Office has modeled the relationship between these prices in the following chart:¹⁷



In addition to these pricing indices, PBMs that negotiate with pharmacies and design plans for sponsors also take into consideration rebates they receive from drug manufacturers.¹⁸ As will be further discussed in Part II-B-1, PBMs do not always reveal these rebates to the other parties.¹⁹

Generic drugs are subject to a different price list, the Maximum Allowable Cost (MAC).²⁰ Unlike the AWP, however, there is no one standard MAC price list, but rather a range of acceptable prices.²¹ While they view the MAC as “an upper

DRUG BENEFIT COST AND PLAN DESIGN REPORT 25 (2009-2010), available at <http://benefitdesignreport.com> [hereinafter 2009 PBMI REPORT].

17. CBO REPORT, *supra* note 12, at 5, 8 (showing that about thirty percent of the manufacturer’s supply goes directly to chain (retail) pharmacies, while sixty-four percent goes through wholesalers).

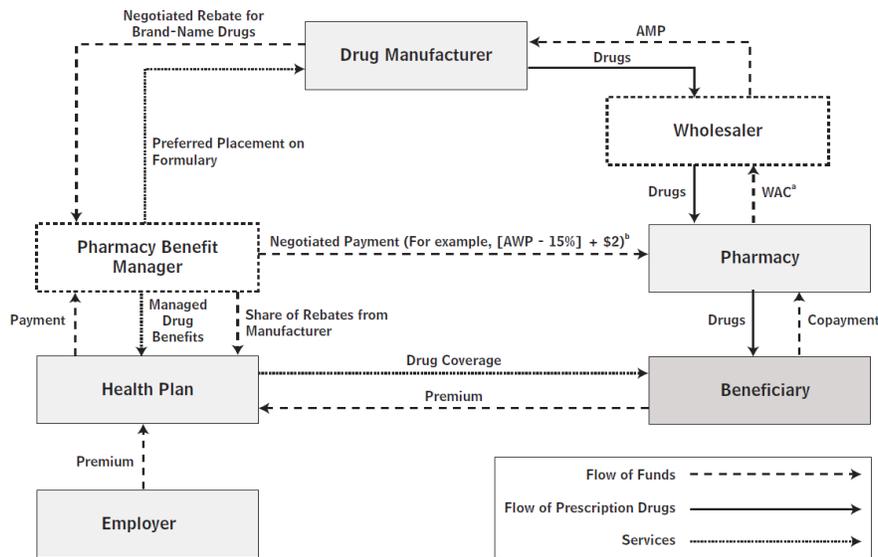
18. Garrett & Garis, *supra* note 2, at 44 (“In effect, the manufacturers pay PBMs to increase their market shares.”).

19. See Allan Zimmerman, *True Transparency: PBM Cost-Control Model of the Future*, 43 BENEFITS & COMPENSATION DIG. (Int’l Found. of Emp. Benefit Plans), No. 10, Oct. 2006 at 1, available at <http://www.ifebp.org/pdf/webexclusive/06oct.pdf>.

20. Garrett & Garis, *supra* note 2, at 40 (explaining that the MAC is “often expressed as an aggregate discount off the AWP”).

21. *Id.* at 40.

payment limit,”²² most plan sponsors are unaware that “PBMs use lower MAC prices to reimburse pharmacies, while charging them higher MAC prices, increasing the spread retained by the PBM.”²³ This, too, will be discussed further in Part II-B-2. Given the complexity of this web of transactions, it is helpful to depict their relationships graphically²⁴:



B. Rebate and Discount Strategies

PBMs turn a profit on prescription drug transactions through three main strategies, each guided by the pricing indices above: manufacturer rebates, generic pricing spreads, and formulary design.²⁵

As previously noted, PBMs negotiate a percentage discount off AWP as the reimbursement rate to pharmacies for a given drug.²⁶ This discount is shared when the PBM charges the plan sponsor whose member or employee purchased the prescription.²⁷ Accordingly, the discount that a PBM can secure from pharmacies is key to attracting clients looking for the lowest

22. *Id.* (quoting CBO REPORT, *supra* note 12, at Glossary).

23. *Id.*; Johnson, *supra* note 6, at 328 (explaining how PBMs generate revenue).

24. CBO REPORT, *supra* note 12, at 11.

25. *Id.*; Garrett & Garis, *supra* note 2, at 37; Johnson, *supra* note 6, at 328. (“A formulary is a listing of preferred prescription drugs that a health plan predetermines will be covered for reimbursement under the terms of its plan.”).

26. Garrett & Garis, *supra* note 2, at 39; CBO REPORT, *supra* note 12, at 3.

27. Garrett & Garis, *supra* note 2, at 43-44.

prices.²⁸ Theoretically, the better the discounts a PBM can secure, the bigger the clients it can attract.²⁹ Somewhat conversely, the more patients covered under a PBM's plans, the more leverage it has to get pharmacies to offer lower rates, lest they be excluded from the PBM's patients' business.³⁰

1. Rebates

While exacting deep discounts from pharmacies helps PBMs to cut costs by sharing in the discounts with plan sponsors, the real money is made through rebates from drug manufacturers.³¹ Manufacturers will offer rebates to PBMs based on how much the PBM increases the manufacturer's market share for a given drug.³² The catch is that the PBMs are not required to share information about these rebates with plan sponsors, and in the vast majority of cases do not.³³ Instead, they pocket some or all of the money saved.³⁴

2. Generic Pricing Spreads

Similarly, PBMs take advantage of the spread in various MAC price lists for generic drugs. By negotiating with manufacturers using a lower-priced list and then setting reimbursement rates with plan sponsors using a higher-priced list, the PBMs are able to create a spread that is pure profit.³⁵ When plan sponsors insist on receiving a greater portion of rebates secured from manufacturers, PBMs can offset this by inflating the MAC prices for generics.³⁶ As an indication of how substantial these amounts can be, in August of 2009 the U.S. Military's healthcare provider, TRICARE, announced that it anticipated saving \$1.67 billion in 2010 by negotiating its own pharmacy benefits instead of using a PBM for its nine million beneficiaries.³⁷

28. *Id.* at 39 (discussing the relationship between PBMs and health plans).

29. *Id.*; CBO REPORT, *supra* note 12, at 3.

30. Garrett & Garis, *supra* note 2, at 46; Johnson, *supra* note 6, at 331-32.

31. Garrett & Garis, *supra* note 2, at 36; Johnson, *supra* note 6, at 328.

32. *See generally* CBO REPORT, *supra* note 15.

33. Zimmerman, *supra* note 19, at 1.

34. *Id.*; Garrett & Garis, *supra* note 2, at 37, n.18.

35. Garrett & Garis, *supra* note 2, at 40.

36. *Id.* (This price measure may become even more important in the future, as the use of generic increases); Vijay Vaitheeswaran, *Generically Challenged*, THE ECONOMIST: THE WORLD IN 2010, Nov. 2009, at 130.

37. Kevin Schweers, *Community Pharmacists Hear Mail Order Complaints; Debunk PBM Myths*, NCPA COMMENTARY (Sept. 23, 2009), <http://www.ncpanet.org/index.php/ncpa-commentary/385-community-pharmacists-hear-mail-order-complaints-debunk-pbm-myths>; Press Release, TRICARE, TRICARE Obtains Lower Prices on Retail Prescription Drugs, (Aug. 4, 2009), <http://www.tricare.mil/pressroom/news.aspx?fid=548>.

3. Formulary Design

Lastly, but significantly, PBMs can amplify the benefits of rebate concealment and spread profits through the careful construction of formularies.³⁸ A formulary is the heart of the plan that sponsors hire PBMs to design for their members or employees.³⁹ The formulary dictates which drugs are covered and what their co-pays are.⁴⁰ The most common type of formulary is a three-tier plan, used by 67.2 percent of employers that hire PBMs.⁴¹ The first tier is for generic drugs and has the lowest co-pay, while the second and third tiers are for preferred and non-preferred brand-name drugs, respectively.⁴² The second tier, preferred brand-name drugs, is largely comprised of drugs for which PBMs receive the deepest rebates from drug manufacturers for increasing their market share.⁴³ The third tier, non-preferred brand-name drugs, has the highest co-pays.⁴⁴

The Pharmacy Benefit Management Institute, a group for “health care purchasers, pharmacy benefit managers, and other industry professionals involved in the delivery of drug benefits,”⁴⁵ found that “52.3% of employers perceive the nature of the financial relationship with their PBM to be transparent.”⁴⁶ This misconception makes it even easier for PBMs to create a preference for drugs and generics that yield the greatest rebates and profits.⁴⁷ What is more, this arrangement actually incentivizes PBMs to promote the drugs for which they receive the largest per-prescription rebate, rather than the cheapest or best-value prescription.⁴⁸ For example, 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. The PBM has an incentive to promote drug B, even though drug A is more cost efficient for the plan sponsor, because it will see a larger rebate. The exception to this is a generic alternative with a spread in MAC pricing greater than the rebate the PBM will see; in that case the patient will

38. Garrett & Garis, *supra* note 2, at 43-44; Johnson, *supra* note 6, at 331.

39. Garrett & Garis, *supra* note 2, at 43-44.

40. *Id.*; 2009 PBMI REPORT, *supra* note 16, at 14.

41. 2009 PBMI REPORT, *supra* note 16, at 14 (explaining that some plans have extra tiers for specialty and lifestyle drugs).

42. *Id.*

43. Garrett & Garis, *supra* note 2, at 44-46.

44. *Id.*

45. *About Us*, PHARM. BENEFIT MGMT. INST., <http://www.pbmi.com/aboutus.asp> (last visited Dec. 19, 2010).

46. 2008 PBMI Report, *supra* note 15, at 7.

47. *Id.*

48. Garrett & Garis, *supra* note 2, at 43.

likely choose the lower co-pay option.⁴⁹ As shown by these incentives, the formulary is a key tool by which PBMs can increase their profit rate.

C. Mail-Order Pharmacies

In addition to these strategies, many PBMs also operate their own mail-order pharmacies.⁵⁰ Mail-order pharmacies offer patients with recurring prescriptions greater convenience and lower co-pays than traditional retail pharmacies.⁵¹ For PBMs, they are an opportunity for even greater revenue. Because PBMs are acting as the pharmacy in this case, the spread between MAC prices is even greater than when dealing with a retail pharmacy.⁵² PBMs can also direct prescriptions to their own mail-order facilities instead of to competitors, in order to maximize their gains on the higher MAC spreads and rebates from manufacturers for brand-name drugs—even if the competitor could do it at a lower cost to the plan sponsor.⁵³ Rebates for mail-order drugs are often larger as well, providing the PBMs with an incentive to encourage the use of mail-order pharmacies over retail pharmacies, regardless of the risk of waste.⁵⁴ Additionally, PBM-owned mail-order pharmacies often contact doctors to encourage them to switch a patient to an alternative drug that is on the patient's formulary or, if generic, has a higher MAC spread.⁵⁵

Understanding the structure of the PBM industry, the relationships among its participants, and the strategies employed in the industry is essential to highlighting the problems and concerns that many of these practices raise. The rest of this paper examines the operation of the PBM industry in the light of federal and state laws, discusses potential violations, and addresses possible solutions related to the way the industry works.

III. ANTITRUST AND OTHER CONCERNS

Understandably, some have challenged the practices outlined above as

49. *Id.* at 43-45 (PBMs, however, rarely notify plan participants about new generic versions of medication they are taking).

50. Garrett & Garis, *supra* note 2, at 66.

51. 2009 PBMI REPORT, *supra* note 16, at 12; *see generally* FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES i (Aug. 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf> [hereinafter FTC PBM REPORT].

52. Garrett & Garis, *supra* note 2, at 67.

53. *Id.*

54. *Id.* at 67-68; 2009 PBMI REPORT, *supra* note 16, at 28.

55. Garrett & Garis, *supra* note 2, at 67; Johnson, *supra* note 6, at 332 (“In a survey of 248 physicians in New York, 83% of these physicians reported that they had been contacted by a health plan, or a PBM pharmacist, to switch a prescription.”).

violating antitrust and other state and federal laws.⁵⁶ And, in fact, plaintiffs in recent litigation have agreed and pursued such claims.⁵⁷ Plaintiffs have also alleged that the PBMs' behavior violates other state and federal laws, including consumer protection laws and the Employee Retirement Income Security Act (ERISA). This section will discuss and examine these matters as a way of highlighting and dissecting alleged abuses in the industry.

A. Investigations and Litigated Claims

Of the dominant firms in the industry, three of the leaders have been under scrutiny in recent years: Caremark Pharmacy Services (Caremark), Medco Health Solutions (Medco), and Express Scripts.⁵⁸ As of the first quarter of 2009, these three firms had market shares of 12.02 percent, 8.79 percent, and 8.06 percent of beneficiaries, respectively, and 15.09 percent, 14.86 percent, and 10.66 percent of prescriptions per year, respectively.⁵⁹ Collectively, this represents 28.67 percent of market share and 40.61 percent of prescriptions per year. An examination of litigation and settlements involving these three firms brings to light several of the antitrust and other legal concerns surrounding the PBM industry.

1. Sherman Act Violations

The Sherman Antitrust Act forbids “[e]very contract, combination in the form of trust or otherwise, or conspiracy” that restrains trade⁶⁰ and makes illegal monopolization and attempts to monopolize.⁶¹ Between 2003 and

56. DAVID BALTO, REVIVING COMPETITION IN HEALTHCARE MARKETS: THE USE OF SECTION 5 OF THE FTC

ACT, *Before the FTC WORKSHOP: SECTION 5 OF THE FTC ACT AS A COMPETITION LAW* (Oct. 17, 2008), available at <http://www.ftc.gov/bc/workshops/section5/docs/dbalto.pdf>; Johnson, *supra* note 6 at 337, *et seq.*; JOHN NICHOLAS DEMOS & STEWART STEWART, AN ASSESSMENT OF THE FEDERAL TRADE COMMISSION CONFLICT OF INTEREST STUDY I, xvi (2006), available at <http://www.ncpanet.org/pdf/ftcassessment-exsum.pdf>.

57. Class Action Complaint at 5-6, *Brady Enters., Inc. v. Medco Health Solutions, Inc.*, (No. 03-4730) 2003 WL 23902806 (E.D. Pa. 2004); *In Re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432 (3d Cir. 2009) (vacating an order by the transferee judge to vacate previous judge's order to compel arbitration between Bellevue Drug Co. and AdvancePCS); *In Re Pharmacy Benefit Managers Antitrust Litigation*, 06-md-01782-JF-ALL (E.D. Pa Feb. 21, 2007) (the other parties had been previously required to file new petitions for class certification).

58. Garret & Garis, *supra* note 2, at 36, nn.12, 14 (explaining that Caremark is a subsidiary of CVS and Medco was formerly of Merck).

59. *Top 25 Pharmacy Benefit Management Companies and Market Share By Membership, as of 1st Quarter 2009*, PHARM. BENEFIT MGMT. INST., <http://www.pbmi.com/PBMmarketshare1.asp> (last visited Dec. 19, 2010) [hereinafter *Top 25 PBMs*].

60. 15 U.S.C. § 1 (2006).

61. 15 U.S.C. § 2 (2006).

2005, several independent pharmacies filed class action suits against one or more of the three PBM industry leaders—Medco, Caremark, and Express Scripts—alleging violations under Sections 1 and 2 of the Sherman Act.⁶² The Judicial Panel on Multidistrict Litigation consolidated these six cases and transferred them to the Eastern District of Pennsylvania in 2006.⁶³ The case is still under way, with at least one of the six cases in compelled arbitration.⁶⁴ Each of the cases, and their accompanying allegations, are discussed below.

In 2004, North Jackson Pharmacy alleged violations of both Sections 1 and 2 of the Sherman Act by the PBMs.⁶⁵ In one of its two complaints filed in the Northern District of Alabama, North Jackson accused Express Scripts of conspiring with other PBMs to fix prices and to monopolize the market for insurance-covered prescription drugs.⁶⁶ The complaint alleged these Sherman Act violations were undertaken through coordination with other PBMs (including Medco and Caremark) and resulted in “horizontal restraints of trade, and monopolization,” specifically, sub-competitive reimbursement rates for independent pharmacies (and thus supra-competitive profits for the PBMs).⁶⁷ To support their allegations, the

62. N. Jackson Pharm., Inc. v. Express Scripts, Inc., 345 F. Supp. 2d 1279 (N.D. Ala. 2004); N. Jackson Pharm., Inc. v. Medco Health Solutions, Inc., No. 5:03-2697, 2004 WL 3372978 (N.D. Ala. 2004); N. Jackson Pharm., Inc. v. Caremark RX Inc., 385 F.2d 740 (N.D. Ill. 2005); Brady Enters., Inc. v. Medco Health Solutions, Inc., No. 03-4730, 2003 WL 23902806 (E.D. Pa. 2003); Bellevue Drug Co. v. AdvancePCS, 333 F. Supp. 2d 318 (E.D. Pa. 2004).

63. *In Re Pharm. Benefit Managers Antitrust Litig.*, 452 F. Supp. 2d 1352 (J.P.M.L. 2006).

64. *In Re Pharm. Benefit Managers Antitrust Litig.*, 582 F.3d 432 (3rd Cir. 2009) (vacating an order by the transferee judge to vacate previous judge’s order to compel arbitration between Bellevue Drug Co. and AdvancePCS). *In Re Pharm. Benefit Managers Antitrust Litig.*, 06-md-01782-JF-ALL (E.D. Pa Feb. 21, 2007) (the other parties had been previously required to file new petitions for class certification).

65. First Am. Class Action Complaint at 13, N. Jackson Pharm., Inc. v. Express Scripts, Inc., 345 F. Supp. 2d 1279 (N.D. Ala. 2004) (No. 5:03-2696).

66. *Id.* (“Defendant has combined, conspired and/or agreed with other parties to unreasonably restrain trade in violation of Sections [*sic*] 1 of the Sherman Act by price fixing schemes. Defendant has also violated Section 2 of the Sherman Act by conspiring with other parties to monopolize or attempt to monopolize the United States market for dispensing and retail sale of prescription drugs that are reimbursed by insurance.”). North Jackson Pharmacy also filed a complaint against Medco alleging nearly identical violations. First Amended Class Action Complaint at 16, N. Jackson Pharm., Inc. v. Medco Health Solutions, Inc., No. 5:03-2697, 2004 WL 3372978 (N.D. Ala. 2004).

67. First Am. Class Action Complaint, *supra* note 66, at 14. *See generally* Milt Freudenheim, *Drug-Plan Manager, Caremark, To Buy a Rival for \$5.6 Billion*, N.Y. TIMES, Sept. 3, 2003, available at <http://www.nytimes.com/2003/09/03/business/drug-plan-manager-caremark-to-buy-a-rival-for-5.6-billion.html> (discussing Caremark’s purchase of AdvancePCS); *see also* CVS Caremark History, CVS CAREMARK <http://info.cvs-caremark.com/our-company/history>.

plaintiffs pointed to the prevalence of “substantially similar contracts” used by each of the PBMs that required pharmacies to submit to “detrimental pricing schemes.”⁶⁸ Additionally, they accused the PBMs of formulary manipulation to promote needlessly expensive drugs whose cost was more of a burden to the pharmacies.⁶⁹ The plaintiffs further alleged that the PBMs used the pharmacies’ data to divert their customers to the PBMs’ own mail-order pharmacies and that they concealed the rebates and discounts received from drug manufacturers.⁷⁰ Lastly, the plaintiffs accused Express Scripts and others of “impos[ing] unconscionable and punitively low reimbursement rates on member pharmacies.”⁷¹ The plaintiffs argued that these activities were possible because the PBMs share their rates with one another, and with eighty percent of the industry participating in “an entity called Hub RX through which they are able to share competitive and pricing information.”⁷²

Expanding on their accusation that PBMs diverted prescriptions from independent pharmacies to their own mail-order pharmacies, the plaintiffs accused Express Scripts and other PBMs of “impos[ing] anti-competitive restrictions on the activities of retail pharmacists that could not exist in an open market” and setting “arbitrary limitations on a pharmacist’s ability to refill prescriptions in order to divert this profitable segment of the prescription drug market to defendant’s own mail-order business.”⁷³ They further accused PBMs of prohibiting independent pharmacies from filling more than a month’s supply for a drug, while allowing their own mail-order pharmacies to fill up to a 90-day supply for a prescription at a lower rate.⁷⁴ These practices, the plaintiffs said, “[deprive them] of the most profitable portion of their business.”⁷⁵ Altogether, North Jackson Pharmacy’s allegations against the PBMs centered on the cartel-like behavior of conspiring to force independent pharmacies to accept sub-competitive reimbursement rates, while attempting to monopolize the mail-order pharmacy sector of their business.⁷⁶

In the Northern District of Illinois, North Jackson Pharmacy filed a third

68. First Am. Class Action Complaint, *supra* note 66 at 14-15.

69. *Id.* at 15.

70. *Id.*

71. *Id.*

72. *Id.* at 17.

73. *Id.* at 17-18.

74. First Am. Class Action Complaint, *supra* note 66 at 18 (finding that the PBMs were selling a ninety day supply for less than the price of three thirty-day co-pays).

75. *See id.*

76. *Id.*

suit under Section 1 of the Sherman Act, this time against Caremark.⁷⁷ There, North Jackson alleged “a conspiracy between Plan Sponsors, using Caremark as their ‘common agent,’ to fix the prices paid independent pharmacies for dispensing prescription drugs to Plan Subscribers” and “a conspiracy between Caremark and PBMs with which it competes to fix those same prices.”⁷⁸

In the Eastern District of Pennsylvania, Brady Enterprises filed a complaint against Medco, alleging horizontal price-fixing as well as issues concerning vertical integration.⁷⁹ The plaintiff pointed out that Medco, through its own mail-order pharmacies, competes with the pharmacies with which it contracts.⁸⁰ This, along with the aggregate market power of Medco’s plan sponsors, allows Medco to “create artificial advantages for its own dispensing activities” and divert sales to its own mail-order pharmacy network.⁸¹ These practices, the plaintiff alleged, “have the purpose and effect of artificially fixing, depressing, standardizing, and stabilizing” the reimbursement rates for independent pharmacies and are violations of Section 1 of the Sherman Act.⁸²

Finally, Bellevue Drug Co. also filed suit in the Eastern District of Pennsylvania, against AdvancePCS (which was later acquired by Caremark),⁸³ alleging violations of Section 1 of the Sherman Act and Sections 4 and 16 of the Clayton Act.⁸⁴ Like Brady Enterprises, Bellevue claimed that AdvancePCS used its “aggregated economic power . . . to set reimbursement rates for retail pharmacies’ brand name and prescription drugs and dispensing services below that which would prevail in a competitive marketplace.”⁸⁵ Although they did not allege a conspiracy with plan sponsors, Bellevue did claim that the plan sponsors were aware of the practices.⁸⁶ In addition, Bellevue reiterated the allegations made in the above-mentioned cases regarding Advance PCS’ mail-order pharmacy

77. *N. Jackson Pharm., Inc. v. Caremark RX, Inc.*, 385 F. Supp. 2d 740 (N.D. Ill. 2005).

78. *Id.* at 744.

79. Class Action Complaint at 5-6, *Brady Enters., Inc. v. Medco Health Solutions, Inc.* (No. 03-4730), 2003 WL 23902806 (E.D. Pa. 2003).

80. *Id.* at 7.

81. *Id.*

82. *Id.* at 26.

83. *Integration of Advance PCS and Caremark*, CVS CAREMARK, https://www.caremark.com/wps/portal/FAQS_CUSTOMER_CARE?cms=CMS-2-009273 (last visited Dec. 19, 2010).

84. *Bellevue Drug Co. v. Advance PCS*, No. 03-4731, 2004 WL 724490 (E.D. Pa. Mar. 2, 2004).

85. *Id.* at *1.

86. *Id.*

practices.⁸⁷

2. Unfair and Deceptive Trade Practices

PBMs have also been subject to litigation under Section 5 of the Federal Trade Commission Act (FTC Act), and equivalent state consumer protection laws, which forbids “unfair or deceptive acts or practices in or affecting commerce.”⁸⁸ In 2008, Attorneys General from 28 states and the District of Columbia entered into settlements with Express Scripts and Caremark after alleging various deceptive trade practices by each company.⁸⁹ Following an investigation that began in 2004, both PBMs were accused of engaging in deceptive trade practices by encouraging doctors to switch patients to preferred drugs and by concealing and retaining profits from these switches and from manufacturer rebates.⁹⁰ As noted previously, PBMs stand to earn substantial profits by encouraging the use of a formulary’s preferred drugs and drugs for which the PBM receives larger rebates from manufacturers.⁹¹

In its complaint against Caremark, the State of Washington specifically accused the PBM of withholding pertinent details regarding drug switches, including financial incentives, and of “[f]ailing to require that its pharmacists form an independent, professional judgment about the propriety of a drug switch before proposing it.”⁹² These practices, the complaint alleged, grew out of Caremark’s strategy of persuading doctors to switch their patients to drugs for which Caremark would receive greater rebates.⁹³ Express Scripts was accused of similar conduct.⁹⁴

87. Class Action Compl. at 6, *Bellevue Drug Co. v. Advance PCS*, 333 F. Supp. 2d. 318 (E.D. Pa. 2003) (No. 2:03-4731).

88. 15 U.S.C. § 45(a)(1) (2010); Garrett & Garis, *supra* note 2, at 56, nn.122-23.

89. Press Release, Ill. Att’y Gen. Lisa Madigan, 28 Attorneys General Reach Settlement with Caremark for Drug Switching Practices (Feb. 14, 2008), *available at* http://www.illinoisattorneygeneral.gov/pressroom/2008_02/20080214.html (The states included: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington).

90. *See, e.g.*, Press Release, Wash. Att’y Gen. Rob McKenna, Attorney General McKenna Announces Caremark to pay \$41 Million to Resolve Multistate Consumer Protection Claims (Feb. 14, 2008), *available at* <http://www.atg.wa.gov/pressrelease.aspx?&id=19122>; Compl. For Inj. And Other Relief Under The Consumer Protection Act, RCW 19.86, *State v. Caremark Rx, LLC*, No. 08-2-06098-5 (Wash. Feb. 14, 2008).

91. 2009 PBMI REPORT, *supra* note 16 at 8; *see supra* notes 32-42 and accompanying text.

92. Compl. For Inj. And Other Relief Under The Consumer Protection Act, RCW 19.86, *supra* note 90, at 7.

93. *Id.*

As part of their settlements and consent decrees, Caremark and Express Scripts were required to pay \$41 million and \$9.5 million, respectively, and to make substantial changes to their operation.⁹⁵ Specifically, the consent decrees required the two PBMs to end a litany of practices involving drug switches.⁹⁶ In addition, both companies were required to make a series of financial incentive disclosures and reimbursements in each case of drug switching, as well as to monitor associated health risks and adopt a code of ethics for their employees.⁹⁷ In the case of Caremark, these provisions apply for only five years and then end.⁹⁸ The agreement with Express Scripts, in a similar fashion, only requires Express Scripts to certify its compliance with the agreement on an annual basis for five years.⁹⁹

94. See Order Approving Entry of Assurance of Discontinuance, *In re Express Scripts, Inc.*, No. 08-2-0155-4 (Wash. May 28, 2008), available at http://www.atg.wa.gov/uploadedFiles/Home/News/Press_Releases/2008/ProposedExpressscriptsAOD.pdf.

95. Press Release, Wash. Att’y Gen., Att’y Gen. McKenna Announces Express Scripts to pay \$9.5 Million to Resolve Consumer Protection Claims (May 27, 2008), available at <http://www.atg.wa.gov/pressrelease.aspx?id=19850>.

96. Press Release, Ill. Att’y Gen., *supra* note 89; see also Press Release, Wash. Att’y Gen., *supra* note 95. They were:

[p]rohibit[ed] . . . from soliciting drug switches when: The cost to the patient will be greater than the cost of the originally prescribed drug; The originally prescribed drug has a generic equivalent and the proposed drug does not; The net drug cost of the proposed drug exceeds the net drug cost of the originally prescribed drug; The originally prescribed drug’s patent is expected to expire within six months; or The patient was switched from a similar drug within the last two years.

97. Press Release, Ill. Att’y Gen., *supra* note 89; Press Release, Wash. State Att’y Gen., *supra* note 95, at 2 (stating full requirements). The full requirements were to:

Inform patients and prescribers of the effect that a drug switch will have on a patient’s co-payment; Inform prescribers of [the PBM’s] financial incentives for certain drug switches; Inform prescribers of material differences in side effects or efficacy between prescribed drugs and proposed drugs; Reimburse patients for out-of-pocket expenses for drug switch-related healthcare costs and notify patients and prescribers that such reimbursement is available; Obtain express, verifiable authorization from the prescriber for all drug switches; Inform patients that they may decline a drug switch and the conditions for receiving the originally prescribed drug; Monitor the effects of drug switches on the health of patients; Adopt a code of ethics and professional standards; Refrain from making any claims of savings for a drug switch to patients or prescribers unless Caremark can substantiate the claim; Refrain from restocking and re-shipping returned drugs unless permitted by applicable law; and Inform prescribers that certain visits by [the PBM’s] clinical consultants and promotional materials sent to prescribers are funded by pharmaceutical manufacturers.

Press Release, Ill. Att’y Gen., *supra* note 89; Press Release, Wash. State Att’y Gen., *supra* note 95.

98. Consent Decree at 41, *State v. Caremark Rx, LLC*, No. 08-2-06098-5 (Wash. Feb. 14, 2008), available at http://www.atg.wa.gov/uploadedFiles/Home/News/Press_Releases/2008/CaremarkConsentDecree.pdf (noting that the terms expire in 2013).

99. Order Approving Entry of Assurance of Discontinuance, *supra* note 94, at 41.

Such massive investigations on the part of states might lead one to assume that the FTC has also been involved in policing PBMs.¹⁰⁰ The FTC, however, has tended—over the objections of observers—to turn a lazy eye towards potential anti-competitive and market power issues in the PBM industry.¹⁰¹ In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress required the FTC to undertake an examination of potential conflicts of interest in the operation of mail-order pharmacies by PBMs.¹⁰² The FTC described the concerns about vertical integration between PBMs and their mail-order pharmacies, which they were directed to examine as

[the] “self-dealing” arrangements [that] purportedly would provide PBMs an opportunity to manipulate drug dispensing at their mail-order pharmacies to enhance their own profits at the expense of plans and members through the three business practices discussed above (lack of generic substitution and dispensing, interchange to more expensive brand products, and repackaging of drugs into more expensive units).¹⁰³

To conduct its investigation, the FTC looked at large PBMs, smaller, and insurer-owned PBMs, retailer-owned PBMs, and stand-alone retail pharmacies and the prices they charged plan sponsors for generic drugs.¹⁰⁴ Finding the data did not support allegations of increased costs to plan sponsors, the FTC said that any fears of conflicts of interest between PBMs owning mail-order pharmacies and their plan sponsors were unfounded.¹⁰⁵

The FTC’s report, however, aimed to determine whether plan sponsors (specifically, federal employee health benefit programs) paid too much to PBMs, not whether PBMs paid too little to independent pharmacies or harmed consumers.¹⁰⁶ The report also specifically abstained from commenting on whether PBM practices surrounding manufacturer rebates violate anti-kickback laws.¹⁰⁷ Critics have pointed to these and other

100. BALTO, *supra* note 56, at 3.

101. *Id.*; see generally David Balto, *The FTC Should Issue a Second Request on Express Scripts’ Proposed Acquisition of Wellpoint’s PBM Business*, AM. ANTITRUST INST. (2009) (outlining the need for an FTC investigation of the merger); but see Dinah Wisenberg Brin & Barbara Martinez, *CVS Caremark Says FTC Is Investigating Its Business Practices*, WALL ST. J., Nov. 6, 2009, at B5, available at <http://online.wsj.com/article/SB10001424052748704013004574517151078308752.html>.

102. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI(B), 117 Stat. 2066, 2071.

103. FTC PBM REPORT, *supra* note 51, at vi.

104. *Id.* at iii-iv.

105. *Id.* at ii.

106. *Id.* at vi.

107. *Id.* at viii.

shortcomings of the FTC's report, going so far as to say that the FTC "misunderstood the fundamental concern of economists and indeed of Congress."¹⁰⁸

3. Federal Statutory Claims

Though the FTC did not address them at the time, the anti-kickback laws have, in fact, been the basis of additional investigation and litigation over the business practices of PBMs.¹⁰⁹ The False Claims Act and ERISA have also taken a central place in accusations of fraud against PBMs.¹¹⁰ Together, these federal statutes have formed the basis of a patchwork-style of regulation of the PBM industry which, though not ideal, has shed significant light on the behavior of PBMs and ways to remedy perceived ills.

i. The False Claims and Anti-Kickback Acts

The False Claims Act (FCA) makes liable for damages any person who submits "a false or fraudulent claim for payment or approval" to the United States government.¹¹¹ The Anti-Kickback Act of 1986 (AKA) prohibits anyone from accepting or offering compensation for preferential treatment relating to a contract with the United States government.¹¹² Two prominent settlements in 2005 and 2006 revealed the ways in which PBMs may be violating these statutes when dealing with government-sponsored health

108. DEMOS & STEWART, *supra* note 56, at ii. Demos and Stewart's report, prepared for the National Community Pharmacists Association (NCPA), pulls no punches in characterizing the FTC's report:

[M]any industry commentators have expressed concern that the FTC conclusions do not provide a balanced perspective adequate to inform Congress and policymakers in their endeavors to protect the fiscal integrity of the MMA prescription drug benefit program. In particular, rather than investigating further, the FTC seems to ignore and set aside the evidence that they themselves have surfaced that would have supported the issues raised in the Self Dealing Study. Further, the FTC methodology has looked at these issues in general terms and using averages rather than considering specific transactions. In doing so, the FTC has masked the underlying conflicts of interest that occur on a transaction-by-transaction basis. The methodologies chosen by the FTC, the degree to which the FTC probed or did not probe in the face of the evidence surfaced and the choice of conclusions relative to the underlying evidence have led to concern as to the balance with which the FTC approached *The Study*.

Id.

109. See, e.g., *infra* notes 113 and 119 (citing cases brought by the United States against PBMs).

110. See, e.g., *infra* text accompanying notes 113, 119, and 134 (describing suits in which the United States alleged violations of the FCA and ERISA).

111. 31 U.S.C. § 3729(a)(1) (2010).

112. 41 U.S.C. §§ 51–58 (2010).

programs.

a. AdvancePCS

In 2002, in the Eastern District of Pennsylvania, the United States filed suit against AdvancePCS (which was later acquired by Caremark).¹¹³ The suit was a whistleblower lawsuit alleging violations of the FCA for receiving and paying kickbacks, submitting false claims, and retaining rebates.¹¹⁴ Acting on the information of several former AdvancePCS employees, the United States alleged that the rebates retained by the PBM were an “improper reward for favorable treatment in connection with the contracts into which AdvancePCS entered to provide services for” the United States government.¹¹⁵ The United States further alleged that these practices on the part of AdvancePCS resulted in the submission of false claims.¹¹⁶ Following the allegations, AdvancePCS and the United States entered into a settlement agreement on September 7, 2005.¹¹⁷ In addition to agreeing to pay \$137.5 million to the government, AdvancePCS entered into a Corporate Integrity Agreement (CIA) with several government departments.¹¹⁸

b. Merck-Medco

In December 2003, the United States Department of Justice (DOJ) filed a complaint against Medco (then Merck-Medco, referred to herein as Medco), also in the Eastern District of Pennsylvania, alleging violations of the FCA.¹¹⁹ Several states later joined the DOJ in its suit, alleging violations of

113. DAVID A. BALTO, FEDERAL AND STATE LITIGATION REGARDING PHARMACY BENEFIT MANAGERS 2 (NAT’L CMTY. PHARMACISTS ASS’N 2009), *available at* <http://www.ncpanet.org/pdf/leg/pbmlitigationfeb08.pdf> [hereinafter BALTO, LITIGATION]; Consent Order of Court for Injunction and Settlement, U.S. v. AdvancePCS, Nos. 02-CV-9236, 02-CV-5425 (E.D. Pa. Sept. 6, 2005), *available at* www.crowell.com/pdf/managedcare/US_v_AdvancePCS_consent-order.pdf.

114. *Id.*

115. Settlement Agreement in the case of United States v. AdvancePCS, 1 (2005), http://www.crowell.com/pdf/managedcare/US_v_AdvancePCS_settlement-agreement.pdf.

116. *Id.* at 7.

117. *Id.* at 1.

118. *Id.* at 9–10, 19. Parties often enter into CIAs as part of a settlement of FCA or AKS violations where the violating party agrees to certain compliance obligation, usually for a term of five years. *See* OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *Corporate Integrity Agreements*, <http://oig.hhs.gov/fraud/cias.asp> (last visited Dec. 19, 2010).

119. *United States v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 434–36 (E.D. Pa. 2004); *see also* Press Release, U.S. Dep’t of Justice, U.S. Announces \$155 Million Settlement of Medco False Claims Case, 1 (Oct. 23, 2006), <http://www.dodig.mil/iginformation/IGInformationReleases/MEDCO.pdf> [hereinafter DOJ Press Release]

their equivalent state laws.¹²⁰ The complaint accused Medco of eight years of defrauding the government by

cancelling and destroying prescriptions, by failing to perform the professional pharmacists' services needed by patients and required by law, by switching patients' prescriptions to different drugs without their knowledge and consent, by shipping medications and billing patients for drugs they never ordered, by creating false records of contact with physicians, by soliciting and receiving inducements from pharmaceutical manufacturers to favor their products by paying kickbacks to obtain contracts by making improper payments to obtain Medicare contracts, and by making false and misleading statements to the United States about its conduct.¹²¹

The complaint also alleged violations of the Fraud Injunction Statute and the Anti-Kickback Act.¹²²

Following a denial of Medco's motion to dismiss the suit, the parties reached a final settlement on October 23, 2006—nearly three years later.¹²³ In addition to an earlier payment of \$29.1 million to the states,¹²⁴ the settlement required Medco to pay the United States \$155 million.¹²⁵ Medco, like AdvancePCS, also consented to “enter into an extensive corporate compliance agreement” with several government departments.¹²⁶

c. Remedies

Both Medco and AdvancePCS, as part of their settlement agreements, concurrently entered into consent decrees and nearly identical corporate integrity agreements (CIAs).¹²⁷ The CIAs entered into by the two PBMs required them to appoint a compliance officer and a compliance committee to oversee enforcement of the CIA's terms.¹²⁸ Under those terms, each

(explaining that the Department of Justice filed its complaint against Medco on December 3, 2003).

120. *Id.* at 433-34.

121. Am. Compl. at 1, U.S. v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430 (E.D. Pa. 2003) (No. 00-CV-737).

122. *Id.*

123. BALTO, LITIGATION, *supra* note 113; *see* DOJ Press Release, *supra* note 119.

124. BALTO, LITIGATION, *supra* note 113.

125. *Id.*

126. *Id.* (this agreement expires in 2011).

127. Corp. Integrity Agreement, U.S. v. AdvancePCS, Nos. 02-CV-9236, 02-CV-5425 (E.D. Pa. 2005) *available at* http://www.ncpanet.org/pdf/legal_agreement_hhs_advance_pcs.pdf; Corporate Integrity Agreement, U.S. v. Merck-Medco Managed Care, L.L.C., No. 00-CV-737, (E.D. Pa. Oct. 23, 2006), *available at* <http://www.secinfo.com/d14D5a.v6K1u.a.htm#1stPage>.

128. Corp. Integrity Agreement at 4, Merck-Medco Managed Care, L.L.C., *supra* note

PBM agreed to establish an internal code of conduct that acknowledged their “commitment to prepare and submit accurate claims” and their expectation that their employees would conduct themselves accordingly.¹²⁹ The PBMs were further required to submit written affirmation that each of their employees had read and understood the code of conduct and that they had written and distributed internal policies addressing the code of conduct, as well as the requirements of the FCA and AKA.¹³⁰ Lastly, Medco and AdvancePCS were required to submit an annual report on their compliance for five years following the enforcement date, the duration of the CIAs.¹³¹

The consent decrees into which Medco and Advance PCS entered required them to submit to rules and restrictions regarding drug switching and promoting transparency.¹³² These included the disclosure of rebates from manufacturers and other financial incentives, the elimination of MAC pricing spreads, requirements to inform patients about the effects of drug-switching, and adoption of a code of ethics.¹³³

ii. ERISA

In addition to claims under the antitrust laws, the FCA, and the AKA, PBMs have been subject to litigation under ERISA.¹³⁴ ERISA seeks to protect employees with employer-created benefit plans by imposing fiduciary responsibilities on certain parties involved in administering the plan.¹³⁵ Under ERISA, a fiduciary must “discharge his duties with respect to the plan solely in the interest of the participants and beneficiaries.”¹³⁶ The central question in the instant context is whether PBMs qualify as

127.

129. *Id.* at 5.

130. *Id.* at 5-7.

131. *Id.* at 25.

132. *See, e.g.*, Consent Order of Court for Inj. and Settlement, *supra* note 113, at 7-18.

133. *Id.*; *Federal Benefits: Are We Meeting Expectations? Hearing Before the Subcomm. on Fed. Workforce, Postal Serv., and D.C.*, 110th Cong. (2007) (statement of Patrick McFarland, Inspector General, U.S. Office of Personnel Management), available at <http://oversight.house.gov/images/stories/documents/20070803145913.pdf>.

134. *See* Garrett & Garis, *supra* note 2, at 48-51; Thomas P. O'Donnell & Mark K. Fendler, *Prescription or Proscription? The General Failure of Attempts to Litigate and Legislate Against PBMs as “Fiduciaries,” and the Role of Market Forces Allowing PBMs to Contain Private-Sector Prescription Drug Prices*, 40 J. HEALTH L. 205 (2007); *see generally* David H. Slade, *Commentary, ERISA Preemption and the Question of Pharmacy Benefit Managers’ Fiduciary Duty*, 30 J. LEGAL MED. 409 (2009).

135. Slade, *supra* note 134, at n.2 (“The purpose of ERISA is to provide a uniform regulatory regime over employee benefit plans.” (quoting *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004))); Employee Retirement Income and Security Act of 1974, 29 U.S.C. § 1001 (2006).

136. Garrett & Garis, *supra* note 2, at 49 (quoting 29 U.S.C. § 1104(a)(1) (2002)).

fiduciaries under ERISA. ERISA defines a fiduciary as

any person who exercises any discretionary control or authority over the management or disposition of plan assets, any person who provides investment advice for a fee to a plan, or any person who has any discretionary authority or responsibility over plan administration.¹³⁷

PBMs have strongly resisted attempts to classify their operations under this definition, because it would subject them to stricter standards on their pricing and rebate strategies.¹³⁸ A fiduciary that neglects its responsibilities under ERISA faces liability for damages and equitable relief in suits by either the Secretary of Labor or individual private plaintiffs.¹³⁹ Many of the alleged practices cited in suits under the FCA and AKA would likely constitute violations of ERISA as well, were fiduciary status established.¹⁴⁰

The answer to this question is not yet clear. According to Thomas O'Donnell and Mark Fendler, "[w]hile the majority of the federal circuits and district courts deciding the issue have held that PBMs are not ERISA 'fiduciaries,' one federal circuit has stated otherwise in dicta and many other courts have left the issues undecided altogether."¹⁴¹ Nor has the Supreme Court taken up the issue.¹⁴²

Nevertheless, the Supreme Court addressed how ERISA treats similarly situated HMOs. In *Pegram v. Herdrich*, the Supreme Court held that an HMO is not a fiduciary, pointing to the mixed nature of the HMO's decisions, which involved eligibility and treatment, as opposed to traditional fiduciary decisions such as the allocation and maintenance of plan assets.¹⁴³ O'Donnell and Fendler explain that "the Supreme Court in *Pegram* made it clear that persons making healthcare treatment decisions under an HMO plan would not be subject to ERISA's fiduciary obligations."¹⁴⁴ Critics have argued that this deprives patients of a meaningful recourse against managed care organizations, such as PBMs.¹⁴⁵

Seven years later, in *Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, the Seventh Circuit decided that PBMs also fail to

137. O'Donnell & Fendler, *supra* note 134, at 207 (citing 29 U.S.C. § 1002(21)(A) (2000)).

138. Garrett & Garis, *supra* note 2, at 49-50.

139. See 29 U.S.C. § 1109(a) (2006); O'Donnell & Fendler, *supra* note 134, at 208.

140. See discussion *supra* Part III.A.3.i, p. 21.

141. O'Donnell & Fendler, *supra* note 134, at 209.

142. *Id.*

143. *Id.* at 214; *Pegram v. Herdrich*, 530 U.S. 217, 229-30, 237 (2000).

144. O'Donnell & Fendler, *supra* note 134, at 214.

145. *Id.*

qualify as fiduciaries under ERISA.¹⁴⁶ Other courts that agree with this holding have followed the Seventh Circuit in finding that PBMs' business practices do not constitute "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."¹⁴⁷ The court also rejected the argument that rebates from drug manufacturers were "plan assets."¹⁴⁸ Despite this trend, as noted above, some courts have declined to address the issue or hinted in dicta that they would come down on the side of plaintiffs.¹⁴⁹

Lastly, ERISA also raises important preemption issues, as it "was designed to provide a comprehensive regulatory scheme."¹⁵⁰ As a result, many state-level efforts to regulate PBM conduct may prove futile if their statutes relate to an ERISA plan.¹⁵¹ This is discussed further below.¹⁵²

B. Summary of Concerns

The behavior underlying the legal concerns regarding the business model of the PBM industry is described well in Paragraph 58 of North Jackson Pharmacy's complaint against Express Scripts.¹⁵³ There, they list

146. Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 467 (7th Cir. 2007).

147. O'Donnell & Fendler, *supra* note 134, at 217 (citing *Carpenters Welfare Fund*, 474 F.3d at 472-73); *id.* at nn.50, 79.

148. *Id.* at 218; *Carpenters Welfare Fund*, 474 F. 3d at 476.

149. O'Donnell & Fendler, *supra* note 134, at 220-21.

150. Slade, *supra* note 134, at 411 (citing *Pegram v. Herdrich*, 530 U.S. 217, 229-30, 233 (2000)).

151. *Id.* at 419; *In Re Express Scripts, Inc.*, No. 4:05-CV-00862 SNL, 2008 WL 1766777 at *4 (E.D. Mo. 2008); *see also* discussion *infra* p. 101.

152. *See* discussion *infra* of ERISA, p. 101.

153. The legal concerns underlying PBM behavior are described there as follows:

As a result of the illegal agreements and/or conspiracies, Defendant has caused the Plaintiffs to suffer financial loss in that Defendant, with its monopolistic market strength: (i) forces independent pharmacies to accept reimbursement rates that are set at unconscionably low levels; (ii) place on its formulary those drugs which affords it the highest "spread" and therefore the greatest profit; (iii) receives kickbacks and rebates from drug manufacturers in exchange for "pushing" its drugs on consumers which is done by placing a manufacturer's drugs on the PBMs' formulary regardless of whether that drug is the cheapest or most effective drug in its particular group; (iv) refuses to give pharmacies access to the market of the retail sale of prescription drugs that are reimbursable by insurance except on terms and reimbursement prices that leave no economic margin for the pharmacies' survival; (v) steers health plan members to mail order pharmacies, which are owned by the PBMs, by prohibiting retail pharmacies from providing more than a 30-day supply of drugs, while allowing the PBMs own mail order pharmacies to provide 90-day supplies; (vi) takes pharmacists and physicians out of the medical care equation by either limiting, or altogether

allegations of monopolistic market power, pocketing pricing spreads, receiving kickbacks, unconscionable contract terms, vertical integration, and abuse of drug-switching practices.¹⁵⁴

These practices, many of them intrinsic to the PBMs' basic business model, represent a significant risk of violating a panoply of state and federal laws. The potential violations include: restraint of trade through supra-competitive and/or coordinated pricing arrangements; attempts to monopolize through the vertical integration of mail-order pharmacies; unfair and deceptive trade practices in the concealment of rebates, the creation of MAC pricing spreads, and drug-switching; self-dealing in the vertical integration of mail-order pharmacies; and kickbacks in the form of drug manufacturer rebates given in exchange for increases in market share. The majority of these behaviors also raise questions of fiduciary negligence under ERISA and false claims under the FCA. If repeated, lengthy, and resource-consuming litigation is to be avoided, and consumers' costs lowered, these are the activities that must be addressed in any prospective regulation.

Admittedly, much of the material discussed above represents only allegations and settlements, rather than verdicts or hard determinations. Undoubtedly, it is also the prudent course of action for PBMs to avoid litigation when at all possible.¹⁵⁵ Yet, concern about PBM behavior extends beyond those with a direct financial interest, such as pharmacies and plan sponsors. A strong consensus among scholars and industry insiders has also developed, citing major problems in the PBM industry and calling for reform and/or regulation of PBMs. The CEO of one PBM, Navitus Health Solutions, has decried the lack of transparency in the industry for leading to inflated costs.¹⁵⁶ David Balto has testified to Congress about the "market imbalance" and "wide range of anticonsumer [*sic*] and fraudulent practices" in the PBM industry.¹⁵⁷ Others have written about financial conflicts of interest in the industry and describe it as "inherently problematic."¹⁵⁸

removing, their discretion to determine the fitness of a prescription drug; . . . and (viii) unilaterally imposes contract changes on Plaintiffs, including changes in reimbursement rates.

First Am. Class Action Compl. at 20, *N. Jackson Pharm., Inc. v. Express Scripts, Inc.*, 345 F. Supp. 2d 1279 (N.D. Ala. 2004) (No. 5:03-2696).

154. *Id.* at 21.

155. Avoiding litigation limits negative publicity and keeps unflattering information out of the reach of the public record. It also prevents the PBMs from accruing a track record. Instead, they can point to a history of 'cooperation'.

156. *See Zimmerman, supra* note 19.

157. David Balto, Testimony Before the H. Health Care Comm., H.R. Wash. (Jan. 20, 2006), available at www.reducedrugprices.org/av.asp?na=244 [hereinafter Balto House].

158. Johnson, *supra* note 6, at 367.

Perhaps most damning is the National Community Pharmacists Association's (NCPA) use of the FTC's own data to show that

it is apparent that PBMs promise savings on drug pricing while pursuing their own interests in drug mix and total utilization. Where these interests diverge at times from those of their clients, PBMs naturally choose to increase their own profits and are not subject to the corrective mechanism of fierce competition for a plan sponsor's business. Instead, PBMs operate in a relatively consolidated industry with significant vertical integration through a mail order channel that allows them to pursue their discretionary interests, while concealing information on their business practices.¹⁵⁹

These substantial and widespread concerns about the business practices of the PBM industry lend extra weight to the numerous state and federal investigations and lawsuits discussed above, leading one to consider that the claims in those cases are likely more than mere allegations.

IV. CURRENT PROPOSALS FOR REGULATION

This daunting laundry list of complaints against the PBM industry has not gone unnoticed by regulators and interest groups.¹⁶⁰ Solving these problems is complicated, however, by the fact that “no federal agency has overall responsibility for the industry's regulation.”¹⁶¹ Scholars, trade groups, and state legislatures have all proposed various means of regulating the PBM industry to eliminate perceived and actual abuses.¹⁶² The suggestions range from *laissez-faire* private solutions to more comprehensive regulatory schemes.¹⁶³ They are discussed in turn in this section.

A. Market-based Solutions

Some commentators and scholars have proposed market-based solutions to the problems arising out of PBM behavior. For example, Allison Garrett and Robert Garis have called for greater awareness of PBM business practices among plan sponsors so that they can insist on transparency in their contracts.¹⁶⁴ Thomas O'Donnell and Mark Fendler describe PBMs as “just one cog in the wheel” of the prescription drug industry and likewise

159. DEMOS & STEWART, *supra* note 56, at xvi.

160. These are addressed in turn throughout this section of the paper.

161. Garrett & Garis, *supra* note 2, at 47.

162. *Id.* at 51-60.

163. *Id.* at 72-74.

164. *Id.* at 78-79.

suggest that plan sponsors simply insist on more competitive prices from PBMs.¹⁶⁵ The status quo of market mechanisms and consumer self-protection even satisfied the FTC.¹⁶⁶ The problem with this point of view, in the words of David Balto, is that “those who have the resources for monitoring the PBMs have in some cases done so, but their success has been mixed. Often even sophisticated buyers have had to turn to litigation to vindicate their rights.”¹⁶⁷ Even when plan sponsors hire consultants to advise them during negotiations with PBMs, the aid is negligible.¹⁶⁸ It is not enough to merely inform plan sponsors of the PBMs’ business model and expect them to negotiate concessions, particularly when it is difficult to even expose the potentially pernicious effects of those practices outside of a government investigation or pre-trial discovery.¹⁶⁹

Others have argued that the market is already taking care of the problem and claim that data cited to the contrary is outdated.¹⁷⁰ John Malley and Watson Wyatt point out that “the three largest PBMs—[Caremark, Medco, and Express Scripts]—offer pass-through pricing at retail as an alternative to the spread-pricing model.”¹⁷¹ This position, however, ignores the fact that at least a sizeable portion of the changes in PBM behavior towards pricing and transparency is due to the consent decrees that came out of the investigations by the states’ Attorneys General and the Department of Justice.¹⁷² More importantly, these provisions expire after five years.¹⁷³ After that, absent new legislation, the PBMs will be in the same situation they were before the consent decrees.¹⁷⁴

It is evident that the disconcerting practices of the PBM industry are neither isolated incidents nor market abnormalities to be ironed out through informed negotiation.¹⁷⁵ Rather, they are systemic problems directly related

165. O’Donnell & Fendler, *supra* note 134, at 237.

166. FTC PBM REPORT, *supra* note 51, at ii (finding “that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests”).

167. See Balto House, *supra* note 157.

168. See Rentmeester & Garis, *supra* note 5, at 976.

169. Even then, the availability of the information will be limited beyond the parties involved, especially if the defendant PBM settles.

170. See John Malley & Watson Wyatt, Commentary, *Response to Rentmeester and Garis*, 33 J. HEALTH POL. POL’Y & L. 965, 971 (2008) (Malley and Wyatt’s work as attorneys representing PBMs raises doubts about the objectivity of their suggestions).

171. *Id.* at 965.

172. See *supra* notes 88-98, 112, 119, 127-133 and accompanying text.

173. See *supra* notes 97-98 and accompanying text.

174. See *infra* note 193.

175. *But see* Kevin C. Green, Regulation of Pharmacy Benefit Managers: An Economic Analysis of Regulation and Litigation as Agents of Health Care Change 25 (Jan. 2008) (unpublished manuscript), available at http://works.bepress.com/kevin_green/1/.

to the PBM business model that has developed since the 1970s.¹⁷⁶ Situations like these are an example of when antitrust enforcement ought to yield to regulation, a function of their complementarity.¹⁷⁷

B. Existing Legislation

Seeing the problems inherent in the PBM business model and the need for regulation, various suggestions have been made to shoehorn PBMs into an existing regulatory or statutory scheme. Despite recent investigations and litigation lending support to some of these proposals, they are ultimately limited by their narrow scope and legal uncertainty.

1. ERISA and State Regulation of PBMs

As discussed above, several battles have been fought over whether or not PBMs are subject to fiduciary responsibilities under ERISA, which would bar them from continuing many of the business practices of which others have complained.¹⁷⁸ Commentators and state legislators have thus proposed statutory provisions imposing fiduciary or fiduciary-like responsibilities on PBMs.¹⁷⁹ This, however, raises a second issue: are state laws preempted by ERISA?¹⁸⁰

In *Lanigan v. Express Scripts*, the federal district court in Missouri dealt with claims under ERISA as well as state law claims.¹⁸¹ The court dismissed each of the state law claims, finding that they were preempted by ERISA.¹⁸² To help clarify some of these issues, in 2003 Maine passed its Unfair Prescription Drug Practices Act (UPDPA), which classified PBMs as fiduciaries and required them to “disclose conflicts of interest, disgorge profits from self-dealing, and disclose to the covered entities certain of their

176. *Rebates & Spreads*, *supra* note 11, at 946.

177. See Dennis W. Carlton & Randal C. Picker, *Antitrust and Regulation* (John M. Olin Law & Econ. Working Paper No. 312, 2006) (manuscript at 22), available at http://ssrn.com/abstract_id=937020; Naturally, a call for regulation may give rise to objections on federalist grounds that additional government bureaucracy would only further complicate the market and increase costs for all participants. Proponents of federalism are caught in a catch-22, however, if they wish to see any reform. As discussed below, regulating on the state level would necessitate voluminous litigation and thereby invite the evil twin of bureaucracy: judicial activism.

178. See *supra* Part III.A.3.ii.

179. See O’Donnell & Fendler, *supra* note 134, at n.99; see *infra* notes 183, 187; But O’Donnell & Fendler, *supra* note 134, at n.98.

180. Slade, *supra* note 134, at 411.

181. *In re Express Scripts, Inc.*, No. 4:05-CV-00862 SNL, 2008 WL 1766777, at *5, *8 (E.D. Mo. Feb. 06, 2008).

182. *Id.* at *13-14.

financial arrangements with third parties.”¹⁸³ Subsequently, the Pharmaceutical Care Management Association sought to enjoin enforcement of the statute, arguing that the UDPDA was preempted by ERISA and violated the dormant Commerce Clause.¹⁸⁴ The First Circuit unanimously upheld the district court’s rejection of both of these claims, paving the way for the enforcement of fiduciary standards against PBMs.¹⁸⁵ Despite an appeal by the plaintiff, the Supreme Court denied certiorari for the matter.¹⁸⁶

As of June 2008, twenty states and the District of Columbia had passed legislation instituting some form of regulation of PBMs, many of which were based on one of the model acts discussed in more detail below.¹⁸⁷ California also passed such legislation in 2004, but Governor Schwarzenegger vetoed the bill.¹⁸⁸ The organization Prescription Policy Choices describes the effect of some of these laws:

Both the Maine and DC laws require the PBM to act as a fiduciary, require transparency and pass-through of rebates and other payments and savings, restrict drug-switching and conflicts of interest, and establish guidelines for drug-switching and other practices [The Iowa, South

183. Nat’l Legis. Ass’n on Prescription Drug Prices, *Pharmacy Benefit Manager Transparency and Fiduciary Standards*, NALRX (Nov. 20, 2008), <http://www.reducedrugprices.org/read.asp?news=2666>; ME. REV. STAT. ANN. tit. 22, § 2699 (2009).

184. Pharm. Care Mgmt. Ass’n v. Rowe, No. 03-153-B-H, 2005 WL 757608, at *5 (D. Me. Feb. 2, 2005).

185. Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 305 (1st Cir. 2005).

186. Pharm. Care Mgmt. Ass’n v. Rowe, 547 U.S. 1179 (2006).

187. Nat’l Cmty. Pharmacists Ass’n, *Laws that Provide Regulation of the Business Practices of Pharmacy Benefit Managers*, NALRX, http://www.ncpanet.org/pdf/leg/leg_pbm_business_practice_regulation.pdf (last visited Dec. 19, 2010) (providing a summary of the following state laws: ARK. CODE ANN. § 17-92-1201 (West 2010); 2007 Conn. Legis. Serv. P.A. 07-200 (S.B. 74); D.C. CODE § 48-832 (2010); FLA. STAT. § 465.188 (2010); GA. CODE ANN. §§ 26-4-110.1, 26-4-118 (West 2010); IND. CODE § 25-26-22 (2009); IOWA CODE ANN. §§ 510B (West 2010); KAN. STAT. ANN. §§ 40-3821 – 40-3828 (West 2010); KY. REV. STAT. ANN. §§ 304.1–5 (West 2009); ME. REV. STAT. ANN. tit. 22, § 2699 (2009); MD. CODE ANN., INS. § 15-1601 (West 2009); MISS. CODE §§ 73-21 – 151-159 (2008); MO. REV. STAT. § 338.600 (2009); N.M. STAT. ANN. § 61-11 - 18.2 (West 2009); N.D. CENT. CODE §§ 26.1 – 27.1-01 (2009); OKLA. STAT. tit. 59 § 356 (2009); R.I. GEN. LAWS. §§ 27 – 29.1-7 (2009); S.D. CODIFIED LAWS § 58-29E (2009); TENN. CODE ANN. § 56-7-3101 (West 2009); TEX. GOV. CODE ANN. § 2158(H) (West 2009); VT. STAT. ANN. tit. 18, §§ 9421, 9471 – 9473 (2009)). For a discussion of the model acts on which many of these laws were based, see *infra* Part IV.C.

188. Pharm. Care Mgmt. Ass’n, *Schwarzenegger Veto of One-Size-Fits-All PBM Disclosure Bill Protects California Consumers & Employers from Higher Prescription Drug Costs* (Sept. 30, 2004), <http://www.pcmanet.org/pcma-schwarzenegger-veto-of-one-size-fits-all-pbm-disclosure-bill-protects-california-consumers-employers-from-higher-prescription-drug-costs>.

Dakota and Vermont laws] seek to address transparency, conflicts of interest disclosure, greater transparency on rebates and other payments, and include more limited fiduciary language¹⁸⁹

While the First Circuit upheld the Maine statute,¹⁹⁰ the D.C. District Court recently held that ERISA preempts D.C.'s Access RX Act.¹⁹¹ It is possible that the future of state-level regulation of PBMs under ERISA will have to be determined on a circuit-by-circuit basis.¹⁹²

2. State Antitrust Laws

In addition to the recent state laws regulating PBMs, states might also continue to pursue enforcement under their antitrust and consumer protection laws. The settlement agreements and consent decrees obtained against Medco, Caremark, and Express Scripts have been fairly comprehensive and addressed a majority, if not all, of the problems discussed in this paper. While the restrictions imposed on the three PBMs expire after five years, permanent injunctions may be obtained through future litigation, if necessary. Of course, the problem with relying on the threat of further litigation is that it fails to prevent future harm and offers only an *ex post* remedy to a repetitive problem.¹⁹³

3. Federal Statutory Enforcement

Likewise, oversight at the federal level could continue through the enforcement of the aforementioned False Claims and Anti-Kickback Acts to curb suspect pricing and drug-switching practices by the PBMs when

189. Prescription Pol'y Choices, *PBM Fiduciary Duty and Transparency*, 4 (2005), http://www.policychoices.org/documents/PBMTransparency_FastFacts.pdf (last visited Dec. 19, 2010).

190. Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 305 (1st Cir. 2005).

191. Pharm. Care Mgmt. Ass'n v. D.C., 605 F. Supp. 2d 77, 88 (D.D.C. 2009), *aff'd*, Pharm. Care Mgmt. Ass'n v. District of Columbia, 613 F.3d 179, 190 (D.C. Cir. 2010) (however, this the District of Columbia Circuit held that ERISA preempted only certain sections of the Access Rx Act)).

192. See *infra* Part IV.D (discussing the limits of current statutes and model acts).

193. It might be objected that such fears are baseless, as PBMs will be wary of trying to resume conduct forbidden under the consent decrees and CIAs, lest the states resume their investigations. However, the very nature of the behavior in question indicates this will not be the case. The consent decrees center on transparency, which is by its own definition difficult to monitor. Absent resumed complaints from pharmacies or a noticeable and unreasonable increase in costs for government programs (which the PBMs could easily avoid by restricting their more predatory strategies to private contracts), it will be difficult to tell whether PBMs have begun a return to their old ways. Any efforts to determine whether they are, and to prosecute them if they are not, will be expensive and, once again, too late to prevent the harm already done.

dealing with government employee and health benefit plans. Federal enforcement beyond the scope of government-sponsored plans could be accomplished through the Sherman Act and the FTC Act.¹⁹⁴ As with state-level antitrust enforcement, consent decrees resulting from any future litigation would ideally impose permanent injunctions against problematic PBM behavior.

Federal statutory regulation is also stems from the Patient Protection and Affordable Care Act (PPACA), though uncertainty exists due to regulatory language not yet issued.¹⁹⁵ Although Senator Maria Cantwell proposed an amendment to the America's Healthy Future Act of 2009¹⁹⁶ that "requires reporting by PBMs to ensure that savings from drug price negotiations are being passed on to consumers and not contributing more to pharmaceuticals' bottom lines,"¹⁹⁷ this did not appear in the PPACA. Rather, the bill calls for greater transparency for health benefits plans or any entity that provides PBM services.¹⁹⁸ Instead, disclosures will include information on (1) the percent of all prescriptions provided through retail pharmacies compared to mail order and the rates of each; (2) the aggregate amount and types of rebates, discounts, and price concessions that the PBM negotiates on behalf of the plan and the aggregate amount of these passed on the plan sponsor; and (3) the average aggregate difference between the amount the plan pays the PBM and the amount the PBM pays the retail and mail order pharmacy

C. Model Legislation

In response to the concerns outlined above, several organizations drafted model acts as guidelines for statutory regulation of PBMs, and several states have used these as the basis for their legislation.¹⁹⁹ A review of these proposals highlights several useful and effective strategies that may be used to efficiently regulate the PBM industry.

194. This is at most unlikely and at best would be checkered. *See* BALTO, *supra* note 56, at 2 ("Unfortunately since the early 1990s, the FTC has used Section 5 in a relatively modest fashion.").

195. The Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, § 6005, 124 Stat. 119, 395 (2010).

196. *Id.*

197. Press Release, Sen. Cantwell, Health Care Reform Bill Includes Major Cantwell Initiatives to Control Costs, Improve Quality of Care, (Oct. 13, 2009), <http://cantwell.senate.gov/news/record.cfm?id=318903>. ("Cantwell's proposal requires reporting by PBMs to ensure that savings from drug price negotiations are being passed on to consumers and not contributing more to pharmaceuticals' bottom lines.").

198. Les Blumenthal, *Senate Panel Approves Cantwell Amendment*, McCLATCHY NEWSPAPERS, (Oct. 1, 2009), <http://www.mcclatchydc.com/homepage/story/76404.html>.

199. *Id.*

1. NAIC

The National Association of Insurance Commissioners (NAIC) has released an extensive proposal called the Health Carrier Prescription Drug Benefit Management Model Act (the NAIC Model Act).²⁰⁰ Though aimed at health insurance carriers (instead of PBMs), the NAIC Model Act has noteworthy disclosure and drug-switching provisions.²⁰¹ For example, committees set up to oversee formulary design must evaluate and disclose potential conflicts of interest.²⁰² Section 6 provides extensive guidelines regarding mandatory disclosures to pharmacies and patients in the event of a formulary change, and there are also requirements for record-keeping.²⁰³ Most importantly, however, the NAIC Model Act provides that

[w]henever a health carrier contracts with another person to perform activities required under this Act or applicable regulations, the commissioner shall hold the health carrier responsible for monitoring the activities of that person with which the health carrier contracts and for ensuring that the requirements of this Act and applicable regulations with respect to that activity are met.²⁰⁴

This requires the plan sponsors, rather than a third party, to engage in oversight over any PBM with whom they contract. The plans would be responsible for ensuring that the PBMs, insofar as they are engaged in practices covered under the Act (such as formulary changes), comply with the disclosure and documentation requirements.²⁰⁵ Though somewhat of a roundabout way of influencing PBM behavior, provisions such as those in the NAIC Model Act could be helpful to plan sponsors in the absence of direct regulation.

2. NLARx

The model act proposed by the National Legislative Association on Prescription Drugs (NLARx and NLARx Act), unlike the NAIC Model Act, goes straight to the heart of anti-competitive PBM practices.²⁰⁶ The

200. Health Carrier Prescription Drug Benefit Management Model Act, § I-22-1 (2003) [hereinafter NAIC Model Act].

201. *Id.* at §§ 6, 10.

202. *Id.* at § 5(2).

203. *Id.* at §§ 6, 8.

204. *Id.* at § 9(B).

205. *Id.*

206. NAT'L LEG. ASS'N ON PRESCRIPTION DRUGS, MODEL POL'Y: PHARMACY BENEFIT MANAGER (PBM) TRANSPARENCY AND FIDUCIARY STANDARDS, *available at* <http://www.reducedrugprices.org/read.asp?news=2666> [hereinafter NLARx ACT].

NLARx Act,²⁰⁷ based on Maine's Unfair Prescription Drug Practices Act,²⁰⁸ requires PBMs to act as fiduciaries and to adhere to transparency standards.²⁰⁹ Under this proposal, "[v]iolations of the act become violations of a state's unfair trade practices or consumer protection laws."²¹⁰

The NLARx Act also aims to prevent PBMs from profiting through drug-switching. If a PBM substitutes one drug for another, it is required to disclose to the plan sponsor any increase in price and to pass on the full amount of "any benefit or payment received in any form by the pharmacy benefits manager either as a result of a prescription drug substitution" or from switching to a cheaper generic from a more expensive drug.²¹¹ This requirement is also extended to manufacturer rebates based on increases in market share.²¹² These too must be passed on in full to the plan sponsor.²¹³

Lastly, the NLARx Act requires full disclosure of "all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler."²¹⁴ These include arrangements based on formularies, incentives for drug-switching, drug promotion, administrative services, and other fees.²¹⁵ The additional disclosure requirements are intended to prevent PBMs from circumventing the other disclosure and pass-through requirements concerning rebates and drug substitutions. Whereas they might otherwise replace rebates with administrative or less-obvious incentives, this section of the NLARx Act would require disclosure of those activities as well.

3. NCPA

The most thorough and comprehensive (and most elegantly constructed) of the proposed model acts is the National Community Pharmacists Association's Pharmacy Benefit Manager Licensure and Solvency Protection Act (NCPA and NCPA Act).²¹⁶ The NCPA Act's novel addition

207. *Id.*

208. Unfair Prescription Drug Practices Act (UPDPA), ME. REV. STAT. ANN. tit. 22, § 2699 (2003).

209. NLARX ACT, *supra* note 206.

210. *Id.* § 1.

211. *Id.* § 2(D)(2).

212. *Id.* § 2(E).

213. *Id.*

214. *Id.* § 2(F).

215. NLARX ACT, *supra* note 206 at § 2(F).

216. NAT'L CMTY. PHARMACISTS ASS'N, PHARMACY BENEFIT MANAGER LICENSURE AND SOLVENCY PROTECTION ACT, available at http://www.ncpanet.org/pdf/leg/leg_pbm_model_licensure_solvency_protection_act.pdf [hereinafter NCPA ACT].

to the previously discussed regulations is that it requires the licensing and certification of PBMs to be conducted under standards applicable to pharmacies, and requires a state's board of pharmacy and department of insurance to administer this process.²¹⁷

As part of a PBM's certification and re-certification process, it would be required to disclose

[a]ll incentive arrangements or programs such as rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company, that relates to prescription drug or device services, including at a minimum information on the formula or other method for calculation and amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of such disbursements.²¹⁸

The PBM must also make all of its contracts available for inspection, and all contracts and agreements between the PBM and pharmacies are subject to prior approval by the Department of Insurance (who is in turn required to consult with the State Board of Pharmacy).²¹⁹

Under the NCPA Act, PBMs would be required to make further substantial disclosures, specifically those dealing with certain types of agreements.²²⁰ These include agreements: with manufacturers to promote their products or share rebates or discounts; to bill plan sponsors more than the PBMs reimburse pharmacies; "to share revenue with a mail-order or internet pharmacy"; and to sell data "concerning the prescribing practices of health care providers in the state."²²¹ These requirements are aimed directly at the underhanded practices alleged against PBMs in the previously discussed investigations and settlements.²²² The mandated disclosures, combined with the audit rights granted to the Department of Insurance, take significant steps toward assuring complete transparency for plan sponsors negotiating with a licensed PBM.

The NCPA Act also provides guidelines to eliminate the abuse of drug-switching to increase rebates by requiring extensive disclosures whenever a substitution is made. Substitutions of more expensive drugs for less expensive drugs must be medically necessary, approved by the prescribing

217. *Id.* §§ 5, 6.

218. *Id.* § 5(B)(8).

219. *Id.* §§ 5(C), 10(C).

220. *Id.* § 7(C).

221. *Id.*

222. First Am. Class Action Complaint, *supra* note 153, at 20.

doctor, and “[t]he PBM shall transfer in full to the covered entity any benefit or payment received in any form by the PBM as a result of a prescription drug substitution,” as described above.²²³

Lastly, the NCPA Act explicitly addresses the PBM industry’s pricing indices and mail-order pharmacy conflicts of interest. Under Section 14, all pharmacy reimbursement rates must be indexed to the industry standard AWP (for brand-name drugs) or a MAC price list dependent upon a third party (for generic drugs).²²⁴ Under Section 16, PBMs are barred from discriminating against pharmacies and specifically prohibited from dictating co-pays and days of supply to pharmacies.²²⁵ Together, these two sections take significant steps toward resolving the concerns created by PBM pricing strategies and their contracts with independent pharmacies.

D. Limits of Current Statutes and Model Acts

Despite the amount of effort that has gone into crafting the existing and proposed solutions to abuses in the PBM industry, the above approaches all suffer from limitations in scope and/or certainty. First, regulation of PBMs through False Claims Act and Anti-Kickback Act litigation is limited to cases involving government contracts.²²⁶ While consent decrees resulting from future litigation under these statutes could conceivably require injunctions pertaining to all of a PBM’s business, this would be a rather ham-handed approach.

Furthermore, regulation under ERISA, though requisitely broad in scope in conjunction with state legislation defining PBMs as fiduciaries, faces preemption challenges from PBM trade associations.²²⁷ With early cases already coming down on opposite sides of this question, such a strategy would require extensive litigation in each circuit. Enforcement would be left in the interim to a patchwork of jurisdictions upholding state statutes that may or may not be later struck down by the Supreme Court. This is hardly a lasting solution to systemic problems.

Even the new disclosure requirements enacted as part of the PPACA fail to ensure adequate protection for patients and consumers. By allowing reporting of discounts to be done in the aggregate, the law still leaves a large loophole for PBMs to conceal conflicts of interest and obscure the nature of their relationships with pharmaceutical manufacturers and distributors.

223. NCPA ACT, *supra* note 216, §§ 11(D)(2)-(3).

224. *Id.* at § 14(A)(B).

225. *Id.* at § 16(E).

226. 31 U.S.C. § 3272(a) (2010); 41 U.S.C. §§ 52(1), (3), (5) (2010).

227. Slade, *supra* note 134, at 415.

At root, the difficulties faced by the existing and currently proposed regulatory schemes can be traced to the fact that they address the causes of the problems they seek to resolve only obliquely. With the exception of parts of the NCPA Act and some of the consent decrees, contemporary approaches to PBM regulation attempt only to stretch or modify existing legal categories in order to bring PBMs under their jurisdiction, instead of dealing with the problems head-on by tailoring new rules to the unique characteristics of the PBM industry.

V. A PROPOSAL FOR FEDERAL REGULATION

This paper proposes taking just such a tack. As noted earlier, market-based proposals (such as encouraging plans to insist on transparency in their contracts) are too optimistic in their expectations, particularly in an industry described by one expert as oligopolistic.²²⁸ The challenges instigated by the behavior in the PBM industry are not anomalies that may be remedied by occasional litigation. Rather, constant investigation and litigation would be necessary to police PBMs and prevent or cure unfair and deceptive practices. When abuse is systemic, it is the place of regulation, not litigation, to solve the problem.

Yet, while regulation is needed, state-level enforcement and existing federal statutes are limited in their ability to do so by their narrow scope and tenuous jurisdiction.²²⁹ Regulation of the PBM industry, in order to avoid unnecessary litigation, ought to be done at the federal level. This regulation should forego substantial reliance on existing statutes in favor of clear and direct limitations upon the specific anti-competitive practices that illicitly inflate PBM profits, and consequently inflate the price of prescription drugs. Like the NCPA Act, this federal legislation should center on pricing controls and the disclosure of all financial incentives concerning pharmaceutical manufacturers. The legislation, however, should also take a page from the AdvancePCS consent decree and specifically prohibit practices such as MAC pricing spreads.

Going further, one might also argue that disclosure and transparency are not enough. Although the rebates and financial incentives passed from manufacturers to PBMs would be exposed, this does not mean that savings would automatically pass on to consumers or, in the case of government-sponsored plans, to taxpayers. Most of the proposed regulations only require transfer of remuneration received by the PBM to the sponsor when

228. Balto House, *supra* note 157, at 77 (also noting the difficulties faced by independent pharmacies attempting to negotiate with PBMs. Currently, they run the risk of violating the antitrust laws if they attempt to collectively negotiate); *id.* at 78.

229. Slade, *supra* note 134, at 423.

it results from drug-switching.²³⁰ Since drug-switching, of all the PBM business practices, actually poses the greatest risk to the patient's health, it is certainly appropriate to remove all non-medical incentives to engage in such behavior.²³¹

When it comes to pricing spreads and rebates, however, disclosure, rather than transfer, is the preferred solution.²³² Presumably, plan sponsors may or may not demand these amounts, but would use them to negotiate their contract with the PBM. Ironically, proposed statutes like the NCPA's are designed to prohibit—rather than merely disclose—this same conduct when it occurs between the PBM and drug manufacturers.²³³ The protection afforded under these regulations, then, is more for the plan sponsor than the consumer.²³⁴ Remembering that PBMs once operated solely on a fee basis, and considering the context of the rising cost of health care, it would be prudent to design further mechanisms to deliver more, if not all, of the savings to the consumer. Inducing the disclosure of hidden profits is hardly meritorious if the PBMs simply re-hide these profits—at least not when done in the name of competition and consumer protection.

There are essentially five areas of concern in the PBM industry that any future regulatory scheme will need to address: (1) coordinated pricing arrangements that impose supra-competitive prices or restrain trade; (2) monopolization through mail-order pharmacies; (3) unfair and deceptive trade practices (rebate concealment, MAC spreads, and drug switching); (4) self-dealing through the vertical integration of mail-order pharmacies; and (5) kickbacks from manufacturers for increasing market shares. While the current proposals for regulation make valiant efforts to tackle the latter three of these problems, they do little to address the market power issues raised by the first two. This gap will remain so long as proposals to regulate PBMs rely heavily on disclosure requirements, rather than actually proscribing behavior or mandating fee and pricing structures.

To this end, federal regulation should require PBMs to use prices indexed to AWP at a statutory rate when reimbursing pharmacies (similar to the NCPA proposal) and mandate universal reimbursement rates for equivalent products or services from the PBMs' mail-order pharmacies and other mail-order pharmacies. Future regulation should also mandate that any and all manufacturer rebates be passed on to plan sponsors in their entirety and that, for each drug, the PBMs use the one and the same MAC

230. Johnson, *supra* note 6, at 358-359.

231. *Id.* at 349.

232. Garrett & Garis, *supra* note 2, at 58-61.

233. Johnson, *supra* note 6, at 336.

234. *Id.*

price list with the pharmacies and the plan sponsors. Drug-switching should only be permitted when prompted by the patient's doctor, and PBMs should be barred from contacting doctors to suggest a switch unless doing so would reduce the cost to the plan sponsor or patient and would pose no health risks. When providing mail-order pharmacy services, PBMs should be required to give the patient or plan sponsor the option of which pharmacy to use (the PBM's or a competitor's). Lastly, to minimize kickbacks, rebates from manufacturers should be either capped or eliminated.

Additionally, while regulation needs to be at the federal level to avoid superfluous litigation, it is also desirable to avoid unnecessary bureaucracy and red tape. Instead of creating an administrative agency at the federal level, federal legislation should rely on the combination of the above objective standards and delegate any discretionary oversight to the appropriate state agencies. Taking a cue from the NCPA Act, this could be accomplished by working with state boards of pharmacy and insurance departments.

VI. CONCLUSION

Reviewing the recent history of investigations and litigation in the PBM industry, it is clear that several practices involved in the PBM business model are anti-competitive and, in some cases, plainly illegal. In fact, the industry's very premise, to earn a profit by helping other companies save money, involves a fundamental conflict of interest when operated on anything other than a fee basis. Yet despite this, regulation of the PBM industry has been slow and difficult to develop. This is, no doubt, at least partly due to the vast amounts spent by drug manufacturers and PBMs lobbying state and federal legislatures.²³⁵

It is not surprising, then, that the regulation and legislation passed thus far has been a patchwork of enforcement under existing state and federal laws, some with tenuous jurisdiction. The efficacy of these regulations is further limited by the fact that they are addressed more to the symptoms of the problem than the defect itself. Passing legislation on the federal level will continue to be difficult, but neither the status quo nor a purely market-based solution will fix the situation. Encouragingly, the PPACA may provide a unique window of opportunity to implement the regulatory reforms that are needed in the PBM industry by emphasizing the money

235. *Pharm. Rsrch & Mfrs of Am.*, OPENSECRETS.ORG., <http://www.opensecrets.org/lobby/clientsum.php?lname=Pharmaceutical+Rsrch+%26+Mfrs+of+America&year=2010> (last visited Dec. 19, 2010) (reporting that PhRMA, a lobbying group representing the pharmaceutical industry, has spent close to \$20 million or more on lobbying since 2007).

they would save for plan sponsors, consumers, and taxpayers. However, we will not know the PPACA's total affect on the PBMs until rulemaking is completed.

The ideal reforms would combine the strict pricing and disclosure requirements of the NCPA Act with clear standards that explicitly and directly prohibit the anti-competitive business practices frequently complained of and stronger mechanisms to pass on savings to the consumer. It should be noted that there is a caveat to this arrangement: even with reform in the PBM industry, drug prices could remain high because of manufacturers. That, however, is beyond the scope of this paper.

What is clear is that pharmacy benefit management companies have developed and grown into a business model that pits their profit incentives against the financial needs of their clients and, at times, the health of patients. Current laws and the majority of proposed laws cannot and will not adequately address this problem. Congress should pass federal legislation creating broad, comprehensive limits on the relationships between PBMs and drug manufacturers to protect pharmacies, plan sponsors, and consumers.