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Beyond The Anti-Kickback Statute: New Entities, New Theories In Healthcare Fraud Prosecutions

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ABSTRACT: The authors analyze existing and developing trends in healthcare fraud litigation. They first review the traditional use of the Medicare-Medicaid Anti-Kickback Statute to prosecute such fraudulent activity. They then consider newer theories that have been employed, or may be employed, in cases involving payors, middlemen, agents, and fiduciaries. These include the use of the Civil False Claims Act, the Federal Travel Act, and the Public Contracts Anti-Kickback (sometimes incorporating violations under state commercial bribery and similar state legislation to form the basis of a federal claim or prosecution). The Article then turns to a discussion and warning of attorneys' potential liability for a client's kickback arrangements. Finally, the Article takes a very brief look at relationships under Medicare Part D that may well prove to be a fertile area of problematic conduct, public and congressional scrutiny, and prosecutions utilizing some of these theories.

Kickbacks, understood as improper payments to obtain referrals of business or favorable treatment, have been prosecuted as healthcare fraud violations since the early 1970s.¹ Until recently, prosecutions have been based almost entirely on the Medicare-Medicaid Anti-Kickback Statute,² which prohibits improper payments between the persons or entities making and receiving patient referrals. As healthcare business arrangements become more complex, however, opportunities for improper influence and fraud are increasing. Specifically, relationships between those making and receiving referrals now often involve intermediaries or "middlemen" that may pay kickbacks or make improper payments to individuals or entities to obtain an unfair business advantage over competitors. These kickbacks may entail payments to obtain or retain contracts or to gain favorable treatment in contracts. They may be designed to induce fiduciaries, employees, and agents to act in their own interests rather than the interests of patients and payors relying upon them. Thus, prosecutors, regulators, and private litigants have begun to respond by applying a variety of fraud statutes and legal theories to address the consequences of these arrangements.

The thesis of this Article is that the Anti-Kickback Statute was not designed and has not been adapted to deal with either the benefits or the risks of many current healthcare relationships. The statute over-deters conduct that is potentially beneficial; it focuses on

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¹ See Social Security Amendments of 1972, P.L. 92-603, § 242(b), (c), 86 Stat. 1329, 1419-1420; see also MICHAEL K. LOUCKS & CAROL C. LAM, PROSECUTING AND DEFENDING HEALTH CARE FRAUD CASES 145 (BNA Books 2001).

² Social Security Act, 42 U.S.C. § 1320a-7b(b) (2000 & Supp. III 2003).

the intentional behavior of individuals rather than organizational acts and the consequences of systems; and it fails to address systemic problems in provider/payor relationships involving improper inducements that can result in higher cost, lower quality, and interference with competition. In response, regulators, prosecutors, and some private litigants are beginning to use other tools to address kickback and undue influence conduct.

This Article provides health law attorneys with an analysis of existing and developing trends. First, it briefly reviews the traditional statutory tools in kickback prosecutions. Second, it considers a new focus on kickback arrangements involving payors, middlemen, agents, and fiduciaries and describes a number of legal theories that have been employed in actions to regulate or prosecute these arrangements. These theories often incorporate violations of traditional federal fraud statutes, or combine federal fraud claims with state law claims. While some of the illustrations used are from a healthcare context, out of necessity others are discussions of nonhealthcare cases, but ones that have clear analogies in the healthcare arena. Third, the Article briefly discusses attorneys' potential liability for a client's kickback arrangements. Finally, the Article takes a brief look forward to relationships under Medicare Part D that may well prove to be a fertile area of problematic conduct, public and congressional scrutiny, and prosecutions utilizing some of these theories. Business arrangements involving managed care and large provider organizations, the significant new role of healthcare information control as a business strategy, and the increasing concentration in certain healthcare areas provide new opportunities for fraud. Law enforcement's focus on these issues will result in development of the law, most likely by private counsel through contract, RICO, and *qui tam* litigation first, and later by prosecutors and the courts.³ Therefore, healthcare transactional counsel must become familiar with all of these theories and the common law doctrines and state statutes that often underlie them.

I. The Traditional Focus of Kickback Prosecutions

The payment of kickbacks for the referral of Medicare and Medicaid patients has been prohibited almost since the beginning of the Medicare and Medicaid programs in 1965.⁴ The prohibition existed to address fundamental weaknesses of a third-party-pay-or program—the ability of providers to make referral decisions in their own economic interest rather than in the best interest of the payor or the patient, leading to unnecessary healthcare services, selection of higher cost providers, and selection of providers other

³ See generally Sharon Finegan, *The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law*, 111 PENN. ST. L. REV. 625, 629, 638 (2007) (explaining that *qui tam* provisions permit private individuals to bring suits against corporations on behalf of the government and that the Racketeer Influence Corrupt Organizations Statute (RICO) allows individuals to enforce criminal law by providing a civil remedy when they are injured by criminal action); Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 322 (1999).

⁴ For discussions of the background on efforts to fight healthcare fraud and the various enforcement authorities and initiatives available to the government, including a review of some of the multimillion dollar recoveries in the 1990s against major healthcare providers, see Tracy D. Hubbell et al., *Health Care Fraud*, 43 AM. CRIM. L. REV. 603 (2006) and Morris & Thompson, *supra* note 3.

than on the basis of quality of care.⁵ In enforcing the Anti-Kickback Statute,⁶ prosecutors traditionally have focused on transactions between the person or entity making a referral and the person or entity receiving it, the evidence of intent to induce referrals by the payor, and the evidence of intent to obtain payments for referrals by the recipient. When Congress was considering amendments to the law in 1977, witnesses described relatively simple transactions, such as laboratory owners paying doctors kickbacks often amounting to twenty-five percent of the cost of each test ordered or using a variety of methods that could amount to as much as thirty to forty-five percent of the medical billings of the physician or clinic that were sent to the lab.⁷ For the past twenty-five years, federal prosecutors primarily have used the Anti-Kickback Statute in criminal prosecutions because, even though kickback and undue influence transactions have become more subtle and complex, this statute has the most developed case law, jury instructions, and regulatory structure.⁸ The statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce business reimbursable under federal healthcare programs.⁹ The offense is classified as a felony and is punishable by fines of up to \$25,000 and/or imprisonment for up to five years.¹⁰

United States v. Greber was the first kickback case to hold that payments or remuneration to a referring physician intended to induce that physician to use a laboratory's services¹¹ violated the Medicare-Medicaid Anti-Fraud and Abuse Amendments to the Anti-Kickback Statute,¹² "even if the payments were also intended to compensate [the physician] for professional services."¹³ The idea that a payment is illegal under the Anti-Kickback Statute if one purpose of the payment, though not the primary purpose, is to induce referrals has been called the "one purpose" rule.¹⁴ Soon after *Greber*, representatives of the health-care industry expressed concern about this rule and argued that "relatively innocuous" business transactions are technically covered by the Anti-Kickback Statute and could lead to criminal prosecution because the statute on its face

⁵ See *Federal Anti-Kickback Law: Aims of the Anti-Kickback and Self-Referral Laws*, Health L. & Bus. Portfolios No. 1500, at § 1500.01(B) (BNA) [hereinafter BNA, *Federal Anti-Kickback Law*].

⁶ 42 U.S.C. § 1320a-7b(b).

⁷ H.R. REP. NO. 95-393(II), at 46 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3048-49.

⁸ Compare *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985) (holding that payments made to a physician by a laboratory to encourage future referrals constituted Medicare fraud), with *Hanlester Network v. Shalala*, 51 F.3d 1390, 1399 (9th Cir. 1995) (partner solicitation of physicians to invest in a laboratory to which physicians referred a large amount of patients did not violate the Anti-Kickback Statute), and *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000) (payments to physicians violate the Anti-Kickback Statute so long as they intend to induce patient referrals, even if that is not the primary purpose of the payment).

⁹ 42 U.S.C. § 1320a-7b(b)(1)(A).

¹⁰ *Id.* § 1320a-7b(b)(1)(B).

¹¹ *Greber*, 760 F.2d at 71-72.

¹² 42 U.S.C. § 1320a-7b(b).

¹³ *Greber*, 760 F.2d at 72; see Hubbell et al., *supra* note 4, at 618 n.110 ("[T]he OIG referred to *Greber* as 'the leading case' because it recognized that 'if one purpose of the payment is to induce future referrals, the Medicare statute has been violated.'" (quoting Preamble to Medicare and Medicaid Programs; Fraud and Abuse Anti-Kickback Provision, 42 C.F.R. § 1001.952)).

¹⁴ Hubbell et al., *supra* note 4, at 615.

was so broad.¹⁵ In response, Congress authorized the Secretary of the Department of Health and Human Services (HHS), in consultation with the U.S. Attorney General, to promulgate a number of Safe Harbor regulations¹⁶ specifying various types of payments and practices that are immune from prosecution even though they are capable of either inducing or rewarding referrals.¹⁷ The HHS Office of Inspector General (OIG), as directed by Congress, also addresses the problem of healthcare kickbacks by: (1) providing advisory opinions¹⁸ to answer actual or hypothetical situations presented by individuals or entities;¹⁹ (2) publishing fraud alerts,²⁰ bulletins,²¹ Safe Harbor explanations and development and compliance guidance;²² and (3) issuing civil monetary penalties²³ and exclusions from federal programs.²⁴ Thus, a very broad criminal statute prohibiting payment for referrals is applied regularly to healthcare business transactions by using a body of specific administrative rules, standards, and pronouncements. Schering-Plough Pharmaceuticals, Astra-Zeneca, and Serono have all agreed to guilty pleas and significant payments to the government for kickback payments.²⁵ An indictment of Alvarado Medical Center in San Diego, owned by Tenet Healthcare Corp.,

¹⁵ See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001). In addition, the bribes and kickbacks provisions of the Fraud and Abuse Statute contain a number of explicit exceptions allowing (a) discounts or reductions in price obtained by providers if properly disclosed and appropriately reflected in the claimed costs or charges of the provider; (b) amounts paid by employers to bona fide employees; (c) group purchasing organizations to be compensated by obtaining rebates from vendors under certain limited circumstances; (d) waivers of Medicare Part B coinsurance obligations by federally qualified health centers for individuals qualifying for subsidized services; and (e) (as part of HIPAA) certain risk-sharing arrangements involving remuneration between a Medicare or Medicaid MCO and a provider of items or services with the MCO or such arrangements that place an individual or entity at substantial financial risk for the cost or utilization of the items or services paid for on a fee-for-service basis by Medicare or Medicaid. 42 U.S.C. § 1320a-7b(b)(3)(A)-(F).

¹⁶ Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93 § 14, 101 Stat. 680 (codified at 42 U.S.C. § 1320a-7b). The set of Safe Harbor provisions is codified at 42 C.F.R. § 1001.952 (1987).

¹⁷ David M. Deaton, *What is "Safe" about the Government's Recent Interpretation of the Anti-Kickback Statute Safe Harbors? . . . And Since When was Stark an Intent-Based Statute?*, 36 J. HEALTH L. 549, 553 (2003); see Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,952.

¹⁸ See Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 253 (2004).

¹⁹ 42 C.F.R. §§ 1008.1-1008.59 (2006); see Social Security Act, 42 U.S.C. § 1320a-7b; see also Office of Inspector Gen. (OIG), U.S. Dep't of Health & Human Servs. (HHS), Fraud Prevention and Detection, Advisory Opinions, at <http://oig.hhs.gov/fraud/advisoryopinions/opinions.html> (last visited Apr. 24, 2007).

²⁰ See OIG, HHS, Fraud Alerts, Bulletins and Other Guidance, at <http://oig.hhs.gov/fraud/fraudalerts.html#1> (last visited Apr. 24, 2007).

²¹ *Id.*

²² *Id.*; see OIG, HHS, Compliance Guidance, at <http://oig.hhs.gov/fraud/complianceguidance.html> (last visited Apr. 24, 2007).

²³ Social Security Act, 42 U.S.C. § 1320a-7a(a)(7) (2000 & Supp. III 2003).

²⁴ *Id.* § 1320a-7(a).

²⁵ See, e.g., Reed Abelson, *Schering Case Demonstrates Manipulation of Drug Prices*, N.Y. TIMES, July 31, 2004, at C1; Press Release, U.S. Dep't of Justice (DOJ), AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay \$355 Million to Settle Charges (June 20, 2003), available at www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm (last visited Apr. 24, 2007); Press Release, DOJ, Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), available at www.usdoj.gov/opa/pr/2005/October/05_civ_545.html (last visited Apr. 24, 2007).

for its alleged payments to the practices of referring physicians resulted in two long trials, two hung juries, and ultimately, an administrative settlement.²⁶

Federal Medicaid law requires drug manufacturers to offer their lowest available prices to Medicaid.²⁷ When two large insurers, Cigna and PacifiCare Health Systems, threatened to replace Schering-Plough's Claritin with Allegra, a less expensive competitor, on their preferred drug list, Schering-Plough refused to lower the price but, instead, offered Cigna a \$1.8 million "data fee" for information that Schering was already receiving, prepayments that, in essence, were interest-free loans, and services below market value.²⁸ PacifiCare received similar loans as well as large discounts on other Schering-Plough products to keep the reported cost of Claritin high.²⁹ These payments were viewed by the government as kickbacks.³⁰ As a result of a whistleblower lawsuit brought under the Federal False Claims Act, Schering-Plough paid \$345.5 million to resolve the government investigation.³¹

Tenet Healthcare Corporation was charged with using kickbacks that were disguised as part of physician relocation agreements to induce doctors to refer patients to its 151-bed Alvarado Medical Center.³² State and federal laws permit hospitals to pay specified physician relocation expenses if they can demonstrate that certain specialists are needed in the area.³³ Federal law, however, prohibits payments to induce referral of any patients covered by Medicare or other federal health programs because such decisions are supposed to be based solely on the best interest of the patient.³⁴ The indictment charged that a substantial portion of the payments Tenet made did not go to the doctors being recruited. Instead they allegedly went to the medical practices in the Alvarado area that the doctors were joining and were aimed at inducing referrals to the facility.³⁵ The case went to trial in the fall of 2004 and ended in a mistrial because of a hung jury.³⁶ The retrial also ended in a mistrial after sixty days of deliberations.³⁷ In May 2006, after HHS proposed excluding Alvarado from federal health programs, the case finally settled with

²⁶ Keith Darcé, *Hospital's New Vision: Ownership Change Helps Morale at Alvarado, but Challenges are Ahead*, SAN DIEGO UNION TRIB., Jan. 7, 2007, available at www.signonsandiego.com/uniontrib/20070107/news_mz1b7darce.html (last visited Apr. 22, 2007); News Release, DOJ, Office of the United States Attorney Southern District of California, Carol C. Lam (May 17, 2006), available at www.usdoj.gov/usao/cas/press/cas60517-1.pdf (last visited Apr. 24, 2007).

²⁷ 42 U.S.C. § 1396r-8 (2000 & Supp. II 2002).

²⁸ Abelson, *supra* note 25.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² See Mark Taylor & Vince Galloro, *Recruitment Predicament: Tenet Settles with Feds for \$21 Million in Kickback Case, but Hospitals Still Wait for Clear Guidance on What's Allowed*, MOD. HEALTHCARE, May 22, 2006, at 6.

³³ See OIG Advisory Opinion No. 01-04 (May 3, 2001); revised hospital compliance guidance 70 Fed. Reg. 4858, 4868 (Jan. 31, 2005). See Lisa Girion, *Tenet Trial Ends with Hung Jury*, L.A. TIMES, Feb. 18, 2005, at C1.

³⁴ See BNA, *Federal Anti-Kickback Law*, *supra* note 5.

³⁵ See Andrew Pollack, *Tenet Hospital Is Accused of Illegally Paying for Patient Referrals*, N.Y. TIMES, July 18, 2003, at C5; Taylor & Galloro, *supra* note 32.

³⁶ Girion, *supra* note 33; Taylor & Galloro, *supra* note 32, at 7 fig.1.

³⁷ Taylor & Galloro, *supra* note 32, at 7 fig.1.

Tenet agreeing to pay the federal government \$21 million and sell or close the hospital.³⁸ Although the case may well have been the first one brought regarding excessive physician relocation expenses, it nonetheless fell into the traditional pattern of kickbacks in return for referrals.

II. The New Prosecutorial Focus—Kickbacks Involving Payors and Middlemen

In the past, kickback enforcement actions have concentrated on three areas: kickbacks related to costs shown on cost re-ports; physician referrals to hospitals, suppliers, and ancillary services; and hospital referrals to entities that provide services to patients after hospitalization, such as medical equipment suppliers or nursing services.³⁹ However, there is an increasing role in healthcare for payors and middlemen who control or influence purchasing decisions by using access to patient health and utilization information and provider data. These payors and middlemen may pay kickbacks to obtain or retain contracts, to receive favorable treatment in contracts, to obtain confidential patient or provider data,⁴⁰ or to influence agents or fiduciaries to exercise discretion on behalf of a principal in favor of the payor. This body of law can be complex because the techniques used by payors and recipients vary by industry, and there are more extensive and complicated money flows among the parties and related entities. Because of the secretive and rapidly evolving nature of these new businesses, administrative agencies often lack the information and expertise to provide public analysis and guidance similar to that provided under the Anti-Kickback Statute. Below is an overview of some of the categories of fact patterns encountered and the legal tools used to prosecute kickback activity involved in these types of healthcare transactions.

A. Middlemen and Medicare Anti-Kickback: PharMerica and Pharmacia

PharMerica, Inc. is a leading case involving a middleman arrangement.⁴¹ PharMerica Drug Systems, Inc. purchased Hollins Manor I, LLC, a small institutional pharmacy that had little in the way of an operating history, for \$7.2 million from five businessmen

³⁸ *Id.* at 6.

³⁹ See Hubbell et al., *supra* note 4, at 654–55.

⁴⁰ For example, a managed care entity might seek data related to potential beneficiaries' prior medical histories in order to prevent the enrollment of expensive or chronically ill patients in a managed care plan. A pharmaceutical company may pay a pharmacy to identify patients currently taking a psychiatric drug soon to go off-patent so that it can contact patients to switch them to a more expensive, longer-patented drug. A marketer of decubitus care products might pay a nurse or administrator for confidential diagnosis information to identify nursing home patients likely to need such products. An oxygen supplier may seek to purchase from physicians and other healthcare providers a list of patients with obstructive pulmonary disease who are likely to need oxygen in the near future. The supplier would then begin marketing directly to the consumer/patients.

⁴¹ See DOJ & HHS, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2005 at 14 (2006), available at www.usdoj.gov/dag/pubdoc/hcfareport2005.pdf (last visited Apr. 24, 2007); *PharMerica to Pay \$6 Million to Settle Kickback Case*, N.Y. TIMES, Mar. 30, 2005, at C4.

affiliated with the HCMF Corporation.⁴² A whistle-blower suit filed by a former executive of HCMF alleged that the \$7.2 million payment was actually made to obtain referral of nursing home and assisted living patient business controlled by HCMF.⁴³ As a result of a 2004 administrative complaint and a 2005 settlement, PharMerica ultimately was subject to nearly six million dollars in civil monetary penalties and a five-year corporate integrity agreement (CIA).⁴⁴ It was alleged to have paid an excessive price for the small pharmacy in return for a commitment from HCMF, which also owned seventeen nursing homes and eight assisted living facilities, “to refer its Medicaid and Medicare pharmacy business [to the company] for the next 7 years.”⁴⁵

The settlement was one of a number of instances in which the OIG “recovered money from a kickback case involving allegations of payments for a future flow of business.”⁴⁶ The sellers in this arrangement arguably were not themselves referral sources, such as an individual physician or a hospital in the more archetypical scenario, but were individual executives and owners of a corporate chain of nursing homes and assisted living facilities.⁴⁷ These individuals were in a position to determine the choice of pharmacy providers by each nursing home and its staff and medical director. Acting as the seller of the pharmacy, these owners and executives of HCMF were able to assure continued favorable treatment of PharMerica for providing drugs ordered by physicians and purchased by patients. Ultimately, through its long-term care facilities, HCMF would serve as the referral source, acting as an intermediary between the residents and the pharmacy. As a practical matter, because of the special requirements of a long-term care pharmacy (individual dose packages, short turnaround requirements, the statutory requirement for consulting pharmacists), it is very difficult to have more than one pharmacy providing medications in a nursing home.

The value of the contract to purchase the pharmacy was alleged to be grossly inflated⁴⁸ and therefore constituted illegal remuneration to the sellers who, in essence, were selling a facility and control over patients to assure a future income stream. In addition to the

⁴² See *PharMerica*, *supra* note 41; Press Release, OIG, HHS, OIG Settles Largest Ever Kickback Civil Monetary Action Against PharMerica (Mar. 29, 2005), available at <http://oig.hhs.gov/publications/docs/press/2005/032905release.pdf> (last visited Apr. 24, 2007). See generally Jen McCaffery, *Light Shines on HCMF Lawsuit*, ROANOKE TIMES, Oct. 31, 2004, at A1; Mark Taylor, *Record Settlement: PharMerica Resolves Kickback Allegations*, MOD. HEALTHCARE, Apr. 4, 2005, at 16.

⁴³ McCaffery, *supra* note 42; Lindsey Nair, *Federal Order Implicates S.W. Virginia Businessmen*, ROANOKE TIMES, June 26, 2004, at A1.

⁴⁴ See Taylor, *supra* note 42; CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PHARMERICA, INC., AND PHARMERICA DRUG SYSTEMS, INC. (Mar. 29, 2005) [hereinafter PHARMERICA CIA], available at <http://oig.hhs.gov/fraud/cia/agreements/Pharmerica.pdf> (last visited Mar. 31, 2007).

⁴⁵ Press Release, OIG, *supra* note 42.

⁴⁶ Taylor, *supra* note 42.

⁴⁷ McCaffery, *supra* note 42; Nair, *supra* note 43.

⁴⁸ Taylor, *supra* note 42.

monetary penalty, the five-year CIA called for by the settlement⁴⁹ requires PharMerica to certify that any “arrangement” it enters into is in compliance with the Anti-Kickback Statute.⁵⁰ In this case and in other CIA cases involving kickbacks, the OIG, in addition to requiring certification and oversight of arrangements with potential referral sources and beneficiaries, has required the recipient organization to make arrangements substantially more transparent.

The complexity of the PharMerica transaction and the control of relevant information about the kickback arrangements by the participants made for a long investigative process involving multiple interlocking corporations and individuals.⁵¹ PharMerica purchased Hollins Manor I from the owners and executives of HCMF in 1997.⁵² In 1998 the former HCMF officer brought the whistleblower suit against the organization and American HealthCare, which had purchased some of HCMF’s assets.⁵³ The nursing home assets of HCMF were transferred to American HealthCare that same year, but the two companies had several of the same owners in common.⁵⁴ In 2001 on behalf of HCMF, William Cranwell, a principal HCMF shareholder, settled a number of federal cost-reporting fraud allegations for \$2.3 million in restitution and prosecution costs as he and the company’s treasurer, Pendleton Smith, were convicted of misdemeanor fraud. Cranwell and the company were also convicted of felony healthcare fraud.⁵⁵ Then, in 2003, Cranwell agreed to pay an additional \$2.55 million to settle the whistleblower suit that had been brought against him and American Health-Care.⁵⁶ American HealthCare also was required to enter into a CIA with the OIG.⁵⁷ Finally, PharMerica settled for \$5.9 million

⁴⁹ The CIA between the OIG and PharMerica is over thirty pages long and man-dates compliance for five years. Among other provisions, the CIA requires actions from all levels of employees, such as anti-kickback training and implementation of a code of conduct. PharMerica must submit annual reports to OIG as well as immediate reports of any overpayments discovered. The appointed compliance officer is responsible for ensuring compliance and must sign off on all reports. The CIA also requires PharMerica to engage an independent review organization to assist with compliance. *See PHARMERICA CIA, supra* note 44.

⁵⁰ *See id.* at 9–11.

⁵¹ One effect of these complex business models may be to increase the likelihood that when a particular company and specific, controlling individuals are excluded from participation in federal programs such as Medicare and Medicaid, the nonexcluded individuals affiliated with that company could use a new, or other, entity to engage in similar activities. In the HCMF case, Chairman William Cranwell and Treasurer Pendleton Smith were subject to mandatory five-year exclusions from the Medicare and Medicaid programs because of their criminal convictions. Robert Cranwell, former CEO Keith Green, and Richard Frizzell, all named in the whistleblower suit as beneficiaries of the PharMerica transaction, were not subject to exclusion. Michael Sluss, *Kilgore: VA. Recovered \$12 Million in Phony Medicaid Payments; Previous Record was \$2.5 Million*, ROANOKE TIMES, Oct. 2, 2002, at B4.

⁵² *See Taylor, supra* note 42.

⁵³ *See Jen McCaffery, \$2.55 Million Slated to Settle Lawsuit Filed In Fraud Case*, ROA-NOKE TIMES, Sept. 20, 2003, at A1; McCaffery, *supra* note 42.

⁵⁴ McCaffery, *supra* note 42.

⁵⁵ *See McCaffery, supra* note 42; Sluss, *supra* note 51

⁵⁶ McCaffery, *supra* note 42.

⁵⁷ *Id.*; *see* CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND AMERICAN HEALTHCARE, L.L.C. (Aug. 1, 2003), available at <http://oig.hhs.gov/fraud/cia/agreements/American%20HealthCare%20LLC%2008%2001%202003.PDF> (last visited Apr. 24, 2007).

and entered into a CIA with the OIG in 2005.⁵⁸ Thus, there was a three-year gap between the initiation of the qui tam suit and any action against HCMF and an eight-year gap between the original transaction and a resolution as to all parties involved. As the Pharmerica case reveals, healthcare attorneys must judge business transactions not only based on reported case law, which usually reflects transactions five or more years old by the time there is a reported decision or settlement, but also by careful examination of recent OIG and DOJ settlement agreements (which describe the allegations of illegal conduct investigated and released), OIG Corporate Integrity Agreements (which describe areas of particular interest to the OIG and compliance and oversight mechanisms to prevent recurrence), and OIG corporate compliance guidance (which is frequently driven by experience with ongoing investigations).⁵⁹

Quite recently, the U.S. Attorney's Office for the District of Massachusetts entered into a plea agreement with Pharmacia, a subsidiary of Pfizer. The agreement settled charges against Pharmacia for its payment in violation of the Anti-Kickback Act. Pharmacia allegedly offered to make payments of over \$12.3 million to a pharmacy benefit manager (PBM) in return for the expectation that the PBM would recommend Pharmacia's products to its clients.⁶⁰ Under the agreement, Pharmacia plead guilty to violations of the Act and will pay a \$19.6 million fine.⁶¹ Additionally, Pharmacia will be permanently excluded from all federal healthcare programs.⁶²

B. Turning Kickbacks into False Claims: United States ex rel Schmidt v. Zimmer, Inc.

The DOJ and whistleblowers have been pursuing payment of kickbacks to and from health providers under the Civil False Claims Act for most of the past two decades.⁶³ The legal theory is that a claim induced by a kickback is a fraudulent claim.⁶⁴ There are distinct advantages to the government in using a Civil False Claims Act theory rather than a criminal theory under the Medicare-Medicaid Anti-Kickback Statute or administrative theory as in PharMerica.⁶⁵

Prosecution of a civil action allows multiple party defendants from different jurisdictions, using the statute's broad joinder and venue provisions, and permits the government to proceed without providing immunity or a favorable deal for any of the participants to the transactions. Parties to a Civil False Claims Act case must decide whether to assert Fifth

⁵⁸ See PharMerica, *supra* note 41.

⁵⁹ See Morris & Thompson, *supra* note 3, at 345–355.

⁶⁰ Press Release, U.S. Dep't of Justice (DOJ), PFIZER SUBSIDIARY AGREES TO PLEAD GUILTY FOR OFFERING KICKBACK AND PAY \$19.68 MILLION CRIMINAL FINE (Apr. 2, 2007), available at <http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Apr2007/Pharmacia-Information.html> (last visited Apr. 30, 2007).

⁶¹ *Id.*

⁶² *Id.*

⁶³ See, e.g., *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998); *United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996); *United States v. Kensington Hosp.*, 760 F. Supp. 1120 (E.D. Pa. 1991).

⁶⁴ See Morris & Thompson, *supra* note 3, at 327–328.

⁶⁵ See generally DAVID E. MATYAS AND CARRIE VALIANT, LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES § 9-3, at 403–407 (3d ed. 2006).

Amendment claims during discovery and at trial that potentially carry adverse discovery decisions or jury instructions. Of course, the civil burden of proof is substantially less, which can be helpful in cases based on adverse witnesses, inferences drawn from circumstantial evidence, and documents. Criminal statutes generally include substantial intent requirements, typically requiring proof that the activities in question were performed “knowingly and will-fully,” whereas the civil case standard may include negligent conduct or actions demonstrating “deliberate ignorance or reckless disregard.” Finally, the scope of discovery after the complaint is filed is far greater in civil cases than in either criminal or administrative actions.⁶⁶ The nature of Anti-Kickback Statute violations, which may be regulatory violations with substantial professional advice and involvement, often make prosecuting the various actors as an entity more appealing than prosecuting cases individually.

Two corporate/individual kickback prosecutions demonstrate the prosecutorial risks of criminal kickback cases against individuals, even after their corporate employer has pled guilty and agreed to cooperate. In *United States v. Caremark*, the corporation pled guilty and agreed to pay “approximately \$161 million in criminal fines, civil restitution and damages” to resolve allegations that it had paid physicians to induce them to prescribe the corporation’s “home infusion, oncology, hemophilia and human growth hormone businesses.”⁶⁷ In *United States v. TAP Pharmaceuticals*, the corporation agreed to plead guilty and pay \$875 million to settle criminal charges and civil liabilities regarding allegations that it had engaged in fraudulent drug pricing and paid physicians to prescribe Lupron to prostate cancer patients.⁶⁸ TAP was accused of providing physicians with free samples of Lupron and encouraging the doctors to bill Medicare for the pills at the stated cost of \$400, as well as providing them with consulting fees, educational grants, and vacations.⁶⁹ On the pricing issue, it was alleged that TAP encouraged the physicians to report paying higher prices for the drug than they actually were charged, which would have the effect of distorting formulas that the government used to establish rates for reimbursement.⁷⁰ Subsequently, four physicians pled guilty and three TAP employees were convicted; but when eight TAP sales managers went to trial on criminal charges, they were acquitted.⁷¹ In this and other unsuccessful criminal cases, undoubtedly part of the defense used is that the defendants relied on corporate (including attorney) review of the questioned transactions to demonstrate a lack of criminal intent.

⁶⁶ See generally Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1 (2002) (exploring the reasons why the Department of Justice likes to use the Civil False Claims Act instead of criminal prosecution).

⁶⁷ Press Release, DOJ, Caremark to Pay \$161 Million in Fraud and Kickback Cases (June 16, 1995), available at www.usdoj.gov/opa/pr/Pre_96/June95/342.txt.html (last visited Apr. 24, 2007).

⁶⁸ See Alice Dembner, *Drug Firm to Pay \$875M Fine for Fraud US Alleges Bribery, Price Manipulation*, BOSTON GLOBE, Oct. 4, 2001, at A13; Jennifer Heldt Powell & J.M. Lawrence, *Drug Maker to Pay \$875M- Payments Will Settle Case of Cancer Treatment Fraud*, BOSTON HERALD, Oct. 4, 2001, at 51; Press Release, DOJ, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), available at www.usdoj.gov/opa/pr/2001/October/513civ.htm (last visited Apr. 19, 2007).

⁶⁹ Jennifer Heldt Powell, *TAP Managers Acquitted; Drug Maker had Already Pleaded Guilty*, BOSTON HERALD, July 15, 2004, at 39.

⁷⁰ *Id.*; Dembner, *supra* note 68; Powell & Lawrence, *supra* note 68.

⁷¹ Powell, *supra* note 69; see also Dembner, *supra* note 68; Powell & Lawrence, *supra* note 68.

The most significant reason kickback cases are prosecuted under the Civil False Claims Act, however, is the availability of that statute's whistleblower provisions, including the right to a share of the recovery and attorney fees.⁷² An excellent recent example is *Schmidt v. Zimmer*.⁷³

In *Schmidt*, an orthopedic surgeon brought a qui tam action under the False Claims Act against Zimmer, Inc., "a manufacturer, seller, and distributor of orthopedic implants."⁷⁴ He alleged that Zimmer entered into a contract with a group purchasing organization (GPO), a purchasing agent for a group of entities that included a healthcare system and a group of hospitals that provide medical services ("participants").⁷⁵ The contract allegedly committed Zimmer to provide orthopedic implants to the participants for five years.⁷⁶ Under the contract, the participants were rewarded with a "conversion incentive" if, by purchasing Zimmer's products in large enough numbers, they helped increase Zimmer's market share.⁷⁷ When a participant purchased more implants than it had purchased the year before, the cost of each additional implant was reduced.⁷⁸ Also, each participant received a two percent bonus on implant purchases if it met agreed upon market share and volume purchase commitments.⁷⁹ The contract also provided for "additional incentives."⁸⁰ The surgeon bringing the action alleged that a hospital at which he practiced ("the hospital"), "induced certain of its physicians and orthopedic departments to assist in meeting Zimmer's prescribed volume and market share levels by sharing with them all or part of the rewards received from Zimmer under the contract."⁸¹

The surgeon claimed violations of the Anti-Kickback Statute, the Anti-Self Referral ("Stark") Law, and the False Claims Act.⁸² He alleged that the Anti-Kickback Statute was violated in that the hospital's actions amounted to receiving unlawful remunerations. Zimmer allegedly paid such unlawful remunerations; the hospital failed to disclose them to the government; and Zimmer knew this was likely to happen.⁸³ Stark allegedly was violated because the hospital and Zimmer presented or caused to be presented "Medicare reimbursement claims for services furnished pursuant to prohibited referrals."⁸⁴ The False Claims Act was alleged to have been violated when the hospital and the other GPO participants filed false certifications in their annual cost reports submitted to the federal government.⁸⁵ "The reporting form . . . required a health care provider to certify that the costs being submitted were true and correct, and that the provider had complied with all

⁷² 31 U.S.C. §§ 3729–3733.

⁷³ *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004).

⁷⁴ *Schmidt*, 386 F.3d at 236–37.

⁷⁵ *Id.* at 237.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Schmidt*, 386 F.3d at 237.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 238–39.

⁸³ *Id.* at 239.

⁸⁴ *Schmidt*, 386 F.3d at 239.

⁸⁵ *Id.*

laws and regulations regarding the provision of health care services.”⁸⁶ According to the complaint, the participants’ failure to disclose the rewards that they allegedly received from Zimmer constituted false certifications, violating three provisions of the False Claims Act:

(1) 31 U.S.C. § 3729(a)(1), which prohibits knowingly presenting, or causing to be presented, . . . a false claim for payment or approval; (2) § 3729(a)(2), which prohibits knowingly making, using and/or causing to be made or used a false record, claim, or statement to get a false claim paid or approved by the federal government; and (3) § 3729(a)(7), barring false certifications intended to conceal, avoid, or decrease an obligation to refund Medicare payments made by the federal government.⁸⁷

In short, the hospital purchased the Zimmer devices from the GPO, for both Medicare and non-Medicare patients. It received a diagnosis-related group (DRG) payment with some upward or downward adjustments from Medicare and a different payment from private insurers. But Zimmer paid a conversion incentive and bonus to the hospital, which passed some of those payments on to its non-employee physicians.⁸⁸ The False Claims Act theory was that doctors referred patients to a hospital from which the doctors received improper financial benefits and the hospital did not disclose the discounts awarded by Zimmer, while certifying in its HCFA-2552 form that it had fully complied with its anti-kickback and cost reporting obligations.⁸⁹ Though the contract required hospitals to disclose discounts and reductions on their cost reports, Zimmer was allegedly aware that the hospital might file a false claim for more than it paid.⁹⁰ Thus, an arguable kickback violation, prosecutable only by the United States, became the basis for a false claim case, allowing Dr. Schmidt to bring his own action, and to continue with the action after the government had declined to intervene.

The district court dismissed the False Claims Act complaint for failure to state a claim because Zimmer never submitted any cost reports.⁹¹ The court concluded that, as a consequence, Zimmer never intentionally and purposely caused the hospital to submit an allegedly false cost report, and therefore could not be liable under the False Claims Act.⁹² The appellate court, however, held that the physician stated a claim with the allegation that Zimmer was liable for false statements made by the hospital on Form HCFA-2552.⁹³

⁸⁶ *Id.* at 237.

⁸⁷ *Id.* at 239–40.

⁸⁸ *Id.* at 237.

⁸⁹ *Schmidt*, 386 F.3d at 239–240. Medicare requires that participants file annual cost reports, which include a certification that the cost reports are in compliance with applicable laws. HCFA-2552 (hospital cost report form) requires the hospital’s administrator or official to certify that the report is true and correct. Robert N. Rabecs, *Kickbacks as False Claims: The Use of the Civil False Claims Act to Prosecute Violations of the Federal Health Care Program’s Anti-Kickback Statute*, 2001 MICH. ST. L. REV. 1, 63–64 (2001).

⁹⁰ *United States ex rel. Schmidt v. Zimmer, Inc.*, No. Civ.A.00-1044, 2005 WL 1806502, at *3 & n.4 (E.D. Pa. July 29, 2005).

⁹¹ *Schmidt*, 386 F.3d. at 240.

⁹² *Id.*

⁹³ *Id.* at 239, 245.

The appellate court held that the purpose of the Act is “to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government,”⁹⁴ and that liability extended to those who “‘cause [a false claim] to be presented’ and to those who ‘conspire’ to obtain payment of such claims.”⁹⁵ The court concluded that even though Zimmer had not “‘reviewed, approved, or received copies of [the Hospital’s] cost reports or participated in their preparation,’” such activities were not necessary to establish a cause of action.⁹⁶ Rather, a party could “assist the filing of a false claim in other ways.”⁹⁷ If a supplier had “knowingly pursued a scheme that, if successful, would ultimately result in the submission of a false claim to the government,” that would be adequate to hold that the supplier “caused those claims to be presented.”⁹⁸ The hospital settled with Dr. Schmidt.⁹⁹ On remand the district court dismissed, with leave to amend, the doctor’s complaint on other grounds, holding that he did not plead the allegations of fraud with sufficient particularity¹⁰⁰ and finding “no nexus between the allegedly illegal marketing scheme and the [False Claims Act].”¹⁰¹ Dr. Schmidt filed an amended complaint to remedy this concern, and the trial court has allowed the action to proceed to discovery.¹⁰²

This case is significant for a number of reasons. First, it shows that a gainsharing allegation is not necessary. That is, a hospital could violate the False Claims Act by failing to disclose discounts on its cost report, even if it does not share those price reductions with its physicians. Second, the case demonstrates that the relationships among hospitals, non-employee physicians, and GPOs, which tend to be complex, are an emerging area of kickback risks and other fraud and abuse concerns. Third, the case shows why transactions with device and pharmaceutical manufacturers require greater scrutiny by healthcare attorneys. Although hospitals reasonably seek to procure good products at low prices and manufacturers seek greater volume before granting discounts or rebates, these payments or price reductions must be in the appropriate form, directed to the actual purchaser of the goods or services, and fully disclosed. Fourth, the case demonstrates that payments made by hospitals to non-employee physicians from funds paid by manufacturers, wholesalers, and GPOs are a particular source of concern. Finally, the case makes clear that kickback claims will increase as qui tam relators bring them under a false claims theory. Consequently, the initiative to file a suit shifts from prosecutors to whistleblowers, and cases can proceed even where a prosecutor believes the kickback allegations lack merit or do not justify the use of public resources and enforcement tools.

⁹⁴ *Id.* At 243.

⁹⁵ *Id.* at 243 (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544 (1943)).

⁹⁶ *Schmidt*, 386 F.3d. at 243.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.* at 240.

¹⁰⁰ *United States ex rel. Schmidt v. Zimmer, Inc.*, No. Civ.A.00-1044, 2005 WL 1806502, at *4 (E.D. Pa. July 29, 2005).

¹⁰¹ *Id.* at *3.

¹⁰² Court Order, *United States ex rel. Schmidt v. Zimmer*, Civil Action No-00-1044 (E.D. Pa. July 26, 2006).

C. Using State Bribery Laws: The Travel Act

In addition to the Civil False Claims Act and administrative sanctions, such as that used by the OIG in the PharMerica case, prosecutors also have recently looked to the Federal Travel Act,¹⁰³ which is one among a set of anti-racketeering statutes, to prosecute kickback violations. The Act states:

Whoever travels in interstate or foreign commerce or uses the mail or any facility in interstate or foreign commerce, with intent to . . . promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of any unlawful activity, and thereafter performs or attempts to perform [such unlawful activity] . . . shall be fined . . . , imprisoned not more than 5 years, or both.¹⁰⁴

“Unlawful activity” includes “bribery . . . in violation of the laws of the State in which committed or of the United States.”¹⁰⁵ In short, one may violate the Travel Act by engaging in interstate commerce with the intent to promote or carry on a violation of a state bribery law. From a prosecutorial perspective, this Act can prove to be of great significance in these cases as it can transform a state misdemeanor (commercial bribery) that is seldom prosecuted separately in state court into a federal felony.¹⁰⁶

Traditionally, federal prosecutions for bribery involve public officials, which do not usually concern healthcare attorneys, with the exception of physicians who are public officials such as physician administrators of public hospitals.¹⁰⁷ With the extension of bribery cases to the healthcare context, however, a couple of questions are raised: what category of individuals, other than public officials, is covered by a given state bribery law and who may not pay a kickback under state law? There are two relevant groups of bribery statutes: (1) those prohibiting commercial bribery,¹⁰⁸ which Black’s Law Dictionary defines as “corrupt dealing with the agents or employees of prospective

¹⁰³ 18 U.S.C. § 1952 (2000 & Supp. II 2002).

¹⁰⁴ *Id.* § 1952.

¹⁰⁵ *Id.* § 1952(a).

¹⁰⁶ *Id.* § 1952(b)(i)(2). This is analogous to situations where federal RICO prosecutions can be based on state bribery statutes. Thus, for example, *see generally* United States v. Parise, 159 F.3d 790 (3d Cir. 1998) (RICO conviction predicated on violation of state commercial bribery statute involving kickback of legal fees); *Pharmacare v. Caremark*, 965 F. Supp. 1411 (D. Hawaii 1996) (RICO conviction predicated on violation of state statute prohibiting bribery of public officials).

¹⁰⁷ *See* News Release, DOJ, DPC (Tianjin) Ltd. Charged with Violating the Foreign Corrupt Practices Act (May 20, 2005), available at www.usdoj.gov/opa/pr/2005/May/05_crm_282.htm (last visited Apr. 24, 2007) (noting that Chinese subsidiary of California-based Diagnostic Products Corporation pled guilty to a criminal information charge for violation of the Foreign Corrupt Practices Act by paying “\$1.6 million in bribes in the form of illegal ‘commissions’ to physicians and laboratory personnel employed by government-owned hospitals” in China).

¹⁰⁸ *See, e.g.*, N.J. STAT. ANN. § 2C:21-10 (West 2007); NY PENAL LAW § 180.00 (McKinney 2007); 18 PA. CONS. STAT. ANN. § 4108 (West 2007). *See generally* United States v. Parise, 159 F.3d 790 (3d Cir. 1998).

buyers to secure an advantage over business competitors,”¹⁰⁹ and (2) those addressing illegal remuneration that have specific provisions regarding improper payments in connection with referral for services.¹¹⁰ Some state bribery statutes are limited to workers compensation or Medicaid,¹¹¹ but many apply to “all-provider[s]/all-payor[s]”¹¹² and some are designed specifically to benefit insurers.¹¹³ Traditionally, attorneys considered Medicare kickback issues and private bribery questions separately, designing different solutions for the two different situations. As a consequence of this ability to use these state statutes, however, attorneys must look for activities that may not only be illegal under a state law which is not actively enforced or administratively interpreted, but may fall under the “unlawful activity” language of the Travel Act. This investigation involves considering state commercial bribery laws,¹¹⁴ state illegal remuneration statutes and, it is reasonable to argue, current professional and ethical standards for physicians, pharmacists, and other healthcare professionals.¹¹⁵

D. False Claims Act and Public Contracts Anti-Kickback Act: United States ex rel. Hunt v. Merck-Medco Managed Care

The Public Contracts Anti-Kickback Act¹¹⁶ prohibits a person from providing, offering to provide, accepting, or soliciting any kickback, including those priced into a contract between a subcontractor and a prime contractor, in connection with an agreement with the United States for the purpose of obtaining supplies, materials, equipment, or services of any kind.¹¹⁷ In *United States ex rel. Hunt v. Merck-Medco Managed Care*, an intervened qui tam action, the government alleged a violation both of the False Claims Act and the Public Contracts Anti-Kickback Act by Merck-Medco (Medco), a PBM that contracted with Blue Cross-Blue Shield to manage prescription drug benefits by providing “mail order prescription drugs to plan beneficiaries, administrative services, and rebate and discount negotiations with manufacturers and pharmaceutical services.”¹¹⁸

¹⁰⁹ BLACK’S LAW DICTIONARY 204 (8th ed. 2004).

¹¹⁰ THOMAS WM. MAYO, STATE ILLEGAL-RENUMERATION AND SELF-REFERAL LAWS 2–9 (NHLA/AAHA, Inc. 1996).

¹¹¹ ALICE G. GOSFIELD, MEDICARE AND MEDICAID FRAUD AND ABUSE § 3.24 (2007); MAYO, *supra* note 110, at 5.

¹¹² MAYO, *supra* note 110, at 3–5.

¹¹³ *See, e.g.*, TEX. PENAL CODE ANN. § 35.02 (Vernon 2006).

¹¹⁴ *United States v. Perrin*, 580 F.2d 730, 734 (5th Cir. 1978) (Congress in enacting the Travel Act, which specifically outlaws extortion, bribery, or arson in violation of state laws, “intended the term ‘bribery’ to be used in its generic sense and not to be limited to its common law meaning,” and thus violation under this section could be based on commercial bribery in violation of a state’s commercial bribery statute.); accord *United States v. Seregos*, 655 F.2d 33, 36–37 (2d Cir. 1981) (for purposes of the Travel Act, kickback constituted bribery under New York law); *U.S. v. Pomponio*, 511 F.2d 953, 957 (4th Cir. 1975) (money paid to bank officer to influence loan decisions could constitute bribery under New York law).

¹¹⁵ *See Miss. State Bd. of Psychological Exam’rs v. Hosford*, 508 So. 2d 1049, 1050–51, 1052–53 (Miss. 1987) (“[A] state-created board, charged with the governance of a learned profession,” was given the authority to discipline a professional who had inappropriately breached confidentiality based on a violation of the then existing code of ethics of a national professional association.).

¹¹⁶ Anti-Kickback Act of 1986, 41 U.S.C. §§ 51–58 (2000).

¹¹⁷ *See id.* §§ 52–53.

¹¹⁸ *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 434 (E.D. Pa. 2004).

Blue Cross-Blue Shield, in turn, had contracted to provide healthcare to federal government employees through the Federal Employee Health Benefits Program (FEHBP).¹¹⁹

The government alleged a variety of bases for its conclusion that Medco's submissions through Blue Cross-Blue Shield to FEHBP were false or fraudulent.¹²⁰ Among them were that Medco failed to meet contractually required turnaround time requirements that should have led to the payment of contractual penalties, but Medco submitted false records indicating on-time delivery;¹²¹ that Medco submitted claims for prescription drugs dispensed "without specific physician authorization" in violation of state law or contractual obligations;¹²² "that Medco charged for drugs that it did not deliver";¹²³ and that Medco made claims based on prescriptions dispensed in violation of state law in that non-pharmacist employees were involved in tasks relating to the dispensing which state law mandated only pharmacists could perform.¹²⁴

With regard to the Public Contracts Anti-Kickback Act, the Government claimed that Medco "both made and received payments for unfair favorable treatment with other companies and health plans."¹²⁵ The government alleged that Medco paid \$87.4 million to the parent company of Oxford Health Plans, ostensibly as a "data fee," but actually to ensure that Oxford's subsidiaries rely exclusively on Medco's services as a pharmacy benefits contractor.¹²⁶ Oxford allegedly agreed to higher prices to be paid by the Oxford subsidiaries which provided services to Medicare beneficiaries in return for payment of the data fee to the Oxford parent.¹²⁷ The government also alleged that Medco received millions of dollars from drug manufacturers to favor more expensive and/or less effective prescription drugs.¹²⁸ Med-co argued that the Public Contracts Anti-Kickback Act did not apply to contracts involving Medicare, but the court, in denying Medco's motion to dismiss,¹²⁹ held that both the payments to Medco from pharmaceutical manufacturers and the payments by Medco to the health plan's parent could be kickbacks under the Anti-

¹¹⁹ *Id.*

¹²⁰ *Id.* at 435–36.

¹²¹ *Id.* at 439.

¹²² *Id.* at 439–40.

¹²³ *Merck-Medco Managed Care*, 336 F. Supp. 2d at 440.

¹²⁴ *Id.* The case is not unlike *Zimmer* in that Medco also did not submit allegedly false certifications directly to the government, but rather it submitted claims for payment for services to Blue Cross that either were not rendered at all or "not performed in accordance with contractual requirements." See text at notes 91-98, *supra*. Blue Cross, in turn, submitted claims to the government based on Medco's submissions to it. *Id.* at 443, 438–39. As in *Zimmer*, Medco unsuccessfully argued that since none of its claims were ever presented "to an officer or employee of the United States Government," it could not be held liable under the False Claims Act. *Id.* at 443, 444–45 (Contractual privity with the government is not required for liability under the statute, as long as "Medco's actions had the predictable consequence of depriving the Government of money it was owed.").

¹²⁵ *Id.* at 434.

¹²⁶ See *id.* at 436; Milt Freudenheim, *Payments by Managers of Drug Plans Face Scrutiny*, N.Y. TIMES, Dec. 11, 2003, at C3.

¹²⁷ *Merck-Medco Managed Care*, 336 F. Supp. 2d at 436; see Freudenheim, *supra* note 126.

¹²⁸ *Merck-Medco Managed Care*, 336 F. Supp. 2d at 436.

¹²⁹ *Id.* at 448–49.

Kickback Act where there was a contract involving benefits to be provided by a Medicare managed-care contractor.¹³⁰

The rationale was that both were kickback payments from a Medicare subcontractor to a higher tier Medicare contractor.¹³¹ The court noted that the Senate report on the Public Contracts Anti-Kickback Act clearly stated that “‘kickbacks’ include payments between [amongst other things] subcontractors and prime contractors.”¹³²

Apart from the recognition that the Public Contracts Anti-Kickback Act applies to Medicare managed-care subcontractors, the case is important in other respects as well. If one contract in a bundle is federal, the contracting entity can be subject to the Public Contracts Anti-Kickback Act whether or not it has knowledge of the federal contract.¹³³ Most federal contracts include specific provisions setting forth the prohibition against kickbacks. The Public Contracts Anti-Kickback Act includes both criminal and civil penalties.¹³⁴ A criminal violation can result in up to ten years in prison and a criminal fine;¹³⁵ a civil penalty is twice the amount of each kickback involved and not more than \$10,000 for each occurrence.¹³⁶ These penalties become important in the context of pharmaceutical contracts under Medicare Part D.

E. Deciphering “Kickbacks” Under State Law

A question arises as to what constitutes a kickback or improper payment under a federal contract. The Public Contracts Anti-Kickback Act states:

The term “kickback” means any money, fee, com-mission, credit, gift, gratuity, thing of value, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor, or subcontractor employee for the purpose of improperly obtaining or rewarding favorable treatment in connection with a prime contract or in connection with a subcontract relating to a prime contract.¹³⁷

A useful analogy may be the Travel Act jurisprudence discussed above. “Bribery” under that law included commercial bribery and violations of insurance codes and professional and ethical standards.¹³⁸ Here, commercial bribery under state law would be compensation “provided” for the “purpose of improperly obtaining” favorable treatment.

¹³⁰ See *id.* at 449–50.

¹³¹ See *id.* at 449.

¹³² *Id.*

¹³³ See *United States v. Purdy*, 144 F.3d 241, 245 (2d Cir. 1998).

¹³⁴ 41 U.S.C. §§ 54–55 (2000).

¹³⁵ *Id.* § 54.

¹³⁶ *Id.* § 55(a)(1).

¹³⁷ *Id.* § 52(2).

¹³⁸ See *United States v. Perrin*, 580 F.2d 730, 734 (5th Cir. 1978); *Miss. State Bd. of Psychological Exam’rs v. Hosford*, 508 So.2d 1049, 1050–51, 1052–53 (Miss. 1987). See also discussion in Section IIC, *supra* notes 103-15 and accompanying text.

State law is one source of the concept of “improperly obtaining favorable treatment” used to define a kickback under the Public Contracts Anti-Kickback Act.

A recognized industry standard, such as the *PhRMA Code on Interactions with Healthcare Professionals*,¹³⁹ referenced within a federal contract or state law,¹⁴⁰ a response to a Request for Proposal, or a statement of corporate policy or intent, could provide another basis for liability based on improperly obtaining favorable treatment under the Public Contracts Anti-Kickback Act. Standards can be demonstrated not only by written, industry-adopted consensus guidelines, but also by expert witnesses who testify as to industry and professional standards, again because of the use of the phrase “improperly obtaining or rewarding favorable treatment” in the Anti-Kickback Act.¹⁴¹ Expert witnesses focus on ethics and apply ethical standards as written. Most healthcare organizations publicly recognize and pledge adherence to professional ethics codes and principles containing language of policy, institutional commitment, and ethical understanding.¹⁴² Thus, a payment that arguably may not even violate the state commercial bribery law or the PhRMA Code may nonetheless be generally recognized as unethical by professional standards and constitute a payment for “improperly obtaining or rewarding favorable treatment” and, therefore, a kickback under the Public Contracts Anti-Kickback Act.

1. Nature of the Injury Needed to Establish Commercial Bribery: 2660 Woodley Road Joint Venture v. ITT Sheraton Corporation

There are only a few reported opinions applying commercial bribery theories in the healthcare context.¹⁴³ But a much more interesting case analyzing improper payments, albeit from another area of law, is *2660 Woodley Road Joint Venture v. ITT Sheraton Corporation*,¹⁴⁴ and a review of its facts and the court’s holding could shed needed light on what very well could occur in a typical healthcare situation.

Hotel owner 2660 Woodley Road Joint Venture (Woodley) entered into a management agreement under which Sheraton consented to act as Woodley’s agent and manage the hotel’s operations in return for a share of the hotel’s gross revenue and net cash flow.¹⁴⁵

¹³⁹ See PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (PhRMA 2004), available at www.phrma.org/files/PhRMA%20Code.pdf (last visited Apr. 24, 2007).

¹⁴⁰ See, e.g., CAL. HEALTH & SAFETY CODE §§ 119, 402 (West 2007).

¹⁴¹ 41 U.S.C. § 52(2) (2000).

¹⁴² See, e.g., Am. Med. Ass’n, Principles of Medical Ethics (2001), at www.ama-assn.org/ama/pub/category/2512.html (last visited Apr. 27, 2007); Am. Ass’n of Nurse Anesthetists, Code of Ethics For the Certified Registered Nurse Anesthetist, at <http://tinyurl.com/2ac2tb> (last visited May 31, 2007); Advanced Med. Tech. Ass’n, Code Of Ethics On Interactions With Health Care Professionals (2003), available at http://www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf (last visited Apr. 27, 2007); Am. Psychologists Ass’n, Ethical Principles of Psychologists and Code of Conduct (2002), available at <http://www.apa.org/ethics/code2002.pdf> (last visited Apr. 27, 2007).

¹⁴³ See, e.g., *Pharmacare vs. Caremark*, 965 F. Supp. 1411, 1414 (D. Haw. 1996) (alleging that Caremark’s payments to physicians in exchange for referrals constituted commercial bribery and violated the Clayton Act, RICO, and a California statute regulating fraudulent business practices).

¹⁴⁴ *2660 Woodley Rd. Joint Venture v. ITT Sheraton Corp.*, 369 F.3d 732 (3d Cir. 2004).

¹⁴⁵ *Id.*

Sheraton negotiated large-volume discounts with vendors to supply Sheraton-managed hotels and directed them to add a surcharge to the individual hotel billing price for each purchase.¹⁴⁶ “However, the surcharge was not itemized, or even disclosed, on any bills or invoices that vendors sent to individual hotels.”¹⁴⁷ “Rather, the surcharge was remitted directly to Sheraton in the form of a ‘rebate.’”¹⁴⁸ Under the agreement, Sheraton was entitled to reimbursement for the costs of acting as a purchasing agent and “claimed that these rebates reimbursed it for the centralized purchasing services it provided . . . as well as associated overhead costs.”¹⁴⁹

Woodley brought an action for commercial bribery under the Robinson-Patman Act,¹⁵⁰ which establishes rules against price discrimination by firms and declared many pricing actions illegal per se.¹⁵¹ Section 13(c) of the Act, which was the basis of Woodley’s claim, states:

It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.¹⁵²

The court recognized that this section encompasses commercial bribery but, consistent with earlier cases, it concluded that to succeed under § 13(c) a plaintiff must show “antitrust injur[ies].”¹⁵³ The court found that “paying inflated purchasing prices to vendors, without more, is [not] ‘an injury of the type the antitrust laws were intended to prevent . . . that flows from that which makes the defendants’ acts unlawful.’”¹⁵⁴ Woodley’s injury, the court said, “was caused by a breach of contract and the corruption of the principal-agent relationship.”¹⁵⁵ The court noted in dicta, however, that “in an appropriate case, a breach of contract or a breach of fiduciary duty could result in the kind of injury ‘the antitrust laws were intended to prevent.’”¹⁵⁶ Thus, the Robinson-

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 735.

¹⁴⁹ *Woodley Rd. Joint Venture*, 369 F.3d at 735.

¹⁵⁰ *Id.*

¹⁵¹ See 15 U.S.C. § 13(c) (2000).

¹⁵² *Id.*

¹⁵³ *Woodley Rd. Joint Venture*, 369 F.3d at 738.

¹⁵⁴ *Id.* at 738–39.

¹⁵⁵ *Id.* at 739.

¹⁵⁶ *Id.*

Patman Act could prove to be another source in the developing law of commercial bribery that would support findings of kickbacks and improper payments.¹⁵⁷

2. Other Sources of Kickback Law—Private Contract Litigation Involving “Illegal Contracts” and Professional Standards: *Vine Street Clinic v. HealthLink, Inc.*

Several recent cases demonstrate a problematic trend for transactional attorneys—the development of anti-kickback law completely outside the context of actions brought by or on behalf of state government agencies. In these cases, private parties assert kickback prohibitions as a basis for voiding a contract, avoiding liability under a contract, obtaining repayment of funds previously paid, or asserting securities violations. Courts are called upon to analyze and interpret laws relating to kickbacks without the assistance, or sometimes even the awareness, of agencies responsible for overseeing development of the law.

Vine Street Clinic v. HealthLink was a private civil case, within the healthcare context, brought by physicians seeking a refund of payments they had made based on an allegation of improper fee-splitting.¹⁵⁸ HealthLink created healthcare networks through agreements with physicians and other healthcare providers and contracted with payors to make “these provider networks available to members of health plans.”¹⁵⁹ Healthcare providers agreed to furnish medical services to health plan members at a discounted rate.¹⁶⁰ HealthLink processed reimbursement claims and sent them to the payors “for benefit determination and payment.”¹⁶¹ It originally required each participating physician to pay “an administrative fee equal to 5% of the amount allowed in HealthLink’s rate schedule for services provided to members by the physician.”¹⁶² Later, it charged a fixed flat fee based on the physician’s specialty and volume of HealthLink claims submitted during the preceding calendar year.¹⁶³

The Illinois Medical Practice Act¹⁶⁴ allows the Department of Professional Regulation to revoke a license to practice medicine or take other action against physicians who divide “with anyone other than physicians with whom the licensee practices . . . any fee, commission, rebate or other form of compensation for any professional services not actually and personally rendered.”¹⁶⁵ The intermediate appellate court found that HealthLink referred patients to physicians through its network of healthcare providers and that both the percentage fee and the flat fee were for referral of patients.¹⁶⁶ It then held that the fee requirement violated the Medical Practice Act and public policy

¹⁵⁷ See, e.g. *Pharmacare v. Caremark*, 965 F. Supp. 1411, 1424–25 (D. Haw. 1996); see also *Fed. Paper Bd. Co. v. Amata*, 693 F. Supp. 1376, 1384–85 (D. Conn. 1988).

¹⁵⁸ *Vine St. Clinic v. HealthLink, Inc.*, 856 N.E.2d 422, 426 (Ill. 2006).

¹⁵⁹ *Id.* at 426–27.

¹⁶⁰ *Id.* at 427.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Vine St. Clinic*, 856 N.E.2d at 427.

¹⁶⁴ Medical Practice Act of 1987, 225 ILL. COMP. STAT. 60/22 (2005).

¹⁶⁵ *Id.* at (A)(14).

¹⁶⁶ *Vine St. Clinic*, 856 N.E.2d at 426, 434–35.

prohibiting fee-splitting.¹⁶⁷ The Illinois Supreme Court, however, while up-holding the prohibition on the percentage-based fee, ruled that the flat fee was permissible, noting that the flat fee charged by HealthLink was “not based or linked to revenue, gross receipts or billings collected.”¹⁶⁸ Rather, it was “based on the volume and complexity of the administrative services provided” and would not increase automatically if the revenue of the participating physicians increased.¹⁶⁹ Therefore, there was no fee-sharing that would violate the statute. This case is significant because the Illinois Supreme Court was called upon to address alleged violations of ethical and professional standards under state licensing laws. These violations, in turn, could well constitute improper payment under the Public Contracts Anti-Kickback Act or bribery under the Travel Act.

The *HealthLink* courts did not address, because the Illinois statute did not require them to, whether a kickback (under the Anti-Kickback Act) or a bribe (under state law applied through the Travel Act) by its very nature has some requirement of specific intent to obtain an unethical or improper advantage or to violate a specific statute. Many payments related to referral of business are prohibited by a state law or professional standards regardless of the payor or recipient’s intent as a prophylactic measure to protect the public reputation of a profession or to avoid creating incentives for inappropriate behavior. The Public Contracts Anti-Kickback Act imposes civil liability for a penalty equal to the amount of the kickback even without intent or knowledge.¹⁷⁰ The Travel Act, however, is violated by interstate travel with the purpose of engaging in the specified unlawful activity,¹⁷¹ which sounds like a specific intent requirement.

In *Nursing Home Consultants v. Quantum Health Servs.*, the court was asked to determine the legality of a nursing home marketing agreement under the Medicare-Medicaid Anti-Kickback Statute.¹⁷² Nursing Home Consultants (NHC) was to be paid under the contract for identifying Medicare recipients who needed the medical supplies that Quantum provided.¹⁷³ NHC’s annual compensation “was to be determined on a per-item basis.”¹⁷⁴ Quantum defended on the ground that the contract was illegal.¹⁷⁵ The court held that it need not consider the intent of the parties. “[T]he subject matter of the [m]arketing [a]greement contrary to the public policy of the United States, as reflected in [the Anti-Kickback Statute]. As such, the Marketing Agreement itself is illegal, and hence unenforceable, irrespective of whether anyone can be prosecuted criminally (or civilly) in connection with that agreement.”¹⁷⁶ The court carefully parsed the language of a Safe Harbor regulation, 42 C.F.R. 1001.952(b), and decided that the agreement was not within it.¹⁷⁷ The court also rejected the argument that parties who enter into such

¹⁶⁷ *Id.* at 434.

¹⁶⁸ *Id.* at 435.

¹⁶⁹ *Id.*

¹⁷⁰ 41 U.S.C. § 55(a)(2) & Revision Notes (2000).

¹⁷¹ 18 U.S.C. § 1952(a), (b)(i)(2) (2000 & Supp. II 2002).

¹⁷² *Nursing Home Consultants v. Quantum Health Servs.*, 926 F. Supp. 835, 841 (E.D. Ark. 1996).

¹⁷³ *Id.* at 839.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 841.

¹⁷⁶ *Id.* at 843 n.18.

¹⁷⁷ *Nursing Home Consultants*, 926 F. Supp. at 844.

agreements should be able to recover on an equitable theory: If people knew that they could enforce these illegal agreements utilizing such a theory, “what would deter them from entering into such arrangements in the first place? This case seems to graphically illustrate that, outside the rather unlikely possibility of some criminal or civil prosecution the answer to this question is probably nothing.”¹⁷⁸

In *Zimmer, Inc. v. NuTech Medical*, Zimmer sought and obtained a declaratory judgment that its distribution agreement with NuTech, which gave NuTech a percentage of sales in exchange for distributing and billing Zimmer’s products, was “illegal and unenforceable.”¹⁷⁹ NuTech placed Zimmer products in physicians’ offices on consignment.¹⁸⁰ Section XI of the agreement provided that Zimmer was to pay NuTech \$100,000 for “100 days of consulting services” to train the Zimmer sales force on NuTech’s sales process and on reimbursement issues, with \$60,000 to be paid within thirty days of signing the agreement.¹⁸¹ Zimmer failed to pay the \$60,000, and when NuTech demanded the payment, Zimmer submitted a request for an OIG advisory opinion about the contract and filed the complaint.¹⁸² The advisory opinion declined to provide immunity for the transaction and pointed out a number of problems with the transaction.¹⁸³ Relying on the advisory opinion, the court held that the agreement was illegal and could not be enforced.¹⁸⁴

There are several difficulties for a transactional attorney reviewing a variety of proposed arrangements or providing advice. First, where should the attorney look for guidance on “improper payments” or “bribery” under state and federal law—if conduct is outside of a Safe Harbor, is the transaction avoidable at the desire of one of the parties? Second, how can the attorney anticipate potentially violative activities that will occur after the operating documents have been created? Third, what kind of risks exist for an attorney or a law firm in negotiating or drafting a contract for a client which is later attacked by one of the parties as a violation of the Anti-Kickback Act?

The University of Pennsylvania’s (Penn) experience with the painful and unnecessary death of research participant Jesse Gelsinger in 1999 at its Institute of Gene Therapy is an excellent example of the risks for transactional attorneys and the complex legal issues involved in these contracts.¹⁸⁵ Penn’s Institutional Review Board (IRB), which reviews and maintains oversight over the institution’s studies, and the Recombinant DNA Advisory Committee (RAC), a part of the National Institutes of Health Office of Biotechnology Activities, were charged with public oversight of gene therapy trials and had both approved a specific Phase I research protocol for an evaluation of gene therapy

¹⁷⁸ *Id.* at 847.

¹⁷⁹ *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 854, 864 (N.D. Ind. 1999).

¹⁸⁰ *Id.* at 856.

¹⁸¹ *Id.* at 852.

¹⁸² *Id.* at 852–53.

¹⁸³ *Id.* at 855–56.

¹⁸⁴ *Zimmer, Inc.*, 54 F. Supp. 2d at 864.

¹⁸⁵ JERRY MENIKOFF & EDWARD P. RICHARDS, *WHAT THE DOCTOR DIDN’T SAY: THE HIDDEN TRUTH ABOUT MEDICAL RESEARCH* 222–35 (Oxford University Press 2006).

in the treatment of a genetic disorder which prevented the elimination of ammonia.¹⁸⁶ Dr. James Wilson, the principal investigator, was also the founder of Genovo, Inc., which had the rights to the gene therapy being tested.¹⁸⁷ If the research involving Jesse Gelsinger was successful, Dr. Wilson was poised to earn millions from the increase in the value of Genovo's stock.¹⁸⁸

Wilson and his colleagues obtained approval from Penn's IRB for his disclosure forms for research participants and for the research protocol and safeguards.¹⁸⁹ It was later alleged that Wilson had not made full disclosure to the IRB, Penn, or Jesse Gelsinger of the full nature of his interests in the results of the study.¹⁹⁰ In addition, Wilson's team had approved Gelsinger's participation in the study even though he did not meet the study criteria and had ignored and not reported (as required by law and the protocol) several adverse events which had previously occurred in monkeys and human participants.¹⁹¹ Ultimately, among other consequences, Penn was required to pay \$517,496 to the government to resolve civil fraud claims involving allegations of false statements and false claims; Dr. Wilson and other investigators were restricted in their clinical research activities.¹⁹² The point to be made here is that those drafting agreements between principal investigators and companies in which they have an ownership or royalty interest need to be aware of the conflict of interest limitations imposed upon them by various federal requirements as well as by the terms of approval by IRBs and other institutional committees which may serve as rules governing the legality of contracts.

F. Limitations on Innovative Healthcare Fraud Theories: State v. Harden

Certainly, there are some limits to the use of these state laws to bring kickback claims. *State v. Harden* illustrates one such restriction.¹⁹³ Florida charged Harden with Medicaid fraud and several other offenses, alleging that he violated the anti-kick-back provision of Florida's Medicaid Provider Fraud Statute¹⁹⁴ by paying drivers (who were "employed by or associated with" entities that provided dental services to children) unlawful cash commissions, on a per child basis, for the "solicitation and transportation" of Medicaid

¹⁸⁶ See INSTITUTE OF MEDICINE (IOM), PRESERVING PUBLIC TRUST: ACCREDITATION AND HUMAN RESEARCH PARTICIPANT PROTECTION PROGRAMS 58 (National Academy Press 2001); Susan Jenks, Gene Therapy Death—"Everyone Has to Share in the Guilt," 92 J NAT'L CANCER INST. 98 (2000); Press Release, U.S. Attorney for the E. Dist. of Pa., U.S. Dep't of Justice, U.S. Settles Case of *Gene Therapy Study that Ended with Teen's Death* (Feb. 9, 2005) [hereinafter Press Release, DOJ], available at <http://66.98.181.12/newsources/uofp.pdf> (last visited Apr. 29, 2007).

¹⁸⁷ Scott Hensley, *Targeted Genetics' Genovo Deal Leads to Windfall for Researcher*, WALL ST. J., Aug. 10, 2000, at B12.

¹⁸⁸ *Id.*; Deborah Nelson & Rick Weiss, *Penn Researchers Sued in Gene Therapy Death: Teen's Parents Also Name Ethicist as Defendant*, WASH. POST, Sept. 19, 2000, at A3.

¹⁸⁹ See IOM, *supra* note 186, at 58 & n.12.

¹⁹⁰ Ben Gose, *U. of Pennsylvania, Doctors, and Ethicist Are Named in Lawsuit Over Gene-Therapy Death*, CHRON. HIGHER EDUC., Sept. 29, 2000, at A34; Rick Weiss & Deborah Nelson, *Methods Faulted in Gene Test Death; Teen too Ill for Therapy, Probe Finds*, WASH. POST, Dec. 8, 1999, at A1.

¹⁹¹ MENIKOFF & RICHARDS, *supra* note 185, at 222–235; see also Weiss & Nelson, *supra* note 190.

¹⁹² Press Release, DOJ, *supra* note 186.

¹⁹³ *State v. Harden*, 873 So. 2d 352 (Fla. Dist. Ct. App. 2004).

¹⁹⁴ FLA. STAT. § 409.920 (2004) (held unconstitutional by *Harden*, 873 So. 2d 352).

eligible children to the facilities.¹⁹⁵ Harden argued that “payment of wages by a Medicaid provider to its employees” for the activities described above was not an unlawful kickback for patient referrals, but “was expressly protected by federal Medicaid statutes and regulations . . . and that the State’s attempt to criminally prosecute this federally protected activity was unconstitutional under the Supremacy Clause.”¹⁹⁶

The appellate court deciding the case noted that “[i]mplied conflict preemption’ occurs when (a) compliance with both federal and state regulations is a physical impossibility, or (b) when a state law is an obstacle to execution and accomplishment of the objectives and purpose” of a federal law.¹⁹⁷ The court found two significant differences between the federal¹⁹⁸ and Florida anti-kickback statutes.¹⁹⁹ First, the federal statute contains a Safe Harbor provision that excludes from the definition of “illegal remuneration” employer-employee payments for the provision of covered items or services.²⁰⁰ Second, “federal [M]edicaid statutes require participating states to provide transportation to those eligible for dental services.”²⁰¹ Thus, the Florida law is without any Safe Harbor provisions and criminalizes activity that the Federal Anti-Kickback Statute protects.²⁰² Additionally, the Federal Anti-Kickback Statute includes a “knowing and willful” *mensrea* requirement, which means that one must have acted with knowledge that the conduct was unlawful.²⁰³ The Florida law only requires that one act “knowingly,” which means a person was aware or should have been aware that his or her conduct was substantially certain to cause the intended result.²⁰⁴ The Florida definition of “knowingly,” which includes “mere negligence,” said the court, criminalizes activity that the Federal Anti-Kick-back Statute intends to protect.²⁰⁵ Consequently, the court held that there was implied conflict preemption and declared the Florida anti-kickback statute unconstitutional.²⁰⁶

III. Attorney Liability for Client Violations of Kickback Laws

Although kickback arrangements can be difficult for attorneys to discover, lawyers who fail to adequately investigate and understand clients’ improper arrangements can be liable to injured third parties, as seen in *Dean Foods Co. v. Pappathanasi*,²⁰⁷ another case outside the healthcare context but nonetheless quite relevant to parallel situations within

¹⁹⁵ Harden, 873 So. 2d at 353.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 354.

¹⁹⁸ See 42 U.S.C. § 1320a-7b(b) (2000 & Supp. III 2003).

¹⁹⁹ Harden, 873 So. 2d at 355.

²⁰⁰ See 42 U.S.C. § 1320a-7b(b)(3)(B).

²⁰¹ Harden, 873 So. 2d at 355; see 42 U.S.C. § 1396a(a)(70).

²⁰² Harden, 873 So. 2d at 355.

²⁰³ *Id.*

²⁰⁴ *Id.*; FLA. STAT. § 409.920(2)(e) (2004) (held unconstitutional by Harden, 873 So. 2d 352); see *State v. Wolland*, 902 So. 2d 278, 281 (Fla. Dist. Ct. App. 2005) (discussing the standard used in *Harden* and holding that “subsection 409.920(2)(a) does not stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as delineated in 42 U.S.C. § 1320a-7b(a)(1)”).

²⁰⁵ Harden, 873 So. 2d at 355.

²⁰⁶ *Id.*

²⁰⁷ *Dean Foods Co. v. Pappathanasi*, No. Civ.A. 01-2595 BLS, 2004 WL 3019442 (Mass. Sup. Ct. Dec. 3, 2004).

the industry. West Lynn Creamery (WLC) received a federal grand jury subpoena in October 1997 regarding payments or rebates it had made to certain donut retailers to whom it had been selling milk products and retained the law firm of Rubin and Rudman to represent it.²⁰⁸ It was unclear at that time whether WLC was a subject, target, or witness.²⁰⁹ Mr. Michael Altman, a litigation lawyer at the firm, investigated a “rebate program” that WLC operated with its customers.²¹⁰ WLC appeared to have offered its customers loans from the credit union it operated.²¹¹ Customers then ordered from WLC specified amounts of products.²¹² WLC paid back to customers, in the form of monthly checks or cash payments, the difference between the amount invoiced and the actual price of products delivered.²¹³ The customers used this rebate money to pay off the loans.²¹⁴ From the Internal Revenue Service’s view-point, the effect of this scheme was to illegally inflate costs of the raw materials purchased by the donut company, thus reducing its net income and corporate tax liability.²¹⁵ The rebate was, in essence, an illegal kickback.

In June 1998, Suiza Foods (later known as Dean Foods) purchased SBHI, the holding company that owned all shares of WLC.²¹⁶ WLC’s law firm, and Altman in particular, represented SBHI in the sale.²¹⁷ The stock purchase agreement included language indicating that to SBHI’s knowledge there was no litigation pending or threatened.²¹⁸ The agreement also required SBHI to deliver an opinion letter of its counsel to a similar effect.²¹⁹ The question of whether the legal problem should have been noted in the stock purchase agreement initially had been raised in a discussion between Altman and Gene Barton, the corporate lawyer at Rubin and Rudman in charge of the stock transaction.²²⁰ Altman indicated that it was his “guesstimate” that the tax evasion matter had “gone away,” given that he had not heard from the U.S. Attorney’s office in almost six months.²²¹ Nonetheless, firm lawyers advised one of the sellers that “it would be wise to include” the grand jury/rebate investigation of which they were aware in the representations made in the stock purchase agreement.²²² But the seller, who was at the meeting, indicated that such a disclosure would “incite family members [minority shareholders] . . . to interfere with the sale,” and consequently he did not want the matter disclosed, and ultimately it was not.²²³ The law firm’s opinion letter likewise included a

²⁰⁸ *Id.* at *1–2.

²⁰⁹ *Id.* at *9.

²¹⁰ *Id.* at *2–6.

²¹¹ *Id.* at *3.

²¹² *See* Dean Foods Co., 2004 WL 3019442 at *3–4.

²¹³ *Id.*

²¹⁴ *Id.* at *3–4.

²¹⁵ *See id.* at *16.

²¹⁶ *Id.* at *6.

²¹⁷ Dean Foods Co., 2004 WL 3019442 at *6.

²¹⁸ *Id.* at *6–7.

²¹⁹ *Id.* at *7–8.

²²⁰ *Id.* at *8.

²²¹ *Id.* At trial, the court accepted expert testimony to the effect that “it was not within the standard of care for a white-collar criminal defense lawyer to conclude as early as June of 1998 that the investigation had gone away.” Dean Foods Co., 2004 WL 3019442 at *16.

²²² *Id.* at *8.

²²³ *Id.*

representation that “nothing has come to our attention which causes us to doubt the accuracy” of the factual matters contained in the purchase agreement.²²⁴

A few months thereafter, in September 1998, WLC became the target of a federal grand jury investigation.²²⁵ It pled guilty in March 2001 to conspiracy to defraud the government and paid a \$7.2 million fine.²²⁶

Dean Foods brought negligence actions against Rubin and Rudman and the selling WLC shareholders, but the claim against the shareholders was resolved by the time of trial.²²⁷ The case proceeded against the law firm and the key concern at trial was “the rendering of an opinion or report by a law firm to an entity that is not its client.”²²⁸ The court concluded that third parties are entitled to rely on opinion letters, which must conform to customary practice including “customary diligence,” and may not be misleading.²²⁹ The court rejected Rubin and Rudman’s expert’s argument, that “trial lawyers are unable to comprehend the elegant nuances of corporate opinion letters or that matters relating to grand jury subpoenas are too ‘arcane’ for corporate lawyers to be expected to divine.”²³⁰ Rather, the court concluded that the law firm’s difficulty lay in “a significant breakdown in the careful process established at [the firm] regarding opinion letters.”²³¹ It noted that one of the firm’s attorneys could easily have called the attorney representing the donut company, with whom the litigation attorney previously had contact on the matter, and learned that the rebate investigation was still ongoing and that, in March 1998, the donut company’s owners had entered into a plea agreement under which they would cooperate fully with the ongoing rebate investigation.²³² The court found that the law firm failed to conform to customary practice,²³³ adding that an opinion preparer (Barton) cannot avoid his or her obligations by blindly adopting the report of a fellow attorney’s (Altman) handling of a criminal matter, particularly when, as here, the “fellow attorney does not even know that he is providing [information] for an opinion letter.”²³⁴ The court noted that the obligation in drafting an opinion letter is to think “not only about the opinion itself but also about areas excluded from the opinion.”²³⁵ As a result, the law firm was liable for \$7.2 million plus attorney fees.²³⁶

The significance of *Dean Foods Co. v. Pappathanasi* is the court’s expectation that attorneys who handle investigations and attorneys who structure transactions within law firms must accept the obligation to communicate about kickback issues. The investigation

²²⁴ *Id.* at *7.

²²⁵ *Id.* at *10.

²²⁶ Dean Foods Co., 2004 WL 3019442 at *10.

²²⁷ See *id.* at *1.

²²⁸ *Id.* at *11.

²²⁹ *Id.* at *12, 13.

²³⁰ *Id.* at *17 n.9.

²³¹ Dean Foods Co., 2004 WL 3019442 at *17.

²³² *Id.*

²³³ *Id.* at *19.

²³⁴ *Id.* at *18.

²³⁵ *Id.* at *18 (quoting Third-Party “Closing Opinions:” A report of the TriBar Opinion Committee, 53 BUS. LAW 591, 602 (1998) (emphasis added)).

²³⁶ Dean Foods Co., 2004 WL 301944 at *20.

in which WLC became ensnared focused initially not on the payor but on the recipients, who were collecting rebates and not reporting them on their income tax returns. Thus, at first, this arguably was not a kickback case. It became a kickback case when the recipient pled guilty, cooperated with prosecutors, and gave information on how the scheme worked. The attorney responsible for the sale of SBHI shares to Suiza Foods was not aware of criminal defense activity in his firm. Kickback cases lend themselves to this kind of breakdown because every kickback case has a payor and recipient. Prosecutors often choose which to target based on which party they are able to convince to cooperate. It is very difficult for a defense attorney to predict whether his client will be a witness or a target in this kind of investigation. It is also unclear how much information obtained in planning a criminal defense a litigator ought to provide to corporate attorneys drafting opinion letters for third parties.

The role of attorney-client privilege is also significant in *Dean Foods Co. v. Pappathanasi*. The court presumably had access to all the law firm's internal documents because the privilege was waived, allowing the court to read the files maintained by the attorney investigating WLC's rebate program.²³⁷ This case is a concern for any lawyer who handles both criminal defense and corporate transactions, but kickback cases present a particularly difficult problem for such lawyers because so often it is unclear if and when a transaction will be subject to criminal prosecution. Such situations present themselves frequently in healthcare because so many entities are likely to receive grand jury subpoenas. Attorney liability for clients' kickback arrangements arises not just in sale of milk to donut shops, but also in the sale of physicians' practices, transactions between hospitals, and contracts with pharmaceutical companies.

IV. The Focus of Enforcement Actions in the Future Under Medicare Part D

Medicare Part D²³⁸ brings a new category of payments and financial relationships into the Medicare system, raising substantial fraud and abuse concerns. Some Medicare beneficiaries are a vulnerable, high-cost population over whom healthcare providers exercise a great deal of control. Nursing home residents, Alzheimer's and psychiatric patients, end-stage renal disease patients on kidney dialysis, and other chronic disease patients receiving custodial or frequent ambulatory treatment often fall into this category. Some of their healthcare providers may be tempted to engage in the type of conduct for which PharMerica was prosecuted. Such conduct includes network charges and state pharmacy fee-splitting; payments related to patient access or product selection in nursing homes, life care centers, and senior living facilities; and contracts involving purchase of facilities or other assets involving patient access. These potentially improper relationships will be closely scrutinized by prosecutors and lawyers representing both whistleblowers and healthcare entities.

²³⁷ *Id.* at *2.

²³⁸ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071 (2003) (codified as amended in scattered sections of 42 U.S.C.).

There are a number of enforcement mechanisms available to prosecutors. The False Claims Act,²³⁹ with its criminal and civil penalties, will play a major role, as qui tam relators expose improper transactions. The Public Contracts Anti-Kickback Act²⁴⁰ also includes criminal and civil penalties. False statements, such as those made on certifications to government payors, can be criminally prosecuted.²⁴¹ The government can also prosecute²⁴² and enjoin²⁴³ healthcare fraud and it can pursue civil monetary penalties²⁴⁴ and program exclusion.²⁴⁵ States also have laws to prosecute healthcare fraud. Unfair trade practices can involve kickback issues. Violations of professional licensure statutes, regulations, and ethical codes may be viewed as kickbacks or improper payments. Commercial bribery laws may apply, as well as insurance fraud statutes. Finally, some states have false claims acts of their own.

V. Conclusion

When anti-kickback legal theories were originally devised, healthcare was dominated by independent physicians who exercised a great deal of discretion over patient care. Therefore, anti-kickback actions focused on relationships between doctors and suppliers of medical devices and other services. Today, large institutions are ascendant and they bring with them business transactions that are vastly more complex. Prosecutors have begun to develop new theories to capture these arrangements, especially those that involve payors and intermediaries. They have looked for new ways to impose administrative sanctions and implicate the False Claims Act, the Travel Act, and the Public Contracts Anti-Kickback Act. The key often has been the interpretation of an alleged violation of a state bribery, insurance, or professional licensure law as a kickback or improper payment under federal law. Failure to recognize that these fresh theories could be used to impose criminal and civil sanctions not only may create liability for the client, but also could lead to attorney liability to injured third parties for client malfeasance. Understanding where these prosecutorial trends are heading will help attorneys handle today's healthcare litigation and business transactions.

²³⁹ 31 U.S.C. §§ 3729–3733 (2000).

²⁴⁰ 41 U.S.C. §§ 51–58 (2000).

²⁴¹ *See* 18 U.S.C. § 1001 (2000 & Supp. II 2002).

²⁴² *See id.* § 1035.

²⁴³ *See id.* § 1345.

²⁴⁴ *See* 42 U.S.C. § 1320a-7a(a)(7) (2000).

²⁴⁵ *See id.* § 1320a-7 (2000 & Supp. III 2003).