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Health Care Fraud Liability for Pharmaceutical Manufacturers

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This paper is submitted in satisfaction of the course requirement for Food and Drug Law.

Abstract

Fraud is an increasingly expensive cost to the health care industry, and the regulatory and prosecutorial focus during the past few decades have focused on health care fraud by pharmaceutical manufacturers. This paper provides an overview of the current statutory and judicial environment. First, it examines some of the industry practices for which pharmaceutical companies may be held liable for fraud (as well as some of the reasons these practices are problematic). It then gives an overview of the dual regime of the Medicare and Medicaid Anti-Kickback Statute and the False Claims Act (“FCA”), as well as some of the other guidance documents available to pharmaceutical manufacturers. It also explores the relevant case history that has shaped liability—for health care providers and suppliers in general and for drug companies in particular—under the Anti-Kickback Statute and the FCA. The 2009 settlement between Pfizer and the government provides a useful example of the present state of affairs for pharmaceutical companies. Finally, the paper concludes with a brief overview of the Medicare Part D prescription drug benefit (and the newly implemented coverage gap discount program), which may result in increasing liability for pharmaceutical manufacturers in the future.

I. Introduction

In the late hours of Friday, April 9, 2011, congressional leaders approved a last-minute budget agreement to keep the federal government running for the remainder of the fiscal year.¹ Republicans and Democrats finally compromised after weeks of back-and-forth to cut approximately \$37.8 billion from the budget.² The cuts came from a number of programs across the federal government, such as a compensation fund for victims of crime, a health care program for children in low-income families, community health centers, high-speed rail, and the Corporation for Public Broadcasting, which supports NPR and PBS.³

The \$37.8 billion budget cuts reluctantly agreed to by members of Congress are just over \$36 billion, which is the estimated amount that health care fraud costs American taxpayers each year.⁴ That is based on estimates by the National Health Care Anti-Fraud Association (“NCHAA”) and the Federal Bureau of Investigation that fraud accounts for three to ten percent of total health care expenditures.⁵ The Centers for Medicare and Medicaid Services (“CMS”) estimates that by the year 2018, health care spending will reach \$4.4 trillion, accounting for 20.3 percent of GDP.⁶ Furthermore, the Medicare and Medicaid programs are the largest single purchaser of health care worldwide.⁷ Thus, the federal budget is impacted when Medicare or Medicaid are overcharged or billed for goods or services that were never provided.

¹ Paul Kane et al., *Government Shutdown Averted: Congress Agrees To Budget Deal, Stopgap Funding*, WASH. POST, Apr. 9, 2011, http://www.washingtonpost.com/politics/reid-says-impasse-based-on-abortion-funding-boehner-denies-it/2011/04/08/AFO40U1C_story.html.

² *Id.*

³ *House Republicans Release Details of Last-Minute Budget Deal*, PBS, Apr. 12, 2011, <http://www.pbs.org/newshour/rundown/2011/04/details-of-budget-deal-to-avert-government-shutdown-released.html>.

⁴ Bria N. DeSalvo et al., *Health Care Fraud*, 47 AM. CRIM. L. REV. 681, 683 (2010).

⁵ *See id.*; Federal Bureau of Investigation, *2009 Financial Crimes Report*, <http://www.fbi.gov/stats-services/publications/financial-crimes-report-2009/financial-crimes-report-2009>; National Health Care Anti-Fraud Association, *The Problem of Health Care Fraud*, http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centr&wpscode=TheProblemOfHCFraud.

⁶ *See* DeSalvo et al., *supra* note 4, at 683.

⁷ *See* DeSalvo et al., *supra* note 4, at 683.

This paper will focus on fraud within one subset of the health care industry, but one that has become increasingly important in recent years: pharmaceutical manufacturers. It will first discuss some of the traditional industry practices for which pharmaceutical companies may be held liable for fraud (as well as some of the reasons these practices are problematic). It will then provide an overview of the current statutory regime regulating the industry, specifically the Medicare and Medicaid Anti-Kickback Statute and the False Claims Act (“FCA”), and the non-statutory guidance promulgated by Congress and the Department of Health and Human Services Office of the Inspector General (“HHS OIG”). Next it will review the relevant case history that has shaped drug company liability under the Anti-Kickback Statute and the FCA, looking in particular at the fairly recent settlement between Pfizer and the government. Finally, it will look at some implications for pharmaceutical manufacturer liability in the future as the Medicare Part D prescription drug benefit is fully implemented.

II. Pharmaceutical Manufacturer Practices

A series of congressional hearings by Senator Ted Kennedy in 1990 perhaps first raised public interest in the promotional practices of prescription drug companies and were likely an impetus for American Medical Association (“AMA”) guidelines on receipt of gifts and benefits from drug manufacturers.⁸ A few years later, in its 1994 Prescription Drug Marketing Fraud Alert, the HHS OIG noted that the increase in drug marketing may interfere with the traditional

⁸ See Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies or Cost-Effectiveness?: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 296–97. (1999). Among other things, the guidelines at the time provided that physicians should accept only gifts that primarily benefit patients and that are not of substantive value (such as textbooks and modest educational meals). *Id.* They could similarly accept gifts of minimal value related to the physician’s work (such as pens and notepads). *Id.* Subsidies for CME and professional meetings were appropriate if paid to the sponsor of the event, not the individual physicians. *Id.* Travel expenses were not appropriate, except for the faculty of events or for students and researchers. *Id.* Physicians could be reimbursed for genuine consulting services. *Id.* The current version of the guidelines is now part of the AMA Code of Medical Ethics. American Medical Association, *Ethical Guidelines for Gifts to Physicians from Industry*, <http://www.ama->

roles of physician and pharmacist.⁹ The ways in which pharmaceutical companies use their marketing budgets draws attention because the amounts of money are so large. For example, in 2000, it was estimated that more than \$11 billion was spent each year by pharmaceutical companies in promoting and marketing, \$5 billion of which went to sales representatives.¹⁰ It was estimated that \$8,000 to \$13,000 was spent each year per physician.¹¹ The public scrutiny has continued in recent years, for example, when Senator Chuck Grassley and the Senate Finance Committee led an investigation into pharmaceutical industry funding of CME programs in 2006.¹²

Pharmaceutical manufacturers thus currently navigate a tricky environment. One drug company employee commented, “Health care is the only industry in America where it’s against the law to be nice to your customers.”¹³ At the same time, manufacturers are pushed by the current economics of the health care system to demonstrate that their products are cost-effective as they try to sell more of their products than their competitors.¹⁴ The past two decades have seen an increased focus on holding drug companies liable for various activities that had long been standard industry practice, such as providing gifts to health care providers, sponsoring Continuing Medical Education (“CME”) programs, and paying health care providers to provide consulting or advisory services. There has also been intensified scrutiny of industry marketing of “off-label” uses of drugs and the methods manufacturers use to report prices to physicians and to the federal health care programs.

assn.org/ama/pub/physician-resources/medical-ethics/about-ethics-group/ethics-resource-center/educational-resources/guidelines-gifts-physicians.page?

⁹ Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

¹⁰ See Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 373 (2000).

¹¹ See *id.*

¹² Linda Pissott Reig et al., *Between a Rock and a Hard Place: Off-Label Communications in an Era of Clinical Trial Registries, Continuing Medical Education*, RA FOCUS, Nov. 2006, at 8, 9–10.

¹³ Bulleit & Krause, *supra* note 8, at 279.

A. Gifts and Direct Marketing to Health Care Providers

Physicians' interactions with the pharmaceutical industry begin as early as medical school and continue throughout their careers.¹⁵ Residents and physicians generally believe that pharmaceutical representatives provide them with accurate information about their drugs, but they also believe that representatives prioritize product promotion above patient welfare.¹⁶ Gifts and business courtesies for health care providers can generally be divided into the categories of personal gifts (meals, tickets to sporting events, etc.), practice aids (pens, calendars, textbooks, etc.), and gifts with features of both (subsidies for professional education, payments for consulting services, etc.).¹⁷

Drug companies know how to spend their money well. For example, Michael A. Steinman et al. undertook a review of the documents involved in a suit regarding the off-label marketing of Neurontin by Pfizer and its subsidiaries.¹⁸ Among their other findings, the authors noted that Pfizer's marketing expenses included explicit targeting of physicians who frequently prescribed anti-convulsants like Neurontin, physicians who had the potential to influence their colleagues, influential physicians at academic medical centers, and residents.¹⁹

There are implications to gift giving in the health care industry. On a common sense level, drug companies would not give away their shareholders' money purely out of disinterested generosity—there is clearly a benefit to them. Mary-Margaret Chren et al. note that there are at least three major effects of gift giving (independent of any ethical repercussions).²⁰ First, gifts

¹⁴ See Bulleit & Krause, *supra* note 8, at 319.

¹⁵ See Wazana, *supra* note 10, at 375.

¹⁶ See Wazana, *supra* note 10, at 375.

¹⁷ Bulleit & Krause, *supra* note 8, at 302–03.

¹⁸ Michael A. Steinman et al., *The Promotion of Gabapentin: An Analysis of Internal Industry Documents*, 145 ANNALS INTERNAL MED. 284 (2006). The case, *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), is discussed in further detail in Part V, *infra*.

¹⁹ *Id.* at 285.

²⁰ Mary-Margaret Chren et al., *Doctors, Drug Companies, and Gifts*, 262 JAMA 3448, 3449 (1989).

cost money, and cost is ultimately passed on to patients without their explicit knowledge, since many gifts are private and not visible to patients like many other forms of advertising.²¹ Second, physicians' acceptance of gifts may (further) erode the perception that the medical profession serves the best interests of patients.²² Third, the acceptance of a gift establishes or reinforces a relationship between the donor and the recipient, which triggers social duties and obligations such as grateful conduct and use and potentially reciprocation.²³ Ironically, formal contracts between a buyer and seller can be easily fulfilled or dissolved, but the relationship between the giver and receiver of a gift is less well defined and often endures.²⁴

B. Continuing Medical Education Sponsorship

Continuing medical education is closely linked with the marketing of pharmaceuticals. Although representatives of the drug companies claim they simply want to generate goodwill and name recognition, the pharmaceutical industry does provide a substantial portion of the billions of the dollars spent on CME annually.²⁵ Pharmaceutical companies may organize and advertise the educational event, prepare teaching slides and curriculum materials, and compile lists of possible speakers.²⁶ Companies often organize teaching conferences in community hospitals.²⁷ Sales representatives are allowed to promote the company's products at or adjacent to the educational sessions.²⁸ There are also increasing numbers of for-profit medical education and communication companies, which put together educational programs and are paid mainly by

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Arnold S. Relman, *Separating Continuing Medical Education from Pharmaceutical Marketing*, 285 JAMA 2009, 2009 (2001).

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

pharmaceutical companies.²⁹ In their study, Steinman et al. found that professional education funding accounted for half to two thirds of the projected Neurontin promotional budgets for 1996 through 1998.³⁰ Educational activities included teleconferences with paid physician moderators, speakers' bureaus and lecture series, and unrestricted grants to medical education and communication companies.³¹

C. Payments for Services

Pharmaceutical companies frequently contract with physicians and other health care providers to provide consulting services, serve on advisory boards, and even conduct additional clinical studies. For example, Steinman, et al., noted a number of expenses related to "services" provided by physicians.³² While explicitly seeking feedback from physicians on their advisory boards, Pfizer also gave them honoraria and paid their food, travel and lodging expenses.³³ They viewed publication as a way to stimulate excitement about off-label uses of Neurontin, and there was some intention that they wanted to publish only favorable results.³⁴ Correspondingly, many companies gave incentives to pharmacists for convincing physicians to switch patients to their drug or for providing patients with instructions on use of their drug (pharmacists are legally and ethically obligated to provide patient counseling).³⁵

Steinman, et al., also noticed that Pfizer provided funding for an uncontrolled, open-label study in patients with epilepsy, in which physicians were instructed to increase the dosage until patients were seizure-free or at a maximum twice the FDA-approved level.³⁶ Unless the FDA has asked for additional research, clinical studies for products that have already received FDA

²⁹ *Id.*

³⁰ Steinman et al., *supra* note 18, at 285.

³¹ Steinman et al., *supra* note 18, at 286–88.

³² Steinman et al., *supra* note 18, at 288–90.

³³ Steinman et al., *supra* note 18, at 288.

³⁴ Steinman et al., *supra* note 18, at 288.

³⁵ See Bulleit & Krause, *supra* note 8, at 312.

market clearance raise suspicion because they are not strictly necessary and may result in the use of products where not medically indicated.³⁷

Among the problems of health care fraud, such as payments for services or clinical studies, are the conflicts of interest that it creates. A conflict of interest can be considered as a set of conditions in which professional judgment concerning a primary interest (such as patient welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as personal financial gain).³⁸ In the realm of clinical studies, although the FDA has some guidelines requiring disclosure of investigator conflicts of interest, physicians may underestimate the extent to which they are influenced.³⁹ A survey of San Francisco area physicians revealed that 85% of those surveyed felt participation in AIDS medication clinical trials would not adversely affect the doctor-patient relationship, and 84% did not believe there was a conflict between the role of physician and researcher.⁴⁰

D. “Marketing the Spread”

There has been a lot of scrutiny of pharmaceutical companies for inflating the prices reported in the Average Wholesale Price (“AWP”), which is used by a number of government agencies in determining reimbursement rates.⁴¹ For example, as of the 2003 Medicare Prescription Drug, Improvement and Modernization Act, the reimbursement rate for Medicare Part B drugs was set at 85 percent of AWP in 2004.⁴² Contractors base their rates on the information in the pharmaceutical pricing publications and databases, which receive their

³⁶ Steinman et al., *supra* note 18, at 289–90.

³⁷ See Bulleit & Krause, *supra* note 8, at 307.

³⁸ See Kevin W. Williams, *Managing Physician Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting*, 59 FOOD & DRUG L.J. 45, 56 (2004).

³⁹ *Id.* at 52–53.

⁴⁰ *Id.* at 65.

⁴¹ Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL’Y 55, 123–24 (2003).

⁴² See *id.* at 124.

information directly from the manufacturers.⁴³ However, the published prices often do not reflect the actual price at which physicians and hospitals can purchase products because manufacturers will frequently offer volume discounts and purchasing incentives.⁴⁴ AWP is jokingly known in the drug industry as “Ain’t What’s Paid.”⁴⁵ Part of this problem is the lack of a standard definition of AWP. No federal statute defines it, and Redbook and First Data Bank, the reporting agencies upon which the state programs rely, do not publish a standard definition.⁴⁶ The commonly accepted definition is the manufacturer’s “suggested retail pharmacy price,” but certain products, like drugs sold directly to patients or hospitals, are not distributed through wholesalers and cannot be priced this way.⁴⁷

The government’s attempts to control AWP reporting have been ongoing for decades. In 1974, the government sought to limit the prices paid to pharmacists under Medicaid, noting, “The Department recognizes that published wholesale prices for drugs [...] are frequently higher than prices actually paid by providers.”⁴⁸ In 1991, HHS noted that the Red Book (one of the main compendia used by the government agencies to calculate rates) overstated the actual prices.⁴⁹ The government again observed the problems of marketing the spread in 2003.⁵⁰ It noted, “For a few drugs, the ‘spread’ is so large that the amount that the Medicare beneficiary pays the physician or supplier for coinsurance is greater than the physician or supplier’s payment to acquire the drug.”⁵¹

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Paul E. Kalb et al., *The Average Wholesale Price: It “Ain’t What the Government Wants to Pay”*, BNA HEALTH CARE FRAUD REPORT, Feb. 21, 2001.

⁴⁶ *See id.*

⁴⁷ *See id.*

⁴⁸ Maximum Allowable Cost for Drugs, 39 Fed. Reg. 40,302, 40,303 (Nov. 15, 1974).

⁴⁹ *See Krause, supra* note 41, at 126.

⁵⁰ Payment Reform for Part B Drugs, 68 Fed. Reg. 50,428, 50,429–30 (Aug. 20, 2003).

⁵¹ *Id.* at 50,430. The example given was for leucovorin calcium, which at the time had a list AWP of \$18.44 but was widely available at a market price of \$2.77. *Id.* Since the Medicare payment was 95 percent of the list AWP

The government made several attempts to revise the calculations of AWP to little avail. In 1997, an attempt to revise the AWP failed when Congress could not reach a consensus.⁵² One main reason was strong opposition from the oncology lobby, who argued that the higher reimbursement rates for drugs helped offset the storage and administering costs.⁵³ In May 2000, the National Association of Medicaid Fraud Control Units ordered First Data Bank (the reporting service on which Medicaid agencies generally rely) to stop reporting the AWP published by the pharmaceutical industry and to instead use the market prices for approximately 50 drug and biologic products.⁵⁴ The AWP calculated with a survey of wholesale catalog prices was 50 or 60 percent lower than the AWP published by manufacturers.⁵⁵ HCFA issued a memo to its contractors announcing the alternative source of AWP, but two months later instructed the contractors not to use the new AWP in calculating reimbursement.⁵⁶

Current OIG guidance states that it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the spread or induct customers to purchase its product.⁵⁷ The OIG has indicated that the conjunction of manipulation of AWP to induct customers to purchase with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the Anti-Kickback Statute.⁵⁸

(\$17.52), the beneficiary's Part B 20 percent coinsurance was \$3.69. *Id.* Thus, the beneficiary was paying more in coinsurance than the physician was paying to actually purchase the drug. *Id.*

⁵² See Krause, *supra* note 41, at 127.

⁵³ See Krause, *supra* note 41, at 127–28.

⁵⁴ See Kalb et al., *supra* note 45.

⁵⁵ See Kalb et al., *supra* note 45.

⁵⁶ See Krause, *supra* note 41, at 126–27.

⁵⁷ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003).

⁵⁸ *Id.* Some of the Corporate Integrity Agreements negotiated by OIG at the settlement of fraud claims related to AWP require manufacturers to report their average sales price (“ASP”) on a regular basis. See Grant Bagley et al., *The Bayer CIA: A Glimpse Into the Future of Pharmaceutical Reimbursements*, BNA HEALTH CARE FRAUD REPORT, Apr. 18, 2001; Krause, *supra* note 41, at 128–29. For example, a CIA negotiated by Bayer and the OIG required Bayer to submit quarterly reports on the ASP for its government reimbursed drugs to state and federal officials. See Bagley et al., *supra*. The CIA defined ASP as the average of all final sales prices charged by Bayer excluding those also excluded from the calculation of “Best Price” for Medicaid rebate purposes and direct sales to

E. Off-Label Marketing

A number of the recent cases against pharmaceutical manufacturers have involved illegal “off-label” marketing of drugs. Although this paper does not delve into all the intricacies of the restrictions on off-label marketing, it is a highly contested area that has resulted in extensive liability for drug companies. The Food Drug & Cosmetic Act (“FD&C”) prohibits the sale of any drug unless the Food and Drug Administration (“FDA”) has approved a new drug application (or an abbreviated application for biosimilars).⁵⁹ Furthermore, the FD&C prohibits the sale of “misbranded” drugs.⁶⁰ It requires that the drug be properly labeled, and labeling includes advertising.⁶¹ A manufacturer cannot advertise a drug for any use for which an application was not approved under section 355(a) or (j).⁶²

The FDA requires that prescription drug advertising be “fairly balanced,” presenting both the benefits and risks of the drug, that it must not contain any claims other than those approved by the FDA and including in the product’s labeling.⁶³ However, the FDA does not require preapproval for drug advertisements—they must simply be submitted to the FDA at the time of initial dissemination.⁶⁴ The Federal Trade Commission (“FTC”) also has a broad mandate to investigate any false advertisement.⁶⁵ The FTC has traditionally deferred to FDA’s specific

hospitals. *See* Bagley et al., *supra*. (The settlement did not clarify the much-debated definition of AWP. *See* Bagley et al., *supra*.) However, it is unclear what HHS intends to do with this information (other than provide a general check on manufacturers’ ability to market the spread). It is also not clear whether CMS has the statutory authority to change its method of calculating reimbursement rates. *See* Krause, *supra* note 41, at 129

⁵⁹ Federal Food Drug & Cosmetic (FD&C) Act § 505(a), 21 U.S.C. § 355(a), (j) (West 2010).

⁶⁰ FD&C Act § 301, 21 U.S.C. § 331.

⁶¹ FD&C Act § 502(n), 21 U.S.C. § 352(n).

⁶² *Id.* This provision in particular has received much criticism, since pharmaceutical manufacturers are the *only* parties who are not allowed to freely disseminate information about the off-label usages of drugs.

⁶³ *See* Kalb et al., *Direct-to-Consumer Marketing: The Food and Drug Administration Is Not Alone*, 58 FOOD & DRUG L.J. 25, 26 (2003).

⁶⁴ *See id.*

⁶⁵ *See id.* at 28–29.

authority over prescription drug advertisement, although recently the FTC has broadened its enforcement to pharmaceutical marketing practices generally.⁶⁶

This area is somewhat distinct from the other pharmaceutical company practices implicated in discussions of health care fraud. Gifts to health care providers, sponsorship of educational programs, and payments for consulting services are potentially problematic because of the potential distortion of the doctor-patient (or pharmacist-patient) relationship when health care providers have conflicts of interest. The practice of marketing the spread also creates conflicts of interest for prescribing physicians, but it does so by directly (though not always obviously) overcharging the federal health care programs. Marketing drugs for off-label indications, by contrast, in theory defrauds the government by seeking payment for goods that would not normally be covered. This is technically possible because the Social Security Act definition of “covered drugs” for both the Medicare and Medicaid programs makes reference to FDA approval.⁶⁷ However, the statute also allows coverage for uses that are included in the compendia and for uses that are included in peer-reviewed literature.⁶⁸ Importantly, the FDA’s mission does not include the regulation of the “practice of medicine,” which has meant that physicians are free to prescribe drugs for any use, whether FDA-approved and listed on the label or not.⁶⁹ As such, suits holding pharmaceutical companies liable for the submission of claims to the federal health care programs are a somewhat indirect means of enforcing the FDA’s prohibition of off-label marketing of drugs.⁷⁰

⁶⁶ *Id.*

⁶⁷ Social Security Act §§ 1860-D2(e), 1861(t)(2)(B), 1927(k)(6), 1927(g) 42 U.S.C. §§ 1395w-102, 1396x, 1396r-8 (West 2011).

⁶⁸ *Id.*

⁶⁹ FD&C Act § 906, 21 U.S.C. § 396 (West 2010).

⁷⁰ As discussed in Part V, *infra*, a few courts have dismissed suits that premised liability solely on a theory of off-label marketing inducing providers to submit false claims without further evidence of actual specific claims being made for payment. The courts in question have considered such suits to be nuisances that had tried to circumvent the

III. Overview of Statutory Regime

The two primary laws under which pharmaceutical companies (and often health care providers and suppliers in general) may be held liable for health care fraud are the Medicare and Medicaid Anti-Kickback Statute and the False Claims Act. There are also a few other potential sources of liability for companies.

A. Medicare & Medicaid Anti-Kickback Act

The Medicare and Medicaid fraud and abuse provisions are found in 42 U.S.C. § 1320a-7b. Section 1320a-7b(b)(2) provides:

[W]hoever 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.

(Section 1320a-7b(b)(1) provides corresponding parallel liability for anyone who “knowingly and willfully solicits or receives any remuneration.”) The law is enforced criminally by DOJ and civilly by the HHS OIG.⁷¹

It is important to note that the Anti-Kickback Statute is a *criminal* law. The main purpose of the law is to prevent inappropriate financial considerations from influencing the amount or type of care, the cost of items or services, or the selection of the provider of care for beneficiaries of the federal health care programs.⁷² With this in mind, the increased cost to the government is

somewhat limited enforcement regime of the FD&C. *See also*, United States *ex rel.* Rost v. Pfizer, 446 F. Supp. 2d 6, 13 (D. Mass. 2006) (referring to “parasitic qui tam actions”).

⁷¹ *See* Bulleit & Krause, *supra* note 8, at 282.

⁷² *See* Bulleit & Krause, *supra* note 8, at 282.

not the sole criterion considered when evaluating potential anti-kickback claims. DOJ and OIG also consider whether an activity may freeze out competing suppliers, prevent potential price reductions, misdirect program funds from other purposes, or create temptations for providers to order more drugs or supplies than they need.⁷³ The law was originally about punishing truly corrupt behavior, but a shift in the interpretation of the statute in the mid-1980s recognized violations if even *one* purpose of a payment was to induce referrals.⁷⁴

The law does not prohibit just simple kickbacks, as they are commonly understood. “Remunerations” under the statute can include gifts and business courtesies (including grants), payments for services (including clinical studies), and discount arrangements (including bundled sales).⁷⁵

Section 1320a-7b(b)(3) of the statute includes a number of “safe harbors” within which providers or suppliers can avoid liability. A few safe harbor provisions were created in 1977, when Congress upgraded the penalty for violating the statute from a misdemeanor to a felony.⁷⁶ In 1987, Congress instructed the Secretary to promulgate regulations regarding the specifics of the safe harbors when it also granted the OIG the authority to exclude violators of the Anti-Kickback Statute.⁷⁷ Thus, HHS has issued detailed regulations interpreting these safe harbor provisions.⁷⁸ The goal of the safe harbor provisions was to “permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy.”⁷⁹ In order for a business arrangement to comply with one of the exemptions, each provision of the

⁷³ See Bulleit & Krause, *supra* note 8, at 282.

⁷⁴ See Bulleit & Krause, *supra* note 8, at 279.

⁷⁵ See Bulleit & Krause, *supra* note 8, at 280.

⁷⁶ See Robert Salcido, *Mixing Oil and Water: The Government’s Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANNALS HEALTH L. 105, 111–12 (1997).

⁷⁷ Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3088 (Jan. 23, 1989); *see also* Salcido, *supra* note 76, at 113–14.

⁷⁸ OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991).

⁷⁹ Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. at 3089.

exemption must be met.⁸⁰ Furthermore, fully complying with an exemption does not necessarily guarantee complete immunity.⁸¹ In a Federal Register Notice on January 23, 1989, the Secretary sought comments on proposed safe harbors relating to investment interests, space rental, equipment rental, personal services and management contracts, sale of practice, referral services, warranties, waiver of deductibles for in-patient hospital care, discounts, employment, and group purchasing organizations.⁸² The Secretary issued the final rule on the safe harbors on July 29, 1991, emphasizing that “the gravamen of a violation of the statute is ‘inducement’ and not necessarily the structure of the arrangement.”⁸³

When a particular practice does not qualify for a safe harbor, the OIG will consider the potential for increased charges or reported costs, possible overutilization of the item or service, the potential for adverse effects on competition, and the intent of the parties involved.⁸⁴ Importantly, no one factor is dispositive, and the OIG has unlimited discretion in determining which cases to pursue.⁸⁵

In addition to the criminal penalties, the OIG can exclude providers who are convicted under the Anti-Kickback Statute.⁸⁶ Prior to the 1990s, the OIG said that it would not seek to exclude manufacturers.⁸⁷ When HHS issued its final rule regarding the OIG exclusion authority in 1991, it stated:

Because the effect of exclusion is denial of payment for items or services furnished by an excluded individual or entity, it would be difficult to administer exclusions against entities which the Secretary does not directly reimburse. Thus, for the present time, to the extent that manufacturers, suppliers and distributors do not receive payment directly from

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 3088.

⁸³ OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,955.

⁸⁴ See Bulleit & Krause, *supra* note 8, at 288.

⁸⁵ See Bulleit & Krause, *supra* note 8, at 288.

⁸⁶ Social Security Act § 1128B(a), 42 U.S.C. 1320a-7b(a) (West 2010).

⁸⁷ See Krause, *supra* note 41, at 72.

the Medicare and State health care programs for the items they supply, these regulations will not affect them.⁸⁸

In 1998, however, HHS changed its policy to permit exclusion for “indirectly furnishing” items or services under the terms of the statute.⁸⁹ When the Secretary promulgated rules updating the OIG’s exclusion authority under the Health Insurance Portability and Accountability Act (“HIPAA”)⁹⁰ and the Balanced Budget Act of 1997,⁹¹ she also “proposed to clarify the current definition of the term ‘furnished’ in § 1000.10 to indicate that exclusions will apply to any individual or entity that provides or supplies items or services, directly *or indirectly*.”⁹² The notice elaborated, “The term ‘indirectly’ means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services.”⁹³ In support of this new interpretation, the Secretary cited section 1862(3) of the Social Security Act, which denies payment for items and services directly provided by an excluded individual *and* for those furnished at the direction or prescription of an excluded physician.⁹⁴ Congress had further indicated its intent when it expanded the scope of the exclusion authority to permit (and sometimes mandate) exclusion of a wider scope of individuals and entities.⁹⁵ When the Social Security Act was amended in 1980, the congressional report

⁸⁸ Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93, 57 Fed. Reg. 3298, 3300 (Jan. 29, 1992).

⁸⁹ See Krause, *supra* note 41, at 72–73.

⁹⁰ Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 29 U.S.C., 42 U.S.C.).

⁹¹ Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (codified as amended in scattered sections of 7 U.S.C., 12 U.S.C., 42 U.S.C., 47 U.S.C.).

⁹² Revised OIG Exclusion Authorities Resulting From Public Law 104-191, 63 Fed. Reg. 46,676, 46,678 (Sept. 2, 1998) (emphasis in original).

⁹³ *Id.* at 46,678 n.2.

⁹⁴ *Id.* at 46,678.

⁹⁵ *Id.*

indicated “payment would not be made to the provider for the cost of any services furnished to or on behalf of the provider by the convicted professional.”⁹⁶ Therefore, the HHS determined, “It is not appropriate to continue to exempt untrustworthy manufacturers and distributors of products from exclusion, when many other providers are excluded every year due to similar concerns.”⁹⁷

B. False Claims Act

The False Claims Act⁹⁸ was originally passed during the Civil War era to prevent fraud against the Union Army.⁹⁹ Specifically the FCA provides that anyone who commits one of the enumerated acts is liable to the government for civil penalties (currently between \$5,000 and \$10,000 for each violation) as well as treble damages.¹⁰⁰ Several of the provisions have been invoked in health care fraud cases. Section 3729(a)(1)(A) provides liability for anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” Similarly, section (a)(1)(B) provides liability when anyone “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” Section (a)(1)(C) provides liability when someone “conspires to commit a violation” of one of the other subparagraphs, including (A) and (B). The statute defines the term “knowingly” to mean that “a person, with respect to information, (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information” and does not require specific intent.¹⁰¹

Importantly, section 3730(b) provides for qui tam suits by private parties. An individual (“relator”) may bring suit in the name of the government.¹⁰² The complaint is filed under seal,

⁹⁶ H.R. REP. NO. 96-1167, at 40–41 (1980).

⁹⁷ Revised OIG Exclusion Authorities Resulting From Public Law 104-191, 63 Fed. Reg. at 46,678.

⁹⁸ False Claims Act, 31 U.S.C. §§ 3729–3733 (West 2009).

⁹⁹ See Salcido, *supra* note 76, at 118.

¹⁰⁰ False Claims Act, 31 U.S.C. § 3729(a).

¹⁰¹ *Id.* § 3729(b)(1).

¹⁰² *Id.* § 3730(b)(1).

and the government has the opportunity to intervene.¹⁰³ If the government intervenes and wins or settles the suit, the relator receives between 15 and 25 percent of the proceeds of the action or settlement as well as reasonable legal costs and fees.¹⁰⁴ If the government chooses not to intervene and the relator proceeds with the suit, he may receive 25 to 30 percent of the proceeds as well as reasonable legal costs and fees.¹⁰⁵

Some courts have allowed *qui tam* suits under the FCA based on the Anti-Kickback Statute.¹⁰⁶ It may be more logical to keep these two statutes distinct, however, because they each have a different *mens rea* standard—it is possible to act recklessly under the FCA without the willful malice required under the Anti-Kickback Statute.¹⁰⁷

C. Other Potential Sources of Liability

In addition to the Anti-Kickback Statute and the FCA, there are numerous state laws with similar provisions.¹⁰⁸ Additionally, the provisions of HIPAA that address “health care fraud” within the insurance industry are potentially implicated by drug company activities if payment arrangements between manufacturers and providers are hidden from insurance plans, including government programs.¹⁰⁹ The Prescription Drug Marketing Act of 1987¹¹⁰ regulates the distribution of drug samples and prohibits their sale.¹¹¹ If the samples have monetary value to their recipient (i.e., free samples given to a physician) and are used to treat Medicare or Medicaid

¹⁰³ *Id.* § 3730(b)(2).

¹⁰⁴ *Id.* § 3730(d)(1).

¹⁰⁵ *Id.* § 3730(d)(2).

¹⁰⁶ *See* Krause, *supra* note 41, at 73.

¹⁰⁷ *See* Salcido, *supra* note 76, at 108.

¹⁰⁸ *See, e.g.,* MASS. GEN. LAWS ch. 175H, § 3 (2007).

¹⁰⁹ *See* Bulleit & Krause, *supra* note 8, at 291–92.

¹¹⁰ Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (codified as amended in scattered sections of 21 U.S.C.).

¹¹¹ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003).

beneficiaries, the improper use of the samples might trigger liability under the FCA and the Anti-Kickback Statute.¹¹²

IV. Guidance Documents

Both Congress and HHS have provided some guidance for pharmaceutical manufacturers (and other providers) to navigate the Anti-Kickback Statute and FCA regime. Additionally, the industry itself self-regulates to an extent with the guidelines published the Pharmaceutical Manufacturers Association (“PhRMA”).

The HHS OIG has issued Special Fraud Alerts to members of the health care industry on a number of topics that indicate when liability may arise. Notably for drug manufacturers, in August 1994, OIG issued a Prescription Drug Marketing Fraud Alert.¹¹³ It provided a number of examples of violations of the Anti-Kickback Statute, including “product conversion” schemes (providing a cash award every time pharmacists switched a patient’s prescription to the company’s brand, giving them an incentive to persuade physicians to change prescriptions), “frequent flier” programs (giving physicians air miles for filling out questionnaires for new patients on a particular drug), and “research grants” (in actuality payments for recordkeeping).¹¹⁴

The Fraud Alert noted that payments may be improper if they are made to a person in a position to generate business for the company, if they are related to the volume of business generated, if they are more than nominal in value, if they are in excess of the fair market value of any legitimate services rendered, or if they are unrelated to any service other than patient referral.¹¹⁵ The Fraud Alert further noted practices that might warrant further investigation by OIG, such as prizes, gifts, cash, or other benefits in exchange for prescribing or marketing drugs

¹¹² *Id.*

¹¹³ Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

(especially if based on volume), grants to providers for studies of questionable scientific value, and payments for changing prescriptions.¹¹⁶

The Fraud Alert emphasized, “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.”¹¹⁷

In 2003, the OIG also issued compliance program guidance for pharmaceutical manufacturers “to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements.”¹¹⁸ The OIG noted that an effective compliance program could demonstrate a good faith effort to comply with the statutes and regulations and the federal health care program requirements and would reduce both the risk of illegal conduct as well as the resulting penalties.¹¹⁹

The guidance noted seven elements that it considered “fundamental” to an effective compliance program: (1) implementation of written policies and procedures; (2) designation of a compliance officer and committee; (3) effective training and education; (4) development of effective lines of communication; (5) internal monitoring and auditing; (6) enforcement of standards through publicized disciplinary guidelines; (7) prompt responses and corrective action for detected problems.¹²⁰ Notably, the compliance officer’s responsibilities include overseeing

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

¹¹⁹ *Id.* at 23,732. The guidance also re-emphasized that inaccurate or incomplete reporting of prices could result in liability under the FCA and Anti-Kickback Statute. *Id.* at 23,734.

¹²⁰ *Id.* at 23,731.

the implementation of the compliance program, reporting to the company's management, coordinating education and training for employees, ensuring that the company does not hire or contract with excluded individuals, assisting the company's internal auditors, investigating compliance-related issues, and reporting self-discovered violations with the company's counsel.¹²¹

On a related note, PhRMA publishes a "Code on Interactions with Healthcare Professionals," last updated in 2008.¹²² The code states that appropriate marketing of drugs ensures that patients have access to the products they need, and cautions that promotional materials given to health care providers should: "(a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other [FDA] requirements governing such communications."¹²³ The code individually addresses many of the common marketing practices of the pharmaceutical industry. Occasional meals may be offered as a business courtesy as long as they are modest, not part of an entertainment or recreational event, and provided to communication information.¹²⁴ Companies should separate their CME grant-making from their sales and marketing departments.¹²⁵ The selection and retention of health care professionals as consultants or speakers should be based on defined criteria, and companies should ensure that these arrangements are not inducements or rewards for prescribing or recommending a particular medicine.¹²⁶

¹²¹ *Id.* at 23,739–40.

¹²² PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF AMERICA, CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2008).

¹²³ *Id.* at 4.

¹²⁴ *Id.*

¹²⁵ *Id.* at 6.

¹²⁶ *Id.* at 7–10.

The OIG has stated that, although compliance with the PhRMA Code does not provide immunity, it does reduce the risk of fraud and abuse in the first place, and it helps to demonstrate a good faith effort to comply with the requirements of the federal health care programs.¹²⁷

V. Relevant Case History

The relevant cases involving the Anti-Kickback Statute and the FCA flesh out the scope of liability under the two laws. The earliest cases interpreted and developed the reach of the Anti-Kickback Statute, while more recent cases have explored its requisite standard of intent. Some cases also demonstrate the interplay between the Anti-Kickback Statute and the FCA in general and more specifically within the realm of prescription drugs. The treatment of medical device manufacturers under the Anti-Kickback Statute and the FCA also serves as a useful contrast. Ultimately, the most recent cases involving pharmaceutical companies have resulted in (large) settlements rather than judicial resolutions.¹²⁸

The earliest cases involving the Anti-Kickback Statute mainly focused on the interpretation of “any remuneration,” and the broad tack taken by most courts means that many of the traditional practices of the pharmaceutical industry could be implicated. In *United States v.*

¹²⁷ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003).

¹²⁸ Although this paper does not examine in depth the specific prohibition on off-label marketing, this was challenged on First Amendment grounds in *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998). The court stated, “Mailing enduring materials and/or discussing off-label uses is not inherently ‘treacherous’; it is only treacherous (if at all) to the extent that physicians choose to pay attention to the message communicated and alter their prescription practices accordingly.” *Id.* at 59. The court noted that the communications at issue were a mixture of commercial and non-commercial speech, since CME seminars, peer-reviewed medical journal article, and medical textbooks outside of the context of manufacturer promotion are scientific and academic speech and receive the highest protection of the First Amendment. *Id.* at 62. Applying the *Bolger* test, though, the court found that the speech here was commercial (and therefore did not require special protection) because it was an advertisement, it related to the specific off-label uses of the drugs at issue, and the drug manufacturer had a clear economic motivation for disseminating the speech. *Id.* at 64–65. The court then applied the *Central Hudson* test to determine whether the restriction on speech advanced the government’s substantial interest in a direct and material way without burdening “substantially more speech than necessary.” *Id.* at 72. Although the government had a substantial interest in incentivizing manufacturers to get approval for off-label uses (although not in paternalistically regulating the information received by physicians), the guidance documents in question were more extensive than necessary to further this interest, and there were less-burdensome alternatives available. *Id.* at 73.

Ruttenberg, the court held that all that is required to violate the Anti-Kickback Statute was payment of a kickback to someone in control of federal funds, which is “in violation of the duty imposed by Congress on providers of services to use federal funds only for intended purposes and only in the approved manner.”¹²⁹ In *United States v. Bay State Ambulance*, the court found that the “gravamen of Medicare Fraud is inducement,” and thus a broad interpretation of “any remuneration” appropriately includes even cases in which some professional services were performed in exchange for payment.¹³⁰

These early cases also emphasized that the main purpose of a payment does not need to be to induce a referral or purchase of goods or services. In *Bay State*, the court held that “the issue of the sole versus primary reason for payments is irrelevant since *any* amount of inducement is illegal.”¹³¹ Additionally, the court in *United States v. Greber* stated, “If one purpose of the payment was to induce future referrals, the Medicare statute has been violated.”¹³² Thus, even if a payment to a physician was intended to compensate for professional services actually performed, the Anti-Kickback Statute was still violated if the payment was intended to induce the physician to use the company’s services.¹³³

Similarly, the early cases established that remunerations could take many forms. In *Hanlester Network v. Shalala*, the court held that proof of the existence of a referral agreement is not required to establish liability under the Anti-Kickback Statute.¹³⁴ The court noted, “The inducement to commit the violation was the bribe, i.e., the *quid pro quo*.”¹³⁵ The court adopted the Secretary’s interpretation of the phrase “to induce” as meaning “an intent to exercise

¹²⁹ *United States v. Ruttenberg*, 625 F.2d 173, 177 (7th 1980) (citing *United States v. Zacher*, 586 F.2d 912 (2d 1978)).

¹³⁰ *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29–30 (1st 1989).

¹³¹ *Id.* at 30.

¹³² *United States v. Greber*, 760 F.2d 68, 69 (3d 1985).

¹³³ *Id.* at 72.

¹³⁴ *Hanlester Network v. Shalala*, 51 F.3d 1390, 1396–97 (9th 1995).

influence over the reason or judgment of another in an effort to cause the referral of program-related business.”¹³⁶ Thus, an explicit agreement between providers is not required. As the Departmental Appeals Board decision below had noted, “‘Remuneration’ was added to the statute precisely to broaden it beyond traditionally recognizable corrupt payments, such as bribes and kickbacks.”¹³⁷

Hanlester is also one of the first of several cases interpreting the requisite level of intent in the Anti-Kickback Statute, and there has been a Circuit split on this issue. In *Hanlester*, the Ninth Circuit construed “knowingly and willfully” to mean that the defendant must both *know* that the Act prohibits offering or paying remuneration to induce referrals *and* engage in the prohibited conduct with specific intent to disobey the law.¹³⁸ The Tenth Circuit also followed this higher intent standard—requiring knowing breach of a specific legal duty—in *United States v. McClatchey*.¹³⁹

In contrast, the Eighth Circuit held in *United States v. Jain* that, although the government must meet a heightened mens rea standard, it must only prove that the defendant knew that his conduct was wrongful, rather than that he knew it violated a specific legal duty.¹⁴⁰ The Eleventh Circuit also followed this reasoning in *United States v. Starks*, holding that “the willfulness requirement of [the Anti-Kickback Statute] does not carve out an exception to the traditional rule that ignorance of the law is no excuse; knowledge that conduct is unlawful is all that is required.”¹⁴¹ The court felt that the Anti-Kickback Statute is not a highly technical tax or

¹³⁵ *Id.* at 1397.

¹³⁶ *Id.* at 1398; *Hanlester Network*, DAB No. 1275 at 10 (1991).

¹³⁷ *Hanlester Network*, DAB No. 1275 at 10.

¹³⁸ *Hanlester Network*, 51 F.3d at 1400; *see also* *United States v. Kats*, 871 F.2d 105, 108 (9th 1989) (finding it appropriate to instruct the jury that it could convict the defendant only if the payment was “wholly and not incidentally attributable to the delivery of good or services”).

¹³⁹ *United States v. McClatchey*, 316 F.3d 1122, 1126 (10th 2003).

¹⁴⁰ *United States v. Jain*, 93 F.3d 436, 441 (8th 1996).

¹⁴¹ *United States v. Starks*, 157 F.3d 833, 838 (11th 1998).

financial regulation that could ensnare someone engaged in seemingly innocent conduct.¹⁴² It noted that “[s]uch kickbacks are more clearly *malum in se*, rather than *malum prohibitum*.”¹⁴³ Under either standard, however, the government must prove, at minimum, that the defendants have “actual” knowledge that the conduct at issue is improper (or illegal).¹⁴⁴

The interplay between the Anti-Kickback Statute and the FCA is also important when considering potential liability for pharmaceutical manufacturers. In *United States ex rel. Pogue v. American Healthcorp*, the plaintiff relator did not allege that the defendants overcharged Medicare or charged it for services that were not performed.¹⁴⁵ Instead, he argued that their failure to comply with the Medicare laws proscribing kickbacks made their Medicare claims by default false or fraudulent.¹⁴⁶ The court held that actual loss was not a necessary element of a FCA claim and that the relator could bring his claim under the FCA if he could show that the defendants’ fraudulent conduct was intended to induce government payment.¹⁴⁷

However, in *United States ex rel. Franklin v. Parke-Davis*, the court cautioned that violations of the Anti-Kickback Statute are *not* per se violations of the FCA, and Anti-Kickback violations are only actionable FCA claims when the claimant certified compliance with the Anti-Kickback provisions.¹⁴⁸ Courts have found liability under theories of both affirmative certification and implied certification (in which a party certifies their compliance with regulations by their very participation in a federal program).¹⁴⁹

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ See Salcido, *supra* note 76, at 117.

¹⁴⁵ *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1510 (M.D. Tenn. 1996).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 1513.

¹⁴⁸ *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 54 (D. Mass. 2001).

¹⁴⁹ *Id.*

The Second Circuit examined the certification theory of liability under the FCA in *Mikes v. Straus*.¹⁵⁰ The plaintiff relator alleged that the defendant had violated the FCA by submitting Medicare reimbursement claims for procedures that were not performed with the appropriate standard of care.¹⁵¹ The relator's theory of liability was based on the defendant's false representation of compliance with the Medicare statutes and regulations.¹⁵² The court contrasted this "legally false" certification with "factually false" certification, which would require inaccurate descriptions of the goods or services provided or requests for goods or services that were never provided.¹⁵³ The court followed the rule of the Fourth, Fifth, Ninth, and District of Columbia Circuits that a claim under the FCA is only legally false where the party certifies compliance with a statute or regulation as a condition to the government's payment.¹⁵⁴

However, the plaintiffs in *Mikes* argued that the defendants had made *impliedly* false certifications on the theory that the act of submitting a claim for reimbursement implies compliance with the rules and regulations in itself.¹⁵⁵ The court noted that this would be appropriate only where the underlying statute or regulation expressly states that the provider must comply in order to receive reimbursement.¹⁵⁶ It implied that this type of liability could be found under the Medicare statute because it states that "no payment may be made" for goods or services that "are not reasonable and necessary for the diagnosis and treatment" of the illness or injury in question.¹⁵⁷ In this particular case, however, the court emphasized that reasonableness and necessity refers to the selection of the treatment, not the quality of its performance.¹⁵⁸

¹⁵⁰ *Mikes v. Straus*, 274 F.3d 687 (2d 2001).

¹⁵¹ *Id.* at 696.

¹⁵² *Id.*

¹⁵³ *Id.* at 697.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 699.

¹⁵⁶ *Id.* at 700.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 701.

A case involving off-label use of medical devices, rather than drugs, demonstrates some of the traditional differences between the two fields. In *Cedars-Sinai Medical Center v. Shalala*, the court evaluated the validity of a 1986 Medicare manual instruction providing that payment could not be made for services using devices that had not been approved by the FDA.¹⁵⁹ As evidence of its existing policy of treating drugs and devices differently, the Secretary provided sample language for claim evaluations that it had given fiscal intermediaries to use in 1977: “In the administration of the Medicare program, we have consistently taken the position that a drug may be covered only where it is being used to treat a condition for which the Food and Drug Administration (the agency specifically charged with responsibility for approving and licensing drugs) has determined it is safe and effective and has approved it for general use.”¹⁶⁰ The court ultimately determined that the manual instructions were a substantive rule and therefore should have been subject to the notice-and-comment requirements of the APA.¹⁶¹

One of the most important cases involving the pharmaceutical industry—and off-label drug marketing in particular—was *Franklin v. Parke-Davis*.¹⁶² This qui tam suit under the FCA by a doctor (and former “medical liaison” for the company) alleged the drug manufacturer (acquired by Pfizer during the course of the litigation) had engaged in a fraudulent scheme to promote the sale of Neurontin for off-label uses and that this illegal marketing caused submission

¹⁵⁹ *Cedars-Sinai Med. Ctr. v. Shalala*, 939 F. Supp. 1457 (C.D. Cal. 1996).

¹⁶⁰ *Id.* at 1460–61.

¹⁶¹ *Id.* at 1465. In a more recent case, *United States ex rel. Bennett v. Medtronic*, No. H-08-3408, 2010 WL 3909447 (S.D. Tex. Sept. 30, 2010), the court seemed similarly unwilling to impute indirect FCA liability, at least in the realm of medical devices. The court found that there were no specific allegations that the defendant itself had submitted false claims for off-label uses of its medical device. *Id.* at *2. The court noted, “While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs, the relators have not pointed to a similar categorical restriction on reimbursement for Category B medical devices. For medical devices, eligibility for reimbursement depends on whether the procedure performed is ‘medically necessary’ or ‘reasonable and necessary.’” *Id.* at *5.

¹⁶² *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001).

of false claims to Medicaid and the VA.¹⁶³ The court emphasized that while physicians may prescribe an approved drug for off-label use (because the FDA’s mission is to regulate pharmaceuticals without interfering with the practice of medicine), a manufacturer cannot market or promote the drug for an unapproved use.¹⁶⁴ “A manufacturer illegally ‘misbrands’ a drug if the drug’s labeling includes information about its unapproved uses.”¹⁶⁵ The court further elaborated on the interaction between FDA approval and federal reimbursement (in this case, Medicaid): “Covered outpatient drugs do not include drugs that are ‘used for a medical indication which is not a medically accepted indication.’ [...] A medically accepted indication, in turn, includes a use ‘which is approved under the Federal Food Drug and Cosmetic Act’ or which is included in specified drug compendia.”¹⁶⁶ The court found that Neurontin was not eligible for reimbursement under Medicaid because the off-label uses for which it was prescribed were not included in one of the compendia.¹⁶⁷

In *Franklin*, it was important that the company’s “medical liaisons,” which are normally connected with a manufacturer’s research functions, were employed exclusively to promote and sell the company’s products.¹⁶⁸ However, they were encouraged to misrepresent themselves to physicians as researchers rather than as sales representatives.¹⁶⁹ They were instructed to make “exaggerated or false claims” about both the efficacy and safety of Parke-Davis drugs¹⁷⁰ and to

¹⁶³ *Id.* at 43.

¹⁶⁴ *Id.* at 44.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 45.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 48–49.

¹⁶⁹ *Id.* at 48.

¹⁷⁰ *Id.* *Franklin* cites a number of specific examples of fraudulent statements that he and other medical liaisons were trained to tell physicians, including fabricated data about off-label uses and dosages. *Id.* A court in 2006 also distinguished a drug manufacturer’s off-label promotion of its drug from *Franklin* because there the company had based its marketing campaign on *false information*. *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, No. 4:05CV570MLM, 2006 WL 1064127, at *10 (E.D. Mo. Apr. 21, 2006).

coach doctors on how to submit payable claims for off-label prescriptions.¹⁷¹ Additionally, many physicians were given kickbacks—allegedly to compensate them for drug studies (which were actually of little scientific value), for services as “consultants,” and for small recordkeeping tasks.¹⁷²

Although the defendant argued that the FCA could not be used as an “end-run around the enforcement provisions” in the FDCA, the court held that liability can be found under the FCA where the failure to abide by another rule or regulation becomes a “material misrepresentation” to receive payment from the government.¹⁷³ Even though Parke-Davis had not directly submitted claims for payment to the government, the court found that “an intervening force only breaks the causal connection when it is unforeseeable.”¹⁷⁴ Since the submission of Medicaid claims by doctors and pharmacists based on the information provided by Parke-Davis was not only foreseeable but also an intended consequence, liability could be found indirectly under the FCA.¹⁷⁵ However, the court rejected the claim that the defendants’ Anti-Kickback violations were per se violations of the FCA because Franklin did not demonstrate that Parke-Davis’ caused or induced a doctor or pharmacist to submit a false or fraudulent anti-kickback certification.¹⁷⁶ The court warned, “This count is an example of the Relator improperly seeking to use the FCA as a means to enforce various regulatory proscriptions of the FDA.”¹⁷⁷

Because of the indirect nature of false claims liability for pharmaceutical manufacturers, courts have varied in the level of specificity required in plaintiffs’ complaints. In *United States ex rel. Westmoreland v. Amgen*, the First Circuit distinguished between standards for cases

¹⁷¹ Franklin, 147 F. Supp. at 48.

¹⁷² *Id.* at 45–46.

¹⁷³ *Id.* at 51.

¹⁷⁴ *Id.* at 52.

¹⁷⁵ *Id.* at 52–53.

¹⁷⁶ *Id.* at 54.

¹⁷⁷ *Id.* at 55.

alleging direct presentment of false claims to the government and ones involving indirect inducement.¹⁷⁸ In *Westmoreland*, the relator alleged that by overfilling its bottles, Amgen was providing built-in free samples of its drugs and that it marketed the potential benefits of billing for unnecessary and unadministered overfill dosages.¹⁷⁹ Additionally, he alleged that Amgen neglected to factor in the overfill when calculating its reported average sales prices.¹⁸⁰ The court noted that, in cases where the defendant directly presented claims to the government, a plaintiff “must provide details identifying particular false claims submitted,” but in situations where the defendant induced third parties to file false claims a “more flexible” standard applied.¹⁸¹ The court found this standard appropriate because a plaintiff whistleblower likely would not have access to forms submitted by third parties prior to conducting discovery.¹⁸²

However, the Eleventh Circuit recently affirmed the dismissal of a qui tam case against Solvay Pharmaceuticals because the complaint did not plead specific false claims with sufficient particularity.¹⁸³ The relators alleged that Solvay and its subsidiary Unimed Pharmaceuticals had marketed off-label use of its synthetic marijuana compound.¹⁸⁴ The court stated:

[T]he Complaint in this case offers detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe. The Complaint also includes what the relators describe as ‘a highly-compelling statistical analysis [that] renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted from [Solvay's illegal marketing] campaign.’ But, the Complaint does not allege the existence of a single actual false claim. In fact, we are unable to discern from the complaint a specific person or entity that is alleged to have presented a claim of any kind, let alone a false or fraudulent claim.¹⁸⁵

¹⁷⁸ United States *ex rel.* *Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 275 (D. Mass. 2010).

¹⁷⁹ *Id.* at 270–71.

¹⁸⁰ *Id.* at 271.

¹⁸¹ *Id.* at 275.

¹⁸² *Id.*

¹⁸³ *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1323–24 (11th 2009).

¹⁸⁴ *Id.* at 1322.

¹⁸⁵ *Id.* at 1325–26.

Although § 3729(a)(2) of the FCA does not require proof that a false claim was actually submitted to the government, the court held that a plaintiff must show proof that the defendant made a false record or statement for the purpose of getting a false claim paid and that the false record or statement caused the government to actually pay a false claim (either to the defendant or to a third party).¹⁸⁶

Recently, courts have been more reluctant to impose FCA liability for simple off-label marketing. In *United States ex rel. Polansky v. Pfizer* in 2009, the court found that while advocacy for off-label use of Lipitor may have violated the FDCA and subjected Pfizer to FDA's enforcement authority, the mere fact of violating FDA regulations does not translate into liability for false claims.¹⁸⁷ The court examined the "legally false" certification theory adopted by the Second Circuit in *Mikes*, but determined that Pfizer had not filed any claims for reimbursement nor made any implied certifications to obtain payment.¹⁸⁸ Polansky also did not allege that Pfizer had made any representations to physicians that the off-label uses were consistent with federal program guidelines.¹⁸⁹ The court further emphasized that the physicians who wrote the prescriptions were "not unsophisticated lay persons."¹⁹⁰ Since prescribing drugs for uses not approved by the FDA is within the professional medical judgment of physicians, an implicit certification that these prescriptions were within the federal program guidelines would not make sense.¹⁹¹

The 2001 settlement with TAP Pharmaceuticals, which was the largest to that date, was notable because it seemed to mark a sea change in the government's treatment of pharmaceutical

¹⁸⁶ *Id.* at 1327.

¹⁸⁷ *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009).

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

manufacturers.¹⁹² In October 2001, TAP agreed to pay \$875 million to settle civil and criminal fraud allegations regarding the sale of the cancer drug Lupron.¹⁹³ The government alleged that TAP knowingly reported AWP information that was significantly higher than the average sales prices, which assured artificially high Medicare reimbursement.¹⁹⁴ They then “marketed the spread,” which gave physicians a financial inducement to prescribe Lupron.¹⁹⁵ The government further alleged that TAP concealed the true pricing from Medicare and falsely advised their customers to report the AWP rather than the actual price they paid, causing their customers to submit false claims.¹⁹⁶ The FCA allegations constituted \$560 million of the total payments and settled two qui tam cases.¹⁹⁷

Many members of the pharmaceutical industry felt it was disingenuous to accuse a company of fraud for their (not unusual) use of a well-known loophole in the system.¹⁹⁸ However, since other methods of revising the AWP calculations have failed, DOJ and HHS have turned to using fraud settlements to close this loophole.¹⁹⁹

The TAP case also demonstrated the growing use of both settlements in general (which may of course be a move on the part of corporations to reduce their own litigation costs) and Corporate Integrity Agreements (“CIA”s) in particular. The TAP CIA required the company to report its average sales price (“ASP”) on a quarterly basis for the duration of the agreement.²⁰⁰

Corporate integrity agreements typically run for five years and include requirements designed to

¹⁹² See Krause, *supra* note 41, at 128.

¹⁹³ See Krause, *supra* note 41, at 125.

¹⁹⁴ See Krause, *supra* note 41, at 125.

¹⁹⁵ See Krause, *supra* note 41, at 125.

¹⁹⁶ See Krause, *supra* note 41, at 125.

¹⁹⁷ See Krause, *supra* note 41, at 125.

¹⁹⁸ See Krause, *supra* note 41, at 126–28.

¹⁹⁹ See Krause, *supra* note 41, at 128.

²⁰⁰ See Krause, *supra* note 41, at 128–29.

ensure compliance with federal program requirements.²⁰¹ The requirements generally include hiring a compliance officer, developing written standards and policies, conducting employee training, reviewing claims submitted to federal health care programs for accuracy, establishing programs for confidential disclosure of fraud, not employing or contracting with excluded individuals, and submitting annual compliance reports to OIG.²⁰²

Such compliance plans became a common business practice after the Federal Sentencing Guidelines for Organizations were implemented in 1991.²⁰³ The Guidelines provided that a corporation could mitigate its sentencing for a federal criminal conviction if it had an effective compliance plan.²⁰⁴ Prosecutors may use discretion in taking action against an organization with an effective compliance plan.²⁰⁵ Some states have also developed standards that pharmaceutical companies must follow in order to do business there. For example, in 2004, California enacted a new law that requires pharmaceutical companies to implement a Comprehensive Compliance Program, which requires them to comply with the PhRMA Code and the OIG Compliance Program Guidelines.²⁰⁶ They must also post their compliance plan along with a written attestation to compliance with the plan available on their website and provide a toll-free number where individuals may obtain copies of the information.²⁰⁷

VI. Pfizer Settlement

In 2009, the TAP settlement was far surpassed in monetary value by a settlement with Pfizer resolving allegations of off-label marketing of a number of drugs. In the settlement agreement on August 31, 2009, Pfizer's subsidiary Pharmacia & Upjohn Company, Inc., agreed

²⁰¹ ANDY SCHNEIDER, TAXPAYERS AGAINST FRAUD EDUCATION FUND, REDUCING MEDICARE AND MEDICAID FRAUD BY DRUG MANUFACTURERS 37 (2003).

²⁰² *Id.*

²⁰³ *See* Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4338 (Jan. 28, 2005).

²⁰⁴ *See id.*

²⁰⁵ *See id.*

²⁰⁶ CAL. HEALTH & SAFETY CODE §§ 119400–119402 (West 2009).

to enter a plea of guilty to a violation of the FDA by introducing into interstate commerce the misbranded drug Bextra.²⁰⁸ The FDA approved Bextra in 2001 for treatment of the symptoms of osteoarthritis, rheumatoid arthritis, and menstrual cramps.²⁰⁹ However, Pfizer marketed Bextra for the off-label treatment of acute pain and surgical pain and at dosages above the FDA-approved level.²¹⁰ They created sales materials and message to promote Bextra for the off-label uses, commissioned market research to test the sales materials, promoted the unapproved uses directly to physicians, used so-called advisory boards and consultant meetings to promote Bextra for unapproved uses, distributed promotional samples to surgeons and other prescribers who had no FDA-approved use for Bextra, and sponsored CME programs to disseminate their message about the off-label uses.²¹¹

Additionally, Pfizer settled civil claims with the federal government (for submitting claims for payment to Medicaid, TRICARE, the Federal Employees Health Benefits Program, the Federal Employees Compensation Act Program, the Department of Veterans Affairs, the Bureau of Prisons, and Medicare) and with certain states and the District of Columbia (for submitting claims to Medicaid).²¹² The civil settlement covered allegations of illegally promoting the sale and use of Bextra, Geodon, Zyvox, and Lyrica for conditions or patients not approved by the FDA.²¹³ Pfizer also allegedly paid “illegal remunerations for speaker programs, mentorships, preceptorships, journal clubs, and gifts (including entertainment, cash, travel and meals)” to

²⁰⁷ *Id.* § 119402(e).

²⁰⁸ PFIZER PLEA AGREEMENT (Aug. 31, 2009), <http://www.justice.gov/usao/ma/news/Pfizer/Plea%20Agreement.pdf>; PFIZER SETTLEMENT AGREEMENT 2 (Aug. 31, 2009), <http://www.justice.gov/usao/ma/news/Pfizer/Pfizer%20Settlement%20Agreement.pdf>.

²⁰⁹ Stop Medicare Fraud, *Pfizer Fact Sheet*, <http://www.stopmedicarefraud.gov/pfizerfactsheet.html>.

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² PFIZER SETTLEMENT AGREEMENT, *supra* note 208, at 3.

²¹³ PFIZER SETTLEMENT AGREEMENT, *supra* note 208, at 3–5.

induce health care professionals to promote and prescribe Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zolof, and Zyrtec.²¹⁴

John Kopchinski, a former Pfizer sales representative, was a relator in one of the qui tam suits resolved by the settlement.²¹⁵ He said that the company had encouraged him and others not to worry about the Neurontin case and encouraged them to participate in similar off-label marketing of Bextra.²¹⁶ Kopchinski stated, “The whole culture of Pfizer is driven by sales, and if you didn’t sell drugs illegally, you were not seen as a team player.”²¹⁷

Pfizer agreed to pay \$2.3 billion to the federal government and the states involved to resolve the criminal and civil claims.²¹⁸ Michael K. Loucks, the acting United States attorney for the District of Massachusetts, said, “Among the factors we considered in calibrating this severe punishment was Pfizer’s recidivism.”²¹⁹ The criminal resolution included a \$1.195 billion fine and a forfeiture of \$105 million (the largest criminal fine imposed in a United States criminal prosecution to date).²²⁰ The combined federal and state civil settlement was \$1 billion.²²¹ The Medicaid portion of the settlement (to both the federal and state governments) was over \$705

²¹⁴ PFIZER SETTLEMENT AGREEMENT, *supra* note 208, at 5.

²¹⁵ Gardiner Harris, *Pfizer Pays \$2.3 Billion to Settle Marketing Case*, N.Y. TIMES, Sept. 3, 2009, at B4.

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ Stop Medicare Fraud, *supra* note 209.

²¹⁹ HHS Press Release, *Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer To Pay \$2.3 Billion For Fraudulent Marketing* (Sept. 2, 2009), <http://www.hhs.gov/news/press/2009pres/09/20090902a.html>. In 2002, Pfizer and its subsidiaries Warner-Lambert and Parke-Davis paid \$49 million to resolve civil claims that it had failed to report accurate best prices for Lipitor under the Medicaid Drug Rebate Statute. Stop Medicare Fraud, *supra* note 209. In 2004, Pfizer subsidiary Warner-Lambert pled guilty and paid more than \$430 million to resolve criminal charges and civil liability for its fraudulent marketing practices of Neurontin. Stop Medicare Fraud, *supra* note 209. In 2007, Pfizer subsidiary Pharmacia & Upjohn paid \$34 million and pled guilty to paying kickbacks for the formulary placement of its drugs and entered a deferred prosecution agreement for the off-label distribution of Genotropin. Stop Medicare Fraud, *supra* note 209.

²²⁰ Stop Medicare Fraud, *supra* note 209.

²²¹ Stop Medicare Fraud, *supra* note 209.

million.²²² The civil settlement also resolved eleven qui tam suits under the FCA.²²³ The United States agreed to pay six relators a total of approximately \$102 million.²²⁴

In addition to the guilty plea and monetary settlement, Pfizer signed a Corporate Integrity agreement with OIG.²²⁵ The agreement provided that Pfizer would establish and maintain a compliance program;²²⁶ appoint a compliance officer to implement the compliance policies and procedures;²²⁷ establish a compliance committee to support and advise the compliance officer;²²⁸ create an audit committee to oversee compliance with the federal health care program and FDA requirements;²²⁹ implement a written code of conduct and written policies and procedures regarding compliance (including, among other things, the types of materials and information that could be distributed by the company, consulting and other arrangements, and the funding of grants and charitable contributions);²³⁰ maintain and publicize its internal disclosure mechanism and non-retaliation policy;²³¹ report any probable violations of criminal, civil or administration laws applicable to the federal health care programs or the FDA;²³² publish on its website an accessible and searchable listing of all physicians or other entities who received payments directly or indirectly from Pfizer;²³³ and submit an annual report to OIG for each the five years of the duration of the agreement.²³⁴

²²² Stop Medicare Fraud, *supra* note 209.

²²³ Stop Medicare Fraud, *supra* note 209.

²²⁴ PFIZER SETTLEMENT AGREEMENT, *supra* note 208, at 8; Stop Medicare Fraud, *supra* note 209.

²²⁵ CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PFIZER INC. (Aug. 31, 2009), http://oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf

²²⁶ *Id.* at 4.

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ *Id.* at 5.

²³⁰ *Id.* at 7–14.

²³¹ *Id.* at 22.

²³² *Id.* at 25–26.

²³³ *Id.* at 36–38.

²³⁴ *Id.* at 44.

The Pfizer settlement made the headlines because of its size, but it is also emblematic of the current liability environment for pharmaceutical manufacturers. Tony West, Assistant Attorney General for the Civil Division, stated, “Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars [...] This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare.”²³⁵ The government allegations against Pfizer included all of those discussed above—from marketing of off-label uses of its drugs to payments to physicians for services of questionable necessity. In many ways, Pfizer has become the “poster child” for pharmaceutical manufacturer liability in the United States.

VII. Future Implications – Medicare Part D

Many of the traditional marketing strategies and business practices of pharmaceutical companies have gone by the wayside under the statutory regime of the Anti-Kickback Statute and the False Claims Act. The cases discussed above, however, including the very large Pfizer settlement, held manufacturers liable for activities that occurred long before the creation of the Medicare prescription drug benefit (Part D), which could have large implications for pharmaceutical company liability in the future. This section will provide a brief summary of the creation and current status of Part D.

The Medicare Modernization Act of 2003²³⁶ established the voluntary outpatient prescription drug benefit for people on Medicare, known as Part D, which went into effect in 2006.²³⁷ Some aspects of Part D were also modified by the enactment of the Patient Protection

²³⁵ HHS Press Release, *supra* note 219.

²³⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

²³⁷ Kaiser Family Foundation, *The Medicare Prescription Drug Benefit Fact Sheet* (October 2010).

and Affordable Care Act²³⁸ and the Health Care and Education Reconciliation Act²³⁹ (collectively referred to as the Affordable Care Act (“ACA”)) passed in 2010.²⁴⁰ All 47 million elderly and disabled Medicare beneficiaries have access to the drug benefit through private plans approved by the federal government, and Medicare replaced Medicaid as the source of drug coverage for dually eligible beneficiaries.²⁴¹ The drug benefit is offered through both stand-alone prescription drug plans (“PDP”s) and Medicare Advantage prescription drug (“MA-PD”) plans, many of which are health maintenance organizations (“HMO”s), that cover all Medicare benefits including drugs.²⁴²

The standard benefit in 2011, for example, has a \$310 deductible and 25% coinsurance up to the initial coverage limit of \$2,840 in total drug costs, followed by a gap or “donut hole” in coverage where enrollees have been responsible for 100% of costs until they reach the catastrophic coverage limit of \$6,448.²⁴³ Beginning in 2011, however, the ACA will gradually lower the out-of-pocket costs in the donut hole by requiring drug manufacturers who want their products covered by Part D to offer a 50% discount to patients on brand-name drugs.²⁴⁴ Further discounts on brand-name drugs and on generic equivalents will be phased in.²⁴⁵ After the catastrophic limit, enrollees pay either 5% of total drug costs or \$2.50 or \$6.30 for each drug.²⁴⁶

²³⁸ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended at 42 U.S.C. § 300gg et seq.).

²³⁹ Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (codified as amended in scattered sections of 26 U.S.C., 42 U.S.C.)

²⁴⁰ See Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes, 75 Fed. Reg. 71,190, 71,194 (Nov. 22, 2010).

²⁴¹ Kaiser, *supra* note 237.

²⁴² Kaiser, *supra* note 237.

²⁴³ Kaiser, *supra* note 237.

²⁴⁴ Kaiser, *supra* note 237. Notably, the MMA prohibits Medicare from negotiating drug prices directly. Kaiser, *supra* note 237.

²⁴⁵ Kaiser, *supra* note 237.

²⁴⁶ Kaiser, *supra* note 237.

Drug manufacturers who do not enter into agreements with CMS under the discount program will not be able to have their outpatient prescription drugs covered under Part D.²⁴⁷ CMS published a model manufacturer agreement in August 2010, which will be used with all manufacturers and which is not subject to individual negotiations.²⁴⁸ The agreement requires pharmaceutical manufacturers to agree to the requirements of the program, and failure to comply with the program's rules will result in a 25 percent surcharge on manufacturer liability.²⁴⁹

The definition of a covered drug under Part D “closely follows” the definition of a covered drug under Medicaid in the Social Security Act.²⁵⁰ Thus, “a covered Part D drug was available only by prescription, approved by the [FDA], used and sold in the United States, and used for a medically accepted indication.”²⁵¹ “Medically accepted indication” is defined as a use approved by the FDA or included in one of the compendia.²⁵² This is somewhat distinct from the definition of “medically accepted indication” for drugs covered under Part B, which also includes indications that are published in peer-reviewed literature.²⁵³

The addition of Medicare Part D has so far increased program outlays considerably, accounting for two thirds of the \$72 billion increase in spending from 2005 to 2006.²⁵⁴ Thus, the

²⁴⁷ Sherine B. Abdul-Khaliq & Kashmira Makwana, *The Impact of the Medicare Coverage Gap Discount Program on the Pharmaceutical Industry: Considerations and Challenges Compliance Officers Need to Keep in Mind*, 12 J. HEALTH CARE COMPLIANCE 45 46 (Sept.-Oct. 2010).

²⁴⁸ *Id.*

²⁴⁹ *Id.* The coverage gap discount program has actually resulted in increased communication between CMS and FDA because the coinsurance for covered Part D drugs in the gap is determined based on whether the drug was approved under an NDA or is a generic drug. Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes, 75 Fed. Reg. 71,190, 71,214 (Nov. 22, 2010). Thus, CMS is working with FDA to make sure that National Drug Code (NDC) Directory listings are up-to-date. Center for Medicare Memo, *Medicare Coverage Gap Discount Program* (Oct. 1, 2010).

²⁵⁰ Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4228 (Jan. 28, 2005).

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ POTETZ ET AL., KAISER FAMILY FOUNDATION, MEDICARE SPENDING AND FINANCING: A PRIMER 4 (2011).

government's interest in cutting down on fraud by pharmaceutical manufacturers is sure to only increase.²⁵⁵

VIII. Conclusion

The track of the evolution of pharmaceutical manufacturer liability for health care fraud over the past two decades has been rapid and increasing. Many of the practices that drug companies formerly engaged in, such as directly marketing and providing gifts to physicians, are no longer permissible, and others, such as compensating health care providers for consulting or research services, have come under close scrutiny. Furthermore, the methods that manufacturers use to report prices to the federal health care programs are watched closely, and the government has used the fraud and abuse statutes to further curtail off-label marketing.

The basic statutory regime that premises health care fraud liability on violations of the Anti-Kickback Statute and the False Claims Act has been shaped through several decades of case law to form an environment in which pharmaceutical companies ultimately pay huge sums of money to settle criminal and civil allegations. The Pfizer settlement in particular demonstrates the types of activities and the financial costs at stake. Importantly, this kind of liability will likely only increase for pharmaceutical manufacturers as the Medicare Part D benefit continues to be implemented.

²⁵⁵ Alternatively, since one study suggested that 21 percent of all prescriptions are for off-label uses, the chilling effect of fraud litigation on off-label communications may indirectly curtail Medicare Part D drug costs. *See* Reig et al., *supra* note 12, at 10.