

Federal and State Litigation Regarding Pharmacy Benefit Managers

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From 2004 – 2008, the three major PBMs (Medco, CVS Caremark, and Express Scripts) faced six major federal or multidistrict cases over allegations of fraud; misrepresentation to plans, patients, and providers; improper therapeutic substitution; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases resulted in over \$371.9 million in damages to states, plans, and patients so far. The most prominent cases were brought by a coalition of over 30 states and the Department of Justice. Below is a summary of these six cases. Note that the regulatory provisions of many of these settlements will expire within the next 2-10 years.

1. *United States v. Merck & Co., Inc., et. al* (also cited as *United States of America v. Merck-Medco Managed Care L.L.C., et al.*) (E.D. Pa.)

Settled: October 23, 2006

Damages: \$184.1 million

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.

Claims:

Whistleblower lawsuits, filed under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc., alleged that Medco:

- systematically defrauded government-funded health insurance by accepting kickbacks from manufacturers in exchange for steering patients to certain products;
- secretly accepted rebates from drug manufacturers;
- secretly increased long term drug costs by switching patients away from cheaper drugs; and
- failed to comply with state-mandated quality of care standards.

Settlement:

- A preliminary settlement in April of 2004:

- Required Medco to pay \$29.1 million to participating states and affected patients;
 - Placed restrictions on the company's ability to switch drugs;
 - Imposed measures to increase transparency; and
 - Required Medco to adopt the American Pharmacists Association code of ethics for employees.
- The final settlement, brokered in October 2006 required Medco to:
 - Pay an additional \$155 million;
 - Enter into a consent decree regulating drugs switching and mandating greater transparency; and
 - Enter into a Corporate Integrity Agreement (CIA) as a condition of Medco's continued participation in government health programs.

The Corporate Integrity Agreement will expire in 2011.

2. *United States of America, et al. v. AdvancePCS, Inc. (Case No. 02-cv-09236)(E.D. Pa.)*

Filed: 2002

Settled: September 8, 2005

Damages: \$137.5 million

Claims:

Whistleblower lawsuit, filed under the Federal False Claims Act, alleging that Advance PCS (now part of CVS Caremark):

- Knowingly solicited and received kickbacks from drug manufacturers in exchange for favorable treatment of those companies' products;
- Paid improper kickbacks to existing and potential customers to induce them to sign contracts with the PBM;
- Submitted false claims in connection with excess fees paid for fee-for-service agreements; and
- Received flat fee rebates for inclusion of certain heavily utilized drugs.

Settlement:

A settlement in September, 2005 required Advance PCS, Inc., to:

- Pay a \$137.5 million settlement and face a five-year injunction;
- Submit to regulations designed to promote transparency and restrict drug interchange programs;
- Enter into a five-year Corporate Integrity Agreement; and
- Develop procedures to ensure that any payments between them and pharmaceutical manufacturers, clients, and others do not violate the Anti-Kickback Statute of Stark Law.

3. *United States of America, et al v. Caremark, Inc. (Case No. 99-cv-00914)(W.D. Tex.)*

Filed: 1999

Pending as of January 2009

States participating: Arkansas, California, DC, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, North Carolina, Tennessee, Texas, Utah and Virginia.

Claims:

This case is prosecuted under the Federal False Claims Act and numerous state False Claims Statutes. It alleges that Caremark (now part of CVS Caremark):

- Submitted reverse false claims to the Government in order to avoid, decrease or conceal their obligation to pay the government under several federal health insurance programs including Medicaid, Indian Health Services, and Veterans Affairs/Military Treatment Facilities.

4. *States Attorneys General v. Caremark, Inc.*

Filed: February 14, 2008

Settled: February 14, 2008

Damages: \$41 million

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

Claims:

Complaint against Caremark by 29 Attorneys General alleges that Caremark:

- Engaged in deceptive trade practices by encouraging doctors to switch patients from originally prescribed brand drugs to different brand name drugs.
- Did not inform clients that Caremark retained all the profits reaped from these drug switches; and
- Restocked and re-shipped previously dispensed drugs that had been returned to Caremark's mail order pharmacies.

Settlement:

In conjunction with the complaints, states issued a consent decree/final judgment that required Caremark to:

- Pay a collective settlement of \$41 million;
- Significantly change its business practices by imposing restrictions on drug switches and creating greater transparency;
- Apply a code of ethics and professional standards; and
- Refrain from restocking and re-shipping returned drugs unless permitted by law.

5. State Attorneys General v. Express Scripts

Settled: May 27, 2008

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

States participating: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, 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.

Claims:

State Attorneys general settled consumer protection claims alleging that Express Scripts:

- Engaged in deceptive business practices by illegally encouraging doctors to switch their patients to different brand name drugs; and
- Illegally increased their spreads and rebates from manufacturers without passing the savings on to the plans.

Settlement:

The settlement required Express Scripts to:

- pay \$9.3 million to the states, plus up to \$200,000 in reimbursements to affected patients.
- Accept restrictions on drug switching practices;
- Increase transparency for plans, patients and providers; and
- Adopt a certain code of professional standards.

6. Local 153 Health Fund v. Express Scripts (In re Express Scripts, Inc. Pharmacy Benefits Management Litigation) (Case No. 4:05-md-01672-SNL)

Case consolidated: April 29, 2005

Pending as of January 2009

Claims:

This case, filed in the Eastern District of Missouri, alleges that Express Scripts:

- Retained undisclosed rebates from manufacturers;
- Enriched itself by creating a differential in fees;
- Failed to pass on or disclose discounted drug rates and dispensing fees;
- Gained kickbacks from drug manufacturers in exchange for favoring certain drugs on the formulary;
- Circumvented “Best Pricing” rules to artificially inflate AWP; and
- Enriched itself with bulk purchase discounts that it failed to pass on to the plaintiffs.

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