Department of Justice

STATEMENT

OF

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BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

"ALLEGATIONS OF WASTE, FRAUD, AND ABUSE IN PHARMACEUTICAL PRICING: FINANCIAL IMPACTS ON FEDERAL HEALTH PROGRAMS AND THE FEDERAL TAXPAYER"

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Testimony
of

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Committee on Oversight and Government Reform
United States House of Representatives

"Allegations of Waste, Fraud, and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"

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Chairman Waxman, Ranking Member Davis, I appreciate the opportunity to appear before you to discuss some of the issues that are the focus of today's hearing. We are grateful for the Committee's leadership on this important topic and to you, Mr. Chairman, for allowing us this opportunity to discuss our enforcement efforts.

I have been asked to provide testimony concerning the efforts of the Department of Justice to combat fraud and abuse by drug manufacturers and others in connection with the delivery of pharmaceuticals. The Department of Justice remains committed to root out and punish corporate wrongdoers, and to recover dollars lost through fraud on our Federal programs, and that commitment takes on even added urgency in the context of health care fraud, where the public dollars are so large and where fraud often has a direct impact on public health. That is why the Department of Justice, through the Civil and Criminal Divisions and through the U.S. Attorney's Offices, continues to fairly and vigorously enforce the various laws at our disposal to deal with those companies and individuals that steal from the taxpayers.

By no means, however, is the Department of Justice alone in the fight to combat fraud and preserve the integrity of the country's health care system. We work closely with our colleagues at the Centers for Medicare and Medicaid Services (CMS), at the Department of Health and Human Services and its Inspector General, with the Food and Drug Administration (FDA), with the Federal Employees Health Benefits Program (FEHBP), at the Office of Personnel Management and it Inspector General, and with our State law enforcement partners in their Offices of Attorneys General and Medicaid Fraud Control Units. Working with our colleagues, since 1999 the Department has obtained recoveries, including criminal fines, as well as Federal and State civil settlements in pharmaceutical fraud matters involving losses to Federal

and State programs that have exceeded $5.3 billion. We have many matters currently under investigation, implicating pricing and marketing practices relating to hundreds of drugs.

It is clear from our experience that drug company violations of the law are causing government healthcare programs to pay too much for prescription drugs. We are not seeing isolated instances of misconduct, but repeated practices within the industry that have resulted in significant losses to Federal health care programs, including Medicare, Medicaid and the Federal Employees Health Benefits Program, among others. We are looking at alleged unlawful practices in the way manufacturers have reported prices which have been historically relied on by Medicare and Medicaid to set their reimbursement rates.

We are also investigating allegations that manufacturers knowingly mis-report to the government the "best prices" for their pharmaceuticals, thereby reducing the rebates they owe by law to the Medicaid program, which funds healthcare for the needy in this country. We have seen fraud in the manner in which pharmacy benefit managers (known as PBMs) administer the drug benefits in our Federal health care programs. And a significant portion of our law enforcement effort is focused now on the practices of manufacturers to promote the sale of their pharmaceuticals for "off label" uses, that is, those not approved by the FDA. These types of illegal conduct can be best illustrated by the successful investigations we have brought, many of which have been initiated by *qui tam* relators possessing "inside" knowledge. The lessons learned from these cases may prove useful to you as you consider possible reforms.

As I mentioned, one of our focuses has been a practice involving the manner in which manufacturers have historically reported their prices to national reporting services which have been used, in turn, by Medicare and Medicaid to establish rates of reimbursement under those programs for pharmaceuticals. This practice has been called "marketing the spread." The manufacturer inflates the prices it reports to the reporting services, and the Federal programs establish a reimbursement rate in reliance on those inflated prices. The manufacturer then charges its customers -- often physicians or other providers -- lower prices, and in many cases much lower, than Medicare and Medicaid reimbursement rates. The manufacturer is then able to market, as an inducement to buy its products, the "spread" between the purchase price and the amount the purchaser will receive from Medicare and Medicaid. We have also seen in connection with some of these cases other inducements offered by the manufacturers to influence purchases. We have successfully pursued a number of manufacturers on this theory.

In the largest settlement of its kind**, TAP Pharmaceutical Products Inc. (TAP),** a joint venture between Abbott Laboratories and Takeda Chemical Industries, paid $875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing of the cancer drug, Lupron. Under an agreement with the Department in 2001, TAP pled guilty in the District of Massachusetts to a conspiracy to violate the Prescription Drug Marketing Act and paid a $290 million criminal fine. To resolve its civil liability under the False Claims Act, TAP agreed to pay the United States $559.4 million for filing fraudulent

claims with Medicare and Medicaid, and to pay $25.5 million for filing fraudulent claims with the States.

Many State Medicaid programs, and during the time period that was at issue, the Medicare program, reimbursed covered drugs in part, on Average Wholesale Price (AWP). The government alleged that TAP set and controlled the price at which the government programs reimbursed physicians for the prescription of Lupron by misreporting its AWP as significantly higher than the average sales price TAP offered physicians and other customers for the drug. TAP allegedly marketed the spread between its discounted prices paid by physicians and the significantly higher Medicare and Medicaid reimbursement based on AWP as an inducement to physicians to obtain their Lupron business. The government further alleged that TAP concealed from Medicare and Medicaid the true discounted prices paid by physicians, and falsely advised physicians to report the higher AWP rather than the real discounted price for the drug. Another component of this case concerned TAP's failure to include the costs of the contingent free goods it offered to physicians in its "patient start program"(under which urologists received free goods for every patient they switched to Lupron) in the best price calculations it reported to CMS.

Similarly, **AstraZeneca Pharmaceuticals LP (AstraZeneca)** pled guilty in the District of Delaware to violating the Prescription Drug Marketing Act and paid $355 million to resolve criminal charges and civil liabilities in connection with its drug pricing and marketing practices arising from its sales of Zoladex, a drug used primarily for the treatment of prostate cancer and the main competitor product to TAP's Lupron.

As part of the plea agreement, AstraZeneca paid a $63.9 million criminal fine, paid $266.1 million to resolve allegations that the company caused false and fraudulent claims to be filed with the Medicare, TriCare and the Railroad Retirement Board Medicare programs, and paid $24.9 million to resolve allegations that its drug pricing and marketing misconduct resulted in false State Medicaid claims.

Our investigation revealed that from January 1991 through December 31, 2002, employees of AstraZeneca provided thousands of free samples of Zoladex to physicians, knowing and expecting that certain of those physicians would prescribe and administer the free drug samples to their patients and thereafter bill those free samples to the patients and to Medicare, Medicaid, and other federally funded insurance programs. In order to induce certain physicians, physicians' practices, and others to purchase Zoladex, AstraZeneca offered and paid illegal remuneration in various forms that included free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting services, and honoraria.

Also, to induce physicians to purchase Zoladex, the United States alleged that AstraZeneca marketed a "Return-to-Practice" program to physicians. In a scheme similar to that engaged in by TAP, AstraZeneca inflated the Average Wholesale Price used by Medicare and

Medicaid for drug reimbursement, deeply discounted the price charged to physicians for the drug, and then marketed the spread between the AWP and the discounted price to entice physicians with the additional profit they stood to gain from Medicare and Medicaid. AstraZeneca set the AWP for Zoladex at levels far higher than what the majority of its physician customers actually paid. As a result, AstraZeneca's customers received reimbursement from Medicare and State Medicaid programs at levels significantly higher than the physicians' actual costs or the wholesalers' average price.

Much like in the TAP case I just mentioned, AstraZeneca also had an extensive free goods discounting program for urologists, including a program under which urologists received free goods for every patient switched to Zoladex, purportedly designed to familiarize office staff and patients with the delivery method of the drug. Because it did not include free goods in its calculations of best price for Zoladex, Zeneca falsely reported its best price to CMS in each of the 24 quarters we examined and consequently underpaid its rebates to the States.

We have reached other civil False Claims Act settlements with a number of manufacturers to resolve allegations of "marketing the spread".

In 2005, **GlaxoSmithKline** paid over $155 million to settle Federal and State civil claims that it had marketed the spread and offered the spread as an inducement in violation of the False Claims Act and Medicare-Medicaid Anti-Kickback statute in connection with its anti-emetics, Kytril and Zofran, used primarily in conjunction with oncology and radiation treatment. As part of a condition for doing business in the future with providers who do business with the Medicare and Medicaid programs, GlaxoSmithKline agreed to enter into an addendum to an existing Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services that, among other things, requires the company to report accurate average sales prices and average manufacturer's prices for its drugs covered by Medicare and other Federal healthcare programs.

Bayer Corporation entered a $14 million settlement in 2001 with the Department to resolve allegations arising from its sale of pharmaceuticals and biological products to government health care programs. The Government alleged that Bayer reported inflated wholesale acquisition costs (WACs), used to establish Medicaid reimbursement, and falsely reported that certain products were not sold to wholesalers and, therefore, no WACs existed.

In 2004, **Warrick Pharmaceuticals Corporation**, agreed to pay the United States and Texas $27 million to settle allegations that it had defrauded the Texas Medicaid program by inflating its reported WACs to national reporting services. In 2003, the State of Texas and the Department settled similar allegations involving the Texas Medicaid program with **Dey, Inc**. for $18.5 million.

We are now in litigation in a multidistrict proceeding in Boston with three manufacturers -- **Abbott, Dey** and **Boehringer Ingelheim Roxane** -- where we have alleged the companies violated the False Claims Act and the Medicare-Medicaid Anti-Kickback statute for marketing the spread in connection with certain of their drugs.

Another area we have targeted in our law enforcement efforts has involved allegations that manufacturers knowingly violated the Medicaid Drug Rebate Statute. In general, the statute requires that with respect to single source or innovator multiple source drugs, manufacturers must report their best price to Medicaid and rebate the difference between the average manufacturers price (AMP) and best price, or a specified percentage of the AMP, whichever is greater. The purpose of the rebate program is to ensure that the Nation's insurance program for the poor receives the benefit of discounts on drugs available in the marketplace. This best price is defined as the lowest price available from the manufacturer to any "wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity within the United States" with certain specified exclusions. The law requires that manufacturers determine best price "without regard to special packaging, labeling, or identifiers on the dosage form or product or package." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(II). It also requires that with respect to single source or innovator multiple source drugs manufacturers pay rebates to each State Medicaid program each quarter, calculated as the product of (I) the total number of units of each dosage form and strength paid for under the State plan in the rebate period, and (ii) the greater of either the difference between average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price. §§ 42 U.S.C. 1396r-8(c)(1)(A) and (B). By overstating the best price (as well as understating the average manufacturer's price), a drug company unlawfully reduces its obligation to pay rebates in violation of the Medicaid program.

In 2003, **Bayer** and **GlaxoSmithKline** entered into agreements to resolve similar allegations of fraud in connection with their reporting under the Medicaid Rebate Statute. We determined through our investigations that "private labeling" is a device used by some manufacturers to affix the customer's label and, more importantly, the customer's National Drug Code (NDC) to the drug to avoid the manufacturer's statutory reporting or payment obligations with respect to that drug. Although private labeling has legitimate uses in the industry, for example, where a chain pharmacy wants to offer a store brand in addition to a brand name product, the practice may run afoul of the Medicaid Rebate program where it is done to avoid the manufacturer's best price reporting or rebate obligations.

In the Bayer investigation, the United States Attorney's Office in Boston alleged that Bayer private labeled two of its most popular drugs, Cipro and Adalat CC. The government alleged that Bayer's private label arrangements were intended to provide deeply discounted prices on these drugs to the HMOs while evading its statutory and contractual obligations to provide the same favorable prices to the Medicaid program. In addition, Bayer submitted false statements to the Office of Audit of the Inspector General for the Department of Health and

Human Services and to the FDA to further conceal its obligation to pay additional Medicaid rebates in connection with private labeling.

The Government's investigation concluded that Bayer failed to pay rebates owed to the Medicaid program and overcharged certain Public Health Service entities at least $9.4 million. Bayer pled guilty in the District of Massachusetts to a one count criminal Information of violating the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 331(p), 333(a)(2), and 360(j), and failing to list the private label product with the FDA, and it paid a criminal fine of nearly $5.6 million. Together with the agreed-upon civil settlement amount of $251.6 million, the total resolution was $257.2 million.

In a related investigation, **GlaxoSmithKline (Glaxo)** paid $87.6 million to settle similar allegations based on its relationship with the HMO, Kaiser Permanente Medical Care Program (Kaiser). We learned that at the time of our investigation, Kaiser provided care and treatment to more than 6 million persons and often purchased drugs directly from drug manufacturers to save on costs for its members. That is perfectly legal. However, we learned also that Glaxo – much like Bayer had done – provided discounted prices to Kaiser for its drugs and engaged in "private labeling" for Kaiser, affixing different labels to its drug products to avoid reporting the low prices to CMS. Glaxo also repackaged and privately labeled Paxil, an anti-depressant, and Flonase, a nasal spray at discounted prices for Kaiser and then failed to report these lower prices as part of its mandated "best price" calculation submitted to the government.

Both settlements also ensured full repayment to the Public Health Service program, a safety net for the Nation's most vulnerable citizens, which provides certain drug pricing protections to clinics, community health centers and hospitals that treat the country's poorest citizens. Drug companies are required to offer pricing concessions to PHS entities based in part on the Medicaid rebates they owe. Both companies executed a corporate integrity agreement with HHS-OIG, designed to ensure that they accurately report their "best price" information to the Government.

In 2004, **Schering Plough** paid $292.9 million to resolve allegations arising from its contracts with two managed care customers. The government alleged that Schering entered into two contracts to ensure that its drug, Claritin, stayed on the customers' formularies while evading its Medicaid rebate obligations and derivative Public Health Service liability. The government alleged that from 1998 through 2000, Schering provided additional "value" to PacifiCare to ensure that Claritin stayed on PacifiCare's formulary. Our investigation revealed that, with one exception, the value of these additional price concessions was not credited in Schering's calculation of the Medicaid "best price" reported to CMS and not used by the manufacturer in determining rebate obligations.

The investigation, conducted in the Eastern District of Pennsylvania, also determined that from 1999 through 2002, Schering provided additional "value" to Cigna to ensure that Claritin

stayed on Cigna's formulary. Once again we concluded that none of the value of these additional price concessions was credited in Schering's calculation of its Medicaid best price reported to CMS and was not used in determining rebate obligations. Schering paid more than $282.3 million to settle its Medicaid liability, and more than $10.6 million to resolve its liability to the Public Health Service.

A parallel criminal investigation was conducted against Schering and, as a result, Schering Sales Corporation pled guilty to one count of offering and paying a kickback in violation of 42 U.S.C. §1320a-7b. The plea arose from Schering Sales Corporation's payment of a "data fee" for data already obtained in connection with Schering's efforts to maintain formulary status for Claritin at Cigna. Schering Sales Corporation paid a criminal fine in the amount of $52,500,000 pursuant to the plea, over and above the $292.9 million paid to resolve its civil liability.

King Pharmaceuticals, Inc. paid $75 million in 2006 to resolve allegations that it underpaid rebates owed under the Medicaid program. King paid an additional $50 million to several State governments based on the same allegations. The settlement addressed King's alleged understatement of the "average manufacturer price" as well as its overstatement of its "best price." In a similar matter against **Parke-Davis,** a subsidiary of **Pfizer,** we alleged that the company provided discounts to a large managed care account in Louisiana without properly reporting those discounts to CMS under the obligations created by the Medicaid Rebate program. Our investigation revealed that Parke-Davis provided at least $250,000 of discounts to the Louisiana managed care account in exchange for an agreement that the managed care account extend unrestricted drug formulary status to Lipitor and sign a contract to buy Lipitor. The government alleged that these discounts were reported neither to the CMS as part of the best price calculations, nor to the States. The matter settled when Pfizer paid $49 million to settle State and Federal Medicaid claims.

A third area we have addressed relates to the services provided to Federal healthcare programs by pharmacy benefit managers. In the past several years, the Department has resolved matters with **Advance PCS** and **Medco Health Solutions,** two of the Nation's largest PBMs.

Advance PCS paid $137.5 million in 2005 to resolve its civil liability under the False Claims Act and the Public Contract Anti-Kickback Act arising from payments made by pharma manufacturers for favorable treatment in connection with its drugs, and payments by Advance PCS to customers and potential customers who had contracts with federally funded healthcare plans to ensure Advance PCS was selected or retained as their PBM.

In 2006, **Medco** agreed to pay the United States $155 million plus interest to settle allegations that the Parsippany, N.J.-based company submitted false claims to the government, solicited and accepted kickbacks from pharmaceutical manufacturers to favor their drugs, and paid kickbacks to health plans to obtain business. Medco manages the prescription drug benefits

of over 60 million Americans, including millions of Medicare beneficiaries. We had alleged that Medco submitted false claims for mail order prescription drug services it was required by contract to provide to millions of Federal employees, retirees and their families under the Federal Employees Health Benefits Program. Additionally, we alleged that the company cancelled valid prescriptions it could not timely fill in order to avoid paying penalties under its contract; shorted pills from prescriptions it filled; failed to conduct concurrent drug utilization review for all prescriptions in order to identify potential adverse drug interactions; and, when filling prescriptions, used drugs other than those prescribed by the physician to earn undisclosed rebates from drug manufacturers. The government also alleged that the company violated the Public Contract Anti-Kickback Act by soliciting payments from pharmaceutical companies to favor their products on Medco's published list of drugs, and by paying kickbacks to induce health plans to award contracts to provide the mail order pharmacy benefits for plan beneficiaries. As a condition of continued participation in government health programs, the United States required that Medco enter into a corporate compliance agreement with the Office of Inspector General, Department of Health and Human Services; and with the Office of Inspector General of the Office of Personnel Management.

Finally, as I alluded to earlier, the most active area for the Department in recent years has arisen from allegations involving violations of the Food, Drug and Cosmetic Act, including off label marketing and unlawful promotional activities.

One of the leading cases in this area involved **Warner-Lambert**, which was acquired by Pfizer in 2000, acting through its wholly-owned pharmaceutical division, Parke-Davis. The allegation was that Parke Davis engaged in the illegal marketing and promotion of the prescription drug Neurontin for uses that were not approved by the FDA. This was another matter initiated by the filing of a *qui tam* that alleged that the drug Neurontin, which had been approved by the FDA as an adjunct therapy for epilepsy, had been marketed by Pfizer for numerous other "off-label" and unapproved uses, such as for the treatment of pain and psychiatric conditions.

While doctors are permitted to prescribe drugs for uses that are not approved by the FDA, pharmaceutical companies must specify the intended use of a product in its new drug application to the FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses - any use not specified in an application and approved by FDA. As a general proposition, the Federal law and regulations governing Medicaid reimbursement do not provide for reimbursement for off-label prescriptions where the use is not medically accepted. The government alleged that Parke-Davis' marketing scheme induced physicians to prescribe Neurontin for off-label uses through a variety of means, including the fraudulent practices of the payment of kickbacks to doctors and distribution of false statements to doctors about the safety, efficacy and approval status of Neurontin. Neurontin was launched into the marketplace in February of 1994; from mid-1995 to at least 2001, the growth of off-label sales was tremendous. While not all of these sales were the consequence of Warner-Lambert's illegal marketing, the

marketing scheme was very successful in increasing Neurontin prescriptions for unapproved uses.

Under the terms of the settlement, Warner-Lambert pled guilty in the District of Massachusetts to a criminal information charging it with violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(a)(2). Because Warner-Lambert had previously been convicted of criminal violations under the FDCA in 1996, these misdemeanor offenses became felonies under 21 U.S.C. §333(a)(2). As part of the $430 million settlement amount, Warner-Lambert paid a criminal fine of $240 million and paid $190 million to resolve Federal and State Medicaid claims, and to resolve State consumer protection claims. **Pfizer Inc.**, Warner-Lambert's parent company, agreed to comply with the terms of a corporate compliance program, which ensures that the changes Pfizer made after acquiring Warner-Lambert in June 2000, are effective in training and supervising its marketing and sales staff, and ensures that any future off-label marketing conduct is detected and corrected on a timely basis.

In the wake of the **Parke Davis** settlement, we have resolved a number of very significant cases. In 2005, the Swiss corporation **Serono, S.A.**, one of the world's largest biotech manufacturers, paid $704 million to resolve criminal charges and civil liabilities in connection with several illegal schemes to promote and sell its drug, Serostim. These schemes had resulted in the submission of false claims to Medicaid and other federally funded health care programs. The FDA had granted accelerated approval for Serostim in 1996 to treat AIDS wasting, a condition involving profound involuntary weight loss in AIDS patients, then a leading cause of death in AIDS patients. Following the advent of protease inhibitor drugs, the incidence of AIDS wasting markedly declined, and Serono launched a campaign to create a market for Serostim.

Serono pled guilty to conspiring with RJL Sciences, a medical device manufacturer, to unlawfully promote a device called a bioelectrical impedance analysis (BIA) device, for use in measuring body cell mass ("BCM") and diagnosing so-called "BCM wasting." This was an adulterated medical device because the FDA had not approved the devices for these uses. RJL and its owner also pled guilty to their roles in the conspiracy. In addition, Serono pled guilty to conspiring to offer doctors kickbacks in the form of free trips to Cannes, France, to induce them to prescribe Serostim.

The $704 million Serono settlement consisted of $305 million (plus accrued interest) paid by Serono to resolve civil False Claims Act allegations, $262 million plus interest paid to State Medicaid programs, as well as $136.9 million in criminal fines. The government alleged that Serono knowingly caused the submission of false claims for Serostim that were not eligible for reimbursement because they were for medically unnecessary or medically unaccepted indications and because the claims were for prescriptions induced by kickbacks to physicians and pharmacies.

This past year, **Eli Lilly and Company** agreed to plead guilty and to pay $36 million in connection with its illegal promotion of its pharmaceutical drug Evista. In pleading guilty to a criminal count of violating the Food, Drug, and Cosmetic Act by misbranding its drug Evista, the Indianapolis-based company agreed to pay a $6 million criminal fine and forfeit to the United States an additional sum of $6 million. In addition to the criminal plea, Lilly 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.

Evista is approved by the FDA for the prevention and treatment of osteoporosis in postmenopausal women. The government alleged that the first year's sales of Evista in the U.S. were disappointing compared to Lilly's original forecast; the company reduced the forecast of Evista's first year's sales in the U.S. from $401 million to $120 million. In order to expand sales of the drug, it was alleged, Lilly sought to broaden the market for Evista by promoting it for off-label uses, such as for the prevention and reduction in risk of breast cancer, and the reduction in the risk of cardiovascular disease. Lilly promoted Evista as effective for reducing the risk of breast cancer, even after Lilly's proposed labeling for this use was specifically rejected by the FDA.

In another case concluded during the past year, **InterMune, Inc.** agreed to enter into a deferred prosecution agreement and to pay nearly $37 million arising out of its illegal promotion of Actimmune. The Information, filed in the Northern District of California, charged InterMune with violating the Food, Drug, and Cosmetic Act by promoting Actimmune for the treatment of idiopathic pulmonary fibrosis (IPF), a condition for which the drug has not been approved by FDA. Actimmune has been approved to treat rare conditions affecting a small number of patients. InterMune sought to increase the market for Actimmune by promoting it for IPF, a debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts a significant number of patients.

The illegal conduct involved, in particular, a press release issued by InterMune that deceptively portrayed the results of a clinical trial for Actimmune as demonstrating the drug's survival benefit in patients with IPF. In fact, the trial had failed as to all of the endpoints specified in the study protocol, including patient survival. With InterMune's approval, the misleading information in the press release was distributed both to pulmonologists who treat IPF and directly to their patients. InterMune disseminated this misleading information despite having been informed by FDA representatives that more clinical evidence was required to demonstrate Actimmune's safety and efficacy before the agency could approve the drug to treat IPF.

Also this past year, **Schering-Plough Corporation**, together with its subsidiary, Schering Sales Corporation, agreed to pay a total of $435 million to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for its drugs Temodar, used in the treatment of brain tumors and metastasis, and Intron A, used in the treatment of

superficial bladder cancer and hepatitis C. The resolution also pertained to Medicaid fraud involving Schering's drugs Claritin RediTabs, a non-sedating antihistamine, and K-Dur, used in the treatment of stomach conditions.

Schering Sales Corporation agreed to plead guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry concerning certain illegal promotional activities by the company's sales representatives at a national conference for oncologists. The false statements were designed to reassure the FDA that the promotional activities were isolated ones and not directed by the home office when, in fact, the activities were widespread and part of the national marketing plan. In addition, the company sought to falsely lull the FDA into believing it had taken appropriate steps to reinforce the message to its sales force that such promotion was prohibited when, in fact, the company knew and expected that those activities would continue.

Schering Sales also agreed to plead guilty to charges that it conspired with others to give free Claritin Redi-Tabs to a major health maintenance organization (HMO) to disguise a new lower price being offered to the HMO to obtain its business. Under the Medicaid Rebate statute, drug companies must report their best price on certain drugs provided to certain commercial customers, including HMOs, to HHS, and to pay quarterly rebates to the Medicaid program, in order to ensure that Medicaid obtains the benefit of that low price. From April 1998 through 1999, the company reported a false best price to the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) which failed to include the new low price of Claritin Redi-Tabs provided to the HMO, in order to avoid paying millions in additional rebates to Medicaid.

The $435 million settlement included a criminal fine of $180 million, a civil settlement under the False Claims Act for $159 million, as well as a resolution of the company's liability to the States and the District of Columbia for $91 million. The Public Health Service programs that were also entitled to a lower price on certain drugs received $3.9 million. In addition, Schering Sales was permanently excluded from participation in Federal health care programs and Schering Plough Corporation agreed to amend an existing corporate integrity agreement and extend that agreement by two years.

Now, I would like to quickly add here that under no circumstances are our attorneys attempting to inhibit the professional judgment of medical professionals who prescribe drugs for purposes not yet approved by the FDA. We know that physicians are permitted to prescribe medications for off label uses as they see fit in their medical judgment. A drug manufacturer's dissemination of reprints of peer reviewed medical journal articles, reference textbooks, and independent continuing medical education regarding the safety and efficacy of drugs can be beneficial to health care practitioners and their patients. However, as we saw in the Parke-Davis and Serono cases, certain companies may seek to vastly increase their market share by promoting their products for off-label purposes, by disseminating false and misleading evidence

to support those unapproved uses, and by bestowing gifts and other remuneration on doctors to influence their prescription writing practices. Clearly, the law does not give drug manufacturers carte blanche to promote drugs for off-label uses by any means. Nor does the law create vast exceptions that render the Food Drug and Cosmetic Act or the Anti-kickback statute inapplicable to pharmaceutical manufacturers.

From these efforts, we have learned that pharmaceutical manufacturers engage in very aggressive -- and sometimes illegal -- methods to assure the commercial success of their products. We also have learned:

- By manipulating and then marketing the "spread" between the Medicare or Medicaid reimbursement rate and the amount the pharmacy or doctor actually pays for a drug, the manufacturers are able to induce purchases of their drugs and obtain market share, all at the expense of government programs. Although the MMA redresses this problem on a going-forward basis for Medicare Part B reimbursed drugs by using average sales prices as the operative reimbursement benchmark, the Medicaid program remains vulnerable to the schemes at issue in the TAP, AstraZeneca, Warrick, and Dey cases.

- Manufacturers have engaged in abuses of the Medicaid Rebate statute, a law that was designed to ensure that the Medicaid program obtain the savings that manufacturers offered to other large commercial customers, however those savings were passed along. A close examination of the statute and the potential need for enhanced provisions is timely and warranted by the issues that have arisen in our enforcement efforts.

- By providing free pharmaceuticals to physicians and then instructing them how to bill Medicare and Medicaid for the free products, manufacturers have surreptitiously caused the government to pay for the illegal kickbacks with which they induce physicians to prescribe their drugs. By disguising the true nature of these free products, manufacturers obscure their best prices and deny these cash strapped programs of the full benefit of the rebate program. Best price violations that affect Medicaid also directly impact Public Health Service entities, whose prices are based on a derivative formula.

- By inducing physicians to prescribe for uses that have not been approved by the Food and Drug Administration, either by promoting compromised "science" or offering financial incentives, manufacturers are subverting a healthcare system that necessarily relies on the objective medical judgment of practitioners, and their actions may also harm the public health.

- The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), remains a vital law enforcement tool in assuring that sound medical judgment is not subverted by the payment of inducements that sometimes cause medical professionals to prescribe drugs based on financial considerations and not medical necessity or safety.

CONCLUSION

As you can see, the Department has been very active in this area. We have been greatly assisted by industry insiders who have taken advantage of the *qui tam* provisions of the False Claims Act, but we also have been fortunate to have prosecutors who have waded into these complex and difficult cases in a successful effort to protect the integrity of the Nation's health system.

As you well know, the government is providing prescription medication to our Nation's elderly and often neediest citizens, and it is doing so at a time when resources are increasingly scarce. We simply cannot afford to let government-funded health care programs be victimized by the schemes that I have discussed here today. Toward that end, I know I speak for Attorney General Gonzales when I say that the Department of Justice will continue to work with this Committee and its staff to identify problems and work toward formulating solutions.

Again, I thank the Committee for seeking the views of the Department of Justice on these issues. The Committee can be assured that the Department will continue to play a lead role in policing the healthcare system for fraud and abuse, and will work with this Committee in addressing the myriad issues which I have briefly discussed this morning.