

Regulation of Pharmacy Benefit Managers: An Economic Analysis of Regulation and Litigation as Agents of Health Care Change

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Abstract

Pharmacy benefit managers or “PBMs” have come under intense legal and regulatory scrutiny in recent years. Each of the major PBMs has been targeted by public and private litigation including a major ongoing task force comprised of U.S. Attorneys and Attorneys General from twenty states. Moreover, more than 30 bills to regulate PBMs have been introduced in state legislatures since 2002. This paper provides an economic analysis of PBM regulation. I analyze the economic arguments put forward on both sides of the regulation debate and evaluate the existing empirical evidence on PBM conduct in the context of these arguments. I also use stock price data to show that consumer and investor responses to litigation and regulation developments have imposed substantial market discipline on PBMs. In response to customer and investor concerns, PBMs have changed their business models to address transparency and conflict issues in advance of broad-based regulation. This suggests that litigation is acting in the PBM market as a more adaptive and flexible catalyst of change than broad-based regulation.

I. Introduction

Prescription drugs are the most rapidly increasing component of U.S. health care expenditures. Increased drug usage and rising prices pushed prescription drug spending to \$179.2 billion in 2003, accounting for roughly 10.7 percent of national health expenditures.¹ Due to the combination of rapid growth in drug spending, a number of high profile legal investigations into PBM conduct, and their complex and often poorly understood business models, pharmacy benefit managers or “PBMs” have come under intense scrutiny from many sources in recent years.

In fact, the Chair of the National Legislative Association on Prescription Drug Prices (NLARx), recently stated “We know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, especially a market with such a significant impact on taxpayers.”² In addition to the large number of investigations and legal actions, many states have considered broad-based PBM regulation of one form or another in recent years. Since 2002, more than 30 bills have been introduced in the legislatures of at least 25 states, plus Washington, DC.³

Advocates of PBM regulation claim that comprehensive regulation is necessary to deal with fundamental conflicts of interest, lack of transparency, and other problems in the PBM business model. In contrast, PBMs and their supporters have continually denied allegations of wrongdoing and argue that competition, rather than regulation, will produce efficiencies and reduce drug costs for health plan sponsors and consumers. Indeed, PBMs assert that additional regulation will reduce benefits, increase costs and make consumers worse off.

This paper provides an economic analysis of the role played by litigation and regulation in the PBM industry. Section II reviews the role played by PBMs in the pharmaceutical marketplace and surveys recent legal and regulatory actions taken against PBMs. Section III analyzes the economic arguments put forward on both sides of the

¹ FTC, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005, p. i.

² National Legislative Association on Prescription Drug Prices, Senator Mark Montigny, Chair of the Board, Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005.

³ Colorado Department of Regulatory Agencies, Office of Policy, Research and Regulatory Reform, 2004 Sunrise Review, Pharmacy Benefit Managers, October 15, 2004, p. 11.

regulation debate. Section IV evaluates the available empirical evidence on PBM conduct in the context of these arguments. Evidence from the stock market indicates that litigation and corresponding market responses have imposed substantial market sanctions on PBMs for potentially improper conduct. Market evidence indicates that these forces have reinforced and accelerated changes in PBM behavior. In response to concerns about transparency and conflict issues by customers, regulators and investors, PBMs are attempting to change their business models in ways that ease concerns without substantially undermining their ability to perform their key functions.

The evolution of the PBM industry is consistent with the interpretations of prior research concluding that litigation has a large effect on health care markets through its influence on market actors' perceptions and expectations.⁴ In anticipation of adverse legal outcomes and in response to consumer and investors concerns, health providers modify their business strategies and practices. This suggests that litigation has acted in the PBM market as a more adaptive and flexible catalyst of change than broad-based regulation. The observation of M. Gregg Bloche and David M. Studdert, that "Markets are more agile than law" appears to apply to the PBM market as well as the HMO market they studied.

II. The Legal and Regulatory Environment for PBMs

A. The Role of PBMs in the Pharmaceutical Marketplace

It has been estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.⁵ PBMs perform a variety of functions to help manage the pharmacy benefits of health plan providers. PBMs help design formularies which detail the particular drugs the benefit plan will cover in each therapeutic category. The PBM then helps design co-payments and other incentives to encourage plan members to use preferred formulary drugs in each category. PBMs also assemble networks of retail pharmacies and use their ability to deliver retail customers to

⁴ See, e.g. M. Gregg Bloche and David M. Studdert, "A Quiet Revolution: Law As An Agent Of Health System Change," *Health Affairs*, Vol 23, Issue 2, 29-42.

⁵ Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Luke M. Froeb, Director, Bureau of Economics, Susan A. Creighton, Director, Bureau of Competition, U.S. FTC, Letter to Senator Richard L. Brown, North Dakota Senate, March 8, 2005.

negotiate favorable pharmacy reimbursement rates.

Because of their ability to influence patient and prescriber behavior through formulary design, therapeutic substitution, and tools, PBMs play a major role in negotiating with drug manufacturers. The contracts between PBMs and drug manufacturers often requires the pharmaceutical manufacturer to pay rebates for preferred placement of drug products on the PBM's formulary, and/or if the PBM achieves contractual targets for drug sales or market share. The specific details of the contracts between PBMs and health plan sponsors then determine the extent to which these rebates are retained by the PBM or "passed through" to the payor.

B. Arguments made in support of PBM regulation

Much of the controversy over the PBMs role in pharmaceutical markets has focused on PBM contracts with drug manufacturers. Proponents of PBM regulation argue that the PBM business model and their financial reliance on rebates from drug manufacturers create fundamental conflicts of interest between PBMs and their clients. It is argued that these conflicts lead PBMs to act in ways that benefit themselves to the detriment of health plans and consumers. For example, the NLARx stated:

"Our own experience as state legislators dealing with state agencies which must negotiate with PBMs has shown that PBMs often act contrary to the interests of the buyers they represent. ...PBMs often direct individuals to drugs that provide the PBM with the highest rebates, and the greatest margins, while failing to pass those savings on to purchasers. ... The operations of PBMs are often not transparent, which enables them to engage in these practices without regulation from market forces. There have been numerous state and federal investigations and enforcement actions that have uncovered a variety of deceptive and fraudulent practices by PBMs."⁶

Some proponents of regulation have argued that these types of PBM conflicts of interest are particularly severe when the PBM both administers the pharmacy benefits and sells drugs to the client's members via the PBM's owned mail-order pharmacy.⁷ Each of the three large publicly traded PBMs operates their own mail order pharmacy.⁸ It is

⁶ National Legislative Association on Prescription Drug Prices, Senator Mark Montigny, Chair of the Board, Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005.

⁷ JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003), at <http://www.mpaginc.com/news/pbmreport.pdf>.

⁸ The economic literature on vertical integration suggests that it can lower costs. First, integration can reduce transaction costs. In addition, it also avoids double markups (or what economists call "double

alleged that this vertical integration provides PBMs additional opportunities to manipulate drug dispensing at their mail-order pharmacies to enhance their own profits at the expense of plans and members through such business practices as avoiding generic substitution to maximize rebates on brand name drugs, inappropriate switching to more expensive brand products with higher rebates, and repackaging of drugs into more expensive units. One widely cited study by James Langenfeld and Robert Maness concluded that this type of “self-dealing” could cost the U.S. Government and Medicare beneficiaries up to \$30 billion during the period 2004-2013.⁹

Most PBM critics also believe regulation is necessary because PBMs do not provide sufficient information about their internal operations and financial dealings with drug manufacturers to their clients, and that such information would facilitate competition and efficiency in the marketplace. For example, David Balto, a prominent advocate of PBM regulation stated:

“Although PBMs can provide a valuable service, consumers and plan sponsors often do not receive their full benefits due to certain market characteristics and a lack of transparency in the process. Substantial entry barriers and significant switching costs dampen the degree of competition in PBM markets. A lack of transparency about the compensation PBMs receive from pharmaceutical manufacturers prevents plan sponsors from effectively securing the lowest pharmaceutical prices.”¹⁰

Accordingly, one of the primary goals of PBM regulation and litigation has been to provide purchasers of PBM services with more detailed information about the internal financial workings of the PBMs and the details of their relationships with pharmaceutical manufacturers.

C. Government Investigations, Litigation and Regulatory Efforts

marginalization”) in which two independent, vertically related firms each have some ability to charge above marginal cost. A PBM that owns a mail-order pharmacy may have an incentive to charge a lower overall price for the product than two independent entities setting prices optimally.

⁹ JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM “SELF-DEALING” UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003), at <http://www.mpaginc.com/news/pbmreport.pdf>.

¹⁰ David Balto, “Competitive Concerns and Price Transparency in the PBM Market,” FDLI Update, September / October 2003. See also, “Proactive Litigation Against PBMs,” 9/6/05. Similar arguments were expressed by U.S. Magistrate Judge Margaret Kravchuck in her February 2005 opinion recommending that the Maine law regulating PBMs be upheld. (see, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, v. G. STEVEN ROWE, Civil No. 03-153-B-H (April 2005)(at 4-5). 03-153-B-H, RECOMMENDED DECISION ON CROSS-MOTIONS FOR SUMMARY JUDGMENT, UNITED STATES DISTRICT COURT, DISTRICT OF MAINE.)

1. Government investigations and litigation

Concerns about PBM conflicts of interest have led to intense legal scrutiny in recent years. As cited above, the Chair of the National Legislative Association on Prescription Drug Prices, recently stated “We know of no other market in which there has been such a significant number of prominent enforcement actions and investigations.” Perhaps the most widely followed example of this litigation is a case brought by the U.S. Attorney’s Office for the Eastern District of Pennsylvania in *United States of America v. Merck-Medco Managed Care L.L.C., et al.*¹¹ This case has grown since the first complaint was filed in 2000, to ultimately involve 20 state Attorneys General and U.S. Attorneys from Pennsylvania and Boston. The complaint alleged a variety of inappropriate conduct by Medco, including switching patients to higher priced drugs that benefited Medco at the expense of its clients, unwarranted therapeutic interchange, failing to adequately disclose financial arrangement with drug manufacturers, and failing to pass on various payments to PBM clients.

The state Attorneys General also established a task force to conduct investigations of several PBMs. Most of these investigations focus on whether PBMs have defrauded state healthcare plans by such actions as improperly switching drugs to financially benefit the PBM and improperly retaining drug rebates.¹²

A major milestone in the regulatory scrutiny of PBMs occurred on April 26, 2004, when the United States and 20 state attorneys general agreed to a settlement of claims and alleged violations of unfair trade practice laws with Medco and its parent Merck & Co., Inc.¹³ Medco agreed to pay \$20 million in damages, \$6.6 million in fees and costs, and \$2.5 million in restitution to patients who incurred expenses related to certain drug switches undertaken by Medco. Perhaps more importantly, the settlement provided important injunctive relief. In particular, the settlement commits Medco to provide greater disclosure of its financial incentives for drug switches to physicians and patients,

¹¹ Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania.

¹² See, e.g. John Carroll, Contributing Editor, “When Success Sours: PBMs Under Scrutiny -- Pharmacy benefit managers are under fire from many corners. What will the push for transparency mean for the industry?” *Managed Care Magazine*, September 2002.

¹³ Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

and it prohibits switches where the net cost of the proposed drug exceeds the cost of the originally prescribed drug. As discussed further below, several of these elements in the Medco settlement are similar to those featured in recent state regulatory proposals.

The Medco case and its settlement have been cited by PBM critics as a significant step forward in holding PBMs accountable and making their activities more transparent. For example, U.S. Attorney Patrick Meehan, stated: "... we believe that the changes in Medco's business practices resulting from this agreement will positively impact health care consumers across the nation."¹⁴

The settlement also provides a prominent example of how litigation and commercial pressure from clients and investors can act as a catalyst to reinforce and accelerate changes in business practices well before such changes are mandated by explicit regulation. David B. Snow Jr., Medco chairman, president and CEO, stated:

"This constructive approach to resolving issues raised by the attorneys general and the Justice Department serves the interests of our company and our customers -- extending across our book of business elevated standards of practice that are designed to help our clients, and their employees or members, better understand and trust the value delivered through their pharmacy benefit program, ... This arrangement is consistent with our goal to position Medco as the most transparent company in our industry." (Medco 4/26/04 press release)

However, the settlement did not resolve all of the charges in the ongoing investigations. As discussed in section IV below, additional enforcement actions by the U.S. Attorney's and the attorneys general task force have continued to occur.

2. Private litigation

In addition to the actions of federal and state prosecutors, numerous private cases have also been filed against PBMs. Some of these cases are "whistleblower" actions alleging violations of federal claims acts statutes. Other cases allege violations of state unfair trade practice statutes, breach of contract claims, or allegations that PBMs violated

¹⁴ Melissa Davis, "Medco Ponies Up to States," TheStreet.com Senior Writer, 4/27/2004, URL: <http://www.thestreet.com/stocks/melissadavid/10156476.html> ; MILT FREUDENHEIM, "Medco to Pay \$29.3 Million to Settle Complaints of Drug Switching," New York Times, April 27, 2004.

As a matter of law, the terms of the Medco settlement may not be legally binding on residents of those states that were not a party to the lawsuit. However, some observers believe that Medco will likely adopt the requirements of the consent decree for all of its operations, because it would not be cost effective to maintain multiple substantially different systems.

fiduciary obligations to health plans or plan members.¹⁵ There are also a number of antitrust cases filed by retail pharmacies against PBMs alleging that they have illegally hampered retail pharmacies efforts to compete with PBMs mail-order operations and/or conspired to reduce the compensation that pharmacies receive for filling prescriptions.¹⁶

For example, in one large private action, the American Federation of State County & Municipal Employees filed a lawsuit in 2003 alleging that the largest PBMs have engaged in unfair and deceptive practices under California state law.¹⁷ Among other charges, the complaint alleges that the PBMs failed to pass on rebates from drug manufacturers to health plans and consumers. It also alleges that the PBMs developed a pricing system to inappropriately inflate prices set by the drug manufacturers, and that the defendants' pocketed secret payments from drug manufacturers.

In one of the few fully litigated PBM cases, on 12/19/05 an Ohio jury ordered Medco to pay \$7.8 million for allegedly defrauding and violating its legal duties to the state's teacher retirement system. The jury found that Medco owed a duty to the teacher's retirement system, and that Medco breached that duty. They also found that Medco committed "constructive fraud." Medco is appealing the verdict, and argues that it has no legal bearing on the fiduciary duty issue in other ongoing PBM litigation.¹⁸

3. Government regulation

¹⁵ Lists of cases against PBMs can be found in National Legislative Association on Prescription Drug Prices, Senator Mark Montigny, Chair of the Board, Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005, Appendix of Legal Actions; and David A. Balto "Ongoing Federal and State Litigation Regarding Pharmacy Benefit Managers," October 2006, www.nlarx.com

¹⁶ See, e.g. *Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al.* and *Bellvue Drug Co., et al. v. Advance PCS* - These companion lawsuits were filed on August 15, 2003 in the U.S. District Court for the Eastern District of Pennsylvania by individual pharmacies, as well as the Pharmacy Freedom Fund and the National Community Pharmacists Association. (Civ Nos. 03-4730 and 03-4731, respectively). The lawsuits allege that each of the defendant PBMs violated Section I of the Sherman Act by engaging in anticompetitive conduct such as negotiating and fixing reimbursement levels and rates, restricting the level of service offered to customers, and arbitrarily limiting the ability of retail pharmacies to compete on a level playing field with the PBMs' mail order pharmacy.

¹⁷ *American Federation of State County and Municipal Employees v. AdvancePCS, et al.*- Filed on March 18, 2003, in the Superior Court of California (Los Angeles)(Case No. BC 292227)

¹⁸ See, e.g. Melissa Davis, "Mixed Courtroom Decision at Medco," *TheStreet.com*, 12/20/2005. Other examples of plaintiffs in suits against PBMs can be found in National Legislative Association on Prescription Drug Prices, Senator Mark Montigny, Chair of the Board, Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005, Appendix of Legal Actions, HJM 98 Report 2005 9, David A. Balto "Ongoing Federal and State Litigation Regarding Pharmacy Benefit Managers," October 2006, www.nlarx.com

In addition to public and private investigations and legal actions, many states have considered broad-based PBM regulation in recent years. Since the PBM business model has evolved significantly over time, PBM critics argue that pre-existing regulations were not developed to address the potential for conflicts of interest facing the current PBM industry. While PBMs historically were primarily performing administrative functions such as processing claims, they now play a larger role and can have significant influence over the prescription drug options available to consumers.¹⁹ While most states oversee managed care providers through their insurance regulations, these agencies generally do not oversee PBMs.²⁰ At the federal level, the Federal Trade Commission's oversight over PBMs has been limited to anti-trust issues.²¹ Similarly, the Department of Labor has not attempted to regulate PBM business practices using ERISA statutes. PBMs have consistently maintained that they are not legally subject to the standards required of an ERISA fiduciary.²²

Accordingly, a number of states have attempted to fill a perceived void and subject PBMs to much more comprehensive regulation. Since 2002, more than 30 bills have been introduced in 25 different states.²³ These regulatory efforts have been vigorously opposed by PBM trade organizations. Despite the large amount of proposed legislation, only three states (Maine, Maryland and South Dakota) and Washington, DC,

¹⁹ See, e.g. *AMICI CURIAE BRIEF OF AARP, LEGAL COUNSEL FOR THE ELDERLY, AND THE PRESCRIPTION ACCESS LITIGATION PROJECT IN SUPPORT OF THE DISTRICT OF COLUMBIA* in *Pharmaceutical Care Management Association v. The District of Columbia, et. Al.* Civil Action No.: 04-0182(RMU)

²⁰ Some PBMs may provide drug coverage on a capitated basis or assume financial risk pursuant to contracts with clients, which could be subject to state insurance regulation. See, Johnson, *supra* n.8, at 333.

²¹ The antitrust issues raised by the vertical market integration when drug companies own PBMs has been the subject of FTC regulation. See, Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration With Pharmacy Benefit Managers: The Need for a New Regulatory Approach*, 54 Food Drug L.J. 151 (1999); David Balto, *A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution*, 52 Food Drug L. J. 83 (1997).

²² "We believe that, in general, the conduct of our business is not subject to the fiduciary obligation of ERISA." Caremark Rx, Inc., 2003 Annual Report 6 (2003). "We believe that the conduct of our business is not generally subject to the fiduciary obligations of ERISA, and our agreements with our clients provide that we are not the fiduciary of the applicable plan." Express Scripts, 2003 Annual Report 12. In fact, in a recent case by a health plan against a PBM claiming that it had breached state law fiduciary duties in failing to perform functions imposed by their contractual agreement, on a remand petition, a federal district court found that it lacked subject matter jurisdiction over the case under ERISA because it doubted that the PBM was an ERISA fiduciary. *Group Hospitalization v. Merck-Medco Managed Care*, 295 F.Supp. 2d 457, 460, 464-65 (D.NJ 2003).

²³ Colorado Department of Regulatory Agencies, Office of Policy, Research and Regulatory Reform, 2004 Sunrise Review, Pharmacy Benefit Managers, October 15, 2004, p. 11.

have actually enacted comprehensive legislation to regulate PBMs. In addition, PBM legal challenges have largely suspended the enforcement of these laws until very recently.

While there is significant variation in the details of regulatory schemes across states, some of the most common elements include oversight and monitoring of PBM activities by the state pharmacy board or insurance commissioner, disclosures of financial arrangements between PBMs and drug manufacturers, and provisions that seek to prevent certain types of prohibited conduct. To address confidentiality concerns raised by PBMs, drug manufacturers and others, the information disclosed by PBMs under state statutes is generally considered confidential. Other provisions cover auditing procedures, guidelines for substituting drugs, and providing status reports to regulators on a regular basis. Some bills also require PBMs to meet fiduciary standards or otherwise to conduct their activities in the interests of the plans, providers and/or beneficiaries.²⁴

The state with the most comprehensive PBM regulation appears to be Maine. In 2003, the legislature of Maine passed S.P. 194 – L.D. 554 which imposes a fiduciary duty on a PBM to act in the benefit of the PBM’s client. The bill also imposes upon the PBM a responsibility to disclose to its client any potential conflicts of interest as well as any financial or drug utilization information the client may request. The bill also outlines a number of steps that must be taken for drug substitutions and mandates that any savings realized by a PBM based on sales volume must be passed on to the PBM’s client. In addition, the Maine act requires PBMs to disclose all terms and arrangements between the PBM and drug manufacturers.

The Maine act was scheduled to take effect on September 13, 2003, but the Pharmaceutical Care Management Association (PCMA), a trade association of PBMs, filed a petition in the U.S. District Court to prevent implementation of the act. The court granted a preliminary injunction suspending implementation of the act on March 9, 2004. The Court apparently believed that the provision in the Maine act requiring PBMs to disclose their financial relationships with drug manufacturers may constitute unlawful

²⁴ Additional information on state PBM regulation can be found in Colorado Department of Regulatory Agencies, Office of Policy, Research and Regulatory Reform, 2004 Sunrise Review, Pharmacy Benefit Managers, October 15, 2004, Appendix B.. See also New Mexico Task Force on PBM Regulation and [Community Pharmacists].

disclosure of “trade secrets” which, if disclosed, could harm a PBM’s ability to compete. The court also found that the Maine act may impose internally inconsistent legal obligations on PBMs by creating a fiduciary duty on PBMs to the benefit of their clients, while at the same time prohibiting the substitution of a drug unless such a substitution would benefit both the client and the individual enrollee.

While the PCMA succeeded in obtaining a preliminary injunction in 2004, a magistrate judge recommended in February 2005 that the preliminary injunction be lifted, allowing the law to take effect.²⁵ Federal judge Brock Hornby agreed in his decision in April of 2005. Finally, on November 8, 2005, in a unanimous decision, a federal appeals court agreed with Judge Hornby and ruled that Maine's Unfair Prescription Drug Practices (“UPDPA”) Act is in fact constitutional and should be implemented.²⁶

In light of the foregoing developments, the future path of PBM regulation is difficult to predict. Based on the PBMs initial legal success in obtaining preliminary injunctions to stop the enforcement of PBM laws in Maine and Washington DC in 2004, many analysts appeared to be discounting the likelihood of broad-based PBM regulation. Similarly, after the flurry of activity in 2002-2004, state efforts to regulate PBMs seem to have slowed somewhat. PBM industry trade group PCMA reports that in 2004 and early 2005, the following states rejected or delayed PBM fiduciary duty and/or disclosure legislation: Arkansas, Colorado, Iowa, Illinois, Maryland, Minnesota, Mississippi, and New Mexico, California, New York, Florida, Washington State, Maryland, Minnesota, Mississippi, Kansas, Iowa, and Vermont.²⁷

Another factor that may have slowed the drive to regulate PBMs is the opposition to regulation by the U.S. Federal Trade Commission. Official FTC publications have questioned the need for regulation and FTC staff members have filed detailed comments opposing several state regulatory proposals.²⁸ In addition, in August of 2005 the FTC

²⁵ PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, v. G. STEVEN ROWE, Civil No. 03-153-B-H, RECOMMENDED DECISION ON CROSS-MOTIONS FOR SUMMARY JUDGMENT, UNITED STATES DISTRICT COURT, DISTRICT OF MAINE.

²⁶ “Federal Court of Appeals Upholds First-in-Nation PBM Law,” NLRx Press Release, 2005-11-08, United States Court of Appeals for the First Circuit, No. 05-1606, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION v. G. STEVEN ROWE, APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE, November 8, 2005.

²⁷ “PCMA Intends to Immediately Appeal U.S. District Court Ruling on Maine PBM Fiduciary-Disclosure Law,” PCMA Press Release, 4/13/05.

²⁸ See Letter to California Assembly Member Greg Aghazarian, Sept. 4, 2004; Letter to Senator Richard T.

issued a comprehensive report which analyzed many of the self-dealing claims against PBMs, and concluded that many of the claims were inconsistent with the data.²⁹

However, some industry observers believe that the recent favorable Federal Court decisions for Maine in its legal battles with the PBMs in April and November 2005 may provide a spur for similar laws in other states. Sharon Treat, a former state lawmaker who sponsored the Maine PBM disclosure law and now works with NLARx, a national organization promoting regulatory initiatives in the pharmaceutical sector, stated: "This is a very strong decision. And it should embolden a number of other states to be more supportive about passing legislation" of their own.³⁰

III. Economic Arguments Against Broad-Based PBM Regulation

A. PBM regulatory proposals require more information disclosure than is typical in competitive markets.

As discussed above, one of the primary goals of PBM regulation and litigation has been to provide purchasers of PBM services with more information disclosure about the internal financial workings of PBMs and the details of their contractual relationships with pharmaceutical manufacturers. While it is hard to argue with the general proposition that additional information about their suppliers can be valuable to buyers of health care services, most PBM regulatory proposals advocate disclosure that goes well beyond the level of transparency that exists in most well functioning competitive markets. For example, in most markets consumers are able to make intelligent purchasing decisions based on the price and value of goods and services that a potential supplier offers by comparing to the offerings of competing suppliers even though they may have limited information about the cost structure and internal financial workings of their suppliers. Similarly, when group health plan sponsors contract with PBMs, they can compare the net prices of the services they are obtaining across suppliers without understanding all of the details of the PBMs contracts with drug manufacturers. Accordingly, imposing such regulations on PBMs generally holds them to a disclosure standard that does not exist in

Brown, March 8, 2005.

²⁹ Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005.

³⁰ NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, News Release, April 13, 2005, "FEDERAL DISTRICT JUDGE UPHOLDS FIRST-IN-NATION PBM LAW, Adopts Recommendation of Magistrate Judge and Holds for State on Every Count."

most other industries.

B. Competition in the PBM industry appears to be sufficient to produce appropriate levels of transparency.

In addition, it is argued that the competition among PBMs for contracts can generally can be relied on to assure that the prices of PBM services are not out of line with their costs. Various sources estimate that there are roughly 50-60 PBMs operating in the United States.³¹ While this appears to represent more than enough rivals to produce vigorous competition, the FTC reports that only about 12 PBMs have more than five million covered lives.³² The largest of these are the three large independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. These three PBMs have emerged from a decade of rapid growth and consolidation to cover a combined 190 million lives and manage a combined \$80 billion in drug spending.³³

In addition, a number of large insurers such as Wellpoint, Aetna, Prudential and Cigna manage pharmacy benefits primarily for members of their medical health plans. The FTC reports that six of the top twelve PBMs are owned by large health insurers, and provide benefits to approximately 40 percent of covered lives in the United States. Some PBMs are also owned by large retail supermarket/pharmacy chains (e.g. Eckerds, Walgreens and the recently proposed merger of Caremark and CVS). In addition, there are many smaller privately held PBMs.³⁴ Based on its antitrust investigations in the PBM industry for the merger of Caremark and Advance PCS, the FTC recently concluded that competition between PBMs for contracts with plan sponsors was “vigorous.”³⁵

In contrast to allegations that PBMs are isolated from effective competition by high concentration, switching costs and other factors, the evidence also indicates that health plan sponsors frequently employ competitive bidding in selecting their PBM. In competing for health plan contracts PBMs compete on a variety of price and non-price dimensions. These include the financial terms of the bid (such as the reimbursement rate

³¹ See, e.g. Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 2004 HEALTH AFFAIRS (Web Exclusive), W4-504, 506, at <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.504>.

³² FTC, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005, pp. I 2-3.

³³ *Ibid.*

³⁴ *Ibid.*

³⁵ Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Luke M. Froeb, Director, Bureau of Economics, Susan A. Creighton, Director, Bureau of Competition, U.S. FTC, Letter to Assembly Member Greg Aghazarian, September 7, 2004, p. 6.

and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees), plan design, the extent of the retail network, and the availability and pricing of mail order pharmacy service.^{36 37}

Some proponents of PBM regulation have also claimed that up-front competition and bidding for contracts does not ensure that the benefits of competition carry over after the health plan provider has entered into its PBM contract. It is argued that the complexity of PBM contracts and a lack of transparency may give PBMs incentives to engage in post-contractual opportunistic behavior.³⁸ However, there are obviously many industries in which buyers and sellers use complex long-term contracts, but market mechanisms such as reputation, brand-names, and the possibility of legal action for contract breach has been sufficient to control such opportunism without additional government regulation. In addition, vigorous competition among PBMs does help ensure contractual performance because it makes it more likely that an opportunistic PBM will be punished by losing future contracts.

Many plan sponsors are clearly large, sophisticated purchasers of health care services such as large employers and health insurance companies. However, some critics argue that disclosure requirements are needed because smaller plan sponsors are not sophisticated and can be exploited by PBMs who “realize who the unsophisticated buyers are.”³⁹ However, to the extent that some smaller buyers may lack such capabilities, there appear to be many knowledgeable consultants that provide services to the industry.⁴⁰ Moreover, if plan sponsors feel they have been treated unfairly, the various lawsuits against PBMs discussed above illustrate the viability of private litigation as an additional

³⁶ Even if a relatively small portion of payors actually switch their PBM in a given year, this does not imply that they did not have a realistic option to do so if they were dissatisfied with their service.

³⁷ FTC, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005, pp. 1 8-9.

³⁸ JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM “SELF-DEALING” UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003) at <http://www.mpaginc.com/news/pbmreport.pdf>.

³⁹ David Balto, quoted by Judy Chi in “Should PBMs disclose their contracts?” *Drug Topics* May 17, 2004;148:52.

⁴⁰ For example, the website for pharmacy consultant Trivantage states: “There are many qualified PBMs, who, just like your business, are unique; each with a different approach to managing the pharmacy benefit. Trivantage understands the PBM industry from the inside out. Using this knowledge, we develop a customized RFP that addresses the specific needs of our client. Moreover, we ask the critical questions often overlooked by other RFPs.” (www.trivantageps.com, Downloaded on 12/6/05)

remedy for opportunistic behavior.

C. Regulation could impose substantial additional costs on PBMs and raise the costs of providing drug benefits to health plan sponsors.

While the foregoing analysis indicates that the economic benefits to broad-based PBM regulation are likely to be small, it is also important to analyze the potential costs of such regulation.

1. Disclosure requirements could inadvertently reduce manufacturer rebates.

As described above, most PBM regulatory proposals require PBMs to disclose certain financial information to purchasers, prospective purchasers, and/or prescribers. To address confidentiality concerns, they often specify that rebate information may be provided in a somewhat aggregated form to purchasers and prospective purchasers and does not have to be provided unless purchasers and prospective purchasers agree to keep the information confidential. In some cases, (such as California's proposed AB1960) no such confidentiality restrictions apply to the disclosure of information to prescribers.⁴¹

Despite precautions, confidential information on contract terms with pharmaceutical manufacturers disclosed by PBMs under such transparency regulations could become more widely dispersed among competitors. Pharmaceutical manufacturers could potentially use such information to better estimate the prices their competitors were offering to PBMs. Manufacturers might also become less likely to grant such discounts if they are concerned that favorable prices they grant to a particular PBM will more rapidly become known to competitors. Such disclosure could also enhance the possibility of oligopolistic pricing coordination among drug manufacturers in concentrated therapeutic categories. Consequently, the required disclosures could lead to higher prices for both drugs and PBM services.

Regulation proponents counter that such concerns are greatly exaggerated. For example, they argue that it is unlikely that prescribers would have an incentive to share the information they are provided by the PBM. They also argue that the FTC has failed to show that this type of information sharing has actually happened in the states where

⁴¹ Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Luke M. Froeb, Director, Bureau of Economics, Susan A. Creighton, Director, Bureau of Competition, U.S. FTC, Letter to Assembly Member Greg Aghazarian, September 7, 2004.

transparency has been mandated.⁴² Finally, they argue that in situations where additional transparency could facilitate collusion or cause other problems, these concerns could be addressed by additional protections against unauthorized disclosure.⁴³

2. Regulation could raise costs and/or deter beneficial drug interchange

Opponents of PBM regulation also argue that many proposed bills may have the unintended consequences of raising the costs of PBM drug substitutions that can reduce costs and promote competition between branded drug makers. Some regulatory proposals include limitations on switching or additional procedures PBMs must follow to undertake drug substitutions. While most bills seek to prevent actions that are designed to increase PBM profitability without corresponding benefits to health plans or consumers, they could have the unintended effect of making some efficient drug substitutions more difficult or costly as well. The FTC has argued that these concerns are particularly great if PBM regulation reduces the incentives for generic substitution, since the competitive benefits of generic competition have been well documented.⁴⁴ The FTC has also argued that some regulatory proposals may also inadvertently increase health care costs and distort competition by inefficiently favoring PBMs that are vertically integrated with health plan providers by allowing such plans to avoid regulation.

IV. Economic Evidence on PBM Regulation

A. Evidence from the Stock Market

In general, it is often difficult to measure the expected effects of business regulation with event studies. The legislative process, in particular, tends to be relatively slow moving and subject to substantial information “leakage.” Investor expectations evolve gradually as proposed bills move through various committees and are frequently

⁴² See, e.g. National Legislative Association on Prescription Drug Prices, Senator Mark Montigny, Chair of the Board, Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005.

⁴³ Ibid. As discussed above, the disclosures made by the PBMs to covered entities under the Maine Law are protected by confidentiality and are not available to the public. (Me. Rev. Stat. Ann. tit. 22, §§ 2699(2)(A-G) (2005).)

⁴⁴ Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Luke M. Froeb, Director, Bureau of Economics, Susan A. Creighton, Director, Bureau of Competition, U.S. FTC, Letter to Assembly Member Greg Aghazarian, September 7, 2004. Many states, such as California, already require prior prescriber approval for therapeutic interchange.

subject to multiple votes, etc.⁴⁵ Hence, while there can be many potential “events” for a given piece of legislation, it is often the case that none of them convey significant new information in a way that is readily measurable. Litigation events tend to be somewhat more amenable to event study analysis, and such studies have been employed to study the effects of many kinds of corporate litigation.⁴⁶

As discussed above, the investigations of PBM business practices conducted by the US Attorneys and many state Attorneys General have been at the forefront of PBM regulatory efforts. Evidence from the stock market indicates that these investigations have had a substantial effect on the equity values of the PBMs. For example, on March 7, 2000, PCS Health Systems Inc and Merck-Medco Managed Care LLC, two of the biggest pharmacy-benefit management companies, announced that they had received subpoenas from the U.S. Department of Justice in 1999 as part of a broad federal probe of drug-marketing practices. Apparently, this represented the first conclusive information to investors that a major federal investigation of PBM business practices was underway. As shown in Table 1, the stock price impact was immediate and dramatic. Each of the three large PBMs that were publicly traded at the time experienced a large stock price decline over the three day period from 3/6/00 to 3/8/00. For example, PCS declined by an astounding -50.0 percent. While Medco was not publicly traded at the time, Express Scripts declined by -17.6 percent and Caremark declined by -11.5 percent. For the PBMs as a group the average decline over the three day period was -26.4 percent. This decline was highly statistically significant with a t-statistic of 4.6.

The next major public announcement in the ongoing federal and state investigations occurred in May of 2002. On May 2nd several sources reported that the Justice Department had subpoenaed Express Scripts.⁴⁷ On May 6th Express Scripts clarified that it was not the target of the investigation. Shortly thereafter, on May 10th Caremark announced that it had also received a Justice Department subpoena, although,

⁴⁵ Bhagat and Romano state: “Event studies of regulatory change raise more difficult methodological issues than those involving corporate law and corporate governance, because of the typically long time period in which the event of interest occurs.” Sanjai Bhagat and Roberta Romano, “Event Studies and the Law—Part I: Technique and Corporate Litigation,”

⁴⁶ Ibid

⁴⁷ CBS MarketWatch, May 2, 2002 Thursday, NEWS & COMMENTARY; SEC FILINGS, 244 words, “Justice Dept. subpoenas Express Scripts,” Leticia Williams, CBS.MarketWatch.com

like Express Scripts, it was not identified as the target of the investigation.⁴⁸ However, the market appeared to infer that the investigation of the industry was widening, since during this period Express Scripts and Caremark declined roughly -11.4 percent and -7.1 percent respectively, relative to the S&P500, and the PBM industry average declined by -7.8 percent (see Table 1). A similar set of disclosures in August of 2002 caused PBM stock prices to decline by an additional -17.4 percent.

As discussed above, on April 26, 2004, the United States and 20 state attorneys general agreed to a settlement of claims for injunctive relief and alleged violations of unfair trade practice laws with Medco and its parent Merck & Co., Inc.⁴⁹ Medco agreed to pay \$20 million in damages, \$6.6 million in fees and costs, and \$2.5 million in restitution to patients who incurred expenses related to certain drug switches and also agreed to significant injunctive relief. While this settlement was widely seen as a significant milestone in PBM regulatory efforts, the settlement terms were apparently anticipated correctly by investors, since the announcement had little measurable impact on PBM stock prices.⁵⁰

Shortly after the Medco settlement, another round of actions by state regulators further reduced PBM stock prices during July and August of 2004. On July 6 Caremark revealed that 19 states were investigating a variety of its business practices. Similarly, on July 28 Express Scripts announced it received a "notice of proposed litigation" from the New York Attorney Elliot Spitzer alleging that Express Scripts had violated civil laws and breached its contract with the state. At the same time the company also stated that it had received a "civil investigative demand" from the attorney general of Vermont seeking "documents regarding a wide range" of its business practices. It also indicated that it expected similar subpoenas from 18 other states.⁵¹ On August 4, New York Attorney General Spitzer announced that settlement discussions with Express Scripts had reached

⁴⁸ PR Newswire, May 10, 2002 Friday, FINANCIAL NEWS, 499 words, "Caremark Receives Subpoenas - Not Identified As Target."

⁴⁹ Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

⁵⁰ See, e.g. Melissa Davis, "Medco Ponies Up to States," TheStreet.com Senior Writer, 4/27/2004, URL: <http://www.thestreet.com/stocks/melissadavid/10156476.html>; MILT FREUDENHEIM, "Medco to Pay \$29.3 Million to Settle Complaints of Drug Switching," New York Times, April 27, 2004.

⁵¹ Melissa Davis, "Express Scripts Takes a Tumble," TheStreet.com, 7/29/2004.

an impasse and that he was proceeding to file a lawsuit.⁵² The suit accused Express Scripts of engaging in a number of practices such as inflating the cost of generic drugs, pocketing drug rebates intended for customers, improperly switching patient prescriptions, selling patient data to outsiders and misrepresenting drug discounts to the state.⁵³ Express Scripts denied all of the allegations.

The cumulative effects of the July and August announcements on PBM stock prices is summarized in Table 1. By the time of the August 4th announcements, Express Scripts had declined -18.5 percent relative to the S&P 500 index. Similarly, Medco Health Systems had declined -9.4 percent and the third major PBM, Caremark declined by -12.0 percent. For the three PBMs as a group the average decline was -13.2 percent. As shown in Table 1, the t-statistics for the three individual event windows are 2.8, 3.6 and .3. For the three events as a group the combined t-statistic is 3.7. Clearly, these additional announcements of enhanced regulatory scrutiny of PBM business practices had further substantial impacts on the perceived profitability of the PBMs.

The substantial magnitude of the declines in PBM equity values from these legal and regulatory developments can also be illustrated by estimating the dollar amount of PBM equity value lost during these event windows. Table 2 shows the estimated decline in equity value associated with announcements of government investigations and litigation against PBMs. The estimates are calculated by multiplying the cumulative net of market returns during each of the event windows times the average combined market capitalization of the four major publicly traded PBMs. As shown in Table 2, for the March 2000 announcements the estimated decline in equity value was \$2.21 billion. For the announcements in May and August of 2002 the estimated decline was \$3.66 billion. Finally, for the July and August 2004 announcements the estimated decline was \$3.96 billion. The grand total over the four announcement periods was \$9.83 billion.

Additional information on the market's expectations about PBM regulation can also be seen in the reactions to the Maine PBM regulation. As discussed above, Maine was the first state to enact a comprehensive regulatory scheme for PBMs. Given the PBM's initial success in obtaining a preliminary injunction against both the Maine and

⁵² See Express Scripts Press Release 8/4/2004, Melissa Davis, "Spitzer Takes Aim at Express Scripts," TheStreet.com, 8/4/2004, <http://www.thestreet.com/stocks/melissadavid/10176404.html>

⁵³ Ibid

DC regulatory schemes, many observers appeared to be surprised by the April and November 2005 federal court decisions upholding the Maine law. Accordingly, these court decisions provide a relatively unique opportunity to observe the market's response to a discreet and unanticipated increase in the probability of state level PBM regulation. As described above, these decisions also have been hailed as major victories for proponents of state regulation. For example, Sharon Treat, a former state lawmaker who sponsored the PBM disclosure law and now works with NLARx stated: "This is a very strong decision. ... More than ten states have pending PBM regulatory bills," ... "Now that the Federal Court has clarified the law, I am sure that there will be numerous other states interested in joining these efforts." Similarly, Maine State Representative John Brautigam, who is a member of the Association and helped draft the PBM law when he was an Assistant Attorney General in Maine said, "PBMs stand right in the middle of the confounding prescription drug pricing problem. Now a respected Federal Judge has confirmed that Maine has the legal authority to act in this area. This decision will encourage other states to move forward with their own common sense measures like Maine's. Greater scrutiny of PBMs and their various hidden relationships will help bring prices down."⁵⁴

Predictably, PBMs took a very different view. PCMA President Mark Merritt said: "Maine's consumers, employers, unions and public employees should be deeply concerned about this law. ... PCMA intends an immediate and vigorous appeal of today's ruling," said PCMA President Mark Merritt. "If left intact, this law will give drug makers the upper hand in drug price negotiations with PBMs. As a result, Maine consumers and employers could see prescription drug costs increase by more than 10 percent, or \$1.7 billion dollars, over the next decade."

The stock price responses to the Maine decisions are summarized in Table 3. The decision of Magistrate Judge Kravchuck on February 2, 2005 recommending that the law be upheld had relatively little effect. The decision of federal district court judge Brock Hornby on April 13 accepting Judge Kravchuck's recommendations did have a negative - 1.3% effect on PBM stock prices, although this was not statistically significant (t-statistic

⁵⁴ NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, News Release, April 13, 2005, "FEDERAL DISTRICT JUDGE UPHOLDS FIRST-IN-NATION PBM LAW, Adopts Recommendation of Magistrate Judge and Holds for State on Every Count."

of .7). However, the November 8 decision of the federal appeals court upholding Judge Hornby's decision was associated with a -4.3% decline with a t-statistic of 2.2. The combined effect of the 4/13 and 11/8 decisions was -5.5% with a t-statistic of 2.03. The dollar value of the estimated decline in PBM equity values is \$1.93 billion.

The combined effect of the announcements cited above is a \$11.5 billion dollar decline in PBM equity value. This decline is extremely large relative to the actual and potential direct fines that have resulted to date from these investigations. For example, Medco paid only \$29.3 million to settle the state claims in the fall of 2004 and \$155 million to settle federal claims in October 2006.⁵⁵ Similarly, Caremark paid \$138 million to settle charges against its Advance PCS subsidiary made by the U.S. Attorney in September of 2005.⁵⁶

The very large magnitude of the stock market responses likely indicates that investors were updating their expectations about the expected future effects of all forms of PBM litigation and regulation. That is, the announcements caused investors to substantially increase their projections that such future actions were likely to result in substantial financial penalties and/or changes in business practices that would adversely affect future PBM profitability.

To some extent, the jury is still out on whether such expectations will ultimately be borne out. The government investigations undoubtedly turned the spotlight on PBM business practices and caused many other public and private entities to consider whether additional litigation and/or other regulatory constraints on PBMs were necessary. As discussed above, at least 34 PBM regulation bills have been introduced in state legislatures since 2002. Despite the large amount of proposed legislation, however, only three states (Maine, Maryland and South Dakota) and Washington, DC, have actually enacted comprehensive regulatory legislation. Accordingly, while it would be a mistake to attribute all or most of the substantial decline in PBM equity values solely to the

⁵⁵ "Medco to Pay U.S. \$155 Million to Settle False Claims Act Cases," MONDAY, OCTOBER 23, 2006 WWW.USDOJ.GOV/CIV

⁵⁶ "Caremark Rx, Inc. Subsidiary AdvancePCS Settles With U.S. Government With No Admission of Wrongdoing," Caremark Press Release, Sep 08, 2005.

specific investigations cited above, these investigations clearly played a substantial role in the evolution of the legal and regulatory process in the PBM industry.⁵⁷

IV. Other Empirical Evidence

A. Economic evidence that PBMs reduce drug spending

The U.S. General Accounting Office released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, a program for federal government employees that covered about 4.5 million lives.⁵⁸ The study compared prices that three types of customers paid for 14 brand name drugs and four generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. The study found that the prices negotiated by PBMs for federal plan members were substantially below prices paid by uninsured buyers, and the lowest average prices were obtained when the drug was purchased through the PBM's mail order pharmacy. For generic drugs purchased through a retail pharmacy, enrollees in health plans managed by PBMs paid an average 47 percent less than cash customers. For prescription drugs dispensed through mail-order pharmacies, the average mail-order price was about 27 percent below the average cash-price paid by consumers for a brand name at a retail pharmacy and 53 percent below the average cash-price paid for generic drugs. For drugs dispensed at the retail pharmacy counter, PBMs negotiated discounts of 18 percent below what consumers

⁵⁷ As a point of context, it also is noteworthy that these large negative stock price reactions have occurred during a period in which PBMs have generally enjoyed tremendous financial performance. PBM stock prices have dramatically outperformed broad-based market indexes such as the S&P 500 during the 2000 to 2005 period. Given this substantial growth in equity values, it is possible that the adverse reactions to many of these litigation and regulatory events were partially or even fully reversed in subsequent time periods as the market has continually revised its expectations about the legal and regulatory environment for PBMs. The efficient market hypothesis, and voluminous scholarly research on the event study methodology, indicate that the immediate stock price response to an event generally is an unbiased predictor of the market's perceptions based on the information at the time of the announcement. However, this does not imply that the market's estimates would not evolve over time if new information arrives.

⁵⁸ GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 17-18 & tbl.3 (2003), at <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196>. The GAO reports that the largest of these plans, BCBS, held contracts with two PBMs: AdvancePCS, which handled their retail network; and Medco, which supplied their mail order pharmacy benefits. Another plan, GEHA, contracted solely with Medco. The third plan, PacifiCare, used a PBM called Prescription Solutions, which is a subsidiary of PacifiCare, which also sells independent PBM services.

would pay in cash at the retail pharmacy counter for 14 brand name drugs and 47 percent below what consumers would pay for 4 selected generic drugs.⁵⁹

Similarly, in October 2002, the Congressional Budget Office (CBO) estimated that PBMs have the potential to save as much as 30 percent in total drug spending relative to unmanaged purchases of prescription drugs when PBMs can use their full range of price discounts and rebates, utilization control tools, and other tools for managing drug utilization.⁶⁰

B. Economic evidence that PBMs do not systematically act contrary to their clients' interests.

1. The 2005 FTC Study

As discussed above, proponents of PBM regulation have identified a number of “self-dealing” practices (such as lack of generic substitution and dispensing, interchange to more expensive brand products, and repackaging of drugs into more expensive units) that could potentially be employed by PBMs to manipulate drug dispensing at their mail-order pharmacies to enhance their own profits at the expense of plans and members. The FTC attempted to test these allegations directly using detailed pharmacy claims data submitted by major PBMs. Their report, released in September of 2005, appears to be the most comprehensive and detailed analysis of these issues to date. The FTC report was developed in response to a Congressional request in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and examined whether private-sector entities that offer prescription drug coverage pay more for such drugs when using a mail-order pharmacy owned by a Pharmacy Benefit Manager (PBM), as opposed to using a mail-order or retail pharmacy that the PBM does not own.

In general, the FTC Report concluded that allegations of wide-spread systematic self-dealing by PBMs were not supported by the data.⁶¹ To the extent that PBM

⁵⁹ Some potential limitations of the GAO study are that it used data provided by the PBMs and stated that it “did not independently verify information provided by the plans, PBMS or pharmacies.” In addition, the GAO study focused on federal employee health plans and not on a large fraction of PBM covered populations that have non-federal coverage.

⁶⁰ GAO, “FEDERAL EMPLOYEES’ HEALTH BENEFITS: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies,” January 2003, GAO-03-196.

⁶¹ FTC, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005.

opportunism continued to exist, it was not widespread or systematic among the PBMs that provided data to the FTC.⁶² According to FTC Chairman Deborah Platt Majoras, “Data in the report demonstrate that PBMs’ use of owned mail-order pharmacies generally is cost-effective for plan sponsors.”

2. Other Studies

Garis; Langenfeld and Manness

Proponents of PBM regulation have often cited studies by Robert Garis and a study by James Langenfeld and Robert Manness.⁶³ However, these studies do not appear to be based on systematic data or valid research methodology. Rather, the Garis studies appear to be based on anecdotal examples. Similarly, the Langenfeld and Manness study has been criticized by the FTC and others for failing to control for differences in generic substitution rates across distribution channels and therapeutic categories.

Wosinska and Huckman, *Health Affairs*, July 28, 2004,

A July 2004 analysis of 670 million prescription drug claims by Harvard Business School economists Marta Wosinska, Ph.D., and Robert Huckman, Ph.D., reported results on PBM generic substitution rates that were consistent with those of the FTC. In particular, they found that after adjusting for “therapeutic mix,” generic substitution and generic dispensing rates at retail pharmacies and PBM mail-service pharmacies are essentially the same. This adjustment takes into account the differences in the types of drugs consumers seek at mail-service pharmacies versus retail pharmacies.⁶⁴

C. Evidence that the PBM marketplace is responding to client demands for more transparency.

⁶² It is also noteworthy that the 2002-2003 study period used by the FTC pre-dated the 2004 settlement of the Medco litigation with the states.

⁶³ Robert I. Garis, RP, MBA PhD, Alladin Mohammed, PharmD (Candidate), “Mail Order Prescription Pricing: A Critical Examination,” Robert I. Garis, RP, MBA PhD, Farrukh Syed, PharmD (Candidate). “Spread Pricing in the Prescription Benefit,” ; JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM “SELF-DEALING” UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003) at <http://www.mpaginc.com/news/pbmreport.pdf>.

⁶⁴ In the retail pharmacy setting, consumers typically seek prescriptions for acute conditions, whereas mail-service pharmacies are more likely to dispense prescriptions treating chronic conditions. The authors assert that this “therapeutic mix” adjustment is essential to allowing direct comparisons between PBM mail-service pharmacies and retail pharmacies, and represents a major flaw of prior studies that do not make such adjustments.

The available evidence indicates that health plan sponsors appear to have the ability to trade off such terms and features to design a plan that fits their individual objectives. There do not appear to be significant artificial barriers to negotiation between health plan sponsors and PBMs for the specific terms of PBM contracts. This flexibility includes how the PBM is to be compensated and the details of how the rebates that PBMs receive from drug manufacturers are to be shared between PBMs and health plan providers.^{65, 66} For example, the 2005 FTC Report provided data showing significant variation in rebate retention policies within and across different types of PBMs. As shown in Figure 2, on the high end of the scale, a small or insurer owned PBM had a retention rate of rates of 91 percent, while on the low end, a different small or insurer-owned PBM had an average rate of only 25 percent. Among large PBMs, the average rebate retention rates varied from 69 percent to 32 percent.⁶⁷

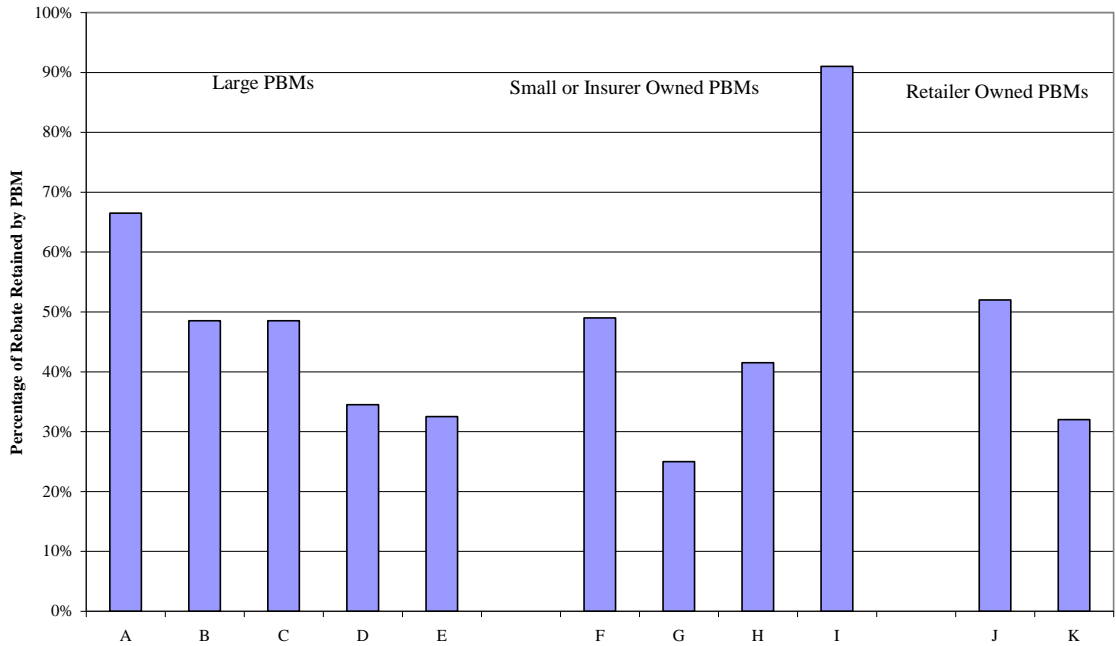
Figure 2

⁶⁵ See Jack Calfee, American Enterprise Institute, Health Care Hearings, *supra* note 13, at 99; David Balto, White & Case, Health Care Hearings, *supra* note 13, at 99. See also Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Luke M. Froeb, Director, Bureau of Economics, Susan A. Creighton, Director, Bureau of Competition, U.S. FTC, Letter to Assembly Member Greg Aghazarian, September 7, 2004, p. 7.

⁶⁶ See Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

⁶⁷ Figures graphed are the averages reported for each PBM for 2002 and 2003.

Rebate Retention Rates Vary Significantly Across PBMs



Source: FTC, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005.

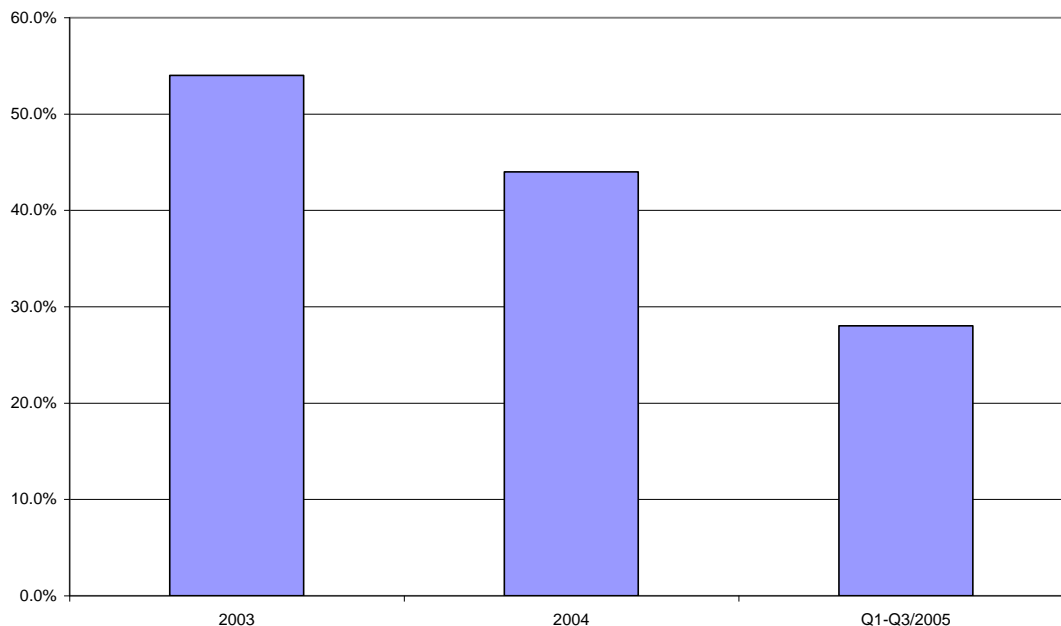
In addition to varying significantly across PBMs, there is also evidence that PBM rebate retention rates have declined over time in response to concerns about transparency issues and other factors. For example, as shown in Figure 3, Medco’s rebate retention rate has declined from 54 percent in 2003 to 44 percent in 2004 and 28 percent in the first nine months of 2005.⁶⁸ Similarly, Express Scripts President and CEO George Paz was quoted in the financial press saying that Express Scripts' rebate retention rate has also “declined over the years” and that the firm tries to align itself with client requests, with some keeping as much as 100 percent of rebate dollars.⁶⁹

Figure 3

⁶⁸ Medco Health Services Analyst Day Presentation 2005, 11/10/05. Similarly, Medco’s 2004 10-K states: “Competitive pressures in the PBM industry have also caused us and many other PBMs to share with clients a larger portion of the rebates received from pharmaceutical manufacturers and to increase the discounts offered to clients.”

⁶⁹ “Express Scripts Rocks Wall Street With Strong Third-Quarter Earnings,” Drug Benefit News, November 11, 2005.

Medco Rebate Retention Rates Have Declined Substantially



Source: Medco Health Services 10-Q for third quarter 2005.

There also is substantial evidence that PBMs are responding to the increased marketplace demands for transparency from clients, regulators and investors. These market responses have come in several forms. New firms have entered the PBM marketplace seeking to exploit the demand for increased transparency. For example, the web-site for one of these firms describes its services as follows:

- “Envision Pharmaceutical Services, Inc. is a privately held PBM created to provide a completely transparent product (EnvisionRx). The EnvisionRx business model is based on transparency, full disclosure and “pass through pricing,” features that only are beginning to be recognized by traditional PBMs. EnvisionRx was launched in September 2001 and is rapidly gaining market acceptance as the true alternative to traditional PBMs.”⁷⁰

Some of these firms have been termed pharmacy benefit administrators or “PBAs” to distinguish them for more traditional PBMs.

In addition to these new entrants, the existing PBMs have begun offering greater transparency and alternative contracting options to their clients. Many of these options

⁷⁰ See www.envisionrx.com/about.aspx

feature some or all of the following characteristics: 1) either the pass-through of all money paid by the client to retail pharmacies (no spread pricing) or the identification of the amount retained by the PBM, 2) the identification of the rebates received at a detailed, e.g. drug specific level, 3) greater levels of sharing of manufacturer rebates with plan sponsors, and 4) the elimination and or identification of non-rebate monies paid by pharmaceutical manufacturers to PBMs.⁷¹

Medco, in particular, perhaps based on the changes it implemented following its 2004 settlement with the states, has been aggressively using greater transparency as a way of differentiating themselves from their competitors. The following examples illustrate these trends:

- “The HR Policy Association’s Pharmaceutical Purchasing Coalition ... has successfully recruited three major corporate pharmacy benefit managers (PBMs) – Aetna Pharmacy Management, MedImpact Healthcare Systems, Inc., and Walgreens Health Initiatives, Inc. – to certify that they meet new principles outlined in the Transparency in Pharmaceutical Purchasing Solutions (TIPPS) platform. TIPPS was created by the Coalition and requires full commitment to an extraordinarily high set of transparency requirements in the way pharmacy benefits are purchased by large employers and administered on behalf of their employees and dependents. Preliminary estimates show Coalition members could collectively save up to nine percent of drug costs using the participating certified vendors while simultaneously propelling the market toward transparency.”⁷²
- Medco was selected in late 2005 as a PBM for the California Public Employees' Retirement System. A press release announcing the contract noted the company was chosen "following a rigorous competitive-bidding and capabilities-review process that included disclosure and transparency surrounding pricing and operations." David B. Snow Jr., Medco's chairman, president and CEO stated that "Winning back a former client serves to validate Medco's transformation into a customer-focused PBM leading the industry in transparency,"⁷³ The Calpers press release stated that the contract "...asks for unprecedented disclosure of what the manager receives in discounts and rebates from manufacturers. The contract requires 100 percent pass-through to CalPERS of all manufacturers' rebates associated with the

⁷¹ See, e.g. John D. Jones, R.Ph., J.D., “The Truth About Transparency,” Rx Solutions, Pharmacy Benefits Insider, September 2004.

⁷² HR Policy Association, “Employer Coalition Gains Transparency in Drug Pricing --Three Vendors Committed to New, Open Contracting Platform,” For Immediate Release: August 10, 2005

⁷³ Maureen Minehan, “HR Policy Association Pursues Pharmacy Benefit Transparency,” *Pharmaceutical Costs*

CalPERS account and audit rights to verify contract compliance.”⁷⁴

- “Pass-through pricing agreements between the pharmacy benefit manager Medco Health Solutions and employers involved in a national coalition led by Towers Perrin are proof that transparency in PBM contracts is taking hold, the organizations say. In January, the number of employers involved in the coalition, called Rx Collaborative, topped 30. "That's more than \$800 million in annual drug spend," says Paul Schott, a consultant at Towers Perrin, the human resources consulting firm.... "Our goal is to change the PBM business model," Schott says. ... Members of the coalition, for example, pay Medco an administrative fee based on the number of prescriptions filled. That's in return for full pass-through pricing, which means that the employers receive all of the manufacturers' discounts and rebates related to their purchases.”⁷⁵
- “Premera Blue Cross today announced that the company delivered \$45.5 million in 2004 prescription drug cost-containment resulting from more favorable contracting terms and greater “contract transparency” initiated in 2001 with Medco Health Solutions, Inc. “The PBMI’s transparency guidelines aim to identify factors that may influence not only decisions about which drugs to include in an insurer’s formulary, but also the resulting costs to customers,” said Ed Wong, Premera pharmacy director. “Premera has addressed every guideline published by the PBMI.”– Premera Blue Cross Press Release, May 10, 2005.
- In February, the state of Illinois replaced Caremark with Medco, in part because Caremark opposed the state's wish to release the details of its PBM contract to the public. "We're winning business on our elevated level of transparency," says Medco Chief Executive David B. Snow Jr.⁷⁶
- “At least two state groups, including the giant California Public Employees' Retirement System, have recently abandoned Caremark in favor of seemingly more transparent PBMs. Alan Kellogg, a consultant who helps big organizations negotiate with PBMs, says "Everybody is moving toward transparency," says Kellogg, a principal at the consulting firm HealthLinX. "So unless Caremark changes its strategy, I think it could have problems.”⁷⁷
- “More health plan and PBM clients are now insisting on transparency in their pharmacy benefit arrangements to ensure they know all the revenues and costs involved. Find out what strategies for employers exist in transparency for pharmacy benefit plans. Learn about a value-based approach to formulary selection, full pass-through of rebate and rebate-related revenue,

⁷⁴ CalPERS, “CalPERS Selects Medco To Manage Pharmacy Benefits For PPO Health Plans,” Press Release dated December 14, 2005.

⁷⁵ MargaretAnn Cross Transparency Catches Eye In Coalition's Deal With Medco

⁷⁶ “BW 50: Can Caremark's Health Hold Up?,” Business Week, May 9, 2005.

⁷⁷ Melissa Davis, “Medco's Talking Cure,” The Street.com, 12/7/2005

administrative fee-based billing and real-time claim processing.”⁷⁸

- Medco CEO David Snow announced. “This arrangement is consistent with our goal to position Medco as the most transparent company in our industry.” Similarly, Express Scripts CEO stated “Our long-term strategy of aligning interests with our clients has differentiated us from the competition and has solidified our position as an industry leader.”⁷⁹

This anecdotal evidence is also consistent with other evidence that PBMs have been forced to share a larger portion of rebate revenues with their clients in recent years. For example, as shown above in Figure 3, Medco’s rebate retention rate has declined from 54 percent in 2003 to 44 percent in 2004 and 28 percent in the first nine months of 2005.⁸⁰

Despite the large amount of press coverage devoted to transparent PBM contracting, a survey of pharmaceutical benefit trends conducted by Mercer Consulting and released in October of 2005 indicated that a relatively small percentage of plan sponsors are switching their business from traditional PBMs to PBAs or other new firms that are dedicated to a fully transparent model.⁸¹ For example, the Mercer survey reports that:

“The survey revealed little action on the part of employers in pursuing transparent pricing arrangements (the pass-through and disclosure of arrangements with pharmacies and pharmaceutical manufacturers), with only 6 percent of employers reporting that they are utilizing a pharmacy benefit administrator, or “transparent” PBM, and only another 2 percent likely to engage one in the next two years.”⁸²

However, many plan sponsors appear to be successfully demanding greater transparency from their traditional PBM:

“Employers interested in transparent pricing have been able, for the most part, to secure this arrangement through their current PBM or health plan,” ... “Many of the new PBAs or transparent PBMs are small, and employers may fear they lack the critical mass to provide a consistently high level of service. In addition,

⁷⁸ Symposium sponsored by Atlantic Information Services, Inc., publishers of *Drug Benefit News*, *Specialty Pharmacy News* and *Managed Care Week*.

⁷⁹ Medco 4/26/04 press release, Melissa Davis, “Medco Ponies Up to States,” TheStreet.com Senior Writer 4/27/2004, URL: <http://www.thestreet.com/stocks/melissadavid/10156476.html>

⁸⁰ Medco Health Services Analyst Day Presentation 2005, 11/10/05

⁸¹ Mercer Human Resource Consulting, “Employees pay as much as 30 percent of drug cost; employers seek new ways to manage Rx benefit cost,” Mercer Health & Benefits releases large-employer pharmacy benefit survey New York, 31 October 2005.

⁸² Ibid

employers are realizing that pricing transparency is only a partial solution and that other changes are needed to truly manage the pharmacy benefit.”⁸³

The relatively modest demand for a fully transparent contracting model also is consistent with Medco’s characterization of its contract mix. Tim Wentworth, Group VP for National Accounts for Medco was recently quoted as saying:

“Five years ago, calls for transparency from employers didn't exist. But employers are becoming more sophisticated, and they want to know where their money is going in terms of pharmacy costs. Medco offers all of its clients a variety of contracting options, including pass-through pricing and agreements in which Medco agrees to disclose all discounts but still keeps a percentage of them. "Some employers don't want to pay administrative fees, but they want a better understanding of rebate sharing," he says. How common is each type of deal? "I'd say we have a small but significant number of pass-through arrangements; a larger number of transparent contracts in which we still share rebates; and an even larger percentage of clients who have audit rights, meaning they could have an auditor come in to ensure they are getting what they're paying for," Wentworth says.”⁸⁴

In sum, the evidence reveals that the marketplace is responding to the demand for greater transparency in a variety of ways. New firms have entered that specialize in pass-through contracting and transparency. In addition, traditional PBMs are competing with one another by offering greater disclosures and a menu of alternative contracting arrangements to their clients. This data supports the FTC view that marketplace competition is likely to produce an optimal amount of transparency and flexibility in PBM contracting arrangements.

V. Conclusions

Based solely on economic theory considerations, the case for PBM regulation appears weak. The market for PBM services is highly competitive, and there do not appear to be significant barriers preventing health plan providers from negotiating contract terms that provide appropriate levels of transparency and protect their interests against potential opportunistic behavior. While the large number of lawsuits and investigations indicate that some episodes of opportunistic conduct may have occurred, more comprehensive empirical evidence indicates that such conduct is not systematic in

⁸³ Ibid

⁸⁴ Margaret Ann Cross, “Transparency Catches Eye In Coalition's Deal With Medco,” *Managed Care Magazine*, March 2005.

the industry.

Evidence from the equity markets reinforces this conclusion by indicating that litigation and market responses have imposed substantial market sanctions on PBMs for potentially improper conduct and are reinforcing and accelerating marketplace changes in PBM behavior. This is consistent with the interpretations of health care analysts who have observed that litigation has a large effect on health care markets through its influence on market actors' perceptions and expectations.⁸⁵ Health providers change their business strategies and practices in response to consumers' and investors' concerns and in anticipation of adverse legal outcomes. Moreover, such changes often predate explicit regulatory actions. This suggests that litigation has acted as a more adaptive and flexible catalyst of change than broad-based regulation. The observation of M. Gregg Bloche and David M. Studdert, that "Markets are more agile than law" appears to apply to the PBM market as well as the HMO market they studied.

Broad based state regulatory efforts do not appear to be currently justified by existing empirical evidence and do run a significant risk of chilling pro-competitive business practices and raising prescription drug costs. While private losses in PBM equity values are not necessarily dispositive on the regulation debate, when combined with the weak theoretical basis for regulation and the other evidence that PBM self-dealing is not currently prevalent, the evidentiary bar that regulation proponents should have to clear appears to be quite high.

⁸⁵ See, e.g. M. Gregg Bloche and David M. Studdert, "A Quiet Revolution: Law As An Agent Of Health System Change," *Health Affairs*, Vol 23, Issue 2, 29-42.

Table 1

The Effect of Litigation and Regulation Events on the Stock Prices of Pharmacy Benefit Managers

Date	Express Scripts	Net of Market Stock Price Return ¹				Announcement
		Caremark	Advance PCS	Medco Health	PBM Average	
03/07/00	-17.6%	-11.5%	-50.0%		-26.4%	PCS Health Systems Inc and Merck-Medco Managed Care LLC received subpoenas in 1999 as part of a broad federal probe of drug-marketing practices.
05/03/02	-6.1%	-1.1%	-4.6%		-3.9%	Express Scripts revealed in a regulatory filing that it has been subpoenaed by the U.S. attorney's office in Boston.
05/10/02	-5.7%	-6.1%	-0.3%		-4.0%	Caremark Receives Subpoenas --Not Identified As Target
08/02/02	-7.8%	-4.5%	-15.6%		-9.3%	Advance PCS shares fall after report of Federal fraud inquiry
08/13/02	-12.3%	-9.0%	-6.9%		-9.4%	Express Scripts receives federal subpoena
07/02/04	-2.8%	-6.3%		-6.4%	-5.1%	Caremark Receives Subpoena Over Business Practices
07/28/04	-13.5%	-3.1%		-7.0%	-7.9%	Express Scripts reports that 19 states are investigating drug switching practices.
08/04/04	-3.1%	-3.0%		4.0%	-0.7%	Express Scripts accused of fraud by New York state.
10/20/04	-2.9%	-8.4%		-0.7%	-4.0%	PBMs take a hit over concerns that problems in the broader insurance sector -- which is targeted by New York Attorney General Eliot Spitzer for alleged bid-rigging.
04/26/04	0.2%	0.6%		4.7%	1.8%	MHS settles 2 year investigation by state AG and non-monetary issues in US whistleblower case.
02/02/05	0.8%	1.5%		0.1%	0.8%	A magistrate judge recommends that the court grant the Maine Attorney General's motion and deny PCMA's motion for summary judgment.
04/13/05	0.6%	-3.5%		-1.2%	-1.4%	Maine PBM law upheld in Federal District Court
11/08/05	-3.6%	-6.1%		-3.1%	-4.3%	Main PBM Law Upheld on Appeal
09/06/05	2.8%	2.4%	0.0%	6.5%	3.9%	FTC Issues Report on PBM Conflicts of Interest

1. Net of market returns are defined as percentage change in company stock price less percentage change in S&P 500 market index.

Table 2

The Estimated Effect of Litigation and Regulation Events on the Market Values of Pharmacy Benefit Managers

Year	PBM Equity Market Value (Thousands)¹	Net of Market Change in PBM Stock Prices²	Change in PBM Equity Value (Thousands)
1999	\$ 5,941		
2000	\$ 12,202	-24.4%	\$ (2,212)
2001	\$ 14,488		
2002	\$ 15,194	-24.7%	\$ (3,658)
2003	\$ 25,853		
2004	\$ 35,059	-13.0%	\$ (3,960)
2005	\$ 35,059	-4.8%	\$ (1,685)
Change in PBM Equity Value 2000-2004			\$ (9,830)
Change in PBM Equity Value 2005			\$ (1,685)
Total Change in PBM Equity Value			\$ (11,516)

Notes:

1. Calculated as average number of shares outstanding x average stock price during the year for the following publicly PBMS: Advance PCS, Caremark, Express Scripts, Medco Health Solutions.
2. Cumulative net of market returns during event windows identified in Table 1 and Table 3.

Table 3

**The Effect of Litigation and Regulation Events on the
Stock Prices of Pharmacy Benefit Managers**

Date	Express Scripts	Net of Market Stock Price Return ¹				PBM Average	Announcement
		Caremark	Advance PCS	Medco Health			
02/02/05	0.8%	1.5%		0.1%	0.8%	A magistrate judge recommends that the court grant the Maine Attorney General's motion and deny PCMA's motion for summary judgment.	
04/13/05	0.6%	-3.5%		-1.2%	-1.4%	Maine PBM law upheld in Federal District Court	
11/08/05	-3.6%	-6.1%		-3.1%	-4.3%	Main PBM Law Upheld on Appeal	
09/06/05	2.8%	2.4%	0.0%	6.5%	3.9%	FTC Issues Report on PBM Conflicts of Interest	

1. Net of market returns are defined as percentage change in company stock price less percentage change in S&P 500 market index.