EPSTEIN BECKER GREEN

PHARMACEUTICAL & MEDICAL DEVICE MANUFACTURERS: RECENT SETTLEMENTS AND INVESTIGATIONS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES*

PUBLIC SETTLEMENTS & INVESTIGATIONS

PREPARED BY
EPSTEIN BECKER & GREEN, P.C.

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* This chart summarizes publicly available information relating to select pharmaceutical and medical device manufacturer investigations and select PBM/HMO investigations/litigation related to pharmaceuticals and medical devices. It is based solely on secondary sources on file with author. For more information, please contact wgoldstein@ebglaw.com or sgiesting@ebglaw.com

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PHARMACEUTICAL & MEDICAL DEVICE MANUFACTURERS:
PUBLIC SETTLEMENTS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES

SELECT SETTLEMENTS

Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Biovail Pharmaceuticals, Inc. (subsidiary of Biovail Corp.)	$24.6 million	September 2009 Settlement first announced in May 2008	Cardizem LA (diltiazem)	Biovail Pharmaceuticals, Inc. (a subsidiary of Biovail Corp.) pled guilty to conspiracy and kickback charges and to pay a criminal fine of $22.2 million to settle charges with the DOJ. These charges include paying physicians up to $1,000 each as inducements for prescribing or recommending Cardizem LA. Biovail also agreed to pay $2.4 million in civil fines to resolve allegations that its conduct caused the submission of false claims to the United States. Biovail entered into a 5 year CIA with the OIG.

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Pfizer Inc.	Total: $2.3 billion $1.3 billion in criminal fines and forfeiture $1 billion combined federal and state civil false claims act ($668,514,830 – federal share; $331,485,170 – states' share)	August 2009	Bextra, Geodon Zyvox, Lyrica Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec	Phamacia & Upjohn, Inc., a Pfizer subsidiary, charged with one count felony misbranding of Bextra (relating to off label promotion of Bextra for acute pain and surgical pain and for dosages above the FDA approved maximum levels; false and misleading safety and efficacy claims made through headquarter marketing plans, sales force promotion, advisory boards, consultant meetings, promotional samples, CME events and publications activities). Civil settlement resolves allegations that the federal FCA was violated by illegal off label promotion of Bextra, Geodon, Zyvox and Lyrica; making and disseminating unsubstantiated and false representations regarding the safety and efficacy of these four drugs; and paying kickbacks to HCPs to induce them to prescribe these four drugs. Also resolves FCA allegations relating to the payment of kickbacks to HCPs in connection with the marketing of Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec. Pfizer entered into a 5 year CIA with the OIG.

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Aventis	Total: $95.5 million $49 million to the U.S. government $40 million to participating state Medicaid programs $6 million to public health service programs	May 2009	Azmacort Nasacort Nasacort AQ	Aventis entered into a settlement agreement to resolve allegations that it violated the False Claims Act by misreporting drug prices in order to reduce its Medicaid Drug Rebate obligations. Aventis and its corporate predecessors were alleged to have "knowingly" misreported the lowest prices for its steroid-based anti-inflammatory nasal sprays between 1995 and 2000. Aventis allegedly negotiated "private label" agreements with Kaiser Permanente in an attempt to avoid rebate payments obligations. According to the DOJ, the agreements allowed Aventis to repackage the same drug under a new label at a cheaper price for Kaiser without offering the government aid program the same rate. An addendum to the Sanofi-Aventis Corporate Integrity Agreement with the OIG was entered into.
Amgen Inc.	$2.4 million	March 2009	Various	Amgen Inc. entered into a settlement agreement to resolve allegations that it defrauded the Kentucky Medicaid Program by inflating the average wholesale prices for prescription drugs, knowing that state Medicaid officials use those prices to calculate pharmacy reimbursement rates. The inflated prices allegedly bore no relationship to prices Amgen actually charged its customers. Similar settlements have been reached with Immuex Corp. for $145,000 and Bristol-Myers Squibb Co. for $3 million.

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Sandoz Pharmaceuticals (owned by Novartis Inc.)	$78.4 million $29 million compensatory damages $50 million punitive damages	February 2009	Various	An Alabama circuit court ordered Sandoz to pay the state $78.4 million in compensatory and punitive damages for falsely reporting wholesale drug prices and "marketing the spread."
Eli Lilly and Company	$1.415 billion $515 million criminal fine $100 million criminal forfeiture $438 million Federal civil settlement $362 million state civil settlement	January 2009	Zyprexa	Eli Lilly agreed to pay civil and criminal fines totaling $1.415 billion to settle allegations that it marketed Zyprexa for off-label uses, including the treatment of elderly patients for sleep disorders, Alzheimer's and dementia. Eli Lilly pled guilty to a misdemeanor charge of introducing misbranded drugs into interstate commerce between September 1999 and November 2003, and paid a $515 million criminal fine and $100 million in forfeiture. As part of its civil settlement agreement, Eli Lilly paid fines of approximately $438 million to settle allegations that it caused invalid claims for payment to be submitted to various government programs including Medicaid. Eli Lilly also agreed to pay various state Medicaid programs approximately $362 million to settle similar claims. The civil settlement settles four whistleblower suits filed by former sales representatives. Eli Lilly entered into a 5 year CIA with the OIG.

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Dey LP and its subsidiary Mylan Inc.	$5 million	January 2009	Various	Dey LP entered into a settlement agreement with the Mississippi Attorney General to resolve allegations that it manipulated average wholesale prices and used covert discounts, kickbacks and rebates to increase market share.
Teva Pharmaceuticals USA Inc. and its subsidiary Ivax Corp.	$7 million	January 2009	Acetaminophen with Codeine, Amiodarone, Carbamazepine, Cephalexin, Clonazepam, Naproxen, Sulfamethoxazole/ Trimethoprim, Albuterol, Baclofen, Clozapine	Teva and its subsidiary Ivax agreed to pay $7 million to the Massachusetts Medicaid program to settle allegations that it falsely inflated prices that were reported to national pharmaceutical price reporting services between 1997 and 2003.
Amgen Inc. and Immunex	$1.7 million	December 2008	Various	Amgen and its subsidiary Immunex agreed to pay $1.7 million to settle charges that they defrauded Wisconsin's Medicaid program by publishing false average wholesale prices for their products.

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Bristol-Myers Squibb Co., KV Pharmaceuticals, Amgen Inc., Roxane Laboratories, Bayer Pharmaceuticals	$28 million (breakdowns by company not available)	December 2008	Various	Several drug manufacturers settled allegations that they fraudulently used a wholesale pricing scheme and caused the Alabama Medicaid Agency to overpay pharmacists and physicians for Medicaid Drugs.
Bayer HealthCare LLC	$97.5 million plus interest	November 2008	Diabetic supplies	Bayer agreed to pay $97.5 million plus interest to settle allegations that it paid kickbacks to a number of diabetic suppliers and caused those suppliers to submit false claims to Medicare. Specifically, the government alleged that Bayer engaged in a cash-for-patient scheme through which the company paid 11 diabetic suppliers to convert their patients to Bayer's products from supplies manufactured by its competitors between 1998 and 2007.
Warrick Pharmaceuticals, division of Schering-Plough	$31 million	October 2008	Various	Settles a lawsuit filed initially in 2005 that alleges that Warrick Pharmaceuticals, a division of Schering-Plough, did not accurately report prices of drugs sold to pharmacies participating in the Missouri Medicaid program. The lawsuit also alleges that Warrick hid the actual costs of products by providing free samples, rebates and other inducements.

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Pfizer Inc.	$60 million	October 2008	Celebrex and Bextra	The Company agreed in principle to settle allegations that Pfizer promoted these painkillers for off-label uses and misrepresented the safety of the products. Thirty-three states and the District of Columbia took part in the settlement. This settlement is part of a larger $894 million deal to settle related personal injury and consumer fraud suits for these products.
Eli Lilly and Company	$62 million	October 2008	Zyprexa	The Company agreed to settle allegations that it engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses and failed to adequately disclose potential side effect to healthcare providers. Thirty-three states joined in the settlement. The settlement requires Eli Lilly to, among other things, disclose information about grants on its website, provide each participating Attorney General a list of promotional speakers and consultants who were paid more than $100, and register and submit results for certain clinical trials.

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Cephalon Inc.	$425 million	September 2008 Agreement in Principle announced in November 2007	Gabitril, Provigil, Actiq	Cephalon has agreed to a settlement with the Philadelphia U.S. Attorney's Office and the U.S. Department of Justice after being investigated for off-label sales and marketing practices of Gabitril (epilepsy drug), Provigil (narcolepsy drug) and Actiq (cancer pain reliever). Under the agreement, Cephalon paid $425 million as part of a comprehensive settlement of all Federal and related state Medicaid claims. Cephalon also agreed to a single misdemeanor violation of the Federal Food, Drug, and Cosmetic Act and entered into a corporate integrity agreement with the OIG. The settlement involved four *qui tam* actions, three of which were filed by former Cephalon sales representatives.
Boehringer Ingelheim Roxane, Inc.	$1.8 million	September 2008	Various products reimbursed by the Medicaid program	The Company agreed to pay the Commonwealth of Massachusetts to settle False Claims Act allegations that charged that falsely inflated the average wholesale prices of its drugs resulting in the Medicaid program overpaying for products.
Abbott Laboratories	$28 million	September 2008	Various products reimbursed by the Medicaid program	The Company agreed to pay to settle Medicaid-fraud allegations filed by a whistleblower in the State of Texas alleging that it misreported prices for Medicaid products causing the State to overpay for products. The Company also agreed to make quarterly report of the average manufacturer's price to the Texas Vendor Drug Program for each Company product on the Texas Drug Code Index for a period of 10 years.

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Walgreen Co.	$35 million	June 2008	Ranitidine (Zantac), Fluoxetine (Prozac), Eldepryl or Selegiline (Eldepryl)	Walgreen Co. agreed to pay a total of $35 million to the federal government, 42 states and Puerto Rico to settle Medicaid prescription drug fraud claims initiated by a whistleblower. For each of three drugs (Ranitidine, Fluoxetine and Eldepryl), Walgreens allegedly switched Medicaid patients from a cheaper version of the drug to a more expensive version solely to increase the reimbursement rate. As part of the settlement, Walgreens also agreed to enter into a five-year CIA with HHS OIG to prevent the company from engaging in this type of drug switching activity in the future.
Express Scripts Inc.	$9.5 million	May 2008	statins	Pharmacy benefits manager, Express Scripts Inc., agreed to pay $9.5 million to settle states' claims that it improperly encouraged physicians to switch patients to different brand-name prescription drugs. Express Scripts denied any wrongdoing, but agreed to pay 28 states and the District of Columbia $9.3 million for alleged violations of consumer protection laws. The company also agreed to pay patients $200,000 for costs related to switches between statins. The states alleged that Express Scripts encouraged physicians to switch patients to different brand-name prescription drugs without adequately disclosing information about potential consumer costs or rebates that the company earned from manufacturers.

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Medtronic Spine, LLC, formerly known as Kyphon, Inc.	$75 million	May 2008	Kyphoplasty procedure	Medtronic Spine entered into an agreement with the DOJ and OIG in May 2008 to settle allegations that it "engaged in a seven-year marketing scheme that resulted in certain hospitals billing Medicare for certain kyphoplasties performed on an inpatient basis rather than less costly and clinically appropriate outpatient kyphoplasty treatment," in violation of the Federal False Claims Act. Medtronic also entered into a Corporate Integrity Agreement (CIA).
Otsuka Pharmaceutical Co. Ltd.	$4 million	March 2008	Abilify	The U.S. subsidiary of the Japanese drug firm Otsuka Pharmaceutical Co. Ltd. agreed to pay $4 million to settle allegations that it violated the False Claims Act by marketing the antipsychotic drug Abilify off-label for pediatric and geriatric dementia-related psychosis. The drug received FDA approval only for the treatment of bipolar disorder and schizophrenia in adults. The case was handled by the U.S. Attorney's office in Boston and DOJ's civil division. The settlement involved the last of the allegations in a qui tam action that also included charges against Bristol-Myers Squibb Co., a co-promote partner with Otsuka, for its involvement in the off-label marketing of Abilify. In September 2007, Bristol-Myers entered into a $515 million settlement agreement to resolve the Abilify-related charges and unrelated drug pricing-related allegations. Of the $4 million settlement, $2.3 million will go to the federal government, and the remaining $1.7 million will go to state Medicaid programs. As part of the settlement, Otsuka also entered into a CIA with HHS OIG.

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CVS Caremark Corp.	$36.7 million	March 2008	Ranitidine	CVS Caremark Corp. agreed to pay $36.7 million to resolve claims that, between 2000 and 2006, it improperly switched patients from a tablet version of the generic drug Ranitidine to a more expensive capsule version to increase Medicaid reimbursement while providing no additional medical benefit to beneficiaries. In 2003, a qui tam action was filed under the False Claims Act in the U.S. District Court for the District of Illinois. The U.S. Attorney's Office in Chicago supervised the joint federal and state health care fraud investigation with assistance from DOJ's Civil Division; the National Association of Medicaid Fraud Control Units; HHS OIG; the Federal Bureau of Investigation; and the U.S. Food and Drug Administration. The federal government will receive approximately $21.1 million of the settlement, and 23 states and the District of Columbia will share $15.6 million under separate settlement agreements. The whistleblower, a licensed pharmacist, will receive more than $4.3 million as his share of the federal and state agreements. CVS Caremark also agreed to enter into a five-year CIA with HHS OIG.

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Caremark	$41 million	February 2008	Drug interchange program involving cholesterol medications	Caremark agreed to pay $41 million to 28 states and the District of Columbia to settle claims of deceptive business practices. The states alleged that Caremark encouraged doctors to switch patients to different brand name prescriptions, while falsely claiming that switching medications would save the consumers money and concealing the fact that rebates acquired through the switching process would not be passed along to health plans and patients. The states also claimed that Caremark restocked and reshipped prescriptions that had been returned to the company's mail order pharmacies. Caremark will pay $2.5 million in direct reimbursements to consumers, while $22 million of the settlement will be used by the states to support programs for low-income, disabled or elderly consumers, and $16.5 million of the settlement will pay for the states' investigation costs. The settlement agreement further requires Caremark to update its business practices, including its procedures for soliciting and carrying out patient prescription switches.

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Merck & Co.	Total: $650 million $360 million to the federal government $290 million to 49 states (not Arizona) & Washington, DC[1]	February 2008	Mevacor Vioxx Zocor Pepcid	Merck & Co. entered into a settlement agreement to resolve allegations that Merck paid kickbacks to doctors to induce them to prescribe certain drugs. The settlement also resolves False Claims Act suits that accused the company of overcharging Medicare. [2] Merck argued that it did not have to report any discounted prices that are "nominal" in amount. However, the DOJ claimed that the prices Merck offered hospitals were improperly termed as "nominal" and, therefore, the exception to the Medicaid Rebate Statute did not apply. Merck also agreed to enter into a five year Corporate Integrity Agreement with the OIG.

[1] The three False Claims Act suits were filed by two individuals, Dean Steinke and William St. John LaCorte. Steinke commenced suit in both Pennsylvania and Nevada, whereas LaCorte commenced suit in Louisiana. Therefore, there is a certain degree of confusion in reports as to whether the settlement resolves two or three qui tam actions.

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Merck & Company	$650 million	February 2008	Zocor Vioxx	Merck agreed to pay $650 million to the federal government and states to resolve allegations in two separate lawsuits that it failed to pay proper rebates to Medicaid and other government health care programs. The settlement agreements also resolve allegations that Merck paid illegal remuneration to health care providers to induce them to prescribe the company's products. The two whistleblower lawsuits were filed under the False Claims Act in the U.S. District Court for the Eastern District of Pennsylvania and in the U.S. District Court for the Eastern District of Louisiana. Under the combined settlement agreements, Merck will pay the federal government $355.5 million plus interest, and pay the states $293.5 million plus interest. Merck also agreed to enter into a five-year corporate integrity agreement with the OIG.
Glaxo Smith Kline	$1.4 million	November 2007	Kytril; Zofran; Amoxil	Glaxo Smith Kline ("GSK") agreed to a settlement with the Texas Attorney General to pay $1.4 million for reporting false, inflated prices to the state Medicaid program for three prescription drugs between 1994 and 2002. The products included the anti-emetic drugs Kytril and Zofran, as well as the antibiotic Amoxil. Federal and state damages for the three drugs totaled nearly $2.8 million, of which 60% was remitted to the federal government. Texas will receive approximately $1.4 million, including attorneys' fees.

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Stryker Orthopedics	N/A	September 2007	Hip and knee surgical implants	Stryker entered into a 18 month non-prosecution agreement (NPA) in September 2007 with the United States Attorney's Office for the District of New Jersey to settle an investigation related to violations of the Federal Anti-Kickback Statute between 2002 and 2006. The company agrees to prominently post the DPA on its website for the term of the DPA; comply with certain legal and compliance measures outlined in the DPA; and engage a Monitor.
Biomet, Inc. DePuy Orthopedics, Inc. Smith & Nephew, Inc. Zimmer, Inc.	$26.9 million $84.7 million $28.9 million $169.5 million	September 2007	Hip and knee surgical implants	Entered into an 18 month Deferred Prosecution Agreement ("DPA") in September 2007 with the United States Attorney's Office for the District of New Jersey. Simultaneously, a criminal complaint was filed in the United States District Court for the District of New Jersey, charging the Company with conspiracy to commit violations of the Federal Anti-Kickback Statute between 2002 and 2006. Each company agrees to prominently post the DPA on its website for the term of the DPA; comply with certain legal and compliance measures outlined in the DPA; and engage a Monitor. Each company also entered into a civil settlement with the DOJ and OIG for allegations related to the Federal Anti-Kickback Statute and False Claims Act. Each company agreed to a 5 year CIA.

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Bristol-Myers Squibb Company	$515 million	September 2007	Abilify, Serzone, Plavix, Pravachol Taxol	Bristol-Myers Squibb Company (BMS) and its wholly owned subsidiary, Apothecon, Inc., agreed to pay over $515 million to resolve a series of civil allegations related to drug marketing and pricing for drugs that included Abilify, Serzone, Plavix, Pravachol, and Taxol. The government alleged that from approximately 2000 through mid-2003, BMS knowingly and willfully paid illegal remuneration to health care providers to induce them to purchase BMS drugs. The government also alleged that from 1994 through 2001, Apothecon paid illegal remuneration such as stocking allowances, price protection payments, market share payments, and free goods in order to induce retail pharmacies and wholesalers to buy its products, thus causing the submission of false and fraudulent claims to the federal health care programs. The government further alleged that from 2002 through 2005, BMS knowingly promoted Abilify, an antipsychotic drug, for "off-label" uses that included pediatric use and treatment for dementia-related psychosis. The government also charged both BMS and Apothecon with using fraudulent and inflated prices for various oncology and generic drug products. Finally, the government alleged that BMS knowingly misreported its best price for Serzone, an anti-depression drug.

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				Out of the settlement amount, the federal recovery is over $328 million, of which over $25 million constitutes disgorgement of profits under the FDCA resulting from BMS's illegal promotion of Abilify. BMS also will pay over $187 million to the Medicaid participating states, and $124,000 to certain Public Health Service entities. The settlement resolves in whole or in part allegations made in seven qui tam actions brought under the False Claims Act. As part of the settlement, BMS entered into a CIA with OIG that will require the company to maintain a compliance program and provide accurate reports of average sales prices and average manufacturer prices for drugs covered by Medicare and other federal health care programs.

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Aventis Pharmaceuticals Inc.	$190 million	September 2007	Anzemet	Aventis agreed to pay over $190 million to settle False Claims Act allegations concerning its pricing and marketing of Anzemet, an anti-emetic drug used in conjunction with oncology and radiation treatment. The United States alleged that Aventis marketed the drug by promoting the "spread" between the inflated prices reported to the government for reimbursement purposes and the actual prices charged to the company's customers. The United States alleges that reimbursement from federal programs was based on the fraudulent, inflated prices and, therefore, that Aventis caused false and fraudulent claims to be submitted to federal health care programs. An investigation began after a qui tam False Claims Act suit was filed by Ven-A-Care of the Florida Keys Inc., a home-infusion company. As part of the settlement, the Ven-A-Care whistleblowers will receive approximately $32 million as their share of the settlement. Aventis agreed to pay $179,787,726 in federal recovery, as well as $10,645,600 to various states and the District of Columbia. In addition, as part of the settlement, Aventis agreed to enter into a Corporate Integrity Agreement with the OIG. This Corporate Integrity Agreement will govern, among other issues, the company's procedures for accurate price reporting.

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Guidant Corporation	$16.75 million	August 2007	Implantable Cardioverter Defibrillators (ICD)	In August 2007, Guidant entered into a multistate settlement with 36 state attorneys general offices and agreed to pay a fine of $16.75 million. The AGs offices alleged that Guidant continued to sell until May 2005 unmodified versions of an ICD that it knew to contain faulty wiring. As part of the settlement, Guidant agreed to, among other things, establish a Patient Safety Advisory Board of independent experts to evaluate ICD performance and risk assessment data; establish a Patient Safety Officer position; disclose and disseminate to the public on a quarterly basis specific information about its ICD products; post a notice on its website within 30 days of any modification to any of its ICDs to correct a failure pattern; solicit the return of out-of-service ICDs; and, maintain a data system to track the serial numbers, implant dates, and explant dates of all ICDs Guidant distributes in the United States.

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Jazz Pharmaceuticals/ Orphan Medical	$20 million	July 2007	Xyrem	Jazz Pharmaceuticals agreed to pay $20 million in penalties and victim compensation to resolve parallel criminal and civil investigations conducted by the United States Attorney's Office for the Eastern District of NY into the illegal marketing of Xyrem, a narcolepsy treatment, by Orphan Medical, a wholly-owned subsidiary of Jazz. In pleading guilty, Orphan admitted to off-label promotion of Xyren for uses that included fatigue, insomnia, chronic pain, weight loss, depression, bipolar disorder, and Parkinson's Disease. Orphan pled guilty to felony misbranding of a pharmaceutical product in violation of the Federal Food, Drug and Cosmetic Act. Pursuant to a non-prosecution agreement with the United States, Jazz agreed to guarantee Orphan's obligation to pay criminal restitution to public and private insurers of approximately $12.2 million and a criminal fine of $5 million. Pursuant to the civil settlement agreement, Jazz and Orphan agreed to pay $3.75 million, plus interest, to resolve the government's civil False Claims Act claims. A portion of the restitution ordered in the criminal case is also accounted for as a part of the civil settlement, resulting in a total payment by Jazz and Orphan of $20 million. Under the terms of the settlement, Jazz also has agreed to enter into a five-year corporate integrity agreement with the OIG.

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Medicis Pharmaceutical Corp.	$9.8 million	May 2007	Loprox	The company agreed to settle charges that it illegally marketed the topical skin preparation Loprox. The case began in 2004 when four former company employees filed a whistleblower suit against the company. In the settlement agreement, the Department of Justice alleged that the company violated the Food, Drug and Cosmetic Act by promoting Loprox for diaper dermatitis and other skin disorders in children under the age of 10, despite the product only being approved as a fungicide for patients over the age of 10. The Department of Justice also alleged that the company violated the False Claims Act by causing claims for such off-label Loprox uses to be submitted to the Medicaid and TRICARE programs. The company agreed to enter into a five-year corporate integrity agreement, and to pay $9.8 million to settle the charges. Of this settlement, approximately $4.4 million will go to state Medicaid programs, $4.4 million will go to the federal government, and $1 million will go to the whistleblowers.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Purdue Pharma L.P.	$440 million – criminal fines, forfeiture, Virginia Prescription Monitoring Program payment, a set-aside for private civil liabilities and other ancillary payments made by Purdue Pharma L.P. $34.5 million – criminal fines paid by two current and one former executive of Purdue Pharma L.P. $160 million – civil penalty paid to the United States and the States. $19.5 million – state Consumer Protection settlement with 26 states and the District of Columbia. Total = $654 million	May 2007	OxyContin	The criminal and civil penalties relate to the single felony guilty plea entered by Purdue Frederick, a holding company for Purdue Pharma L.P. to resolve allegations of misbranding related to the marketing of OxyContin prior to July 2001. The government alleged, among other things, that the company improperly promoted the drug as having less potential for addiction and abuse than other pain medication in the same therapeutic class. Under the plea, misbranding refers to statements some employees made, or told other employees to make, that went beyond the FDA-approved prescribing information for the product in promoting OxyContin to some health care professionals. In addition to the settlement amounts, Purdue Pharma L.P. will enter into a five year CIA with the HHS OIG. The $34.5 million criminal fines were paid by the company's former Chief Scientific Officer and current General Counsel and CEO in conjunction with single-count criminal strict liability misdemeanor pleas for misbranding.

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Pharmacia & Upjohn Company, Inc. (subsidiary of Pfizer Inc.)	$19.68 million – criminal fine paid by Pharmacia & Upjohn Company, Inc. $15 million – civil penalty paid by Pharmacia & Upjohn, LLC Total = $34.7 million	April 2007	Genotropin	The criminal penalty relates to the guilty plea submitted in response to the charge that the company offered a kickback in connection with an outsourcing contract for the administration and distribution of the product. The $12.3 million kickback was offered to a subsidiary of a pharmacy benefits manager based on the expectation of obtaining improved formulary positioning and additional benefits. The civil settlement, including a 36 month deferred prosecution agreement, settles the claims that the company engaged in illegal, off-label promotion of the product for anti-aging, cosmetic and athletic performance enhancing purposes.
Dey, Inc.	$670,000	April 2007	Various drugs (including respiratory medications) reimbursed by Nevada's Medicaid program	The company agreed to pay the state of Nevada under terms of a nationwide class-action settlement to resolve claims in consolidated Multidistrict Litigation pending in the U.S. District Court for the district of Massachusetts that charged that the company inflated the average wholesale prices of its drugs resulting in the Medicaid program overpaying for products.

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Cell Therapeutics Inc.	$10.5 million	April 2007	Trisenox	Cell Therapeutics announced that it reached an oral agreement with the U.S. Attorney's Office to settle a government investigation related to its promotion practices for Trisenox, an injectable leukemia drug which it sold to Cephalon Inc. in July 2005. The investigation also involved the company's reporting of revenue related to the drug and representations regarding the drug's eligibility for Medicare reimbursement when used for off-label purposes. The settlement is pending final agreement and remains subject to change. As a result of a private party qui tam action relating to employment and attorney fee issues that is apparently related to the subject of the settlement., the documents relating to the settlement remain under seal.
Eli Lilly	$500 million	January 2007	Zyprexa	The company settled 18,000 suits by individuals (representing cases filed in state and federal courts by 14 plaintiffs' law firms or groups of firms) who claimed they had developed diabetes or other diseases after taking Zyprexa, Lilly's drug for schizophrenia and bipolar disorder. The suits claimed that Lilly knew of the increased risk of diabetes and other diseases and failed to disclose such risks. The settlement will not affect continuing civil or criminal investigations of Zyprexa by state attorneys general and federal prosecutors.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Bristol-Myers Squibb Co.	$499 million	December 2006	Drugs reimbursed by Medicare and Medicaid	The company settled investigation with the Department of Justice and the U.S. attorney in Massachusetts that charged that the company inflated the average wholesale prices of its drugs. This settlement concludes suits filed by several states and several counties in New York. The company also entered into a corporate integrity agreement with the HHS OIG.
Intermune	~ $36.9 million ($30.2 million will reimburse the federal Medicaid program, Medicare, the Veteran's Administration, the Department of Defense and the Federal Employees Health benefits Program. $6.7 million will reimburse the state Medicaid programs.)	October 2006	Actimmune	The Department of Justice, in conjunction with numerous other federal government agencies, alleged that Intermune knowingly caused the submission of false and fraudulent claims for Actimmune to government healthcare programs that were not eligible for reimbursement because they were for unnecessary and/or off label uses. Intermune was charged with one criminal count of violating the FDCA by promoting, with intent to defraud or mislead, its drug for off label uses. In addition to the settlement amounts, Intermune will enter into a Deferred Prosecution Agreement with the United States and a five year CIA with the HHS OIG.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Schering-Plough	Schering Sales Corp.: $180 million fine and guilty plea to one count of conspiracy to make false statement to the government. Schering Sales Corp. is excluded permanently from participation in federal health care programs. Schering-Plough: $255 civil damages Total: $435 million	August 2006	Temodar, Intron, Claritin RediTabs, K-Dur	The Department of Justice alleged that Schering sales representatives marketed cancer treatments for off-label uses and that Schering paid illegal remuneration to doctors to induce the utilization of Temodar. The alleged illegal remuneration was provided through advisory boards that existed to give stipends and entertainment to doctors. The DOJ further alleged that prestigious and profitable clinical studies were awarded to doctors based on their volume of Temodar prescribing. With respect to the Claritin RediTabs, the government alleged that Schering defrauded Medicaid of $4.3 million by failing to give the government its best price after the company did not incorporate into its best price calculations free product provided to an HMO. In addition, Schering allegedly underpaid rebates due the government on K-Dur. In addition to the permanent exclusion of Schering Sales Corp. from participation in federal health care programs, Schering-Plough entered into a five year addendum to its existing CIA.
GlaxoSmithKline	~ $41 million	August 2006	Unnamed anti-emetics and an antibiotic	The settlement with the U.S. Justice Department, the National Association of Medicaid Fraud Control Units and New York Attorney General settles allegations that GSK fraudulently inflated the AWP of these products, resulting in increased prices to state Medicaid programs. In addition, the government also alleged that GSK marketed the spread to physicians in order to induce physicians to prescribe the GSK products.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Medtronic Inc., Medtronic Sofarnor Danek diviston	$40 million	July 2006	Spinal products	Medtronic entered into a civil settlement with the DOJ and OIG in July 2006. The government alleged that, between 1998 and 2003, Medtronic paid kickbacks to HCPs, in violation of the Federal Anti-Kickback Statute and the False Claims Act. In addition to a fine of $40 million, Medtronic agreed to a 5 year CIA. Under the CIA, Medtronic must, among other things, establish an electronic database to track transactions with its customers unrelated to device sales
Baxter International Inc.	$8.5 million	June 2006	AWP reporting for intravenous fluids and other products	The State alleged that Baxter "misreported" drug prices to the State's Medicaid program, resulting in the program reimbursing pharmacies at above-market rates.
Astra USA Inc., Bristol-Myers Squibb and other manufacturers	Class action claims dismissed	May 2006	Drugs reimbursed by Medicaid	The class action suit, brought in August 2005, alleged the manufacturers overcharged county health care providers participating in the 340B program. The county alleged violations of the state Unfair Competition Law and False Claims Act, breach of contract, breach of covenant of good faith and negligence. The county intends to rewrite the claim to conform to the judge's ruling.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
TAP Pharmaceutical Products, Inc.	$798,000	May 2006	Lupron	This settlement arises from a nationwide class action filed in federal court in Massachusetts. The suit alleged that TAP illegally influenced doctors to prescribe Lupron by providing doctors with free samples, rebates, bribes, lavish trips and other inducements. As a result of such illegal activities, the suit claims that the company defrauded Medicare by artificially increasing the price for Lupron.
Lincare Holdings, Inc. and Lincare, Inc.	$10 million	May 2006	Unclear	The OIG and U.S. DOJ settled a series of cases, including one initiated in Florida in 2000, one in Massachusetts, one in Tennessee and one in Idaho. Among the allegations made by the government were that the company paid physicians kickbacks, such as sporting and entertainment tickets, rounds of golf, golf equipment, fishing trips, meals, offices expenses and medical equipment to induce the physicians to refer patients to the company. The government also alleged that Lincare provided kickbacks in the form of purported consulting agreements. In addition, the government alleged that Lincare violated the Stark Law by accepting referrals from parties to the consulting agreements. The settlement involves the company entering into a 5 year CIA.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Medco Health Solutions	$163 million	May 2006	Various products and programs	This is an agreement in principle with the U.S. Attorney for the Eastern District of PA. on the financial terms of the settlement. The other terms of the settlement, including the CIA, have not yet been finalized. The settlement applies to three matters: 1) the government complaint filed in conjunction with two qui tam actions arising from an industry-wide investigation initiated in 1999; 2)a separate lawsuit that remains under seal; and 3) an issue disclosed in March 2005 involving a federal recovery program where Medco detected issues and self-reported to an oversight agency. The qui tam actions related to alleged violations of the Federal False Claims Act in which the complaint alleges that Medco defrauded Medicare and Medicaid by falsely reclassifying rebates and discounts as "data" or "service" fees and defrauded the states under the Medicaid rebate program by inflating the "best price" of drugs by not including the value of various discounts and goods given to providers. The complaint further alleged that Medco offered and paid kickbacks to induce placement of its products on formularies and for the promotion of its products.
GlaxoSmithKline PLC	$14 million	March 2006	Paxil	GlaxoSmithKline reached a settlement with California, 46 other states, Puerto Rico, Washington D.C. and the Virgin Islands regarding claims that the company violated state and federal antitrust laws and state laws prohibiting unfair business practices by engaging in "sham" litigation to prevent competing drugs from entering the market. The suit had been filed in the Easter District of Pennsylvania.

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Eli Lilly	$36 million	December 2005	Evista	The company agreed to plead guilty to a criminal count of violating the Food, Drug and Cosmetic Act in its off-label promotion of Evista. The company agreed to pay a $6 million criminal fine and to forfeit to the United States an additional sum of $6 million. In addition, the company agreed to settle civil Food, Drug and Cosmetic Act liabilities by entering into a consent decree of permanent injunction and paying the United States $24 million in equitable disgorgement.
Boehringer Ingelheim Corp. and subsidiaries, Roxane Laboratories Inc. and Ben Venue Laboratories Inc.	$10 million damages	November 2005	AWP price of drugs reimbursed by Texas Medicaid	Boehringer settled the whistleblower suit originally initiated by Ven-a-Care in 2000. The suit alleged that the company falsified the AWP of several prescription drugs causing the Medicaid program to overpay for the medications. Dey Inc. and Schering-Plough were also named in the suit. Dey settled in 2003 for $18.5 million and Schering-Plough settled in 2004 for $27 million.
King Pharmaceuticals	$124 million - $62 million for underpayments - $62 million for interest, costs and penalties	November 2005	AWP for Medicaid reimbursed drugs	The suit, filed in the US District Court for the Eastern District of Pennsylvania alleged that King failed to accurately report AWP and best price for Medicaid-reimbursed drugs from 1994 – 2002. Simultaneous settlements were reached with the US Attorney for the Eastern District of Pennsylvania, the Department of Justice and the Department of Veterans Affairs.

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Serono	$704 million - $136,935,000 criminal fine - $$567,065,000 civil liabilities Serono Laboratories, Inc. is excluded from federal health care programs for five years	October 2005	Serostim	Serono pled guilty to conspiring with device manufacturer to introduce device and software to diagnose AIDS wasting without approval from FDA in order to increase demand for Serostim. Serono employees directly administered tests using software to patients to induce doctors to prescribe the drug, which was reimbursed by Medicaid and other payors. The company also pled guilty to conspiracy for offering physicians all-expense trip to Cannes for writing new prescriptions for Serostim. The civil settlement addresses allegations that the company caused the submission of false/fraudulent claims based on use of unapproved diagnostic device and treating separate conditions for which the drug was not reimbursable. The allegation that that the company caused the submission of false/fraudulent claims by inducing pharmacies to sell Serostim by paying rebates and discounts and by inducing physicians to prescribe the drug by giving them free devices and software, free trips and other kickbacks was also settled.
GlaxoSmithKline	~ $150 million	September 2005	Zofran, Kytril	The company fraudulently reported inflated wholesale prices for the drugs that were higher than what the majority of customers actually paid. The Company marketed the spread between the reported price and the price the drugs were actually sold at to health care providers. The company also allegedly encouraged providers to use leftover amounts of Kytril from several vials, combine the leftovers , administer the drug and charge for another injection.

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Caremark	$137 million	September 2005	Drug interchange and rebate programs	Caremark caused false claims to be submitted to Medicare and other federal health care programs by skewing best price information reported. The company allegedly paid kickbacks to managed care plans and receiving rebates from manufacturers that were not appropriately disclosed to payors. Rebates were provided to health plans as rewards for favorable formulary treatment. In addition, the company allegedly profited from drug interchange programs that were not properly disclosed, created additional cost and were without clinical benefit for patients.
Mylan Laboratories	$12 million (potential award could be tripled based on anti-trust implications)	June 2005	Key ingredient for clorazepate and lorazepam	Jury verdict for four insurers, including Blue Cross and Blue Shield of Minnesota, against the company for obtaining exclusive agreements for the key ingredients for the drugs and then raising prices for the generic anti-anxiety drugs.
Kaiser Permanente (HMO)	Suit dismissed	December 2004	Pill-splitting	The company was sued in 2000 by the Trial Lawyers for Public Justice, alleging that the company's policies requiring patients to split pills violated California's unfair competition law. Plaintiffs alleged that increasing the company's revenue did not justify the risks involved in pill-splitting. The dismissal was upheld by the California Court of Appeals.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Forest Laboratories	Forest will disclose information regarding clinical studies on its drugs via a new online clinical trials register.	September 2004	Probably focused on antidepressants Celexa and Lexapro	Attorney General Eliot Spitzer had initiated an investigation in to Forest's clinical studies disclosure practices in June, 2004, due to a concern that Forest may have been promoting its products for off-label uses. No subpoena was issued.
GlaxoSmithKline	$2.5 million GlaxoSmithKline will disclose information regarding clinical studies on all of its drugs via a new online "Clinical Trials Register"	August 2004	Paxil	State Attorney General Eliot Spitzer alleged in a lawsuit that GlaxoSmithKline (GSK) engaged in persistent fraud by concealing and failing to disclose negative information about Paxil. Specifically, the complaint alleged that GSK conducted studies that failed to demonstrate the efficacy of Paxil in children and raised questions about its safety, but only released one study showing mixed results, GSK represented to its sales force that Paxil was effective for adolescents, and misrepresented the results of the studies in letters to physicians. The suit seeks disgorgement of profits.
Bristol-Myers Squibb	$75 million	August 2004	Inflated sales figures	Bristol-Myers Squibb paid $75 million to settles charges by the SEC that it inflated its sales figures. The company allegedly provided wholesalers discounts to buy more drug than the wholesalers could sell in order to inflate sales numbers.

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Schering-Plough	Schering Sales Corp.: $52.5 million fine and guilty plea one criminal charge that it had violated the anti-kickback statute. This plea resulted in mandatory exclusion for this entity from participation in federal health care programs for five years. Schering-Plough: $293 civil damages Total: $345.5 million	August 2004	Claritin, failure to provide lowest prices to Medicaid	Schering-Plough settled the qui tam case, originally brought in 1999, in which the government had intervened. The company allegedly provided data fees to private providers, inducing them to buy products at high prices, and then charged Medicaid those higher prices without the fees being reported or calculated into the price. As a result, the private providers received a better price for drugs than the Medicaid program.
Schering-Plough	$500,000	June 2004	Unavailable	Securities and Exchange Commission settled complaint that alleged the company's Polish subsidiary made improper donations of $76,000 between February 1999 and March 2002 to a charitable organization whose director was also the director of a government health fund that provided money for the purchasing of pharmaceuticals. The donations, which were not properly reflected in the company's books were made in order to influence the government fund to purchase Schering-Plough pharmaceuticals.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Merck KGaA	$850,000	May 2004	Abuterol sulfate and other drugs	Subsidiary Dey, Inc. inflated the average wholesale price (AWP) of abuterol sulfate and other drugs in reports to the state to increase providers' Medicaid reimbursement rates and thus giving them an incentive to prescribe those drugs. The settlement covers drugs purchases by the West Virginia Public Employees Insurance Agency and the Worker's Compensation program as well as the Medicaid payments.
Pfizer (Warner-Lambert)	Total $430+ million $240 criminal fine $152 million civil fines to be divided among state and federal Medicaid agencies and the whistleblower $38 million to state consumer protection divisions	May 2004	Neurontin	Warner-Lambert unit of Pfizer pled guilty to criminal wrongdoing for kickbacks given to physicians in connection with promoting the drug for off-label uses.
Schering-Plough Corp.	Total: $27 million	May 2004	Albuterol sulfate solution and inhaler products	Subsidiary Warrick Pharmaceuticals submitted false price information that led providers to submit inflated reimbursement claims for drugs to Texas Medicaid.

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
Medco Health Solutions (formerly known as Merck-Medco)	Total: $29.3 million for state claims	May 2004	Rebated/discounted products	Medco switched patients to drugs for which Medco received undisclosed rebates, did not pass savings on to consumers and represented that the switches saved the consumer money. Only the injunction against fraud count is addressed by settlement, which focuses on Medco's business practices and sets forth the requirements for drug interchange program at Medco. The motion to dismiss other five counts, (False Claims Act, unjust enrichment, active and constructive fraud, public contracts anti-kickback and payment under mistake of fact) was pending as of date of settlement. In September 2004, the active and constructive fraud count against Medco was dismissed by the federal court judge. The other four counts remain. An agreement has been reached with the Justice Department regarding certain counts relating to business practices, but not monetary damages. (See below)
GlaxoSmithKline, P.L.C.	Total: $87.6 million $49.6 million for federal claims $38 million for state claims	June 2003	Flonase Paxil	Violated Medicaid "best price" law in connection with improper reporting of best price for "repackaged" products to a single customer

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AstraZeneca LP	Total: $354.7 million $266 million for Medicare, TriCare, Department of Defense and Railroad Retirement Board claims $24.9 million for U.S. and State Medicaid claims $63.8 million for criminal penalties	June 2003 (Allegedly wrongful acts occurred in the mid-1990s)	Zoladex	Predecessor company improperly encouraged physicians to bill government programs for samples and employed other marketing activities involving samples and other arrangements to induce doctors to use its drug for prostate cancer.
Bayer Corp.	$242 million	April 2003	Cipro Adalat	Allegedly violated Medicaid "best price" law in connection with improper reporting of best price for repackaged products to commercial buyers; violated PDMA (Drug Listing Act). (criminal)
Pfizer Inc	Total: $49 Million $21 million for state claims $28 million for federal claims	October 2002	Lipitor	Alleged False Claims Act violations of Medicaid drug rebate law involving its Lipitor anti-cholesterol drug caused by improper grants to an MCO.

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Bayer Corp.	$14 million	August 2001	Includes hemophilic factor drugs	Exaggerated its reported drug prices to state and federal Medicaid programs, which use reported drug prices to determine Medicaid reimbursement for drugs, then sold the drugs to physicians at sharply reduced prices, enabling them to collect "excess reimbursement from private and government insurers" thereby "marketed the spread" and concealed "best price."

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Pharmaceutical or Medical Device Manufacturer	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
TAP Pharmaceutical Products (a joint venture between Abbott Labs and Takeda Chemical Industries, Ltd.)	$875 million	October 2001	Lupron	1) TAP sales reps provided free Lupron samples to HCPs, knowing and expecting that the HCPs would prescribe or administer the samples to patients and illegally bill for the free samples to various federal health care programs. 2) Reps. offered physicians a variety of incentives as a way to maintain Lupron's market share and encourage physicians to prescribe Lupron including: • Provided illegal payments to certain physicians, physicians' practices, HMOs and others in various forms including, grants, free Lupron, debt forgiveness, travel and entertainment, consulting and auditing services, administration fees, nominally priced drugs and VCRs and TVs to unlawfully obtain orders to purchase Lupron. • TAP's National Account Manager (NAM), illegally attempted to have an HMO switch its formulary from Zoladex (a less expensive competing drug) to Lupron by offering an unrestricted educational grant and deeper discounts on other products. Other similar grants were made to a urology practice and a New Haven, CT. hospital. 3) TAP offered/paid to physicians illegal inducements by marketing the "Return to Practice" program, that included: (i) artificially inflating the AWP; (ii) deeply discounting the price paid by physicians to TAP for the drug; and (iii) marketing the spread. 4) TAP knowingly misreported/underpaid its best price for Lupron.
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Genentech, Inc.	$50 million	September 1999	Human Growth Hormone	Illegally marketing human growth hormone between 1985 and 1994 for medical uses that had not been approved by the FDA as well as introducing misbranded drugs in interstate commerce.
Mallinckrodt Chemical, Inc.	$100,000	May 1998		Promoted drugs to major retail drug stores in violation of Massachusetts' anti-kickback statute.
Miles, Inc.	$605,000	June 1994	Adalat CC	Employed certain marketing and advertising practices to promote its prescription hypertensive drug in violation of state consumer protection laws. Pharmacists provided consumer information to Miles without the consumer's consent. Miles offered to pay pharmacists for "the cognitive and counseling services provided to new patients receiving an initial prescription of Adalat CC."

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PHARMACEUTICAL & MEDICAL DEVICE MANUFACTURERS: RECENT INVESTIGATIONS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES*

SELECT PUBLIC INVESTIGATIONS

* This chart summarizes publicly available information relating to select pharmaceutical and medical device manufacturer investigations and select PBM/HMO investigations/litigation related to pharmaceuticals and medical devices. It is based solely on secondary sources on file with author. For more information, please contact wgoldstein@ebglaw.com or sgiesting@ebglaw.com

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SELECT PUBLIC INVESTIGATIONS

Pharmaceutical / Medical Device Manufacturer[2]	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
Elan Corp.	SEC	September 2009	Tysabri bapineuzumab	SEC requested records and other information from Elan Corp. related to a potentially lethal brain disease linked to Tysabri. SEC also requested records and other information related to an announcement in July 2008 of data from a study for its experimental Alzheimer's drug, bapineuzumab.
Gilead Sciences Inc.	United States Department of Health and Human Services' Office of the Inspector General	August 2009	Ranexa	On August 14, 2009, the Office of the Inspector General of the U.S. Department of Health and Human Services subpoenaed information regarding the development, marketing and sales of Ranexa, a prescription medication used to treat adults with chronic angina.

[2] This chart includes a sampling of current, on-going investigations and is not intended to be an exhaustive list.

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(1) Boston Scientific Group (2) Guidant Corp. (3) Medtronic, Inc (4) St. Jude Medical Inc. (5) Atricure, Inc. (6) Endoscopic Technologies Inc.[3]	DOJ U.S. District Court for the Southern District of Texas Qui Tam Actions	July 2009	The device manufacturers' microwave ablation products	Whistleblower lawsuits alleged that a group of medical device manufacturers initiated a campaign that included the use of kickbacks and other improper payments[4] to convince doctors and hospitals to use their products for off-label use. The suit alleges that the manufacturers initiated the campaign because the only cost-effective use of their products is the off-label treatment of atrial fibrillation, a use that is not approved by the FDA. The complaint further alleges that the companies promoted their products by emphasizing the spread between Medicare reimbursement for procedures performed using their devices and the cost of those procedures, therefore, claiming that the campaign causes increased Medicare costs due to inappropriate inpatient surgical procedures.

[3] Endoscopic Technologies settled for $1.4 million prior to suit.
[4] It is alleged that the manufacturers also provided free equipment to hospitals and free advertising and referral services to cardiothoracic surgeons.

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Wyeth	DOJ U.S. Attorney's Office for the District of Massachusetts The Offices of Inspector General of the Department of Health and Human Services 15 Intervening States and the District of Columbia	May 2009	Protonix Oral Protonix IV	The U.S., 15 states (California, Delaware, Florida, Illinois, Indiana, Louisiana, Massachusetts, New York, Michigan, Nevada, New Hampshire, Tennessee, Texas, Virginia and Wisconsin) and the District of Columbia have joined in two whistleblower suits filed in the U.S. District Court for the District of Massachusetts against Wyeth. The suits allege that between 2000 and 2006, Wyeth knowingly failed to give the government the same discounts it provided to private purchasers of Protonix Oral and Protonix IV. Wyeth allegedly sold the drugs to hospitals at a deep discount in a bundled package called the Protonix Performance Agreement. The deal allegedly gave some hospitals as much as a 94% discount, a discount that was not extended to Medicaid programs. As a result of the pricing arrangement, it is alleged that Wyeth avoided paying hundreds of millions in rebates owed to Medicaid programs.

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Scios Inc. and its parent company, Johnson & Johnson	DOJ 2 qui tam actions	February 2009	Natrecor	The DOJ intervened in two qui tam suits against Scios and J&J in February 2009, alleging that the companies engaged in off-label marketing of cardiac drug Natrecor for outpatient infusions for less severe heart failure, a use that was not approved by the FDA. The two qui tam actions were brought by former Scios sales managers in 2005 in the U.S. District Court for the Northern District of California. Scios also received subpoenas related to off-label marketing practices for Natrecor in 2007 from the U.S. Attorney's office in San Francisco and in 2005 from the U.S. Attorney's office in Boston.
Forest Laboratories	U.S. Attorney's Office FBI OIG FDA VA OIG 11 states & D.C.	February 2009	Celexa Lexapro	In February 2009, a civil complaint was filed against Forest Laboratories, alleging that it illegally promoted its antidepressant drugs Celexa and Lexapro that caused false claims to be submitted to the federal health care programs. The complaint alleges that Forest actively promoted the drugs for pediatric uses although not approved by the FDA and trial results showing increased risk of suicide. Forest also induced physicians to prescribe the drugs by offering various forms of illegal remuneration in violation of the federal anti-kickback statute. The Government intervened in two qui tam suits brought against Forest. 11 States and the District of Columbia also joined the lawsuit.

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Blackstone Medical Inc., a subsidiary of Orthofix International N.V.	Whistleblower complaint, Office of the Inspector General	December 2008	Various	In December 2008, Orthofix International N.V. announced that a federal court in Boston unsealed a whistleblower complaint alleging that Blackstone Medical Inc. paid kickbacks to doctors to induce them to use its products. The complaint, filed by a former regional manager and a former independent distributor, alleges that kickbacks included sham consulting arrangements, research grants, entertainment, travel, payments in excess of fair market value, and "other illegal incentives." Orthofix announced that it also is under investigation by the OIG based on similar allegations.
Medtronic	U.S. DOJ	November 2008	Infuse Bone Graft product	In November 2008, Medtronic announced that it had received a subjpoena from the DOJ regarding off-label use of its Infuse Bone Granft Product. Specifically, the DOJ is investigating whether Medtronic marketed the product for purposes that have not been approved by the FDA.
Eli Lilly and Co.	United States Department of Health and Human Services' Office of the Inspector General U.S. Attorney for the Western District of New York	November 2008	Alimta	The U.S. Department of Health and Human Services' Office of the Inspector General issued a subpoena on Eli Lilly and Co. relating to government reimbursement for Alimta. No additional information on the specific conduct under investigation is available.

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Merck & Co and Schering-Plough Corp.	U.S. DOJ and 35 State AGs	November 2008	Vytorin	In November 2008, Merck announced that it and Schering-Plough each received subpoenas from attorneys general in New York and New Jersey and a letter from the attorney general in Connecticut seeking information related to two major clinical trials and marketing practices related to Vytorin. Merck also received a letter from the DOJ in September 2008 stating that the DOJ was conducting an investigation into whether the promotion of the drug by the two companies caused false claims to be submitted to the federal health care programs.
AtriCure	U.S. DOJ	October 2008	Devices used for surgical ablation	AtriCure announced that is received a letter on October 27, 2008 from the DOJ's Civil Division informing the company that it was conducting an investigation for potential False Claims Act and common law violations related to AtriCure's devices for surgical ablation. Specifically, the DOJ is investigating certain marketing practices related to the use of device to treat atrial fibrillation, a use not approved by the FDA, and whether AtriCure instructed hospitals to bill Medicare for surgical ablation using incorrect billing codes.
Spectranetrics Corp.	U.S. Immigration and Customs Enforcement and the Food and Drug Administration	September 2008	Ultraviolet laser used in cardiovascular procedures	Spectranetics reported that two locations were searched by the U.S. Immigrations and Customs Enforcement and the FDA. According to the company, the search warrants related to the "promotion, use, testing, marketing and sales of certain products including catheters made by third parties outside the U.S.; two post-market studies and payments to medical personnel in connection with the studies; and compensation packages for company personnel."

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Wyeth Laboratories	Massachusetts District Attorney's Office	August 2008	Protonix	Wyeth reported that it received subpoenas seeking information and grand jury testimony related to marketing practices for Protonix and pricing practices for the IV and tablet formulations of the drug.
Boston Scientific	State of New Hampshire, Office of the Attorney General	July 2008	Medical devices or equipment intended to be used in the administration of spinal cord stimulation trials	Company received a subpoena requesting information in connection with sales of medical devices or equipment intended to be used in the administration of spinal cord stimulation trials to practitioners other than practicing medical doctors.
Cordis, a subsidiary of Johnson & Johnson; Abbott Laboratories; Boston Scientific; Medtronic	United States Attorneys Office for the District of Massachusetts	June 2008	Bile duct stents	Each company announced that it received a subpoena relating to the marketing of bile duct stents to determine whether there were violations of the federal False Claims Act, Food and Drug Cosmetic Act and Anti-Kickback Statute in connection with Medicare and Medicaid Reimbursement.

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Organon Inc.	Private whistleblower complaint	April 2008	Raplon	A whistleblower complaint was filed in the District of New Jersey on April 14, 2008 by Jeffrey Feldstein, former associate director of medical services for antithrombotics of Organon Inc. (now part of Schering-Plough Inc.). The complaint alleges that safety problems associated with the now withdrawn Raplon, a neuromuscular blocking agent, caused false claims to be submitted to the Medicare and Medicaid programs. The complaint alleges that Organon intentionally withheld from FDA information about serious adverse events associated with Raplon, and made misrepresentations about Raplon's safety, both before and after the drug's approval in 1999. After its approval, Raplon was linked to patient deaths and nonfatal adverse events. Organon voluntarily withdrew the drug in 2001. The whistleblower suit seeks restitution and damages from Organon to the United States under the False Claims Act, as well as compensation for Feldstein.
Johnson & Johnson	Michigan Attorney General / Delaware Attorney General	March 2008 / April 2007	Not specified in 10-Q where company reported investigations	Johnson & Johnson received a letter from the Michigan Attorney General's Office seeking details on nominal price transactions. Michigan's inquiry follows two subpoenas last year from the Delaware Attorney General's Office, also demanding documents on nominal pricing agreements. In the two Delaware subpoenas, nominal pricing deals were defined as arrangements in which the company agreed to provide a pharmaceutical product for less than 10% of the average manufacturer price for that product.

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Schering-Plough Corp.	Senate Aging Committee	March 2008	Zetia	The Senate Aging Committee has asked Schering-Plough to turn over documents concerning what the Committee believes to be an aggressive marketing plan for the cholesterol-lowering drug Zetia. The Committee has requested specific information about Schering-Plough's "49 Plan," a 49-day push designed to increase Zetia prescriptions across the country. The Committee believes that this marketing plan instructs drug sales representatives to offer free meals and entertainment to physicians in order to influence prescribing. The Committee has requested a written description of the marketing plan for Zetia, as well as information on the number of sales representatives involved in the program, how the plan has complied with industry guidelines and ethics, and details concerning internal oversight of the plan.
Allergan Inc.	U.S. Department of Justice	March 2008	Botox	Allergan received a subpoena from the DOJ investigating the promotion of Botox. The DOJ is seeking documents pertaining to promotional, educational and other activities regarding the alleged off-label promotion of Botox for the treatment of headaches. Botox currently is not approved as a headache treatment, although Allergen is conducting trials to investigate the use of Botox for this potential indication.

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CEO of InterMune, Inc., W. Scott Harkonen	U.S. District Court Northern District of California (Indictment)	March 2008	Actimmune	W. Scott Harkonen, former CEO of InterMune (from 1999 to 2003), was indicted on felony charges for devising a scheme to promote Actimmune off-label for IPF. According to the indictment, part of this scheme to defraud included causing the media and InterMune's sales force to falsely portray Phase III clinical trial results as showing the efficacy of Actimmune for treating IPF.
Boston Scientific	Department of Justice	February 2008	Bile duct stents	Boston Scientific said that the Justice Department was investigating whether the manufacturer had promoted the device for unapproved uses, including repair of weakened blood vessels.
DePuy Orthopaedics, Inc., a Johnson & Johnson subsidiary	U.S. Senate Special Committee on Aging	February 2008	Hip and knee replacement products	DePuy received a written request for information as a follow-up to earlier inquiries, concerning a number of aspects of the DPA.
Bayer Corp.	U.S. District Court for the District of New Jersey	January 17, 2008	Baycol (cerivastatin)	The qui tam action alleges that Bayer violated federal and state false claims act by exaggerating the safety and efficacy of Baycol and concealing knowledge of its risks. The complaint also alleges that Bayer paid kickbacks to doctors who prescribed Baycol and that federal and state officials would not have paid for the prescriptions in their government-funded health insurance programs if they were aware of those facts.

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Merck & Co. Schering-Plough Corp.	New York Attorney General	January 2008	Vytorin	Merck and Schering-Plough received subpoenas from the New York Attorney General in an investigation into whether research data on Vytorin (anti-cholesterol statin drug) were deliberately concealed. The investigation will focus on whether the companies mislead consumers and physicians in their marketing of the drug, and on whether investors were misled about the value of company stock. The first prong of the investigation is based on the state False Claims Act, and the second on the Martin Act (New York securities regulation statute).

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				The investigation stemmed from the release of clinical trial results (from the "ENHANCE" trial) showing Vytorin to be no more effective against arterial plaque buildup than a generic. The Attorney General alleges that the companies did not disclose these findings, but continued to widely market Vytorin as highly effective in lowering cholesterol. The subpoenas seek all documents concerning marketing and advertising of Vytorin, all documents pertaining to the ENHANCE trial, all communications between the company and its drug representatives concerning the marketing of Vytorin and the ENHANCE trial, and all documents concerning communications between the company's drug representatives and physicians or any other medical personnel concerning Vytorin. They also seek all documents and information about the officer and director compensation, including incentives; all communications with investors, analysts, or the investing public with references to Vytorin or the ENHANCE trial; all documents and information regarding disclosure or delay of disclosure of the ENHANCE results; and all documents and information about insider sales of company stock or the exercise of stock options. The House Energy and Commerce Committee also began an investigation into the ENHANCE clinical trial in December 2007 because of the companies' delays in releasing the clinical trial data.

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Amgen, Inc.	New Jersey Attorney General	January 2008	Enbrel (etanercept)	The New Jersey Attorney General initiated an investigation into potential off-label marketing and violations of patient confidentiality laws in Amgen's marketing of its psoriasis drug Enbrel (etanercept). They Attorney General issued a subpoena to Amgen for various documents and information related to the sale, marketing and prescribing of Enbrel. The investigation was prompted after accusations from two former Amgen sales representatives, who claim to have been pressured by their managers to gain access to patient data to identify patients with psoriasis who might be candidates for treatment with Enbrel. The employees also allege that Amgen marketed Enbrel for mild psoriasis, although it is only approved for moderate or severe psoriasis. The two former employees are currently in arbitration with Amgen, claiming to have been terminated after refusing to engage in certain marketing practices.
Pfizer, Inc.	House Committee on Oversight and Investigations	January 2008	Lipitor	Investigation into Pfizer's direct-to-consumer television marketing campaign that uses celebrity endorsement by an unlicensed doctor who appears to be giving medical advice on the benefits of Lipitor.
DePuy Orthopaedics, Inc., a Johnson & Johnson subsidiary	Attorney General of the Commonwealth of Massachusetts	November 2007	Hip and knee replacement products	DePuy received a civil investigative demand seeking information regarding financial relationships between a number of Massachusetts-based orthopedic surgeons and providers and DePuy, which relationships had been publicly disclosed by DePuy pursuant to the DPA.

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Sandoz, Inc. Mylan Laboratories, Inc. Teva Pharmaceuticals, Inc.	Texas Attorney General	June 2007	Drugs reimbursed through Texas' Medicaid program	The state has charged Sandoz, Mylan Laboratories, and Teva Pharmaceuticals, along with subsidiaries of each company, with selling Medicaid-covered drugs to retailers at deep discounts while failing to properly report these retail prices to the state as required under the Texas Medicaid program.
Amgen, Inc.	New York Attorney General	May 2007	Drugs reimbursed through Medicaid	Amgen received a subpoena from the New York Attorney General seeking documents related to its promotional activities, as well as documents pertaining to its sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications.
Eli Lilly	Utah Attorney General	May 2007	Zyprexa	The state has charged Lilly with improperly promoting Zyprexa and failing to warn of adverse side effects, including the risk of diabetes, weight gain, and pancreatitis. The state is alleging that the company promoted Zyprexa off-label for conditions such as Tourette's syndrome, Alzheimer's, and anorexia. Utah is one of several states that has filed such a lawsuit against the company for off-label promotion of the Medicaid subsidized drug.

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Johnson & Johnson and subsidiaries, including Ortho-McNeil and Janssen	U.S. Attorney's Offices for Boston, San Francisco and Philadelphia	March 2007	Risperdal, Topamax and Natrecor	The separate investigations are part of a series of ongoing investigations into the sales and marketing of certain of the company's products. The most recent subpoenas, one each from the Boston, San Francisco and Philadelphia U.S. Attorney offices also relate to the company's supervision of its subsidiaries selling the medicines. The Boston U.S. Attorney previously issued a subpoena related to Natrecor in July 2005 and a subpoena related to Topamax in December 2003. Note also, the New York Attorney General requested similar information, for six drugs, including Risperdal, Topamax and Natrecor in July 2004 (see listing below).
Boston Scientific and Johnson & Johnson subsidiary Cordis	House Committee on Oversight and Government Reform	March 2007	Drug-eluting stents (Taxus and Cypher)	The committee sited FDA's Circulatory System Devices Panel, which concluded in December that there is insufficient evidence to support safe use of drug-eluting stents in populations not specifically assessed in the companies' pivotal clinical trials. The committee is requesting that both companies provide detailed information on all trials, studies, and reports and documents concerning the development of labeling. The companies say they will comply with the investigation.

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Elan Corp.	U.S. Department of Justice and the Department of Health	March 2007	Zonegran	The investigation is in regards to possible failure to comply with anti-kickback and false claims laws, and to past marketing and promotion practices in connection with Zonegran. The investigation covers the period of 2000-2004, and apparently relates to potential off-label promotion of the drug. Elan sold its interests in Zonegran to Esai in 2004.
Lilly, AstraZeneca, Cephalon	House Committee on Oversight and Government Reform	March 2007	Zyprexam Seroquel, Actiq and Fentora (respectively)	The investigation is addressing allegations that the drug makers promoted drugs off label. The committee is requesting information on clinical trials and external presentations, marketing materials, etc. The companies are asked to respond by March 21. The three companies have said they intend to cooperate with the inquiry.
Johnson & Johnson	United States Attorney for the Central District of California	February 2007	Remicade	The Centocor unit of Johnson & Johnson received a subpoena regarding its pricing of Remicadem, a treatment for rheumatoid arthritis and other inflammatory diseases. Centocor received the subpoena in November 2006, in connection with an investigation by the US Attorney for the Central District of California. Centocor is cooperating with the investigations, but would not comment further.

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Endo Pharmaceuticals Inc.	Department of Health and Human Services' Office of Inspector General	January 2007	Lidoderm (topical analgesic patch)	HHS is investigating whether Endo Pharma knew that physicians were prescribing the company's topical analgesic patch for unapproved uses. Lidoderm was approved by the FDA in 1999 to treat the pain associated with post-herpetic neuralgia (PHN). Endo said it intends to cooperate with the investigation.
Cephalon, Inc.	Connecticut Attorney General	November 2006	Actiq	Based on public documents, the focus of the investigation appears to be on whether Cephalon set unrealistically high sales quotas and pushed larger prescriptions at higher doses.
Gilead Sciences	U.S. Attorney's Office, San Francisco	December 2006	Viread (tenofovir) Emtriva (emtricitabine) Truvada (combination of above two)	The limited public information indicates that the investigation involves Gilead's marketing and medical education programs for the three products.

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AstraZeneca, Bristol-Myers Squibb, Eli Lilly and Pfizer	California Attorney General	November 2006	Antipsychotic drugs (Abilify, Zyprexa, Geodon)	According to Eli Lilly, the subpoena it received requests documents relating to its marketing and promotional practices for Zyprexa and the company's efforts to maintain the drug's status on the California state formulary. All three companies report cooperating with the investigation. Vermont and Illinois are now part of a five-state civil investigation into Lilly's promotion of Zyprexa. Specifically and whether Lilly tried to hide the drug's risk of causing weight gain and other risks associated with diabetes. Lilly says it will cooperate with the investigation and continues to deny that it marketed Zyprexa off-label, but documents indicate the contrary. Illinois' investigation is civil, while others are both civil and criminal.
Abbott Laboratories, Baxter, Dey, Boehringer Ingelheim Roxane and Schering-Plough	South Carolina Attorney General	August 2006	Drugs reimbursed through South Carolina's Medicaid program	The suit alleges that the companies intentionally and fraudulently misrepresented the AWP of certain drugs reimbursed by the South Carolina Medicaid program, resulting in the State overpaying $40 million dollars for prescription drugs.

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Eli Lilly and Co.	Mississippi Attorney General	July 2006	Zyprexa	The suit alleges that the manufacturer's sales representative marketed the drug to Mississippi physicians for off-label uses, resulting in the state Medicaid programming paying millions of dollars for Zyprexa prescriptions. The suit also alleges that the company concealed the dangers of the drug, causing the State to incur further costs to treat the resulting conditions of Medicaid prescriptions. The suit seeks civil penalties as well as punitive damages and litigation costs.
Dr. Peter Gleason Jazz Pharmaceuticals	U.S. Attorney's Office, Brooklyn Food & Drug Administration	June 1006	Xyrem	Dr. Gleason, an independent contractor hired by the product's manufacturer, Jazz pharmaceuticals, was indicted for conspiring to promote the product for off label uses. During his promotional and CME talks, for which he was paid by the manufacturer, Dr. Gleason advocated the product for off-label use, claimed the product was safe for children and made other similar claims.
Abbott Laboratories	U.S Department of Justice	May 2006	Injectable and intravenous rugs reimbursed by Medicare and Medicaid, including Vancomycin	The DOJ joined Ven-A-Care's whistleblower lawsuit against Abbott alleging that Abbott violated the federal false claims act by reporting exaggerated AWPs for certain drugs sold by its Hospital Products Division (now Hospira). Abbott allegedly reported AWPs inflated by as much as 1000% and marketed the spread to its customers, allowing the customers to profit at the expense of higher costs to the Medicaid and Medicare programs.

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44 pharmaceutical companies, including Abbott Laboratories, Inc.	Hawaii Attorney General	May 2006	Drugs reimbursed through Hawaii's Medicaid program	The suit, filed April 27, 2006 alleges that the companies engaged in deceptive trade practices, violation of the false claims act, unfair competition, nondisclosure and unjust enrichment by manipulating and/or misstating the AWP of products reimbursed by the Hawaii Medicaid program resulting in millions of dollars of overpayment by consumers and the government. The suit seeks treble damages.
AstraZeneca	U.S. Attorney's Office Los Angeles	March 2006	Unclear	The U.S. Attorney began investigating the company's promotional activities in the area served by the company's Los Angeles regional business center. The preparation and dissemination of patient education and similar materials to physicians appears to be the focus of the investigation.
Pfizer Inc.	Union and employee insurance plans	March 2006	Lipitor	The lawsuit alleges that Pfizer committed fraud, violated state consumer protection and other laws and violated RICO by promoting Lipitor for off-label uses, leading the plans to incur costs for billions of dollars for medically unnecessary prescriptions. The suit also alleges that Pfizer paid third parties to promote off-label uses of the product through articles and educational courses.
Eli Lilly & Co. and 44 other subpoenas to undisclosed manufacturers and other healthcare organizations	Connecticut Attorney General	March 2006	Products sold through Healthcare Research & Development Institute, LLC	The Connecticut Attorney General is investigating whether the activities of the Healthcare Research & Development Institute is violating anti-trust rules in its arrangements to buy services and supplies.

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Genentech Inc. and Biogen Idec Inc.	Private whistleblower suit	January 2006	Rituxan	A former Genentech employee filed suit in July 2005 alleging that the companies (who co-promote the drug) illegally promoted the drug for off-label uses. The suit also alleges that the companies used sham consulting agreements to pay rheumatologists to influence other doctors to prescribe the drug and that he was fired in retaliation for bringing the issue to the attention of Genentech executives. The Justice Department declined to intervene in the case.
42 drug companies, including Abbot Laboratories and Baxter Healthcare Corp.	Arizona Attorney General	December 2005	AWP for drugs covered by Arizona's Medicaid program and Medicare	The lawsuit, filed December 7, 2005 alleges the drug companies defrauded Arizona consumers and Medicare out of millions of dollars by inflating or misstating the AWP.
GlaxoSmithKline	Private whistleblower complaint: *McRae v. SmithKline Beecham Corp d/b/a GlaxoSmithKline*	November 2005	Sales and promotion of Baycol, Augmentin XR, Paxil CR and Requip	The suit alleges the company directed some of its sales reps to provide gifts, bribes and sponsorships of social activities to influence health care providers, and paid bounties to providers to persuade other doctors to use the products. Also, the complaint alleges that reps were directed to promote off-label uses of products and the use of Baycol despite information that the product caused deaths due to kidney failure. McRae was allegedly fired in retaliation for objecting to these practices.
Eli Lilly and Co.	U.S. Attorney for the Eastern District of Pennsylvania	October 2005	Axid, Evista, Prozac, Zyprexa, Humalog and Humulin	The US Attorney's office is reviewing Lilly's Medicaid best price reporting as it relates to the Company's rebate agreements with a PBM covering the specific drugs.

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86 pharmaceutical manufacturers, including Abbott, Novartis, GlaxoSmithKline and Schering-Plough	Mississippi Attorney General	October 2005	Drugs reimbursed by Medicaid	The suit filed in Hinds County Chancery Court alleges the drug companies fraudulently inflated AWP for drugs reimbursed by the state Medicaid resulting in the state paying grossly excessive prices. Pfizer is not named in the suit and reports being in settlement discussions with the Attorney General's office.
Pfizer	Community Catalyst and Health Care for All (consumer groups)	September 2005	Lipitor	The suit, filed in the U.S. District Court in Boston, alleges that the company violated state consumer protection laws by marketing the drug for patient populations for which the drug was not tested in clinical trials. The suit seeks reimbursement for those classes of patients and third-party payors.
39 pharmaceutical manufacturers	California Attorney General	August 2005	Drugs reimbursed by Medi-Cal (Medicaid)	The suit, which amends a 2003 suit against Abbott and Wyeth, alleges that the manufacturers defrauded the state by overcharging for drugs reimbursed by Medicaid.
Johnson & Johnson	Senate Finance Committee	July 2005	Propulsid	The committee is conducting an inquiry into whether educational grants were provided to promote the pediatric use of the drug even though there was evidence at the time linking the drug to adverse complications, including death.
Eli Lilly and Co.	Florida Attorney General	June 2005	Zyprexa	Florida Medicaid Fraud Control Unit is investigating the sales and marketing of Zyprexa.

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Dey Pharmaceuticals, Warrick Pharmaceuticals	Missouri Attorney General	May 2005	AWP reporting for drugs reimbursed by the Medicaid program	The Attorney General alleges that the companies engaged in price-inflation schemes over the past 11 years resulting in at least $15 million in excess charges to the state's Medicaid program. The suit seeks treble damages under the Missouri Health Care Payments Fraud and Abuse Act and an injunction.
Merck	Nevada Attorney General	April 2005	Zocor	Suit in Second Judicial Circuit for Nevada alleges that Merck engaged in a nominal pricing scheme designed to circumvent best price requirements which resulted in Medicaid paying higher prices for the drug. Specifically, the suit alleges that Merck offered a discount of over 90% to hospitals that achieved a 70% market share, resulting in large discounts for the hospitals that were not offered to Medicaid.
Serono Laboratories executives	U.S. Attorney for Massachusetts	April 2005	Serostim	Four former company executives have been indicted for conspiracy and offering to pay illegal remuneration related to the sales and marketing of the AIDS-wasting drug Serostim. The indictment alleges that the executives devised a plan to essentially bribe physicians with trips to France if they wrote a target number of prescriptions.
McKesson, Cardinal Health and AmeriSourceBergen	New York Attorney General	April 2005	Pharmaceuticals on the secondary market	The three companies, the largest prescription drug wholesalers in the U.S., received subpoenas from the New York Attorney General requesting documents and other information relating to the secondary wholesale market for pharmaceuticals.

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Sandoz Inc., Ivax Pharmaceuticals, Purepac Pharmaceuticals, Alpharma, Inc. Alpharma USPD, Barre Parent Corp., Faulding Inc., Ivax Corp., Mayne Group, Novartis AG	Florida Attorney General	April 2005	AWP reporting for drugs reimbursed by the Medicaid program, including drugs used for depression, schizophrenia, seizures and angina	The suit filed in Florida Circuit Court in Tallahassee against the three major manufacturers and their parent and/or subsidiaries may be the result of the July 2004 subpoenas issued to six manufacturers. The suit alleges violations of the Florida False Claims Act, which are subject to treble damages, and common law fraud. The suit claims that the manufacturers overbilled Medicaid by $25 million by inflating reported AWP for generic medications and marketed the spread to physicians.
77 Drug companies	Monroe County, New York	April 2005	AWP reporting for drugs reimbursed by the Medicaid program	The suit claims the companies fraudulently inflated the AWP for drugs reimbursed by Medicaid and underpaid rebates due to the county under federal law. The County pays for 25% of the reimbursement for drugs covered by Medicaid.
Wyeth Pharmaceuticals	U.S. Attorney for Massachusetts	March 2005	Protonix	The subpoena seeks information dating back to 2000 relating to the pricing and quarterly calculations AWP for Protonix.
GlaxoSmithKline PLC	Department of Justice[5]	March 2005	Nominal pricing arrangements affecting a number of its products	The company is cooperating with the investigation into whether the nominal prices charged (less than 10% of average manufacturer price) for a number of products violate civil laws or law relating to Medicaid.

[5] In 2004, the Senate Finance Committee requested information from pharmaceutical manufacturers including GlaxoSmithKline.

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77 pharmaceutical manufacturers, including Aventis, Novartis, Merck and GlaxoSmithKline	Erie County, New York	March 2005	AWP reporting for drugs reimbursed by the Medicaid program	The suit alleges that the manufacturers overstated their AWP, causing the Medicaid program in Erie County to overpay for drugs for Medicaid recipients.
Biogen Idec	Whistleblower suit	March 2005	Amevive	Former employee alleges in her suit for wrongful termination that the company paid kickback to physicians who ordered the drug by providing a combination of free samples and price discounts to physicians who were denied reimbursement by insurance companies. The "Security Program for Amevive" was the name of the program the plaintiff alleges was developed to guarantee reimbursement for physicians who were denied reimbursement by insurers, and there was a similar program for another drug, Zevalin. The suit also claims that the company failed to properly report and account for the physician discounts, inflating revenue.

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48 Pharmaceutical manufacturers	Illinois Attorney General	February 2005	AWP reporting for drugs reimbursed by the Illinois Medicaid program and Medicare beneficiaries	Suit filed in the Circuit Court in Cook County alleges that manufacturers fraudulently published inflated prescription drug prices, leading the state Medicaid program and Medicare beneficiaries to pay inflated prices. The lawsuit alleges violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, Public Assistance Fraud Act and Whistleblower Reward and Protection Act. The suit seeks injunctive relief, as well as all court costs and civil penalties of $50,000 - $60,000 per violation.
Roxanne Laboratories	Ohio Attorney General	November 2004	AWP for drugs reimbursed by the Ohio Medicaid program	The Ohio Attorney General filed suit against the drug manufacturer, charging it with fraud, unjust enrichment, and violations of the state anti-kickback law allegedly arising from the provision of false and misleading wholesale price and acquisition data. The suit seeks compensatory and punitive damages as well as civil penalties.
Priority Healthcare Corporation, InterMune	U.S. Department of Justice	November 2004	Actimmune	Both Priority Healthcare Corporation, a specialty pharmacy and distribution firm, and InterMune the manufacturer of the drug, were subpoenaed for information relating to the marketing and promotion of Actimmune. A former employee filed suit in March accusing InterMune of actively promoting off-label use of the drug. Both companies have indicated that they intend to cooperate with the investigation.

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AstraZeneca	U.S. Attorney for the Eastern District of Pennsylvania	November 2004	Nexium and Prilosec	The company was informed that it would be receiving a subpoena relating to the formulary status of Nexium and Prilosec at a regional HMO and a national PBM. The company intends to cooperate with the subpoena.
AstraZeneca	Class action suit brought on behalf of several benefit funds in New York	November 2004	Nexium	Suit filed in Delaware Superior Court on behalf of benefit funds associated with the Teamsters union Local 237. AstraZeneca allegedly carried out a massive misleading marketing campaign that compared unequal dosages with the aim to convince physicians that Nexium was superior to its predecessor, Prilosec, which was significantly less expensive than Nexium. The suit seeks to recover overpayments the funds made to purchase Nexuim instead of its Prilosec.
V, Fresenius Medical Care AG, DaVita, Inc., Renal Care Group Inc. and Nichols Institute Diagnostics (a subsidiary of Quest Diagnostics)	U.S. Attorney Eastern District of new York	November 2004	Parathyroid Hormone testing and vitamin D therapies	The subpoenas request a broad range of documents relating to parathyroid hormone testing and vitamin D therapies, possibly as part of a joint civil and criminal investigation. It is unclear whether the subpoenaed companies are the targets of the investigation.
Bone Care International, Inc.	U.S. Department of Justice	October 2004	Unclear (main product is Hectorol)	The subpoena requests documents on a wide range of subjects relating to company operations. It specifically requests documents on testing for parathyroid hormone levels and vitamin D therapies.

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AstraZeneca	Private suit by AFL-CIO, Congress of California Seniors and California Alliance for Retired Americans	October 2004	Nexium	Suit filed in Los Angeles Superior Court alleging violations of California's unfair competition and false advertising laws. AstraZeneca allegedly carried out a massive misleading marketing campaign that compared unequal dosages with the aim to convince physicians that Nexium was superior to its predecessor, Prilosec, which was significantly less expensive than Nexium. The suit seeks to stop the allegedly illegal behavior and recover damages and allegedly illegally obtained profits.
Ortho Biotech Products (subsidiary of Johnson & Johnson)	Office of the Inspector General	October 2004	Procrit	The subpoena requested documents related to the sales and marketing of Procrit. J & J has indicated that it is cooperating with the subpoena. In May 2007, it was reported that documents produced in connection with the investigation allege that the company created purchasing programs that could violate anti-kickback laws by offering doctors discounts and cash rebates on Procrit, offering hospitals price incentives to prescribe a certain volume of Procrit, and creating "right of first refusal" contracts for doctors in prescribing Procrit over a competitor's product. The documents also allege that the company promoted the drug off-label for higher-than-approved doses.

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Genetech	U.S. Attorney for the Eastern District of Pennsylvania	October 2004	Rituxan	The company received a subpoena relating to the promotion of Rituxan. The investigation is both criminal and civil in nature.
Cephalon, Inc.	U.S. Attorney for the Eastern District of Pennsylvania	September 2004	Provigil, Actiq and Gabitril	The focus of the investigation appears to be sales and promotional practices. The subpoena is broad in that it requests documents dating back to 1998 and covering all three of the company's products.
Caremark Rx	23 State Attorney Generals (Including Washington and Washington D.C.)	August 2004 and prior	PBM business practices	Washington and other states requested information on Caremark's business operations as they related to state consumer protection laws. A Caremark spokesman indicated that the requests are related to recent industry settlements, which would include AWP pricing claims and drug switching programs. The company intends to cooperate with the requests.
Pfizer, Inc., Johnson & Johnson, Bristol-Myers Squibb Co., Abbot Laboratories and 11 other pharmaceutical manufacturers	19 California pharmacies	August 2004	Price fixing of drugs in the U.S. market	The lawsuit, filed in Alameda County Court charges the pharmaceutical manufacturers with violating California antitrust and unfair business practices laws by conspiring to inflate drug prices in the U.S., while charging lower prices for the same drugs outside of the U.S.

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Merck & Co.	Inspector General of the District of Columbia	August 2004 (subpoena received in April 2004)	Unknown	The Inspector General is conducting an investigation into the company's interactions with physicians in D.C., Maryland, and Virginia.
Mylan Laboratories	California Attorney General	August 2004	Marketing and price reporting practices	The subpoena reportedly seeks information relating to the company's price reporting and marketing activities.
Eli Lilly & Co., Abbott Laboratories, Merck & Co., Roche Labs, Schering-Plough and 39 other pharmaceutical manufacturers	New York City Law Department	August 2004	AWP for drugs reimbursed by the New York Medicaid program	The suit alleges violation of federal and state Medicaid law, fraud, breach of contract, unfair and deceptive trade practices and unjust enrichment. According to the suit, the companies inflated the AWP for drugs reimbursed by the Medicaid program by reporting false, inflated and misleading pricing information, which led to artificially low rebates being given to the Medicaid program.

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Express Scripts	New York Attorney General	August 2004	Empire Plan (NY's largest employee health plan)	Attorney General filed lawsuit alleging breach of contract and violation of civil law. Specifically, the suit alleges that Express Scripts enriched inflated the cost of generic drugs for its own enrichment and at the expense of the Empire Plan, diverted to itself millions of dollars in manufacturer rebates that belonged to the Empire Plan, engaged in fraud to induce physicians to switch a patient's prescription from one prescribed drug to another for which Express Scripts received money from the second drug's manufacturer, sold data belonging to the Empire Plan without the permission of the Empire Plan and in violation of the State's contract, and induced the State to enter into the contract by misrepresenting the discounts the Empire Plan was receiving for drugs purchased at retail pharmacies.
Johnson & Johnson	New York Attorney General	July 2004	Topamax, Risperdal, Procrit, Reminyl, Remicade and Aciphex	A request for information, such as marketing practices and results of clinical trials, related to the off-label promotion of six drugs were received by Johnson & Johnson July 27, 2004.
Forest Laboratories	New York Attorney General	July 2004	Clinical trials and off-label promotions	The Attorney General requested information from the company related to any clinical trials or promotion of off-label uses for its products. The request alluded to possible violations of state law. The company intends to cooperate with the request.

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Pfizer Inc	California class action (other states pending as well)	July 2004	Neurontin	A class action lawsuit was filed the California Superior Court claiming that marketing of the drug violated the state's unfair business practices statutes. The suit requests injunctive relief and disgorgement of gains and profits from the allegedly illegal marketing scheme. At least a dozen other such cases exist in other states, most of which have been removed to federal court
Teva USA, Watson Pharmaceuticals, Inc., Mylan Laboratories Inc., Sandoz Inc. (formerly Geneva, subsidiary of Novartis) Ivax Inc., PurePac Pharmaceutical Co. (Alpharma subsidiary)	Florida Attorney General	July 2004	AWP reporting	Civil subpoenas seeking information on pricing for 1994 to the present were served on the six manufacturers. The AG believes the companies may have inflated the AWP for drugs, resulting in overpayments by the Medicaid program of more than $100 million.
Eli Lilly & Co., Merck and other drug companies	Central Alabama Comprehensive Healthcare Inc.	July 2004	Outpatient prescription drugs	Public health hospital that treats indigent patients filed suit in the U.S. District Court in Montgomery Alabama alleging that the companies overcharged them for outpatient prescription drugs for indigent patients. Drugmakers are required to discount their prices for outpatient drugs to qualified hospitals that treat the poor, children, and the disabled.

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Caremark Rx	Employee benefit plan member (seeking class action status)	July 2004	Discounting and rebating practices	The lawsuit, filed in the U.S. District Court in Nashville alleges that Caremark practice of negotiating discounts and rebates with manufactures and pharmacies violates federal law. The suit alleges that Caremark keeps the money from rebates and discounts it negotiates rather than sharing the savings with the benefit plan. Caremark is also accused of providing plan members with more expensive rather than cheaper alternatives in order to increase rebates.
Caremark Rx	Qui tam action Office of the Inspector General	July 2004	Unavailable	OIG subpoenaed documents from the attorney prosecuting a qui tam case against requesting documents relating to all auditing records, monitoring records, consulting reports and other reviews relating to mail-order pharmacy operations. It is unclear whether Caremark has been subpoenaed or even whether Caremark is the target of the investigation.
Caremark Rx	Florida Attorney General	June 2004	Re-selling and billing for returned drugs	The state intervened in a qui tam suit filed in January 2003 by two former Caremark Rx employees. The suit alleges that Caremark illegally re-sold drugs returned to its mail order pharmacy and billed the state twice for those drugs.
Pfizer, Johnson & Johnson, Bayer Corp. and 17 other drug companies	Wisconsin Attorney General	June 2004	Allegations relating to rebated/discounted products	The lawsuit, filed in Dane County Circuit Court, alleges that pharmaceutical manufacturers inflated wholesale prices for drugs and kept secret deep discounts given to providers, thereby inflating the reimbursement to providers and increasing costs to Medicaid and other payers.

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GlaxoSmithKline	New York Attorney General	June 2004	Paxil	State Attorney General Eliot Spitzer filed a lawsuit in New York State Supreme Court on June 2, 2004 alleging that GlaxoSmithKline (GSK) engaged in persistent fraud by concealing and failing to disclose negative information about Paxil. Specifically, the complaint alleges that GSK conducted studies that failed to demonstrate the efficacy of Paxil in children and raised questions about its safety, but only released one study showing mixed results, that GSK represented to its sales force that Paxil was effective for adolescents, and misrepresented the results of the studies in letters to physicians. The suit seeks disgorgement of profits.
Abbott Laboratories, Baxter Healthcare Corp., and B. Braun Medical, Inc.	Texas Attorney General	May 2004	AWP reporting for intravenous fluids and other products	Whistleblower suit alleges that false reporting of AWP prices for various intravenous fluids and other products led the Texas Medicaid program to reimburse providers at inflated rates, which encouraged the providers to do business with the drug manufacturers. The suit seeks treble damages, plus civil penalties and attorneys fees and costs. The suit against Baxter was settled June 2006, while the claims against the other manufacturers remain pending.
Abbott Laboratories	Federal Trade Commission	May 2004	Norvir (AIDS)	Senators Charles Schumer, John McCain and Ernest Hollings requested the FTC to investigate Abbott's fivefold increase in the price of Norvir via letter dated May 19, 2004. The letter accused Abbott of using the Norvir patent to create a monopoly for its newer HIV drug (Kaletra).

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InterMune	See summary comments	May 2004	Actimmune	Suit by former employee who claims she was fired for refusing to engage in off-label promotions of the drug. InterMune "has not publicly indicated that it is under investigation" by the FDA or any government agency.
Eli Lilly	U.S. Attorney's Office in Philadelphia	April 2004	Evista (osteoporosis), Prozac (anti-depressant), Zyprexa (antipsychotic)	Civil investigation into the manner that Eli Lilly markets and promotes its products.
Schering-Plough Corp.	Massachusetts U.S. Attorney's Office	April 2004	Proventil, Vanceril, Vancenase, Nitro-Dur, Imdur, K-Dur, and Claritin	Additional subpoena in this investigation requesting • documents from certain managed care entities; • documents relating to all contracts where the price of one drug is dependent on the purchase of another; • documents relating to outside audits in the Medicaid best price area • documents concerning Warrick, the Company's generic subsidiary During the 2003 third quarter, the Company increased its litigation reserves related to the investigations by the U.S. Attorney's Office for the District of Massachusetts and the investigation by the U.S. Attorney's Office for the Eastern District of Pennsylvania, by $350 million.

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aaiPharma Inc.	Independent investigation	April 2004	Earnings statements; Brethine & Darvocet	Following an independent investigation, the company announced that it would be restating its earnings for 2003. Adjustments to earnings were made relating to the recognition of revenue on new product launches, a consignment sale transaction with a distributor in Puerto Rico, sales transactions with a distributor relating to Brethine and sales of 500-count bottles of Darvocet.
Pfizer	U.S. Department of Justice	April 2004	Genotropin & Bextra	Investigation relating to the marketing and sale of Genotropin and Bextra, as well as certain managed care payments.
AaiPharma	U.S. Attorney for W.D. North Carolina	April 2004	Brethine (asthma drug) Darvocet-N (painkiller)	Received grand jury subpoenas on April 2 and April 6 for documents and potential testimony relating to 2002 and 2003 financial reports, sales of certain key products, corporate officers' public comments about the company's financial health, certain loans to the company and the "terms and conditions" of employment for some senior managers. AaiPharma may also receive subpoenas from the Securities and Exchange Commission.

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Dey, Warrick Pharmaceuticals, Schering-Plough Corp., Schering Corp., Abbott Laboratories and Pharmacia Corp.	Ohio Attorney General	March 2004	Drugs paid for by Ohio Medicaid	The suit alleges fraud, violations of the Consumer Sales Practices Act, Medicaid fraud, unjust enrichment and violations of the state ant-kickback statute by the pharmaceutical manufacturers who allegedly provided false and misleading information regarding pricing. The information is used to set state reimbursement rates for the drugs. The suit was filed in the Court of Common Please of Hamilton County, Ohio.
Merck & Co.	Texas Attorney General	February 2004	All drugs purchased, sold and/or administered by Merck for the care and treatment of any patient or client who is eligible for or who has applied for Medicaid coverage or benefits	Civil Investigation Demand (CID) sent to Merck on February 2, 2004 requesting documents and other information that may be relevant to an investigation into possible false and inaccurate reporting of information regarding Medicaid patient charges and payments, as well as related programs administered by National Heritage Insurance Co. and other governmental agencies.
GlaxoSmithKline	U.S. Attorney for the District of Colorado	February 2004 (subpoenaed information for January 1997 to present)	Advair, Flovent, Imitrex, Lamictal, Lotronex, Paxil, Valtrex, Wellbutrin, and Zolfrain	Investigation regarding sales and promotional practices.

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Abbott Laboratories	Illinois and New York Attorneys General	February 2004	Norvir (AIDS)	Investigation to determine whether Abbott's decision to drastically increase the price of Norvir violates state antitrust and fraud statutes. The price went from $55/month to $250/month.
CVS, Eckerd, Wal-mart, Rite Aid and Walgreen[6]	House Committee on Energy and Commerce	January 2004	Albuterol, Buspirone, Doxazosin, Fluoxetine, Furosemide, Ipratropium Bromide, Buspar, Cardura, Celbrex, Oxycontin, Oxycodone, Zyprexa	Investigation related to the rebating and reimbursement rates, including reporting of AWP and WAC, for certain drugs paid for by the Medicaid program.
Janssen Pharmaceutical Products, L.P. (subsidiary of J&J)	Inspector General at the Office of Personnel Management (OPM) OPM is responsible for administration of the Federal Employees Health Benefits Program.	January 2004	Risperdal	OIG is seeking information on the marketing and promotion of Risperdal to physicians or pharmacists from Jan. 1, 1997 to Sept. 20, 2003. OIG has also requested documents concerning educating or consulting physicians.

[6] See pharma manufacturer counterpart letter of June 2003.

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Forest Pharmaceuticals, Inc. (subsidiary of Forest Laboratories, Inc.)	Inspector General at the Office of Personnel Management (OPM) OPM is responsible for administration of the Federal Employees Health Benefits Program.	January 2004	Celexa	OIG is seeking information on the marketing and promotion of Celexa to physicians or pharmacists from Jan. 1, 1997 to Sept. 20, 2003. OIG has also requested documents concerning educating or consulting physicians.
Wyeth Pharmaceuticals	Inspector General at the Office of Personnel Management (OPM) OPM is responsible for administration of the Federal Employees Health Benefits Program.	January 2004	Effexor (anti-depressant)	IG is seeking information on the marketing and promotion of Effexor to physicians or pharmacists from Jan. 1, 1997 to Sept. 20, 2003. IG has also requested documents concerning educating or consulting physicians.

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Watson Pharmaceuticals, Inc.	Office of the Inspector General	December 2003	Ferrlecit (used to treat patients on dialysis who have an iron deficiency)	Investigation of whether Watson paid kickbacks to doctors to prescribe its anemia medicine.
Medco Health Solutions (formerly known as Merck-Medco) U.S. ex rel. Hunt v. Merck-Medco Managed Care, LLC (E.D. Pa., Case No. 00-CV-737)	U.S. Attorney for the Eastern District of Pennsylvania	December 2003	Allegations relating to rebated/discounted products	In May 2004, Medco announced a settlement with state attorney generals on this matter (see above) and that it had reached an agreement with the Justice Department as to certain counts relating to business practices but not monetary damages. In March 2003 the government filed the original complaint in the 1999 false claims whistleblower case[7] alleging, among other items, that Merck-Medco switched patients from their prescribed drugs to "target drug" which were either Merck-manufactured or manufactured by a company with whom Merck had an undisclosed rebate contract. The amended complaint, filed in December 2003, also includes an additional allegation of violations under the Public Contract Anti-Kickback Act for making improper payments to health plans to induce them to select Medco as a PBM for government contracts.

[7] Originates from the subpoena issued in the Spring of 1999.

PHARMACEUTICAL & MEDICAL DEVICE MANUFACTURERS:
RECENT INVESTIGATIONS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES

SELECT PUBLIC INVESTIGATIONS

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King Pharmaceuticals	Office of the Inspector General	November 2003	Altace (cardiovascular), Aplisol (tuberculosis detection), Levoxyl (hypothyroidism treatment)	Investigation of sales and marketing. On August 5, 2004 the company announced it had set aside $130.4 million to settle with the government the claims in this investigation and the SEC investigation.
Merck & Co.	Department of Justice	August 2003	Unavailable	Investigation of sales and marketing activities at a number of pharmaceutical manufacturers (possibly Medicaid pricing concerns)
Johnson & Johnson, Centocor	(1) New Jersey U.S. Attorney's Office (2) House Committee on Energy and Commerce (3) Class Action in Superior Court of New Jersey (Middlesex County)	(1) August 2003 (2) June 2003 (3) April 2002	Remicade (autoimmune disorders, e.g., rheumatoid arthritis and Crohn's disease)	(1) Investigating marketing practices related to Remicade. (2) Investigating pharmaceutical reimbursements and rebates under Medicaid. (3) Allegations that Centocor intentionally misstated the AWP for Remicade and that J&J and Centocor encourage doctors and other providers to base charges to Medicare and third-party payers on the full AWP, "and pocket the difference." Class includes Prescription Access Litigation (PAL), New Jersey Citizen Action and United Senior Action of Indiana.

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Epstein Becker & Green, P.C.

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Bristol-Myers Squibb	(1) SEC and DOJ (2) U.S. Attorney in Massachusetts (3) House Committee on Energy and Commerce	July 2003	Unavailable	(1) Investigation of revenue overstatements that the company made by improperly recording sales to wholesalers toward the end of fiscal quarters. In March 2003, BMS admitted to overstating its revenue by $2.5 million between 1999 and 2001. (2) Investigating the marketing practices employed by BMS and other drug manufacturers (3) Investigating BMS, along with about 2 dozen other pharmaceutical companies, for Medicaid fraud.
Johnson & Johnson, Premier and Novation medical supply companies	New York & Connecticut Attorneys General FTC	July 2003	Bundling contracts	Investigation into the business practices of medical device supply companies that involve requiring companies to purchase supplies "bundled" together. The Connecticut Attorney General indicated that the practice may violate anti-trust laws as well as health care laws and regulations.
Various pharmaceutical manufacturers and distributors[8]	House Committee on Energy and Commerce	June 2003	Albuterol, Buspirone, Doxazosin, Fluoxetine, Furosemide, Ipratropium Bromide, Buspar, Cardura, Celbrex, Oxycontin, Oxycodone, Zyprexa	Investigation related to the rebating and reimbursement rates, including reporting of AWP and WAC, for certain drugs paid for by the Medicaid program.

[8] Manufactures identified in the subsequent January 2004 letter are: Abbott Laboratories; Alpharma, Inc.; Apotex, Inc.; Barr Laboratories, Inc.; Bristol-Myers Squibb Co.; Dey, Inc.; Eli Lilly and Company; Ethex Corp.; Geneva Pharmaceuticals, Inc.; IVAX Corp.; Mylan Laboratories, Inc.; Par

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Wyeth Pharmaceuticals	Department of Justice	February 2003	Over-the counter drugs	The company announced that it was anticipating a subpoena relating to an inquiry into whether the company colluded with Schering-Plough to lower the commission rates paid to a broker that sold the companies' over-the-counter drugs in vending machines on off-shore oil rigs.
Abbott Laboratories & Wyeth Pharmaceuticals	California Attorney General	January 2003	AWP reporting	Prompted by whistleblowers from Ven-a-Care pharmacy in Florida, the Attorney General sued both companies claiming that they grossly misrepresented their prices, leading the state to pay inflated prices for pharmaceuticals on behalf of beneficiaries of the state Medicaid program.

Pharmaceutical, Inc.; Pfizer Inc.; Purdue Pharma L.P.; Purepac Pharmaceutical Co.; Roxane Laboratories, Inc.; Teva Pharmaceuticals USA, Inc; Unit Dose Laboratories, Inc.; Watson Pharmaceuticals, Inc.

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Schering-Plough	Massachusetts U.S. Attorney's Office	November 2002	Intron A & Rebetron (hepatitis C drugs), Temodar (oral chemotherapy agent for brain tumors)	2 additional grand jury subpoenas delivery on November 12, 2002 for investigation of sales and marketing practices, including marketing contacts with insurers and doctors. Focus on 4 specific areas: • Drug samples, clinical trial grants, and other items and services of value given to physicians to induce the purchase of Schering-Plough products in violation of federal anti-kickback laws; • The off-label promotion of certain drugs; • False pricing information submitted to the government for Medicaid rebate purposes regarding items specially packaged for a managed care customer; and • The destruction of documents and other obstructions of justice relating to the investigation This investigation was a subject of a August 5, 2004 CNN show, where a physician stated Schering offered him over $1,000 per patient to enroll patients in a clinical trial of Intron-A in which accurate data was not collected.
Eli Lilly & Co.	Department of Justice	August 2002	Evista/raloxifene (osteoporosis)	Investigation of off-label promotion of the drug for the prevention of breast cancer.

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Abbott Laboratories, Bayer, Lilly, Merck, Pfizer and other manufacturers; Walgreens and other pharmacies	Florida Attorney General	July 2002	Marketing agreements with pharmacies; Prozac	The Attorney general subpoenaed documents from manufacturers and pharmacies relating to their marketing agreements. The investigation is looking at whether the marketing arrangements, including a Prozac promotion where samples were sent to patients in Walgreens envelopes constitute unfair business practices under state law.
Purdue Pharma	Florida Attorney General	November 2001	OxyContin (pain medication)	Investigation regarding marketing practices (There was a 59% rise in people dying from overdoses of hydrocodone and oxycodone—the generic name for OxyContin.) Documents relating to the marketing plans of Purdue for OxyContin were released in February 2003 following a lawsuit filed by two Florida newspapers seeking to make the papers public.
Eli Lilly & Co.	Massachusetts Attorney General	May 2001	Unavailable	Investigation of pricing practices and Medicaid reimbursement.
(1) Schering-Plough Corp. (2) Bristol-Myers Squibb (3) TAP Pharmaceutical Products, Inc.	Massachusetts Attorney General	March 2001	Unavailable	Investigation regarding allegations that some drug companies circumvented the law requiring them to sell prescription drugs to Medicaid at the best market price.

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Pharmaceutical / Medical Device Manufacturer[2]	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
(1) SmithKline Beecham (2) TAP Pharmaceutical Products, Inc.	House Commerce Committee	(1) September 2000 (2) July 2000	(1) Kytril (anti-nausea) (2) Lupron (prostate cancer)	Investigation into possible improprieties in the way the Medicare-covered drugs are priced.
AdvancePCS (legacy PCS Health Systems)	U.S. Attorney for the Eastern District of Pennsylvania	November 1999	Allegations relating to rebated/discounted products	Following a subpoena from the Office of the Inspector General, an investigation by the U.S. Attorney for the E.D. Pa. into relationships with pharmaceutical manufacturers and retail pharmacies, and its programs relating to drug formulary compliance, including rebate and other payments made by pharmaceutical manufacturers to AdvancePCS, and payments made by AdvancePCS to retail pharmacies in connection with therapeutic intervention activity.

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