

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

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**David A. Balto  
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# I. STATE ATTORNEYS GENERAL CASES

*States Attorneys General v. Caremark, Inc., et al.* (filed Feb. 14, 2008)

**Filed:** February 14, 2008

**Cause of Action:** Consumer Protection Acts

**States Participating:** *Arizona, Arkansas, California, Connecticut, Delaware, Washington D.C. Florida, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia and Washington.*

**Settled:** February 14, 2008

**Damages:** \$41 million

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## Background

On February 14, 2008, 28 states and the District of Columbia issued complaints and consent orders against Caremark and two of its subsidiaries: Caremark, L.L.C. and CaremarkPCS, L.L.C. (formerly AdvancePCS) for their alleged illegal drug switching practices, which violates each of the States' Consumer Protection Acts. In conjunction with the complaints, the States each also issued a consent decree/final judgment with Caremark agreeing to a collective settlement of \$41 million (\$38.5 million to the states and \$2.5 million in reimbursement to patients who incurred expenses related to certain switches between cholesterol-controlling drugs).

## Alleged Unlawful Conduct

The States allege that Caremark engaged in deceptive trade practices by encouraging doctors to switch patients from originally prescribed brand drugs to different brand name prescription drugs. The representation made by Caremark was that the patients and/or health plans would save money. However this drug switch did not adequately inform doctors of the actual effect this switch would have on costs to patients and health plans. Moreover, Caremark did not clearly inform their clients that money Caremark earned from the drug switching process would be retained by Caremark and not passed directly to the client plan. The allegations further state that Caremark restocked and re-shipped previously dispensed drugs that had been returned to Caremark's mail order pharmacies.

## Settlement

The settlement requires Caremark to significantly change its business practices, and generally prohibits Caremark from soliciting drug switches when:

- The net cost of the proposed drug exceeds the net cost of the originally prescribed drug;
- The cost to the patient will be greater than the cost of the originally prescribed drug;

- The originally prescribed drug has a generic equivalent and the proposed drug does not;
- The originally prescribed drug's patent is expected to expire within six months; or
- The patient was switched from a similar drug within the last two years.

The settlement imposes informational requirements on Caremark. The settlement requires Caremark to:

- Inform both patients and prescribers the effect that a drug switch will have on the patient's co-payment;
- Inform prescribers of material differences in side effects or efficacy between prescribed drugs and proposed drugs;
- Inform patients that they may decline a drug switch and the conditions for receiving the originally prescribed drug;
- Inform prescribers of Caremark's financial incentives for certain drug switches;
- Inform prescribers that visits by Caremark clinical consultants and promotional materials sent to prescribers are funded by pharmaceutical manufacturers, if that is the case.

Finally, in addition to preventing Caremark from engaging in certain drug switches and providing additional information to patients and prescribers, the settlement requires Caremark to:

- Reimburse patients for out-of-pocket expenses 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;
- Monitor the effects of drug switches on the health of patients;
- Adopt a certain code of ethics and professional standards;
- Refrain from making any claims of savings for a drug switch to patients or prescribers unless Caremark can substantiate the claim; and
- Refrain from restocking and re-shipping returned drugs unless permitted under the law



*State Attorneys General v. Express Scripts, Inc.* (filed May 27, 2008)

**Filed:** May 27, 2008

**Cause of Action:** Consumer Protection

**States Participating:** *Arizona, Arkansas, California, Connecticut, Delaware, Washington D.C. Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington*

**Settled:** May 27, 2008

**Damages:** \$9.3 million to the states, plus up to \$200,000 to affected patients

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### **Background**

On May 27, 2008, State Attorneys General in 29 states and the District of Columbia settled consumer protections claims against Express Scripts for \$9.3 million plus up to \$200,000 reimbursement to affected patients. The settlement, in the form of an Assurance of Voluntary Compliance, claims that Express Scripts engaged in deceptive business practices by illegally encouraging doctors to switch their patients to different brand name drugs for the purpose of saving the patients and their health plans money despite the fact that these switches did not necessarily result in any savings for the patients or the plans, but actually resulted in higher spreads and bigger rebates for Express Scripts.

### **Settlement**

The settlement prohibits Express Scripts from soliciting drug switches when the net drug cost of the proposed drug exceeds the net cost of the originally prescribed drug, the cost to the patient will be greater, the original drug has a generic equivalent and the proposed drug does not, the original drug's patent is set to expire within six months, or the patient was switched from a similar drug within the last two years.

The settlement also requires Express Scripts to:

- inform patients that they may decline a drug switch and the conditions for receiving the originally prescribed drug;
- inform patients and prescribers what effect a drug switch will have on the patient's copayment;
- obtain express, verifiable authorization from the prescriber for all drug switches;
- inform prescribers of Express Scripts' financial incentives for drug switches;
- monitor the effects of drug switching on the health of patients;

- inform prescribers of material differences in side effects or efficacy between prescribed drugs and proposed drugs;
- reimburse patients for out-of-pocket expenses for drug-switch related health care costs and notify patients and prescribers that such reimbursement is available;
- adopt a certain code of ethics and professional standards;
- refrain from making any claims of savings for a drug switch to patients or prescribers unless Express Scripts can substantiate the claim; and
- inform prescribers that visits by Express Scripts' clinical consultants and promotional materials sent to prescribers are funded by pharmaceutical manufacturers

*United States ex rel. Hunt, Gauger, Piacentile, et al. v. Merck-Medco Managed Care, L.L.C., et al.*, Nos. 2:99-cv-02332, 2:00-00737 (E.D. Pa. filed May 6, 1999 and Feb. 10, 2000).<sup>1</sup>

**Filed:** May 6, 1999; February 10, 2000

**Cause of Action:** False Claims Act

**States Participating:** *Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington*

**Settled:** April 26, 2004; October 23, 2006

**Damages:** \$29.1 million; \$155 million (cumulatively \$184.1 million)

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## **Background**

Medco contracted with Blue Cross Blue Shield Association to provide PBM services for government employees. In these whistleblower lawsuits, George Bradford Hunt, Walter W. Gauger and Joseph Piacentile filed complaints under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc. On June 20, 2003, the United States elected to intervene in the lawsuit.

## **Alleged Unlawful Conduct**

The United States' complaint alleged that Medco "defrauded patients, clients, and the United States" by:

### **1. Cancelling and destroying prescriptions**

Medco made performance guarantees for its mail order pharmacy services with state and federal government plans and private plans.<sup>2</sup> The performance guarantees obligated Medco to maintain quality standards, and where Medco failed to meet certain performance metrics the company was required to pay a penalty; however, where it met or exceeded performance measures, the company could receive a new contract award.<sup>3</sup> The complaint alleged that Medco directed its employees to permanently delete both prescriptions and open invoice reports so that it would appear that the mail order facilities had fewer delayed and unfilled prescriptions and that Medco

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<sup>1</sup> For decision on PBMs' motion to dismiss, see *United States v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430 (E.D. Pa. 2004).

<sup>2</sup> Compl. *United States v. Merck-Medco Managed Care, et al.*, No. 2:00-cv-00737 at ¶ 23 (E.D. Pa. Sept. 29, 2003).

<sup>3</sup> *Id.*

achieved its productivity rates.<sup>4</sup> The complaint alleges that employees falsified records and that patients did not receive prescriptions or in some cases their prescription drugs.<sup>5</sup>

2. Failing to perform pharmacists' services needed by patients and required by law

Medco's pharmacists are evaluated based on a quota system called the "maximum quality per hour."<sup>6</sup> Medco pharmacists allegedly would "cherry pick" the easiest prescriptions to read, review and fill while avoiding "prescriptions which appeared to have issues of accuracy, reliability, and/or interaction requiring professional judgment and analysis."<sup>7</sup> Further, pharmacy technicians would perform functions that pharmacists were legally required to perform (or under a pharmacist's direct supervision).<sup>8</sup> Employees would falsify records to show that they achieved their maximum quality per hour.<sup>9</sup> Moreover, senior officials were aware of false reporting.<sup>10</sup> Senior officials were also aware of false reporting of physician contacts, this "helped pharmacies meet turnaround times, reduced processing costs for prescriptions, and allowed drug switching to occur."<sup>11</sup>

3. Switching patients' prescriptions to different drugs without their knowledge and consent

Medco would tell patients that their prescription had never been received when Medco had received the prescription but cancelled improperly it.<sup>12</sup> The complaint alleged that Medco directed customer service representatives and pharmacists responding to patients' inquires to provide false or misleading answers to patients.<sup>13</sup> Where patients were unhappy with being switched to a new medication, Medco represented to patients that they would be required to personally call the physician and receive a prescription for the original drug, even though this was not true.<sup>14</sup> Furthermore, Medco told patients that their doctor ordered the drug switches, when Medco switched to increase its own profits.<sup>15</sup> In some cases, Medco told patients that to switch back to their original prescription would require that the patients pay two co-pays.<sup>16</sup>

4. Shipping medications and billing patients for drugs they never ordered, by creating false records of contact with physicians

Medco's Drug Utilization Review (DUR) department was responsible for contacting physicians to review patients' personal drug history, to prevent drug-to-drug interactions and duplicate

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<sup>4</sup> *Id.* at ¶ 25.

<sup>5</sup> *Id.* at ¶ 27.

<sup>6</sup> *Id.* at ¶ 30.

<sup>7</sup> *Id.* at ¶ 30a.

<sup>8</sup> *Id.* at ¶ 30b.

<sup>9</sup> *Id.* at ¶ 30c.

<sup>10</sup> *Id.* at ¶ 31.

<sup>11</sup> *Id.* at ¶ 31c.

<sup>12</sup> Amended Compl., *Merck-Medco*, No 2:00-cv-00737 at ¶ 99c (E.D. Pa. Dec. 9, 2003).

<sup>13</sup> *Id.* at ¶ 98.

<sup>14</sup> *Id.* at ¶ 99a.

<sup>15</sup> *Id.* at ¶ 99b.

<sup>16</sup> *Id.* at ¶ 99c.

therapy.<sup>17</sup> Because of productivity pressures employees from the DUR department allegedly fabricated physician calls to maintain hourly call quota rates; completed calls to physicians without having pharmacists ever verify information with the physician's office; changed prescriptions without the pharmacist's intervention; and falsified records to show that calls were made to physicians when they were not.<sup>18</sup> The reimbursement Medco receives from providers is based on properly performed DUR-related services; where the services are not provided the government asserts that Medco submits false claims to the government.<sup>19</sup>

5. Soliciting and receiving inducements from pharmaceutical manufacturers to favor their products by paying kickbacks<sup>20</sup> to obtain Medicare contracts

The complaint alleges that Medco made payments to health plans to obtain favorable consideration in its bid for the PBM contract.<sup>21</sup> Where the prime contract was between the United States and a health plan, Medco allegedly made additional payments in cash and in services "to induce the plans to select Medco Health as a pharmacy benefit management subcontractor, or to retain Medco Health as a pharmacy benefit management subcontractor."<sup>22</sup> The complaint asserts that Medco's direct payment of \$87.4 million to the health plan to obtain the PBM contract was for an improper purpose and constituted a kickback.<sup>23</sup>

6. Making false and misleading statements to the United States about its conduct

The complaint alleges that Medco presented false or fraudulent claims to the United States for payment or approval.<sup>24</sup> According to the government, the claims Medco submitted were false "because Medco Health failed to abide by laws, rules, regulations, and professional standards governing pharmacy practice, and consumer protection laws. These failures amount to material misrepresentations made to obtain a government benefit, that is, payment for prescriptions not authorized by law and contract."<sup>25</sup>

According to the United States, Merck and Medco breached their contracts with government-funded health insurance programs by engaging in the above conduct. In addition the complaint alleged that the companies secretly accepted rebates from drug manufacturers in exchange for increasing product market share, secretly increasing long-term drug costs, and failed to comply with state-mandated quality of care standards.

## Settlements

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<sup>17</sup> *Id.* at ¶ 76.

<sup>18</sup> *Id.* at ¶ 82.

<sup>19</sup> *Id.* at ¶ 84.

<sup>20</sup> In violation of the Public Contracts Anti-Kickback Act of 1986, 41 U.S.C. § 51 (2006).

<sup>21</sup> Amended Compl. at ¶ 159.

<sup>22</sup> *Id.* at ¶ 162.

<sup>23</sup> *Id.* at ¶ 165.

<sup>24</sup> *Id.* at ¶ 176.

<sup>25</sup> *Id.*

On April 26, 2004,<sup>26</sup> the United States, 20 state attorneys general, and the defendants agreed to a settlement of claims for injunctive relief and unfair trade practice laws.<sup>27</sup> A separate consent order was filed by the states to cover the injunctive and monetary claims. Medco paid \$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 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 switching and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- 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.

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<sup>26</sup> Consent Order of Court for Permanent Injunction and Settlement, *United States v. Merck-Medco Managed Care, L.L.C.*, Nos. 99-cv-2232, 00-cv-737 (E.D. Pa. Apr. 26, 2004) <http://www.justice.gov/usao/pae/News/Pr/2006/oct/MedcoConsentOrder2004.pdf>.

<sup>27</sup> The United States and the following state Attorneys General 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.

On October 23, 2006 a final settlement in this case was reached with Medco agreeing to pay \$155 million.<sup>28</sup> 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.

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<sup>28</sup> Press Release, *U.S. Department of Justice, Medco to Pay U.S. \$155 Million to Settle False Claims Act Cases* (Oct. 23, 2006), [http:// www.usdoj.gov/opa/pr/2006/October/06\\_civ\\_722.html](http://www.usdoj.gov/opa/pr/2006/October/06_civ_722.html).

*United States ex rel. Ramadoss v. Caremark Inc.*, No. SA-1999-ca-00914-WRF (W.D. Tex. filed Aug. 15, 1999)

**Filed:** August 15, 1999

**Cause of Action:** False Claims Act

**States Participating:** *Arkansas, California, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, North Carolina, Tennessee, Texas, Utah and Virginia*

**Withdrawal:** *Florida, Tennessee*

**Pending as of:** November 23, 2010

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### **Background**

The case was originally filed by a relator, Janaki Ramadoss on August 15, 1999 on behalf of the United States and several states against Caremark, a pharmacy benefit company which created a network of more than 57,000 independent and chain pharmacies. Ramadoss, a former employee of Caremark who worked as a quality assurance representative in the company's paper claims processing department, filed the claim under seal per the False Claims Act.<sup>29</sup> The relator complaint alleged that the company consistently refused to honor valid requests for reimbursement from state Medicaid agencies. The relator's complaint alleges that "Caremark has been denying reimbursement of Medicaid claims for up to three years despite the repeated requests in writing from the Medicaid program" and she had "identified these reimbursement problems to Caremark's management over the last two years and no corrective action was forthcoming."<sup>30</sup>

According to the relator, Caremark would assign a dummy code to transactions requesting reimbursement from Medicaid. Normally, Caremark would use the National Association of Boards of Pharmacy number to identify the pharmacy where the Caremark-covered drug was purchased. Caremark uses this number to determine whether a pharmacy is "in-network" or "out-of-network." Certain Caremark-administered plans only cover prescriptions that are filled at in-network pharmacies. For these plans, prescriptions filled at any pharmacy designated out-of-network could lead to the denial of a claim. However, when Medicaid submitted reimbursement requests, rather than using the normal pharmacy number, Caremark tagged them with a dummy code instead. Caremark would then classify the dummy code in its computer system as an out-of-network pharmacy, which would prompt Caremark to deny coverage. The effect of this practice was that Caremark designated the Medicaid program as an out-of-network pharmacy.

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<sup>29</sup> 31 U.S.C. § 3729 et seq. Specifically, a private citizen may commence an action by filing under seal a complaint in the government's name to allege fraud on the Government. *Id.*, § 3730(b). If the government elects to intervene and obtains a judgment, the private citizen, referred to as a "relator," gets a percentage. *Id.*, § 3730(d)(1).

<sup>30</sup> Appellate Brief at \*8.



After the relator filed her complaint, the complaint filed under seal and served on the United States so that the United States (“the government”) could consider whether to take over the litigation.<sup>31</sup> In April 2005, after seeking numerous extensions, the government concluded its investigation and elected to intervene. On May 26, 2005 the complaint was unsealed, nearly six years after filing.<sup>32</sup> The United States and the States filed notices of intervention and a joint complaint in intervention. The relator also filed an amended complaint to the district court, which stated that since the complaint was unsealed, the States of Arkansas, Florida, Louisiana, Tennessee, and Texas intervened. (After the amended complaint California moved to intervene on May 19, 2006.)

### **Alleged Unlawful Conduct**

The joint complaint alleges that from at least 1996 to the present, Caremark fraudulently denied, rejected, or reduced thousands of claims from Medicaid agencies (as well as claims from Indian Health Services, Veteran’s Administration, and Military Treatment Facilities) costing the United States Treasury millions of dollars. The complaint asserts that Caremark knowingly avoided or decreased its obligation to reimburse Medicaid and other federal health insurance programs in dual coverage situations and submitted reverse false claims to the Government in order to avoid, decrease, or conceal their obligation to pay federal and state governments.

Further elaborating on the relator’s complaint, the United States identified four specific practices employed to deny Medicaid reimbursement requests.<sup>33</sup>

#### **1. Dummy Codes (Out-of-Network Restrictions)**

Caremark assigned a dummy code when processing Medicaid reimbursement requests, which would sometimes lead to out-of-network denials even if the pharmacy where the prescription was filled is actually in the relevant network.

#### **2. Card Presentation of Paper Claims Restrictions**

Some Caremark plans included either card presentation<sup>34</sup> or paper claims<sup>35</sup> restrictions, which require plan beneficiaries to identify themselves as a Caremark member when they purchase their prescription, and if they fail to do so they forfeit their right to coverage. When Caremark applied these restrictions to reimbursement requests on behalf of Medicaid beneficiaries, the plan terms made it impossible for Medicaid to recover from Caremark. This is because “Medicaid

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<sup>31</sup> See 31 U.S.C. § 3730(b)(2).

<sup>32</sup> United States ex rel. Ramadoss v. Caremark Inc., 586 F. Supp. 2d 668, 672 (W.D. Tex. 2008).

<sup>33</sup> Appellate Brief, \*10-12.

<sup>34</sup> “Card presentation” restrictions require those insured to present their Caremark card at the point of sale.

<sup>35</sup> “Paper-claims” restrictions prevent those insured from paying out of pocket for a prescription and then at a later date, seeking reimbursement (via a paper claim) from Caremark.

only pays for prescription drugs when the beneficiar[ies] identify [themselves] as Medicaid recipient[s] – and not a Caremark member-- when buying the drug.”<sup>36</sup>

### 3. Timely Filing Restrictions

Some of the Caremark plans include “timely filing” restrictions.<sup>37</sup> These plans allow for after the fact reimbursement, but impose temporal deadlines on reimbursement from the health provider. Generally, these filing restrictions impose deadlines that are too tight for Medicaid, so the agency would be unable to comply with the filing restrictions. “Caremark would nonetheless reject ostensibly late reimbursement requests from Medicaid.”<sup>38</sup>

### 4. Preauthorization Requirements

Plans administered by Caremark also included restrictions on various categories of drugs; specifically, that the plan would not cover a certain category of drug without preauthorization from Caremark. Under these plans, when a Caremark beneficiary provides their Medicaid card to fill a prescription for a drug that falls into Caremark preauthorization category, Caremark would refuse reimbursement requests on the grounds that Caremark had not preauthorized the sale of the drug. According to the government “[a]s a practical matter, this made it impossible to recoup money for drugs subject to preauthorization.”<sup>39</sup>

The court stated that the “primary issue in this litigation is whether Caremark can apply existing restrictions to reject a reimbursement request from . . . [these agencies] and whether Caremark’s application of the restriction in accordance with a health plan constitutes a reverse false claim under the False Claims Act.”<sup>40</sup>

## **Withdrawals**

Tennessee and Florida subsequently withdrew their interventions from the law suit on August 17, 2006 and May 4, 2007, respectively.

## **Proceedings**<sup>41</sup>

After the court unsealed the complaint, Caremark moved to dismiss each complaint and the court denied each of these motions. On March 24, 2006 Caremark filed answers to the Complaint in Intervention filed jointly by the United States, and the states of Texas, Florida, Arkansas, and Tennessee. The answers assert a total of nine affirmative defenses. The Seventh Affirmative Defense asserts that Caremark is “entitled to a set-off and/or recoupment of all amounts paid to

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<sup>36</sup> Appellate Brief at \*11.

<sup>37</sup> Plans with timely filing restrictions give beneficiaries a limited number of days to file for reimbursement from their private health plan after a prescription has been filled.

<sup>38</sup> Appellate Brief at \*11.

<sup>39</sup> *Id.* at \*12

<sup>40</sup> *Caremark*, 586 F. Supp. 2d at 677.

<sup>41</sup> For cases on the litigation *see* U.S., *ex rel. Ramadoss v. Caremark Inc.*, 586 F. Supp. 2d 668 (W.D. Tex. 2008) and *Texas v. Caremark, Inc.*, 584 F.3d 655 (5th Cir. Tex. 2009).

the Plaintiffs to which Plaintiffs were not entitled.”<sup>42</sup> Essentially, Caremark asserted that it had overpaid the States because of miscalculations that it made about the amounts due to the States on claims for Medicaid reimbursements and as such, Caremark was entitled to recover the overpayments.

The United States, relator, and States filed motions to dismiss the Seventh Affirmative Defense.<sup>43</sup> The States argued that this defense was actually a counterclaim and moved to dismiss the counterclaim on grounds of sovereign immunity. Further, the United States argued that it “waived sovereign immunity only over claims put at issue by its False Claims Act Complaint, i.e., claims for reimbursement that Caremark falsely rejected, denied or reduced - not claims that Caremark paid.”<sup>44</sup> In denying the motions to dismiss the counterclaims the district court stated that “while the States’ sovereign immunity arguments were potentially meritorious, dismissal of the Seventh Affirmative Defense was “premature”; without giving further reasons. . . .”<sup>45</sup>

The States then filed an interlocutory appeal on the Eleventh Amendment claim. The district court judge opined that the Fifth Circuit should not rule on the issue of sovereign immunity until the district court resolved other legal issues and further discovery was conducted.<sup>46</sup> The Fifth Circuit vacated the decision stating that sovereign immunity matters should always be considered first in litigation, and that the court improperly denied the States’ motion to dismiss without considering the merits.<sup>47</sup> On remand, the district court judge denied the States’ motion.<sup>48</sup>

The parties filed cross motions for partial summary judgment on false claims issues, and in August 2008, the court granted several of Caremark’s motions and denied the motions filed by the government.<sup>49</sup> The government argued that Caremark made a “false record” by applying the plan restrictions to reject the Medicaid reimbursement requests; thus subjecting Caremark to liability under the False Claims Act.<sup>50</sup> However, the district court disagreed with the government and stated that for “claims where Caremark applied a restriction to deny a state Medicaid request for reimbursement, and the restriction actually existed in the corresponding plan, the

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<sup>42</sup> See Answer to the Complaint in Intervention, United States ex rel. Ramadoss v. Caremark Inc., No. SA-99-CA-00914-WRF, Docket #126 (Mar. 26, 2006) at 21.

<sup>43</sup> See Plaintiffs’ Motion to Dismiss Caremark’s Affirmative Defense, United States ex rel. Ramadoss v. Caremark Inc., No. SA-99-CA-00914-WRF, Docket # 324, 327, 329, 331, 334, 335 (July 16, 2007).

<sup>44</sup> Response in Opposition to Caremark’s Motion to Amend Its Seventh Affirmative Defense, United States ex rel. Ramadoss v. Caremark Inc., No. SA-99-CA-00914-WRF, 2008 WL 4518547 (W.D. Tex. Aug. 8, 2008).

<sup>45</sup> *Texas v. Caremark*, 584 F.3d at 657.

<sup>46</sup> *Id.* The district court also issued an “Advisory to the Fifth Circuit” stating that the reason it had denied the states’ motion was “because . . . it was necessary to first address the numerous motions for summary judgment regarding threshold legal questions,” and that the district court’s “inclination . . . has been to address the major legal issues in the action in logical order,” with the first step being resolution of the pending summary judgment motions.” *Id.*

<sup>47</sup> *Id.* at 660.

<sup>48</sup> See Order Denying States’ Motion to Dismiss on Grounds of Eleventh Amendment Sovereign Immunity, United States ex rel. Ramadoss v. Caremark Inc., No. SA-99-CA-00914-WRF (W.D. Tex. June 8, 2010).

<sup>49</sup> See U.S., ex rel. Ramadoss v. Caremark Inc., 586 F. Supp. 2d 668 (W.D. Tex. 2008).

<sup>50</sup> *Id.* at 686.

Government cannot establish that Caremark made a “false record or statement” and FCA liability does not apply.”<sup>51</sup> Also, the court concluded that Caremark owed no obligation to the United States at the time of the alleged false statements because Caremark received reimbursement requests from state Medicaid agencies and not directly from the federal government.<sup>52</sup>

Specifically, the district court rejected the government’s claims for out-of-network restrictions and preauthorization requirements because they were substantive and not a procedural restriction stating that the “relevant inquiry is whether the health plan denies coverage on the sole ground that an individual is a Medicaid recipient.”<sup>53</sup> The district court acknowledged that the card presentation and timely filing restrictions were unlawful under *Caremark v. Goetz*,<sup>54</sup> however, because the law was unsettled before *Goetz*, Caremark’s pre-*Goetz* reliance on the restrictions could not amount to a false statement.<sup>55</sup>

Following the district court order, the government appealed to the Fifth Circuit seeking to overturn the summary judgment order.<sup>56</sup> The Fifth Circuit has not yet issued its ruling on the matter.

Also, in April 2009, the Texas AG Civil Medicaid Fraud Division filed suit a separate lawsuit against Caremark for falsely rejecting reimbursements.<sup>57</sup> The claims and issues in this lawsuit are related to those pending in the main federal *qui tam* lawsuit. The State of Texas sought injunctive relief, damages and civil penalties alleging that Caremark violated the Texas Medicaid Fraud Prevention Act.

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 693.

<sup>53</sup> *Id.* at 710.

<sup>54</sup> 403 F.3d 779, 784 (6th Cir. 2007).

<sup>55</sup> *Caremark*, 586 F. Supp. 2d at 710-12.

<sup>56</sup> *USA v. Caremark, Inc., et al.*, No. 09-50727 (5th Cir. filed Aug. 8, 2009).

<sup>57</sup> See CVS Caremark Corp. Form 10-K for 2009, filed Feb. 26, 2010 at \*29.

## II. MULTIDISTRICT LITIGATION

### A. In re Express Scripts, Inc. Pharmacy Benefits Management Litigation No. 4:05-md-01672-SNL (E.D. Mo. Apr. 29, 2005)

**Complaint Filed:**     **October 3, 2002**  
**Consolidated:**       **April 29, 2005**  
**Cause of Action:**    **ERISA**  
**Pending as of:**      **December 2, 2010**

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*Local 153 Health Fund v. Express Scripts, Inc.*, No. 4:05-cv-00862 (E.D. Mo. Oct. 3, 2002)

#### **Background**

The Office of Professional Employees International Union established the Local 153 to provide ERISA benefits to around 145,000 of its members.<sup>58</sup> For self-funded prescription drug plans, participating employers would deposit money into a trust fund to pay for their employee's drug claims.<sup>59</sup> Local 153 contracted with National Prescription Administrators (NPA) to provide PBM services and in April 2002, Express Scripts purchased NPA assuming NPA's contractual obligations.<sup>60</sup>

On April 29, 2005 a number of interrelated cases were consolidated in the District Court for the District of Eastern Missouri via an order of the Multi-District Litigation Judicial Panel.<sup>61</sup> Local 153 filed its class action complaint against Express Scripts on May 27, 2005, but the action was not consolidated into the multidistrict litigation until January 2007.

#### **Alleged Unlawful Conduct**

According to the Local 153, Express Scripts engaged in a series of unlawful acts, "which inflated the costs of pharmacy benefits, improperly steered plan participants toward certain drugs, and

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<sup>58</sup> *In re Express Scripts, Inc. Pharmacy Benefits Manager Litigation*, Nos. 4:05-md-01672-SNL (Master) and 4:05-cv-00862 (Member), 2008 WL 1766777 at \*1 (E.D. Mo. Feb. 6, 2008).

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *See In re Express Scripts, Inc., Pharmacy Benefits Mgmt. Litigation*, 368 F. Supp. 2d 1356, 1358 (Jud. Pan. Mult. Lit. 2005) *consolidating* *Central Laborers' Welfare Fund v. Express Scripts, Inc.*, et al., C.A. No. 3:04-00791 (S.D. II. Oct. 29, 2004); *Minshew v. Express Scripts, Inc.*, C.A. No. 4:02-01503 (E.D. Mo. Oct. 3, 2002); *Mixon, et al. v. Express Scripts, Inc.*, C.A. No. 4:03-01519 (E.D. Mo. Oct. 23, 2003); *Cameron v. Express Scripts, Inc.*, C.A. No. 4:03-01520 (E.D. Mo. Oct. 23, 2003); *Fidelity Insurance Co., et al. v. Express Scripts, Inc.*, et al., C.A. No. 4:03-01521 (E.D. Mo. Oct. 20, 2003); *Lynch, etc. v. National Prescription Administrators, Inc.*, et al., C.A. No. 1:03-01303 (S.D.N.Y. Feb. 26, 2003); *Powell, et al. v. National Prescription Administrators, Inc.*, et al., C.A. No. 1:04-07472 (S.D.N.Y. Sept. 21, 2004); *Scheuerman, et al. v. Express Scripts, Inc.*, C.A. No. 1:04-07616 (S.D.N.Y. Sept. 27, 2004)

violated the participants' privacy."<sup>62</sup> According to Local 153, Express Scripts profited from their unlawful pricing practices, and failed to pass along savings to members, which resulted in higher prices for the class members and inflated prescription drug prices. Specifically, Local 153 alleged that Express Scripts:

1. Retained undisclosed rebates from manufacturers

The complaint alleges that Express Script would utilize its buying power to negotiate favorable discounts, rebates, and other concessions from drug manufacturers.<sup>63</sup> However, Express Scripts did not disclose these rebates to plan participants, which served as additional compensation to Express Scripts.<sup>64</sup>

2. Created a spread in discounts

Express Scripts allegedly entered into pricing contracts with pharmacies that provided undisclosed discounts directly to Express Scripts as additional compensation for steering participants to the particular pharmacy.<sup>65</sup>

3. Created a spread in dispensing fees

The price of a drug at a pharmacy is generally a combination of wholesale price of the drug and the dispensing fee that the pharmacy gets for dispensing the drug to a plan participant.<sup>66</sup> According to Local 153, Express Scripts would negotiate the appropriate dispensing fee with the plan and with the pharmacy thereby pocketing the difference between the two (i.e., the spread).<sup>67</sup>

4. Favored specific drugs and engaged in drug switches

The complaint alleges that Express Scripts obtained kickbacks from drug manufacturers.<sup>68</sup> In exchange for these kickbacks, Express Scripts designates specific drugs higher on the plan's formularies or on other preferred medication lists. Express Scripts encouraged pharmacies to switch participants' drugs to those manufactured by companies who provide kickbacks Express Scripts or who have favorable contractual agreements with Express Scripts.<sup>69</sup> In addition to unjustly enriching Express Scripts, Local 153 alleged that the drug switching scheme violated participants' privacy rights because in the process of obtaining the kickbacks Express Scripts disclosed individual plan participants' medical information to drug manufacturers.<sup>70</sup>

5. Circumvented "Best Pricing" rules

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<sup>62</sup> *In re Express Scripts*, 2008 WL 1766777 at \*3.

<sup>63</sup> Compl., Local 153 Health Fund v. Express Scripts, Inc., No. 4:05-cv-00862, ¶ 5(a) (E.D. Mo. May 27, 2005).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at ¶ 5(b).

<sup>66</sup> *Id.* at ¶ 5(c).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at ¶ 5(d).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

Express Scripts allegedly helped manufacturers distort the Average Wholesale Price (AWP) of their drugs by entering into the above agreements, thereby artificially inflating the AWP.<sup>71</sup>

6. Received undisclosed bulk purchases discounts on mail order prescriptions

Allegedly, Express Scripts and its mail pharmacy would received bulk purchase and prompt payment discounts from manufacturers and would retain those payments for itself.<sup>72</sup>

7. Caused accounting errors

The complaint alleged that Express Scripts systematically made accounting errors in administering the pharmacy benefits by: paying claims outside eligibility; paying duplicate prescriptions; making erroneous dosing criteria; paying prescriptions outside refill parameters; making “dispense as written” errors; making prior-authorization errors; and making system-edit errors.<sup>73</sup>

### **Proceedings**

On July 26, 2005 Express Scripts moved to dismiss for lack of subject matter jurisdiction, and failing to state a claim upon which relief can be granted.<sup>74</sup> On February 6, 2008, after Local 153 was consolidated with *In re Express Scripts, Inc. Pharmacy Benefits Management Litigation*, the court ruled on Summary Judgment motion, granting in part and denying in part.<sup>75</sup> Judge Limbaugh denied the motion on the charge of lack of subject matter jurisdiction.<sup>76</sup> However, he granted the motion in respect to a number of claims of relief sought by plaintiffs. Plaintiffs’ claims of breach of fiduciary duty under New York Common Law, deceptive business practices, breach of contract, conversion, breach of the Covenant of Good Faith and Fair Dealing, and unjust enrichment were all dismissed. The Court found that the ERISA preempts each of these claims because they are all based on state and common law.

The litigation proceeds on the Plaintiffs’ claim for breach of fiduciary duty under ERISA, which has been adequately pled. The case proceeded to trial per the February 6 order. The case is pending as of November 4, 2010 with 21 of the 22 multidistrict litigation actions pending before the court.<sup>77</sup>

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<sup>71</sup> *Id.* at ¶ 5(e).

<sup>72</sup> *Id.* at ¶ 5(f).

<sup>73</sup> *Id.* at ¶ 5(g).

<sup>74</sup> Motion to Dismiss, *Local 153 Health Fund*, No. 4:05-cv-00862, Entry No. 8 (E.D. Mo. July 26, 2005).

<sup>75</sup> See *In re Express Scripts*, 2008 WL 1766777.

<sup>76</sup> See *id.* at \*4-5.

<sup>77</sup> Distribution of Pending MDL Dockets (November 4, 2010), UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, available at [http://www.jpml.uscourts.gov/Pending\\_MDL\\_Dockets-November-2010-Modified.pdf](http://www.jpml.uscourts.gov/Pending_MDL_Dockets-November-2010-Modified.pdf).

**B. In re Medco Health Solutions, Inc., Pharmacy Benefits Mgmt. Litigation**  
No. 7:03-MDL-01508 CLB (S.D.N.Y. Mar. 12, 2003)<sup>78</sup>

**Commenced:** December 17, 1997  
**Consolidated:** March 12, 2003  
**Cause of Action:** ERISA  
**Settled:** May 24, 2004 (Appealed)  
**Damages:** \$42.5 million  
**Mostly Resolved:** August 20, 2010 (3 Cased Pending as of December 2, 2010)

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**Background**

This action was initially commenced on December 17, 1997, with the filing of the Genia Gruer’s class action complaint.<sup>79</sup> The court consolidated *Gruer* with four other cases each of which asserted substantially similar claims to those presented in the *Gruer* complaint.<sup>80</sup> By May 2004, the Judicial Panel on Multidistrict Litigation transferred 12 additional actions with similar allegations of breaches of fiduciary duties owed to employee benefit plans under ERISA.<sup>81</sup> In March 2008, the District Court certified a subclass consisting of all members of the Class that were self-funded plans and the claim administrator mailed a Notice of Certification of Subclass.

**Alleged Unlawful Conduct**

The plaintiffs assert claims against Medco and Merck for breaches of fiduciary duty by promoting more expensive drugs made by Merck and other manufacturers over less costly alternatives as well as other violations under ERISA. The plaintiffs claimed that pharmacy benefit plan sponsors relied on Medco promises of cost containment and the sponsors entrusted the Medco with discretionary authority over certain aspects of their pharmacy benefit plan management.<sup>82</sup> The plaintiffs alleged that Medco and the parent company Merck engaged in transactions that are prohibited under ERISA.<sup>83</sup>

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<sup>78</sup> Other dockets include U.S. Court of Appeals Second Circuit Nos. 04-03300, 04-03464, 04-03545, and 04-03871.

<sup>79</sup> See *Gruer v. Merck-Medco Managed Care, L.L.C., et al.*, No. 7:97-cv-09167 CLB (S.D.N.Y. Dec. 17, 1997)

<sup>80</sup> See *Green v. Merck-Medco Managed Care, L.L.C., et al.*, No. 7:98-cv-00847 CLB (S.D.N.Y. Feb. 6, 1998); *Bellow v. Merck-Medco Managed Care, L.L.C., et al.*, No. 7:98-cv-04763 CLB (S.D.N.Y. July 6, 1998); *Janazzo v. Merck-Medco Managed Care, L.L.C., et al.*, No. 7:99-cv-04067 CLB (S.D.N.Y. June 4, 1999); and *O’Hare v. Merck-Medco Managed Care, L.L.C., et al.*, No. 7:01-cv-03805 CLB (S.D.N.Y. May 3, 2001).

<sup>81</sup> *In re Medco Health Solutions, Inc., Pharmacy Benefits Mgmt. Litigation*, No. 7:03-MDL-1508 (CLB), 2004 WL 1243873 at \*1 (S.D.N.Y. May 25, 2004) *vacated and remanded by* Central States Southeast and Southwest Areas Health and Welfare Fund v. Merck-Medco Managed Care, L.L.C., 433 F.3d 181 (2d Cir. 2005).

<sup>82</sup> *Id.* at \* 2.

<sup>83</sup> *Id.* This included the “effective transfer of plan assets to Merck through drug-purchase contracts with Merck negotiated by Medco on behalf of the plans.” See *Central States*, 433 F.3d at 188.



Specifically, the plaintiffs claim that Medco “systematically misused its fiduciary authority, and its management of formularies and drug-switching programs, among other purposes (i) to increase the market share in specific drugs of its parent company Merck, and (ii) to divert rebates from drug manufacturers to itself, both at the expense of the plans.”<sup>84</sup> The plans alleged that Medco entered into drug-purchase contracts with pharmaceutical manufacturers, including Merck, “that included price, rebate, discount, and other terms that were not advantageous to the interests of the plans but instead tended to favor the interests of Merck and of Medco itself.”<sup>85</sup> Similarly, the plaintiffs alleged that Medco “refused to enter into contracts that would have reduced costs for the plans but increased competition for Merck.”<sup>86</sup> According to the plaintiffs, because of these practices Medco “did not disclose the nature of its plan management practices or the extent to which the plans failed to obtain benefits, or incurred costs.”<sup>87</sup>

The complaints 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.

### **Proceedings**

The plaintiffs initially filed a motion for summary judgment which was deferred pending discovery so the court did not rule on the merits of either the plaintiffs’ claims or the defendants’ defenses. Eventually, the motion was withdrawn because of settlement discussions.<sup>88</sup> The five parties began settlement negotiations in summer 2001 under the supervision of the Special Master and the district court, which led to the first settlement agreement. The district court preliminarily approved settlement of the cases on July 31, 2003, after which the parties sent notices to around 815,000 potential class members.<sup>89</sup> 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.<sup>90</sup>

Some members of the class (around 200 individual plans) objected to the settlement.<sup>91</sup> Sweetheart Cup Company, Iron Workers Tri-State Welfare Fund and Central States Southeast

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<sup>84</sup> *In re Medco*, 2004 WL 1243873 at \*2.

<sup>85</sup> *Central States*, 433 F.3d at 188.

<sup>86</sup> *Id.*

<sup>87</sup> *In re Medco*, 2004 WL 1243873 at \*2.

<sup>88</sup> *Id.* at \*3.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at \*2. The following plaintiffs wanted to opt out of the settlement: (i) Betty Jo Jones on behalf of Daimler Chrysler Prescription Drug Plan; (ii) Rosemary DeLong on behalf of the Verizon Prescription Drug Plan; (iii) David

and Southwest Areas Health & Welfare Fund each objected to the plan. They contested the settlement “claiming that the allocation between the self-funded drug plans and the insured or capitated drug plans [was] unfair, inadequate and unreasonable.”<sup>92</sup> The three plans argued that the settlement “unfairly favor[ed] the insured and capitated, as opposed to the self-funded plans.”<sup>93</sup> Further, they argued that no plaintiff adequately represented their interests and argued that there was a conflict of interest in the representation of the class because only a self-funded plan could adequately represent their interests.<sup>94</sup>

Following the district court’s approval of the settlement 13 of the 17 dockets were set to close.<sup>95</sup> On May 25, 2004 the court approved a \$42.5 million settlement proposal offered by Medco Health Solutions to the employee welfare benefit plans.<sup>96</sup> After the district court approved the settlement, the objecting class members appealed the court’s approval along with other related matters.<sup>97</sup> The Second Circuit held that there were still issues of Constitutional standing that needed to be resolved and remanded the case to the district court.<sup>98</sup>

The district court found that the plaintiffs had standing.<sup>99</sup> On appeal, the Second Circuit stated that self-funded plans differ significantly from insured or capitated plans because “only self-funded Plans assumed the direct risk of absorbing any increases in prescription drug costs that were caused by Medco's conduct.”<sup>100</sup> Because the antagonistic interests apparent in the class should be adequately and independently represented, the Second Circuit remanded the case back to the district court “for certification of a subclass encompassing the self-funded plans in order to better protect their claims in this litigation.”<sup>101</sup>

On June 25, 2010, the settlement checks were mailed to all eligible claimants. However as of November 4, 2010, 3 of the 18 multidistrict litigation actions are pending before the court.<sup>102</sup>

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J. Gibson on behalf of the DuPont Prescription Drug Plan; (iv) Carl J. Goodman on behalf of the DuPont Dow Elastomers Prescription Drug Plan; (v) Pamela Stolz on behalf of the Northwest Airlines Prescription Drug Plan (“Northwest”); (vi) Margaret Weesner on behalf of the American Standard/TRANE Prescription Drug Program; and, (vii) Mattie Garcia on behalf of the Lucent Technologies Prescription Drug Plan. *Id.* at \*5.

<sup>92</sup> *Id.* at \*4.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Central States*, 433 F.3d at 189.

<sup>96</sup> See *In re Medco Health Solutions, Inc., Pharmacy Benefits Mgmt. Litigation*, No. 7:03-MDL-1508 (CLB), 2004 WL 1243873 (S.D.N.Y. May 25, 2004).

<sup>97</sup> See *Central States Southeast and Southwest Areas Health and Welfare Fund v. Merck-Medco Managed Care*, L.L.C., 433 F.3d 181 (2d Cir. 2005).

<sup>98</sup> See *id.* at 203-204.

<sup>99</sup> See *In re Medco Health Solutions, Inc., Pharmacy Benefits Mgmt. Litigation*, No. 7:03-MDL-1508 (CLB) (Aug. 1, 2006) available at: <http://completeclaimssolutions.com/erisasettlement/pdfs/MemoOrder081006.pdf>.

<sup>100</sup> *Central States Southeast and Southwest Areas Health and Welfare Fund v. Merck-Medco Managed Care*, L.L.C., 504 F.3d 229, 246 (2d Cir. 2007) (hereinafter *Central States II*).

<sup>101</sup> *Id.* at 246.

<sup>102</sup> Distribution of Pending MDL Dockets (November 4, 2010), UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, available at [http://www.jpml.uscourts.gov/Pending\\_MDL\\_Dockets-November-2010-Modified.pdf](http://www.jpml.uscourts.gov/Pending_MDL_Dockets-November-2010-Modified.pdf).



**C. In re Pharmacy Benefit Managers Antitrust Litigation**  
No. 2:06-MDL-01782 (E.D. Pa. Aug. 28, 2006)

*Bellevue Drug Co., et al. v. Advance PCS*, No. 2:03-cv-04731; and *Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al.*, No. 2:03-cv-04730 (E.D. Pa. Aug. 15, 2003)

**Complaint Filed:** August 15, 2003  
**Consolidated:** August 26, 2006  
**Cause of Action:** Sherman Act  
**Pending as of:** December 1, 2010

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**Background**

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 seeking treble damages and injunctive relief.<sup>103</sup> The claims were initially sent to arbitration based on contract terms between the pharmacies and CaremarkPCS.

**Alleged Unlawful Conduct**

The lawsuits allege that each of the PBM defendants, Merck-Medco and AdvancePCS, violated Section 1 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 parties sought class action status and alleged 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.

**Bellevue Drug Co. v. Advance PCS**

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

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<sup>103</sup> See *Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al.*, No. 2:03-cv-04730 (E.D. Pa. Aug. 15, 2003); and *Bellevue Drug Co., et al. v. Advance PCS*, No. 2:03-cv-04731 (E.D. Pa. Aug. 15, 2003).

the defendant to harm retail pharmacies. In March 2004, the court denied Advance PCS' motion to dismiss.<sup>104</sup> In June 2004, the defendant filed a motion seeking to compel arbitration of the claims and dismissing the court action.<sup>105</sup> In August 2004, this motion was granted and the lawsuit was stayed pending the outcome of arbitration.<sup>106</sup> Plaintiffs filed a motion for reconsideration, or in the alternative, for certification for interlocutory appeal, which was denied on June 17, 2005.<sup>107</sup> On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.<sup>108</sup>

### **Brady Enterprises v. Medco**

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.<sup>109</sup> 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.<sup>110</sup> On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.<sup>111</sup>

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.<sup>112</sup> Caremark F/K/A Advance PCS appealed this decision to the 3rd Circuit on January 24, 2007.<sup>113</sup> On September 24, 2009, the 3rd Circuit vacated the prior instant judge's order and remanded with directions to reinstate

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<sup>104</sup> See Memorandum and Order, *Bellevue Drug Co.*, No. 2:03-cv-04731, Entry No. 13 (E.D. Pa. Mar. 2, 2004).

<sup>105</sup> See Motion to Compel Arbitration, *Bellevue Drug Co.*, No. 2:03-cv-04731, Entry No. 32 (E.D. Pa. June 21, 2004).

<sup>106</sup> See Memorandum and Order, *Bellevue Drug Co.*, No. 2:03-cv-04731, Entry No. 51 (Aug. 23, 2004).

<sup>107</sup> See Motion for Reconsideration, *Bellevue Drug Co.*, No. 2:03-cv-04731, Entry No. 52 (Sept. 7, 2004); see also Order Denying Motion for Reconsideration, Entry No. 66 (June 17, 2005).

<sup>108</sup> See *In re Pharmacy Benefit Managers Antitrust Litigation*, 452 F. Supp. 2d 1352 (Jud. Pan. Mult. Lit. 2006).

<sup>109</sup> Motions to Dismiss for Failure to State a Claim Upon Which Relief Can Be Granted, *Brady Enterprises*, No. 2:03-cv-04730, Entry Nos. 5, 6 (Nov. 17, 2003).

<sup>110</sup> Memorandum and Order, *Brady Enterprises*, No. 2:03-cv-04730, Entry No. 10 (Aug. 2, 2004).

<sup>111</sup> See *In re Pharmacy Benefit Managers Antitrust Litigation*, 452 F. Supp. 2d 1352 (Jud. Pan. Mult. Lit. 2006).

<sup>112</sup> See *In re Pharmacy Benefit Managers Antitrust Litigation*, No. 03-cv-04731-JF, 2006 WL 3759712 (E.D. Pa. Dec. 18, 2006) vacated by *In re Pharmacy Benefit Managers Antitrust Litigation*, 582 F.3d 432 (3d Cir. 2009).

<sup>113</sup> See *In re Pharmacy Benefit Managers Antitrust Litigation*, No. 07-1151 (3d Cir. Jan. 24, 2007).

the previous judge's order compelling arbitration.<sup>114</sup> As of November 4, 2010, 6 of the 6 multidistrict litigation actions are pending before the court.<sup>115</sup>

*North Jackson Pharmacy, Inc., et al. v. Medco Health Solutions, Inc., et al.*, C.A. Nos. 5:03-02696; 5:03-2697; and 1:04-5674 (N.D. Ala. Oct. 1, 2003 and N.D. Ill. Aug. 30, 2004)

**Filed:**                   **October 1, 2003**

**Cause of Action:**   **Sherman Act**

**Transferred:**       **September 6, 2006 and September 13, 2006**

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## **Background**

Plan sponsors hire pharmacy benefits managers to administer prescription drug benefits on behalf of its plan subscribers (i.e., employees or members). The pharmacy benefit managers each create a network of retail pharmacies where their plan subscribers can purchase drugs at discounted prices. To build this network, the PBMs approach independent pharmacies and negotiate their inclusion in the PBM's network. However, before independent pharmacies can be included in the PBMs' networks, the pharmacies must agree to dispense drugs to the PBMs' plan subscribers at a discounted rate from the pharmacy's other customers.<sup>116</sup> The agreement between the pharmacy and the PBM determines the discounted rate that the pharmacy dispenses at.<sup>117</sup>

According to North Jackson, negotiations with these PBMs leave independent pharmacies with a choice between being included in a PBM's network while being required to accept unconscionable low reimbursement rates for drugs; and alternatively, being excluded from the PBM's network and losing access to the plan subscribers who have an incentive to fill their prescriptions at network pharmacies.<sup>118</sup> On October 1, 2003, North Jackson Pharmacy filed three related lawsuits against Advance PCS and Caremark, Express Scripts, and Medco in the U.S. District Court for the Northern District of Alabama challenging these pricing practices.<sup>119</sup>

## **Alleged Unlawful Conduct**

In these actions, North Jackson Pharmacy alleges that the PBM defendants engaged in price fixing and other unlawful concerted actions to restrain trade in the dispensing and sale of prescription drugs. According to the Complaint, the defendants' actions have harmed participants in programs or plans who have purchased their medications from retail pharmacies. North

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<sup>114</sup> *In re Pharmacy Benefit Managers Antitrust Litigation*, 582 F.3d 432 (3d Cir. 2009).

<sup>115</sup> Distribution of Pending MDL Dockets (November 4, 2010), UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, available at [http://www.jpml.uscourts.gov/Pending\\_MDL\\_Dockets-November-2010-Modified.pdf](http://www.jpml.uscourts.gov/Pending_MDL_Dockets-November-2010-Modified.pdf).

<sup>116</sup> *North Jackson Pharmacy, Inc. v. Caremark RX, Inc.*, 385 F. Supp. 2d 740, 744 (N.D. Ill. 2005).

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *See* *North Jackson Pharmacy, Inc., et al. v. Express Scripts Inc., et al.*, C.A. No. 5:03-02696 (N.D. Ala. Oct. 1, 2003) (designated as the lead case); *see also* *North Jackson Pharmacy, Inc., et al. v. Medco Health Solutions, Inc., et al.*, C.A. No. 5:03-02697 (N.D. Ala. Oct. 1, 2003); and *North Jackson Pharmacy, Inc., et al. v. Caremark RX Inc., et al.*, C.A. No. 5:03-02695 (N.D. Ala. Oct. 1, 2003).

Jackson objects to Caremark's "creation of retail pharmacy networks and its negotiation of reimbursement rates on plan sponsors' behalf."<sup>120</sup> Further, North Jackson Pharmacy alleges 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.

### **Proceedings<sup>121</sup>**

The defendants argued that the plaintiffs' allegations failed to convincingly explain how consumers or the marketplace were injured as a result of the defendants' alleged anticompetitive behavior. On October 13, 2004, the court in the two of the actions, the actions against Express Scripts and Medco, denied the defendants' motion to dismiss the plaintiff's second amended complaint.<sup>122</sup> The court, 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 September 15, 2006 these cases were transferred to the Eastern District of Pennsylvania with Judge John P. Fullam presiding.<sup>123</sup> Additionally, they have been joined to the *In re: Pharmacy Benefit Managers Antitrust Litigation* multidistrict litigation in the Eastern District of Pennsylvania.

On August 3, 2004, the action against Caremark Rx was transferred to the U.S. District Court for the Northern District of Illinois.<sup>124</sup> 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.<sup>125</sup> 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.<sup>126</sup> Case was reopened on April 12, 2006, but was transferred to the Eastern District of Pennsylvania on September 16, 2006 with Judge John P. Fullam presiding.<sup>127</sup> Additionally this case have been joined to the *In re: Pharmacy Benefit Managers Antitrust Litigation* multidistrict litigation in the Eastern District of Pennsylvania.<sup>128</sup>

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<sup>120</sup> North Jackson Pharmacy, Inc. v. Caremark RX, Inc., 385 F. Supp. 2d 740, 744 (N.D. Ill. 2005).

<sup>121</sup> For opinions see North Jackson Pharmacy, Inc. v. Caremark RX, Inc., No. 1:04-cv-05674, 2004 WL 2491630 (N.D. Ill. Nov. 3, 2004); North Jackson Pharmacy, Inc. v. Caremark RX, Inc., 385 F. Supp. 2d 740 (N.D. Ill. 2005); and North Jackson Pharmacy, Inc. v. Express Scripts, Inc., Nos. 5:03-02696, 5:03-02697, 2006 WL 6625864 (N.D. Ala. Mar. 3, 2006).

<sup>122</sup> See Order Denying Motion to Dismiss, *Medco*, No. 5:03-2697, Entry No. 37 (N.D. Ala. Oct. 13, 2004).

<sup>123</sup> Docket Nos. 2:06-cv-04114 and 2:06-cv-04115.

<sup>124</sup> Docket No. 5:03-02695 was transferred to No. 1:04-05674

<sup>125</sup> See Memorandum Order, *Caremark Rx*, No. 1:04-05674, Entry No. 118 (N.D. Ill. Nov. 2, 2004).

<sup>126</sup> Order Dismissing Action, *Caremark Rx*, No. 1:04-05674, Entry No. 155 (N.D. Ill. Mar. 24, 2006).

<sup>127</sup> Docket No. 1:04-05674 was transferred to 2:06-cv-04305.

<sup>128</sup> See *In re Pharmacy Ben. Managers*, 452 F. Supp. 2d 1352 (Jud. Pan. Mult. Lit. 2006).

### III. FEDERAL CASES

*Aetna, Inc. et al. v. Express Scripts, Inc. et al.*, No. 2:07-cv-05541 (E.D. Pa. filed Dec. 31, 2007).

**Filed:** December 31, 2007  
**Cause of Action:** Breach of Contract  
**Settled:** October 22, 2009  
**Damages:** \$30 million

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#### Background

On August 1, 2004 Aetna and Priority Healthcare (a specialty pharmacy company) entered into a series of agreements creating ASP, a joint venture for the purpose of “establishing, building, owning and operating a stand alone integrated specialty pharmacy business and included Clinical Programs.”<sup>129</sup> One of the provisions in the agreements created an option that allowed Aetna to purchase Priority’s interest in ASP for \$75 million (the Purchase Option).<sup>130</sup> On October 14, 2005 Express Scripts acquired Priority.

Following the merger, Aetna gave Priority notice that it intended to exercise the Purchase Option of Priority’s stake in ASP.<sup>131</sup> On December 30, 2005, Aetna wired Express Scripts \$75 million as a payment for the Purchase Option in the agreements.<sup>132</sup> Aetna sought the return of the \$75 million, among other damages and injunctive relief. During a conference call on August 8, 2006, the CEO of the newly merged company represented that Priority would not honor its continuing obligations under the agreements.<sup>133</sup> On December 31, 2007, Aetna filed suit against Express Scripts, Inc. in the United States District Court for the Eastern District of Pennsylvania.

#### Alleged Unlawful Conduct

Aetna is accusing Express Scripts of harming the health insurer by illegally disrupting agreements Aetna made with Priority Healthcare. Aetna’s complaint surmises that Express Scripts violated agreements forged between Aetna and Priority in their joint venture, and thus Express Scripts has “gained an unfair competitive advantage” that precludes Aetna and its specialty pharmacy business from “prospective advantageous relationships and markets.”

#### Settlement

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<sup>129</sup> Compl., *Aetna, Inc. et al. v. Express Scripts, Inc. et al.* No. 2:07-cv-05541 at ¶ 18 (E.D. Pa. Dec. 31, 2007).

<sup>130</sup> *Id.* at ¶ 33.

<sup>131</sup> *Id.* at ¶ 69.

<sup>132</sup> *Id.* at ¶ 79.

<sup>133</sup> *Id.* at ¶¶ 83, 86.



On October 22, 2009, the court dismissed the lawsuit after the parties settled for \$30 million. Aetna received approximately \$19.6 million net of fees and expenses.<sup>134</sup>

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<sup>134</sup> Aetna Inc. Form 10-K for fiscal year 2009, Exhibit 13.1 Annual Report at 5 (filed Feb. 26, 2010) available at: [http://www.sec.gov/Archives/edgar/data/1122304/000112230410000024/ex13\\_1.htm](http://www.sec.gov/Archives/edgar/data/1122304/000112230410000024/ex13_1.htm).

*American Medical Security Holdings, Inc. v. Medco Health Solutions, Inc.*, No. 1:03-cv-00431-WCG (E.D. Wis. filed May 13, 2003)

**Filed:** May 13, 2003  
**Cause of Action:** Breach of Contract  
**Settled:** March 23, 2004  
**Damages:** \$5.85 million

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### **Background**

In 2000, Merck-Medco agreed to acquire ProVantage, Inc., a pharmacy benefits manager. American Medical Security Holdings (AMS) was a former customer of ProVantage. This lawsuit was filed on May 13, 2003 in the U.S. District Court for the Eastern District of Wisconsin by AMS against Medco based in Green Bay. The case appeared before Judge William Griesbach.

### **Alleged Unlawful Conduct**

The dispute related to pricing and prescription drug fees charged from 1995 through 2002. The suit alleged breach of contract involving discounted pricing and prescription dispensing fees and demanded \$16,400,000.

### **Settlement**

On March 23, 2004, American Medical Security Holdings and Medco announced that they had reached a settlement agreement. Under the terms of the agreement, AMS would receive a one-time payment of \$5.85 million.<sup>135</sup> On April 8, the parties entered into a stipulation and order to dismiss the case on the merits with prejudice.

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<sup>135</sup> Press Release, *American Medical Security Group Settles Dispute Involving Former Pharmacy Benefits Manager*, American Medical Security Group, Inc., Included in Form 8-K, Exhibit No. 99 (filed Mar. 23, 2004) available at: <http://www.sec.gov/Archives/edgar/data/878897/000087889704000020/exhibit99.txt>.

*Bickley v. Caremark Rx, Inc., et al.*, No. 2:02-cv-02197 (N.D. Ala. filed Sept. 6, 2002)

**Filed:** September 6, 2002  
**Cause of Action:** ERISA  
**Resolved:** Against Plaintiff on June 27, 2006 (Appeal)  
**Damages:** N/A

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### **Background**

Roland Bickley was a participant in the Georgia Pacific Corporation Life Health and Accident Plan, and other self-funded group health plans (collectively “the health plans”). The health plans are “employee benefit plans” under the Employee Retirement Income Security Act (ERISA),<sup>136</sup> which utilized Caremark as their pharmacy benefits manager. Caremark’s role in administering the health plans was to contract with retail pharmacies so that they would provide drugs to beneficiaries at discounted rates; also, Caremark purchased drugs directly from the manufacturer at a discounted price to sell through Caremark’s mail order pharmacies.

On September 6, 2002, in his capacity as a participant, Bickley brought a class action on behalf of the health plans in the Northern District of Alabama.<sup>137</sup> The judge who heard the case was Judge Virginia Emerson Hopkins.

### **Alleged Unlawful Conduct**

Bickley alleged that Caremark qualifies as a fiduciary under ERISA and that as a fiduciary of the health plans; Caremark breached its fiduciary duties.<sup>138</sup> Bickley alleges three ways that Caremark breached its fiduciary duties. According to Bickley: Caremark used pricing spreads to divert discounts from the health plans to itself;<sup>139</sup> Caremark utilized its “vast buying power and ability to control market share” to negotiate terms with drug manufacturers, requiring them “to pay Caremark kickbacks in the form of rebates, discounts and other soft dollars;”<sup>140</sup> finally, Caremark helped drug manufacturers inflate the average wholesale price of their drugs.

#### **1. Pricing Spreads**

While acting as the pharmacy benefits manager for the health plans, Caremark entered into contracts with retail pharmacists agreeing to pay certain prices for beneficiaries’ drugs. The complaint alleges that through its fiduciary relationship with the health plans, Caremark utilized

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<sup>136</sup> Employee Retirement Income and Security Act of 1974, 29 U.S.C. § 1001 et. seq. (2006).

<sup>137</sup> Bickley alleged he had standing pursuant to 29 U.S.C. § 1132(a)(2) (2006).

<sup>138</sup> First Amended Compl. at ¶ 2.

<sup>139</sup> First Amended Compl. *Bickley v. Caremark Rx, Inc., et al.*, No. 2:02-cv-02197 ¶ 3 (N.D. Ala. Filed Oct. 4, 2002).

<sup>140</sup> *Id.* at ¶ 4.

its leverage to obtain discounted rates on drugs from retail pharmacies – i.e., that Caremark would reimburse pharmacies less than the pharmacies typically would charge for a given drug because pharmacies wanted access to Caremark’s large beneficiary network.<sup>141</sup> The complaint alleged that for brand-name drugs, Caremark would pay a dispensing fee and the drug’s Average Wholesale Price minus a specific discount; for generic drugs, Caremark would typically pay a dispensing fee and the drug’s Maximum Allowable Cost minus a discount.<sup>142</sup>

Bickley alleges that Caremark failed to disclose that it was receiving discounts on brand-name and generic drugs. This failure allowed Caremark to create a spread between the amount that the health plans gave Caremark to pay pharmacies (on behalf of beneficiaries) and the amount that Caremark actually paid to retail pharmacies for the drugs.<sup>143</sup> Essentially, when Caremark obtained a discount, rather than passing the savings onto health plan beneficiaries, Caremark held onto those discounts for itself without informing the health plans. Further, Caremark also allegedly utilized its leverage to negotiate discounts when it purchased drugs from manufacturers, which Caremark would sell to beneficiaries through mail-order prescriptions. Again, Caremark did not pass along the discounts to beneficiaries and did not disclose that it received discounts.<sup>144</sup>

## 2. Kickbacks

The complaint alleges that Caremark negotiated with manufacturers to favor more expensive (but equivalent) drugs in Caremark’s drug switching program in exchange for compensation from the manufacturer. These kickbacks were in the forms of rebates, mail-order discounts and other “soft dollars.” Bickley alleges that the practice both increased costs to the health plans by favoring more expensive products, and that Caremark deprived the health plans of assets that should have been passed along to them. Caremark would also favor less expensive drugs, but still would retain manufacturers’ discounts, rebates, and “soft dollars.”

## 3. Best Pricing Rules

The Omnibus Budget and Reconciliation Act of 1990 sets forth “best price” rules to ensure that the government can obtain the lowest price from manufacturers on drugs.<sup>145</sup> The best price is based on a drug’s Average Wholesale Price, but also includes any rebates and discounts provided to any third-party purchasers, including PBMs.<sup>146</sup> Because the government is a large purchaser of drugs, manufacturers have an incentive to increase their drugs’ Average Wholesale Price. The complaint alleges that Caremark assisted drug manufacturers in distorting the Average Wholesale Price of drugs by accepting incentives from manufacturers other than discounts or

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<sup>141</sup> *Id.* at ¶ 29.

<sup>142</sup> *Id.* The Maximum Allowable Cost is the maximum price that the federal government will pay for generic drugs.

<sup>143</sup> *Id.* at ¶ 30.

<sup>144</sup> *Id.* at ¶ 31.

<sup>145</sup> *Id.* at ¶ 37.

<sup>146</sup> 42 U.S.C. § 1396r-8 (2006).

rebates (things that are not included in the “best price” calculation). These incentives may include health management and data sales fees, or other indirect forms of compensation. Caremark allegedly breached its fiduciary duties by increasing the health plans’ prescription drug costs and also depriving the health plans of the benefits of the incentives that Caremark received from the manufacturers.

### **Proceedings**<sup>147</sup>

On October 4, 2002, shortly after the filing of the complaint, Caremark filed a motion to dismiss denying that it had a fiduciary duty to the health plans under ERISA. Caremark challenged Bickley’s standing to maintain an action stating that he failed to exhaust administrative remedies before bringing suit. On December 30, 2004, the court granted Caremark’s motion to dismiss finding that Caremark was not a fiduciary reasoning that Caremark did not have sufficient discretion over benefit decisions for the health plans.<sup>148</sup> The court noted that the health plan’s contract with Caremark explicitly allowed Caremark to receive rebates from drug manufactures; however, the court held that “advantageous contracts” do not convert a party into an ERISA fiduciary.<sup>149</sup> Thus, according to the court, Bickley lacked standing to bring suit under ERISA because Caremark was not an ERISA fiduciary to the health plans.

Bickley appealed to the 11th Circuit.<sup>150</sup> Bickley argued to the court that he should not have been required to exhaust all administrative remedies because there were no administrative remedies available to him in his claim of breach of fiduciary duty. The court disagreed with this argument stating that every plaintiff in an ERISA case is required to exhaust all administrative remedies before filing suit. Thus, on June 27, 2006, the court affirmed district court’s ruling.<sup>151</sup> However, the circuit judge court noted that the district court has the discretion to waive exhaustion if the judge deems it appropriate under the circumstances. Furthermore, the court ruled that the district court did not abuse its discretion when it ruled that Bickley should have exhausted all administrative remedies before bringing suit.

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<sup>147</sup> See *Bickley v. Caremark Rx, Inc.*, 361 F. Supp. 2d 1317 (N.D. Ala. 2004); *Bickley v. Caremark RX, Inc.*, 461 F.3d 1325 (11th Cir. 2006).

<sup>148</sup> *Bickley v. Caremark Rx, Inc.*, 361 F. Supp. 2d 1317, 1332 (N.D. Ala. 2004)

<sup>149</sup> *Id.*

<sup>150</sup> *Roland H. Bickley v. Caremark Rx, Inc.*, No. 05-10973 (11th Cir. filed Feb. 24, 2005).

<sup>151</sup> See *Bickley v. Caremark RX, Inc.*, 461 F.3d 1325 (11th Cir. 2006).

*Healthfirst, et al. v. Merck-Medco, et al.*, No. 1:03-cv-05164-RLC (S.D.N.Y. filed July 11, 2003)

**Filed:** July 11, 2003  
**Cause of Action:** Breach of Contract  
**Settled:** November 5, 2007  
**Damages:** Undisclosed

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### **Background**

On February 1, 1999, Healthfirst<sup>152</sup> and Medco<sup>153</sup> entered into an Integrated Prescription Drug Program Agreement. The agreement required Medco to provide pharmacy benefit management services. Healthfirst is a nonprofit healthcare management company and entered into the agreement with Medco “to contain costs and achieve savings by providing drug benefits through a managerial care” program.<sup>154</sup> The agreement provided that Healthfirst was entitled to the rebates that Medco received when administering the Healthfirst’s plan.<sup>155</sup> Medco agreed to pass along all rebates that Medco received from manufacturers for dispensing drugs under the Healthfirst retail program.<sup>156</sup> Medco would retain 20% or 25% of the rebate as a management fee.<sup>157</sup>

In 2002, a dispute arose over Medco’s fees. Medco claimed that Healthfirst owed Medco for savings achieved under the agreement amounting to over \$1 million.<sup>158</sup> When Healthfirst requested detailed billing information on the amounts withheld, Medco refused to provide the information “purportedly because doing so would violate the confidentiality provisions in their contracts with pharmaceutical companies.”<sup>159</sup> Instead, Medco told Healthfirst that if it wanted to have an outsider review the rebates, Healthfirst would need to hire a “Big Four Accounting

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<sup>152</sup> “Healthfirst” includes Healthfirst Inc., Managed Health, Inc., Healthfirst PHSP, Inc. and HF Administrative Services Inc.

<sup>153</sup> “Medco” includes Medco Health Solutions, Inc., Systemed, L.L.C., Merck-Medco Rx Services of Massachusetts, L.L.C., and Paid Prescriptions, L.L.C.

<sup>154</sup> *Healthfirst, Inc. v. Medco Health Solutions, Inc.*, No. 03-cv-5164 (RLC), 2006 WL 3711567 at \*1 (S.D.N.Y. Dec. 15, 2006).

<sup>155</sup> Amended Complaint and Request for Declaratory Judgment, *Healthfirst, et al. v. Merck-Medco, et al.*, No. 03-cv-05164-RLC at ¶ 30 (S.D.N.Y. Dec. 26, 2006). The agreement stated that the Net Effective Discount “is calculated by giving effect to the impact of the values of: the negotiated network discount, MAC pricing, U&C Pricing, the applicable Dispensing Fee, and savings achieved through PAID’s pharmacy audit program, against the AWP of all prescriptions dispensed under the Program and submitted by Participating Pharmacies via TelePAID.” *Id.* at ¶ 32.

<sup>156</sup> *Id.* at ¶ 30.

<sup>157</sup> *Id.*

<sup>158</sup> Specifically, Medco claimed that in addition to the \$0.73 dispensing fee, Healthfirst owed \$1.27 for each prescription that was dispensed. *Healthfirst*, 2006 WL 3711567 at \*1.

<sup>159</sup> *Id.*

Firm.”<sup>160</sup> Healthfirst filed suit against Medco for breach of contract on July 11, 2003 in the Southern District of New York. The case appeared before Judge Robert L. Carter.

### **Alleged Unlawful Conduct**

Healthfirst’s complaint included six causes of action: breach of contract, fraud, breach of duty of good faith and fair dealing, conversion, and actions for a declaratory judgment against the defendants and an action for accounting.

Healthfirst alleged that Medco regularly refused to pass through or accurately account the discounts and rebate payments that Medco received from manufacturers.<sup>161</sup> Medco withheld rebates from Healthfirst that were due during their 2002 contract, which Healthfirst alleged were an “illegal offset to ‘phantom’ savings” and Medco used these phantom savings to induce Healthfirst to renew its contract.<sup>162</sup> Based on these practices, Healthfirst alleged that Medco “regularly engages in deceptive business practices” when it calculates the Net Effective Discount and claims that its customers owe money that they does not owe.<sup>163</sup> Furthermore, Medco would allegedly refuse to provide customers with reports demonstrating Medco’s calculations.<sup>164</sup> These actions fell outside of the scope of the contract.

Healthfirst also alleged that Medco reports a savings “each time a prescription is flagged under the Managed Rx Coverage Program even if the retail pharmacist ignores the flag.”<sup>165</sup> Medco overrides the code and fills the prescription with a drug priced higher or lower.<sup>166</sup> Medco’s allegedly manipulated its savings calculations to appear as though Medco saved money, even where no money had been saved, and then demanded payment from the client on the savings.<sup>167</sup>

### **Proceedings**

Healthfirst sought to amend its complaint to add state law claims for breach of contract, fraud, breach of the covenant of good faith and fair dealing, conversion and declaratory judgment. Also, Healthfirst moved for summary judgment against Medco to reject Medco’s submissions of responses to Healthfirst’s Requests for Admissions because they were late. The court granted Healthfirst’s motion to amend its complaint and denied its motion for summary judgment.<sup>168</sup>

### **Settlement**

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<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at ¶ 46.

<sup>162</sup> *Id.* at ¶ 48.

<sup>163</sup> *Id.* at ¶ 59.

<sup>164</sup> *Id.* at ¶ 60. For example, Medco contracted with a network of pharmacies with an average dispensing fee of \$0.73 a claim. Around July 16, 2002, when Medco presented the amounts Healthfirst owed under the Net Effective Guarantee, Medco claimed that Healthfirst owed \$2.00 per claim. *Id.* at ¶ 64.

<sup>165</sup> *Id.* at ¶ 69.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at ¶ 71. One way Medco accomplished this was by calculating savings based on the average length of therapy.

<sup>168</sup> *Healthfirst*, 2006 WL 3711567 at \*5.

On November 5, 2007 the parties agreed to settle for an undisclosed amount and the Court dismissed this case.



*Moeckel v. Caremark RX, Inc., et al.*, No. 3:04-cv-00633 (M.D. Tenn. July 19, 2004)

**Filed:** July 19, 2004  
**Cause of Action:** ERISA  
**Resolved:** Against Plaintiff (April 3, 2008)  
**Damages:** N/A

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### **Background**

This ERISA action was commenced against Caremark Rx, Inc. and Caremark in July 19, 2004 in the US District Court for the Middle District of Tennessee. Moeckel, an employee of the John Morrell Company, brought suit against its prescription drug benefits administrator for alleged breach of fiduciary duties under the ERISA Act by failing to disclose to the plans the discounted price that Caremark had paid for drugs purchased by plan participants and beneficiaries at retail pharmacies.

### **Alleged Unlawful Conduct**

Moeckel claimed that by providing PBM services to John Morrell Co., Caremark became a fiduciary under ERISA. Specifically, the complaint alleged that Caremark created and retained a pricing spread between the discounted price it paid to retail pharmacies and manufacturers and the price at which Caremark agreed to be reimbursed by the plans. Further, Moeckel alleged that Caremark contracted with manufacturers in ways that enriched Caremark and engaged in self-dealing by characterizing compensation in ways that would maximize Caremark's revenue at the detriment to John Morrell Co.

### **Proceedings**

September 10, 2004, defendants filed a motion to dismiss for lack of standing and failure to state a claim upon which relief can be granted; or in the alternative, transfer venue to the Northern District of Alabama. On August 29, 2005, the court granted the motion to dismiss with respect to Caremark Rx, Inc., but denied the rest of the motion and denied a transfer of venue. Discovery commenced hereafter.

On May 7, 2007, both plaintiff and defendant filed cross-motions for partial summary judgment on the issue of Caremark's fiduciary status under ERISA. Plaintiff argued that Caremark acted in a fiduciary manner with respect to the following five acts of ERISA plan management: 1) Caremark set the price the plan paid for generic prescriptions; 2) Caremark solely selected the AWP source Caremark used to set plan prescription prices; 3) Caremark solely decided whether a drug would be adjudicated and priced as a brand-named or generic prescription; 4) Caremark solely decided when it would dispense a brand-named drug as a generic prescription at its mail order facilities, and 5) Caremark solely managed the plan's prescription drug benefit formulary

and decided which member drugs to switch to formulary-preferred prescriptions. Caremark responded by stating that the activities identified by the plaintiff relate to the basic administration of Caremark's own business, which is a non fiduciary one.

On November 13, 2007, Judge Trauger sided with defendant Caremark, granting its motion for partial summary Judgment. Trauger ruled that Caremark did not exercise discretionary authority or control over the management of the John Morrell Co. plan, that Caremark's activities related to the basic administration of Caremark's own duties, which is non-fiduciary in nature, and therefore that Caremark's activities relating to the plan administration were outside the scope of ERISA's regulatory framework. On April 3, 2008 the court dismissed Moeckel's claims with prejudice.

*Mulder v. PCS Health Systems, Inc.*, No. 2:98-cv-01003-WGB (D.N.J. filed Mar. 6, 1998)

**Filed:** March 6, 1998  
**Cause of Action:** ERISA  
**Resolved:** Against Plaintiff on April 18, 2006  
**Damages:** N/A

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### **Background**

Ed Mulder worked for Scott Printing Company, Inc. in 1997 and 1998 and participated in the employee health plan offered by Scott. The employee sponsored plan had coverage through Oxford Health Plans and Oxford contracted with PCS Health Systems to provide PBM services. Mulder received a notice from PCS that the company was switching his cholesterol lowering drug, Mevacor, to a more expensive prescription, Pravachol.

On March 6, 1998, on behalf of all PCS beneficiaries, Mulder filed a class action complaint against PCS in the New Jersey District Court for alleged breaches of its fiduciary duties under ERISA by not passing on rebates and discounts to the plan participants that the PBM had negotiated with drug manufacturers. Accordingly, Mulder sought a judgment:

- (1) declaring PCS's practices unlawful;
- (2) enjoining PCS from continuing the practices;
- (3) granting equitable relief including
  - a) an accounting of all illegal profits,
  - b) establishing a constructive trust on behalf of all affected employee benefit plans, and
  - c) ordering PCS to disgorge all illegal profits into a constructive trust to be “distributed appropriately to the affected employee benefit plans;”
- (4) awarding Mulder and other class members their litigation costs and reasonable attorneys' fees; and
- (5) “[c]reating an appropriate claims resolution facility for the resolution of individual issues, if any, remaining after resolution of class issues.”<sup>169</sup>

### **Alleged Unlawful Conduct**

Mulder alleged that PCS switched the drug to increase its profits through rebates and kickbacks that the PBM received through the manufacturers. Further, Mulder argued that “PCS entered into separate contracts with drug manufacturers that provided PCS with rebates and fees based on the

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<sup>169</sup> *Mulder v. PCS Health Sys., Inc.*, 216 F.R.D. 307, 319 (D.N.J. 2003) quoting *Compl. Mulder v. PCS Health Systems, Inc.*, No. 2:98-cv-1003-WGB at ¶ 52 (D.N.J. filed Mar. 6, 1998).

usage of the manufacturers' drugs by PCS's clients. The greater the usage of certain drugs by PCS's clients, the higher the rebates and fees that were paid to PCS."<sup>170</sup>

Mulder sought relief for PCS's alleged breach the company's fiduciary duties under ERISA.<sup>171</sup> Mulder alleged that "PCS exercised discretionary authority in connection with its drug prescription services and breached its fiduciary duties under ERISA to plan beneficiaries by enriching itself at the expense of the interests of those beneficiaries."<sup>172</sup> Specifically, the complaint alleged that PCS breached its fiduciary duties by: (1) contracting with employee benefit plan which secured illegal windfall profits for PCS; (2) implementing programs to influence pharmacists and physicians to switch the drugs of plan participants; and (3) utilizing a method of determining formulary and preferred drugs that did not serve the best interests of the plan participants.<sup>173</sup>

### **Proceedings**<sup>174</sup>

The court certified the class on July 17, 2003, which consisted "of all participants, from March 5, 1995 through March 5, 1998, in ERISA-covered employee benefit plans administered by Oxford and for which PCS provided PMB services pursuant to its Commercial Contract with Oxford."<sup>175</sup>

PCS moved for summary judgment on July 29, 2005 arguing that the undisputed facts demonstrated that the alleged activities were outside the scope of ERISA's regulatory framework.<sup>176</sup> PCS further argued that PCS had no decision-making authority in exercising the challenged activities as required by ERISA.<sup>177</sup> The District Court judge agreed with PCS that their activities were outside the regulatory scope of ERISA, and granted summary judgment to PCS, dismissing the case on April 18, 2006.

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<sup>170</sup> Mulder v. PCS Health Sys., Inc., 432 F. Supp. 2d 450, 453 (D.N.J. 2006).

<sup>171</sup> Compl. ¶ 49-52. This includes violations under 29 U.S.C. §§ 1104(a)(1)(A), (B) and (D), and 1106(a) and (b).

<sup>172</sup> Mulder v. PCS Health Sys., Inc., 432 F. Supp. 2d 450, 453 (D.N.J. 2006).

<sup>173</sup> Mulder v. PCS Health Sys., Inc., 216 F.R.D. 307, 311 (D.N.J. 2003)

<sup>174</sup> See Mulder v. PCS Health Sys., Inc., 216 F.R.D. 307 (D.N.J. 2003); see also Mulder v. PCS Health Sys., Inc., 432 F. Supp. 2d 450 (D.N.J. 2006)

<sup>175</sup> Mulder v. PCS Health Sys., Inc., 216 F.R.D. 307, 320 (D.N.J. 2003).

<sup>176</sup> Mulder v. PCS Health Sys., Inc., 432 F. Supp. 2d 450, 453 (D.N.J. 2006).

<sup>177</sup> *Id.*

*Pharmaceutical Care Management Ass'n v. Maine Atty. Gen.*, 1:03-cv-00153-B-W (D. Me. filed Sept. 3, 2003)<sup>178</sup>

**Filed:** September 3, 2003  
**Cause of Action:** Statutory Challenge  
**Resolved:** November 8, 2005  
**Damages:** N/A

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### **Background**

The Maine legislature adopted the Unfair Prescription Drug Practices Act, 22 M.R.S.A. § 2699 in 2003 (UPDPA). The act 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.

### **Constitutional Challenge**

The Pharmaceutical Care Management Association (PCMA) filed suit against the State of Maine on September 3, 2003, in the U.S. District Court of Maine, seeking declaratory and injunctive relief from the fiduciary obligations and disclosure requirements set forth in the UPDPA. The PCMA complaint alleged that the statute violated the Commerce Clause by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies. Further, PCMA claimed that the statute constituted a “taking” of property for which

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<sup>178</sup> For appellate docket *see* *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, No. 05-1606 (1st Cir. filed Apr. 25, 2005).

just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. Finally, PCMA argued that ERISA preempts the Maine state law.

### **Proceedings**<sup>179</sup>

On March 9, 2004, the court issued a preliminary injunction temporarily blocking the implementation of the Unfair Prescription Drug Practices Act.<sup>180</sup> On April 16, Judge Brock Hornby issued an order rejecting PCMA's challenge to the Maine statute.<sup>181</sup> Trial began on April 26, 2005 and on February 2, 2005 the federal district court granted summary judgment in favor of Maine on all claims.<sup>182</sup> PCMA appealed to the U.S. Court of Appeals for the First Circuit.<sup>183</sup> However, the First Circuit unanimously upheld the district court's ruling, which effectively required PBMs to disclose information regarding rebates from pharmaceutical manufacturers.<sup>184</sup>

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<sup>179</sup> Pharmaceutical Care Mgmt. Ass'n v. Rowe, 307 F. Supp. 2d 164 (D. Me. 2004); Pharmaceutical Care Mgmt. Ass'n v. Me. Atty. Gen., 332 F. Supp. 2d 258 (D. Me. 2004); Pharmaceutical Care Mgmt. Ass'n v. Rowe, No. Civ. 03-153-B-H, 2005 WL 757608 (D. Me. Feb. 2, 2005); Pharmaceutical Care Mgmt. Ass'n v. Rowe, 429 F.3d 294 (1st Cir. 2005).

<sup>180</sup> Pharmaceutical Care Mgmt. Ass'n v. Rowe, 307 F. Supp. 2d 164 (D. Me. 2004). Judge Woodcock issued the preliminary injunction.

<sup>181</sup> See Pharmaceutical Care Mgmt. Ass'n v. Me. Atty. Gen., 332 F. Supp. 2d 258 (D. Me. 2004).

<sup>182</sup> Pharmaceutical Care Mgmt. Ass'n v. Rowe, No. Civ. 03-153-B-H, 2005 WL 757608 (D. Me. Feb. 2, 2005);

<sup>183</sup> Pharmaceutical Care Mgmt. Ass'n v. Rowe, 429 F.3d 294 (1st Cir. 2005) *cert denied by* Pharmaceutical Care Management Ass'n v. Rowe, 547 U.S. 1179 (2006).

<sup>184</sup> See *id.*

*Pharmaceutical Care Management Ass'n v. District of Columbia, et al.*, No. 1:04-cv-01082 (D.D.C. June 29, 2004)<sup>185</sup>

**Filed:** June 29, 2004  
**Cause of Action:** Statutory Challenge  
**Status:** Supreme Court Appeal Pending  
**Pending as of:** December 2, 2010

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## Background

In response to rising prescription drug prices the D.C. Council unanimously passed the Access Rx Act, which took effect on May 18, 2004.<sup>186</sup> The Council estimated that the Access Rx Act would lower the cost of prescription drugs.<sup>187</sup> The D.C. statute imposes fiduciary duties on Pharmacy Benefits Managers for their dealings with covered entities and requires that PBMs engage in transparent business practices.<sup>188</sup> Specifically, the Act requires that PBMs notify a covered entity of any conflict of interests.

When a PBM receives any payment or benefit of any kind<sup>189</sup> from a drug manufacturer or labeler in connection with the utilization of prescription drugs by covered individuals, the Act requires that the PBM pass along the payments or benefits that the PBM received to the covered entity in full.<sup>190</sup> Furthermore, when requested by a covered entity, the PBM 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).<sup>191</sup> The Access Rx Act 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.<sup>192</sup> 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.<sup>193</sup>

On June 29, 2004, the Pharmaceutical Care Management Association (PCMA) filed suit in the U.S. District Court for the District of Columbia seeking an injunction to block enforcement of Title II of the Access Rx Act of 2004.

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<sup>185</sup> For appeals *see* *Pharmaceutical Care Mgmt Ass'n v. District of Columbia, et al.*, No. 09-7042 (D.C. Cir. Apr. 15, 2009); *see also* *District of Columbia, et al. v. Pharmaceutical Care Mgmt Ass'n*, No. 10A327 (U.S. Sept. 27, 2010).

<sup>186</sup> *See* D.C. Code § 48-832.01 et. seq.

<sup>187</sup> *Pharmaceutical Care Mgmt Ass'n v. District of Columbia, et al.*, 605 F. Supp. 2d 77, 79 (D.D.C. 2009).

<sup>188</sup> *Id.*

<sup>189</sup> This includes payments or benefits based on volume of sales or market share that PBMs pass payments or benefits on to a covered entity in full.

<sup>190</sup> D.C. Code § 48-832.01(d)(3).

<sup>191</sup> *See id.* § 48-832.01(c)(1)(B).

<sup>192</sup> *See id.* § 48-832.01(c)(1)(A).

<sup>193</sup> *See id.* § 48-832.01(d)(2).

### **Alleged Unlawful Conduct**

In its lawsuit, PCMA argued 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 asserted 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 argued that Title II violates the Commerce Clause of the Constitution. AARP filed a motion for leave to file an *amici curiae* brief in support of defendants.<sup>194</sup>

### **Proceedings**

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.<sup>195</sup> 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.<sup>196</sup>

Following the ruling to enjoin, the District of Columbia filed an appeal to the Court of Appeals for the D.C. Circuit.<sup>197</sup> On appeal, the District of Columbia argued that the "First Circuit's ruling in *Rowe*<sup>[198]</sup> precluded the [PCMA] from further litigating the validity of Title II under principles of collateral estoppel."<sup>199</sup> The appeals court remanded the case back to the district court on March 27, 2006 for consideration of this issue. The District of Columbia then passed temporary legislation amending the Title II to "conform the District's law to the Maine law to withstand constitutional and other legal challenges."<sup>200</sup> The amendment took effect on September 19, 2006.

A little under a year later, on March 6, 2007, Judge Ricardo Urbina, of the District Court for the District of Columbia, granted the District of Columbia's motion to vacate the preliminary injunction and supplemental motion for summary judgment. This ruling was partly due to the decision in *PCMA v. Rowe*. Urbina's opinion states "[b]ecause the claims in this case are the same claims raised by this plaintiff and submitted for judicial determination in *Rowe*, because the claims were actually and necessarily determined by the First Circuit, and because applying

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<sup>194</sup> See Motion for Leave to File a Brief *Amici Curiae*, July 22, 2004

<sup>195</sup> Memorandum Opinion, *Pharmaceutical Care Management Ass'n v. District of Columbia, et al.*, No. 1:04-cv-01082, Entry No. 13 (D.D.C. Dec. 21, 2004).

<sup>196</sup> See *id.*

<sup>197</sup> See *PCMA v. District of Columbia*, 522 F.3d 443 (D.C. Cir. 2008).

<sup>198</sup> See *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005).

<sup>199</sup> *PCMA v. District of Columbia*, 605 F. Supp. 2d 77, 80 (D.D.C. 2009).

<sup>200</sup> AccessRx Act Clarification Temporary Amendment Act of 2006 ("Amdt."), 53 D.C. Reg. 40 (2006).



preclusion would not work a basic unfairness on the plaintiff, the plaintiff is collaterally estopped from litigating the validity of Title II of the AccessRx Act before this court.”<sup>201</sup>

PCMA filed a partial motion for summary judgment which the district court granted in part on March 19, 2009.<sup>202</sup> The district court held that the Employee Retirement Income Security Act<sup>203</sup> preempted Title II of the Access Rx Act of 2004.<sup>204</sup> The Court of Appeals for the District of Columbia partially agreed with PCMA that ERISA preempted Title II §§ 48-832.01(a), (b)(1), and (d) “insofar as they apply to a pharmaceutical benefits manager (PBM) under contract with an employee benefit plan (EBP) because they ‘relate to’ an EBP.”<sup>205</sup> However, the judge ruled that ERISA did not preempt Title II §§ 48-832.01(b)(2) and (c) “because each may be waived by an EBP in its contract with a PBM.”<sup>206</sup> Thus, the affirmed in part and reversed in part the rulings of the district court judge. The District of Columbia filed cert with the Supreme Court on September 27, 2010.<sup>207</sup>

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<sup>201</sup> Memorandum Opinion, *District of Columbia*, No. 1:04-cv-01082, Entry No. 66 (D.D.C. March 6, 2007).

<sup>202</sup> *Pharmaceutical Care Mgmt. Ass'n v. District of Columbia*, 605 F. Supp. 2d 77 (D.D.C. 2009).

<sup>203</sup> 29 U.S.C. § 1001 et seq. (ERISA).

<sup>204</sup> *District of Columbia*, 605 F. Supp. 2d at 84-88.

<sup>205</sup> *Pharmaceutical Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179, 182 (D.C. Cir. 2010).

<sup>206</sup> *Id.*

<sup>207</sup> *See District of Columbia, et al. v. Pharmaceutical Care Mgmt Ass'n*, No. 10A327 (U.S. Sept. 27, 2010).

*Southeast Pennsylvania Transportation Authority v. Advance PCS Health, L.P., et al.*, No. 2:07-cv-02919 (E.D. Pa. July 16, 2007).

**Filed:** July 16, 2007  
**Cause of Action:** Breach of Contract  
**Settled:** August 19, 2009  
**Damages:** Undisclosed

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### **Background**

SEPTA entered into an agreement with CaremarkPCS to provide pharmacy and prescription drug benefits to plan participants.<sup>208</sup> During the terms of the contract, Caremark processed around 1.5 million claims and billed SEPTA almost \$119 million.<sup>209</sup> SEPTA requested to conduct an audit of Caremark pursuant to their agreement, but did not provide complete information.<sup>210</sup> In July 2007, SEPTA brought a breach of contract action against Caremark in Pennsylvania's Eastern District.

### **Alleged Unlawful Conduct**

The complaint alleged that Caremark breached its contractual and fiduciary obligations owed to SEPTA and also sought accounting of Caremark's records. Specifically, SEPTA alleged that Caremark obtained compensation far in excess of the administrative fees by engaging in self dealing.<sup>211</sup> According to SEPTA, Caremark wrongfully created and retained pricing spreads on ingredient costs for prescription drugs dispensed through Caremark's retail pharmacy networks. In addition, SEPTA alleged that Caremark: wrongfully created and retained a spread on the retail pharmacy dispensing fees; used an inflated reporting source when setting the AWP and associated price that SEPTA paid for brand-named drugs; failed to disclose and pass on to SEPTA all rebates and related compensation Caremark received from drug manufacturers; improperly switched SEPTA members from low cost drugs to higher cost drugs; and entered into secret agreements with drug manufacturers and retail pharmacies and other third parties and accepted rebates, kickbacks and secret incentives for Caremark's own accounts.<sup>212</sup>

### **Proceedings**

On September 17, 2007, SEPTA filed an Amended complaint, which successfully survived a motion to dismiss in late 2007.<sup>213</sup> The judge ordered that the case be dismissed on August 19, 2009 after the parties reached a settlement for an undisclosed amount.<sup>214</sup>

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<sup>208</sup> Amended Compl. SEPTA v. CaremarkPCS Health, L.P., No. 2:07-cv-02919 at ¶ 15 (E.D. Pa. Sept. 17, 2007).

<sup>209</sup> *Id.* at ¶ 16.

<sup>210</sup> *Id.* at ¶¶ 20-21j.

<sup>211</sup> *Id.* at ¶ 18.

<sup>212</sup> *Id.* at ¶¶ 10-10m.

<sup>213</sup> *See* Order Denying Motion to Dismiss, *SEPTA*, No. 2:07-cv-02919, Entry No. 51 (E.D. Pa. Oct. 11, 2007).

*United States ex rel. Vieux v. AdvancePCS, Inc.*, No. 2:02-cv-09236 (E.D. Pa. filed Dec. 20, 2002).

**Filed:** December 20, 2002

**Cause of Action:** False Claims Act

**Settled:** September 8, 2005

**Damages:** \$137.5 million

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### **Alleged Unlawful Conduct**

In this whistleblower lawsuit, 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.<sup>215</sup> alleged 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.

### **Settlement**

On September 8, 2005, AdvancePCS, Inc. agreed to a \$137.5 million settlement and a five-year injunction. This settlement imposes obligations which are designed to promote transparency and restrict 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;
- 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

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<sup>214</sup> Southeast Pennsylvania Transportation Authority v. Advance PCS Health, L.P., et al., No. 2:07-cv-02919, Entry No. 205 (E.D. Pa. Aug. 19, 2009).

<sup>215</sup> AdvancePCS Inc. was acquired in 2004 by Caremark Rx Inc.

and manufacturer payments for the reporting period as a percentage of the net revenue within a range of three percentage points;

- Reimburse plan participants for costs related to drug switches up to \$200;
- 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;
- 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;
- Provide Client Plans access to information reasonably necessary to audit contract compliance;

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

## IV. STATE CASES

*Alameda Drug Co., Inc, et al.. v. Medco Health Solutions, Inc., et al.*, No. CGC-04-428109 (Cal. Super. Ct. Jan. 20, 2004)

**Filed:** January 20, 2004  
**Cause of Action:** Antitrust  
**Status:** Litigation Case Management  
**Pending as of:** December 6, 2010

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### Background

On January 20, 2004 this lawsuit was filed in the Superior Court of California in San Francisco seeking class action status for California retail pharmacies and pharmacists. The class includes all California retail pharmacies and pharmacists that “contracted with Medco to dispense and sell brand name or generic prescription drugs for any prescription drug benefit plan.”<sup>216</sup>

### Alleged Unlawful Conduct

The complaint relies upon information from the U.S. government’s *qui tam* case in the Eastern District of Pennsylvania<sup>217</sup> 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).<sup>218</sup> 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.

According to the complaint Medco violated California’s Cartwright Act<sup>219</sup> 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.

### Proceedings

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<sup>216</sup> See Compl. ¶ 20(1), *Alameda Drug Co., Inc, et al.. v. Medco Health Solutions, Inc., et al.*, No. CGC-04-428109 (Cal. Super. Ct. Jan. 20, 2004).

<sup>217</sup> See United States ex rel. Hunt, Gauger, Piacentile, et al. v. Merck-Medco Managed Care, L.L.C., et al., Nos. 2:99-cv-02332, 2:00-00737 (E.D. Pa. filed May 6, 1999 and Feb. 10, 2000).

<sup>218</sup> See Consent Injunction, *Bacon-Normandi Corp. d/b/a Lawson-Dyer Pharmacy v. Merck & Co., Inc. et al.*, No. 93-2937-DLJ (N.D. Cal. Feb. 22, 1995)

<sup>219</sup> Ca. Bus. & Prof. § 16720, et seq.

This case is currently pending, and scheduled to continue in court on December 14, 2010.

*Florida ex rel. Fowler, et al. v. Caremark Rx, Inc.*, No. 372003-ca-000064 (Fla. Leon Cty. Ct. Jan. 1, 2003)

**Filed:** January 13, 2003  
**Cause of Action:** Florida False Claims Act  
**Status:** Trial Pending  
**Pending as of:** December 6, 2010

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### **Background**

This whistleblower case was filed in January 13, 2003, in Leon County Circuit Court by Caremark pharmacists Michael Fowler, Peppi Fowler, Victor Cortes and Danny Nevarez who worked at Caremark’s mail-order center in Fort Lauderdale. The state of Florida declined to become involved in the case initially but then sought to intervene.

### **Alleged Unlawful Conduct**

The case was filed under Florida’s False Claims Act<sup>220</sup> 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.

### **Proceedings**

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 Seventh Circuit on appeal.<sup>221</sup> On July 27, 2007 the appeals court affirmed the lower court decision on the merits.<sup>222</sup> The case is still pending as of December 6, 2010.

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<sup>220</sup> See Fla. Gov. Code, § 12650 et seq.

<sup>221</sup> See United States ex. rel. Fowler v. Caremark Rx. L.L.C., No. 06-4419 (7th Cir. July 27, 2007).

<sup>222</sup> United States ex rel. Fowler v. Caremark RX, L.L.C., 496 F.3d 730 (7th Cir. 2007) *cert denied* by United States ex rel. Fowler v. Caremark RX, L.L.C., 552 U.S. 1183 (2008).

*Group Hospitalization and Medical Services v. Merck-Medco Managed Care, L.L.P., et al.*, No. CAM-L-4144-03 (N.J. Super. Ct. 2003)

**Filed:**

**Cause of Action:**

**Status:**

**Pending as of:**

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### **Background**

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”).

### **Alleged Unlawful Conduct**

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.



*In re Pharmacy Benefits Managers Cases*, No. JCCP4307 (Cal. Super. Ct. May 30, 2003)

**Filed:** May 30, 2003  
**Cause of Action:** Consumer Protection  
**Status:** Pending  
**Pending as of:** December 6, 2010

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### **Background**

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.

### **Alleged Unlawful Conduct**

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 have not passed those savings on to health plans and consumers; instead they used those savings to illegally increase their own profits.

### **Proceedings**

On September 19, 2008, the plaintiffs partially dismissed the claims against most defendants except for Wellpoint Health Networks and Professional Claims Service. This case is currently pending in the California Superior Court of Los Angeles County as of December 6, 2010.

*Wagner, et al. v. Express Scripts, Inc., et al.*, No. 122235/2003 (N.Y. Sup. Dec. 31, 2003)

**Filed:** December 31, 2003

**Consolidated:** February 6, 2004

**Status:** Pending

**Pending as of:** December 6, 2010

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### **Background**

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”).

### **Alleged Unlawful Conduct**

The complaint alleges that Express Scripts engaged in fraudulent practices at the expense of union members. According to the complaint, Express Scripts negotiated discounts and rebates with drug manufacturers and then unlawfully withheld them from union members. Also, Express Scripts allegedly distorted the Average Wholesale Price (AWP) of its drugs which artificially inflated drug prices to union members.

### **Proceedings**

This suit was removed from the state court to the United States District Court for the District of Southern New York on February 6, 2004 and consolidated with another matter along the same lines, newly titled *In re Express Scripts PBM Litigation*.<sup>223</sup> Express Scripts filed a motion to dismiss on May 21, 2004. The New York action was transferred to the Eastern District of Missouri on July 8, 2005.<sup>224</sup>

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<sup>223</sup> See *In re Express Scripts, Inc. Pharmacy Benefits Management Litigation*, No. 4:05-md-01672-SNL (E.D. Mo. Apr. 29, 2005).

<sup>224</sup> See *In re Express Scripts, Inc. Pharmacy Benefits Management Litigation*, No. 4:05-cv-01081.

*New York v. Express Scripts, Inc., et al.*, No. 004669/2004 (N.Y. Sup. Aug. 4, 2004)

**Filed:** August 4, 2004  
**Cause of Action:** Breach of Contract  
**Settled:** July 31, 2008  
**Damages:** \$27 million

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### **Background**

After Attorney General Spitzer's office, in cooperation with the Department of Civil Service and the Office of State Comptroller, conducted a one-year investigation. The investigation was sparked by audits of Express Scripts conducted by Comptroller in 2002. On August 4, 2004, the State of New York filed for breach of contract against Express Scripts in the New York State Supreme Court for Albany County. New York sought injunctive relief, restitution, damages, indemnification and civil penalties resulting from defendants' breaches of contract.

### **Alleged Unlawful Conduct**

The complaint alleged that Express Scripts (ESI):

1. Enriched itself at the expense of the Empire Plan (New York's largest employee health plan) and its members by inflating the cost of generic drugs;
2. Diverted millions of dollars in manufacturer rebates that belonged to the Empire Plan;
3. Engaged in fraud by inducing physicians to switch patients' prescription from their prescribed drug to one that Express Scripts was receiving money from the manufacturer;
4. Sold and licensed data belonging to the Empire Plan to drug manufacturers, data collection services without the Empire Plan's permission and in violation of the State's contract; and
5. Induced New York to enter into the contract by misrepresenting the discounts the Empire Plan was receiving for drugs purchased at retail pharmacies.

In furtherance of Express Scripts' scheme to divert and retain manufacturer rebates, the complaint alleges that they disguised millions of dollars in rebates as "administrative fees," "management fees," "performance fees," "professional services fees," and other names. According to the State the drug switches often resulted in higher costs for plans and members.

### **Settlement**

On July 31, 2008, Cigna, who administered the Empire Plan, and Express Scripts agreed to a \$27 million settlement. Under the agreement, consumers served by Express Scripts or any other PBM subcontracting with Cigna in the state of New York will receive notice when a drug switch is initiated and will be informed of their right to refuse the switch. Express Scripts must also adopt new rules to increase transparency, including disclosure of pricing methods, payments received from manufacturers, factors considered when calculating targeted discount rates, and the current discount rates for generics. Both companies agreed to cover the cost of the settlement but did not

admit to any wrongdoing.

*Board of State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc.*, No. A 0309929 (Ohio Hamilton Ct. C.P. Dec. 22, 2003)

**Filed:** December 22, 2003  
**Cause of Action:** Breach of Contract  
**Verdict:** December 19, 2005 (Appealed)  
**Damages:** \$7.8 million  
**Settled:** July 7, 2007

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### **Background**

The State Teachers Retirement System (STRS) contracted with Medco to provide pharmacy benefit manager services starting in January 1999 until December 2001.<sup>225</sup> Medco agreed to pay STRS rebates, provide 99.99% accuracy in dispensing the prescription drugs, process 97% of retail pharmacy claims within 5 days, and further stated that STRS and Medco would share in any cost savings that Medco obtained in administering STRS's prescription drug program.<sup>226</sup> STRS claimed that Medco breached its contractual duties when Medco failed to pay STRS all rebates due under their contract.<sup>227</sup>

On December 22, 2003 the state of Ohio filed a lawsuit in Hamilton County Common Pleas Court against Medco Health Solutions. 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.

### **Alleged Unlawful Conduct**

STRS claimed that Medco breached both contractual and fiduciary duties by engaging in a course of self-dealing by placing Merck's and Medco's interests above STRS's interest.<sup>228</sup> 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 complaint also alleged that Medco steered doctors, pharmacists, and patients to choose brand-name and higher-cost medications manufactured by Merck rather than selecting generic equivalents. An audit conducted by STRS "revealed that prices for more than one-third of prescriptions for generic drugs filled by mail order were higher than prices for the same drugs at retail pharmacies."<sup>229</sup>

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<sup>225</sup> Compl. ¶ 1, *Board of State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc.*, No. A 0309929 (Ohio Hamilton Ct. C.P. Dec. 22, 2003).

<sup>226</sup> *Id.*

<sup>227</sup> *Id.* at ¶ 4.

<sup>228</sup> *Id.* at ¶¶ 3-4.

<sup>229</sup> *Id.* at ¶ 4.

The State Teachers Retirement System argued that the investigations by the federal government show that Medco routinely violates the standards of the pharmacy profession by failing to ensure that drugs get dispensed by licensed pharmacists; failing to adequately perform their contractual obligations of timely and accurately filling their prescriptions; and further that Medco conceals its failures by destroying records and falsifying reports.<sup>230</sup> Accordingly, STRS alleged that Medco defrauded STRS by: cancelling and destroying prescriptions; switching patients' prescriptions to different drugs without the patients' knowledge or consent; billing patients for drugs they never ordered; creating false records of contact with physicians; soliciting for and receiving kickbacks from drug manufacturers; and making false and misleading statements about Medco's conduct.<sup>231</sup>

### **Proceedings**

The State Teachers Retirement System of Ohio alleged that it was overcharged millions of dollars for prescription drugs. On December 19, 2005 the jury returned a verdict in favor of STRS finding Medco liable for constructive fraud and awarded \$7,815,000 total, \$6.9 million in damages plus \$915,000 for the State Teachers Retirement System.<sup>232</sup> Medco appealed this verdict on March 2, 2006.<sup>233</sup> On July 7, 2007, Medco and the State Teachers' Retirement System entered into a settlement agreement for an undisclosed amount.<sup>234</sup>

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<sup>230</sup> *Id.* at ¶ 5.

<sup>231</sup> *Id.* at ¶ 6.

<sup>232</sup> See Final Entry Judgment, Board of State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc., No. A 0309929, 2006 WL 3191976 (Ohio Hamilton Ct. C.P. Feb. 22, 2006).

<sup>233</sup> See appeal denied by Board of the State Teachers Ret. Sys. of Ohio v. Medco Health Solutions, Inc., 852 N.E.2d 1214 (Ohio 2006).

<sup>234</sup> Settlement, Board of State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc., No. A 0309929, 2007 WL 5543832 (Ohio Hamilton Ct. C.P. July 7, 2007).

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David A. Balto  
Attorney At Law  
Law Offices of David Balto  
1350 I Street, NW  
Suite 850  
Washington, DC 20005  
202-577-5424  
[david.balto@yahoo.com](mailto:david.balto@yahoo.com)  
[www.dcantitrustlaw.com](http://www.dcantitrustlaw.com)