

**PHARMACEUTICAL MANUFACTURERS: PUBLIC SETTLEMENTS AND
RECENT INVESTIGATIONS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES.¹**

SELECT SETTLEMENTS

Pharmaceutical Company	Settlement Amount	Date of Settlement	Product	Summary of Significant Description/Allegations
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 Eastern District of Pennsylvania.
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.

¹ This chart summarizes publicly available information relating to select pharmaceutical manufacturer investigations, select PBM /HMO investigations/litigation related to pharmaceuticals. It is based solely on secondary sources on file with author.

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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 dug by giving them free devices and software, free trips and other kickbacks was also settled.

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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.
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.

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Adam Stupak (former Serono Laboratories salesman)	Guilty plea	December 2004	Serostim	Stupak pled guilty to charges that he influenced physicians to prescribe Serostim to HIV-positive or AIDS patients giving the physicians trips to Cannes, France.
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.
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.

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Bristol-Myers Squibb	\$75 million	2004	Inflated sales figures	Bristol-Myers Squibb paid \$75 million to settle 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.
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 <u>for this entity</u> from participation in federal health care programs for five years. Schering-Plough: \$293 civil damages Total: \$345.5 million	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	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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Merck KGaA	\$850,000	2004	Albuterol sulfate and other drugs	Subsidiary Dey, Inc. inflated the average wholesale price (AWP) of albuterol 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	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	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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Medco Health Solutions (formerly known as Merck-Medco)	Total: \$29.3 million for state claims Amount not yet determined for federal claims (see below)	2004	Rebated/discounted products	<p>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.</p> <p>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.</p> <p>In September 2004, the active and constructive fraud count against Medco was dismissed by the federal court judge. The other four counts remain.</p> <p>An agreement has been reached with the Justice Department regarding certain counts relating to business practices, but not monetary damages. (See below)</p>
GlaxoSmithKline, P.L.C.	Total: \$87.6 million \$49.6 million for federal claims \$38 million for state claims	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	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	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	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.
Bayer Corp.	\$14 million	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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TAP Pharmaceutical Products (a joint venture between Abbott Labs and Takeda Chemical Industries, Ltd.)	\$875 million	2001	Lupron	<p>1) TAP sales reps. provided free Lupron samples to physicians, knowing and expecting that those physicians would prescribe/administer such samples to their patients and then illegally bill those free samples to various federal health care programs.</p> <p>2) Reps. offered physicians a variety of incentives as a way to maintain Lupron's market share and encourage physicians to prescribe Lupron including:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>4) TAP knowingly misreported/underpaid its best price for Lupron.</p>
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Genentech, Inc.	\$50 million	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	1998		Promoted drugs to major retail drug stores in violation of Massachusetts' anti-kickback statute.
Miles, Inc.	\$605,000	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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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.

¹ This chart includes a sampling of current, on-going investigations and is not intended to be an exhaustive list.

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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: <i>McRae v. SmithKline Beecham Corp d/b/a GlaxoSmithKline</i>	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.

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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.
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.
Several pharmaceutical manufacturers, including Bristol-Myers Squibb	Santa Clara County, California	August 2005	Drugs reimbursed by Medicaid	The suit alleges the manufacturers overcharged Medicaid by inflating the price of drugs that were supplied to hospitals, clinics and jails. The county is seeking class action status on behalf of other counties.

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Johnson & Johnson	U.S. Attorney Office for Massachusetts, Boston	July 2005	Natrecor	The subpoena requests information relating to the sales and marketing of the congestive heart failure drug.
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.
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 they were not offered to Medicaid.

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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.
Sandoz Inc., Ivax Pharmaceuticals, Purepac Pharmaceuticals, Alharma, Inc. Alharma 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.

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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 ²	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.
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.

² In 2004, the Senate Finance Committee requested information from pharmaceutical manufacturers including GlaxoSmithKline.

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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.
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.

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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.
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.

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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 Nexium 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 requests documents related to the sales and marketing of Procrit. J & J indicated that it is cooperating with the subpoena.
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.

**PHARMACEUTICAL MANUFACTURERS: PUBLIC SETTLEMENTS AND
RECENT INVESTIGATIONS RELATED TO MARKETING, PRICING AND ASSOCIATED ACTIVITIES. ¹**

SELECT PUBLIC INVESTIGATIONS

Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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.
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.

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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.
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.

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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.
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

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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.
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.

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
Medco Health Solutions	Qui tam action U.S. Attorney for the Eastern District of Pennsylvania	June 2004	Allegations relating to rebating and reporting practices and kickbacks	On June 2, 2004, Medco was granted permission and announced it had received a letter from U.S. Attorney Patrick Meehan stating that a sealed qui tam action was pending in the Eastern District of Pennsylvania. The complaint was filed September 26, 2003 and alleges violations of the Federal False Claims Act. 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 alleges that Medco offered and paid kickbacks to induce placement of its products on formularies and for the promotion of its products.
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.

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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.
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).
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.

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
Schering-Plough Corp.	Massachusetts U.S. Attorney's Office	April 2004	Proventil, Vancertil, Vancenase, Nitro-Dur, Imdur, K-Dur, and Claritin	<p>Additional subpoena in this investigation requesting</p> <ul style="list-style-type: none"> • 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 <p>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.</p>
aaPharma Inc.	Independent investigation	April 2004	Earnings statements; Brethine & Darvocet	<p>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.</p>
Pfizer	U.S. Department of Justice	April 2004	Genotropin & Bextra	<p>Investigation relating to the marketing and sale of Genotropin and Bextra, as well as certain managed care payments.</p>

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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.
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 Pleas 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.

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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.
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 ³	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.

³ See pharma manufacturer counterpart letter of June 2003.

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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.	Jan. 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.
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.	Jan. 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.

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Wyeth Pharmaceuticals	Inspector General at the Office of Personnel Management (OPM) OPM is responsible for administration of the Federal Employees Health Benefits Program.	Jan. 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.
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.

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Johnson & Johnson, Ortho-McNeil Pharmaceutical Inc.	Boston U.S. Attorney's Office	December 2003	Topamax (epilepsy)	Subpoena from U.S. attorney's office in Boston requesting documents related to sales and marketing of Topamax.
Medco Health Solutions (formerly known as Merck-Medco) U.S. <u>ex rel.</u> 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	<p>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.</p> <p>In March 2003 the government filed the original complaint in the 1999 false claims whistleblower case⁴ 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.</p> <p>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.</p>

⁴ Originates from the subpoena issued in the Spring of 1999.

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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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Bristol-Myers Squibb	<ul style="list-style-type: none"> (1) SEC and DOJ (2) U.S. Attorney in Massachusetts (3) House Committee on Energy and Commerce 	July 2003	Unavailable	<ul style="list-style-type: none"> (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.

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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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 ⁵	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.
Wyeth	Justice Department	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.

⁵ 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 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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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.

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Schering-Plough	Massachusetts U.S. Attorney's Office	November 2002	Intron A & Rebetrone (hepatitis C drugs), Temodar (oral chemotherapy agent for brain tumors)	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>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.</p>
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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Pharmaceutical Company¹	Government Agency	Approximate Date of Request or Disclosure of Request	Product	Summary of Significant Description/Allegations Based on Public Information
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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(1) SmithKline Beecham (2) TAP Pharmaceutical Products, Inc.	House Commerce Committee	(1) Sept. 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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PHARMACEUTICAL MANUFACTURER KEY INTERACTIONS WITH PART D PLAN SPONSORS:

Overview of Regulatory Considerations

May 1, 2006

Wendy C. Goldstein, Esq.
Epstein Becker & Green, P.C.



PRESENTATION OVERVIEW

- I. Relevant Part D Program Statistics
- II. Contracting with Part D Plans for Price Concessions
- III. Corporate Compliance Programs



**I. RELEVANT PART D
PROGRAM STATISTICS**

I. PART D PROGRAM STATISTICS

- According to a 4/20/06 DHHS Press Release:

CATEGORY	NUMBER
Number of beneficiaries enrolled in Part D	> 30 million (includes > 8 million beneficiaries who have “new” Rx coverage since Part D program began)
Number of beneficiaries who have enrolled in stand alone PDPs	> 8 million
Number of beneficiaries who have enrolled in MA-PDs on their own since the MA-PD program began	~ 1 million
Number of retirees who are enrolled in the Medicare retiree subsidy	~ 6.8 million

I. PART D PROGRAM STATISTICS

- As of today, products offered by entities affiliated with only 6 parent companies have almost 70% of the total enrollment in all PDPs.
 1. UHC – Pacificare
 2. Humana Inc.
 3. Wellpoint, Inc.
- As of today, products offered by entities affiliated with only 5 parent companies have almost 55% of the total enrollment in all MA-PDs.
 1. UHC – Pacificare
 2. Kaiser Permanente
 3. Humana Inc.

I. PART D PROGRAM STATISTICS

- To date, the top States include, PDP and MA-PD enrollment combined:
 - California*
 - Florida
 - Illinois
 - New York*
 - Pennsylvania
 - Texas*

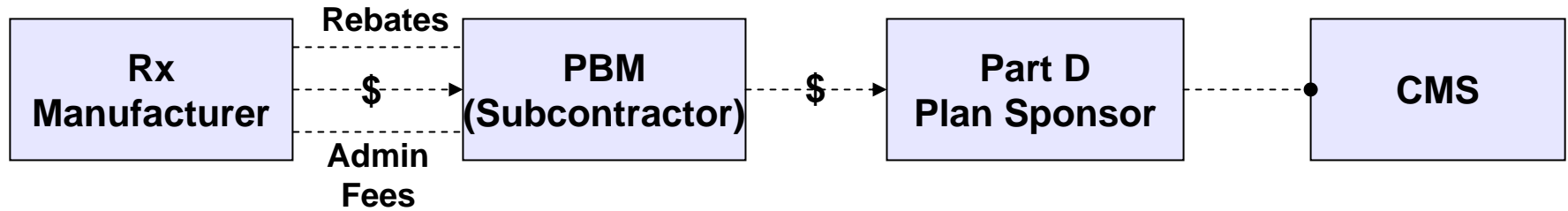
*** Designates state with highest dual-eligibles auto enrollment**

I. PART D PROGRAM TIMELINE

DATE	EVENT
1/1/06	Part D Benefit starts
4/1/06	90-day transition period ends
4/17/06	Proposed CY 2007 formulary submissions due
5/15/06	Enrollment period for Part D benefits in 2006 ends
5/19/06	CY 2007 bids submission opens
6/6/06	CY 2007 marketing material review process starts
10/1/06	Marketing period for CY 2007 begins
10/31/06	Marketing for CY 2006 plans through public media ends
11/15/06- 12/31/06	Annual election period for CY 2007 (open enrollment)
1/1/07	2007 Plan benefit begins

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS



OR



II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

1) REPORTING PRICE CONCESSIONS

www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_01.25.06.pdf

Section X. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

Part D Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D Sponsor's operational costs. CMS recognizes the importance of maintaining confidentiality of these records. CMS will do everything within its authority to limit access to those who have appropriate use or oversight role and will track those who have accessed these records.

Rebates, discounts, and other price concessions will be reported at the CMS Part D Sponsor level. Reporting will not be combined by the subcontractor PBM to include multiple Part D Sponsor data. For example: (1) national Part D sponsors with multiple regional plans contracting independently or through a PBM will report rebates from the level of the national Part D sponsor; (2) regional or local Part D sponsor whether utilizing subcontractor PBM or not report at the Part D sponsor specific level; (3) PBM providing Part D coverage outside of a subcontractor role will report rebates at the PBM level. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	September 30	December 31	March 31	June 30

Data files to be uploaded through the HPMS at the CMS Part D Sponsor level as specified above:

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

1) REPORTING PRICE CONCESSIONS

- Part D Plans are expected to report to CMS Rebates:
 - Manufacturer Name
 - Brand Name
 - Rebate Received
 - Pending Rebate
 - Prior Rebate
- Part D Plans may require Rx manufacturers to certify the accuracy of the data used to calculate rebates.
 - Review carefully the scope of the certifications, reps, warranties to determine which way the information is flowing
 - Avoid overbroad language – facilitation claim (?)

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

1) REPORTING PRICE CONCESSIONS

- Example:

“Pharma agrees that it shall validate and pay the Rebates to Part D Plan in an accurate and complete manner, based upon all information available to Pharma at the time of such validation. Pharma further agrees that all supporting documentation furnished by Pharma in connection with Rebate calculations and payment shall be accurate and complete and adequate to support the applicable Rebates payment.”

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

2) REPORTING PRICE CONCESSIONS – OTHER

- Medicare Part D Reporting Requirements requires Part D Plan Sponsors to report “Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions”
- “Other Price Concessions” include
 - Non-rebate discounts, price concessions
 - Other Value adds such as gifts-in-kind or other programs (e.g., coupons or disease management programs specific to Part D Plan Sponsors)

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

2) REPORTING PRICE CONCESSIONS – OTHER

- CMS acknowledges that these other price concessions will not be reportable in the same format described above – additional Excel file will be needed
- Information will include:
 - Manufacturer name
 - Description of the price concession or the value add
 - Value of the price concession or the value add.
 - Justification for receipt of the price concession or the value add

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

2) REPORTING PRICE CONCESSIONS – OTHER

- Rx Manufacturers should consider all such non-rebate arrangements
 - Characterization of the programs from Rx Manufacturer perspective (service agreement) vs. CMS (price concession) perspective
 - Personal services safe harbor elements
 - Discount safe harbor
 - Part D business: Part D Plan Sponsor reporting activities
 - Non- Part D business:
 - intent of the program - price concession?
 - Affect on Government price filings

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

3) COVERED PART D DRUGS

- Part D Plans are expected to negotiate prices with manufacturers for “Covered Part D Drugs”
- Part D Drugs are defined as:
 1. Dispensed only upon a prescription
 2. FDA - approved for safety and efficacy
 3. A biological product
 4. Insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, gauze
 5. Vaccines
- A drug is considered a Part D Drug if prescribed for a medically accepted indication
 - Covered Part D Drugs specifically exclude drugs, drug classes or medical uses that are excluded/restricted under the Medicaid program. See, 1860D-2(e)(2) of MMA

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

3) COVERED PART D DRUGS

- Is the Rx Manufacturer paying rebates to the Part D Plan Sponsor for utilization of excluded indications/drugs?
- Chapter 9 Part D Program to Control Fraud, Waste and Abuse Guidance, pg. 64
“ Thus it is the responsibility of the Part D Plans to prohibit the inappropriate payment for these excluded drugs or indications, i.e., edits or prior authorizations.”
- PDPs?
- Do the Rebate Agreements provide protection?
 - Carve-outs
 - Audits

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

3) COVERED PART D DRUGS

- Do the Rebate Agreements provide protection?
 - Excluded transactions from rebate payments
 - Data sets
 - Audit rights
- Rx Manufacturer Liability?
 - Market share

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

4) LTC REBATES

- In the Preamble to the Part D Regulations and Issue Paper 26, “High Quality Access to Long-Term Care Pharmacies” (1/21/05), CMS shows it is aware that some manufacturers make performance payments or extend Discounts to large LTC Pharmacies.
 - Queries whether it will continue
- CMS FAQ #6326 (11/28/05)
 - “[R]ebates or discounts paid to LTC pharmacies to provide access or move market share in the context of Part D could create significant fraud and abuse concerns...”
 - “...the principles of MMA ... clearly contemplate that the rebates will inure to the benefit of the Medicare beneficiaries who purchase those drugs. This will not occur unless there is full disclosure to the Part D sponsor that these rebates are being paid. The plan sponsor would then have to account for this benefit in the plan's bid...”

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

4) LTC REBATES

- CMS Final Part D Plan “Call Letter” (4/06)
 - “Sponsors shall have a provision in all pharmacy contracts that requires pharmacies to fully disclose any and all discounts and rebates or any other direct or indirect remuneration from drug manufacturers or other parties when such remuneration is designed to directly or indirectly influence or impact utilization of Part D drugs. Such disclosure shall detail the source of the funds, the purpose and the specific dollar amounts paid to the pharmacy from the manufacturer for these purposes.”

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

4) LTC REBATES

- Are manufacturers permitted to continue to contract with LTC Pharmacies?

“To the extent that a LTC pharmacy is being paid by a manufacturer to move market share in the context of a Part D plan without the knowledge or approval of a Plan, not only does this raise the same concerns about increased program and beneficiary costs, but if a manufacturer is paying price concessions to LTC pharmacies in exchange for formulary access or moving market share, the LTC pharmacy may be inducing demand for higher-tiered or non-formulary drugs and thus actually increasing the costs to the plan and the government.”

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

4) LTC REBATES

- Include provisions that require LTC pharmacies to disclose rebates to Part D Plans
- Include exception to confidentiality provisions in LTC rebate agreements to permit disclosure by manufacturer to Part D Plans
- Reps and warranties relating to the coordination with drug utilization management programs of Part D Plan Sponsors
- Consider rebate structure – market share vs. access
- What else?

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

5) EMPLOYER SUBSIDY

- Consider the prescription drug utilization of retirees who are enrolled in employer health plans where the employer is participating in the Federal Drug Subsidy Program
 - Commercial rebate agreement v. Part D rebate agreement?
 - Formulary considerations
- Does the commercial rebate agreement with the health plan expressly exclude utilization that is reimbursable by the Federal government?
 - What is the scope of the exclusion?
- Separate lines of business
 - Medicare
 - Commercial

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

5) EMPLOYER SUBSIDY

- Is the utilization under a “qualified retiree prescription drug plan” = Part D utilization?
- Clearly express intent in the contract
- Consider Best Price implications
 - Price concessions offered in connection with the Part D benefit are excluded from the Best Price calculations
 - Price concessions offered in connection with a qualified retiree prescription drug plan also are excluded from the Best Price calculations
- Employer certifications relating to retiree drug subsidy application
- Operational considerations to flag claims

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

6) ADMINISTRATIVE FEES

- Administrative fees Paid by Rx Manufacturers to PBMs
 - Per Part D final Regulation, to the extent administrative fee represents “fair market value” for “bona fide services” then the administrative fee is not a price concession
 - Distinction from other CMS guidance regarding administrative fees
 - Best Price, Average Manufacturers Price and ASP
 - Fair market value is defined as the value paid by the majority of participants in the marketplace
 - Is there a duty for PDP to inquire?
 - If not fair market value, must be treated as a price concession
 - Reported to PDPs and CMS
 - Inconsistent with other fair market value guidance

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

6) ADMINISTRATIVE FEES

- Administrative fees to PBMs
 - For third party Part D Plans?
 - For Part D Plans sponsored by PBM?
- Require appropriate disclosures of administrative fees to Part D Plans
 - GPO safe harbor (42 C.F.R. § 1001.952(j)) for guidance
 - Part D Regulations

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

6) ADMINISTRATIVE FEES

- Administrative fees to PBMs
- For third party Part D Plans?
- For Part D Plans sponsored by PBM?
- Best Practice Considerations:
 - Require appropriate disclosures of administrative fees to Part D plans
 - Look to GPO safe harbor (42 C.F.R. § 1001.952(j)) for guidance

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II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

7) SPAPs

- State pharmaceutical assistance programs (SPAPs) have been enacted by the states to assist uninsured or underinsured residents in obtaining prescription drug coverage at reasonable prices.
- Currently, there is significant activity underway to re-examine and restructure SPAPs in light of the Part D Drug benefit to ensure coordination among the state benefit and the myriad of formularies offered by the Part D Plan sponsors.
- Some SPAPs will “wrap around” coverage with Part D Plans (e.g., in the “donut hole”)

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

7) SPAPs

- Potential “double dip” issue -- Part D Plan and SPAP may seek rebates on same claims
 - SPAPs may be exempt from inclusion in Best Price
 - Each SPAP requires an analysis prior to participation
- Address double dipping in Part D contracts (***and*** SPAP contracts, if negotiable)
 - Default = primary payor on an Rx claim gets rebate?

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

8) NO-CAUSE TERMINATION

- Common in commercial rebate agreements
- Challenging in Part D context because:
 - Part D Plans may change the therapeutic categories and classes of drugs only at the beginning of each year or as permitted by the HHS Secretary to take into account newly approved covered Part D drugs and new therapeutic uses
 - Part D Plans may not remove a drug from its formulary or change a drug's preferred or tiered cost-sharing status unless the PDP notifies CMS, affected beneficiaries, physicians, pharmacies and pharmacists
 - As of last week, enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year, with some exceptions -- if new research shows the drug was unsafe or if a new generic equivalent becomes available

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

8) NO-CAUSE TERMINATION

- If an Rx manufacturer seeks to include such a provision, a longer time frame may be more appropriate to recognize Part D limitations

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

9) SWAPPING

- Contract Negotiations
 - Many Part D Plans also offer commercial products
 - As a result manufacturers may have more than one relationship with the entity
 - Rebate negotiations for the separate lines of businesses should be separated to prevent improper conduct
 - EXAMPLE:
 - If a manufacturer offers greater price concessions or better terms for the commercial business in order to influence the FHCP business, there is a potential swapping issue.
 - Safe harbor for discounts does not protect reductions if offered to one payor, but not to Medicare or Medicaid

II. CONTRACTING WITH PART D PLANS FOR PRICE CONCESSIONS

9) SWAPPING

- To the extent possible, “firewall” commercial and Part D rebate negotiations
- If a firewall is not possible, train (and document training of) individuals with rebate contracting or managed care responsibilities regarding keeping deals separate
- Maintain separate contracts for Part D and commercial business
 - Part D regulations
 - Audit rights
 - Payments disputes

II. CONTRACTING WITH PART D PLANS FOR BONA FIDE SERVICES

10) Bona Fide Service Arrangements

- Consistency between the characterization of relationships as service arrangements or price concessions
 - Commercial
 - Part D
- How is the payment reported?
 - Government price reporting
 - By Part D plan Sponsor

II. CONTRACTING WITH PART D PLANS FOR BONA FIDE SERVICES

10) Bona Fide Service Arrangements

- Potential guidance in other context
 - Personal Services and Management Agreement Safe Harbor including (but not limited to) -
 - Fair Market Value
 - Arms-Length Transaction
 - Commercially reasonable
 - Not based on the volume or value of referrals between the parties
 - Written, detailed agreement

II. CONTRACTING WITH PART D PLANS FOR BONA FIDE SERVICES

10) Bona Fide Service Arrangements

- Potential guidance in other context
 - Part B - Average Sales Price Guidance:
 - “Bona fide service fees’ means expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities”

III. CORPORATE COMPLIANCE PROGRAMS

III. CORPORATE COMPLIANCE PROGRAMS

- Medicare Part D

“[G]iven the size of the program, all the usual forms of fraud, including kickbacks, bribes and unmeritorious service contracts, could be magnified under Part D. On the drug side, common frauds like... promotion of off-label uses of drugs represent vulnerabilities of the new program.”

- John Bettac, inspector with HHS OIG Office of Investigations, November 8, 2005 as reported by BNA Health Care Daily

III. CORPORATE COMPLIANCE PROGRAMS

- Medicare Part D

- Presentation by James G. Sheehan, Associate United States Attorney: Fraud Issues in the Operation of Pharmacy Benefits Under Medicare Part D
 - Identified issue relating to computation of TrOOP when manufacturers provide vouchers, coupons and other assistance
 - Compliance officers should be aware of possible kickbacks in their business relationships (refers to AdvancePCS settlement)
 - Lists forms that kickback payments might take:
 1. Newsletters to physicians
 2. Disease management programs
 3. Patient file review programs
 4. Closed category fee
 5. Formulary fee
 6. Data fee Medicare Part D

III. CORPORATE COMPLIANCE PROGRAMS

- **OIG Work Plan**
 - 26/117 OIG Work Plan items relating to Medicare Drug Items
 - Part D Drug Reimbursement (ASP, AMP, BP, CAP, ESRD ...)
 - Part D Administration (Integrity, safeguards, TrOOP, Marketing Materials, Part D Plan Sponsor's use of formularies, P&T Committee operations)

III. CORPORATE COMPLIANCE PROGRAMS

- MMA mandates Part D Plans to have a program to control fraud, abuse and waste regarding covered Part D Drugs.
- Part D Regulations include greater detail regarding Part D Plans obligations
 - Articulates the 7 elements (FSS and OIG compliance guidances)
 - Each Part D Plan also must have a “comprehensive fraud and abuse plan” to detect, correct and prevent fraud, waste and abuse, including procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.”
- MEDICs will be used to identify and investigate potential Part D fraud and abuse
 - Referrals to law enforcement
 - Auditor or Part D operations and their subcontractors
 - Areas include – rebates, formulary and P & T Committee

III. CORPORATE COMPLIANCE PROGRAMS

- CMS released the final Prescription Drug Benefit Manual – Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
 - Includes guidance for Part D plans and stakeholders
 - Identifies potential risk areas conducted by among others – Rx manufacturers (Section 70.1.6)
 - Identifies “potential schemes, risks and vulnerabilities to the Part D benefit”
 - Refers to the 3 risk areas from the 2003 OIG Final Compliance Program Guidance for Rx Manufacturers
 - Integrity of reported data, kickbacks, sampling
 - States not an exhaustive list
 - Update corporate compliance programs and initiatives

III. CORPORATE COMPLIANCE PROGRAMS

- Regarding Part D, Rx manufacturer may be liable under FCA, CMPs and AKS if there is data is not reported completely or accurately
 - Update compliance programs to address the following, for example:
 - Characterization of “other price concessions” and service agreements
 - Value of the “other price concessions” or the value add
 - FMV under service agreements
 - Systems used to verify rebate utilization

III. CORPORATE COMPLIANCE PROGRAMS

- Regarding kickbacks and other illegal remuneration, the following examples are provided in Section 70.1.6:
 1. Inappropriate marketing and/or promotion of products and
 2. Inappropriate inducements such as inappropriate discounts, product support services, educational grants, research funding or other remuneration
- Update compliance programs to address the following, for example:
 - Interactions with customers and prescribers using Part D examples
 - Anti-swapping in the context of discounts
 - Product support services and Part D rules

III. CORPORATE COMPLIANCE PROGRAMS

- Regarding formulary and formulary support activities, Section 70.1.6 identifies inappropriate relationships with formulary committee members, payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary as examples of potential fraud and abuse concerns.
 - Greater scrutiny of interactions with P & T Committee members and Part D Decision Makers
 - Carefully select consultants, speakers and advisers

III. CORPORATE COMPLIANCE PROGRAMS

- Regarding potentially inappropriate relationships with between pharmaceutical manufacturers and physicians, Section 70.1.6 identifies
 - “Switching” arrangements (defined when manufacturers offer physicians cash payments or other benefits each time a patient’s prescription is changed to the manufacturer’s product from a competing product)
 - Incentives offered to physicians to prescribe medically unnecessary drugs
 - Consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research funding
 - Improper entertainment or incentives offered by sales agents

III. CORPORATE COMPLIANCE PROGRAMS

- Section 70.1.6 also identifies the following:
 - Illegal promotion of off-label drug usage through marketing, financial incentives or other promotional campaigns.
 - Training required on MMA and Part D Rules
 - Formulary presentations
 - Providing free samples to physicians knowing and expecting those physicians to bill the federal health care programs for the samples.

III. CORPORATE COMPLIANCE PROGRAMS

1. “Expect” the federal (and state) government enforcement agencies to deliver on promises to increase oversight of Part D activities.
2. “Know” that the government has specifically identified Rx manufacturer activities relating to Part D as enforcement targets.

III. CORPORATE COMPLIANCE PROGRAMS

3. “Understand” that Part D Plans legally are obligated to operate comprehensive fraud, waste and abuse programs to identify potential non-compliance, and will be audited on their performance of this compliance function.
4. “Recognize” the significant new potential role for MEDICs in ferreting out and reporting suspected Part D fraud to other law enforcement agencies.

PHARMACEUTICAL MANUFACTURER KEY INTERACTIONS WITH PART D PLAN SPONSORS:

Overview of Regulatory Considerations

May 1, 2006

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