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Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry[‡]

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I. INTRODUCTION

The pharmaceutical industry as a whole has come under increased regulatory scrutiny by federal and state governments as well as the plaintiff's bar over the past several years. While the government is more rigorously enforcing the laws, rules, and regulations applicable to the pharmaceutical industry, allegations of fraud and abuse are being aggressively pursued by governmental agencies, including the United States Department of Justice (DOJ), the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS), and the various state attorney generals' offices and Medicaid Fraud Control Units. In addition, on the heels of the government's increased activity, the plaintiff's bar has seized the opportunity, pursuing *qui tam* and other civil actions on behalf of patients, payors, and other persons who have allegedly been injured.¹ This recent and continuing focus on the pharmaceutical

[‡] *Disclaimer:* This paper represents the personal views of the authors and not necessarily of their respective firm or employer. Nothing in this paper may be interpreted as legal advice. Legal advice may only be given based on specific facts and circumstances discussed with properly engaged legal counsel.

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1. A *qui tam* action is brought under 31 U.S.C. §§ 3729 – 3730 (2000), commonly

industry has caused confusion and uncertainty between pharmaceutical manufacturers and the providers and suppliers with whom they conduct federal health care program business.²

This paper attempts to demystify the legal and regulatory environment surrounding the sale of prescription drug products by covering the most recent government enforcement actions focusing on the pharmaceutical industry, the basis for the implementation of a successful compliance program for pharmaceutical manufacturers, and some of the “hot” legal and regulatory issues of which pharmaceutical manufacturers and the providers and suppliers with which they conduct federal health care program business should be aware in 2006 and beyond.

II. RECENT GOVERNMENT ENFORCEMENT ACTIONS FOCUSED ON PHARMACEUTICAL INDUSTRY

A. *Why the Focus*

There are two primary reasons for the increased interest in prosecuting and suing pharmaceutical manufacturers. First, from the perspective of the federal and state governments, the high cost of health care is causing fiscal budgetary concerns. The increased demand and rising cost of prescription drugs is blamed as a primary cause of excessive health care costs. The creation of the Medicare Part D benefit under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), effective January 1, 2006, is only fueling these concerns by making prescription drugs available to Medicare beneficiaries.³ The Medicare Part D benefit means the total dollars spent by the federal government on prescription drugs should greatly increase in the coming years as compared to the amount spent historically when only Medicaid included a prescription drug benefit.

Second, the government views the pursuit of fraud and abuse allegations in the pharmaceutical industry as a priority and plans to aggressively pursue

known as the False Claims Act, originally enacted in March 1863. The *qui tam* provisions allow private citizens to sue, on the government's behalf, companies that defraud the government. “*Qui tam*” is short for the Latin phrase, “*Qui tam pro domingo rege quam pro se ipso in hac parte sequitur,*” which roughly means “he who brings an action for the king as well as for himself.”

2. The term “federal health care program” means “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded directly, in whole or in part, by the United States government” or any state health plan. 42 U.S.C. § 1320a-7b(f) (2000).

3. Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

pharmaceutical manufacturers to recover profits allegedly made at the expense of taxpayers. The Office of Inspector General Work Plan for Fiscal Year 2005⁴ identifies work plans for the OIG that specifically focus on pharmaceutical manufacturers. A similar focus should be expected in the OIG's 2006 work plans. The OIG's final Compliance Program Guidance for Pharmaceutical Manufacturers, released April 28, 2003, also reveals the government's focus on the industry.⁵ Because of the increased spending on prescription drugs under the federal health care programs, the government is anticipating an increase in fraudulent schemes and activities. The OIG Work Plan and Final OIG Guidance, along with an overview of the focus in the United States Congress on the pharmaceutical industry, are discussed below.

To date, federal and state governments have regained more than \$2.4 billion in payment recoveries and fines from pharmaceutical manufacturers for claims of fraud and abuse.⁶ On the coat-tails of these governmental actions, private plaintiffs are also targeting pharmaceutical manufacturers and chasing the same dollars through *qui tam* lawsuits.⁷

According to Peter Keisler, an Assistant United States Attorney General for the Civil Division of the DOJ, there were approximately 100 whistleblower cases under seal involving allegations against over 200 drug manufacturers with respect to 500 different products as of late 2004.⁸ If only one out of ten of these cases settles during 2005 at the same average amount as the settlements to date, the recoveries in 2005 alone will be about \$2.4 billion.⁹ Therefore, the pharmaceutical industry can count on more cases and settlements in 2006 and beyond. The question going forward is not whether there will be future settlements, but rather when the settlements will be announced and how large they will be.

4. Office of Inspector General Work Plan for Fiscal Year 2005 (Oct. 12, 2004), available at <http://www.oig.hhs.gov/publications/docs/workplan/2005/2005%20Work%20Plan.pdf> [hereinafter OIG Work Plan].

5. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) [hereinafter Final OIG Guidance].

6. ANDY SCHNEIDER, TAXPAYERS AGAINST FRAUD EDUCATION FUND, THE ROLE OF THE FALSE CLAIMS ACT IN REDUCING MEDICARE AND MEDICAID FRAUD BY DRUG MANUFACTURERS: AN UPDATE 17 (Nov. 2004), available at <http://www.taf.org/publications/TAFSingle.pdf>.

7. See discussion of "*qui tam*," *supra* note 1.

8. Peter Keisler, Assistant Att'y Gen., Civil Division, U.S. Dep't of Justice, Remarks to the TAFEF Conference for Relators' Counsel, Washington, D.C. (Oct. 14, 2004), cited in SCHNEIDER, *supra* note 6, at 5.

9. SCHNEIDER, *supra* note 6, at 5.

1. OIG Work Plan

The mission of the OIG is to improve HHS programs and operations by protecting them against fraud, waste, and abuse.¹⁰ The OIG Work Plan identifies the project areas perceived as critical to the mission of the OIG and HHS.¹¹

Specific to pharmaceutical manufacturers, the OIG Work Plan states that there will be continued focus on certain Medicare and Medicaid drug reimbursement issues, including average sales price, average manufacturer price (AMP), average wholesale price (AWP), “best price,” classification of generic versus brand-name drugs, and off-label drug promotion.¹² Regarding average sales price, the OIG plans to conduct several studies in 2005 related to the computation of average sales price for various drugs, measure pharmaceutical manufacturers’ methodologies for computing average sales price, and assess the adequacy of the system of the Centers for Medicare & Medicaid Services of the HHS (CMS) for collecting and maintaining average sales price data.¹³ As for the Medicaid drug rebate programs, the OIG will assess CMS’s oversight of pharmaceutical manufacturers’ reporting of average manufacturer price, average wholesale price, “best price,” and the classification of generic versus brand-name drugs to ensure that Medicaid programs do not overpay for prescription drugs.¹⁴ The OIG intends to continue evaluating the adequacy of state systems to calculate and collect Medicaid drug rebates.¹⁵ The OIG also plans to assess the United States Food and Drug Administration’s (FDA) oversight and review of allowable promotion of off-label drug uses by pharmaceutical manufacturers.¹⁶

The OIG and FDA are clearly focused on pharmaceutical manufacturers and want to ensure that applicable laws, rules, and regulations are followed in marketing, obtaining, using, and distributing prescription drugs in order to deter the alleged practice of price inflation by those producers.

10. See OIG Mission, available at <http://www.oig.hhs.gov/organization/OIGmission.html>.

11. OIG Work Plan, *supra* note 4, Introduction at 1.

12. *Id.* at Centers for Medicare & Medicaid Studies at 30-31, Public Health Agencies at 6. Average sale price is used for determining the Medicare reimbursement of certain classes of drugs. Average manufacturer price is used for Medicaid drug rebate purposes and is based on actual sales for drug manufacturers. Average wholesale price is the published catalogue price that most states use as a basis for Medicaid drug reimbursement and also for prescription drugs under the Medicare Part B program.

13. *Id.* at Centers for Medicare & Medicaid Studies at 14-15, 30.

14. *Id.* at Centers for Medicare & Medicaid Studies at 30-31.

15. *Id.* at Centers for Medicare & Medicaid Studies at 31.

16. OIG Work Plan, *supra* note 4, Public Health Agencies at 6.

2. OIG Compliance Guidance for Pharmaceutical Manufacturers

The Final OIG Guidance is the eleventh set of voluntary guidelines published by the OIG. It outlines the principal fraud and abuse risk areas for pharmaceutical manufacturers including the integrity of data used by federal and state governments to establish payment amounts, kickbacks and other illegal remuneration, and compliance with laws regulating drug samples.¹⁷ The Final OIG Guidance is intended to put pharmaceutical manufacturers on notice of the OIG's concern about preventing and reducing fraud and abuse in the federal health care programs related to prescription drugs.¹⁸

3. Senator Chuck Grassley's Comments

Senator Chuck Grassley, the chairman of the U.S. Senate Committee on Finance, was the author of the *qui tam* whistleblower amendments to the False Claims Act (FCA).¹⁹ Enforcement of the FCA and its whistleblower provisions has returned more than \$12 billion to the United States Treasury since it was updated in 1986.²⁰

In a May 13, 2004, memorandum issued to reporters and editors, Senator Grassley commented:

We need to see continued aggressive investigation and pursuit of fraud against the taxpayers by pharmaceutical drug manufacturers. Whistleblowers can be a valuable part of that effort . . . and *the Justice Department obviously must stay committed and send a clear message of zero tolerance.* Drug companies that illegally pad their profits with Medicaid dollars that should be going to help low-income people, including pregnant women and children, must be held accountable.²¹

Senator Grassley's letter to U.S. Attorney General John Ashcroft, written on the same date, emphasized that during the remainder of the 108th Congressional session, the U.S. Senate Committee on Finance would

17. Final OIG Guidance, 68 Fed. Reg. at 23,732.

18. Final OIG Guidance, 68 Fed. Reg. at 23,731.

19. Memorandum from Senator Chuck Grassley, Chair of the U.S. Senate Comm. on Fin. (May 13, 2004), available at <http://finance.senate.gov/press/Gpress/2004/prg051304.pdf> [hereinafter the Grassley Memo]. The FCA imposes civil liability on persons or corporations who, among other things: (1) knowingly present or cause to be presented a false or fraudulent claim for payment to the government; (2) knowingly use a false record or statement to obtain payment on a false or fraudulent claim paid by the government; or (3) engage in a conspiracy to defraud the government to obtain allowance for or payment of a false or fraudulent claim. 31 U.S.C. § 3729 (2000).

20. Grassley Memo, *supra* note 19.

21. *Id.* (emphasis added).

continue to look closely at the business practices of drug companies with respect to the federal health care programs and the exorbitant costs that American taxpayers are paying for drugs.²² Grassley quoted a non-profit organization, Taxpayers Against Fraud, as follows:

Since 2001, the Department of Justice (DOJ) has settled seven cases involving allegations of Medicare and Medicaid drug pricing and marketing fraud against six pharmaceutical manufacturers: AstraZeneca, Bayer, Dey, GlaxoSmithKline, Pfizer, and TAP Pharmaceuticals . . . [a]mong these are three of the top five companies (by sales volume) in the industry: Pfizer (#1), GlaxoSmithKline (#2), and AstraZeneca (#5). *The total paid out by these manufacturers to settle these cases is nearly \$1.66 billion . . . Remarkably, these recoveries resulted from allegations involving just a handful of drug products.*²³

Senator Grassley further stated that:

Every one of these settlements involved Medicaid liability and likely represents just the tip of the proverbial iceberg. With astronomical profits at hand, it appears that some drug companies are not always abiding by the letter of the law, and in other cases not abiding by the spirit of the law . . . Any drug company that improperly lines its pockets with Medicaid dollars, which are intended to benefit low-income Americans, pregnant women and poor children, should know that America's taxpayers, myself included, expect that it should be held fully accountable.²⁴

In April 2004, Senator Grassley and Senator Max Baucus sent letters to nineteen different drug companies requesting pricing information on eight different classes of drugs.²⁵ The main focus of the inquiry was the use of the nominal price exception to "best price" reporting. The letter quoted the Final OIG Guidance, in part, as follows:

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program.

22. *Id.*

23. *Id.* (emphasis added).

24. *Id.*

25. Grassley Memo, *supra* note 19. These nineteen drug companies were Pfizer, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals Inc., Abbott Laboratories, Hoffman-La Roche Inc., TAP Pharmaceutical Products Inc., Schering-Plough Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., Sanofi-Synthelabo, and Eisai, Inc.

Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discounts to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.²⁶

In June 2005, Senators Grassley and Baucus again sent letters to twenty-three different drug companies asking them to explain their “educational grant” programs, which are marketing practices by which the companies give money to state governments and other organizations in forms of grants.²⁷ The senators are concerned that these grants are more focused on product promotion than education, and may improperly influence Medicare and Medicaid purchasing decisions.²⁸ The letter stated, in part:

The Committee has identified the use of grants, particularly educational grants, as a practice with potential for abuse and has gathered the following background information on this topic. The use of educational grants was an element in a recent settlement involving off-label promotion of a prescription drug. Also, educational grants were identified by the Department of Health and Human Services Office of Inspector General (HHS OIG) as a key risk area in its OIG Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guidance), issued in 2003. In addition, existing Federal and industry guidance is not specific about what activities educational grants may be used to support or what kinds of organizations may provide those activities, and it appears that some manufacturers may be using organizational grants to

26. *Id.* (quoting Final OIG Guidance, 68 Fed. Reg. at 23,735).

27. Press Release, U.S. Senate Comm. on Fin., Drug Companies Asked for More Information About Grant Money Awarded to Promote Particular Medicines (June 10, 2005), available at <http://finance.senate.gov/press/Gpress/2005/prg061005.pdf> [hereinafter Finance Committee Press Release]. These twenty-three drug companies were Pfizer, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Sanofi Aventis Pharmaceuticals Inc., Eisai, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Schering-Plough Corporation, Hoffman-La Roche Inc., Forest Pharmaceuticals, Inc., Abbott Laboratories, Genetech, Inc., Biogen Idec Inc., Genzyme Corporation, Chiron Corporation, Serono, Inc., and TAP Pharmaceutical Products Inc.

28. Finance Committee Press Release, *supra* note 27.

fund activities primarily to promote their products.²⁹

B. Recent Federal Government Settlements

The large dollar amount of payment recoveries and fines, along with the large number of pending cases and investigations, clearly demonstrates that federal and state governmental authorities have been actively investigating and prosecuting a number of practices by pharmaceutical manufacturers. All indications are that the government's scrutiny of pharmaceutical manufacturers will continue, and will likely even increase, during the rest of 2006 and the years that follow.

The landmark TAP Pharmaceutical Products, Inc. settlement in 2001 set the standard for future settlements with pharmaceutical manufacturers for fraudulent drug pricing and marketing activities. This was the first FCA settlement with a drug manufacturer involving both civil and criminal fines. TAP agreed to pay a total of \$875 million in criminal fines and civil liabilities.³⁰

A summary of the six most recent federal government settlements with pharmaceutical manufacturers follows. These settlements are significant because they demonstrate the DOJ's commitment to health care fraud enforcement generally and the more specific goal of combating fraud by pharmaceutical manufacturers.³¹ The DOJ has announced that it is committed to rooting out and prosecuting health care fraud to protect Americans from inappropriate conduct by pharmaceutical manufacturers.³²

1. "Value Added" Packages, "Data Fees," and "Risk-Sharing" Arrangements

On July 29, 2004, Schering Sales Corp., the sales and marketing subsidiary of drug manufacturer Schering-Plough Corporation, agreed to pay \$345 million to settle criminal and civil charges for the fraudulent pricing and illegal marketing of Claritin.³³ Schering was charged with offering and paying Cigna Healthcare, a health maintenance organization, a

29. *Id.*

30. Press Release, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2003), available at <http://www.usdoj.gov/opa/pr/2001/October/513civ.htm>.

31. Press Release, U.S. Dep't of Justice, Schering-Plough to Pay \$345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004), available at http://www.usdoj.gov/opa/pr/2004/July/04_civ_523.htm [hereinafter Schering Press Release].

32. See Schering Press Release, *supra* note 31.

33. *Id.*

kickback to induce Cigna to keep Claritin on its formulary (the list of drugs that Cigna covers for its beneficiaries).³⁴ Following Cigna's decision to remove Claritin from its formulary, Schering offered to make up the difference between the price of Claritin and the less expensive alternative Allegra by offering Cigna a "value added" package in lieu of an actual price reduction on Claritin.³⁵ The government alleged that the package included a kickback disguised as a "data fee" of 2% of the value of Schering drugs (the "data fee" in 2000 totaled \$2.4 million), \$3 million worth of deeply discounted Claritin Reditabs, health management services at far below fair market value, and an interest-free loan in the form of prepaid rebates.³⁶

In announcing the settlement, U.S. Attorney for the Eastern District of Pennsylvania, Patrick L. Meehan, said:

Schering used terms like 'data fee' and 'value added' as camouflage for what was nothing more than an old-fashioned kickback . . . This wasn't a mistake. It was a marketing strategy. The result was that programs created to provide healthcare to the poorest among us were actually paying more for drugs than those who have private health insurance. There is a point at which pursuit of market share crosses the line that separates competition and illegal conduct. This case serves as an example that the consequences of stepping over that line can be costly.³⁷

Schering's actions also gave rise to civil liability under the FCA. Under the Medicaid drug rebate statute, drug manufacturers are required to report their "best prices" to the federal government and to pay quarterly rebates to Medicaid to ensure that the nation's insurance program for the poor receives the benefit of the most favorable drug prices offered to other large purchasers of drugs.³⁸ Schering attempted to avoid additional rebate obligations under the Medicaid drug rebate program by funding significant concessions to Cigna and another health maintenance organization, PacifiCare Health Systems, through an assortment of payments and services to disguise the ultimate fact that Schering was offering a lower price for Claritin and not reporting this lower price to the government.³⁹ With Cigna, Schering offered the "value added" package that included "data fees."⁴⁰ With PacifiCare, Schering entered into a "risk sharing" agreement, whereby Schering effectively lowered the price of Claritin by paying a portion of

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. 42 U.S.C. § 1396r-8 (2003).

39. Schering Press Release, *supra* note 31.

40. *Id.*

PacifiCare's costs for antihistamine drugs.⁴¹

Under the terms of the settlement, Schering agreed to: (1) plead guilty and pay a \$52.5 million fine for violating the Medicare and Medicaid Patient Protection Act of 1987 (Anti-Kickback Statute) by paying kickbacks to customers in exchange for the preferred treatment of Claritin on its formulary; (2) settle its liability under the FCA and pay the United States, all fifty state Medicaid programs, and certain public health service entities \$292,969,482 as a result of Schering's failure to report its true "best price" for Claritin; and (3) enter into a corporate integrity agreement with the HHS that addressed sales, marketing and pricing of its drugs to government programs in order to correct its government pricing and Medicaid rebate reporting failures.⁴² As a result of the criminal plea, Schering is excluded from participation in all federal health care programs for at least five years.⁴³

The whistleblowers that began this case, Charles Alcorn, Beatrice Manning and Raymond Pironti, Jr., all former employees of ITG, Inc., a subsidiary of Schering, will receive \$31.6 million of the government's civil recovery.⁴⁴

41 *Id.* Over three years, Schering's "risk sharing" payments to PacifiCare totaled \$25 million. SCHNEIDER, *supra* note 6, at 12.

42 *Id.* See also 42 U.S.C. § 1320a-7b (2003). The Anti-Kickback Statute provides, in pertinent part, that:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person - A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

43. Schering Press Release, *supra* note 31. See also Settlement Agreement and Release by and among the United States of America, Schering-Plough Corp., Charles Alcorn, Beatrice Manning and G. Raymond Pironti, Jr. 1, 20 (July 29, 2004), available at <http://www.usdoj.gov/usao/pae/News/Pr/2004/jul/jul04.html>.

44. Schering Press Release, *supra* note 31.

2. Off-Label Marketing, “Consulting Meetings,” and “Independent Medical Education” Events

On May 13, 2004, Warner-Lambert Company, a subsidiary of Pfizer Inc., agreed to plead guilty and pay more than \$430 million to resolve criminal charges and civil liabilities in connection with its Parke-Davis division’s illegal and fraudulent promotion of unapproved uses for the drug Neurontin.⁴⁵ Under the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), a company must specify the intended uses of a product in its new drug application to the FDA.⁴⁶ Once approved, the drug may not be marketed or promoted for so-called “off-label” uses, which are any uses not specified in an application and approved by the FDA.⁴⁷ It was alleged that Warner-Lambert’s strategic marketing plans showed “that Neurontin was aggressively marketed to treat a wide array of ailments for which the drug was not approved.”⁴⁸ Warner-Lambert used a number of tactics to achieve its marketing goals, including encouraging sales representatives to provide one-on-one sales pitches to physicians about off-label uses of Neurontin, making false or misleading statements to health care professionals regarding Neurontin’s efficacy and whether it had been approved by the FDA for the off-label uses, and paying doctors to attend “consulting meetings” and “independent medical education” at which Warner-Lambert paid for expensive dinners, lavish weekends, and trips to Florida, and even paid for physicians who would listen to presentations about off-label uses of Neurontin to visit the 1996 Atlanta Olympics and Hawaii.⁴⁹ The DOJ said that these tactics were part of a coordinated national effort to implement an off-label marketing plan without seeking FDA approval for any of the new uses.⁵⁰ Warner-Lambert not only promoted Neurontin for off-label uses, but even promoted it for uses even when scientific studies had shown it to be ineffective.⁵¹

In announcing the settlement, Associate United States Attorney General Robert D. McCallum, Jr. stated:

The Department of Justice is committed to rooting out and prosecuting

45. Press Release, U.S. Dep’t of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm [hereinafter Warner Lambert Press Release].

46. 21 U.S.C. § 355 (1999).

47. 21 U.S.C. § 360aaa-3 (1999).

48. Warner-Lambert Press Release, *supra* note 45.

49. *Id.*

50. *Id.*

51. *Id.*

health care fraud . . . It is of paramount importance that the Department use every legal tool at its disposal to assure the health and safety of the consumers of America's health care system, and to pursue companies and individuals that steal from the taxpayers and inflict suffering on patients and families. The Department's commitment to effective health care fraud enforcement is driven by a mandate that wrongdoers be brought to justice, to deter conduct which threatens the safety and welfare of all Americans, and the need to protect the resources of the Medicare Trust Fund, state Medicaid programs, and other government health programs.⁵²

Massachusetts United States Attorney, Michael J. Sullivan, also commented:

This illegal and fraudulent promotion scheme corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk. . . This scheme deprived federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals – judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor. The pharmaceutical industry will not be allowed to profit from such conduct nor subject the poor, the elderly and other persons insured by state and federal health care programs to experimental drug uses which have not been determined to be safe and effective.⁵³

Warner-Lambert and Pfizer agreed to the following under the terms of their settlement: (1) to plead guilty to two counts of violating the FDCA with regard to its misbranding of Neurontin by failing to provide adequate direction for use and by introduction into interstate commerce of an unapproved new drug, and to pay a \$240 million criminal fine; (2) to settle its federal civil FCA liabilities and pay the United States a total of \$83.6 million, plus interest, in civil damages for losses suffered by the federal portion of the Medicaid program as a result of Warner-Lambert's fraudulent drug promotion and marketing misconduct; (3) to settle its civil liabilities to the fifty states and the District of Columbia in the amount of \$68.4 million, for losses the state Medicaid programs suffered as a result of fraudulent drug promotion and marketing misconduct; (4) to settle its civil liabilities to the fifty states and the District of Columbia in the amount of \$38 million for harm caused to consumers and to fund a remediation program to address the effects of Warner-Lambert's improper marketing scheme; and (5) to enter into a corporate integrity agreement to ensure that the changes Pfizer made

52. *Id.*

53. *Id.*

after acquiring Warner-Lambert in June 2000 are effective in training and supervising its marketing and sales staff.⁵⁴

The whistleblower in this case, Dr. Franklin, a former medical liaison for Warner-Lambert, will receive \$24.64 million of the civil recovery.⁵⁵

3. Marketing the Spread and Texas Medicaid Fraud Prevention Act

a. Warrick

On May 3, 2004, Schering Corporation, Schering-Plough Corporation, and Warrick Pharmaceuticals Corporation (a division of Schering-Plough Corporation), agreed to pay the United States and the State of Texas a total of \$27 million to settle allegations of health care fraud.⁵⁶ Warrick manufactures prescription drugs for the treatment of allergies and respiratory diseases.⁵⁷ The government alleged that Warrick submitted false pricing information and caused providers to submit fraudulently-inflated reimbursement claims to the state and federally-funded Texas Medicaid program.⁵⁸ The United States claimed Warrick submitted false pricing information to the Texas Vendor Drug Program, which resulted in inflated reimbursement for the Warrick drugs at issue, which are primarily used to treat asthma and other respiratory conditions.⁵⁹

b. Dey

On June 11, 2003, Dey, Inc., a manufacturer of prescription drugs for the treatment of allergies and respiratory diseases, agreed to pay the United States and the State of Texas a total of \$18.5 million to settle allegations of health care fraud.⁶⁰ The government alleged that the company submitted false pricing information and caused providers to submit fraudulently-inflated reimbursement claims to the state and federally-funded Texas

54. Warner-Lambert Press Release, *supra* note 45.

55. *Id.*

56. Press Release, U.S. Dep't of Justice, Schering-Plough to Pay U.S. & Texas \$27 Million to Settle Medicaid Fraud Allegations (May 3, 2004), *available at* http://www.usdoj.gov/opa/pr/2004/May/04_civ_292.htm [hereinafter Schering-Plough Texas Press Release].

57. Schering-Plough Texas Press Release, *supra* note 56.

58. *Id.*

59. *Id.*

60. Press Release, U.S. Dep't of Justice, Pharmaceutical Company, Dey, Inc. to Pay U.S. & Texas \$18.5 Million to Settle Allegations of Medicaid Fraud (June 11, 2003), *available at* http://www.usdoj.gov/opa/pr/2003/June/03_civ_350.htm [hereinafter Dey Texas Press Release].

Medicaid program.⁶¹ The United States claimed that Dey submitted false pricing information to the Texas Vendor Drug Program, which resulted in inflated reimbursement for the Dey drugs at issue, the asthma inhalants Albuterol Sulfate and Ipratropium Bromide.⁶² The Civil Medicaid Fraud Section of the Texas Attorney General's office sued Dey as part of its ongoing effort to combat Medicaid fraud in Texas.⁶³ In addition, pursuant to the Settlement Agreement and Release, Dey agreed to certain reporting requirements in the Texas Vendor Drug Program.⁶⁴

4. "Free Samples" of Zoladex

On June 20, 2003, AstraZeneca Pharmaceuticals pleaded guilty and agreed to pay a total of \$355 million in a criminal and civil settlement relating to the pricing and marketing of Zoladex, a drug used for treating prostate cancer.⁶⁵ AstraZeneca allegedly provided thousands of "free samples" of Zoladex to physicians "knowing and expecting" that some physicians would prescribe the drug samples to their patients and bill Medicare, Medicaid, TriCare, and other federal governmental health care programs for the samples.⁶⁶ The government also alleged that AstraZeneca offered and paid illegal remuneration in various forms including free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting services, and honoraria to induce physicians to prescribe the drug.⁶⁷ Other allegations included that AstraZeneca: (1) marketed the spread between the Medicare average wholesale price and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicare reimbursements for Zoladex under a "Return-to-Practice" program; (2) set the average wholesale price for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug, resulting in reimbursement to the physicians at significantly higher levels than their actual costs or the average wholesale price; and (3) failed to provide its "best price" for

61. Dey Texas Press Release, *supra* note 60.

62. *Id.*

63. *Id.*

64. Settlement Agreement and Release by and between the State of Texas, Ven-a-Care of the Florida Keys, Inc. and Dey, L.P. and Dey, Inc., No. GV002327 (June 11, 2003), available at <http://www.taf.org/settlemetns/dey.pdf>.

65. Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals Pleads Guilty to Healthcare Crime, Company Agrees to Pay \$355 Million to Settle Charges (June 20, 2003), available at http://www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm [hereinafter AstraZeneca Press Release].

66. AstraZeneca Press Release, *supra* note 65.

67. *Id.*

Zoladex to state Medicaid programs by not accounting for off-invoice price concessions provided in the form of services and free goods and grants that were contingent on purchase requirements.⁶⁸

AstraZeneca plead guilty to conspiring to violate the Prescription Drug Marketing Act of 1987 (PDMA)⁶⁹ and paid a \$63,872,156 criminal fine.⁷⁰ To settle its FCA liabilities, AstraZeneca paid the federal government a total of \$266,127,844.⁷¹ AstraZeneca also agreed to pay an additional \$24,900,000 to the federal government and the states.⁷² AstraZeneca agreed to comply with the terms of a corporate integrity agreement which requires, among other things, that it will report to the Medicare and Medicaid programs and will promote, through internal training and other programs and policies, marketing and sales practices that are in full compliance with applicable laws, rules, and regulations.⁷³ In addition, three physicians have been charged, and two have pleaded guilty, for their role in conspiring to bill for Zoladex samples.⁷⁴

In this case, the whistleblower, Douglas Durand, formerly the Vice President of Sales for AstraZeneca's competitor, TAP, will receive approximately \$47.5 million.⁷⁵

5. "Lick and Stick" Scheme

On April 16, 2003, pharmaceutical companies Bayer Corporation and SmithKline Beecham Corporation (doing business as GlaxoSmithKline), agreed to pay a total of \$344 million to settle a Medicaid FCA

68. *Id.*

69. 21 U.S.C. § 353 (1994). Among other things, the PDMA requires state licensing of wholesale distributors of prescription drugs; requires unauthorized wholesale distributors to provide purchasers a statement (also called a pedigree) identifying each prior sale of the drug; and with certain exceptions, prohibits the sale of, or offer to sell, prescription drugs that have been purchased by a hospital or other health care entity or that have been donated or supplied at a reduced price to a charitable organization. According to the FDA's Report to Congress in 2001, the PDMA was enacted to ensure that prescription drug products purchased by consumers would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs were being sold to the American public. U.S. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., THE PRESCRIPTION DRUG MARKETING ACT: REPORT TO CONGRESS (June 2001), available at <http://www.fda.gov/oc/pdma/report2001/#background>.

70. AstraZeneca Press Release, *supra* note 65.

71. *Id.*

72. *Id.*

73. *Id.* See also Corporate Integrity Agreement between the Office of Inspector General of the Dep't of Health and Human Services and AstraZeneca Pharmaceuticals LP and AstraZeneca LP (June 20, 2003), available at <http://www.oig.hhs.gov/fraud/cia/agreements/AstraZeneca06042003.PDF>.

74. AstraZeneca Press Release, *supra* note 65.

75. *Id.*

whistleblower case.⁷⁶ The suit alleged that Bayer and GlaxoSmithKline engaged in a “lick and stick” scheme to avoid paying drug rebates to the federal government.⁷⁷ Bayer and GlaxoSmithKline allegedly offered discounted prices on certain drugs, such as Bayer’s antibiotic Cipro and high blood-pressure drug Adalat, and GlaxoSmithKline’s antidepressant Paxil and nasal spray Flonase, to Kaiser Permanente Medical Care Program, one of the nation’s largest health maintenance organizations, under a “private label” to avoid having to rebate the federal government.⁷⁸ The concealment technique used was “lick and stick,” whereby the manufacturer placed Kaiser’s national drug code number rather than the manufacturer’s national drug code number on the label, and then did not report Kaiser’s discounted price to the federal government for the purposes of calculating the Medicaid rebate.⁷⁹ In the case of Paxil, GlaxoSmithKline was alleged to have sold the drug in bulk quantities to Kaiser, which in turn repackaged and relabeled the drug with its own national drug code number.⁸⁰

Bayer agreed to pay \$5.6 million in criminal fines, which were imposed in connection with Bayer’s guilty plea to violating the FDCA by failing to list a private label product with the FDA.⁸¹ Bayer also agreed to pay \$251 million in civil recoveries to the federal government and forty-nine state governments and the District of Columbia, of which \$109 million was distributed among the states, \$9.5 million was distributed among certain safety net hospitals and clinics, and the remaining \$133 million was paid to the federal government.⁸² In addition, Bayer entered into an addendum to its corporate integrity agreement, which had been in place since January 23, 2001, to ensure the implementation of a compliance program, reporting of average sales price and independent review of managed care transactions.⁸³

76. Press Release, U.S. Dep’t of Justice, Bayer Corporation and GlaxoSmithKline to Pay \$344 Million to Resolve Allegations of Health Care Fraud Against State Programs (Apr. 16, 2003), available at <http://www.usdoj.gov/usao/ma/presspage> [hereinafter Bayer Press Release].

77. Bayer Press Release, *supra* note 76.

78. Melody Peterson, *Bayer Agrees to Pay \$257 Million in Drug Fraud*, N.Y. TIMES, Apr. 17, 2003, at C1.

79. Bayer Press Release, *supra* note 76.

80. *Id.*

81. *Id.*

82. *Id.*; ANDY SCHNEIDER, TAXPAYERS AGAINST FRAUD EDUCATION FUND, REDUCING MEDICARE AND MEDICAID FRAUD BY DRUG MANUFACTURERS: THE ROLE OF THE FALSE CLAIMS ACT 33 (Nov. 2003), available at <http://www.taf.org/publications%5CPDF%5Cdrug%20report.pdf>.

83. Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer Corporation and Addendum (Jan. 23, 2001 & Apr. 15, 2003), available at <http://www.oig.hhs.gov/fraud/cia/agreements/Bayer>

GlaxoSmithKline, which did not face criminal charges, agreed to pay \$87.6 million in civil damages to the federal government, forty-nine state governments, and the District of Columbia.⁸⁴ Of that amount, \$38.3 million went to the states, \$2.6 million was distributed to safety net hospitals and clinics, and the remaining \$46.8 million was returned to the federal government.⁸⁵ GlaxoSmithKline also entered into a corporate integrity agreement to ensure the implementation of a compliance program and independent review of contract pricing.⁸⁶

The settlement against GlaxoSmithKline was the first nationwide fraud settlement to include payment to public health service entities, which include community health centers and disproportionate share hospitals. The whistleblower was the late George Couto, a Bayer marketing executive. His estate will receive approximately \$34.2 million as a result of the settlement.

III. BASIS FOR IMPLEMENTATION OF A SUCCESSFUL COMPLIANCE PROGRAM FOR PHARMACEUTICAL MANUFACTURERS

In the current regulatory environment, the increased likelihood of prosecution of pharmaceutical manufacturers who run afoul of the laws, rules, and regulations applicable to their federal health care program businesses should heighten the importance of compliance programs given by manufacturers. The main historical significance of compliance programs as a mitigating factor under the Federal Sentencing Guidelines is still as crucial as ever, but compliance as a means of prevention and staying off the government's radar screen in the first place should now be given equal or even greater priority.

A. Summary of Compliance Guidance for Pharmaceutical Manufacturers

This section discusses the seven primary industry and governmental sources of compliance guidance for pharmaceutical manufacturers. Although this guidance is voluntary, and no penalties may be imposed based on the failure to follow it, when all the available guidance is read in concert, pharmaceutical manufacturers and the providers and suppliers with which they conduct federal health care program business have the benefit of

Corporation120301.PDF [hereinafter Bayer Corporate Integrity Agreement].

84. Bayer Press Release, *supra* note 76.

85. SCHNEIDER, *supra* note 82, at 35.

86. Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and SmithKline Beecham Corporation d/b/a GlaxoSmithKline (Apr. 15, 2003), available at http://www.oig.hhs.gov/fraud/cia/agreements/SmithKline_Beecham_Corp_db_a_GlaxoSmithKline041503.PDF.

a fairly clear picture or roadmap of the rules by which at least the government and industry sources believe they should conduct their operations. One Assistant United States Attorney General has commented that no pharmaceutical manufacturer should want to be the last one to comply, based on the amount of guidance available.⁸⁷

1. OIG Compliance Program Guidance for Pharmaceutical Manufacturers

The Final OIG Guidance, published in 2003, sets forth the general views of the OIG on “the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.”⁸⁸ The stated purpose of the Final OIG Guidance is to encourage pharmaceutical manufacturers to use internal controls to efficiently monitor adherence to applicable statutes, regulations, and federal health care program requirements themselves, as well as the providers and suppliers with which they conduct federal health care program business.⁸⁹ In the past several years the OIG has also published compliance program guidance for other parts of the health care industry including hospitals, home health agencies, clinical laboratories, third-party medical billing companies, durable medical equipment, Medicare+Choice organizations offering coordinated care, hospices, nursing facilities, individual and small group practices, and ambulance suppliers.⁹⁰

It is not mandatory that pharmaceutical manufacturers use the Final OIG Guidance. The OIG specifically states that the Final OIG Guidance is only intended to present voluntary guidance to the industry instead of providing binding standards for pharmaceutical manufacturers.⁹¹ It also is not a compliance program itself. The Final OIG Guidance is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one; accordingly, it should be viewed as a benchmark.⁹²

According to the OIG, a comprehensive compliance program provides a mechanism that addresses the public and private sectors’ mutual goals of reducing fraud and abuse, while enhancing health care provider operational

87. James Sheehan, Assistant Att’y Gen., U.S. Dep’t of Justice, Remarks at the University of Texas Health Law Seminar, Houston, Texas (Apr. 2003).

88. See Final OIG Guidance, 68 Fed. Reg. at 23,731.

89. *Id.* at 23,731.

90. *Id.*

91. *Id.*

92. *Id.*

functions, thereby improving the quality of health care services while reducing the cost of health care.⁹³ In addition to avoiding submitting false or inaccurate pricing or rebate information or engaging in improper marketing activities, the OIG identified the additional benefits to pharmaceutical manufacturers from the voluntarily implementation of a compliance program, including:

- A concrete demonstration of the company's commitment to honest and responsible corporate conduct to employees and the community-at-large;
- An increased likelihood of preventing (or at least identifying) and correcting unlawful and unethical behavior at an early stage;
- A mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action; and
- Minimizing any financial loss to the government and any corresponding financial loss to the company through early detection and reporting.⁹⁴

The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from a pharmaceutical manufacturer's business operations. However, an effective compliance program that demonstrates a good faith effort by the company to comply with applicable laws, rules, and regulations significantly reduces the risk of unlawful conduct and any resulting penalties.⁹⁵

2. AOA Guidelines on Industry Gifts to Physicians

The American Osteopathic Association's (AOA) House of Delegates provided the following guidelines for professional conduct relating to gifts and subsidies offered to AOA members by representatives of pharmaceutical and medical equipment companies:

- (1) Gifts to physicians should be related to patient care or medical practice and should be of modest value. Gifts of cash should not be accepted.

93. *Id.* at 23,732.

94. Final OIG Guidance, 68 Fed. Reg. at 23,732.

95. *Id.*

- (2) Individual physicians should not accept financial subsidies from industry to defray the cost of attendance at professional conferences.
- (3) Financial support or gifts from industry for transportation, lodging and related expenses for trips which are for primarily recreational and social functions should not be accepted.
- (4) Gifts by industry to students, interns, residents and fellows for professional travel are appropriate if the recipient is selected by the college, training institution, or the sponsor of an educational event.⁹⁶

In addition to these guidelines, the AOA also recommended compliance with the Pharmaceutical Research and Manufacturers of America guidelines.⁹⁷

3. PhRMA Code of Interactions with Health Care Professionals

The Pharmaceutical Research and Manufacturers of America (PhRMA) adopted its Code on Interactions with Healthcare Professionals on July 1, 2002, to govern the pharmaceutical industry's relationships with physicians and other health care professionals.⁹⁸ PhRMA is an industry trade group representing research-based pharmaceutical and biotechnology companies.⁹⁹

The PhRMA Code provides voluntary guidance addressing interactions with respect to marketed drug products and related pre-launch activities. It specifically does not address clinical investigators relating to pre-approved studies.¹⁰⁰ Members of PhRMA are strongly encouraged to adopt procedures to assure adherence to the PhRMA Code.¹⁰¹

The PhRMA Code primarily focuses on five main points:

96. See Am. Osteopathic Ass'n Position Papers, Resolution on Industry Gifts to Physicians, adopted 1991, revised 1994, 1999, 2003; <http://www.osteopathic.org/pdf/aoa-positioning-n.pdf> at 57-58 [hereinafter AOA Resolution on Gifts].

97. AOA Resolution on Gifts, *supra* note 96.

98. Pharmaceutical Research & Manufacturers Ass'n, PhRMA Adopts New Marketing Code (Apr. 19, 2002), <http://phrma.org/publications/quickfacts/19.04.2005.388.cfm> [hereinafter PhRMA Code].

99. PhRMA Code, *supra* note 98.

100. PhRMA Code on Interactions with Healthcare Professionals, at 1, <http://docme.mc.duke.edu/Resources/PhRMA%20Code.pdf> [hereinafter Code on Interactions].

101. Code on Interactions, *supra* note 100, at 5.

- (1) General Interaction. Interaction should focus on informing the health care professional about scientific and educational information and supporting scientific medical research and education to maximize patient benefits.
- (2) Entertainment. Interaction should not include entertainment and must occur at a venue conducive to providing scientific or educational information. Specifically, this means no “dine and dash” or recreational events (for example, sporting events or spa visits).
- (3) Continuing Education. Companies can provide support to the conference sponsor but should not fund individual participants. This means that a company cannot pay an individual’s tuition, but could provide support to the event sponsor. That sponsor may in turn provide grants to individuals to participate, or to reduce the overall registration fees for all attendees.
- (4) Consultants. Legitimate consulting or advisory arrangements are appropriate, but token consulting arrangements should not be used to justify payments to health care professionals. Characteristics of legitimate consulting arrangements include the retention of professionals based on their expertise (rather than as a reward or inducement for prescriptions) and retaining no more consultants than needed for the specific program. For example, it would be inappropriate to retain 10,000 physicians for a program that requires no more than 1,000 physicians, or to select them as a reward for high prescribing.
- (5) Educational and Health Care Practice Related Items. Educational and practice-related items may be provided to health care professionals, but should be for the health care benefit of patients and of less-than-substantial value (\$100 or less). Items for the personal benefit of the health care professional should not be offered or distributed. In short, nothing should be offered or provided that would interfere with the independence of the health care professional’s prescribing practices.¹⁰²

102. *Id.* at 2-5.

4. FDA Final Guidance on Industry-Supported Scientific and Educational Activities

In 1997, the FDA published the Final Guidance on Industry-Supported Scientific and Educational Activities.¹⁰³ The setting for this rulemaking started with requests from the pharmaceutical industry for guidance related to industry-supported scientific and educational activities, which the FDA has not traditionally regulated.¹⁰⁴ However, such activities that are not independent and non-promotional, while they may not be per se illegal, are subject to regulation.¹⁰⁵

The FDA Final Guidance identifies the following factors for evaluating industry-supported scientific and educational activities and determining independence:

- Control of content and selection of presenters and moderators;
- Disclosures of relationships;
- The intent and focus of the program;
- Relationship between the provider and supporting company;
- Provider involvement in sales or marketing;
- Provider's demonstrated failure to meet standards on independence;
- Number of presentations of same program;
- Selection of audience by sales or marketing departments;
- Opportunities for discussion;
- Dissemination of information about supporting company's products;
- Contemporaneous ancillary promotional activities; and
- Complaints about attempts to influence content.¹⁰⁶

5. OIG Special Fraud Alert on Prescription Drug Marketing Schemes

In August 1994, the OIG issued a Special Fraud Alert related to prescription drug marketing schemes.¹⁰⁷ The OIG uses fraud alerts to identify fraudulent and abusive practices within the health care industry.¹⁰⁸

According to the Special Fraud Alert, prescription drug marketing activities run the risk of violating the Anti-Kickback Statute in the

103. Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,073 (Dec. 3, 1997) [hereinafter FDA Final Guidance].

104. Code on Interactions, *supra* note 100, at 5.

105. FDA Final Guidance, 62 Fed. Reg. at 64,074.

106. *Id.* at 64,096-99.

107. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 242, at 65,376 (Dec. 19, 1994).

108. *Id.*

following ways:

In recent years, prescription drug marketing companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specified product. Prescription drugs supplied under one of these programs are often reimbursed under Medicaid. Among the specific activities, which the OIG has identified, are the following actual cases:

- A “product conversion” program which resulted in 96,000 brand-name conversions. In this scenario, for instance, Drug Company A offered a cash award to pharmacies for each time a drug prescription was changed from Drug Company B’s product to Drug Company A’s product. The pharmacies were induced to help persuade physicians, who were unaware of the pharmacies’ financial interest, to change prescription.
- A “frequent flier” campaign in which physicians were given credit toward airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on the drug company’s product.
- A “research grant” program in which physicians were given substantial payments for de minimis recordkeeping tasks. The physician administered the drug manufacturer’s product to the patient and made brief notes, sometimes in a single word, about the treatment outcome. Upon completion of a limited number of such “studies,” the physician received payment from the manufacturer.

If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or “safe harbor” to protect such activities. Thus, a physician, pharmacy or other practitioner or supplier receiving payment under these

activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. The OIG is investigating various drug marketing schemes, and enforcing the anti-kickback laws where these practices affect the Federal health care programs.¹⁰⁹

6. AMA Guidelines on Gifts to Physicians from Industry

In 1992, the American Medical Association's (AMA) Council on Ethical and Judicial Affairs first published guidelines on promotional gifts for physicians, physicians-in-training, and sales representatives of pharmaceutical, device and medical equipment manufacturers.¹¹⁰ The AMA has subsequently updated these guidelines through 2004. The AMA's Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry created the following statement intended to provide guidance regarding the appropriateness of gift-giving between industry and physicians:

Physicians have a unique professional relationship with patients and have an ethical responsibility to place the health and welfare of the patient ahead of economic self-interest. Physicians should be mindful that accepting gifts or other remuneration that does not comply with ethical guidelines may give the appearance of undue influence and jeopardize the physician-patient relationship.

Industry and physicians should recognize that gifts that do not comply with professional guidelines may compromise ethical principles. Industry should share the responsibility to promote the health and welfare of patients by complying with appropriate guidelines.¹¹¹

109. *Id.*

110. See Am. Med. Ass'n, Background and Overview of the Initiative (Jan. 26, 2005), <http://www.ama-assn.org/ama/pub/printcat/4002.html> [hereinafter AMA Overview].

111. Am. Med. Ass'n, Statement of the Gifts to Physicians Working Group, (Nov. 9, 2004), <http://www.ama-assn.org/ama/pub/category/4003.html> [hereinafter AMA Gift Statement]. Guidance for physicians and industry can be found in the current Code of

The AMA Group stated that by failing to follow the guidelines, both physicians and industry representatives are cast in a negative light.¹¹²

The AMA Guidelines consist of seven guidelines along with answers to frequently asked questions that provide additional guidance on specific situations with which AMA member physicians may be confronted. The guidelines provide:

(1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

(2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

(3) The Council on Ethical and Judicial Affairs defines a legitimate 'conference' or 'meeting' as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

(4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the

Medical Ethics, published by the Council on Ethical and Judicial Affairs of the American Medical Association and the ethics statements of medical specialty societies. See Am. Med. Ass'n, Code of Med. Ethics, <http://www.ama-assn.org/ama/pub/category/4001.html> (last visited Nov. 21, 2005). In addition, codes of conduct associated with government, industry, or other institutional employment may apply.

112. AMA Overview, *supra* note 110.

company by the physicians attending the conference.

(5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional or specialty medical associations.

(7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physicians' prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.¹¹³

The project to develop the AMA Guidelines was staffed by both industry representatives and physician organizations. In addition to the AMA, funding was provided by the American Medical Association Industry Roundtable Steering Committee, Eli Lilly & Co., Glaxo Wellcome, Merck & Co., Pfizer, Pharmacia Corporation, AstraZeneca, Bayer Corp., Proctor and Gamble and Wyeth-Ayerst Labs.¹¹⁴

113. AMA Gift Statement, *supra* note 111.

114. AMA Overview, *supra* note 110.

7. Corporate Integrity Agreements

One result of the many settlements the OIG and DOJ have entered into with pharmaceutical manufacturers is that there are now numerous corporate integrity agreements publicly available for companies to review in connection with developing their own compliance programs. Corporations generally enter into corporate integrity agreements in the context of a negotiated settlement with the government. These agreements show the elements of monitoring and ongoing compliance activities that the government believes will be effective to keep the particular pharmaceutical manufacturer, given the unique characteristics of its operations, from violating the applicable laws, rules, and regulations. If a manufacturer is proactively focused on never being compelled to enter into a corporate integrity agreement with the government, it should use prior corporate integrity agreements as a resource in designing its compliance programs to meet or exceed the government's expectations.

B. Elements of an Effective Compliance Program for Pharmaceutical Manufacturers

1. Introduction

Because of the diversity of companies within the pharmaceutical industry, the OIG recognizes there will not be a single "best" pharmaceutical manufacturer compliance program. Some companies are smaller, with limited human and financial resources to devote to compliance. Others are large multi-national companies with well-developed compliance programs already in place. Companies must design and implement compliance programs that address the unique problems and areas of concern and high risk for their particular business operations.¹¹⁵

2. Fundamental Elements of a Compliance Program

The Final OIG Guidance identifies the fundamental, widely recognized elements of an effective compliance program:

- (1) Implementing written policies and procedures;
- (2) Designating a compliance officer and compliance committee;
- (3) Conducting effective training and education;
- (4) Developing effective lines of communication;
- (5) Conducting internal monitoring and auditing;
- (6) Enforcing standards through well-publicized disciplinary guidelines;

115. Final OIG Guidance, 68 Fed. Reg. at 23,732.

and

- (7) Responding promptly to detected problems and undertaking corrective action.¹¹⁶

In order for a compliance program to be effective, it must have the support and commitment of the company's senior management and governing body.¹¹⁷ The long-term benefits of establishing a compliance program will significantly outweigh the initial costs related to designing and implementing the program.¹¹⁸ For this advantage, however, the program must be tailored to the organization and appropriate based on the level of risk identified in the drug company's operations.

3. Major Risk Areas

The major potential areas of high risk for compliance identified by the OIG for pharmaceutical manufacturers are:

- Integrity of data used by federal and state governments to establish payment;
- Kickbacks and other illegal remuneration; and
- Compliance with laws regulating drug samples.¹¹⁹

A compliance program should address these risk areas to the extent they exist in a particular company's operations. However, the OIG cautions that this list is not exhaustive of all the potential risk areas for pharmaceutical manufacturers. Each company must conduct legal review of its own practices and develop specific policies and procedures to reduce or eliminate its particular risk.¹²⁰

a. Integrity of Data

The Final OIG Guidance states that pharmaceutical manufacturers are responsible for ensuring the integrity of the data they generate for government reimbursement purposes.¹²¹ Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. Accordingly, the government sets reimbursements with the expectation that

116. *Id.* at 23,731.

117. *Id.*

118. *Id.*

119. *Id.* at 23,733.

120. *Id.* at 23,732.

121. Final OIG Guidance, 68 Fed. Reg. at 23,734.

the data provided are complete and accurate. Knowingly submitting false, fraudulent, or misleading information is actionable under the FCA or other federal or state health care laws.¹²²

b. Kickbacks and Other Illegal Remuneration

The Final OIG Guidance emphasizes that drug companies, as well as their employees and agents, should be aware that the Anti-Kickback Statute prohibits practices in the health care industry that are common in other industries. Those other practices may not be acceptable or even lawful when soliciting federal health care program business.¹²³

Although violation of the Anti-Kickback Statute depends on a party's intent, the OIG suggests that a pharmaceutical manufacturer may initially attempt to identify problematic arrangements or practices by focusing on the following two areas:

- Identify any remunerative relationships between the pharmaceutical manufacturer (or its employees or agents) and persons in a position to directly or indirectly generate federal health care program business for the manufacturer. Persons in a position to generate such business include purchasers, benefit managers, formulary committee members, group purchasing organizations, physicians, and certain allied health professionals, and pharmacists.
- Determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program. A lawful purpose will not legitimize a payment that also has an unlawful purpose.¹²⁴

If an arrangement or practice is identified as posing some degree of risk, the Final OIG Guidance states that the pharmaceutical manufacturer should ask itself the following questions, among others:¹²⁵

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the

122. *Id.* at 23,733.

123. *Id.* at 23,734.

124. *Id.*

125. *Id.*

arrangement or practice involves providing information to decision makers, prescribers, or patients, is the information complete, accurate, and not misleading?

- Does the arrangement or practice have a potential to increase costs to federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- Does the arrangement or practice have a potential to increase the risk of over-utilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?¹²⁶

The OIG advises that arrangements or practices that present areas of risk should be structured to fit within a safe harbor under the Anti-Kickback Statute whenever possible. Other guidance is also available in the special fraud alerts and advisory bulletins issued by the OIG.

The Final OIG Guidance identifies three primary groups as historical sources of risk under the Anti-Kickback Statute due to their relationships with pharmaceutical manufacturers: purchasers, including those using their formularies, and their agents; persons in a position to make or influence referrals, including physicians and other health care professionals; and sales agents.¹²⁷

(1) Relationships with Purchasers and Their Agents

As a regular part of doing business, drug companies offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Purchasers include both direct purchasers (like hospitals, nursing homes, pharmacies, and some physicians) and indirect purchasers (such as health plans). The OIG cautions that any remuneration from a manufacturer to a purchaser that is expressly or impliedly related to a sale potentially implicates the Anti-Kickback Statute and should be carefully reviewed.¹²⁸

126 *Id.*

127. Final OIG Guidance, 68 Fed. Reg. at 23,735.

128 *Id.* at 23,735.

(a) *Discounts and Other Remuneration to Purchasers*

Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to encourage the purchase of their products. Inducements offered to purchasers potentially implicate the Anti-Kickback Statute if the products are reimbursable to the purchasers under a federal health care program, either in whole or in part, directly or indirectly. Any remuneration from a manufacturer to the purchaser that is expressly or impliedly tied to a sale potentially implicates the Anti-Kickback Statute and should be carefully scrutinized.¹²⁹

(i) Discounts

Discounts are prevalent in the health care industry. Because public policy favors open and legitimate price competition, the Anti-Kickback Statute includes a safe harbor for discounts that are properly disclosed and accurately reported.¹³⁰

The OIG believes that discounting arrangements deserve special attention in the pharmaceutical industry because of their likelihood of implicating the best price requirements of the Medicaid rebate program.¹³¹ The OIG goes on to suggest that “because the Medicaid rebate program in many instances requires that states receive rebates based on the best price offered by a manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discount to the states.”¹³²

(ii) Product Support Services

Product support services offered by pharmaceutical manufacturers to purchasers, such as billing assistance and reimbursement consultation, are not problematic under the Anti-Kickback Statute when standing alone.¹³³ However, the OIG believes that when product support services that have no independent value are offered in connection with another service or program that does afford a benefit to the referring provider, such as a reimbursement guarantee that eliminates normal financial risk, the Anti-Kickback Statute is implicated.¹³⁴

129. *Id.*

130. *Id.* The discount safe harbor is at 42 C.F.R. § 1001.952(h) (2004).

131. Final OIG Guidance, 68 Fed. Reg. at 23,735.

132. *Id.* at 23,735.

133. *Id.*

134. *Id.*

(iii) Educational Grants

Educational grants funded by pharmaceutical manufacturers can be a source of valuable information to the medical and health care industries. However, funding that is conditioned, either in whole or in part, on the purchase of a product implicates the Anti-Kickback Statute.¹³⁵ The Final OIG Guidance states that manufacturers should completely separate their grant-making functions from their sales and marketing functions to reduce the risk that grant programs may be used improperly to induce purchases or market products.¹³⁶

(iv) Research Funding

Contracts between manufacturers and purchasers of pharmaceuticals to conduct research activities on behalf of the manufacturer implicate the Anti-Kickback Statute. The OIG suggests that the function of awarding research contracts should be separated from sales and marketing to reduce the risk of violations. These contracts should also be structured to fit within the personal services safe harbor under the Anti-Kickback Statute.¹³⁷

(v) Other Remuneration

The Final OIG Guidance identifies other problematic situations under the Anti-Kickback Statute, wherein a pharmaceutical manufacturer may provide remuneration to a purchaser of its products. These include "prebates" and "upfront payments," other free or reduced-price goods or services, payments to cover the costs of "converting" from a competitor's product, and selective offers based on the volume or value of purchases.¹³⁸

(b) Formularies and Formulary Support Activities

Although formulary support activities are an essential element of successful pharmacy benefits management, the OIG has determined there is the potential for abuse under certain circumstances.¹³⁹ First, relationships between pharmaceutical companies, formulary committee members of health plans, and other drug purchasers, and any remuneration flowing out of those relationships must be carefully scrutinized.¹⁴⁰ Second, rebates or

135. *Id.*

136. *Id.* at 23,735-36.

137. Final OIG Guidance, 68 Fed. Reg. at 23,736-37. The personal services safe harbor is at 42 C.F.R. § 1001.952(d) (2004).

138. Final OIG Guidance, 68 Fed. Reg. at 23,736.

139. *Id.* at 23,736.

140. *Id.*

other payments by drug manufacturers to pharmacy benefit managers that are based on or otherwise related to the PBM customer purchases may implicate the Anti-Kickback Statute.¹⁴¹ These contracts should be structured to satisfy the group purchasing organization safe harbor.¹⁴² Finally, lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic.¹⁴³

(c) Average Wholesale Price

The Final OIG Guidance states that the Anti-Kickback Statute is implicated if a pharmaceutical manufacturer purposefully manipulates the average wholesale price to increase its customer's profit by increasing the amount the federal health care programs reimburses its customer.¹⁴⁴ This can occur because, in many situations under the federal health care programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers will be reimbursed by federal health care programs.¹⁴⁵ It is illegal for a manufacturer to knowingly establish or inappropriately maintain a particular average wholesale price if one purpose is to manipulate the "spread" to induce customers to purchase its products.¹⁴⁶ The Final OIG Guidance recommends that pharmaceutical manufacturers review their average wholesale price reporting practices and methodology to ensure they are not influenced by marketing considerations.¹⁴⁷ The OIG recognizes manipulation of the average wholesale price to induce customers to purchase a product, along with active marketing of the spread, as strong evidence of the unlawful intent necessary to trigger the Anti-Kickback Statute.¹⁴⁸

(2) Relationships with Physicians and Other Persons in a Position to Make or Influence Referrals

Pharmaceutical manufacturers and their agents are involved in numerous relationships with persons in a position to refer, order, prescribe (or influence the referral, ordering, or prescribing of) drugs, even though the

141. *Id.*

142. *Id.* The group purchasing organization safe harbor is at 42 C.F.R. § 1001.952(j) (2004).

143. Final OIG Guidance, 68 Fed. Reg. at 23,736.

144. *Id.* at 23,736-37.

145. *Id.* at 23,736.

146. *Id.* at 23,737.

147. *Id.*

148. *Id.*

persons or entities may themselves not purchase (or in the case of group purchasing organizations and pharmacy benefits manufacturers, arrange for the purchase of) those drugs.¹⁴⁹ Pharmaceutical manufacturers frequently cultivate relationships with physicians in a variety of ways, including gifts, entertainment, and personal service compensation arrangements.¹⁵⁰ The OIG cautions that these types of relationships are inherently risky under the Anti-Kickback Statute and historically have generated a substantial number of violations.¹⁵¹ Whenever possible, these relationships should be structured to fit within an available safe harbor under the Anti-Kickback Statute, such as the personal services and management contracts or employee safe harbors.¹⁵² If an arrangement cannot be structured to fit squarely within a safe harbor, the OIG advises that it should be evaluated in light of the totality of all the facts and circumstances, including the following factors, among others:

- Nature of the relationship between the parties;
- Manner in which the remuneration is determined;
- Value of the remuneration;
- Potential federal health care program impact of the remuneration; and
- Potential conflicts of interest.¹⁵³

(a) Consulting and Advisory Payments

It is common for pharmaceutical manufacturers to engage physicians and other health care professionals in the provision of personal services to the company, such as consulting or advising.¹⁵⁴ The OIG is concerned with “consulting” arrangements under which physicians are expected to attend meetings or conferences in a passive capacity and with arrangements connected to marketing and sales activities of a manufacturer.¹⁵⁵ The Final OIG Guidance recommends that arrangements for services between pharmaceutical manufacturers and physicians and other health care providers be structured to comply with a safe harbor under the Anti-Kickback Statute.¹⁵⁶

149. Final OIG Guidance, 68 Fed. Reg. at 23,737.

150. *Id.*

151. *Id.*

152. *Id.* The personal services and management contracts safe harbor is at 42 C.F.R. § 1001.952(d) (2004), and the safe harbor for employees is at 42 C.F.R. § 1001.952(i) (2004).

153. Final OIG Guidance, 68 Fed. Reg. at 23,737.

154. *Id.*

155. *Id.*

156. *Id.* The personal services safe harbor is at 42 C.F.R. § 1001.952(d) (2004).

(b) Payments for Detailing

The OIG states that it is highly suspect under the Anti-Kickback Statute for pharmaceutical manufacturers to compensate physicians for time spent listening to sales representatives market their products or for time spent accessing web sites to view or listen to marketing information.¹⁵⁷ The Final OIG Guidance strongly discourages these types of activities.¹⁵⁸

(c) Business Courtesies and Other Gratuities

If a purpose of the variety of remunerative relationships between pharmaceutical manufacturers and physicians or others in a position to influence referrals for the purchase of products is to generate business for the manufacturer, the Anti-Kickback Statute is potentially implicated.¹⁵⁹ Examples of these relationships include entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations, and gifts, gratuities, and other business courtesies.¹⁶⁰ The OIG recommends compliance with the PhRMA Code when participating in these types of activities in order to substantially reduce the manufacturer's risk of violating the Anti-Kickback Statute.¹⁶¹

(d) Educational and Research Funding

The Final OIG Guidance cautions that contracts for research activities between a physician and pharmaceutical manufacturer originating from marketing and product promotion are problematic.¹⁶² The contracts should be structured to fit within the personal services safe harbor under the Anti-Kickback Statute.¹⁶³

(3) Relationships with Sales Agents

The OIG states that a pharmaceutical manufacturer's commitment to an effective fraud and abuse compliance program can often be determined in large part by the company's commitment to training and monitoring its sales force.¹⁶⁴ Because sales agents, whether employees or independent

157. Final OIG Guidance, 68 Fed. Reg. at 23,378.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. Final OIG Guidance, *supra* note 5, at 23,738. The personal services safe harbor is at 42 CFR 1001.952(d) (2004).

164. Final OIG Guidance, *supra* note 5, at 23,739.

contractors, are paid to recommend and arrange for the purchase of a pharmaceutical manufacturer's products, their compensation arrangements should also be carefully reviewed and structured to comply with the employment or personal services safe harbors to the greatest extent possible.¹⁶⁵ The OIG advises that if an arrangement does not fit with a safe harbor, the following factors should be considered: the amount of compensation, the identity of the sales agent engaged in the marketing or promotional activity, the sales agent's relationship with his audience, the nature of the marketing or promotional activity, the item or service being promoted or marketed, and the composition of the target audience.¹⁶⁶ Finally, the OIG warns that a compensation arrangement satisfying a safe harbor can still evince a manufacturer's improper intent under the Anti-Kickback Statute.¹⁶⁷ For example, if the manufacturer provides sales employees with unusually large bonuses or expense accounts, an inference that the manufacturer is intentionally motivating the sales force through lavish entertainment and other improper remuneration may be drawn.¹⁶⁸

c. Compliance with Laws Regulating Drug Samples

The Final OIG Guidance states that the provision of drug samples is a widespread industry practice that can benefit patients, but can also pose potential risks to pharmaceutical manufacturers.¹⁶⁹ Manufacturers should closely follow the requirements of the Prescription Drug Marketing Act of 1987 (PDMA)¹⁷⁰ with risk of violations generally under the PDMA itself as well as under the FCA and the Anti-Kickback Statute.¹⁷¹ The OIG advises that manufacturers may minimize their risk of violations by: (1) training their sales force to meaningfully inform sample recipients that samples may not be sold or billed; (2) clearly and conspicuously labeling individual samples as units that may not be sold; and (3) including on packaging and any documentation related to the samples a conspicuous notice that the samples are subject to the PDMA and may not be sold.¹⁷²

165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.*

169. Final OIG Guidance, 68 Fed. Reg. at 27,739.

170. Prescription Drug Marketing Act (PDMA) of 1987, 21 U.S.C. § 353(c)(1) (2000). The PDMA governs the distribution of drug samples and forbids their sale.

171. Final OIG Guidance, 68 Fed. Reg. at 27,739.

172. *Id.*

IV. "HOT" LEGAL AND REGULATORY ISSUES TO BE AWARE OF AS 2006 GETS UNDERWAY

A new slate of legal and regulatory challenges face pharmaceutical manufacturers in 2006 and the years that follow against the backdrop of the confusion and uncertainty that already exists in the pharmaceutical industry because of the increased governmental scrutiny and attention of the plaintiff's bar. This section provides an overview of several of these challenges and how they may require changes in the way business is conducted by pharmaceutical manufacturers and the providers and suppliers with which they conduct federal health care program business.

A. Drug Re-Importation—The FDA Versus the States

Legalization of the re-importation of prescription drugs from Canada and Western European countries could have a tremendous impact on pharmaceutical manufacturers. Re-importation of prescription drugs is a result of the federal policy of banning wholesalers from selling drugs back to the United States.¹⁷³ Even though the FDA does not think that legalizing prescription drug re-importation is appropriate, state governments are challenging the system and attempting to import drugs from Canada and certain Western European countries. In fact, a growing number of states and cities are defying federal law and the power of the pharmaceutical industry by helping people buy prescriptions drugs from abroad. For example, Illinois, Minnesota, New Hampshire, Wisconsin, and the District of Columbia are pointing residents to websites of prescreened foreign pharmacies.¹⁷⁴ Moreover, the State of Rhode Island enacted a law in 2004 allowing pharmacies licensed in Canada to do business in Rhode Island,¹⁷⁵ and the California legislature has passed a packet of re-importation bills.¹⁷⁶ In all, twenty-four states have considered such measures.¹⁷⁷ Vermont even filed a lawsuit against the FDA in August 2004 after the agency rejected the state's request to set up a pilot program to establish a program for the importation of prescription drugs from Canada.¹⁷⁸

173. Tomas J. Philipson, *Long-Term Ramifications of Reimportation for the Health Care System*, MANAGED CARE, June 2004, Vol. 13, No. 6, at 17, 17.

174. Patricia Barry, *States Defy FDA on Drug Importation*, AARP Bulletin, Oct. 2004, http://www.aarp.org/bulletin/prescription/a2004-10-08-fda_importation.html.

175. FDA issued a detailed letter warning the Rhode Island Attorney General of the illegality of such imports and potential liability. See Letter from William K. Hubbard, FDA, to Patrick C. Lynch, Rhode Island Attorney General (Jan. 28, 2005), *available at* <http://www.fda.gov/oc/opacom/hottopics/importdrugs/lynch012805.html>.

176. Barry, *supra* note 174.

177. *Id.*

178. Statement on Vermont's Lawsuit on Importing Prescription Drugs from Canada

The Bush administration and drug makers are adamantly opposed to any re-importation bill because they contend that legalizing re-importation would open American borders to a flood of counterfeit and unsafe medicines.¹⁷⁹ In addition, there is concern that allowing large American pharmacy chains and wholesalers to import drugs in huge quantities could swamp the Canadian market and even prompt the Canadian government, which controls drug prices through its health system, to close down cross-border trade.¹⁸⁰

B. Full Disclosure of Clinical Trials

The FDA wants to require pharmaceutical manufacturers to fully disclose all clinical trial findings before making a determination about recalling prescription drugs. Pharmaceutical manufacturers have been accused of selection bias in reporting clinical trial results by highlighting positive trials while playing down or burying negative data. One recent example involved the pediatric use of antidepressants.¹⁸¹ The FDA is proposing that any and all adverse events reported in clinical trials be disclosed to the FDA. Furthermore, those in the medical industry are encouraging the FDA to make those clinical trial results available and accessible to health care providers, researchers, and the public.

On October 7, 2004, the Fair Access to Clinical Trials Act of 2004 bill was introduced to Congress. This bill would require prescription drugs and medical device manufacturers to register clinical trials of their products in a public database before they begin testing and then report the results.¹⁸² This bill modifies an existing federal law that requires the disclosure of clinical trials to a government database.¹⁸³ The FDA, however, has not enforced this already existing federal law, primarily because the statute does not explicitly give the agency authority to crack down on violators or impose penalties.¹⁸⁴ The new bill, however, provides an enforcement mechanism by which the FDA can penalize and sanction pharmaceutical manufacturers

(Aug. 20, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01107.html>.

179. Patricia Barry and Barbara Basler, *Battle Lines Drawn on Rx Imports*, AARP Bulletin (July-Aug. 2004), <http://www.arp.org/bulletin/prescription/Articles/a2004-06-22-reimportation.html>.

180. Barry and Basler, *supra* note 179.

181. Barry Meier, *Drug Industry Plans Release of More Data About Studies*, N.Y. TIMES, Jan. 7, 2005, at C4, available at <http://www.nytimes.com/2005/01/07/business/07trials.html>.

182. H.R. 5252, 108th Cong. (2004); S. 2933, 108th Cong. (2004).

183. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, §113 (1997), available at <http://www.fda.gov/cder/guidance/105-115.htm>.

184. Shankar Vedantam, *USA: Drugmakers Prefer Silence on Test Data*, WASH. POST, July 6, 2004, at A1.

who do not comply with the disclosure requirements.

In addition, pharmaceutical manufacturers have been investigated over how they disclose information from clinical studies. The New York Attorney General's Office inquired into GlaxoSmithKline's non-disclosure of certain clinical studies of Paxil under the theory it had misrepresented or concealed material facts by not disclosing negative clinical trial results.¹⁸⁵ GlaxoSmithKline entered into a settlement agreement whereby it became the first major pharmaceutical manufacturer to publicly disclose information on clinical studies of its drugs. Specifically, GlaxoSmithKline agreed to release both positive and negative studies about the safety and efficacy of its drugs.¹⁸⁶

Some pharmaceutical manufacturers are even voluntarily releasing more information about clinical trial results. Faced with pressure from lawmakers and editors of medical journals, four trade groups representing the world's biggest pharmaceutical manufacturers said that their members planned to release more data about clinical drug trials.¹⁸⁷ The plans, which are voluntary on the companies' part, reflect an effort by the pharmaceutical manufacturers to defuse controversies over clinical trials, such as the concealment of negative clinical trial results.¹⁸⁸ Pharmaceutical manufacturers need to be aware of the trends being set to voluntarily register clinical trials and then publicly release information about the results of the clinical trials.

C. Mandatory Compliance—Recent California Legislation

California's new statute, SB 1765, effective July 1, 2005, converts voluntary industry guidance into legally binding standards.¹⁸⁹ SB 1765 requires pharmaceutical companies to adopt and publicly disclose a comprehensive compliance program that is in accordance with the Final OIG Guidance and the PhRMA Code, establish specific annual dollar limits on gifts or incentives provided to medical or health care professionals, and make an annual declaration of compliance publicly available.¹⁹⁰ This

185. *Assistant New York Attorney General Warns Pharma Not to Underestimate the Investigative Scope of Information Disclosure Cases*, 3 RX COMPLIANCE REP., Dec. 3, 2004, at 6.

186. Press Release, Office of N.Y. State Att'y Gen., Eliot Spitzer, Settlement Sets New Standard for Release of Drug Information (Aug. 26, 2004), available at http://www.oag.state.ny.us/press/2004/aug/aug26a_04.html.

187. Meier, *supra* note 181.

188. *Id.*

189. CAL. HEALTH & SAFETY CODE §§ 119400, 119402 (West 2005).

190. *New California Law Mandating Pharma Compliance Programs Riddled with Unanswered Questions*, 3 RX COMPLIANCE REP., Dec. 3, 2004, at 2 [hereinafter *Unanswered Questions*].

statute presents a number of implementation challenges that may require manufacturers to develop expensive new systems or expand pre-existing ones.¹⁹¹ The reason that the statute may be difficult to implement is that there are many ambiguities and other aspects of the statute that raise significant questions. As a result of the broad definition of a “pharmaceutical company,” which may or may not include out-of-state pharmaceutical companies doing business in California, it is unclear what the scope of SB 1765 is and to what extent it affects companies based outside of California.¹⁹² In addition, requiring pharmaceutical companies to comply with the Final OIG Guidance is difficult because it merely provided recommendations and not “requirements,” thus giving pharmaceutical manufacturers a tough time in discerning the subtle differences.¹⁹³ Finally, while the statute does not identify a specific enforcement mechanism, there are ways the government and the plaintiff’s bar could attack pharmaceutical companies. Pharmaceutical companies are subject to allegations of unfair business practices under the Unfair Competition Law of the California Business and Professions Code § 17200.¹⁹⁴ In addition, False Claims Act liability could arise under the California False Claims Act and Section 1871.7 of the California Insurance Code.¹⁹⁵

The lesson to take away is that pharmaceutical manufacturers around the country need to watch what happens in California to see how the federal and state governments and the plaintiff’s bar proceed in making claims against pharmaceutical manufacturers under SB 1765.

D. State Marketing and Gift Reports – Minnesota and Vermont

Some states have enacted laws that require pharmaceutical manufacturers to report gifts and marketing expenditures to state regulatory bodies. Minnesota has a statute prohibiting pharmaceutical manufacturers from making certain gifts to “practitioners”¹⁹⁶ and a related statute that imposes reporting obligations when giving certain non-prohibited payments to

191. *Id.* See also Pfizer Corporate Compliance Code, stating that “Pursuant to California SB 1765, Pfizer has modified certain policies and procedures that regulate interactions with covered medical and health care professionals in the State of California. Pfizer has set a specific annual dollar limit on gifts, promotional materials, or items or activities that we may give or otherwise provide to an individual medical or health care professional pursuant to the [OIG Guidance] and with the PhRMA Code,” available at http://www.pfizer.com/pfizer/subsites/corporate_citizenship/corporate_compliance.jsp (last visited Nov. 26, 2005).

192. *Unanswered Questions, supra* note 190, at 2.

193. *Id.*

194. *Id.* at 3.

195. *Id.*

196. MINN. STAT. § 151.461 (2005).

practitioners.¹⁹⁷ Minnesota's gift statute generally prohibits any "manufacturer or wholesale drug distributor, or any agent thereof" from offering or giving any gift of value to a "practitioner."¹⁹⁸ A "gift" does not include: samples of a drug provided to doctors for free distribution to patients, items with a total combined retail value of less than \$50 in any calendar year, payments to sponsors of medical conferences or meetings if certain requirements are met, reasonable honoraria or payments of reasonable expenses of a practitioner serving as faculty at a professional conference or meeting, compensation for substantial professional or consultation services of a doctor in connection with research projects, publications and educational materials, or salaries or other benefits paid to employees.¹⁹⁹ In addition, manufacturers and wholesale drug distributors are required to report specified non-prohibited payments to practitioners.²⁰⁰ Annual reports to the Minnesota Board of Pharmacy must identify all payments made to practitioners in Minnesota during the preceding calendar year that fall within the exceptions in the statute, as well as all payments totaling more than \$100 to a particular practitioner.²⁰¹

Vermont also has a statute imposing various disclosure requirements on pharmaceutical manufacturing companies.²⁰² The statute generally requires "pharmaceutical manufacturing companies" to make annual disclosures to the Office of the Attorney General.²⁰³ With specified exceptions, a manufacturer's annual submission must disclose "the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs."²⁰⁴ In addition, another new Vermont statute, the Pharmaceutical Marketer Price Disclosure Law,

197. MINN. STAT. § 151.47 (2005).

198. MINN. STAT. § 151.461 (2005); *see also* MINN. STAT. §151.01 (2005). The definition of "practitioner" includes a licensed physician, osteopath, dentist, optometrist, podiatrist, or veterinarian, as well as physician assistants and advanced practice nurses authorized to prescribe, dispense, and administer drugs.

199. MINN. STAT. §151.461 (2005).

200. MINN. STAT. §151.47 (2005).

201. MINN. STAT. §151.47 (2005).

202. VT. STAT. ANN. tit. 33 § 2005 (2005).

203. The term "pharmaceutical manufacturing company" is defined broadly, but excludes wholesale drug distributors and pharmacists. VT. STAT. ANN. tit. 33 § 2005(c)(5) (2005).

204. VT. STAT. ANN. tit. 33 § 2005 (2005).

governs the type of marketing conducted by pharmaceutical marketers.²⁰⁵ This statute states that when a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs, the marketer shall disclose the average wholesale price of the drugs being marketed.²⁰⁶ In conjunction with this statute, the Vermont Attorney General's Office issued a proposed guide to compliance with the Pharmaceutical Marketer Price Disclosure Law.

In addition to Minnesota and Vermont, there are several other states that are considering new laws to regulate marketing related payments by pharmaceutical manufacturers to potential prescribers.²⁰⁷ These state regulations underscore the importance of keeping up to date with changes in state laws that require pharmaceutical manufacturers to increasingly disclose more about its relationships with doctors, hospitals, health maintenance organizations, or other entities authorized to prescribe drugs. Pharmaceutical manufacturers must be attentive and conscientious about compliance with federal and state regulations governing their relationships with potential prescribers.

E. GPO Practices

The OIG Work Plan identifies a continued focus on how group purchasing organizations and their members use revenue from vendor fees.²⁰⁸ The OIG plans to analyze the impact of group purchasing organization arrangements on the Medicare program, including how their owners and members report vendor fees on Medicare cost reports.²⁰⁹

F. Direct-to-Consumer Advertising

Consumers today are faced with an overwhelming amount of choices in prescription drug therapy. This decision is made even more difficult by creative pharmaceutical advertising and marketing that results in decisions being made on the glitz and glamour portrayed in drug advertisements as opposed to medical decisions by medical professionals that are in the best interest of the patient.²¹⁰ On July 1, 2005, Senate Majority Leader Bill

205. VT. STAT. ANN. tit. 33 § 2005a (2005).

206. VT. STAT. ANN. tit. 33 § 2005a(a) (2005).

207. *NCSL Reports at least 48 Drug Marketing Bills*, 4 RX COMPLIANCE REP., May 20, 2005.

208. OIG Work Plan, *supra* note 4, at 42.

209. *Id.*

210. *Senate Majority Leader Frist Targets Direct-To-Consumer Drug Marketing*, HEALTH LAW. WKLY., July 8, 2005.

Frist, M.D. (R-TN) asked pharmaceutical companies to voluntarily impose a two-year ban on direct-to-consumer (DTC) advertising for all new drugs.²¹¹

This request follows plans announced by the American Medical Association on June 21, 2005, to further study DTC drug advertising.²¹² In a June 13, 2005, web site posting, Bristol-Myers Squibb drug company promised to voluntarily refrain from promoting its drugs directly to consumers for at least one year.²¹³ Osteopathic physicians have also recently sought to limit drug ads aimed at consumers.²¹⁴ On July 21, 2005, direct to consumer guidelines were tentatively approved by PhRMA.²¹⁵ This is another topic of great interest to monitor in the coming months.

V. CONCLUSION

The confusion and uncertainty in the legal and regulatory environment surrounding the sale of prescription drug products will create opportunities in 2006 and beyond for those pharmaceutical manufacturers and the providers and suppliers with which they conduct federal health care program business to embrace the challenges and modify their practices in order to comply with the current requirements and attempt to stay ahead of the evolving requirements.

211. *Id.*

212. *Id.*

213. *Id.*

214. Bruce Japsen, *Osteopathic Physicians Seek Limits on TV Drug Ads Aimed at Consumers*, CHI. TRIB., July 21, 2005, at A3.

215. Press Release, Pharmaceutical Research & Manufacturers Ass'n, DTC Voluntary 'Guiding Principles' Receive Preliminary Approval by PhRMA Board of Directors (July 21, 2005), available at <http://www.phrma.org/mediaroom/press/releases/21.07.2005.1193.cfm>.