

**TESTIMONY OF  
DAVID A. BALTO**

**Before the United States House of Representatives  
Committee on the Judiciary  
Antitrust Task Force**

**HEARING ON  
“THE IMPACT OF OUR ANTITRUST LAWS ON COMMUNITY  
PHARMACIES AND THEIR PATIENTS”**

**Thursday, October 18, 2007**

**9:30 a.m.**

**2141 Rayburn House Office Building**

**Testimony of David A. Balto**

**Before the Antitrust Taskforce of the House Judiciary Committee**

**The Impact of Our Antitrust Laws on  
Community Pharmacies and Their Patients**

**Thursday, October 18, 2007**

I appreciate the privilege of testifying before you today about the impact of our antitrust laws on independent community pharmacies and their patients. As I explain in my testimony, H.R. 971, the Community Pharmacies Fairness Act of 2007, is a necessary and appropriate response to a severe imbalance in the pharmaceutical distribution network. While Pharmacy Benefit Managers (PBMs) make record profits, independent pharmacies are driven from the market and consumers are suffering from anticompetitive and deceptive PBM practices. Efforts by independent pharmacies to collaborate to redress this imbalance or protect consumers are quashed by the threat of antitrust litigation. This legislation is a prudent response to this significant market imbalance and its enactment will benefit both consumers and competition.

I have practiced antitrust law for over twenty years, primarily as a public servant in the Antitrust Division of the Department of Justice and the

Federal Trade Commission.<sup>1</sup> At the FTC in the 1990s, I was attorney advisor to Chairman Robert Pitofsky and led the Policy Office of the Bureau of Competition.<sup>2</sup>

It is important that the Task Force is holding this Hearing on the impact of the antitrust laws on independent pharmacies. Independent pharmacies are a critical component to the delivery of drugs throughout the United States. They serve numerous underserved rural, inner-city and urban areas. Because of the face-to-face relationship with their local independent pharmacist, patients are more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions. Patient access to the thousands of independent pharmacies helps to lower health care costs by promoting patient health every day.

My testimony makes the following points:

- The pharmaceutical distribution market is broken. PBMs engage in a wide range of anticonsumer and fraudulent practices. There is a significant disparity in power between PBMs and independent pharmacies and PBMs exploit that disparity by forcing “take it or

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<sup>1</sup> In the past I have represented both chain and independent pharmacies, pharmacy benefit managers, insurance companies, and employers who have purchased PBM services. I testified on behalf of the State of Maine in *PCMA v. Maine* a case involving a Maine statute regulating PBMs. I also regularly represent consumer advocacy groups, such as the Consumer Federation of America, Consumers Union, U.S. PIRG and Families USA. A list of my recent public interest advocacy is listed in Appendix A.

<sup>2</sup> I have written numerous articles on healthcare and pharmaceutical antitrust, including what is considered one the seminal articles on collaboration by pharmacies. David A. Balto, “Cooperating to Compete: Antitrust Analysis of Healthcare Joint Ventures,” 32 *Saint Louis University Law Journal* 191 (1998).

- leave it” deals on independent pharmacies and preventing pharmacies from advocating on behalf of consumers;
- Collective negotiation by independent pharmacies is a necessary response to this disparity;
  - Consumers suffer if independent pharmacies cannot collectively negotiate;
  - The threat of antitrust liability prevents collective negotiation;
  - An antitrust exemption to permit collective negotiation is appropriate and consistent with past Congressional actions; and
  - Anticompetitive effects from an antitrust exemption are highly unlikely because independent pharmacies are too small to have market power.

#### I. The Broken Market of Pharmaceutical Distribution

Seven years ago, Congress considered, and the House of Representatives passed the Health Care Quality Coalition Act, H.R. 1304, a bill co-sponsored by Congressmen Campbell and Conyers (and 220 other members). Part of the reason for the Act was the significant imbalance in the market between large insurers and healthcare providers and the belief that collective negotiation would and “will create a more equal balance of negotiating power, will promote competition and will enhance the quality of patient care.”

These concerns are now even greater seven years later. Both the health insurance and PBM markets have become significantly more concentrated as continual consolidation has gone unabated by antitrust enforcement. The top three PBMs have become industry giants with almost

\$2 billion in annual revenue. At the same time independent pharmacies have average sales below \$3.5 million annually and these entrepreneurs are increasingly being driven out of the market by anticompetitive and coercive PBM tactics.

Over the past seven years there have been over a score of PBM acquisitions that have led to three firms – Express Scripts, CVS/Caremark, and Medco—dominating the market. None of these acquisitions have been challenged by the FTC. In fact, the merger that eliminated the fourth largest firm, (Caremark’s acquisition of Advance PCS) was resolved based on merely a “quick look” review and CVS’ subsequent acquisition of Caremark was completed without a Second Request for additional information.<sup>3</sup> These three firms now have over 200 million covered lives and are significantly larger than any of their rivals.<sup>4</sup> Simply no pharmacy, whether independent or chain, can survive without serving the major PBMs. Not surprisingly the result has been higher costs for the buyers of PBM services, substantially reduced fees for independent pharmacies and higher co-pays for consumers.

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<sup>3</sup> The law firm that represented one of the parties in the Caremark/AdvancePCS merger observed that the investigation was closed on a “quick look” review. See [http://www.jonesday.com/experience/experience\\_detail.aspx?exID=S9298](http://www.jonesday.com/experience/experience_detail.aspx?exID=S9298). This means that the Commission did not conduct a full investigation of that merger.

<sup>4</sup> A description of the competitive problems in the PBM market and the exercise of market power by PBMs is contained in a recent white paper to the FTC. “Express Script’s Proposed Acquisition of Caremark: An Antitrust White Paper,” Sept. 6, 2006. [http://www.antitrustinstitute.org/archives/files/AAI\\_Express%20Scripts\\_Caremark\\_2-14\\_021520071110.pdf](http://www.antitrustinstitute.org/archives/files/AAI_Express%20Scripts_Caremark_2-14_021520071110.pdf)

The PBM market has become a tight oligopoly and the results are predictable. The Wall Street Journal recently observed that healthcare networks have not functioned effectively and middlemen (especially PBMs) often exercise market power to the detriment of consumers:

[W]hile the Internet, deregulation and relentless corporate cost-cutting have squeezed middlemen elsewhere, the health-care middlemen are prospering. **The three largest pharmaceutical benefit managers, for instance, had net income of \$1.9 billion last year, a sum that exceeds the annual operating budget of New York's Sloan Kettering cancer center.** In corners of the system such as Medicaid managed care and nursing-home drugs, little-known intermediaries rack up tens or hundreds of millions of dollars in profit.<sup>5</sup>

PBMs have used their power to drive independent pharmacies out of business or close to their breaking point. PBMs have consistently driven reimbursement rates down, even though they often deceive the plan sponsors as to the actual dispensing rates.<sup>6</sup> Almost all PBMs own mail order operations and they seek to drive consumers to more highly profitable mail order distribution and away from independent pharmacies that offer the level of quality, advice and personal service consumers prefer. Unfortunately, consumers often suffer from the conversion to mail order: they are given little choice, there is a greater chance of adverse reactions, and there is little

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<sup>5</sup> Barbara Martinez, et al., "Health-Care Goldmines: Middlemen Strike it Rich," *Wall Street Journal*, A1 (December 29, 2006).

<sup>6</sup> Many of the deception and fraud cases brought against PBMs allege that they have "played the spread" suggesting to plan sponsors that they provide a higher dispensing rate than actually paid to pharmacies.

if any consumer service. Any consumer who has spent hours on the phone waiting for an answer on a mail order prescription sees little “efficiency” from driving independent pharmacies from the market.

Moreover, the PBM industry has been plagued with precedent-setting enforcement actions, and substantial allegations of fraudulent, deceptive, and anticompetitive conduct. As a bipartisan group of state legislators has noted:

We know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, especially in a market with such a significant impact on taxpayers. Simply put, throughout the United States, numerous states are devoting considerable enforcement resources to combating fraudulent and anticompetitive conduct by PBMs. This is because those activities are taking millions of taxpayer dollars and denying government buyers the opportunity to drive the best bargain for the state.<sup>7</sup>

In the past three years alone, cases brought by the U.S. Department of Justice (DOJ) and State Attorneys Generals (AGs) have secured over \$300 million in penalties and fines for deceptive and fraudulent conduct by the major PBMs.<sup>8</sup> Several investigations of the three major PBMs continue by a group of AGs and the DOJ. The current concentrated nature of the national PBM market has exacerbated these problems and has increased the need for

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<sup>7</sup> Letter from Senator Mark Montigny to FTC Chairman Deborah Platt Majoras (May 11, 2005).

<sup>8</sup> A description of these enforcement actions and other cases challenging anticompetitive and fraudulent conduct by PBMs is contained at Appendix B.

both government enforcement and potential regulatory oversight of the PBM industry.<sup>9</sup>

## II. Collective Negotiation by Pharmacies is Necessary Response to a Broken Market

No one testifying today can dispute that there is a significant bargaining imbalance between PBMs on the one hand and independent pharmacies on the other hand. PBMs and insurance companies have tremendous power in the market because of their size and their concentration in the market. This power is typically called *monopsony* or *oligopsony* power. With this power, PBMs, either individually or collectively, are able to drive compensation below competitive levels.<sup>10</sup> The result is that independent pharmacies have been driven out of business at a rapid rate, thereby reducing consumer choice, increasing waiting times, and increasing quality-adjusted prices for consumers.<sup>11</sup> Consumers who prefer the level of personal service they receive at their independent pharmacy suffer. The

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<sup>9</sup> These practices are similar to those identified by Chairman Conyers as the reason for enactment of H.R. 1304 an earlier immunity bill: “The dangers posed by the ever-increasing market concentration are exacerbated by the practice of health insurers engaging in rather heavy handed negotiating tactics, in some instances requiring exclusionary contractual commitments from health care providers. These restrictive terms are frequently offered on a take-it-or leave it basis under the threat of the loss of the provider’s patients or exclusion from access to their patients.” Hearings Transcript at 5.

<sup>10</sup> As Judge Hopkins in an antitrust case brought against PBMs has observed, “By conspiring to hold down prices paid to independent pharmacies (among other alleged action), PBMs would bankrupt those pharmacies, thereby capturing a larger segment of the insurance paid prescription market for the PBM’s own prescription dispensing business and allowing the PBMs to charge higher prices for that service.” (*N. Jackson Pharm., Inc. v. Express Scripts, Inc.*, 345 F. Supp. 2d 1279, 1292)

<sup>11</sup> These are particularly serious concerns for rural consumers. Over 58% of independent pharmacies are located in an area with a population of less than 20,000.



individual care and attention these pharmacists provide may become of relic of the past due to the anticompetitive conduct of the major PBMs.

Moreover, there is a second imbalance in the market. Independent pharmacies compete against much larger chain pharmacies, with billions of dollars of sales, thousands of stores and their own mail order operations. Many chains such as CVS and Walgreens own their own PBMs. As such the chain pharmacies have a superior bargaining position than independent pharmacies. As described below, independent pharmacies cannot secure a similar position because the threat of antitrust liability prevents them from jointly bargaining. Thus, the threat of antitrust litigation currently places independent pharmacies at a significant competitive disadvantage to chain pharmacies, and as a result, patients and customers are suffering.

The inability of independent pharmacies to jointly negotiate also prevents them from advocating for consumers with the PBMs on the fraudulent and deceptive practices that have led to the numerous enforcement actions described above. Because PBMs have oligopolistic power, they are able to force a “contract of adhesion” on independent pharmacies. The result is that independent pharmacies have little choice but to accept one-sided, non-negotiable service agreements, often contracts with provisions that harm consumers. Some of the practices include:

- preventing independent pharmacies from dispensing 90 days of medication;
- impeding independent pharmacies from adequately counseling their patients;
- requiring “all product clauses” that require pharmacies to participate in all plans of a PBM, even at an adverse reimbursement rate;
- preventing pharmacies from informing consumers of less expensive and more appropriate prescriptions; and
- forcing onerous contract requirements and significant contract penalties.

PBMs may assert they are simply trying to derive the best bargain for their “customers”--the “plan sponsors”--that buy PBM services.<sup>12</sup> But PBMs do not engage in these practices simply because they are trying to derive the best bargain. PBMs have their own mail-order operations, which are typically far more profitable to the PBM than dispensing through independent pharmacies. Thus, it is in the PBM’s interest to drive independent pharmacies from the market, and to compel consumers to use mail-order distribution where they make significant profits by increasing the volume of transactions they conduct through this method and the rebates from drug manufacturers.

### III. Consumers Suffer When Pharmacies cannot Negotiate

In this larger battle to control healthcare costs, the question often arises: Who will speak for the consumer? As I articulated in recent

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<sup>12</sup> A plan sponsor is the employer, union, or insurance company that purchases the PBM services.

testimony to the Nevada Insurance Commissioner on the United Healthcare/Sierra merger, perhaps the party in the best position to advocate for consumers in a managed care environment is the healthcare provider itself.<sup>13</sup> The healthcare provider is the sole actor who has a face-to-face relationship with the healthcare consumer. Actions by managed care entities reduce the quality of care directly and also negatively impact the healthcare provider. Moreover, the healthcare provider, because of their ethical obligations as a healthcare professional, has a responsibility to not only protect the interest of the consumer but also to provide a high quality of care. Insurance companies and PBMs directly interfere with the ability of the healthcare provider to fulfill this obligation.

When healthcare providers (including pharmacies) are essentially forced to accept a “take it or leave it offer,” both the provider and the consumer suffer. The insurers and PBMs can reduce compensation to such a level that the healthcare provider has to increase volume, reduce the level of service, increase waiting times, and reduce staff or close its business. Moreover, this take-it-or-leave-it environment healthcare providers from

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<sup>13</sup> Testimony of David Balto on behalf of the American Antitrust Institute and Consumer Federation of America Before the Nevada Commissioner of Insurance on the United Health Group Proposed Acquisition of Sierra Health Services, July 27, 2007.

being able to expand, innovate, and provide new services.<sup>14</sup> In the pharmacy environment the PBM's unbridled power prevents independent pharmacies from increasing staffing, and adding additional services such as blood pressure, cholesterol, or lipid screening, or ongoing counseling programs.

Enabling independent pharmacies to negotiate will allow the pharmacist to serve as advocate for the consumer, addressing some of the anticonsumer conduct addressed above. Some of the issues a pharmacy collaboration could negotiate over include:

- the level of disclosure to consumers (especially of copay requirements),
- dispensing 90-day prescriptions,
- limitations on formularies that restrict patient treatment options;
- onerous pre-authorization requirements; and
- and adequate notice and approval of drug switches.

#### IV. The Threat of Potential Antitrust Liability Prevents Independent Pharmacies from Collaborating

As you well know, the antitrust laws provide relatively few bright line proscriptions on conduct. Although this can be beneficial, as it enables the law to evolve as markets evolve, it can also be harmful to the extent that antitrust uncertainly prevents efficient or competitively neutral conduct.

Antitrust law imposes potentially severe penalties for violation: treble damages, attorneys fees, and costs. In addition, the cost and time of antitrust

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<sup>14</sup> See *United States v. Aetna*, Revised Complaint Impact Statement, Civil Action 3-99CV1398-H (N.D.Tex, 1999).

litigation can be extremely burdensome. Thus, the mere threat of antitrust litigation can often prevent procompetitive or competitively neutral conduct.

Unfortunately PBMs, with their substantial resources, are more than ready to exploit antitrust uncertainty and use the threat of antitrust litigation to stifle collaboration by independent pharmacies. When these pharmacies make any material attempt to collaborate or collectively negotiate, they are met with an all-too willing antitrust litigation adversary. In those cases, independent pharmacies face the threat of treble damage liability as well as the costs of exhaustive discovery.<sup>15</sup> In effect, pharmacies are “gagged” at the bargaining table by this threat of antitrust litigation.

Moreover, because of uncertainty in the law the PBMs can allege that these arrangements are per se illegal, rather than illegal under the rule of reason. That means that a PBM plaintiff need not demonstrate that some pharmacy collaboration actually harmed competition or led to higher prices. Under the per se rule a collaboration between two small pharmacies could face antitrust liability, even though it is indisputable that it could not cause anticompetitive harm.

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<sup>15</sup> A good example of this is the antitrust suit brought by Merck-Medco against an alliance of independent pharmacies in Maryland in the mid-1990s. Although the case was ultimately dismissed because the Court held “no genuine issue ... existed on the issue...that the defendants conspired to boycott,” the litigation took over three years and cost millions of dollars to defend.

I would expect some to suggest that pharmacies could receive approval for collaborations under the Healthcare Policy Statements, but I would not consider that to be a viable option. History has shown the limited avenue for approval under the Health Care Policy Statements. The process and cost of approval can be daunting. It can take several months and cost the providers considerable legal fees. Not surprisingly only physician groups consisting of hundred of providers have been able to survive this process and the FTC has cleared less than a handful of these arrangements in the past seven years. Independent pharmacies simply lack the resources to survive this time-consuming and expensive process.<sup>16</sup>

The question being evaluated by the agencies in these matters is not whether the collaboration can be competitively harmful. Rather, the question is simply whether the collaboration is per se illegal. Thus, under the agencies' approach, collaboration even by a small group of providers can be condemned even if there is indisputably no likelihood of any adverse impact on consumers.

#### V. An Antitrust Exemption is Appropriate

Antitrust exemptions and immunities are not favored by antitrust enforcers. Sometimes antitrust exemptions can be used to create market

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<sup>16</sup> In addition, even if an entity can secure a staff advisory opinion under the Policy Statements, that opinion does not prevent later private litigation.

power or prevent the forces of competition from working. A good example of this is the McCarran-Ferguson Act which provides broad immunity to insurance companies. This is an exemption that has clearly outlived its utility.

On the other hand, in other cases limited antitrust exemptions may serve important social, political, or competition goals. The antitrust laws are not perfect. Congress has recognized on several occasions the need to provide exceptions to the antitrust laws for a wide variety of reasons. Sometimes Congress has enacted exemptions to protect the interests of individuals and firms who need some degree of countervailing power to assure a competitive market. In other cases Congress has acted prudently to afford firms antitrust exemptions when antitrust liability (or the threat of antitrust liability) prevented conduct which ultimately benefited consumers. The proposed legislation is consistent with both of these objectives.

#### Countervailing power

As discussed above, permitting pharmacy collaboration will fulfill numerous procompetitive and proconsumer goals. Creating countervailing power that may curb the monopsony or oligopsony power of PBMs will ultimately benefit consumers and independent pharmacies. With greater power at the bargaining table independent pharmacies can negotiate for

better terms, more disclosure and greater choice. Congress has acted to permit small firms to create some level of countervailing power. For example, the Capper-Volstead Act protects the ability of small farmers to form agricultural cooperatives to sell their products collectively.<sup>17</sup> Absent the Capper-Volstead Act, large agricultural processors could exercise their monopsony power and drive numerous farmers out of business. H.R. 971, in a similar fashion, redresses the bargaining imbalances between independent pharmacies and PBMs.<sup>18</sup>

#### Resolving antitrust uncertainties to protect procompetitive conduct

The antitrust laws, of course, are elastic. And as such, these laws are often interpreted in ways that deter competitive conduct. In some cases, the mere threat of the potential liability, cost and time of antitrust litigation deters market participants from engaging in collaborative conduct which could ultimately benefit competition and consumers. Congress has acted on a number of occasions to protect the interests of rivals to engage in conduct that may prospectively be procompetitive. Such exemptions include the National Cooperative Production Research Act, the Standards Development

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<sup>17</sup> 7 U.S.C. § 291.

<sup>18</sup> The benefits of facilitating countervailing power by granting an antitrust immunity are discussed in “Antitrust Immunities and Exemptions”, prepared for the December 1, 2005 Hearing of the Antitrust Modernization Commission by Professor Peter C. Carstensen.



Organization Advancement Act, the Charitable Donation Antitrust Immunity Act, and the Medical Resident Matching Program Act.

As discussed earlier, the threat of antitrust litigation deters procompetitive collaboration among independent pharmacists. Some might suggest that antitrust uncertainty is simply the cost of doing business that most businesses have to shoulder. Congress clearly has not accepted that notion. By enacting the Standards Development Organizations Advancement Act, Congress was protecting the interests of prosperous high tech firms such as Dell, Intel and Hewlett Packard. If these large companies needed protection from antitrust litigation aren't independent pharmacies even more vulnerable and thus also deserving of protection?

VI. There is no Likelihood of Anticompetitive Effect from the Legislation

One can expect that the opponents of the legislation will suggest anticompetitive results from permitting independent pharmacies to negotiate. They will suggest that pharmacists will be able to secure market power by collaborating and use that market power to charge PBMs supracompetitive prices for access to their pharmacies. Such arguments are clearly unsupported by the facts.

On occasion, the FTC has recognized the potential for chain pharmacies to raise prices to PBMs by acquiring market power through

mergers. In the mid-1990s, for example, the FTC challenged the merger of Rite Aid and Revco because it would have given the merged firm the ability to raise the rate of compensation to PBMs.

More recently, the FTC appears to have found that these concerns over the exercise of market power by chain pharmacies over the PBMs have diminished. In its evaluation of Rite Aid's acquisition of Eckerd, the third and fourth largest pharmacy chains in the U.S., the FTC carefully evaluated the impact on several geographic markets. Even though the merged firm's post-merger market share exceeded 40% in numerous upstate New York metropolitan markets, the FTC did not seek relief in any of those markets. Nor did they seek relief to protect PBMs from the exercise of market power by the merged firm. The FTC did require the divestiture of over 20 stores in numerous markets to protect "cash paying customers," those without insurance coverage, but again they found it unnecessary to protect the PBMs.

The FTC's action in the Rite Aid merger suggests that in the context of pharmacies exercising market power against PBMs a market share substantially above 40% is necessary to pose a competitive threat. It seems highly unlikely that there are many markets where independent pharmacies exceed a 40% market share. Moreover, it seems unlikely that any

collaboration would necessarily include all independent pharmacies. It seems highly dubious that any independent pharmacy collaboration could be large enough to turn the tables and extract supracompetitive prices from powerful PBMs.

VII. The Reasons to Oppose Collective Negotiation are even less persuasive than they were in 2000

As you know, this Committee and the House of Representatives passed the Healthcare Quality Improvements Act of 2000. That Act provided the same antitrust exemptions as H.R. 971 for all healthcare providers, including doctors, dentists, and other types of healthcare professionals. When the bill was proposed there was a well-funded and well-organized opposition by insurance groups. The opposition to the bill consisted of basically two arguments. First, legislation was unnecessary because collective negotiation could be permissible under the DOJ/FTC Healthcare Policy Statements. Second, if there was a problem with the bargaining imbalance, the answer was stronger enforcement against health insurer and PBM anticompetitive conduct and mergers. Yet in both respects, history has proven the arguments of the opponents to the legislation wrong.

As to collective negotiation, in the seven years since the legislation was passed, the FTC has approved less than a handful of physician-based joint ventures. The physician-based joint ventures that were approved, came

only after extensive investigations that cost those physician groups (which were very large physician groups) hundreds of thousands of dollars.

As to the suggestion that the proper response to anticompetitive behavior was to attack anticompetitive mergers or anticompetitive practices, the Antitrust Division and the FTC have simply not stepped up to the plate. In the past seven years, the Division and the FTC have brought no cases against anticompetitive conduct by insurance companies or PBMs, even though state enforcement officials and private plaintiffs have brought numerous actions. Moreover, the FTC has not challenged any PBM merger, and the Antitrust Division has challenged just a single insurance merger. Not surprisingly, in the last seven years both the PBM and the insurance markets have become far more concentrated. To the extent that this Committee and the House of Representatives recognized the need for this legislation in 2000, that need is far more substantial today.

#### VIII. Conclusion

The pharmaceutical distribution system has significant problems. Consumers value the work of their pharmacist more than any other participant in the distribution system. PBMs have a level of market power so substantial that they can effectively coerce independent pharmacies into arrangements that keep them barely viable. Through the threat of antitrust

litigation, PBMs can effectively gag pharmacies from advocating on behalf of consumers, and from helping to prevent anticompetitive practices by PBMs. H.R. 971 should be enacted to eliminate this antitrust uncertainty and allow independent pharmacies to fully participate in the marketplace.

## Appendix A: Public Interest Advocacy

- Testimony before the Antitrust Subcommittee of the Senate Judiciary Committee on the competitive impact of the XM/Sirius Merger. (Mar. 20, 2007)
- Advocacy on behalf of the American Antitrust Institute in opposition to the Express Scripts/Caremark merger. (white paper to FTC, Feb. 2007)
- Testimony on behalf of the American Antitrust Institute, Consumer Federation of America and Consumers for Healthcare Choices before the Nevada Commissioner of Insurance in opposition to United Healthcare's acquisition of Sierra. (July 27, 2007)
- Advocacy on behalf of the National Black Farmers Alliance in opposition to the Monsanto/Delta Pine merger. (Mar. 2007)
- Advocacy on behalf of the Organization for Competitive Markets, the National Farmers Union, and the UFCW in opposition to the Premium Standard/Smithfield merger (Sept. 2006)
- Advocacy on behalf of several consumer groups in opposition to SCI/Alderwoods merger. (May 2006)
- Advocacy on behalf of the Consumers Union, Consumer Federation of America, and U.S. PIRG in opposition to the FTC's proposed Consent Order against Kmart for deceptive marketing of gift cards. (Apr. 2007)
- Testimony before the State Legislature of Texas on PBM reform legislation. (Nov. 2006)
- Testimony before the State Legislature of Vermont on PBM reform legislation. (Apr. 2007)
- Testimony before the State Legislature of Iowa on PBM reform legislation. (Mar. 2006)

- Testimony before the State Legislature of Arkansas on PBM reform legislation. (Feb. 2006)
- Testimony before the City Council of the District of Columbia on PBM reform legislation. (Jun. 2006)
- Amicus brief on behalf of the American Antitrust Institute and Consumer Federation of America in *Broadcom v. Qualcomm* (Third Cir., Dec. 2006).
- Amicus brief on behalf of American Antitrust Institute and Consumer Federation of America in *McKenzie v. Peace Health* (Ninth Cir., Mar. 2007).
- Amicus brief on behalf of Consumer Federation of America, Consumers Union and Families USA in *DDAVP Antitrust Litigation* (Second Cir., May 2007).
- Amicus brief on behalf of American Antitrust Institute, Consumer Federation of America, and Organization for Competitive Markets in *FTC v. Whole Foods* (D.D.C., Aug. 2007).

## Appendix B: PBM Litigation

### **Ongoing Federal and State Litigation Regarding Pharmacy Benefit Managers**

**David A. Balto  
September 2007**

#### **I. *Qui Tam* – “Whistleblower” Lawsuits**

*United States, ex rel. George Bradford Hunt and Walter W. Gauger, et al. v. Merck & Co., Inc., Merck-Medco Managed Care, L.L.C. and Medco Health Solutions, Inc., and United States, ex rel. Joseph Piacentile v. Merck & Co., Inc. and Merck-Medco Managed Care, L.L.C.; Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania; Judge Anita B. Brody. (Also cited as *United States of America v. Merck-Medco Managed Care L.L.C., et al.*)*

In these whistleblower lawsuits, complaints were filed under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc. (“Medco”). The cases allege that Merck and Medco systematically defrauded government-funded health insurance programs by accepting kickbacks in exchange for referring patients to certain products, secretly accepting rebates from drug manufacturers in exchange for increasing product market share, secretly increasing long-term drug costs, and failing to comply with state-mandated quality of care standards. This manner in which this was done included: (1) inducing physicians to switch patient medications (drug interchange) by providing misleading, false or incomplete information that subverted patient care to profit motives; (2) secretly increasing the cost of drugs provided to beneficiaries by knowingly interchanging patients’ medications to prevent them from taking advantage of soon to be released available generic drugs; and, (3) violating basic state requirements governing pharmacist supervision of prescription drug fulfillment processes. Through such conduct the United States alleges that Merck and Medco violated their contracts with government-funded health insurance programs.

These cases were brought by the whistleblowers on behalf of the United States. The *Hunt and Gauger* amended complaint was filed on March 18, 2003. The *Piacentile* complaint was filed on February 10, 2000. On June 20, 2003, the United States intervened following an extensive investigation of the factual allegations and evidentiary support provided by the relators. This investigation was conducted by numerous federal agencies, including the U.S. Attorney’s Office, the Eastern District of Pennsylvania, the Office of Inspector General of the Office of Personnel Management, the Office of Inspector General of the Department of Health and Human Services, and the Defense



Criminal Investigative Service. On December 9, 2003, the United States amended its complaint adding two executives of Medco as defendants. In the amended complaint these executives were accused caused of (1) covering up the intentional destruction of patient prescriptions, (2) destroying and directing the destruction of patient prescriptions, and (3) making misleading statements about the cover-up when questioned by the Department of Justice. The amended complaint also added a count against Medco under the Public Contract Anti-Kickback Act for making improper payments to health plans to induce them to select Medco as a pharmacy benefit manager for government contracts.

On April 26, 2004, the United States, 20 state attorneys generals, and the defendants agreed to a settlement of claims for injunctive relief and unfair trade practice laws.<sup>19</sup> A separate consent order was filed by the states to cover the injunctive and monetary claims. This order instructs Medco to pay \$20 million to the states in damages, \$6.6 million to the states in fees and costs, and about \$2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. The consent order filed in the federal district court of the Eastern District of Pennsylvania excluded claims for damages, penalties, or restitution under federal statutes and common law.

The settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care 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 the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and

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<sup>19</sup> 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.

- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

On October 23, 2006 a final settlement in this case was reached with Medco agreeing to pay \$155 million. As part of the settlement agreement, Medco and the government entered into a consent decree that includes prohibitions on drug switches resulting in the dispensing of more expensive drugs or drugs without generic substitutes.

The consent decree requires Medco to:

- Disclose to prescribing physicians any material safety and efficacy differences between the switched drugs.
- Disclose to both prescribing physicians and patients the fact that it receives payments from pharmaceutical manufacturers for drug switching that do not inure to the benefit of the health plan.
- Disclose in its communications with patients and physicians the role of its Pharmacy and Therapeutics Committee in initiating, reviewing, approving or endorsing the drug switch.
- Provide a periodic accounting of payments to health plans that have contracted to receive from Medco any manufacturer payments (*e.g.*, rebates or market share incentives paid by manufacturers).
- Disclose to existing or prospective health plan clients, in advance of executing an agreement with the health plan, the fact that Medco will solicit and receive manufacturer payments and may or may not pass such payments through to the plans.

As part of the settlement, Medco and the Department of Health and Human Services Office of Inspector General entered into a corporate integrity agreement (CIA) as a condition of Medco's continued participation in government health programs. The CIA will last for a period of five years, and requires that agreements under which Medco receives payments from manufacturers (*e.g.*, rebates and market share incentives) be in writing and meet certain conditions.

***United States of America, et al. v. AdvancePCS, Inc. (Case No. 02-cv-09236); U.S. District Court for the Eastern District of Pennsylvania; Judge Norma L. Shapiro.***

In this whistleblower lawsuit, like the ones described above, the complaint was filed under the federal False Claims Act. The complaints, the first of which was filed in 2002 on behalf of the United States against AdvancePCS, Inc, acquired by Caremark Rx Inc. in 2004, allege the PBM knowingly solicited and received kickbacks from pharmaceutical manufacturers. These kickbacks were allegedly paid in exchange for favorable treatment of the manufacturers' products under contracts with government programs, including the Federal Employees Health Benefit Program, the Mailhandlers Health Benefit Program

and Medicare + Choice programs. The lawsuit also alleges that improper kickbacks were paid by AdvancePCS to existing and potential customers as an inducement to their signing contracts with the PBM, and that excess fees paid to AdvancePCS in connection with fee-for-service arrangements resulted in the submission of false claims. The government also incorporated in the Settlement Agreement allegations involving flat fee rebates which were allegedly received for inclusion of certain heavily utilized drugs.

This case was brought by the whistleblowers on behalf of the United States. The first complaint was filed on December 20, 2002. The first amended complaint was filed on April 11, 2003; both complaints filed under seal. On September 8, 2005, AdvancePCS, Inc. agreed to a \$137.5 million fee and a five-year injunction and settlement agreement with the United States Department of Justice and the U.S. Attorney's Office in the Eastern District of Pennsylvania. This landmark litigation will impose extensive forthcoming requirements on AdvancePCS which are designed to promote transparency and restrictions on drug interchange programs.

The settlement requires AdvancePCS to:

- Disclose in new or amended contracts with Client Plans, descriptions of the products and services provided and amounts paid;
- Use the same national data source for pricing to Client Plans and reimbursement to the dispensing pharmacy;
- Provide Client Plans access to information reasonably necessary to audit contract compliance;
- Disclose to each client with an existing or proposed contract that it receives Manufacturer Payments that may or may not be passes through to the Client Plans;
- Disclose to each client with an existing or proposed contract that it will provide quarterly and annual reports detailing the net revenue from sales of prescription drugs to clients and manufacturer payments for the reporting period as a percentage of the net revenue within a range of three percentage points;
- Ensure that contracts with pharmaceutical manufacturers describe all discounts, rebates, administrative fees, fees for service, data utilization fees or any other payments paid to or received by either party;
- And reimburse plan participants for costs related to drug switches up to \$200;

AdvancePCS has also entered into a standard five-year Corporate Integrity Agreement, which includes the requirements of training, policies, a confidential disclosure program, and certain hiring restrictions. Additionally, AdvancePCS is required to develop procedures to ensure that any payments between them and pharmaceutical manufacturers, clients and others do not violate the Anti-Kickback Statute of Stark Law. AdvancePCS must hire an Independent Review Organization to evaluate the adequacy of these procedures.

## **II. Other Federal District Court Lawsuits**

*North Jackson Pharmacy, Inc., et al. v. Medco Health Solutions, Inc., et al.*- On October 1, 2003, three related lawsuits were filed in the U.S. District Court for the Northern District of Alabama against Advance PCS and Caremark (Case No. CV-03-2695), Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc. (Case No. CV-03-2697). In these actions, *North Jackson Pharmacy* plaintiffs allege that the PBM defendants engaged in price fixing and other unlawful concerted actions to restrain trade in the dispensing and sale of prescription drugs. The complaint alleges that the defendants actions have harmed participants in programs or plans who have purchased their medications from retail pharmacies. *North Jackson Pharmacy* plaintiffs allege that the defendants engaged in various forms of anticompetitive conduct citing violations of the Sherman Act, including: (1) setting pharmacy reimbursement rates at unreasonably low levels; (2) imposing vertical maximum prices restrictions for how much pharmacies can charge PBMs and how much the PBMs may reimburse the retail pharmacies; and (3) operating illegal tying arrangements through horizontal price-fixing.

On October 13, 2004, the court in the Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc (Case No. CV-03-2697) cases denied defendants' motion to dismiss the second amended complaint. (*see* Opinion Regarding Motion to Dismiss Second Amended Complaint, October 13, 2004). The defendants alleged that the *North Jackson Pharmacy* plaintiffs' allegations failed to convincingly explain how consumers or the marketplace were injured as a result of the defendants' alleged anticompetitive behavior. The court, however, ruled that the complaint provided the PBMs and drug manufacturers with fair notice as to the nature and basis of the claims set forth against them. On November 1, 2004, defendants filed their answers to the second amended complaint. These cases were then transferred to the US Dist. Court for the Eastern District of Pennsylvania on September 15, 2006 with Judge John P. Fullam presiding (2:06CV04114 and 2:06CV04115 respectively).

On August 3, 2004, the *North Jackson Pharmacy, Inc. v. Caremark Rx, Inc.* case (Case No. CV-03-2695) was transferred to the U.S. District Court for the Northern District of Illinois. (Case No. 04-c-5674). In November 2004, citing to the Alabama court's October 13 denial of defendants' motion to dismiss in the related actions, the Illinois court also denied Caremark's motion to dismiss (*see* Memorandum Order, November 2, 2004). Accordingly, that court proceeded and on November 19, 2004 heard arguments on class certification. On March 22, 2006, this case was transferred to another Judge within the same court, Judge Samuel Der-Yeghiayan who consequently dismissed the case without prejudice on March 24, 2006 allowing plaintiff to file a motion to reopen the case within 10 days. Case was reopened on April 12, 2006, but was transferred to the US Dist. Court for the Eastern District of Pennsylvania on September 16, 2006 with Judge John P. Fullam presiding (2:06CV04305).

***Pharmaceutical Care Management Association v. the District of Columbia, et al.*** - On June 29, 2004, the Pharmaceutical Care Management Association (PCMA) filed suit in the U.S. District Court for the District of Columbia (Civil No. 04-cv-01082) seeking an injunction to block enforcement of Title II of the Access Rx Act of 2004. Title II of this Act requires transparent business practices among PBMs and states that PBMs owe a fiduciary duty to a covered entity. The Act requires that PBMs notify a covered entity of any conflict of interests, and that PBMs pass payments or benefits on in full to a covered entity where the PBM has received from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs by covered individuals, including payments or benefits based on volume of sales or market share. The Act also requires that PBMs, upon request by a covered entity, must provide information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs (including all rebates, discounts, and other similar payments). It requires that PBMs disclose to covered entities all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler. Finally, the Act sets forth certain provision which must be applied to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual.

In its lawsuit, PCMA argues that Title II is pre-empted by ERISA and the Federal Employees Health Benefits Act in determining who is (and who is not) a fiduciary of an ERISA-covered plan and FEHBA's comprehensive regulation of federal employee plans. Second, PCMA asserts that the law's disclosure requirements effect an unconstitutional taking of PBMs' property by destroying the value of trade secrets. And, finally, in seeking an injunction, PCMA argues that Title II violates the Commerce Clause of the Constitution. AARP has filed a motion for leave to file an *amici curiae* brief in support of defendants (*see* Motion for Leave to File a Brief *Amici Curiae*, July 22, 2004).

On December 21, 2004, the Court granted PCMA's motion for interim injunctive relief enjoining the District of Columbia from enforcing Title II of the Act. The court concluded that the plaintiff had demonstrated substantial likelihood that at least part of Title II may be unconstitutional; that aspects of Title II would represent an illegal takings of private property; and, that Title II could have the unintended effect of actually driving the PBM business and its attendant benefits out of the District of Columbia. That decision is being reconsidered in light of the decision in *PCMA v. Rowe*.

***Pharmaceutical Care Management Association v. Rowe*** – This lawsuit filed on September 3, 2003, in the U.S. District Court for the District of Maine (Civ. No. 03-153-B-W), seeking declaratory and injunctive relief from LD 554 with regard to the fiduciary obligations and disclosure requirements set forth in this Maine law enacted in 2003. LD 554 imposes extensive duties of disclosure from the PBM to the client, including the duty to disclose: (1) any “conflict of interest”; (2) “all financial and utilization information requested by the covered entity relating to the provision of benefits”; and, (3) “all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler, including, without limitation,

formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees. . . .” While the Act allows a PBM to substitute a lower-priced generic drug for a therapeutically equivalent higher-priced prescriptive drug, it prohibits the PBM from substituting a higher-priced drug for a lower-priced drug unless the substitution is made “for medical reasons that benefit the covered individual” and the “covered entity”. The Act also imposes disclosure and approval obligations on the PBM before any drug interchange. It also requires that benefits of special drug pricing deals negotiated by a PBM be transferred to consumers rather than being collected as profit by a PBM. The Act contains a limited confidentiality provision, as well: if a covered entity requests financial and utilization information, the PBM may designate the information as confidential and the covered entity is required not to disclose the information except as required by law.

In its lawsuit, PCMA alleged violation of the Commerce Clause by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies; and, “taking” of property for which just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. PCMA also argued that ERISA preempts this state law. On March 9, 2004, a decision by the judge temporarily blocked the implementation by issuing a preliminary injunction of LD 554. On April 13, an order was issued by U.S. District Judge D. Brock Hornby that rejected PCMA’s challenge to the Maine statute.

Pharmaceutical Care Management Association appealed and the case went to the U.S. Court of Appeals for the First Circuit (Case No. 05-1606). Trial began on April 26, 2005.

On November 8, 2005 the federal district court granted summary judgment in favor of Maine on all claims. Furthermore, the First Circuit Court of Appeals upheld this decision unanimously blocking the attempted PBM strike down of a Maine statute requiring them to disclose information regarding rebates from pharmaceutical manufacturers.

***In re Pharmaceutical Industry Wholesale Price Litigation*** – Originally filed in multiple jurisdictions in 2001, this consolidated class action case was initiated on September 6, 2002 in the U.S. District Court for the District of Massachusetts. (MDL No. 1456; Civil Action No. 01-cv-12257-PBS). The consolidated complaint alleges that the forty-two (42) defendant drug manufactures violated RICO and eleven (11) unfair and deceptive trade practices acts, including the Clayton Act, the Sherman Act, antitrust status of 22 states, state consumer protection statutes in 11 states, and civil conspiracy law. Specifically, defendants allegedly engaged in fraudulent conduct by artificially inflating the average wholesale prices (“AWP”) for at least 321 identified drugs causing plaintiffs to substantially overpay for those drugs. Plaintiffs allege that defendants used this AWP fraud to increase market share for their drugs covered by MediCare Part B, and to maintain the high price of their brand name drugs outside of MediCare Part B. Plaintiffs claim that they are damaged by this fraudulent conduct since they are frequently required to make either full payment or copayments for a covered drug or a brand name drug and such payments are based on inflated AWP.

In February 2004, the court issued a ruling that the plaintiffs had set forth sufficient facts to state claims concerning: (1) the alleged RICO enterprises between the drug manufacturer and four PBMs with the common objective of promoting fraudulent AWP's; (2) the alleged price-fixing conspiracy of one prescription card program in violation of antitrust laws; and, (3) RICO claims involving multi-source drugs. The court accepted class plaintiffs arguments which proposed that the drug companies had manipulated the prices of multi-source and generic drugs, claims which had previously been dismissed by the court without prejudice. Importantly, the order let stand the allegation of an ongoing conspiracy between the drug manufacturers and PBMs, who allegedly profit from the spread between the discounted price they pay and the AWP for which they are reimbursed by patients and other payers. (*See* Memorandum and Order, February 24, 2004).

***Peabody Energy Corp. v. Medco Health Solutions, Inc., et al.*** - Peabody filed this lawsuit in Missouri against Medco Health Solutions on April 2, 2003 (Case No. 03-cv-417-ERW) alleging violations of ERISA; this case was filed under seal. In December 2003, the case was transferred to the multidistrict litigation case in the Southern District of New York, in order to consolidate pretrial proceedings (see Order of MDL Transfer, December 10, 2003) (see below, *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation*, which was initiated on March 12, 2003).

***Gruer v. Merck-Medco Managed Care, L.L.C.; Green v. Merck-Medco Managed Care, L.L.C.; Bellow v. Merck-Medco Managed Care, L.L.C.; Janazzo v. Merck-Medco Managed Care, L.L.C.; and, O'Hare v. Merck-Medco Managed Care, L.L.C.*** (also referred to as *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation, MDL Case No. 1508*) - This action was initially commenced on December 17, 1997, with the filing of the *Gruer* complaint. The *Gruer* case was soon consolidated by the court with five other cases each of which asserted substantially similar claims to those presented in the *Gruer* complaint. The complaints that comprise the action, sought class action status on behalf of all individuals who were fiduciaries, beneficiaries, or participants or in employee welfare benefit plans that provided prescription benefit coverage. Class status applied to individuals who: (1) had contracts with Medco or any subsidiaries of Merck; (2) received prescription benefit services from Medco during the Class Period; and (3) used on an "open" formulary basis Medco's Preferred Prescriptions Formulary or Medco's Rx Selections Formulary. The action asserts claims against Medco and Merck for breaches of fiduciary duty and other violations under ERISA.

The Court preliminarily approved settlement of the cases on July 31, 2003. On May 25, 2004 the court approved a \$42.5 million settlement proposal offered by Medco Health Solutions to the employee welfare benefit plans. The settlement applied to those who directly or indirectly (through third party administrators, HMOs, insurance companies, Blue Cross Blue Shield entities or other intermediaries) held contracts with Medco between December 17, 1994 and May 25, 2004. This settlement was reached to conclude lawsuits which alleged that Medco violated its fiduciary duty by promoting more expensive drugs made by Merck and other manufacturers over less costly alternatives.

The court did not rule on the merits of either the plaintiffs' claims or the defendants' defenses. This settlement was recently reversed by the Second Circuit.

***Healthfirst, et al v. Merck-Medco, et al.***- In this lawsuit filed on July 11, 2003, Healthfirst, a managed care prescription drug benefit program consisting of retail and mail pharmacy services, claimed that Medco breached its contract obligations by: (1) concealing the full amounts of manufacturer rebates and discounts it received with regard to Healthfirst's plans, and failing to pass through to Healthfirst any payments to which it was due; (2) demanding additional dispensing fee payments, which were outside the scope of the contract; (3) demanding monies for alleged savings derived from the Managed Rx Coverage Program and the Managed Prior Authorization Programs, while concealing both the amounts and sources of these alleged savings. Discovery in this case continues.

***Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al. and Bellvue Drug Co., et al. v. Advance PCS - In re: Pharmacy Benefit Managers Antitrust Litigation*** - 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 have violated Section I of the Sherman Act by engaging in anticompetitive conduct which substantially affects interstate commerce. These alleged violations include: 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. The lawsuits seek class action status and allege that, acting as the common agent for plan sponsors, the two PBMs limited competition by: (1) setting reimbursement rates for pharmacies far below the rates that would apply in a competitive market; (2) fixing and artificially depressing the prices to be paid to pharmacies for generic drugs; (3) prohibiting retail pharmacies from providing more than a 30-day supply of drugs while the PBMs' own mail order pharmacies routinely provide a 90-day supply; (4) requiring retail pharmacies to charge an effectively higher co-pay than the co-pay that the PBMs' own mail order pharmacies charge; and, (5) imposing one-sided contracts and added costs and inefficiencies on retail pharmacies.

The lawsuit against Advance PCS asserts two antitrust violations: (1) horizontal price-fixing conspiracy/agreement among buyers of prescription drugs; and, (2) abusive business conduct by the defendant to harm retail pharmacies. In March 2004, the court denied Advance PCS' motion to dismiss (*see* Memorandum and Order, March 3, 2004). In June 2004, the defendant filed a motion seeking to compel arbitration of the claims and dismissing the court action. (*see* Motion to Compel Arbitration, June 21, 2004). In August 2004, this motion was granted and the lawsuit was stayed pending the outcome of arbitration (*see* Memorandum and Order, August 23, 2004). Plaintiffs filed a motion for reconsideration, or in the alternative, for certification for interlocutory appeal (*see* Motion for Reconsideration, September 7, 2004), which was denied on June 17, 2005. Judge Eduardo C. Robreno ordered on Sept. 20, 2005 this case be placed in the suspense.



On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* (06-md-01782) and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.

The lawsuit against Medco asserts the same antitrust violations as in the Advance PCS case and names Merck as a co-defendant on the grounds that Medco is merely the “alter ego” for Merck in promoting its brand name drugs. On November 17, 2003, defendants filed a motion to dismiss for failure to state a claim. In August 2004, the judge issued an order denying this motion to dismiss (citing to and supporting the judge’s March 2004 ruling in the Advance PCS case); concluding that the Pharmacy Freedom Fund and the National Community Pharmacists Association do have standing to seek declaratory and injunctive relief; and, that plaintiffs’ assertions of Merck’s control over Medco were sufficient to withstand dismissal. (*See* Memorandum and Order, August 2, 2004). As such, a scheduling order was issued in September 2004 setting forth the discovery schedule extending well into 2005 (*see* Scheduling Order, September 30, 2004). On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* (06-md-01782) and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.

On December 18, 2006 Judge Fullam vacated the August 2004 order granting defendant’s motion to compel arbitration as well as a stay of the proceedings (*See* Memorandum and Order, Dec. 18, 2004). Caremark F/K/A Advance PCS appealed this decision to the 3<sup>rd</sup> Circuit (07-1151) on January 24, 2007. Both cases, the consolidated lower court case and the court of appeals case are pending.

***American Medical Security Holdings Inc. v. Medco Health Solutions, Inc.***– This lawsuit was filed on May 14, 2003 in the U.S. District Court for the Eastern District of Wisconsin (Case No. 03-cv-431-WCG) by American Medical Security Holdings Inc., a former customer of Medco based in Green Bay. The suit alleged breach of contract involving discounted pricing and prescription dispensing fees. This case settled on March 24, 2004 with Medco agreeing to pay American Medical Security Holdings \$5.85 million.

### **III. State Court Lawsuits**

#### **California**

***In re Pharmacy Benefits Managers Cases (Case No. JCCP4307)*** – On March 17, 2003, the Prescription Access Litigation Project (PAL) and the American Federation of State, County, and Municipal Employees (AFSCME), AFL-CIO, filed suit against the nation’s four largest PBMs for inflating prescription drug prices: Advance PCS, Express Scripts, Medco Health Solutions, and Caremark Rx.

The lawsuit, filed in California, charges that through a pattern of illegal, secret dealings with drug companies the PBMs force health plans and health care consumers to pay inflated prescription drug prices. The lawsuit also alleges that the four drug benefit

managers have reaped billions of dollars in illegal profits by steering health insurers and health care consumers into reliance on more costly drugs. It also contends that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies but haven't passed those savings on to health plans and consumers; instead they've used those savings to illegally increase their own profits.

This case is currently pending in the California Superior Court of Los Angeles County. *Alameda Drug Co., Inc, et al. v. Medco Health Solutions, Inc., et al.*- On January 20, 2004 this lawsuit was filed in the Superior Court of California (San Francisco) (Case No. CGC-04-428109) seeking class action status for California retail pharmacies and pharmacists. The complaint alleges violation of California's Cartwright Act (Section 16720, *et seq.*, of the California Business & Professions Code) by fixing, raising, stabilizing and maintaining prices of prescription drugs manufactured by Merck and others at supra-competitive levels. The complaint also alleges violations of the California Unfair Competition Law by the defendants' unfair, unlawful and/or fraudulent business acts, omissions misrepresentations, practices and non-disclosures. The complaint relies upon information from the U.S. government's *qui tam* case in the Eastern District of Pennsylvania and alleges that Medco has unfairly increased its market share, increased its market power and restricted price competition at the expense of the plaintiffs and to the detriment of consumers. The complaint alleges that since the expiration of a 1995 consent injunction entered by the U.S. District Court for the Northern District of California, the defendants have failed to maintain an Open Formulary (as defined in the consent injunction). Furthermore, the complaint alleges that Merck has fixed and raised the prices of its drugs and those of other manufacturers' who do business with Medco above competitive levels, while at the same time reducing the amount of reimbursement to the plaintiffs for dispensing these drugs under Medco Health Plans.

## Florida

***Fowler, Florida ex rel. v. Caremark Rx Inc.*** – This whistleblower case was filed in January 2003, in Leon County Circuit Court by two pharmacists, Michael and Peppi Fowler who worked at Caremark’s mail-order center in Fort Lauderdale. The case was filed under Florida’s False Claims Act alleging that Caremark engaged in six fraudulent schemes: (1) failing to provide a credit for returned prescription drugs; (2) changing prescriptions without proper approval; (3) misrepresenting the savings obtained from its recommendations; (4) failing to substitute a generic version of “Prilosec;” (5) failing to credit for prescriptions lost in the mail; and (6) manipulating the mandatory times for filing prescriptions. The state of Florida declined to become involved in the case initially but then sought to intervene. However, on July 27, 2004, the judge ruled that the Florida’s Attorney General Office had not provided sufficient legal reasoning to justify its intervention more than a year after it had declined to become involved.

Three amended complaints were filed in this case, but the court ruled in favor of Caremark on the merits. It went to the 7<sup>th</sup> Circuit on appeal (No. 06-4419). On July 27, 2007 the appeals court affirmed the lower court decision on the merits.

## New Jersey

***Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield v. Merck Medco Managed Care, L.L.P., et al. - No. 03-cv-4144 (N.J. Super. Ct. 2003)*** -- In this suit, the plaintiff Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield (“CareFirst”) alleges state law claims for breach of fiduciary duty, breach of contract, negligent misrepresentation and unjust enrichment, and claims arising under District of Columbia and New Jersey state statutes against Merck-Medco Managed Care, L.L.P. (“Medco”). As a common law fiduciary, Medco had a duty to manage CareFirst’s prescription drug benefits solely its best interest, and to act with undivided loyalty toward CareFirst. Medco was precluded via its fiduciary status from self-dealing or profiting at CareFirst’s expense. Subsequent to the expiration of its Agreements with Medco, CareFirst has alleged that Medco breached those Agreements and its fiduciary duties in at least the following ways:

1. failing to require generic substitution at mail and retail;
2. manipulating pricing at retail and mail so as to regularly and systematically bill claims at rates other than those set forth in its Agreements with CareFirst, in order to profit at CareFirst’s expense;
3. concealing the full amounts of manufacturer rebates and discounts it received with regard to CareFirst’s plans, and failing to pass through to CareFirst the full amount of rebates to which it was due;
4. choosing drugs for its Preferred Prescriptions Formulary based on which drugs would garner the most rebate monies for Medco, rather than based on which drugs would be most cost-effective and efficacious for CareFirst;
5. engaging in drug switching to higher priced drugs without medical justification; and
6. failing to meet performance standards defined in its Agreements with CareFirst.

## **New York**

***New York Unions v. Express Scripts, Inc., et al.*** – This lawsuit was filed before the New York State Supreme Court in New York County on December 31, 2003, by the United University Professions (“UUP”) and the Organization of New York State Managerial Confidential Employees (“OMCE”). The complaint alleges that Express Scripts engaged in fraudulent practices at the expense of union members. According to the suit, Express Scripts negotiated discounts and rebates with drug manufacturers and then unlawfully withheld them from union members. The suit also holds that Express Scripts distorted the Average Wholesale Price (AWP) of its drugs which artificially inflated drug prices to union members. This case is pending.

***People of the State of New York v. Express Scripts, Inc., et al.*** – This breach of contract lawsuit was filed on August 4, 2004 in New York State Supreme Court in Albany County. The suit was the result of a one-year investigation by Attorney General Spitzer’s office in cooperation with the Department of Civil Service and the Office of State Comptroller. The investigation was sparked by audits of Express Scripts conducted by Comptroller in 2002. Plaintiffs are seeking injunctive relief, restitution, damages, indemnification and civil penalties resulting from defendants’ breaches of contract. The lawsuit alleges that Express Scripts: (1) enriched itself at the expense of the Empire Plan (New York State’s largest employee health plan) and its members by inflating the cost of generic drugs; (2) diverted to itself millions of dollars in manufacturer rebates that belonged to the Empire Plan; (3) engaged in fraud and deception to induce physicians to switch a patient's prescription from one prescribed drug to another for which Express Scripts received money from the second drug's manufacturer; (4) sold and licensed data belonging to the Empire Plan to drug manufacturers, data collection services and others without the permission of the Empire Plan and in violation of the State's contract; and, (5) induced the State to enter into the contract by misrepresenting the discounts the Empire Plan was receiving for drugs purchased at retail pharmacies. The lawsuit also alleges, that in furtherance of its scheme to divert and retain manufacturer rebates that belonged to the Empire Plan, Express Scripts disguised millions of dollars in rebates as “administrative fees,” “management fees,” “performance fees,” “professional services fees,” and other names. It further alleges that the drug switches caused by Express Scripts often resulted in higher costs for plans and members.

## **Ohio**

***Ohio v. Medco Health Solutions, Inc.*** - On December 22, 2003 the state of Ohio filed a lawsuit in Hamilton County Common Pleas Court against Medco Health Solutions. The suit held that the State Teachers Retirement System of Ohio was overcharged millions of dollars for prescription drugs. The State Teachers Retirement System sought up to \$50 million from Medco, including \$36 million in alleged overcharges for the dispensing fees on mail-ordered medications. Other allegations claim that Medco undercounted pills when filling prescriptions and permitted non-pharmacists to dispense and cancel patient prescriptions without the necessary oversight by a licensed pharmacist. The case also

contended that Medco steered doctors, pharmacists, and patients to choose brand-name and higher-cost medications manufactured by Merck rather than selecting generic equivalents. On December 19, 2005 the Plaintiff's verdict found Medco liable for constructive fraud and awarded \$7.8 million total, \$6.9 million in damages plus \$915,000 for the State Teachers Retirement System. It was found that PBMs have a fiduciary responsibility. And numerous settlement agreements involving varying degrees of information disclosure strongly recommend transparency as a reasonable solution to the problem.

## **West Virginia**

***West Virginia v. Medco Health Solutions-*** ; Filed in November of 2002 in Kanawha Circuit Court, the West Virginia Attorney General alleged that Medco withheld prescription drug rebates and other savings from the State's Public Employee Insurance Agency ("PEIA"). A central complaint of the case held that Medco deliberately steered PEIA members to purchase Merck manufactured medications even though they were more expensive than therapeutically equivalent alternatives. Another allegation against Medco charged that Medco failed to pass manufacturer rebates on to the consumer. Concurrent to the suit filed by the State against Medco, Medco filed a suit against the State alleging that the State failed to pay for \$2.2 million owed Medco by the State of West Virginia. In December 2003, the circuit court granted Medco's motion to dismiss several of the claims. The judge dismissed allegations of Medco's fraud, conspiracy and tortious interference, and violations of the Consumer Protection Act. The court has permitted the West Virginia Attorney General to re-allege its claims of fraud if it can offer necessary evidence.

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