

CHAPTER 22

SIGNIFICANT SETTLEMENTS

MADELEINE MCDONOUGH, RIKIN MEHTA,*
AND JENNIFER STONECIPHER HILL

I. Introduction

The year 2012 was a record one for settlements involving the pharmaceutical industry. The Department of Justice (DOJ) reported that it has used the False Claims Act (FCA) to recover more than \$10 billion since January 2009 in cases involving fraud against federal healthcare programs.¹ The Food, Drug and Cosmetic Act (FDCA), the Anti-Kickback Statute, and Medicaid pricing laws continue to be lucrative recoupment avenues for federal authorities. Companies faced with these types of allegations have strong motivations—if not practical imperatives—to settle the claims on favorable terms, not only because of the risk of treble damages and substantial per-occurrence penalties under the FCA,² but particularly because companies convicted of certain healthcare-related crimes could be excluded from participating in federal healthcare programs.³

In addition, state attorneys general have become increasingly involved in obtaining significant settlements on behalf of their states. Between January 2009 and July 2012, single-state

* The views expressed in this chapter are the author's, and do not necessarily reflect those of the U.S. FDA.

¹ Press Release, Department of Justice, Boehringer Ingelheim to Pay \$95 Million to Resolve False Claims Act Allegations (Oct. 25, 2012), *available at* <http://www.justice.gov/opa/pr/2012/October/12-civ-1291.html>.

² See 31 U.S.C. § 3729(a)(1).

³ See 42 U.S.C. § 1320a-7.

settlements accounted for more than half (59 percent) of settlements between pharmaceutical manufacturers and government authorities.⁴

In 2012, several companies resolved long-standing disputes with the federal and state governments, often covering allegations of conduct that took place nearly a decade ago.

II. Significant Settlements

A. Marketing Practices

1. Abbott Laboratories Inc.

On May 7, 2012, Abbott Laboratories Inc. (Abbott) announced that it had reached a \$1.5 billion agreement with the federal government, 49 state authorities, and the District of Columbia to resolve civil and criminal allegations arising from the company's sales and marketing practices for the drug Depakote®.⁵ The government alleged that, between 1998 and 2006, Abbott improperly marketed Depakote® to control agitation and aggression in elderly dementia patients and to treat schizophrenia, uses that were not approved by the Food and Drug Administration (FDA).⁶ The government also alleged that Abbott violated the federal Anti-Kickback Statute by providing illegal remuneration to healthcare providers and pharmacies.⁷

As part of the civil settlement, Abbott agreed to pay \$800 million, to be divided among the federal government and state governments that opted to participate in the settlement.⁸ Abbott also agreed to plead guilty to one misdemeanor count of misbranding in violation of the FDCA. As part of the criminal resolution, Abbott agreed to a \$700 million criminal penalty.⁹ The settlement included a five-year Corporate Integrity Agreement (CIA) between Abbott and the Department of Health and Human Services, Office of Inspector General (HHS OIG).¹⁰

2. GlaxoSmithKline

The year 2012 saw the largest healthcare settlement in U.S. history with GlaxoSmithKline's (GSK) settlement of a broad range of allegations relating to events that occurred as early as 1994.¹¹ In July 2012, the DOJ and GSK announced the resolution of an ongoing investigation

⁴ Public Citizen, *Pharmaceutical Industry Criminal and Civil Penalties: An Update* (Sept. 27, 2012), available at <http://www.citizen.org/documents/20731.pdf>.

⁵ Press Release, Department of Justice, *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote* (May 7, 2012), available at <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html>; Press Release, Abbott, *Abbott Reaches Settlement Agreement on Depakote* (May 7, 2012), available at <http://abbott.com/news-media/press-releases/abbott-reaches-settlement-agreement-on-depakote.htm>.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ Press Release, Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), available at <http://www.justice.gov/opa/pr/2012/>

of civil and criminal allegations by the federal government and several state governments.¹² GSK agreed to pay a total of \$3 billion and enter into a five-year CIA with the HHS OIG.

The DOJ's allegations cited the company's marketing practices for nine products, pricing under the Medicaid Rebate Program, and regulatory submissions for one product. Specifically, GSK agreed to plead guilty to three misdemeanor violations of the FDCA for the following conduct: 1) between April 1998 and August 2003, marketing Paxil® for patients under 18 years old, which was not approved by FDA; 2) between January 1999 and December 2003, marketing Wellbutrin® for various off-label uses; and 3) between 2001 and 2007, failing to include certain information in periodic and annual reports submitted to FDA for the drug Avandia®.¹³

GSK further agreed to resolve civil allegations relating to its marketing of Lamictal®, Zofran®, Imitrex®, Lotronex®, Flovent®, Valetrex®, Avandia®, and Advair®, but the company admitted no liability or wrongdoing in the marketing of these products.¹⁴ As part of the civil agreement, GSK also resolved allegations regarding the company's use of the nominal price exception under the Medicaid Rebate Program. The settlement also resolved four *qui tam* actions pending in the district of Massachusetts.¹⁵

3. AstraZeneca

In August 2012, AstraZeneca reached a \$26 million deal to resolve claims asserted by the state of South Carolina. The lawsuit, which was filed in 2009 by a private law firm on behalf of the state, alleged that AstraZeneca engaged in misleading marketing practices related to its antipsychotic drug, Seroquel®, resulting in increased payments by state agencies.¹⁶ The settlement included \$20 million in damages, \$5 million in penalties, and \$1 million in costs.¹⁷ The company had previously entered into a \$520 million civil settlement in 2010 to resolve related allegations associated with off-label promotion.¹⁸ The company was under a five-year CIA as part of the 2010 settlement.¹⁹

4. Janssen Pharmaceuticals Inc.

State governments actively pursued sales and marketing claims against pharmaceutical manufacturers in 2012. One recent example was the settlement by Janssen Pharmaceuticals Inc. and its parent company, Johnson & Johnson, of allegations relating to the marketing of Risperdal®. In August 2012, the company announced that it had entered into a consent decree

July/12-civ-842.html.

¹² Press Release, GlaxoSmithKline, GlaxoSmithKline concludes previously announced agreement in principle to resolve multiple investigations with US Government and numerous states (July 2, 2012), available at <http://us.gsk.com/html/media-news/pressreleases/2012/2012-pressrelease-1164685.htm>.

¹³ *Supra* note 11.

¹⁴ *Supra* note 12.

¹⁵ *Supra* note 11.

¹⁶ Lynne P. Shackleford, SC Attorney General reaches \$26M settlement against AstraZeneca (Aug. 23, 2012), available at <http://www.goupstate.com/article/20120823/articles/120829820>.

¹⁷ *Id.*

¹⁸ Press Release, Department of Justice, Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-label Drug Marketing (Apr. 27, 2010) available at <http://www.justice.gov/opa/pr/2010/April/10-civ-487.html>.

¹⁹ *Id.*

and settlement with 36 states and the District of Columbia to resolve consumer protection allegations under various state laws arising from the company's alleged off-label marketing.²⁰ The state governments claimed that the company promoted Risperdal®, an antipsychotic medication, for various unapproved uses, including treatment of dementia in elderly patients, depression, anxiety, and obsessive compulsive disorder.²¹ The company agreed to pay \$181 million, to be apportioned to each state participating in the settlement.²²

The settlement comes on the heels of a 2011 agreement in principle to settle criminal penalties with the United States Attorney's Office for the Eastern District of Pennsylvania.²³ As of the end of 2012, the agreement remained to be finalized.²⁴

5. Boehringer Ingelheim

On October 25, 2012, Boehringer Ingelheim agreed to settle a *qui tam* lawsuit filed under the FCA in the district of Maryland by a former sales representative.²⁵ Under the terms of the settlement, the company would pay a total of \$95 million, including \$16.5 million for state Medicaid programs.²⁶

The settlement arose from allegations that the company promoted Aggrenox®, Combivent®, and Micardis® for indications not covered by federal healthcare programs.²⁷ The government also claimed that the company paid kickbacks to healthcare professionals to induce them to prescribe Aggrenox®, Atrovent®, Combivent®, and Micardis®. As part of the settlement, the company entered into a five-year CIA. The former sales representative stood to receive more than \$17 million as part of the settlement.²⁸

B. Drug Pricing

Drug pricing claims remained a prime target for both the federal and state government authorities in 2012. There have been several significant settlements focusing on the methods by which drug prices are reported to government agencies for reimbursement. These claims continue to be an active area for large-scale settlements.

²⁰ See David Voreacos and Margaret Cronin Fisk, *J&J Will Pay \$181 Million to Settle Risperdal Ad Claims*, BLOOMBERG BUSINESSWEEK, Aug. 30, 2012.

²¹ Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Settles \$181 Million Deceptive Marketing Case with Janssen Pharmaceuticals and Johnson & Johnson (Aug. 30, 2012), available at <http://www.ag.ny.gov/press-release/ag-schneiderman-settles-181-million-deceptive-marketing-case-janssen-pharmaceuticals>.

²² Johnson & Johnson, Janssen Pharmaceuticals, Inc. announces RISPERDAL® consumer protection settlement with 36 states and the District of Columbia (Aug. 30, 2012), available at <http://www.jnj.com/connect/news/all/janssen-pharmaceuticals-inc-announces-risperdal-consumer-protection-settlement-with-36-states-and-the-district-of-columbia>.

²³ Johnson & Johnson, Quarterly Report (Form 10-Q), at 26-27 (July 1, 2012), available at <http://www.sec.gov/Archives/edgar/data/200406/000020040612000119/jnj2q71201210q.htm>.

²⁴ *Id.*

²⁵ Press Release, Department of Justice, Boehringer Ingelheim to Pay \$95 Million to Resolve False Claims Act Allegations (Oct. 25, 2012), available at <http://www.justice.gov/opa/pr/2012/October/12-civ-1291.html>.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

1. Actavis

The year 2012 began with a reported settlement by pharmaceutical manufacturer, Actavis, relating to alleged fraudulent pricing practices.²⁹ The settlement agreement, filed with the district of Massachusetts in the last days of 2011,³⁰ resolved multistate allegations that the company had reported inflated prices and made false claims to state Medicaid programs.³¹ Actavis agreed to pay \$118.6 million to the federal government and four state governments — Florida, Iowa, New York, and South Carolina.³² In a separate settlement, the company agreed to pay \$84 million to resolve allegations by the state of Texas.³³

Ven-A-Care of the Florida Keys, Inc., a specialty pharmacy, filed the lawsuits under the FCA. The DOJ declined to intervene, but stood to recover more than \$108 million for the federal government.³⁴

2. Various Pharmaceutical Companies and Louisiana

In 2010, the state of Louisiana filed suit against 109 pharmaceutical manufacturers that allegedly provided inflated drug price indices for the state's Medicaid program.³⁵ In February 2012, the Louisiana Attorney General reported that five of the companies, Actavis®, Boehringer Ingelheim, Dey, GlaxoSmithKline, and Schering-Plough, agreed to separate settlements, totaling \$25.2 million.³⁶ By July 2012, eight more companies also settled with Louisiana for an additional \$38 million.³⁷ These companies included Teva Pharmaceuticals USA and Barr Pharmaceutical, Inc., which agreed to pay a combined total of \$20 million, and AstraZeneca Pharmaceuticals and MedImmune, LLC, which agreed to pay a combined total of \$10 million.³⁸

3. Dava Pharmaceuticals Inc.

The drug pricing practices of New Jersey-based Dava Pharmaceuticals, Inc. were investigated by the DOJ. On February 8, 2012, the DOJ announced that Dava had agreed to pay \$11 million to settle claims under the FCA.³⁹ The DOJ alleged that, between October 2005 and September 2009, Dava and its corporate predecessors improperly categorized and incorrectly calculated average prices for certain medications, resulting in underpayment of the company's

²⁹ See David Voreacos and Margaret Cronin Fisk, *Actavis Will Pay \$118.6 Million to End Drug-Pricing Claims*, BLOOMBERG BUSINESSWEEK (Jan. 6, 2012), available at <http://www.businessweek.com/news/2012-01-06/actavis-will-pay-118-6-million-to-end-drug-pricing-claims.html>.

³⁰ United States ex rel. Ven-A-Care of the Florida Keys Inc. v. Actavis Mid Atlantic LLC, No. 08-cv-0852 (D. Mass. Dec. 29, 2011).

³¹ See *supra* note 28.

³² See *supra* note 28.

³³ Press Release, Attorney General of Texas, Texas Attorney General Resolves Medicaid Fraud Enforcement Action against Actavis (Dec. 28, 2011), available at <https://www.oag.state.tx.us/oagnews/release.php?id=3949>.

³⁴ See *supra* note 28.

³⁵ See *State of Louisiana v. Abbott Laboratories, Inc.*, No. 596164 (La. 19th Judicial Dist.).

³⁶ Office of the Attorney General, Attorney General Recovers \$25.2 Million from Drug Companies Charged with Fraud (Feb. 7, 2012), available at <http://www.ag.state.la.us/Article.aspx?articleID=558&catID=2>.

³⁷ *Id.*

³⁸ *Id.*

³⁹ Press Release, Department of Justice, Dava Pharmaceuticals to Pay U.S. \$11 Million to Settle False Claims Act Allegations (Feb. 8, 2012), available at <http://www.justice.gov/opa/pr/2012/February/12-civ-182.html>.

rebate obligations under the Medicaid Prescription Drug Rebate Program.⁴⁰ A total of \$5 million of the settlement would be paid to participating states.⁴¹

4. Mylan

Mylan was also the target of FCA allegations by Ven-A-Care of the Florida Keys, Inc. According to a settlement agreement filed on February 27, 2012, in the district of Massachusetts, Mylan agreed to pay \$57 million to resolve the allegations, which Mylan disputed.⁴² Ven-A-Care, along with the state of California, alleged that Mylan had reported false or inflated prices of its drug since January 1991, resulting in higher reimbursement rates for Medicaid.⁴³ Of the settlement proceeds, \$22.2 million were allocated to the federal government, and \$26.3 million were allocated to the state of California. Nearly \$8.5 million were allocated to Ven-A-Care, as relator, and its attorneys.⁴⁴

5. McKesson

In April 2012, the pharmaceutical distributor McKesson Corporation resolved with the federal government and several state authorities a long-standing case over pricing methods, filed under the *qui tam* provisions of the FCA in 2005. According to the DOJ, McKesson reported to First DataBank Inc. (FDB) artificially inflated pricing information for more than 1,400 drugs.⁴⁵ FDB, in turn, published the information, which was used by various state Medicaid programs to set reimbursement rates for prescription drugs.⁴⁶ The federal and state authorities contended that the inflated data caused them to reimburse prescription drug claims at artificially inflated amounts between August 2001 and December 2009.⁴⁷

McKesson expressly denied any liability or wrongdoing, but the company agreed to settle the federal government's claims for \$190 million.⁴⁸ Subsequently, in July 2012, McKesson agreed to pay a total of \$151 million to resolve similar claims by 29 states and the District of Columbia.⁴⁹

These settlements demonstrate the high stakes for companies facing allegations of improper pricing methods. As illustrated above, even after a company resolves claims with the federal government, it must often contend with follow-on allegations by various state authorities.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Settlement Agreement and Release, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:01-cv-12257-PBS, Doc. 8079-1 (D. Mass. Feb. 27, 2012).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Press Release, Department of Justice, McKesson Corp. Pays U.S. More Than \$190 Million to Resolve False Claims Act Allegations (Apr. 26, 2012), available at <http://www.justice.gov/opa/pr/2012/April/12-civ-539.html>.

⁴⁶ *Id.*

⁴⁷ See Settlement Agreement Between the United States and McKesson Corporation, available at <http://www.justice.gov/usao/nj/Press/files/pdffiles/2012/McKesson%20Executed%20Settlement%20Agreement.pdf>.

⁴⁸ *Id.*

⁴⁹ Timothy W. Martin, McKesson to Pay \$151 Million to Settle Drug-Pricing Suit, WALL ST. J. (July 27, 2012).

C. Kickbacks

1. Orthofix International NV

On November 2, 2012, the DOJ announced that Orthofix International NV had agreed to settle allegations that its subsidiary, Blackstone Medical Inc., had paid illegal kickbacks to physicians to persuade them to use the company's spinal implant and spinal surgery products.⁵⁰ The company agreed to pay \$30 million and enter into a CIA.⁵¹

The parties, however, had encountered unexpected difficulties in resolving a prior settlement that also had alleged illegal kickbacks. In June 2012, the company agreed to pay more than \$42 million to settle criminal and civil allegations relating to the promotion of bone growth stimulators.⁵² The company agreed to plead guilty to a felony count alleging that it manipulated Certificates of Medical Necessity, forms used by Medicare for determining reimbursement.⁵³ The settlement included \$7.65 million in criminal penalties and \$34.23 million in civil penalties and interest.⁵⁴ In September, however, the U.S. District Judge overseeing the case in the district of Massachusetts rejected the company's guilty plea, citing "unease of treating corporate criminal conduct like a civil case."⁵⁵

2. Pfizer Inc.

On August 7, 2012, Pfizer Inc. consented to a judgment against it in a case filed by the Securities and Exchange Commission (SEC) in the District of Columbia. The SEC alleged that Pfizer, through certain foreign subsidiaries, violated both the Foreign Corrupt Practices Act (FCPA) and reporting obligations under section 13(b)(2)(A) of the SEC Act.⁵⁶ Specifically, the SEC alleged that employees of Pfizer's subsidiaries in Europe and Asia improperly induced foreign officials, including healthcare professionals who were employed by foreign governments, to influence regulatory approvals, formulary approvals, and other decisions relating to its products.⁵⁷ The SEC separately charged Wyeth LLC, now a Pfizer subsidiary, with similar allegations.⁵⁸

According to the complaint, Pfizer made an initial voluntary disclosure of its alleged violations in October 2004. Thereafter, the company "diligently and thoroughly undertook a global internal investigation of its operations in no less than 19 countries."⁵⁹ The company

⁵⁰ Press Release, Department of Justice, Orthofix Subsidiary, Blackstone Medical, Pays U.S. \$30 Million to Settle False Claims Act Allegations (Nov. 2, 2012), available at <http://www.justice.gov/opa/pr/2012/November/12-civ-1309.html>.

⁵¹ *Id.*

⁵² United States Attorney's Office, District of Massachusetts, Orthofix, Inc. Agrees to Plead Guilty to Felony (June 7, 2012), available at <http://www.justice.gov/usao/ma/news/2012/June/OrthofixSettlementPR.html>.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ See Jef Feeley and Janelle Lawrence, *Orthofix's Settlement of Medicare Probe Rejected by Judge*, BLOOMBERG, Sept. 6, 2012.

⁵⁶ 15 U.S.C. § 78m(b)(2)(A).

⁵⁷ Complaint, *U.S. Sec. & Exch. Comm'n v. Pfizer Inc.*, No. 1:12-cv-01303 (D.D.C. Aug. 7, 2012).

⁵⁸ Complaint, *U.S. Sec. & Exch. Comm'n vs. Wyeth LLC*, No. 1:12-cv-01304 (D.D.C. Aug. 7, 2012).

⁵⁹ *Supra* note 57, ¶ 5.

also undertook a “comprehensive review of its operations” and implemented a global FCPA compliance procedure.⁶⁰ Pfizer agreed to pay a total of \$60 million to resolve all of the claims.⁶¹

D. Deceptive Advertising

1. CVS Caremark

On January 12, 2012, the Federal Trade Commission (FTC) announced that CVS Caremark Corporation would pay \$5 million to settle allegations that it made deceptive claims relating to the prices of certain Medicare Part D prescription drugs.⁶² The FTC’s complaint alleged that the company, through its subsidiary RxAmerica, violated section 5(a) of the FTC Act⁶³ by misrepresenting the prices that beneficiaries would pay for covered Medicare Part D prescription drugs.⁶⁴

In addition to making a \$5 million payment to the FTC, the company was barred from misrepresenting the price or cost of Medicare Part D prescription drugs or other prices or costs associated with those drugs.⁶⁵

2. Medifast Inc.

Significant settlements of 2012 were not limited to cases involving prescription drugs. In September 2012, Medifast Inc., a manufacturer of meal replacement and diet products, agreed to pay \$3.7 million to settle deceptive advertising claims asserted by the FTC.⁶⁶ The complaint, filed in the District of Columbia, alleged that Medifast’s subsidiary, Jason Pharmaceuticals, violated a 1992 FTC Order that prohibited Jason Pharmaceuticals from making certain unsubstantiated weight loss claims and representations based on consumer testimonials.⁶⁷

The parties filed a consent decree on September 17, 2012. In addition to requiring Medifast to pay \$3.7 million in civil penalties, the decree prohibited Medifast from claiming its weight-loss products would engender certain results. For example, Medifast was enjoined from making any insinuation that consumers can expect results represented by an endorser of its product or that the product will allow consumers to lose a particular amount of weight, unless the claims are non-misleading and supported by specifically defined, reliable scientific evidence.⁶⁸

⁶⁰ *Supra* note 57, ¶ 5.

⁶¹ U.S. Securities and Exchange Commission, SEC Charges Pfizer with FCPA Violations (Aug. 7, 2012), *available at* <http://www.sec.gov/news/press/2012/2012-152.htm>.

⁶² Press Release, Federal Trade Commission, CVS Caremark Corporation Settles FTC Deceptive Pricing Charges (Jan. 12, 2012), *available at* <http://ftc.gov/opa/2012/01/cvs.htm>.

⁶³ 15 U.S.C. § 45(a).

⁶⁴ Complaint, *In re CVS Caremark Corp.*, No. C-4357 (F.T.C. May 3, 2012).

⁶⁵ Decision and Order, *In re CVS Caremark Corp.*, No. C-4357 (F.T.C. May 3, 2012).

⁶⁶ Press Release, Federal Trade Commission, Subsidiary of Diet Plan Marketer Medifast Inc. to Pay \$3.7 Million to Settle FTC Charges (Sept. 10, 2012), *available at* <http://www.ftc.gov/opa/2012/09/jasonpharm.shtm>.

⁶⁷ Complaint, *U.S.A. v. Jason Pharms., Inc.*, No. 1:12-cv-01476 (D.D.C. Sept. 7, 2012).

⁶⁸ Consent Decree, *U.S.A. v. Jason Pharms., Inc.*, No. 1:12-cv-01476 (D.D.C. Sept. 17, 2012).

E. Conclusion

Federal and state authorities are continuing to aggressively pursue a variety of claims against the pharmaceutical and food industries. Notably, in 2012, state governments have assumed a more active role in recovering settlements for state agencies. As marketing and regulatory claims remain lucrative for government agencies and whistleblowers, the current trends may continue into 2013, and the pattern may continue unabated until the risk of federal exclusion (sometimes called the “corporate death penalty”⁶⁹) is challenged or in some way eliminated.

⁶⁹ See Howard E. O’Leary, *Regulating Health Care Costs Through Fraud Enforcement*, DEF. COUNSEL J., Apr. 1995, at 211, 221.