Testimony

Before the
House Oversight and Government Reform Committee

U.S. 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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February 9, 2007
10:00 a.m.
2154 Rayburn House Office Building

Office of Inspector General
Department of Health and Human Services
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Good morning, Chairman Waxman, Ranking Member Davis, and distinguished members of the Committee. I am Lewis Morris, Chief Counsel at the Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to appear before you today to discuss health care fraud and abuse involving the pharmaceutical industry.

OIG has successfully pursued specific cases of fraud and abuse and conducted audits, inspections, and program evaluations to identify systemic vulnerabilities related to prescription drug coverage under Federal health care programs. My testimony today will focus on the enforcement work that OIG and our law enforcement partners have undertaken to combat fraud in the pharmaceutical industry. I will describe three categories of fraudulent and abusive schemes that OIG has identified: fraud in prescription drug pricing, fraud in prescription drug marketing, and fraud in the delivery and dispensing of prescription drugs. I will conclude by presenting some of OIG's strategies to address the problems identified.

The Medicare and Medicaid programs have paid too much for prescription drugs because of fraudulent and abusive schemes targeted at Federal health care programs. Some of this behavior increases health care program costs and can distort medical decisionmaking by putting the financial interest of the prescribing physician ahead of the well-being of the patient. In other cases, unscrupulous providers exploit vulnerabilities in the reimbursement systems, resulting in additional costs to taxpayers.

Prescription drugs play an increasingly critical role in health care. Consequently, expenditures for drugs by the Federal health care programs, including Medicare and Medicaid, are growing rapidly. Medicaid expenditures for prescription drugs in 2005 were estimated at $41 billion, a more than four-fold increase over the $8.9 billion spent in 1994.[1] Prior to 2006, Medicare covered a limited number of prescription drugs. Even so, Medicare expenditures for prescription drugs increased from approximately $1.4 billion in 1994 to $10 billion in 2005.[2] In 2006, the Medicare Part D drug benefit greatly expanded Medicare's coverage of prescription drugs.

Health Care Fraud Involving the Pharmaceutical Industry

Federal and State law enforcement agencies are devoting substantial resources to investigating and prosecuting fraud schemes involving manufacturers and others in the pharmaceutical industry. Working with our law enforcement partners, OIG has

[1] Sources: National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* and CMS, State Drug Utilization Data.

[2] Source: OIG analysis of data from Medicare's Part B Extract Summary System.

participated in the investigation of pharmaceutical fraud cases that have resulted in more than $4 billion in recoveries.[3] Although the specifics of each case vary, the cases can be generally divided into three categories: 1) pricing schemes, 2) marketing schemes, and 3) drug delivery and dispensing schemes.

Fraud in Prescription Drug Pricing

Average Wholesale Price Manipulation

Prior to 2005, the Medicare Part B and Medicaid programs paid for prescription drugs based on the manufacturer's "Average Wholesale Price" (AWP), as described below. The Medicare program has now changed its reimbursement methodology, but many States continue to use AWPs as the basis for Medicaid reimbursement for certain drugs.

Generally, pharmaceutical manufacturers set an AWP for each of their drugs and report the AWPs to data collection agencies. Each State, in turn, obtains the AWP information from the data collection agencies and uses it in setting Medicaid reimbursement for prescription drugs. However, the AWP payment methodology is susceptible to abuse. For example, if a manufacturer reports an inflated AWP, Medicaid reimbursement for the drug will, in turn, be inflated. By reporting an AWP that far exceeds the price at which the drug actually is sold to providers, including physicians, the manufacturer creates a significant price differential between the provider's cost for the drug and the amount the provider will receive in reimbursement for the drug from Medicaid. This price differential is known as "the spread," and physicians who buy drugs administered to their Medicaid patients can profit from it.

Some manufacturers have aggressively used an inflated price spread as a marketing tool to gain market share for their products. Purposeful manipulation of the spread to induce purchases of federally payable drugs implicates the criminal Federal anti-kickback statute (discussed below). For example, a manufacturer manipulated a drug's AWP to create an artificially high spread and then had its sales representatives show doctors reimbursement comparison sheets that graphically demonstrated the profits the doctors would realize by purchasing one product over another.

The Government has settled several cases involving price manipulation schemes of the sort I have described. These settlements illustrate how manufacturers have used the spread to sell drugs in particularly competitive sectors of the pharmaceutical market. For example, Glaxo Wellcome and SmithKline Beecham Corporation were competing with each other in the market for anti-emetics, drugs that help control nausea in patients receiving oncology and radiation treatments. According to the Government's investigation, both companies reported fraudulently inflated AWPs and used the resulting spreads to gain market share. The companies eventually merged, and in 2005, GlaxoSmithKline settled a $149 million case with the United States in connection with the illegal pricing and marketing of these drugs.

[3] This figure includes criminal and civil resolutions with pharmaceutical manufacturers, pharmacy benefit managers, retail pharmacy chains, and institutional pharmacies since 1999.

The Government also resolved criminal and civil cases against two other market competitors who used an artificial AWP spread to promote their products to treat prostate cancer. In 2001, TAP Pharmaceutical Products, Inc., pleaded guilty to criminal charges and paid a total of $875 million to resolve an investigation relating to the marketing of Lupron. In 2003, AstraZeneca Pharmaceuticals LP entered into a $355 million settlement with the Government for similar conduct relating to its drug, Zoladex. During the investigation, OIG learned that the sales representatives of the two companies had routinely called on the same urologists and employed a variety of tactics, including "marketing the spread," to persuade the physicians to prescribe their respective company's drug. Over time, the companies continued to inflate their AWPs to create an even more lucrative illicit spread for their drugs, and some physicians even switched their patients back and forth between Lupron and Zoladex to profit from the artificially inflated spreads. Moreover, the Government contends that the scheme enabled the companies to pass the cost of the physicians' extra profits on to the Federal health care programs.

Fraud in the Medicaid Drug Rebate Program

Another area of pricing fraud involves the Medicaid drug rebate program. This program, designed to reduce expenditures by the Medicaid program, mandates that drug manufacturers provide Medicaid with certain rebates on drugs provided to Medicaid patients. The amount of a rebate is determined by a statutorily defined rebate formula. Manufacturers must report to CMS certain pricing information by drug, including the "Average Manufacturer Price" and, for some drugs, the "Best Price." OIG cases have focused primarily on abuses related to Best Price, which, subject to certain exceptions, should be the lowest price (net of most discounts and rebates) at which a manufacturer sells the drug. For many drugs, the lower a manufacturer's Best Price is, the higher that manufacturer's potential rebate liability will be.

Most discounts must be included in the Best Price calculation, and manufacturers understand that providing a discount could increase the rebate owed to the Medicaid program. Because the rebates are based on the total volume of the drug reimbursed by the State, even a small per unit increase in the rebate can dramatically increase the amount of the total rebate owed to the State. To avoid this, some manufacturers have knowingly mischaracterized discounts by structuring them as educational grants, sham data processing fees, or similar arrangements in an attempt to disguise their status as discounts. The objective is always the same—the preferred customer gets the drug at a deep discount and the manufacturer avoids additional rebate obligations to the State Medicaid programs.

Two cases illustrate how pharmaceutical manufacturers have circumvented the Medicaid drug rebate program. In the first case, according to the Government's investigation, Warner-Lambert paid unrestricted grants to a managed care organization (MCO) in return for favorable formulary treatment for its drug Lipitor. The grant, in effect, substituted for a discount in the price of the drug. However, Warner-Lambert did not include the value

of this grant when calculating its Best Price for Lipitor. In 2002, the United States entered into a $49 million settlement with Pfizer Inc., the company that acquired Warner-Lambert, to resolve the case.

In the second case, the Schering-Plough Corporation allegedly provided financial incentives to two MCOs after they threatened to remove Claritin from their drug formularies, absent deeper discounts on the product. Schering-Plough chose not to lower its price. Rather, it offered the MCOs an array of incentives, including a series of large cash payments described as "data processing fees." Schering-Plough did not include these incentives and "fees" in its calculation of the Best Price for Claritin. In reality, the investigation showed that the data furnished in exchange for the fees had no practical value to Schering-Plough and were already required under the MCO's contract with the manufacturer. According to the Government's investigation, the phantom data processing fees simply substituted for a discount in the price of Claritin. In 2004, the United States entered into a global settlement for almost $293 million with Schering-Plough relating to this scheme.

Impact of Medicaid Drug Rebate Fraud on the 340B Program

Errors or fraud in Medicaid drug rebate information also adversely affect the 340B program. The 340B program, which is managed by the Department's Health Resources and Services Administration (HRSA), provides for sales of outpatient drugs at or below a specified maximum price to certain health care safety net providers (340B entities) such as disproportionate share hospitals, federally qualified health centers, and the Ryan White CARE Act's AIDS Drug Assistance Programs. HRSA estimates that the nearly 12,000 340B entities will spend $4 billion on outpatient drugs in FY 2007.

Although the 340B program differs fundamentally from Medicare and Medicaid in that it does not entail the submission or direct payment of claims, the prices at which 340B entities purchase drugs are statutorily linked to the Medicaid drug rebate program. Under the 340B program, participating drug manufacturers sign an agreement stipulating that they will charge 340B entities at or below a maximum amount, known as the 340B "ceiling price." Ceiling prices are guaranteed whether the 340B entity purchases drugs directly from a manufacturer or through a wholesaler. The ceiling price for each drug is calculated using a statutorily defined formula that is based on the drug's Average Manufacturer Price and the Medicaid rebate amount per unit. Thus, if a drug manufacturer reports a Best Price that does not include all discounts for Medicaid rebate purposes, both the rebate amount and the 340B ceiling price may be adversely affected—the Medicaid program may receive smaller rebates, and the 340B entities may pay too much for the drug.

In view of the connection between the Medicaid drug rebate program and the 340B program, the Government has resolved the 340B pricing fraud during settlement negotiations in Medicaid drug rebate cases. In several instances, manufacturers (including King Pharmaceuticals, Inc., Schering-Plough, Bayer Corporation, and GlaxoSmithKline) have agreed to reimburse the 340B entities for what the Government

believes were overpayments that resulted from illegal manipulation of the Medicaid drug rebate data.

Fraud in the Marketing of Drugs

Illegal Kickbacks

The Federal anti-kickback statute is a criminal prohibition against remuneration (in any form, whether cash or in-kind, direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care business. Marketing practices involving remunerative arrangements implicate the statute. Thus, sales practices that may be common or longstanding in other business sectors are not necessarily acceptable or lawful when Federal health care programs are involved. Illegal marketing activities, including the payment of kickbacks to prescribing physicians or the use of kickbacks to promote drugs for unapproved uses, pose a risk to patients, as well as to the integrity of Federal health care programs. Perpetrators of unlawful kickback schemes may be subject to criminal, civil, and administrative sanctions.

The anti-kickback statute exists for a number of important reasons, two of which are particularly relevant in the context of the marketing and sale of prescription drugs. Kickbacks potentially increase the costs to Federal programs because they encourage overutilization and may encourage the prescribing of more expensive drugs when clinically appropriate and cheaper options (such as generic drugs) may be equally effective. Equally troubling, kickbacks can compromise the independence of medical decisionmaking by putting the financial interests of the physician ahead of the welfare of the patient.

In OIG's experience, kickbacks offered to prescribing physicians by pharmaceutical manufacturers take a variety of forms, ranging from free samples for which the physician bills the programs to all-expense-paid trips and sham consulting agreements. For example, the TAP and AstraZeneca cases discussed previously involved several different kickback schemes designed to increase sales of the companies' prostate cancer drugs. One scheme involved manipulating AWPs and "marketing the spread." The artificially inflated profits realized by the physicians were, in the Government's view, unlawful kickbacks to induce the purchase of the companies' products.

Under a second scheme, TAP and AstraZeneca sales representatives gave physicians free samples of their prostate cancer drugs in return for ordering their products. Although a drug manufacturer may lawfully give a physician drug samples for use by his or her patients, the physician may not sell the samples. If the samples are sold, the profits realized are remuneration that may implicate the anti-kickback statute. The sales representatives knew and expected that the physicians would bill Medicare and other Federal health care programs for the samples and be reimbursed between $400 and $500 for each unit of the drug. The consequence for patients was harmful as well. Senior citizens suffering from prostate cancer paid their physicians a 20 percent Medicare

copayment (approximately $100) for drug samples that should have been provided to them for free.

OIG has found that some drug companies, aided by aggressive sales forces intent on meeting their sales goals, can be very creative in finding ways to induce physicians to order their products. For example, one aspect of the $704 million global settlement with Serono, Inc. involved a kickback in the form of an all-expenses-paid trip for a select group of high-prescribing physicians (and their guests) to a conference in Cannes, France. This trip was part of a concerted sales campaign by the Serono sales force to generate $6 million in sales of its AIDS wasting drug in 6 days from those same physicians.

The $430 million settlement with Pfizer Inc., demonstrates another common form of kickback: the sham consulting agreement. In that case, OIG's investigation showed that physicians received substantial fees for attending expensive dinners or conferences, purportedly for serving as "consultants." The physicians also participated in promotional events, including lavish weekends at resorts and events held at the 1996 Atlanta Olympics and in Hawaii. The Government's investigation found that, in reality, the physicians provided few or no significant consulting services.

Off-Label Promotion

Another significant area of fraud involves improper "off-label promotion." Off-label promotion is the promotion of a product for a use not approved by the Food and Drug Administration (FDA). FDA approves drugs for only those particular uses proven to be safe and effective and sometimes approves a product for only a single, narrow use. While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.

OIG has identified many instances in which promotional and marketing efforts have gone far beyond the approved use. By promoting their products for non-FDA-approved uses, manufacturers may cause the submission of false or fraudulent claims to Medicare, Medicaid, and other Federal health care programs. Moreover, many of these off-label marketing schemes also involve illegal kickbacks to induce sales for non-FDA-approved uses.

OIG's investigations suggest that some pharmaceutical manufacturers may be engaged in a wide range of abusive practices that provide false and misleading information about the safety or efficacy of products for non-approved uses. These practices include:

- using so-called "medical science liaisons" that present themselves (often falsely) as scientific experts in a particular disease to promote off-label uses;

- sponsoring purportedly objective "independent" medical education events designed to discuss off-label uses. In fact, the manufacturer provides extensive subjective input about the topics, speakers, content, and participants of these events; and

- proffering ghost-written articles about off-label uses. In these schemes, manufacturers pay physicians to "write" advocacy articles about off-label uses of products that are, in fact, written by the manufacturer. This practice is particularly insidious, because the publication of such articles in certain medical compendia may be sufficient to qualify the off-label use for reimbursement under some State Medicaid programs.

Financial harm to Medicare and Medicaid is only one problem caused by off-label promotion. Off-label promotion may lead physicians to prescribe a product for a non-approved use based on false, misleading, or erroneous information to the medical detriment of their patients. In addition, off-label promotion fundamentally circumvents the FDA drug approval process, on which Americans rely to evaluate the safety and efficacy of pharmaceutical products.

Fraud in the Delivery of Prescription Drugs

In addition to investigating fraud by pharmaceutical manufacturers, OIG has investigated and resolved cases involving pharmacies and pharmacy benefit managers (PBMs). These schemes typically involve fraud and abuse in the delivery of drugs or other operational aspects of the programs.

For example, OIG has investigated a number of cases involving retail pharmacy chains that allegedly billed Medicaid for prescription drugs that were not provided to beneficiaries. Since the late 1990s, the United States has entered into a series of settlements with national retail pharmacy chains (including CVS, Eckerd, and Rite-Aid) relating to claims submitted by these pharmacies to Medicaid for alleged "short-filled" prescriptions. Based on our investigations, the Government found that when pharmacies were unable to provide the full amount of the medication prescribed, they nonetheless billed Medicaid for the entire amount of the prescription. In total, this short-fill fraud resulted in the collection of more than $30 million in settlements with these pharmacy chains.

OIG and its law enforcement partners also have pursued cases in which pharmacies switched the drug prescribed to the patient to exploit Medicaid reimbursement rules. For instance, in November 2006, the Government entered into a $49.5 million settlement with Omnicare, Inc., a nationwide institutional pharmacy that exclusively serves nursing home patients. The investigation found that Omnicare switched generic Zantac tablets with capsules to avoid a Federal payment upper limit set by CMS and the "maximum allowable cost" set by State Medicaid programs for the tablets. By these and other drug switches, Omnicare gained additional Federal and State dollars to which it was not otherwise entitled.

PBMs undertake several functions in the provision of prescription drug benefits. These functions may include price negotiations with drug manufacturers, the development of formularies, and the provision of mail order pharmacy services to members of health

plans. The Government's recent $155 million settlement with the Medco Health Solutions, Inc., a PBM, involved a range of alleged improper conduct that harmed Medicare and other Federal programs, including the Federal Employee Health Benefits Program. The Government's investigation found that Medco had solicited and received kickbacks from manufacturers to induce Medco to promote their products submitted false claims to health plans for services allegedly provided by Medco's mail order pharmacy business, and offered and paid kickbacks to health plans to induce them to enter contracts with Medco.

These cases serve as cautionary tales about the activities of pharmacies, PBMs, and others who play a role in the delivery of drug benefits and who have incentives to exploit the reimbursement rules at the expense of the public and program beneficiaries.

OIG Strategies To Promote Integrity

Federal and State law enforcement agencies continue to investigate many fraud schemes similar to those outlined in my testimony. Criminal and civil investigations are resource intensive, time consuming, and require extensive coordination between Federal and State agencies. Furthermore, the parties engaged in these frauds are adept at modifying schemes in response to Government efforts to strengthen program integrity. The large and growing size of Federal expenditures for prescription drugs will continue to attract those intent on defrauding Medicare and Medicaid. Accordingly, we intend to enhance our existing fraud prevention and detection efforts to meet new challenges as they arise.

OIG is increasingly using its administrative authorities to sanction individuals engaged in fraudulent and abusive practices. Administrative sanctions complement criminal and civil enforcement, providing an additional avenue for Government enforcement. OIG has the authority to exclude individuals and entities from the Federal health care programs and to impose civil monetary penalties for a range of abusive practices, including kickbacks and false claims.

For example, OIG has pursued administrative cases involving kickbacks to physicians, including those involved in the TAP and AstraZeneca schemes described previously. A physician who accepts a kickback from a pharmaceutical manufacturer in return for prescribing its drugs to Medicare patients is as culpable as the drug company that provided the kickback. In some cases, the physician has initiated the crime by demanding the kickback as a condition of prescribing a drug to patients.

In the past, criminal prosecutors targeted their limited resources on companies paying kickbacks and generally did not focus on these physicians. This may have created the misimpression by some physicians that they can demand kickbacks from drug companies with impunity. However, OIG has stepped into this breach and is using its authority to impose program exclusion and significant monetary penalties to target these kickback recipients. Hopefully, OIG administrative enforcement also will prompt physicians to think twice before accepting kickbacks from pharmaceutical companies.

"Pay-and-chase" enforcement alone will not adequately address the problem. For this reason, OIG remains fully committed to promoting the prevention of fraud and abuse through voluntary compliance efforts by the regulated community. We are committed to working with industry stakeholders to ensure the integrity of the Federal health care programs. OIG cannot do it alone.

To this end, OIG issued a "Compliance Program Guidance for Pharmaceutical Manufacturers" (CPG), one in a series of compliance program guidances that OIG developed for the various health care sectors. The CPG provides detailed information for drug manufacturers on establishing and operating an effective internal compliance program and identifying fraud and abuse risk areas. The guidance describes the relevant fraud and abuse authorities and the major risk areas under these laws. It also offers concrete suggestions on ways manufacturers can mitigate their risk. The risk areas include, for example:

- reporting data used to establish or determine Government reimbursement,
- discounts,
- product support services,
- educational grants,
- research funding,
- relationships with formulary committees,
- payments to PBMs,
- formulary placement payments,
- Average Wholesale Price,
- "switching" arrangements,
- consulting and advisory payments,
- business courtesies and other gratuities,
- relationships with sales agents, and
- drug samples.

Although the guidance is targeted at manufacturers, much of its content pertains to PBMs, customers, prescribers, and other parties involved in the provision of prescription drugs. It is important guidance for participants in the new Part D drug benefit. OIG also encourages health care entities who uncover violations of program requirements to use OIG's Self-Disclosure Protocol to resolve their potential liabilities. The Protocol has proven a successful means for OIG to collaborate with health care companies in resolving issues that are identified as part of an effective compliance program.

In addition, OIG issues advisory opinions, fraud alerts, and advisory bulletins on issues of concern to the pharmaceutical industry and other health care entities as part of its overall strategy to encourage compliance. These guidance products, including the CPG, are available to the public on OIG's web site at www.oig.hhs.gov. OIG supplements these guidance efforts with frequent outreach efforts to the regulated industry, its counsel, and the public.

Conclusion

As I have testified, the Medicare and Medicaid programs are vulnerable to fraud and abuse through a number of schemes related to prescription drug pricing, marketing, and delivery. There are no simple solutions to these problems. Those intent on gaming Federal health care programs are adept at modifying their schemes in response to changes in the reimbursement systems and Government enforcement tactics. Consequently, Federal and State agencies must continue to develop proactive enforcement strategies. Of equal importance, pharmaceutical manufacturers and other participants in the health care system should be encouraged to embrace policies and procedures that promote compliance with Federal program requirements.

OIG shares the Committee's commitment to protect the integrity of Federal health care programs and the health and safety of beneficiaries. We will continue to fight fraud in Medicare and Medicaid and promote compliance by the pharmaceutical industry. We will also bring our enforcement and oversight experience to bear as we work to protect the integrity of the Medicare Part D drug benefit. As set forth in more detail in the OIG's 2007 Work Plan, we are undertaking an ambitious effort to monitor the integrity and effective operation of this benefit.

This concludes my testimony. I would be pleased to answer your questions.