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FALSE CLAIMS ACT LIABILITY FOR OFF-LABEL PROMOTION
OF PHARMACEUTICAL PRODUCTS

Stephanie Greene

PENNSTATE



The Dickinson
School of Law

False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products

Stephanie Greene*

I. Introduction

The \$400 billion pharmaceutical industry remains one of the most profitable industries, even at a time when “health care” is inevitably paired with “crisis.” Despite its continued profitability, the industry has faced challenges due to lack of innovation, patent expiration on blockbuster drugs, and competition from generic manufacturers. In response to such pressures, many manufacturers increased marketing efforts in order to spur sales and create new markets for existing drugs. From 1996 to 2001, pharmaceutical companies doubled the number of sales representatives in the United States¹ and nearly doubled the amount of money they spent on sales promotion.² Most drug makers now spend twice as much on marketing existing drugs as they do on researching new ones.³

In a 2000 study, the National Institute for Health Care Management concluded that “more aggressive marketing of prescription drugs to both doctors and consumers,” is one of the factors contributing to the rise in prescription drug spending.⁴ While the advent of direct-to-consumer

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1. American Medical Association, *Module 4: American Medical Association Ethical Guidelines on Gifts to Physicians from Industry*, <http://www.ama-assn.org/ama/noindex/category/9984.html> citing Chin T., American Medical News at www.amednews.com, May 6, 2002 (sales representatives in the United States doubled from some 87,000 in 1996).

2. *Id.* citing Gammage, J. & Stark, K., *Under the Influence*, PHILA. INQUIRER, Mar. 9, 2002, (the industry spent \$15.7 billion on promotion in 2001, up 43% from 1997).

3. See Gardiner Harris, *Treatment by Incentive; As Doctor Writes Prescription, Drug Company Writes a Check*, N.Y. TIMES, June 27, 2004, at 1. See generally MARCIA ANGELL, M.D., *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 37-51 (2004) (maintaining that the true cost of research and development is substantially less than the drug companies claim).

4. See National Institute for Health Care Management, *Prescription Drug Expenditures in 2000: The Upward Trend Continues*, available at

advertising has bombarded the public with messages about how we can be healthier, happier and sexier, the \$2.4 billion spent on consumer advertising pales in comparison to the more than \$8 billion spent each year on marketing to physicians.⁵ Physicians “hold the keys to the pharmaceutical kingdom” and are a critical contact for companies seeking entrée for new drugs or for new uses of existing prescription drugs.⁶ The importance of physician contact is evident in statistics provided by the American Medical Association (AMA). According to AMA data, for example, there is one industry representative for every 4.7 physicians and the average physician sees about ten pharmaceutical representatives each month.⁷ The AMA data indicates that doctors, who have little time in their busy schedules for sales pitches, often spend less than one minute with representatives who come to “call.”⁸ Consequently, marketing teams may resort to a variety of techniques to get a physician’s ear.

Marketing to doctors takes many forms including promotional gifts, fees for speaking engagements, and payment for participation in continuing medical education (CME) programs. Some doctors respond to such overtures while others are quick to recognize and dismiss marketing endeavors. Aggressive marketing techniques, however, are often disguised so that sales pitches reach even those doctors most reluctant to entertain sales representatives. The interaction of pharmaceutical companies and health care professionals raises legal and ethical questions, as some tactics cross the line from aggressive or creative to illegal marketing techniques. As the new Medicare bill increases the government’s responsibility to pay for prescription drugs, it is no surprise that government agencies have scrutinized these practices, with the goal of uncovering fraud and recouping losses attributed to fraudulent activity. Such investigations may be sparked by information provided by whistleblowers, usually employees within the pharmaceutical industry, who bring evidence of suspect marketing activity to the government’s attention. Criminal investigations and civil lawsuits relating to pharmaceutical marketing practices have led to guilty pleas, settlements, the payment of substantial fines, and corporate integrity agreements.⁹

www.nihcm.org/spending2000.pdf at 14 [hereinafter NIHCM Report].

5. See Marcia Angell & Arnold S. Relman, *America’s Other Drug Problem*, THE NEW REPUBLIC 27, 34 (Dec. 16, 2002).

6. See CARL ELLIOTT, BETTER THAN WELL: AMERICAN MEDICINE MEETS THE AMERICAN DREAM 120 (2003).

7. See *id.*

8. See *id.*

9. Recent cases include the following: In 2004, Pfizer agreed to pay \$430 million and pled guilty to criminal charges involving the marketing of Neurontin. See David

Off-label promotion of products is one marketing strategy that has caught the attention of federal investigators. An off-label use is one other than that for which the drug was FDA approved. If a company has a product that is approved by the Food and Drug Administration (FDA), it may seek off-label uses for that product in order to gain market share without the expense and time demanded by the standard FDA approval process. While doctors may legally prescribe a drug approved by the FDA for unapproved or "off-label" uses, manufacturers are generally prohibited from promoting such "off-label" usage.¹⁰ While some off-label uses are scientifically valid and provide tremendous benefits to patients, there is strong temptation for manufacturers to promote off-label use of products purely for profit. Such off-label promotion exposes the public to health risks and the pharmaceutical company to legal liability.

In addition to safety and efficacy concerns, off-label promotion also raises concerns about how limited resources of state and federal agencies are tapped. For example, Medicaid spending on prescription drugs tripled between 1990 and 1999 from \$4.8 billion to \$17 billion.¹¹ Because some off-label uses may not be eligible for reimbursement by government programs, a marketing campaign that promotes off-label use of a drug, with the knowledge that such prescriptions will be charged to a government program such as Medicaid or Medicare, may lead to allegations of fraudulent conduct by the pharmaceutical company.¹² Strategies instituted to attract physicians to prescribe for off-label use

Armstrong & Rachel Zimmerman, *Pfizer to Settle Medicaid-Fraud Case*, WALL ST. J., May 13, 2004, at A4.; AstraZeneca paid \$355 million in 2003 "to resolve criminal and civil liabilities in connection with its drug pricing and marketing practices with regard to Zoladex," used in treatment of prostate cancer. Department of Justice, *AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay \$355 Million to Settle Charges*, http://www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm; TAP Pharmaceuticals paid \$875 million in 2001. See Department of Justice, *TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 million to Settle Charges*, available at www.usdoj.gov/opa/pr/2001/October/513civ.htm; Schering Plough pled guilty to fraud for violating the Anti-Kickback Statute and paid \$425 million in fines and to settle a False Claims Act case. The United States Government and Medicaid recovered losses resulting from the company's failure to report its true best price for the drug Claritin. See Press Release, United States Attorney's Office, Schering-Plough to Pay \$345 Million to Resolve Criminal & Civil Cases, (July 30, 2004).

10. See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001) (recognizing that the FDA attempts to regulate "off-label" use "without directly interfering with the practice of medicine"); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 76 (1998) (citing examples of court decisions and FDA recognition of the value of off-label use).

11. See NIHCM Report, *supra* note 4, at 4.

12. See discussion *infra* Part IV.A.

may also violate the Medicaid and Medicare Anti-Kickback Statute (AKS), implicating both the pharmaceutical company and physicians.¹³

The FDA has power to regulate the marketing practices of pharmaceutical companies and the Department of Justice may bring criminal charges under the AKS. While the administrative and criminal processes may have grave consequences for pharmaceutical companies, the False Claims Act (FCA)¹⁴ may be a more powerful weapon and deterrent for unlawful marketing strategies. Fraudulent marketing schemes may come to light through policing by the FDA as well as through investigations by the Department of Justice. The FCA, however, allows an individual who has knowledge of fraudulent activity to bring suit on behalf of the government. Employees at pharmaceutical companies, such as sales representatives or executives, may become whistleblowers who provide valuable information to the government, leading to guilty pleas and settlement of civil allegations of fraudulent activity. The successful case brought under the FCA will recoup losses sustained by the government and reward the whistleblower with a percentage of the government's recovery.

Health care fraud is combated on several fronts, including industry regulation, guidance, and litigation, which all contribute to monitoring and shaping health care law.¹⁵ Thus, the law regarding off-label promotion of drugs is subject to federal legislation, as well as to industry guidance and precedent from litigation. The Federal Food, Drug and Cosmetic Act (FDCA), the AKS and the FCA all play important roles in regulating off-label promotion. The interpretation of these laws by the courts also plays an important role in determining how pharmaceutical companies may conduct their marketing affairs. Finally, guidance issued by the Department of Health and Human Services Office of the Inspector General (OIG), as well as industry guidelines promulgated by the Pharmaceutical Manufacturers of America (PhRMA) and the American Medical Association (AMA), provide valuable and practical information to the industry and physicians.¹⁶

This paper will explain the current law on off-label promotion of pharmaceutical products. Part II of the paper will explain the FDA's role in regulating off-label promotion, including why such regulation is

13. See discussion *infra* Part IV.B.

14. 31 U.S.C. §§ 3729 *et seq.*

15. See Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 243 (2004) (maintaining that "the combination of cumbersome rulemaking procedures, the proliferation of unofficial forms of guidance, and the growing use of litigation as a regulatory strategy has created an increasingly untenable situation for the health care industry"). *Id.*

16. See discussion *infra* Part VI.

necessary. Part III discusses FDA guidance and its codification in the Food and Drug Administration Modernization Act (FDAMA) regarding specific limits to the dissemination of material regarding off-label promotion as well as CME information on off-label promotion. The First Amendment challenge to the FDA guidance and FDAMA are explored to illustrate that, despite an apparent victory on First Amendment grounds, the litigation did little to broaden the potential for increased off-label promotion. In Part IV, the paper explains how the FCA and AKS can be used to investigate and punish companies that unlawfully promote off-label use of drugs. In Part V, *United States ex rel. Franklin v. Parke-Davis*¹⁷ serves as a vivid example of a marketing campaign that successfully increased the off-label use and raised the profit of a product through off-label promotion, but was ultimately exposed as unlawful by a whistleblower. Part VI synthesizes the various codes promulgated by the OIG, PhRMA, and the AMA regarding appropriate interaction between physicians and the pharmaceutical industry, especially as these codes and guidelines relate to off-label promotion of pharmaceuticals. The paper concludes that increased government scrutiny of marketing practices in the health care industry should alert companies to educate their employees about laws that could have serious legal repercussions for unlawful marketing strategies. Furthermore, pharmaceutical companies should implement meaningful policies and procedures that assure that marketing strategies comply with the law and the guidelines issued by both the industry and government.

II. FDA Regulation of Off-Label Promotion

FDA regulations provide that “a new drug may not be approved for marketing unless it has been shown to be safe and effective for its intended use(s).”¹⁸ FDA approval is use specific and the labeling that accompanies the product must accurately reflect its approved use.¹⁹ An

17. No. CIV.A.96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003).

18. 21 C.F.R. § 310.303(a) (2003). The FDCA states that new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) & (d) (2005).

19. The package insert that accompanies the drug is the most obvious “labeling.” The FDA has also considered any promotional printed material related to the product as labeling. See 21 C.F.R. § 202.1 (1997); see also *Kordel v. United States*, 335 U.S. 345, 350 (1948) (pamphlets shipped prior to or subsequent to the shipment of the drug considered “labeling” in determining misbranding); *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755, 765-66 (D. Neb. 1955) (display posters that described the use of the drug shipped separately from the drug were considered labeling); *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D. D.C. 1998) (stating that in addition to package inserts that accompany the drug, labeling “has also been construed to include nearly

off-label use is one other than that for which the drug was FDA approved. It is unlawful for a manufacturer to introduce a drug into interstate commerce with the intent that it be used for an off-label purpose.²⁰ A company that includes information about off-label uses in its labeling information has committed the criminal offense of "misbranding."²¹

The FDA has the power to seize drugs that are introduced into interstate commerce without agency approval.²² The FDA may also issue injunctions against the unlawful promotion of drugs²³ and it may seek criminal penalties for off-label marketing.²⁴ There is, however, no private right of action to enforce these FDA regulations.

While the FDA regulates the promotion of off-label uses, it does not control off-label prescription by physicians. The legislation specifically states that it will not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."²⁵ Thus, "once a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling."²⁶ Off-label prescription of drugs is common, with as many as forty percent of all prescriptions issued involving off-label use.²⁷ Moreover, in many cases, off-label drug prescription may represent the standard of care in the industry.²⁸

every form of drug company promotional activity, including booklets, pamphlets, mailing pieces, bulletins, and all literature that supplements, explains, or is otherwise textually related to the product.") *Id.*

20. 21 U.S.C. § 331(d).

21. 21 U.S.C. § 331(a) & § 352. In 1999, Genentech pleaded guilty to introduction of a misbranded drug in interstate commerce, paying over \$50 million in criminal fines. The company promoted its FDA approved drug Protropin for short stature in healthy children, as well as for other off-label uses. Thus, Genentech introduced its product Protropin into interstate commerce intending it to be used for medical conditions for which it had not been approved and had not been shown to be safe and effective. See Vita Maria Salvemini, *Idiopathic Short Stature or Just Plain Short: Why the Federal Government Should Regulate the Administration of Human Growth Hormone to Healthy Children*, 38 GA. L. REV. 1105, 1120 (2003-04).

22. 21 U.S.C. § 334(a) (2005).

23. 21 U.S.C. § 332(a) (2005).

24. 21 U.S.C. § 333 (2005).

25. 21 U.S.C. § 396 (2005).

26. Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 2004).

27. See David Armstrong & Anna Wilde Mathews, *More Off-Label Drug Use is Seen*, WALL ST. J., May 14, 2004, at B1.

28. See, e.g., Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Drugs and Devices; Request for Comments, 59 Fed. Reg.

The primary benefit of off-label promotion is to inform the health care community about scientific advances that will benefit patients, thus improving the quality of health care without waiting for the lengthy FDA approval process.²⁹ While the practice of prescribing off-label is widespread, it has been especially prevalent and noteworthy in treating cancer and HIV/AIDS.³⁰ Other well-known, examples of prescriptions for off-label use include the prescription of aspirin to reduce the risk of heart attacks and the use of Viagra, originally approved to treat chest pain, as an impotency drug.

Despite the successes of some off-label prescription and use, off-label promotion by the pharmaceutical industry raises concerns about public health and safety. While off-label promotion of some products may improve the quality of health care and save lives, the promotion of other products for off-label use may harm or endanger patients. Professor Steven Salbu's analysis, contrasting the positive off-label experience of breakthroughs in HIV/AIDS treatment with the negative experience of off-label promotion of the diet drug phen-fen, illustrates the cost/benefit issues associated with off-label promotion.³¹ Phen-fen was prescribed and used widely for off-label uses despite the fact that the combination of fenfluramine and phentermine was not approved. In addition, the drug was used for time periods that exceeded those approved by the FDA, and the drug was prescribed to patients who did not meet the medical definition of obesity.³² Widespread off-label prescription of phen-fen led to reports of heart valve damage in many patients. The risks posed to the public from off-label prescription such as that involving phen-fen has led some critics of off-label use to equate the practice with dangerous medical experimentation. Even in cases where an off-label use does not produce harmful side effects, harm may result from the fact that an ineffective prescription has been substituted for an effective drug.³³

59,820, 59,821 (Nov. 18, 2004); see also Beck & Azari *supra* note 10, at 79.

29. See generally Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 193-201 (1999) [hereinafter Salbu I]; James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANN. HEALTH L. 295, 302-05 (2003); Edmund Polubinski, III, Note, *Closing the Channels of Communication: A First Amendment Analysis of the FDA's Policy on Manufacturer Promotion of "Off-Label" Use*, 83 VA. L. REV. 991, 1005 (1997).

30. Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, Aids, and the Diet Drug Debacle*, 79 B.U. L. REV. 93, 96. (1999) [hereinafter Salbu II].

31. See *id.* at 107-36.

32. See *id.* at 136.

33. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 56-57 (D.

Proponents of off-label marketing also maintain that avoiding the lengthy and expensive FDA approval process has cost containment benefits, both in terms of controlling price increases and in saving tax dollars channeled to FDA efforts.³⁴ This financial cost argument, however, must be balanced with the FDA's underlying mission of ensuring the safety and efficacy of products. The concern is that off-label promotion may be motivated by profit maximization. For example, manufacturers who are under pressure to maximize profits before patents expire, or who are searching to expand the market for an approved drug, may seek to market a product for a new use by bypassing the formal FDA approval process and its costs.

The FDA has struggled with its role in controlling off-label promotion of drugs to health care providers. Before 1997, off-label marketing was prohibited. Under pressure by the industry to liberalize its rules about off-label promotion, the FDAMA was passed in 1997 to allow manufacturers to disseminate information about off-label uses to health care providers under certain circumstances.³⁵ The dissemination of such information is controversial, however, and the impact of the 1997 amendments is still unclear. The FDAMA and the lawsuits that tested the limits of this act are discussed in the following section.

III. Defining the Scope of Off-Label Promotion

While recognizing a physician's right to prescribe any FDA approved drug for off-label use, the FDA has resisted and generally condemned efforts by pharmaceutical manufacturers to disseminate information about off-label uses to health care professionals. The agency has two reasons for discouraging the dissemination of such information. First, the FDA worries that information provided by the pharmaceutical companies may be incomplete, so that doctors are not fully informed in making prescription choices. As one court pointed out, even truthful information may be misleading where a manufacturer provides physicians with "'the one' article that supports use of their drug, even if there exists considerable evidence to the contrary."³⁶ Second, the FDA worries that allowing the dissemination of information about off-label

D.C. 1998) [hereinafter *WLF I*].

34. See Salbu I *supra* note 29, at 195. A new trend in the pharmaceutical industry hopes to reduce the substantial costs associated with drug development, and especially the tremendous costs associated with late failures. "Experimental medicine," involves small-scale trials on humans, rather than animals, before launching the expensive and time consuming full-scale clinical trials. Such experimental medicine could change the traditional pattern of drug testing. See Andrew Pollack, *In Drug Research, Some Guinea Pigs are Now Human*, THE N.Y. TIMES, August 4, 2004, at A1.

35. See 21 C.F.R. § 99.1-.501 (2003).

36. *WLF I*, 13 F. Supp. 2d at 65.

uses will encourage companies to bypass the FDA regulatory process.

Before FDAMA, a pharmaceutical company could market, promote and advertise only those uses that the FDA determined to be safe and effective for a particular drug. Thus, for many years, the FDCA expressly forbade the sale of a drug whose labeling or advertising claims of effectiveness had not yet received approval from the FDA. Pharmaceutical manufacturers could not discuss off-label uses with health care professionals nor could they distribute written materials that mentioned off-label uses. The FDA allowed the dissemination of information about off-label uses only when such information was solicited by the physician.

A. The Food and Drug Administration Modernization Act

The FDA's first steps in allowing controlled dissemination of information about off-label uses came in the form of guidance documents.³⁷ Recognizing the importance of scientific and educational discussions, "including discussions of unapproved uses," the FDA published Guidance allowing manufacturers to disseminate information to health care providers under certain conditions.³⁸ FDA Guidance addressed the dissemination of journal article reprints and textbooks, so-called "enduring materials," to physicians. In general, the FDA stated that manufacturers should distribute enduring materials to health care professionals only if the materials were unabridged and were primarily about approved FDA uses.³⁹

The FDA also issued Guidance concerning a manufacturer's involvement in continuing medical education (CME) seminars at which off-label uses were presented. The Guidance encouraged the exchange of educational discussions "including discussions of unapproved uses."⁴⁰ But the CME Guidance also sought to distinguish between CME programs in which the content was independent of the influence of a pharmaceutical company from those controlled by a pharmaceutical company.⁴¹ The FDA's CME Guidance provided a list of twelve factors to determine whether a program is independent of manufacturer influence and, therefore, permissible.⁴²

37. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997); Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

38. See *WLF I*, 13 F. Supp. 2d at 57.

39. See *id.*

40. See *id.*

41. See *id.* (citing 62 Fed. Reg. 64074, 64095-99 (Dec. 3, 1997)).

42. See *id.* The twelve factors include who controls the content and selects the presenters and the moderator; whether there is meaningful disclosure as to the company's

The Guidance on enduring materials was subsequently passed in 1997, as section 401 of FDAMA.⁴³ Many provisions in FDAMA modify the regulation of approval for medical products, streamlining the process to make promising drugs available more quickly.⁴⁴ While many of FDAMA's reforms were popular, section 401's provisions regarding the dissemination of information on off-label uses provoked controversy. FDAMA was a compromise between those who believed that off-label promotion would allow the public access to potentially life-saving treatments and those who believed that off-label promotion and use of drugs posed a threat to public health.⁴⁵ Although FDAMA liberalizes regulation of the drug industry in general, and purports to liberalize the dissemination of information regarding off-label use to health care professionals, the requirements for legally disseminating such information are burdensome. The law requires the manufacturer to submit a supplemental application to the FDA seeking approval of the off-label use within thirty-six months of dissemination of the material in question; to provide the materials to the FDA sixty days prior to dissemination; to disseminate materials in unabridged form; and to disclose to recipients that the materials pertain to an unapproved use of the drug.⁴⁶ The law also requires extensive reporting and recordkeeping regarding the off-label use subsequent to dissemination of such information.

B. Washington Legal Foundation Challenges Restrictions on Off-Label Promotion

Before FDAMA was signed into law, the Washington Legal Foundation (WLF), a national public interest center,⁴⁷ challenged the

funding; whether unapproved uses will be discussed; whether the central theme of the program is on one product; the relationship between supporting companies and the CME provider; audience selection; opportunities for meaningful discussion and questioning; dissemination of information; ancillary promotional activities; and complaints by the provider, presenters or attendees regarding attempts by the supporting company to influence content. See Final Guidance on Indus. Supported Scientific Ed. Activities, 62 Fed. Reg. 64074, 64097-99 (Dec. 3, 1997).

43. Pub. L. No. 105-115, 111 Stat. 2296.

44. Some important reforms include the reauthorization of the Prescription Drug User Fee Act of 1992 for five more years. This provision substantially increased the number of employees at the FDA, by assessing user fees to the pharmaceutical industry. The reform allowed the agency to reduce the average time for drug review from thirty to fifteen months. FDAMA also codifies FDA regulations to increase patient access to experimental drugs and medical devices.

45. See O'Reilly & Dalal, *supra* note 29, at 302-03.

46. See 21 U.S.C. § 360(a) (2005).

47. See WLF MISSION, at <http://www.wlf.org/Resources/WLFmission> (last visited May 23, 2005).

constitutionality of the FDA Guidance that preceded FDAMA regarding enduring materials and CMEs. WLF sought to prevent the FDA from restricting a manufacturer's promotion of off-label uses, by arguing that the restrictions violate free speech provisions of the First Amendment.⁴⁸ In *Washington Legal Foundation v. Friedman (WLF I)*,⁴⁹ the court held that the Guidances regarding enduring materials and CME Guidances restricted speech more than necessary.⁵⁰

In *WLF I*, the court recognized that scientific and academic materials merit constitutional protection as "commercial speech" when the goal of disseminating such materials is to "increase the sales volume of their drugs."⁵¹ Because the speech in question was commercial, the court applied the analysis outlined by the United States Supreme Court in *Central Hudson Gas & Electric v. Public Service Commission of New York*.⁵² The four point *Central Hudson* analysis considers: 1) whether the speech is inherently unlawful or misleading; 2) whether the government has a substantial interest in regulating the speech; 3) whether the government regulation directly advances the government interest; and 4) whether the regulation is more extensive than necessary to advance the government's interest.⁵³ In *WLF I*, the court held that the possibilities for abuse in disseminating information do not make such information "inherently misleading" or illegal.⁵⁴ While the court recognized the government's interest in regulating off-label promotion of drugs to protect the public health, the court found that the Guidances in question were more restrictive of speech than necessary, thereby violating the *Central Hudson* test.⁵⁵ The court held that the FDA could not prohibit manufacturers from disseminating enduring materials "regardless of whether such [materials] include a significant or exclusive focus on off-label uses and from proscribing manufacturers from suggesting content to CME program providers."⁵⁶ The court's order recognized that the FDA could continue to enforce rules and regulations regarding the dissemination of information that was "false or misleading" and that the FDA could require manufacturers to make disclosures about their financial support or involvement in any of the disseminated materials.⁵⁷

48. *WLF I*, 13 F. Supp. 2d at 51.

49. *Id.*

50. *Id.* at 65-74.

51. *Id.* at 62-64.

52. *Central Hudson*, 447 U.S. 557 (1980).

53. *Id.* at 561-566.

54. *WLF I*, 13 F. Supp. 2d at 67.

55. *Id.* at 65-74.

56. *Id.* at 74-75.

57. *Id.* at 75-76.

When FDAMA was passed in 1997, the WLF challenged its provisions on the same grounds that it had challenged the preceding FDA Guidances.⁵⁸ In *Washington Legal Foundation v. Henney (WLF II)*, the court held that the provisions of FDAMA, like the FDA Guidance provisions it had previously analyzed, are unconstitutional and infringe on manufacturers' rights to disseminate information about off-label use.⁵⁹ The court was particularly concerned about the requirements for supplemental applications, stating "the supplemental application requirement of the act amounts to a kind of constitutional blackmail—comply with the statute or sacrifice your First Amendment rights."⁶⁰

On appeal, the FDA maintained that the section 401 provisions of FDAMA merely provided a "safe harbor" and that neither the FDAMA nor the CME Guidance authorizes the FDA to prohibit or sanction speech.⁶¹ The FDA's position that FDAMA and the CME Guidance were merely official FDA interpretations eliminated the controversy about the constitutionality of FDAMA, leading the United States Court of Appeals for the District of Columbia Circuit to vacate the injunction of the lower court.⁶²

With the district court's orders enjoining the FDA from enforcing provisions of FDAMA vacated, the WLF sought to clarify its position and the status of the court's order.⁶³ In *Washington Legal Foundation v. Henney (WLF IV)*, the district court lamented that "after six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved" leaving drug manufacturers "still without clear guidance as to their permissible conduct."⁶⁴

C. *Impact of the WLF Litigation*

Despite the court's pessimistic view of the WLF litigation, the decisions provide some parameters to guide both the FDA and pharmaceutical manufacturers about promoting off-label use. The WLF decisions indicate that manufacturers may disseminate scientific publications concerning the off-label use of their products as well as support CME programs for doctors. In fact, based on WLF, manufacturers are permitted not only to provide financial support for

58. *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 82 (D. D.C. 1999).

59. *Id.*

60. *Id.* at 87.

61. *Washington Legal Foundation v. Henney*, 202 F.3d 331, 332 (D.C. Cir. 2000) [hereinafter *WLF III*].

62. *Id.* at 335.

63. *Washington Legal Foundation v. Henney*, 128 F. Supp. 2d 11, 12 (D. D.C. 2000) [hereinafter *WLF IV*].

64. *Id.* at 15.

CME programs that discuss off-label uses but they may also suggest the content or the speakers for the event. As the FDA itself suggested, the requirements of FDAMA should be construed as a “safe harbor,” so that a manufacturer that complies with the statute’s requirements, would be safe from FDA prosecution for off-label promotion or misbranding.

Some commentators suggest that the WLF litigation indicates a triumph of the First Amendment over FDA regulation, with important regulatory implications.⁶⁵ But the First Amendment issues involved in the WLF litigation are more likely to prove remarkable from an academic rather than a practical point of view. While the courts’ rulings recognize First Amendment protection of off-label promotion as commercial speech, such recognition does not expand the opportunity for aggressive or creative marketing techniques, nor does it protect false and misleading representations in marketing materials.

The “safe harbor” provisions of FDAMA survive as guideposts for the pharmaceutical industry, but these requirements are so burdensome that pharmaceutical companies are unlikely to comply with them. When the goal of disseminating information on off-label use is to alert the medical community to the discovery of exciting advances or improvements in medical treatment and such information is based on reliable scientific studies, manufacturers should feel comfortable disseminating such information. The WLF litigation, however, does nothing to protect the manufacturer from marketing campaigns that involve false or misleading information. Although the litigation gave no clear guidance regarding the dissemination of off-label materials, voluntary codes promulgated by the AMA and the pharmaceutical industry, as well as guidelines from the OIG, provide much clearer information to pharmaceutical companies and health care professionals about behavior that may lead to liability for off-label promotion.⁶⁶ When pharmaceutical companies engage in practices that might be unlawful, the FCA and the AKS may be the basis for whistleblower lawsuits.

IV. Combatting Fraud in Off-Label Promotion

A. *The False Claims Act*

While the FDA can take administrative or criminal action against a manufacturer for off-label promotion, the FCA may be a more immediate

65. See John Kamp, Daniel E. Troy, Elizabeth Alexander, *FDA Marketing v. First Amendment: Washington Legal Foundation Legal Challenges to Off-Label Policies May Force Unprecedented Changes at FDA*, 54 FOOD & DRUG L.J. 555 (1999) (suggesting that the WLF litigation will substantially influence the FDA’s approach to marketing).

66. See discussion *infra* at Part VI.

threat to companies mounting aggressive marketing campaigns.⁶⁷ Although the FDCA does not provide any right for private enforcement of its provisions, including off-label marketing, the FCA may fill this gap. The statute “*can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit.”⁶⁸ Thus, even though Congress did not provide a cause of action for money damages against a manufacturer for off-label promotion, an FCA claim may be brought to recover money where the manufacturer has caused the government to pay a false claim.⁶⁹

The FCA is the primary tool for the United States Government to combat fraud perpetrated upon it.⁷⁰ Characterized as a broad remedial statute intended to reach all types of fraud that might result in financial loss to the government, the statute imposes civil liability on any person who knowingly presents a false or fraudulent claim to the government.⁷¹ An individual may bring a “qui tam” suit,⁷² a suit on behalf of the United

67. The FDA may seize the drugs that are being illegally promoted or seek an injunction to prohibit unlawful promotional activities. 21 U.S.C. § 332 (a) and § 334. The FDA may also institute criminal proceedings for off-label marketing violations. 21 U.S.C. § 333(a).

68. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51 (D. Mass. 2001).

69. See 31 U.S.C. § 3729(a)(1) (2005).

70. The FCA provides:

Any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government . . . is liable to the United States Government for a civil penalty . . . , plus three times the amount of damages which the government sustained because of the act of that person. . . .

31 U.S.C. § 3729(a).

71. See *United States v. Neifert-White Co.*, 390 U.S. 228, 232-233 (1968) (noting Congress wrote the FCA expansively, meaning to “reach all types of fraud, without qualification, that might result in financial loss to the Government”); see also *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003). The provisions of the FCA are further defined as follows: A person acts “knowingly” if he has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. No specific intent to defraud is required. 31 U.S.C. § 3729(b)(1) (1994); see also DeeDee Baba and Paul E. McGreal, *Applying Coase To Qui Tam Actions against the States*, 77 NOTRE DAME L. REV. 87, 127 (2001). A claim is “any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(c).

72. The term “qui tam” comes from the expression “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,” which translates, “who as well for the king as for

States Government, and participate in a percentage of any sum recovered.⁷³ The whistleblower or relator himself need not suffer injury because the United States remains the real party in interest, and has theoretically assigned its right to sue to the relator.⁷⁴ Furthermore, the relator need not have an adversarial relationship with the defendant, so long as there is a “clearly defined adversarial relationship between the government and the defendant.”⁷⁵ Justifications for the *qui tam* provisions of the FCA include: the need to provide private incentives to expose fraudulent conduct; the unwillingness of some agencies to expose fraud; and the limited enforcement resources available to the government.⁷⁶

Passed in 1863, the FCA has been subject to both praise and criticism. The Act was a response to the profiteering actions of “unscrupulous businessmen” who sold faulty rifles, ammunition, and lame horses to the United States government during the Civil War.⁷⁷ Although the FCA originally allowed any citizen with knowledge of fraud against the government to bring suit in the name of the United States and to receive a sizable portion of the recovery for his efforts, abuse of this opportunity led to more narrow interpretations of the FCA and eventually to amendments to curb parasitic lawsuits. The 1943 amendments denied recovery to relators who raised claims “based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought” even if the relator was the original source of the government’s information.⁷⁸

In 1986, amendments to the FCA showed renewed appreciation for

himself sues in this matter.” BLACK’S LAW DICTIONARY 1282 (8th ed. 2004).

73. 31 U.S.C. §§ 3729-3733 (2005).

74. See *United States ex rel. Hall v. Tribal Dev. Corp.*, 49 F.3d 1208, 1213 (7th Cir. 1995).

75. See *id.* at 1213; see also *United States ex rel. Fallon v. Accudyne Corp.*, 921 F. Supp. 611, 627 (W.D. Wis. 1995).

76. See James Roy Moncus III, Note, *The Marriage of the False Claims Act and the Freedom of Information Act: Parasitic Potential or Positive Synergy?*, 55 VAND. L. REV. 1549, 1550 (2002). The United States has a long history of private citizens participating in public law enforcement. Following English law precedent, the Continental Congress included *qui tam* provisions in ten of the fourteen penal statutes enacted. See *United States ex rel. Stillwell v. Hughes Helicopters, Inc.*, 714 F. Supp. 1084, 1086 (C.D. Cal. 1989). The landmark case, *McCulloch v. Maryland*, was a *qui tam* action, in which a relator sued on his own behalf as well as for the state of Maryland to collect taxes levied on the Second Bank of the United States. 17 U.S. 316 (1819).

77. See 132 CONG. REC. 22, 335 (1986); see also Robert Fabrikant and Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 107 (1999) (tracing the origins and development of the FCA and *qui tam* provisions).

78. See *id.* at 107.

the value of the relator in exposing fraud on the government. The 1986 amendments recognize that the government may benefit from private citizens pursuing cases of fraud without the investment of limited government resources and that the relator may have knowledge of the nexus between events and fraudulent acts. The 1986 amendments increase the scope of qui tam suits in several ways. The amendments allow the relator to be a party to the action even if the government chooses to intervene in the action, while also allowing the relator to pursue his suit if the government declines to intervene.⁷⁹ They provide the relator with a minimum recovery of 15 percent and a maximum of 25 percent if the government intervenes and a minimum of 25 percent and a maximum of 30 percent if the government does not intervene.⁸⁰ After reviewing the relator's information, which must be submitted under seal, the government also has the power to dismiss the suit.⁸¹

Provisions in the 1986 amendments that give whistleblowers opportunity, incentive, and protection, have produced results for the federal government. The statute provides for civil penalties of \$5,500 to \$11,000 per claim, plus three times the amount of damages sustained by the government.⁸² One source reports that FCA suits involving civil health care fraud instituted by whistleblowers have resulted in recovery of some \$5.26 billion by the government during the period from 1999-2003.⁸³

B. The Anti-Kickback Statute

The AKS prohibits payments in any form, direct or indirect, made purposefully to induce or reward the referral or generation of federal health care business.⁸⁴ Although there is no private right of action under

79. 31 U.S.C. § 3730(b)(4), (c)(3) (2000).

80. 31 U.S.C. § 3730(d)(1) & (2).

81. 31 U.S.C. § 3730(d)(1) & (2).

82. 31 U.S.C. § 3729(a) (2000); 28 C.F.R. 85.3(a)(9) (2003) (increasing penalties by 10 percent).

83. See TAXPAYERS AGAINST FRAUD, at <http://www.taf.org> (last visited May 23, 2005).

84. See 42 U.S.C. § 1320a-7b. The Statute provides:

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—

(A) in return for referring 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, 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

the AKS, the FCA has been used successfully as a vehicle for whistleblowers to bring claims of fraud based on AKS violations. Courts have consistently held that actions that violate the AKS may serve as a basis for liability under the FCA.⁸⁵ Several courts have held that a false implied certification may be the basis for a false claim in the context of the FCA, or that non-compliance with laws and regulations render submitted claims "false" for purposes of the FCA.⁸⁶

A recent case illustrates how courts view the AKS as the basis for a claim under the FCA. In *United States ex rel. Bidani v. Lewis*, the United States District Court for the Northern District of Illinois reasoned that compliance with the AKS is crucial to the government's treatment of claims for reimbursement under federal health care programs.⁸⁷ Because the AKS criminalizes receiving remuneration intended to affect decisions to purchase products for which payment may be made under Medicare or Medicaid and those convicted under the AKS are barred from participating in the federal health care program,⁸⁸ reimbursing a claimant for such purchases would "put the government in the position of funding

be fined not more than \$25,000 or imprisoned for not more than five years, or both.

Id.

85. See, e.g., *U.S. ex rel. Thompson v. Columbia/HCA*, 125 F.3d 899, 903 (5th Cir. 1997); *U.S. ex rel. Barrett v. Columbia/HCA*, 217 F. Supp. 2d 28, 29 (D. D.C. 2003) (holding that a violation of AKS can give rise to an FCA claim); *U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 613 (N.D. Ill. 2003); *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp. 2d 258 (D. D.C. 2002). The government has also twice obtained consent decrees enjoining companies from submitting claims to Medicare or Medicaid for patients referred pursuant to a kickback scheme. The defendants paid significant sums to resolve their FCA liability. See *Shalala v. Radiation Care*, No. 1:94-CV-3339-RCF, 1995 U.S. Dist. LEXIS 749 (N.D. Ga. 1995); *Shalala v. T2 Medical*, No. 1-94-CV-2549-ODE, 1994 WL 686949 (N.D. Ga. 1994).

86. See, e.g., *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 415 (6th Cir. 2002); *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (holding that claimants of Medicare reimbursement implicitly certify that they have complied with statutes or regulations that expressly require compliance as a prerequisite to Medicare payments); *Pogue*, 238 F. Supp. 2d at 266 (D. D.C. 2002) (affirming earlier holding that Medicare claimants impliedly certify compliance with AKS, stating that the "developing law has supported [the court's] finding that violations of Anti-Kickback and Stark laws can support a claim under the False Claim Act."); *United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504 (S.D. Ohio 1994); *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429 (1994), *aff'd*, 57 F. 3d 1084 (Fed. Cir. 1995); *United States v. Incorp. Village of Island Park*, 888 F. Supp. 419, 439 (S.D.N.Y. 1995); *United States v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436, 445 (S.D.N.Y. 1999) (stating that submission of a false claim by a participant in a venture extends that false claim to all parties).

87. 264 F. Supp. 2d 612 (D. Ill. 2003)

88. 42 U.S.C. § 1320a-7b(b)(1) (criminalizing receiving remuneration intended to affect decisions to purchase supplies for which payment may be made under Medicare); 42 U.S.C. § 1320a-7(a)(1) (barring those convicted under the AKS from participating in the federal health care program).

illegal kickbacks after the fact.”⁸⁹ Consequently, the court upheld the AKS as a basis for a claim under the FCA. Similarly, other courts have held that where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent.⁹⁰ Although some courts have expressed reservations about the implied certification theory as a basis for FCA actions, they have not expressly rejected the theory.⁹¹

The case described in the following section illustrates how the FCA and the AKS may be used to combat unlawful off-label promotion of pharmaceuticals.

V. *United States ex rel. Franklin v. Parke-Davis*: Off-Label Marketing and the FCA

A. Background

*United States ex rel. Franklin v. Parke-Davis*⁹² involved claims of fraud and deception brought by a former employee of Parke-Davis.⁹³

89. *Bidani*, 264 F. Supp. 2d at 616.

90. See *Ab-Tech Constr., Inc.*, 31 Fed. Cl. at 434.

91. In *United States ex rel. Siewick v. Jamieson Science & Engineering, Inc.*, 214 F.3d 1372 (D.C. Cir. 2000), the court held that the relator did not have a sufficient claim of implied certification, but the court did not discredit the theory of implied certification. In *United States ex rel. Barmak v. Sutter Corp.*, 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. May 14, 2002), the court held that it was “not convinced that a *qui tam* plaintiff can use the FCA as a vehicle for pursuing a violation of the anti-kickback statute in this circuit.” *Id.* The court rejected implied certification but did so in dicta on a matter not fully briefed and not squarely before it. The court rejected the relator’s claim for failure to establish a causal connection between the alleged kickback violations and claims for reimbursement, failure to allege certification of compliance with the anti-kickback statute, and failure to allege that the government relied on such certification to make payments. *Id.* In *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 n.8 (4th Cir. 1999), the court expressed some doubts about the implied certification theory, but did not directly address the issue. See generally Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003 (maintaining that violation of the AKS does not render a claim “false” because the violation does not cause the government injury and that the FCA should not be used as a means for enforcing the AKS because congressional intent indicates that only the federal government, not *qui tam* plaintiffs, could enforce the AKS).

92. 147 F. Supp. 2d 39 (D. Mass. 2001).

93. Pfizer, the world’s largest pharmaceutical company, acquired Warner Lambert, including its pharmaceutical division, Parke-Davis. The activities involved in the lawsuit occurred before Pfizer’s acquisition. Parke-Davis, Warner-Lambert and Pfizer were named as defendants in the case. This paper will refer to all of the defendants collectively as Parke-Davis.

The relator maintained that the defendant, Parke-Davis, defrauded the United States Government by engaging in a marketing campaign that caused physicians to write off-label prescriptions of its product, Neurontin to patients, and then required Medicaid to reimburse the health care providers for such prescriptions. The FCA claim is based on the fact that the defendants promoted the drug product for uses not approved by the FDA, resulting in federal reimbursement payments for Neurontin prescriptions that were ineligible under Medicaid.

David Franklin, the relator, holds a doctorate degree in biology and was hired by Parke-Davis as a medical liaison in 1996. Franklin maintains that during the four months he was employed by Parke-Davis, he and other medical liaisons were trained to promote various off-label uses of Neurontin by giving physicians false information about the safety and efficacy of off-label uses.⁹⁴ For example, Franklin revealed that medical liaisons were trained to mislead doctors to believe that a body of data existed to support the use of Neurontin in treating a variety of conditions, including bipolar disease and attention deficit disorder, when no such data existed. Furthermore, these medical liaisons led doctors to believe that clinical trials supported the safety and efficacy of such off-label uses. Franklin also maintains that he and other medical liaisons were trained to pose as research personnel and medical doctors, rather than as sales representatives, to gain the trust of the physicians they visited.

The product, Neurontin, the brand name for the drug gabapentin, was approved by the FDA in 1994 as a treatment to be used in conjunction with other drugs for controlling epilepsy, at approved dosages ranging from 900 to 1800 mg per day.⁹⁵ According to Franklin, during his four month tenure with Parke-Davis, Neurontin was promoted for a variety of uses, including pain control, attention deficit disorder, and bipolar disease, even though there was no scientific evidence to demonstrate that Neurontin was effective for such indications.⁹⁶ Despite the lack of evidence to support claims that Neurontin was effective in treating a variety of disorders and conditions, Franklin alleged that the company engaged in a deliberate marketing strategy to expand the off-label prescription of Neurontin in lucrative markets such as pain management and psychiatric uses.

Confidential internal documents and taped voicemail messages indicate the scope of the company's deliberate attempt to promote off-label uses, without regard for the public's health and safety. One senior

94. *Parke-Davis*, 147 F. Supp. 2d at 44.

95. *See id.*

96. *Id.*

executive, explaining the “Neurontin push,” rallied his sales representatives with the following speech: “I want you out there every day selling Neurontin . . . holding their hand, whispering in their ear—Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything. . . . I don’t want to see a single patient coming off Neurontin before they’ve been up to at least 4,800 milligrams a day.”⁹⁷

Franklin also alleged that doctors who prescribed large amounts of Neurontin received kickbacks in the form of cash payments, travel benefits, and Olympic tickets.⁹⁸ Payments were sometimes disguised as remuneration for consulting services or participation in studies.⁹⁹

The success of the off-label marketing campaign is evident from its results, as specific off-label usage always increased dramatically shortly after an organized promotion effort. For example, one calendar quarter after the campaign started, pain uses of the product increased 2500 percent, and in the second quarter of 1996, within three months after the program to promote migraine use began, usage increased 800 percent. When the defendant initiated its off-label marketing campaigns in late 1995, off-label uses for Neurontin were less than 15 percent of its sales. In 2003, use of Neurontin for unapproved uses accounted for nearly 90 percent of its sales.¹⁰⁰ Moreover, while Parke-Davis initially estimated the lifetime sales of Neurontin at \$500 million, the drug has grossed over \$2 billion annually in the last several years.

B. Applying the FCA

The basis for the FCA action in this case was that the defendant, Parke-Davis, engaged in a scheme of fraud that caused doctors to write prescriptions for a variety of off-label uses of the product, a substantial number of which were reimbursed by Medicaid. The relator maintains that the product was not eligible for reimbursement from Medicaid when prescribed for an off-label use because its off-label uses were not included in any of the compendia as required by federal law.¹⁰¹ The court recognized a viable cause of action because of evidence that the defendant engaged in “an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government

97. “Drug Giant Accused of False Claims,” *Dateline* (NBC television broadcast, July 11, 2003) (transcript on file with author).

98. *Parke-Davis*, 147 F. Supp. 2d at 46.

99. *Id.*

100. See Anna Wilde Mathews & David Armstrong, *Pfizer Case Signals Tougher Action on Off-Label Drug Use*, WALL ST. J. May 14, 2004, at B1.

101. See 42 U.S.C. § 1396r-8(g)(1)(B)(i).

under Medicaid.”¹⁰²

The kickback claims, regarding improper compensation to doctors who increased their prescriptions of Neurontin, were dismissed early in the litigation because they were not pleaded with sufficient particularity.¹⁰³ This left the plaintiff with the task of making an appropriate case under the FCA based on the allegation that the defendant’s off-label promotion of its product caused ineligible claims to be submitted for Medicaid reimbursement.

In denying a motion for summary judgment for the defendants, the Massachusetts District Court made several important interpretations about the FCA and its application to off-label promotion.¹⁰⁴ Most significantly, the court concluded that even “truthful off-label marketing” may be the basis for a cause of action under the FCA.¹⁰⁵ The court reached this conclusion by recognizing critical distinctions in the requirements of sections 3729(a)(1)-(2) of the FCA.

The defendant argued that the FCA has a “double falsehood” requirement that the plaintiff failed to meet. Although the plaintiff introduced many allegations of false statements made by the defendant in its off-label marketing campaign, the defendant insisted that the plaintiff had to prove “that Parke-Davis intentionally made a material false statement that led to the filing of a false claim.”¹⁰⁶ The court disagreed, finding that section 3729(a)(1) of the FCA does not require the relator to present evidence that false claims were the result of false statements. In other words, the relator was not required to prove that statements made to physicians about the product’s safety or efficacy were false. The statute, the court maintained, requires only that the defendant “causes to be presented” a false claim for payment or approval.¹⁰⁷ While the court recognized a double falsehood requirement under section 3729(a)(2), it concluded that the language of section 3729(a)(1) clearly indicates otherwise.¹⁰⁸ The court pointed to several other cases supporting its interpretation that evidence of a false statement is not necessary under section 3729(a)(1).¹⁰⁹

102. *Parke-Davis*, 147 F. Supp. 2d at 52; *cf.*, *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543-44 (1943) (stating that payments under government contract that was executed as a result of collusive bid constituted actionable false claims).

103. *Parke-Davis*, 147 F. Supp. 2d at 55.

104. *United States ex rel. Franklin v. Parke-Davis*, No. CIV. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003).

105. *See id.* at *4.

106. *See id.* at *3.

107. *See id.* (citing 31 U.S.C. § 3729(a)(1)).

108. *See Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *4.

109. *Id.* at *3-4 (“FCA liability under 3729(a)(1) may arise even absent an affirmative or express false statement” by the defendant.) (citing *Shaw v. AAA Eng’g & Drafting, Inc.*, 213 F.3d 519, 532 (10th Cir. 2000); *United States ex rel. Fallon v. Accudyne Corp.*,

Recognizing that section 3729(a)(1) of the FCA does not have a double falsehood requirement, the court answered what it had identified in an earlier opinion as a distinction between unlawful off-label marketing activity, such as a “mere technical violation of the FDA’s prohibition on off-label marketing,” and “an unlawful course of fraudulent conduct, which includes knowingly making false statements.”¹¹⁰ According to the court’s interpretation of the FCA, as long as the defendant caused the false claim for ineligible Medicaid reimbursement to be filed, the cause did not have to be fraudulent or “otherwise independently unlawful.”¹¹¹

A more difficult question for the court involved the extent to which government programs cover off-label uses. The defendant, Parke-Davis, maintained that forty-two state Medicaid programs permit reimbursement for off-label, non-compendium drug prescriptions or grant the states discretion to reimburse for off-label uses.¹¹² If states have discretion in determining whether such claims are reimbursable, then the submissions for reimbursement could not be considered “false” claims.¹¹³

The answer to this question hinges on interpretation of the Medicaid statute provision, which states that “[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if—(i) the prescribed use is not for a medically accepted indication.”¹¹⁴ The defendant reads this language to show that the states have discretion in whether or not to reimburse for off-label uses. The relator, however, argues that the statute provides discretion only for “covered outpatient drugs.”¹¹⁵ The court found it unnecessary to decide the question for purposes of summary judgment. Because eight states clearly do not allow discretion in covering off-label uses, the court concluded that liability could be premised on claims submitted in those eight states.¹¹⁶

921 F. Supp. 611, 627 (D. Wis. 1995) (noting that a claim under section 2 requires an “affirmative false statement” while a claim under section 1 does not).

110. *Parke-Davis*, 147 F. Supp. 2d at 52. As an example of a “mere technical violation” the court noted that a sales representative might provide one doctor with information of another doctor’s experience with an off-label use. *See id.*

111. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *6.

112. *Id.* at *7.

113. *See* 42 U.S.C. § 1396r-8(d)(1)(B).

114. *Id.*

115. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *8.

116. *Id.* at *9-10. While finding it unnecessary to answer the question regarding state’s discretion, the court appeared to criticize the relator’s interpretation because it violates rules of statutory construction by interpreting certain provisions of the statute to be superfluous. *See id.* The court requested amicus briefs from federal officials to clarify the extent to which states have discretion to provide coverage for off-label prescriptions. *Id.*

The defendant also raised lack of a causal connection between its actions and the false claims as grounds for summary judgment. According to the defendant, the involvement of the physicians broke the chain of causation.¹¹⁷ The court, however, found that the plaintiff had sufficient evidence of causation to defeat the defendant's motion. Using a common law tort analysis of causation, the court found that the plaintiff had introduced enough circumstantial evidence to raise a question of fact regarding causation in fact. Records that showed the differences in off-label prescription rates before and after contact between the physicians and Parke-Davis representatives, as well as market research reports that recorded the doctors' state of mind after meetings with sales representatives, provided sufficient circumstantial evidence, according to the court.¹¹⁸ The court did not require proof that individual doctors relied on false statements by sales representatives.

The court recognized the oft-cited principle that an intervening force breaks the causal connection only when such intervention is unforeseeable.¹¹⁹ The court noted that in this case, the participation of physicians in the "submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud."¹²⁰

The fact that the doctors actually submitted the claims for Medicaid reimbursement does not alleviate the liability of the manufacturers who caused such claims to be submitted. In reaching this conclusion, the court relied on similar decisions that held defendants liable under the FCA even though a third party had actually presented the false claim. The court found the instant case similar to that in *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, in which doctors received kickbacks for referring patients to various hospitals.¹²¹ Although the hospitals submitted the claims for Medicare reimbursement, the court in *Pogue* found that the doctors could be held liable under the FCA for causing such false claims to be submitted.¹²² Thus, an argument that a third party submitted the claims will not allow the party who caused the claims to be submitted to escape liability under the False Claims Act.¹²³

117. *Id.* at *12.

118. *Id.* at *13.

119. *Id.* at *14 (citing *United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 416 (3rd Cir. 1999)); D. Dobbs et al., *Prosser and Keeton on Torts* § 44 at 303-04 (5th ed. 1984); *Restatement (Second) of Torts* § 443 (1965).

120. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *15.

121. 238 F. Supp. 2d 258 (D. D.C. 2002).

122. *Id.* at 267.

123. See *id.* at 266. Cf. *United States v. Mackby*, 261 F.3d 821, 827 (9th Cir. 2001) (affirming FCA liability of owner/managing director of physical therapy clinic who

The court did not fully consider the AKS as a basis for the FCA claim in this case, but it recognized the viability of this theory and that “recent case law supports implied-certification FCA claims in the healthcare context, including kickback-based claims. . . .”¹²⁴ The court failed to consider the issue, however, because it was raised by the government, and the government had not intervened as a party in the case.¹²⁵

The court’s conclusions about the viability of an FCA claim based on off-label promotion undoubtedly contributed to the settlement of this case. Within a year of the court’s decision, the defendant agreed to plead guilty to criminal wrongdoing and to pay \$430 million in fines to settle both criminal allegations and the FCA claims. The defendant also agreed to sign a corporate integrity agreement that allows the government to monitor its marketing practices.¹²⁶

In its promotion of off-label uses for Neurontin, Parke-Davis engaged in activities that clearly violate the AKS. Although charges based on allegations of such violations were not litigated in this case, a review of recent guidelines by the government, the pharmaceutical industry, and the medical profession indicate the extent of Parke-Davis’ misconduct.

VI. Appropriate Interaction Between Health Care Professionals and the Pharmaceutical Industry

The convoluted trajectory of the Washington Legal Foundation litigation left the pharmaceutical industry without clear guidance regarding permissible off-label promotion.¹²⁷ Voluntary codes established by the AMA and PhRMA, and guidance by the OIG, provide more concrete guidance and address legal, ethical, and socially responsible interaction between health care professionals and the pharmaceutical industry.¹²⁸ Many of the provisions of the codes and

instructed the clinic’s billing company to use an improper code on Medicare reimbursement claim forms, stating, “[a] person need not be the one who actually submitted the claim forms in order to be liable.”); *United States v. Krizek*, 111 F.3d 934, 935-37, 942 (D.C. Cir. 1997) (holding that when psychiatrist’s wife submitted invalid Medicare and Medicaid reimbursement claims, “[the psychiatrist] is no less liable than his wife for these false submissions”).

124. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *19.

125. *Id.* at *19-20.

126. See David Armstrong, *Pfizer to Settle Medicaid-Fraud Case*, WALL ST. J., May 13, 2004, at A3.

127. See discussion *supra* at Part III.B.

128. American Medical Association Guidelines E-8.061 Gifts to Physicians from Industry [hereinafter AMA Guidelines], available at <http://www.ama-assn.org/ama/pub/category/8484.html> (last updated Jan. 7, 2005); PhRMA Code on Interactions with Healthcare Professionals [hereinafter the PhRMA Code], adopted on April 18, 2002,

guidance address interaction between healthcare professionals and pharmaceutical manufacturers that is likely to arise in the context of off-label promotion. The AMA, PhRMA, and the OIG all address specific circumstances that might give rise to improper conduct, violation of the AKS, and potential liability under the FCA.

According to the PhRMA Code and AMA Guidelines, pharmaceutical manufacturers may offer, and physicians may accept, educational and practice related items if they are primarily for the benefit of the patient and if they are not of substantial value.¹²⁹ Items should be valued at \$100 or less and may include textbooks that serve a genuine educational function or items of minimal value associated with a healthcare professional's practice, such as pens, pencils, notepads, and similar items.¹³⁰ Even the offer or acceptance of educational and practice related items may be prohibited, however, if such items are offered on more than an occasional basis.¹³¹ Items of substantial value, such as a TV or VCR, items intended for the healthcare professional's personal benefit such as artwork, music or tickets to a sporting event, and payments of cash or gift certificates are not allowed.¹³² The OIG Guidance also cautions against interactions between physicians and manufacturers that might implicate the AKS.¹³³ The OIG recommends that relationships between manufacturers and physicians should be structured to fall within safe harbors, such as those for personal services and management contracts.¹³⁴ The OIG also specifically recommends compliance with the PhRMA Code, noting that "compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute," but that "it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."¹³⁵

The OIG Guidance recognizes that physicians may accept remuneration at fair market value for bona fide consulting or advisory

available at <http://www.phrma.org/mediaroom/press/releases/19.04.2002.390.cfm> (revised Jan. 2004); Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) [hereinafter OIG Guidance].

129. PhRMA Code at 17; AMA Guidelines, at E-8.061(2).

130. *Id.*

131. PhRMA Code at 17.

132. PhRMA Code at 17; AMA Guidelines, at E-8.061(1).

133. OIG Guidance, 68 Fed. Reg. at 23,734. The OIG Guidance cautions that "practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business." The OIG Guidance also cautions that "a violation of the anti-kickback statute may give rise to liability under the False Claims Act." *Id.*

134. *Id.* (referring to 42 CFR 1001.952(d) and 42 CFR 1001.952(i), among others).

135. *Id.* at 23,737.

services.¹³⁶ Nevertheless, in order to minimize the risk of investigation for fraud and abuse, the OIG recommends that physicians and industry representatives document the consulting arrangement, including the need for such services, the nature of the services provided, and the compensation to be provided.¹³⁷

Both the OIG Guidance and the PhRMA Code recommend that pharmaceutical manufacturers separate educational grant programs from marketing and sales programs, and that they establish objective criteria for awarding grants that do not take into account the volume of purchases made by or anticipated from the grant recipient.¹³⁸ Furthermore, all of the guidelines emphasize that pharmaceutical manufacturers may not condition funding of educational grants, scholarships, subsidies, or support on the purchase of a product, in exchange for a healthcare professional prescribing products, or for a commitment to continue prescribing products.¹³⁹ Although manufacturers may provide funding for educational presentations, the guidelines provide that they should have no control over the speaker or content of the presentation in these forums.¹⁴⁰

Similarly, manufacturers may fund educational and research programs such as CMEs, but they should not influence the content of the program or seek to generate business through improper remuneration of program participants.¹⁴¹ Moreover, any financial support should be given to the conference's or program's sponsor rather than to any one healthcare professional, in order to reduce the overall conference fee for all participants and to avoid the appearance of an inappropriate cash gift.¹⁴²

According to the PhRMA Code and AMA Guidelines, pharmaceutical companies may not provide financial support for a healthcare professional's spouse or other guests to take part in educational conferences or presentations.¹⁴³ Other provisions of the PhRMA Code and AMA Guidelines specify that physicians should not be compensated for time spent as "consultants" when they attend educational meetings or conferences in a primarily passive capacity.¹⁴⁴

136. *Id.* at 23,738.

137. *Id.*

138. *Id.* at 23,735-36; PhRMA Code, *supra* note 128, at 15.

139. OIG Guidance, 68 Fed. Reg. at 23,735-36; PhRMA Code at 19; AMA Guidelines, at E-8.061(7).

140. *Id.*

141. *Id.*

142. PhRMA Code, *supra* note 128, at 9; AMA Guidelines, *supra* note 128, at E-8.061(4), (7).

143. *Id.*

144. PhRMA Code, *supra* note 128, at 9; AMA Guidelines, *supra* note 128, at E-

Nor should such token consultants receive reimbursements for travel expenses associated with conference attendance.¹⁴⁵ The PhRMA Code indicates that such conferences should be purely professional and that entertainment or recreational activities should not be offered at such programs.¹⁴⁶

The circumstances under which a physician may accept remuneration or other benefits from a manufacturer are specific and limited. Manufacturers may offer reimbursement for reasonable travel, meals and lodging expenses incurred in performance of bona fide consulting or advisory services.¹⁴⁷ Occasional meals accompanying informational discussions by industry representatives are also allowed so long as they are modest and occur in a manner conducive to the exchange of scientific information and provide educational value.¹⁴⁸ A company may not, however, pay for a meal that will be eaten without a company representative being present.¹⁴⁹

In addition to addressing questions about the behavior of health care professionals and industry representatives, the OIG Draft Guidance urges pharmaceutical companies to implement meaningful compliance programs that include written standards of conduct. Companies should also address specific areas of potential fraud and abuse such as price and rebate reporting and sales and marketing practices.¹⁵⁰ The OIG Draft Guidance also recommends that companies establish education programs for employees as well as agents of the pharmaceutical companies; clear, confidential channels of communication for reporting issues of non-compliance; and appropriate disciplinary procedures and non-retaliatory policies.¹⁵¹

VII. Conclusion

Pharmaceutical manufacturers should approach off-label promotion with caution. Neither the provisions of FDAMA nor the rulings in the

8.061(5).

145. PhRMA Code, *supra* note 128, at 11; AMA Guidelines, at E-8.061(5).

146. PhRMA Code, *supra* note 128, at 7.

147. PhRMA Code, *supra* note 128, at 9; AMA Guidelines, at E-8.061(5).

148. PhRMA Code, *supra* note 128, at 7; AMA Guidelines, *supra* note 128, at E-8.061(5).

149. PhRMA Code, *supra* note 128 at 7.

150. See OIG Guidance, 68 Fed. Reg. at 23,739-40.

151. *Id.* at 23,739-42. See also Press Release, Grassley Urges Drug Companies to Inform Employees about False Claims Act, (July 30, 2004), available at: <http://grassley.senate.gov/releases/2004/p04r07-30a.htm>. Senator Charles E. Grassley, chairman of the Committee on Finance and author of the 1986 amendments to the FCA wrote to several pharmaceutical companies, urging them to educate employees about the FCA and to implement anti-fraud programs as outlined by the OIG.

Washington Legal Foundation litigation increase the breadth of off-label marketing opportunities or diminish the FDA's power to regulate and enforce the dissemination of any information that is false or misleading. Thus, the conclusion that off-label promotion merits First Amendment protection is limited at best. The FDAMA's burdensome "safe harbor" provisions may be overly restrictive, but manufacturers should observe at least the spirit of these provisions when promoting off-label use.

Pharmaceutical manufacturers should be aware of the potential for off-label promotion to trigger claims under the FCA. The trend is for courts to interpret the FCA broadly, and to recognize the viability of several theories of fraud. In fact, a Massachusetts court recently held that even truthful off-label promotion could be grounds for a claim under the FCA, if the pharmaceutical manufacturer was aware that its actions would cause the submission of ineligible Medicaid claims. Courts are also inclined to recognize FCA actions based on a theory of implied certification of the AKS.

Increased government scrutiny of marketing practices in the healthcare industry should encourage companies to educate their employees about the implications of the AKS and the FCA. Employees of pharmaceutical companies should be well trained to observe the guidelines promulgated by PhRMA. Finally, manufacturers should implement compliance programs as specified in the OIG's Draft Guidance.

Most importantly, the law and industry guidelines must prevent industry marketing efforts from interfering with the trustworthiness of the medical profession. The FDA continues to play an important role in monitoring off-label promotion and the interaction between the industry and healthcare professionals. Physicians should have access to the most recent information in order to provide the best care possible to their patients. But doctors must be able to rely on the information they receive from manufacturers, without suspicion that marketing goals are more important than the delivery of safe and effective healthcare.