

**Health Care Compliance Association**

**2010 Compliance Institute**

**Health Care and the False Claims Act: 2009's Greatest "Hits"**

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Fiscal Year 2009 was another banner year for recoveries under the False Claims Act (FCA). The United States Justice Department announced in November 2009 that it had secured \$2.4 billion in civil settlements and judgments in cases involving fraud against the United States in FY 2009.<sup>1</sup> In addition, another \$3.2 billion was collected in criminal fines and forfeitures, and in Medicaid fraud recoveries paid to the states.<sup>2</sup> As in the past, the vast majority of these recoveries arose from health care cases. The cases below are among the most significant health care FCA cases that were resolved in 2009.

### **Pharmaceutical Off-Labeling Cases**

#### **Pfizer: Sept. 2, 2009**

Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (Pfizer) agreed to pay state and federal governments \$1 billion in a civil FCA settlement and an additional \$1.3 billion in criminal fines. Pfizer was accused in a series of whistleblower suits of marketing numerous prescription drugs for off-label uses and paying kickbacks to induce health care providers to prescribe its drugs. Pharmacia & Upjohn Company Inc. pleaded guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding the anti-inflammatory drug Bextra.

#### **Eli Lilly and Company: January 15, 2009 (E.D. Pa.)**

Eli Lilly agreed to pay state and federal governments \$1.4 billion to settle criminal and civil charges that it marketed Zyprexa, an atypical antipsychotic drug, for off-label uses and that it paid kickbacks to prescribing physicians. Of the 1.4 billion, \$800 million was paid as a civil settlement under the FCA and an additional \$615 was paid in criminal fines and forfeitures.

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<sup>1</sup> <http://www.prnewswire.com/news-releases/justice-department-recovers-24-billion-in-false-claims-cases-in-fiscal-year-2009-more-than-24-billion-since-1986-70521362.html>

<sup>2</sup> <http://www.taf.org/total2009.htm>

## **Kickback Cases**

### **Omnicare and IVAX: November 3, 2009 (D. Mass.)**

Omnicare, Inc., the largest long-term care pharmacy provider in the country, paid \$98 million to state and federal governments to settle kickback charges made in several whistleblower FCA lawsuits. Generic drug manufacturer IVAX Pharmaceuticals agreed to pay \$14 million for its role in the kickback scheme. On January 15, 2010, the United States intervened in two FCA lawsuits against co-defendant Johnson & Johnson. J&J is accused of paying kickbacks to Omnicare to promote its drugs, including its anti-psychotic drug Risperdal, for use for nursing home patients.

### **Diabetes Treatment Center of America: March 25, 2009 (D.DC.)**

Diabetes Treatment Centers of America, a subsidiary of Healthways Inc., paid \$28 million to settle FCA claims that it violated the Anti-Kickback Statute and Stark Law by paying kickbacks to physicians, in the form of medical directorships, to induce physicians to refer patients to its treatment facilities. DTCA paid an additional \$12 million to relator's counsel for attorneys' fees and expenses.

### **McAllen Hospitals L.P. : October 30, 2009 (W.D. Tex.)**

McAllen Hospitals L.P., d/b/a/ South Texas Health System (a subsidiary of Universal Health Services Inc.), paid \$27.5 million to settle FCA claims that it violated the Anti-Kickback Statute and Stark Law by paying compensation to doctors, through sham contracts, medical directorships and lease agreements, to induce physicians to refer patients to its hospitals.

### **Condell Medical Center: December 1, 2008**

Following a self-disclosure report to the HHS OIG reporting that Condell Medical Center had paid kickback to physicians in the form of office leases at below market value rates and improper loans, Condell agreed to pay the United States \$36 million in settlement of FCA claims. The self-disclosure was made in connection with the sale of the hospital to Advocate Health Care.

**St. John Health System: December 22, 2009**

Following a self-disclosure to the HHS OIG in which St. John Health System of Tulsa, OK reported that it had submitted claims to Medicare and Medicaid that were tainted by the hospital's financial relationships with referring physicians, St. John Health System agreed to pay the United States \$13 million as an FCA settlement.

**Medicaid Overcharges**

**Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca Pharmaceuticals and Ortho McNeil Pharmaceutical: October 19, 2009 (D.N.H.)**

Four pharmaceutical companies -- Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca Pharmaceuticals and Ortho McNeil Pharmaceutical -- agreed to pay a total of \$124 million to the federal and state governments to resolve claims that they violated the FCA by failing to pay proper rebates to state Medicaid programs for prescription drugs. A whistleblower suit charged the companies with misclassifying certain prescription drugs as "non-innovator drugs," which have a lower rebate rate under Medicaid.

**Aventis Pharmaceuticals: May 28, 2009 (D. Mass.)**

Aventis Pharmaceuticals Inc. agreed to pay \$124 million to the federal and state governments to resolve claims that it violated the FCA by inflating its Best Price for three anti-inflammatory nose sprays in order to decrease rebates it owed to Medicaid based on Best Price.

**Warrick Pharmaceuticals/Schering Plough: December 17, 2009 (California FCA)**

Warrick Pharmaceuticals, a subsidiary of Schering-Plough, paid the state of California \$21.3 million to settle whistleblower claims brought under the California FCA alleging that the company overcharged California's Medicaid program for Albutrol and other drugs by inflating the Average Wholesale Prices in its reports to California.

**The State of New York and New York City (Speech Therapy): July 17, 2009**

The State of New York and New York City agreed to pay the United States \$540 million to settle allegations under the FCA that they failed to insure that local districts and counties complied

with Medicaid requirements for coverage of speech therapy and instead passed on claims to the federal Government for services they knew were not covered or properly documented.

### **Home Health & Hospice Care**

#### **Nursing Personnel Home Care, Extended Home Care, and Excellent Home Care:**

**December 17, 2009**

Three home health care agencies paid \$24 million to the United States and New York State to settle whistleblower FCA lawsuits alleging that they supplied aides with fake training certificates and billed Medicaid and Medicare programs for services provided by these untrained aides.

#### **Visiting Physicians Association: December 23, 2009 (S.D. Ohio and E.D. Mich.)**

Visiting Physicians Association, a Michigan-based home health care provider, paid \$9.5 million to the United States and the State of Michigan to settle a whistleblower FCA lawsuit alleging that it billed Medicare and Medicaid for unnecessary services, including unnecessary home visits, tests and procedures, and for more complex evaluation and management services than the services that were actually provided.

#### **SouthernCare Incorporated: January 15, 2009 (N.D.AL.)**

SouthernCare Inc., a hospice provider, paid \$24.7 million to the United States to resolve two whistleblower FCA lawsuits alleging that it billed Medicare and Medicaid for services provided to patients who did not meet guidelines for hospice services.

### **Miscellaneous Cases**

#### **Quest Diagnostics: August 6, 2009**

Quest Diagnostics and its former subsidiary Nichols Institute Diagnostics paid \$302 million to the federal and state governments to resolve civil and criminal allegations first raised in a whistleblower FCA lawsuit that Nichols manufactured and sold faulty diagnostic kits to laboratories throughout the country. According to the lawsuit, these defective kits produced false-positive test results. As a result, patients received unnecessary treatment that was billed to Medicare and Medicaid. The \$302 million payment included a \$40 million criminal fine.

**Kyphoplasty: September 29, 2009**

Medtronic Spine LLC, the corporate successor to Kyphon Inc, and nine hospitals in Indiana, Alabama and Minnesota paid over \$83 million to the United States to settle a whistleblower FCA lawsuit alleging that the hospitals, in concert with Kyphon, overcharged Medicare by performing kyphoplasty, a minimally-invasive procedure used to treat spinal fractures, on an in-patient rather than an out-patient basis, solely to increase their Medicare billings.