

Relator Fees and Settlements in Pharmaceutical Cases

In November of 2019, the **whistleblower received \$1.9 Million** as her share of the government's recovery when a hospital pharmacy agreed to pay **\$10 million** to the federal government to settle claims that it violated the FCA by submitting false claims to Medicare for prescription drugs that did not meet Medicare coverage requirements. The settlement also resolved allegations that the company submitted claims to Medicare that resulted from improper remuneration provided to Medicare beneficiaries in the form of free blood glucose testing supplies and waiver of co-payments and deductibles for insulin, in violation of the AKS. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Kentucky Hospital to Pay over \$10 Million to Resolve False Claims Act Allegations (Nov. 20, 2019), <https://www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations>.

In November of 2019, the **whistleblowers received \$3.7 Million** when Compound Ingredient Supplier Fagron Holding USA LLC agreed to pay **\$20.5 million** to settle allegations concerning the establishment of false and inflated Average Wholesale Prices (AWPs) for active pharmaceutical ingredients used in compound prescriptions. The settlement resolved claims that the company knowingly inflated the AWPs for its ingredients to increase the reimbursement that its pharmacy customers received from federal health care programs for using the company's ingredients to prepare and fill specially-made compound prescriptions. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Compound Ingredient Supplier Fagron Holding USA LLC to Pay \$22.05 Million to Resolve Allegations of False and Inflated Average Wholesale Prices for Ingredients Used in Compound Prescriptions (Nov. 7, 2019).

In September of 2019, three **whistleblowers received more than \$17.7 Million** as a Relator share when a pharmaceutical company was charged for paying kickbacks to a health care provider to prescribe the company's drug to beneficiaries of federal health care programs. The company agreed to pay more than **\$108 million** in criminal penalties, forfeiture, and civil damages. DOJ alleged that the pharmaceutical company paid kickbacks in the form of money, honoraria, travel, and meals to health care providers of elderly patients at long-term care facilities to induce them to prescribe the company's drug for behaviors associated with dementia patients, which is not an approved use of the drug. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act

Violations (Sept. 26, 2019), <https://www.justice.gov/opa/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves-related>.

In July of 2019, Reckitt Benckiser Group agreed to pay the federal government **\$1.4 billion** to resolve potential criminal and civil liability related to the marketing of an opioid addiction treatment drug. DOJ alleged that the consumer goods conglomerate directly, or through its subsidiary pharmaceutical company, knowingly (1) promoted the sale and use of the drug to physicians who were writing prescriptions for unsafe and medically unnecessary uses, and (2) promoted the sale or use of the drug to physicians and state Medicaid agencies with false claims that the drug was less susceptible to diversion, abuse, and accidental pediatric exposure than alternative drugs. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History (Jul. 11, 2019), <https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case>.

In September of 2019, the **whistleblowers received approximately \$2.9 million** as their share of the settlement when Mallinckrodt agreed to pay **\$15.4 million** to settle allegations that it paid illegal kickbacks under the FCA and AKS by providing meals and entertainment to health care providers allegedly to induce them to prescribe the company's drug. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Drug Maker Mallinckrodt Agrees to Pay Over \$15 Million to Resolve Alleged False Claims Act Liability for "Wining and Dining" Doctors (Sept. 4, 2019), <https://www.justice.gov/opa/pr/drug-maker-mallinckrodt-agrees-pay-over-15-million-resolve-alleged-false-claims-act-liability>.

In September of 2019 a compounding pharmacy agreed to a **\$21.4 million** settlement in total to resolve allegations that they violated the FCA through their involvement in an alleged kickback scheme to induce referrals of prescriptions that were reimbursed by TRICARE. DOJ alleged that the compounding pharmacy paid kickbacks to outside "marketers" that paid telemedicine doctors to prescribe military members and their families compounded creams and vitamins that were formulated to ensure the highest reimbursement from TRICARE. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay \$21.36 Million to Resolve False Claims Act Allegations (Sept. 18, 2019), <https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million>.

In December of 2018, Actelion agreed to pay **\$360 million** to settle claims that it used a non-profit foundation as an illegal conduit to pay copays of Medicare patients taking its drug, in violation of the AKS, based on allegations that, rather than allowing financially needy Medicare patients to participate in the company's free drug program, it referred them to the foundation, which paid their copays, resulting in claims to Medicare for the remaining cost. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Drug Maker Actelion Agrees to Pay \$360 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 6, 2018), <https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>.

The **whistleblower** received a **Relator Fee** of approximately **\$93 million** of the **\$260 million settlement** in October of 2018, in a case where Amerisource Bergen Corporation agreed to resolve allegations that they improperly repackaged and distributed overfill oncology drugs and allegedly provided kickbacks to induce physicians to purchase the repackaged drugs. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, AmerisourceBergen Corporation Agrees to Pay \$625 Million to Resolve Allegations That it Illegally Repackaged Cancer-Supportive Injectable Drugs to Profit from Overfill (Oct. 1, 2018), <https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally>.

Pfizer Inc. (Pfizer) entered into a civil settlement to resolve its FCA liability associated with donations it made to a 501(c)(3) foundation, which operated funds that pay the copayments of certain patients, including Medicare patients. Specifically, Pfizer resolved allegations that, from 2012 through 2016, it used the foundation as a conduit to pay the copayments of Medicare patients taking Sutent, Inlyta, and Tikosyn, in violation of the Anti-Kickback Statute. Pfizer agreed to pay **\$23.85 million**. *See* 2016 OIG Annual Report.

In December of 2016, Forest Laboratories LLC, located in New York and Forest Pharmaceuticals Inc. agreed to pay **\$35.5 million** to settle federal civil FCA allegations that Forest paid kickbacks in violation of the Anti-Kickback Statute to induce prescriptions of the drugs Bystolic, Savella, and Nameda. The government alleged that Forest employed speaker program payments and meals as improper inducements; Forest allegedly provided these benefits even when the speaker programs were cancelled, no licensed health care professionals attended the programs, the same attendees had attended multiple programs over a short period of time, or the meals associated with the

programs exceeded Forest's internal cost limitations. *See* 2016 OIG Annual Report.

In July of 2017, drug manufacturer Celgene Corp. agreed to pay approximately **\$259.3 million** to settle federal civil FCA allegations that it caused the submission of false claims to federal health care programs for non-covered uses for two drugs manufactured by Celgene. The settlement resolved claims that Celgene promoted two cancer treatment drugs, Thalomid and Revlimid, for uses that were not approved by the FDA and not covered by federal health care programs. In addition to the federal recovery, Celgene paid approximately **\$20.7 million to resolve state Medicaid liability**. *See* 2017 OIG Annual Report.

In July of 2017, Novo Nordisk Inc., headquartered in Plainsboro, New Jersey, paid a disgorgement of approximately **\$12.2 million** to settle allegations under the Federal Food, Drug, and Cosmetic Act that it failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes drug Victoza. At the time of Victoza's approval, the FDA required a REMS to mitigate the potential risk in humans of a rare form of cancer called Medullary Thyroid Carcinoma associated with the drug. *See* 2017 OIG Annual Report.

In August 2017, drug manufacturers Mylan Inc. and Mylan Specialty L.P., headquartered in Canonsburg, Pennsylvania, agreed to pay approximately **\$231.7 million** to settle federal civil FCA allegations that Mylan underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP) and caused the submission of false claims to Medicaid. The government alleged that Mylan erroneously classified its patented, brand name drug EpiPen, which has no therapeutic equivalents or generic competition, as a generic drug to Medicaid while significantly increasing its price, thereby avoiding its obligation to pay higher rebates for EpiPen and its price increase. Between 2010 and 2016, Mylan allegedly increased the price of EpiPen by approximately 400 percent yet paid only a fixed 13 percent rebate to Medicaid during the same period. The government further alleged that while Mylan claimed generic treatment for Medicaid purposes, it advocated the drug as a unique brand product elsewhere – including before the FDA. In addition to the federal recovery, **Mylan also paid \$213.9 million to resolve state Medicaid liability**. *See* 2017 OIG Annual Report.

In December of 2016, Bristol-Myers Squibb Company agreed to pay **\$19.5 million** to settle claims with forty-three state attorneys general concerning the alleged off-label promotion of its schizophrenia drug. The company allegedly promoted the drug for use in pediatric populations and to treat dementia and Alzheimer's in elderly patients, despite the fact that those were not FDA-approved uses. *See* Press Release, Office of the Att'y Gen. of Tex., AG Paxton: Texas and 42 States Reach \$19.5 Million Settlement with Bristol-Myers Squibb Company (Dec. 8, 2016). *See* 2016 OIG Annual Report.

In September of 2016, the owners of a compound pharmacy agreed to pay **\$7.75 million** to resolve allegations that they violated the FCA by purportedly submitting claims for reimbursement that were not reimbursable because it had procured the prescriptions through the use of illegal kickbacks, in violation of the AKS. *See* Press Release, U.S. Atty's Office for the Middle Dist. of Fla., U.S. Dep't of Justice, United States Settles False Claims Act Allegations Against Compound Pharmacy Owners For \$7.75 Million (Sept. 14, 2016), <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-compound-pharmacy-owners-775>.

The whistleblower received a **Relator Fee** of approximately **\$10 million** from a **\$67 million settlement** in June of 2016, when pharmaceutical companies agreed to resolve allegations that the companies misled providers about the effectiveness of a certain drug to treat non-small cell lung cancer. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Companies to Pay \$67 Million to Resolve False Claims Act Allegations Relating to Tarceva (June 6, 2016), <https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-67-million-resolve-false-claims-act-allegations-relating-tarceva>.

In June of 2016, a North Carolina-based pharmaceutical company agreed to pay **\$54 million** to resolve claims related to its speakers' program, which held more than 10,000 sessions between 2009 and 2013. The company admitted that, during some of the programs, the pre-recorded presentation was not played or the designated speaker was not called following the presentation to answer questions, but was nevertheless paid the honorarium. *See* Stipulation and Order of Settlement and Dismissal, *United States ex rel. Steven R. Peikin v. Salix Pharmaceuticals, Inc.*, No. 12-cv-03870 (S.D.N.Y. June 9, 2016).

In February of 2016, two compounding pharmacies and four physicians agreed to pay **\$10 million** to settle allegations that the physicians prescribed pain and scar creams that often were not used by patients, and that the profits from federal reimbursement for the creams were shared in part with the physicians. *See* Press Release, U.S. Atty's Office, Middle Dist. of Fla., U.S. Dep't of Justice, United States Announces Approximately \$10 Million Settlement With Four Physicians And Two Compounding Pharmacies (Feb. 11, 2016), <https://www.justice.gov/usao-mdfl/pr/united-states-announces-approximately-10-million-settlement-four-physicians-and-two>.

In October of 2015, Warner Chilcott U.S. Sales LLC—a subsidiary of pharmaceutical manufacturer Warner Chilcott PLC—paid **\$91.5 million** to settle civil FCA allegations that it violated the AKS by paying illegal remuneration, including payments for “Medical Education Events” and speaker programs to prescribing physicians to induce prescriptions for several of the company’s drugs. *See* 2016OIG Annual Report.

In November 2015, Novartis Pharmaceuticals paid **\$286.8 million** to settle civil federal FCA allegations of a kickback scheme involving marketing and selling an iron chelation drug known as Exjade and an anti-rejection drug for kidney transplants known as Myfortic. The government alleged that Novartis paid kickbacks in the form of patient referrals and rebates to specialty pharmacies, Bioscrip, Inc. and Accredo Health Group to induce those pharmacies to recommend Exjade refills while understating the drug’s serious, potentially life-threatening side effects, and to recommend to doctors that they switch patients to Myfortic from competitor drugs. In addition to the federal recovery, Novartis paid approximately **\$80 million** to resolve state Medicaid liability. Novartis also made a civil forfeiture payment of \$20 million. *See* 2016 OIG Annual Report.

In April 2016, drug manufacturers Wyeth and Pfizer, Inc. paid **\$413 million** to settle civil federal FCA allegations that Wyeth underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP) and caused the submission of false claims to the federal health care programs. Pursuant to the MDRP, drug manufacturers must pay quarterly rebates to state Medicaid programs in exchange for Medicaid’s coverage of the manufacturers’ drugs. In addition to the federal recovery, Wyeth paid **\$371.4 million** to resolve its **state Medicaid liability**. *See* 2016 OIG Annual Report.

In June 2016, Genentech, Inc. and OSI Pharmaceuticals, LLC paid **\$62.6 million** to resolve civil FCA allegations that they caused the submission of false claims to the federal health care programs when making misleading statements to market and sell the drug Tarceva. The FDA approved Tarceva to treat certain patients with non-small cell lung cancer or pancreatic cancer. *See* 2016 OIG Annual Report.

In June 2016, Salix Pharmaceuticals paid a total of **\$46.5 million** to settle civil FCA allegations of a kickback scheme involving marketing and selling at least seven products used to treat various gastroenterology conditions. The government alleged that Salix paid kickbacks to physicians to induce them to increase their prescriptions for the products. The alleged remuneration paid to the physicians included substantial honoraria for speaker programs at high-end restaurants during which little to no time was spent discussing the products with the same physicians attending multiple dinners with their spouses who were not health care professionals. *See* 2016 OIG Annual Report.

In November of 2015, Novartis Pharmaceuticals agreed to pay **\$390 million** to settle claims that it provided improper kickbacks in the form of financial incentives and patient referrals to specialty pharmacies, allegedly in exchange for prescriptions of specific drugs produced by the company, which were purportedly less effective and costlier than alternatives. The company will pay **\$370 million to resolve state and federal FCA claims**, comprised of \$286.9 million for the federal government and \$83.1 million for the settling states. *See* Press Release, U.S. Atty's Office for the Southern Dist. of New York, U.S. Dep't of Justice, Manhattan U.S. Attorney Announces \$370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals for Kickback Scheme Involving High-Priced Prescription Drugs, Along With \$20 Million Forfeiture of Proceeds from the Scheme (Nov. 20, 2015), <http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis>.

In November of 2015, six compounding pharmacies and owners agreed to pay more than **\$30 million** in combined fines and repayments to settle claims that they fraudulently billed TRICARE. The largest individual payment, of more than \$4.7 million, came from one pharmacy that resolved allegations that it provided illegal kickbacks to marketers, filled prescriptions that it knew or should have known were illegitimate, and mailed prescriptions to states in which it had no license. *See* Press Release, U.S. Atty's Office for the Middle

Dist. of Florida, U.S. Dep't of Justice, United States Announces New Round of Compound Pharmacy Settlements to Result in More Than \$30 Million in Fines and Repayments (Nov. 25, 2015), <http://www.justice.gov/usao-mdfl/pr/united-states-announces-new-round-compound-pharmacy-settlements-expected-result-more-30>.

In October of 2015, a pharmaceutical manufacturer agreed to pay **\$125 million** to settle criminal and civil claims that the manufacturer illegally marketed certain drugs, caused the submission of false claims to government health care programs, violated the AKS by paying physicians illegal remuneration, and caused the submission of false prior authorization requests for certain drugs. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Werner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations (Oct. 29, 2015), <http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>.

In a **whistleblower** case originally brought by former employees of the pharmaceutical manufacturer, one of whom **received a \$1 million Relator share** from a **\$9.25 million settlement** in October of 2015, when one of the country's largest nursing home pharmacy companies agreed to settle allegations that it both solicited and received kickbacks from a pharmaceutical manufacturer in exchange for recommending a certain drug to nursing home residents. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Nation's Second-Largest Nursing Home Pharmacy to Pay \$9.25 Million to Settle Kickback Allegations (Oct. 7, 2015), <http://www.justice.gov/opa/pr/nations-second-largest-nursing-home-pharmacy-pay-925-million-settle-kickback-allegations>.

In a *qui tam* case in July of 2015, a multinational drug manufacturer agreed to pay **\$46.5 million** and another drug manufacturer agreed to pay **\$7.5 million** to the United States and participating states. The settlement resolved claims that the companies knowingly underreported prices for certain drugs, leading to underpayment of quarterly rebates owed to the states under the Medicaid Drug Rebate Program and overcharges to the United States for payments to the states. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, AstraZeneca and Cephalon to Pay \$46.5 Million and \$7.5 Million, Respectively, for Allegedly Underpaying Rebates Owed Under Medicaid

Drug Rebate Program, (July 6, 2015), <http://www.justice.gov/opa/pr/astrazeneca-and-cephalon-pay-465-million-and-75-million-respectively-allegedly-underpaying>.

In case that began as a *qui tam* suit filed by a former pharmacist employee who received a **Relator Fee** of **\$4.3 million** out of the **\$31.5 million settlement proceeds** in May of 2015, a pharmacy agreed to settle claims that it fraudulently billed Medicare for Schedule II controlled drugs it allegedly distributed without a valid prescription. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Long-Term Care Pharmacy to Pay \$31.5 Million to Settle Lawsuit Alleging Violations of Controlled Substances Act and False Claims Act (May 14, 2015), <http://www.justice.gov/opa/pr/2015/May/15-civ-614.html>.

In April of 2015, a pharmaceutical manufacturer agreed to pay the State of Texas **\$11.25 million** to settle claims that the company reported inflated drug prices to Medicaid. The Texas Attorney General initiated the investigation against the manufacturer under the Texas Medicaid Fraud Prevention Act. *See* Press Release, Attorney General of Texas, Attorney General Paxton Recovers \$25 Million for State of Texas, U.S. Medicaid Program (Apr. 7, 2015), <https://www.texasattorneygeneral.gov/oagnews/release.php?id=5012>.

In June of 2015 in a *qui tam* suit filed by two former employees who collectively received a **Relator Fee** of **\$1,422,000** out of the **\$7.9 million settlement** proceeds, when AstraZeneca agreed to settle claims that the manufacturer engaged in a kickback scheme with a pharmacy benefit manager company. The manufacturer allegedly provided remunerations to the benefit manager in exchange for its agreement to maintain the sole and exclusive status of one of the manufacturer's drugs on certain formularies and through some of the company's other related marketing activities. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, AstraZeneca to Pay \$7.9 Million to Resolve Kickback Allegations (Feb. 11, 2015), <http://www.justice.gov/opa/pr/2015/February/15-civ-166.html>.

The **whistleblower**, one of the company's former sales representatives, received a **Relator Fee** of **\$6.1 million** from the government's recovery of **\$39 million** in January of 2015, in a case where Daiichi Sankyo Inc. agreed to settle claims that it paid kickbacks to entice physicians to prescribe certain drugs produced by the company. *See* Press Release, Office of Pub. Affairs,

U.S. Dep't of Justice, Daiichi Sankyo Inc. Agrees to Pay \$39 Million to Settle Kickback Allegations Under the False Claims Act (Jan. 9, 2015), <http://www.justice.gov/opa/pr/2015/January/15-civ-017.html>.

In February and May of 2015, Medco Health Solutions, Inc. agreed to pay a total of **\$15.8 million** to settle civil FCA allegations of a kick-back scheme involving marketing and selling pharmaceutical products. The government alleged that AstraZeneca paid kickbacks to Medco in exchange for identifying Nexium as the “sole and exclusive” proton pump inhibitor on certain of Medco’s prescription drug lists known as formularies. *See* 2015 OIG Annual Report.

In July of 2015, drug manufacturers AstraZeneca LP and Cephalon, Inc. agreed to pay a total of **\$54 million** to settle civil FCA allegations that they knowingly underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP). Pursuant to the MDRP, drug manufacturers must pay quarterly rebates to state Medicaid programs in exchange for Medicaid’s coverage of the manufacturers’ drugs. The settlements with AstraZeneca and Cephalon resolved allegations that they underreported Average Manufacturer Prices (AMPs) for a number of their drugs by improperly reducing the reported AMPs for service fees they paid to wholesalers. *See* 2015 OIG Annual Report.

In May of 2015, PharMerica Corporation, a national long-term care pharmacy provider, entered into two settlements for a total of **\$31.5 million** to resolve claims that it violated the FCA and the Controlled Substances Act. The government alleged that PharMerica dispensed and billed Medicare for schedule II controlled substances without a valid prescription. *See* 2015 OIG Annual Report.

In July of 2015, Blanding Health Mart Pharmacy, a compounding pharmacy, agreed to pay **\$8.4 million** to resolve civil FCA allegations that it sought reimbursement for compounding pharmaceutical prescriptions that were not medically necessary and were written by physicians that had never actually seen the patients. *See* 2015 OIG Annual Report.

In August of 2015, the Chief Executive Officer of a Kentwood, Michigan pharmacy was sentenced to **ten years in prison**, agreed to a 50-year exclusion from federal health care programs, and is likely to pay over **\$8 million in restitution** in connection with a conspiracy to commit health care fraud by

billing Medicare Part D plans, Medicaid, and private insurers for over **\$79 million** in drugs that were adulterated and misbranded in violation of the Federal Food, Drug, and Cosmetic Act. *See* 2015 OIG Annual Report.

In July of 2014, a pharmaceutical manufacturer agreed to pay **\$19.5 million** to the State of Texas to resolve civil Medicaid fraud allegations. State law requires drug manufacturers to report the prices they charge to pharmacies, distributors, and wholesalers for their products as part of the calculation for Medicaid reimbursement. The manufacturer allegedly reported inflated market prices for the drugs resulting in reimbursement by Medicaid at inflated rates. *See* Press Release, Attorney General of Texas, Attorney General Abbott Recovers \$19.5 Million for State of Texas, U.S. (Aug. 11, 2014), <https://www.texasattorneygeneral.gov/oagnews/release.php?id=4814>.

In September of 2014, a generic drug manufacturer agreed to pay the State of Texas **\$39.75 million** to resolve allegations that it reported inflated drug prices to the Medicaid program in violation of the Texas Medicaid Fraud Prevention Act. These inflated prices allegedly resulted in increased reimbursements. *See* Press Release, Attorney General of Texas, Attorney General Abbott Recovers \$39.75 Million for State of Texas, U.S. Medicaid Program (Oct. 16, 2014), <https://www.texasattorneygeneral.gov/oagnews/release.php?id=4874>.

In August of 2014, in a case initiated by a **whistleblower**, McKesson Corp. agreed to a settlement with the U.S. government under which it paid **\$18 million** to resolve allegations that it failed to comply with the shipping and handling requirements of its vaccine distribution contract with the Centers for Disease Control and Prevention ("CDC"). The company allegedly submitted false claims to the CDC for shipping and handling services when it had not satisfied its contractual obligations. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, McKesson Corp. to Pay \$18 Million to Resolve False Claims Allegations Related to Shipping Services Provided Under Centers for Disease Control Vaccine Distribution Contract (August 8, 2014), <http://www.justice.gov/opa/pr/mckesson-corp-pay-18-million-resolve-false-claims-allegations-related-shipping-services/>.

A **whistleblower**, a former executive at the pharmaceutical company, received a **Relator Fee** of **\$5.9 million** from a **\$56.5 million settlement** in September of 2014, when Shire Pharmaceuticals LLC agreed to settle allegations that it made false and misleading statements in the marketing and

promotion of several drugs treating attention deficit hyperactivity disorder. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Shire Pharmaceuticals LLC to Pay \$56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices (Sept. 24, 2014), <http://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug>.

A **whistleblower**, a former employee at the company, received a **Relator Fee** of **\$1.02 million** from a **\$6 Million settlement** in September of 2014, when Caremark agreed to resolve claims that the company knowingly declined to reimburse Medicaid for prescription drug costs paid on behalf of dual eligible individuals. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Caremark Will Pay \$6 Million to Resolve False Claims Act Allegations (Sept. 26, 2014), <http://www.justice.gov/opa/pr/caremark-will-pay-6-million-resolve-false-claims-act-allegations>.

In October of 2014, Caremed Pharmaceutical Services agreed to pay **\$9.5 million** to settle allegations that it engaged in double-billing, billed for prescriptions not actually provided, and made false statements to receive prior authorization from Medicare Part D sponsors. *See* Press Release, U.S. Attorney's Office, S. Dist. of N.Y., U.S. Dep't of Justice, Manhattan U.S. Attorney Settles Civil Fraud Claims Against Caremed Pharmaceutical Services for Engaging in Fraudulent Conduct (Oct. 9, 2014), <http://www.justice.gov/usao/nys/pressreleases/October14/CareMedSettlementPR.php>.

A **whistleblower** received a **Relator Fee** of **\$708,852** of the **\$7.3 Million settlement** proceeds in April of 2014, in a case where Astellas Pharma US Inc. agreed to resolve claims that it marketed and promoted one of its drugs for pediatric use, when only adult use was medically accepted. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Astellas Pharma US Inc. to Pay \$7.3 Million to Resolve False Claims Act Allegations Relating to Marketing of Drug Mycamine (Apr. 16, 2014), <http://www.justice.gov/opa/pr/2014/April/14-civ-391.html>.

In March of 2014, a major pharmaceutical manufacturer and its subsidiary agreed to pay **\$27.6 million** to settle allegations that the companies made improper payments to an Illinois physician to prescribe one of their drugs. The physician allegedly had received numerous payments and other

benefits and soon became the largest prescriber of the drug in the United States. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company to Pay \$27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs (Mar. 11, 2014), <http://www.justice.gov/opa/pr/2014/March/14-civ-251.html>.

In June of 2014, a national provider of pharmaceuticals and pharmacy services to nursing homes agreed to pay **\$124.24 million** to resolve allegations that it offered improper financial incentives to skilled nursing facilities in exchange for contracts to be the supplier of the facilities' pharmaceutical needs. The settlement resolved two *qui tam* suits, and the **relator**, a former employee of the company, **received a \$17.24 million Relator share** of the recovery. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Nation's Largest Nursing Home Pharmacy Company to Pay \$124 Million to Settle Allegations Involving False Billings to Federal Health Care Programs (June 25, 2014), <http://www.justice.gov/opa/pr/2014/June/14-civ-670.html>.

In November of 2013, pharmaceutical company Johnson & Johnson (J&J) and certain subsidiaries agreed to pay over **\$2.2 billion** to resolve criminal and civil allegations relating to the prescription drugs Risperdal, Invega, and Natrecor. In a criminal information, the United States alleged that Janssen Pharmaceuticals, Inc., a J&J subsidiary, marketed the antipsychotic drug Risperdal off-label to control behavioral disturbances in non-schizophrenic dementia patients at a time when the drug was approved only to treat schizophrenia. *See* 2013 OIG Annual Report.

In February 2014, pharmaceutical company Endo Health Solutions Inc. and its subsidiary Endo Pharmaceuticals Inc. (Endo) agreed to pay **\$192.7 million** to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved by the FDA. During the relevant time period, Lidoderm was approved only for the relief of pain associated with post-herpetic neuralgia (PHN), a complication of shingles. However, the government charged that Endo introduced into interstate commerce Lidoderm that was misbranded because its labeling lacked adequate directions for use in the treatment of non-PHN related pain, including low back pain, diabetic neuropathy, and carpal tunnel syndrome. These uses were intended by Endo but never approved by the FDA. The resolution included a deferred prosecution agreement and forfeiture totaling

\$20.8 million and civil FCA settlements totaling \$171.9 million. *See* 2014 OIG Annual Report.

In March of 2014, Israeli pharmaceutical company, Teva Pharmaceuticals USA Inc., agreed to pay **\$27.6 million** to settle civil FCA allegations that it and a subsidiary paid kickbacks to a Chicago psychiatrist. The United States alleged that the company, which manufactures the anti-psychotic drug clozapine, paid the psychiatrist kickbacks in the form of consulting and speaking fees in exchange for his agreement to prescribe clozapine to several thousand patients over an eight-year period. The United States also filed a civil suit against the psychiatrist which remains pending. *See* 2014 OIG Annual Report.

In April of 2014, pharmaceutical company Astellas Pharma, US, Inc. agreed to pay **\$7.3 million** to resolve civil FCA allegations relating to its promotion of the prescription drug Mycamine to treat pediatric patients, even though that use was not a medically accepted indication and, therefore, not covered by government health care programs. *See* 2014 OIG Annual Report.

In September of 2014, pharmaceutical company Shire Pharmaceuticals LLC agreed to pay \$56.5 million to resolve civil FCA allegations relating to its promotion of Adderall XR, Vyvanse and Daytrana (which are approved for the treatment of attention deficit hyperactivity disorder), and Pentasa and Lialda (which are approved for the treatment of mild to moderate active ulcerative colitis). *See* 2014 OIG Annual Report.

In February of 2014, long-term care pharmacy provider Omnicare, Inc. agreed to pay **\$4.2 million** to resolve civil FCA allegations that it knowingly caused false claims for the drug Aranesp to be submitted to federal health care programs. The settlement resolves allegations that Omnicare solicited and received kickbacks from the drug manufacturer Amgen Inc. in return for implementing “therapeutic interchange” programs designed to switch beneficiaries from a competitor drug to Aranesp. Amgen previously paid **\$24.9 million** to resolve allegations relating to payments to Omnicare and other pharmacies. *See* 2014 OIG Annual Report.

In March of 2014, Sears Holdings Corporation and Kmart Corporation (collectively, Kmart) agreed to pay **\$3.3 million** to settle allegations that Kmart offered and paid remuneration in the form of gift cards and coupons to beneficiaries of federal health care programs to induce the beneficiaries to transfer or fill their prescriptions at Kmart pharmacies. The government

alleged that, as a result of this conduct, Kmart violated the FCA by submitting improper claims for payment to Medicare, TRICARE, the Veterans Affairs program, and Medicaid. Sears wholly owns Kmart, which operates retail stores containing pharmacies throughout the United States. *See* 2014 OIG Annual Report.

In June of 2014, long-term care pharmacy provider Omnicare Inc. agreed to pay **\$124 million** to resolve civil FCA allegations that it offered improper financial incentives to skilled nursing facilities to select Omnicare to supply drugs to elderly Medicare and Medicaid beneficiaries. The government alleged that Omnicare entered into below-cost contracts to supply prescription medication and other pharmaceutical drugs to skilled nursing facilities and their resident patients in order to induce the facilities to select Omnicare as their pharmacy provider. *See* 2014 OIG Annual Report.

In September of 2014, CVS Caremark agreed to pay **\$6 million** to settle civil FCA allegations that it failed to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark administered private health plans. The settlement resolved allegations that CVS Caremark improperly deducted certain co-payments and deductible amounts from payments that Medicaid was entitled to receive, causing Medicaid to incur prescription drug costs that should have been paid for by the Caremark-administered private health plans. *See* 2014 OIG Annual Report.

In December of 2013, a global pharmaceutical and health care company resolved allegations that it paid kickbacks to physicians by agreeing to a **\$5.475 million** settlement with the DOJ. The government alleged that the company paid kickbacks by offering physicians teaching assignments, speaking engagements, and trips to conferences with the understanding that these physicians would use the company's products at their respective hospitals. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Abbott Laboratories Pays U.S. \$5.475 Million to Settle Claims That Company Paid Kickbacks to Physicians (Dec. 27, 2013), <http://www.justice.gov/opa/pr/2013/December/13-civ-1367.html>.

In March of 2013, the **Whistleblowers received over \$4 Million** in relator fees when a New Jersey-based pharmaceutical company pleaded guilty to criminal charges and resolved civil allegations that it unlawfully marketed and promoted a prescription drug for uses not approved by the FDA (off-label promotion). The total **settlement** was **\$45 million**, of which \$22.5 represented

civil damages. *See* Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Par Pharmaceuticals Pleads Guilty and Agrees to Pay \$45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing (Mar. 5, 2013), <http://www.justice.gov/opa/pr/2013/March/13-civ-270.html>.

In a settlement that stemmed from a *qui tam* action initiated by a former executive of the company, the **whistleblower** received a **Relator Fee** of **\$48.6 million** from the federal share of the settlement amount of **\$350 million** which represented civil damages under the FCA. In May of 2013, Ranbaxy agreed to plead guilty and settle allegations that the company made false statements to the FDA regarding the quality of its drugs and failed to comply with current good manufacturing practices. *See* Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Ranbaxy Pleads Guilty to Violations of the Food, Drug, and Cosmetic Act and Making False Statements – Agrees to Pay \$500 Million in Fines and to Resolve Civil Claims (May 13, 2013), http://www.justice.gov/usao/md/PublicAffairs/press_releases/Press13/RanbaxyPleadsGuiltyToViolationsOfTheFDCAAndMakingFalseStatements-AgreesToPay500Million.html.

In May of 2013, the **whistleblower**, a former manager at the company, initiated the suit under the *qui tam* provisions of the FCA, and **received** approximately a **Relator Fee** of **\$10 million** as her share of the **\$48.26 million** civil settlement. In that case, a New Jersey-based medical products manufacturer agreed to resolve allegations that the company had knowingly caused false claims to be submitted to Medicare by providing illegal remuneration to induce customers and physicians to use its products to treat prostate cancer. *See* Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, C.R. Bard Inc. to Pay U.S. \$48.26 Million to Resolve False Claims Act Claims (May 13, 2013), <http://www.justice.gov/opa/pr/2013/May/13-civ-547.html>.

The *qui tam* **whistleblowers** who assisted the government in a major case received a total of **\$167.7 million** as their **relators' share** from a total **settlement** of **\$2.2 billion** (including **\$1.72 billion in civil damages** and penalties). In that case, which was resolved in November of 2013, Johnson & Johnson agreed to resolve claims that it engaged in off-label marketing and paid kickbacks to boost sales of two pharmaceutical products. The subsidiary of the company allegedly marketed schizophrenia medication as being safe and effective for non-schizophrenic patients that included children, the elderly, and individuals with mental disabilities. *See* Press Release, Office of

Pub. Affairs, U.S. Dep't of Justice, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), <http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html>.

In July of 2013, Wyeth Pharmaceuticals agreed to pay **\$490 million** to resolve criminal and civil liability arising from allegations that it marketed a prescription drug for uses not approved as safe and effective by the FDA. The government alleged that the company violated the FCA by promoting a drug for unapproved uses, some of which were not covered by Medicare, Medicaid, or other federal health care programs. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Wyeth Pharmaceuticals Agrees to Pay \$490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses (July 30, 2013), <http://www.justice.gov/opa/pr/2013/July/13-civ-860.html>.

In February of 2013, it was announced that two pharmaceutical companies agreed to pay the State of Texas **\$10.9 million** to resolve allegations that the companies fraudulently reported inflated drug prices to the state's Medicaid program. *See* Ama Sarfo, Upsher, Forest Ink \$11M Drug Price Inflation Settlement, Law360 (Feb. 13, 2013, 6:54 PM), <http://www.law360.com/articles/415348/upsher-forest-ink-11m-drug-price-inflation-settlement>

Four **whistleblowers** received a **Relator Fee** of **\$84 million** from the federal settlement, and received more from the states, from a **\$1.5 Billion settlement** announced in May of 2012. In that case, Abbott Laboratories, Inc. pleaded guilty to criminal and civil charges of unlawful marketing and promotion of a prescription drug for uses not approved by the FDA (off-label promotion). Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote (May 7, 2012), <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html>.

Four **whistleblowers** shared a **\$250 million award** from a July of 2012 settlement, when the DOJ announced that GlaxoSmithKline LLC agreed to plead guilty and to pay a total of **\$3 billion** to settle allegations that the company provided unlawful kickbacks and promoted certain prescription drugs off-label, failed to report drug safety data, and falsely reported drug prices. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012),

<http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>. See Richard Blackden, Glaxo Whistleblowers to Share \$250m Windfall, *The Telegraph*, July 4, 2012, <http://www.telegraph.co.uk/finance/newsbysector/pharmaceuticals/9374104/Glaxo-whistleblowers-to-share-250m-windfall.html>.

The **relator** who initiated the underlying *qui tam* action received a **Relator Fee of more than \$17 million from a \$95 million** settlement announced in October of 2012, when Boehringer Ingelheim agreed to resolve allegations of off-label drug promotion and illegal kickbacks involving four of its prescription drugs. See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Boehringer Ingelheim to Pay \$95 Million to Resolve False Claims Act Allegations (Oct. 25, 2012), <http://www.justice.gov/opa/pr/2012/October/12-civ-1291.html>.

The **relator** who initiated a *qui tam* action received a **Relator Fee of \$8 million** from a **\$30 million** settlement announced in November of 2012, when Blackstone Medical agreed to settle civil allegations that the company's subsidiary paid kickbacks to surgeons in exchange for using its products. See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Orthofix Subsidiary, Blackstone Medical, Pays U.S. \$30 Million to Settle False Claims Act Allegations (Nov. 2, 2012), <http://www.justice.gov/opa/pr/2012/November/12-civ-1309.html>.

In a settlement announced in December of 2012, which resolved a *qui tam* lawsuit filed by a former sales representative, the **Relator** received **\$18.5 million** as his **Relator share** of the **\$109 million recovery**. In that case, *Sanofi-Aventis U.S., Inc.*, agreed to resolve allegations that the company, facing pressure from a lower-priced competitor, provided its sales representatives with samples of a product, which the representatives then gave free to doctors as purchase incentives. *United States ex rel. Giddarie v. Sanofi-Aventis U.S., Inc.*, No. 10-CV-10070 (D. Mass.).