

**Tainted Prosecutiou of Tainted Claims: The
Law, Economics, and Ethics of Fighting
Medical Fraud Under the Civil
False Claims Act**

DAYNA BOWEN MATTHEW*

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* Assistant Professor of Law, University of Kentucky College of Law; J.D., 1987, University of Virginia; B.A., 1981, Harvard-Radcliffe College. My sincere thanks to Pamela H. Bucy, Rutherford B. Campbell, Jr., Chris W. Frost, Joan Kraus, Frances H. Miller, Paul E. Salamanca, John M. Rogers, and Sarah N. Welling for their thoughtful comments on earlier drafts. I also thank Samuel Brown, Ph.D., for his helpful suggestions, and Scott Richardson and Holly Turner for their able research assistance.

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I. INTRODUCTION

In politics, a “hot” issue is one that gets voters excited, candidates elected, and politicians visibility. Typically, these issues address legitimate problems that resonate across a broad cross section of the population. These issues are all the more beloved by politicians if they reap not only political but tangible financial benefits for those devotees acting (on principal, of course) to advance a popular cause or address a pressing problem. The effort to quash Medicare and Medicaid fraud is such a “hot” issue. At bottom, the billions of dollars wasted to pay fraudulent medical claims is a legitimate and quantifiable problem.¹ Moreover, this problem cuts broadly as every American faces the very real question of how to control health care costs.² However, this Article questions the economic and ethical wisdom of one of the “hottest” legal weapons in the fight against medical fraud: tainted-claims prosecutions under the Federal Civil False Claims Act the (“FCA”).³

1. “According to the General Accounting Office (GAO), as much as 10 percent of total health care costs are lost to fraudulent or abusive practices by unscrupulous health care providers.” H.R. REP. NO. 104-496, at 69 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1869.

2. The original impetus for the antifraud bills was the well-documented proliferation of illegitimate medical financing practices such as “ping-ponging” and “ganging” (medically unnecessary physician referrals prevalent in urban Medicaid mills); “steering” (directing patients to related pharmacy or laboratory facilities, ignoring freedom of choice) and “upgrading” (increasing billing above services actually provided). *See* H.R. REP. NO. 95-393, at 45 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047-48.

3. 31 U.S.C. § 3729 (1994). The FCA provides in pertinent part as follows:

(a) Liability for Certain Acts. Any person who

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

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

....

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than

Traditional FCA claims require the plaintiff to prove that the defendant knowingly submitted or caused to be submitted, a false or fraudulent request for payment to the government. "Tainted claims," however, are requests for payment submitted to the government which, though neither false nor fraudulent in themselves, are nevertheless actionable under the FCA because the defendant requested payment from the government while allegedly in violation of a separate regulation, statute, or law. In the health care context, plaintiffs and prosecutors using the tainted-claims approach can impose liability on health care providers even if their Medicare or Medicaid request for payment was true, accurate, reasonable, and arose from the provision of competent, medically necessary care. FCA liability in these cases turns merely on the "taint" of the underlying violation, not on proof that the defendant violated the terms of the FCA.

This Article focuses specifically on tainted-claims cases based on alleged violations of three medical antifraud statutes: the criminal section of the Medicaid and Medicare Antifraud Act,⁴ or the Stark I⁵ and II⁶ bans against physician self-referrals.⁷ This Article argues that using the FCA to avoid the criminal, civil, and administrative requirements of these statutes raises five important problems.

First, the tainted-claims approach to antifraud enforcement permits plaintiffs and government prosecutors to effectively replace existing bodies of state common law,

\$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

Id. § 3729(a).

Note, however, that the civil penalties under this section have been increased to not less than \$5500 and not more than \$11,000 by regulation under the Debt Collection Improvement Act of 1996. *See* 28 C.F.R. § 85.3(a)(9) (2000).

4. Throughout this Article the "Medicare and Medicaid Antifraud Act" refers collectively to both the criminal and civil provisions of the Social Security Act that address medical fraud. In fact, the criminal and civil laws are two separate statutes. The criminal anti-kickback provisions were originally enacted in 1972. Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1329, 1419-20 (codified as amended at 42 U.S.C. § 1320a-7b (1994)). Hereinafter, this criminal section of the antifraud law will be referred to as the anti-kickback act, law, or statute. The civil section of the Medicare and Medicaid Antifraud Act was enacted as part of the Medicaid Program and Patient Protection Act of 1987, Pub. L. No. 100-93, § 3, 101 Stat. 680, 686 (codified as amended at 42 U.S.C. § 1320a-7a (1994)); this section is also called the Civil Monetary Penalties Law. Hereinafter, the civil section of the Medicare and Medicaid Antifraud Act will be referred to as the "CMPL" or by its full name.

5. Enacted as part of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (codified as amended in scattered sections of 42 U.S.C.). *See infra* Part III.A.2.

6. Enacted as part of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (codified as amended in scattered sections of 42 U.S.C.). *See infra* Part III.A.2.

7. 42 U.S.C. § 1395nn (1994 & Supp. IV 1998), amended by Act of Nov. 29, 1999, 42 U.S.C.S. § 1395nn (Law. Co-op. Supp. 2000). Together, these two self-referral statutes are popularly called the "Stark Law," named after the representative who sponsored the bills, California Representative Fortney Pete Stark. In the Article, however, for clarity the Stark Law is called by the term describing its function: "self-referral law." Therefore, hereinafter the terms "Stark Law" and "self-referral law" will be used interchangeably.

regulations, and statutes, as well as existing federal statutes, with a body of federal common law based on the FCA. Second, the tainted claims cases extend the scope of the FCA far beyond what Congress intended, and abandon the detailed statutory approach to controlling medical fraud that Congress designed under the anti-kickback and self-referral laws. Third, by presuming that all referral fee arrangements give rise to "inappropriate" financial considerations, the tainted-claims approach imposes costly penalties on an overly broad range of commercial activity resulting in the loss of productive economic activity due to overdeterrence. Fourth, by allowing antifraud enforcement to proceed under the FCA, the tainted-claims approach creates a private cause of action where Congress has not. Perhaps the most troubling problem of all, however, is the extent to which financial self-interest appears to influence *both* private qui tam⁸ plaintiffs and public prosecutors proceeding in tainted-claims actions under the FCA.

Private plaintiffs are attracted to the FCA to challenge medical fraud because the qui tam provision of the FCA rewards private parties who bring an action on behalf of the government with up to a thirty percent share of the damages, penalties, or settlement proceeds recovered from defendants.⁹ In medical fraud cases, the plaintiff's share of the potential recoveries represents a virtual lottery jackpot since trebled penalties and damages accrue for each allegedly tainted patient bill submitted to the government. Similarly, the government prefers to prosecute medical fraud under the FCA because public prosecutors, like private qui tam plaintiffs, are rewarded by being able to use their share in the proceeds from antifraud cases in future enforcement efforts.¹⁰ Unlike private prosecutors, public prosecutors do not

8. "Qui tam" is short for a Latin phrase given to private causes of action brought on behalf of the government. The phrase in its entirety is "qui tam pro domino rege quam se ipso in hac parte sequitur," which roughly translated means "he who brings action for the king as well as for himself." BLACK'S LAW DICTIONARY 1262 (7th ed. 1999).

9. 31 U.S.C. § 3730 (1994). The FCA sets forth a private civil cause of action, which provides in pertinent part:

(b) Actions by Private Persons. (1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

....

(d) Award to Qui Tam Plaintiff. (1) If the Government proceeds with an action brought by a person under subsection (b), such person shall . . . receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds.

Id.

10. In 1996, Congress created a Health Care Fraud and Abuse Control Account ("Control Account") that government officials can use to finance their future antifraud enforcement

reap personal financial gain from their enforcement activities. Rather, each enforcement agency¹¹ reaps financial benefits both to the extent that the agency's deposits are recognized for its enforcement accomplishments, and because the funds agencies collect through enforcement are ultimately the source of appropriations used to finance future antifraud enforcement.¹² This Article takes the position that both public and private prosecutors have an unethical financial interest in prosecuting¹³ medical fraud and this self-interest best explains the reason tainted-claims actions continue to expand despite the substantive, economic, and policy problems with the underlying doctrine.

This Article sounds a serious note of caution. The anti-kickback and self-referral laws are intended to control the dangers of allowing financial self-interest to distort health care providers' medical judgment.¹⁴ Ironically, the tainted-claims cases present similar dangers because the financial incentives motivating public and private

activities. *See* 42 U.S.C. § 1395i(k)(3)(C) (Supp. IV 1998). The Control Account is funded each year by the penalties, damages, and settlement proceeds collected from defendants in antifraud cases. *Id.* § 1395i(k)(2)(C); *see also infra* Part VI. Under § 1395i(k)(2)(A)(iii), these collections are paid into the Federal Hospital Insurance Trust Fund ("Trust Fund"). Then, under § 1395i(k)(3), these collections paid into the Trust Fund are appropriated to the Control Account.

11. Primary enforcement authority for the anti-kickback and self-referral statutes rests with the Office of Inspector General, the Department of Health and Human Services, and the Federal Bureau of Investigation. Also, virtually all the Offices of U.S. Attorneys have established health care fraud units as well. For a complete listing and summary of state and federal enforcement agencies with jurisdiction over Medicare and Medicaid antifraud efforts, see PAMELA H. BUCY ET AL., *HEALTH CARE FRAUD: CRIMINAL, CIVIL, AND ADMINISTRATIVE LAW* § 1.05 (4th release 1999).

12. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS. & U.S. DEP'T OF JUSTICE, *HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 1999* (2000), <http://www.usdoj.gov/dag/pubdoc/hipaa99ar21.htm> (last visited Apr. 5, 2001) [hereinafter 1999 FRAUD ANNUAL REPORT]. The report places a table and information regarding Department of Health and Human Services and Department of Justice deposits into the Trust Fund. This information is immediately followed by a table and summary of the amounts appropriated to each enforcement organization in 1999.

13. Throughout this Article, private *qui tam* plaintiffs are referred to as "private prosecutors" who "prosecute" fraud. This is because when these private litigants bring tainted-claims cases based upon criminal anti-kickback violations, they stand in the same position as government prosecutors seeking conviction under the underlying criminal statute.

14. *Physician Financial Relationship with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements*, 60 Fed. Reg. 41,914, 41,923 (Aug. 14, 1995) (codified at 42 C.F.R. pt. 411).

We believe that [the Stark Law] was enacted out of concern over the findings of various studies that physicians who have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least 10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.

Id.

prosecutors in these cases are much like "kickbacks" that threaten to distort prosecutorial discretion and ultimately the quality of the medical antifraud effort overall. This Article concludes that the solution to this problem requires Congress to return control of medical antifraud enforcement to expert government prosecutors who have no financial interest in their cases but instead are motivated solely by their obligation to the public to fight medical fraud.

The Article begins by exploring the puzzling body of federal common law that has evolved in the tainted-claims cases. Part I explores the increasingly aggressive theories that public and private prosecutors have developed in order to use the FCA to prosecute this new category of allegedly fraudulent activity. Part II explores the structure and legislative histories of the anti-kickback and self-referral statutes to conclude that the common-law tainted-claims approach departs from Congress's intent. Part III of the Article uses a microeconomic model to explain theoretical misunderstandings that underlie the tainted-claims approach. Part IV examines the effects of using financial incentives to motivate public and private prosecutors to use the FCA to prosecute medical providers involved with illegal kickbacks and self-referral fees. This Part analyzes empirical trends in the antifraud effort. Then, applying public-choice theory, it concludes that the tainted-claims approach most benefits the legislators and prosecutors who have advocated broad use of the FCA, but does not serve the public good. Finally, Part V of the Article concludes that enforcement authority over the anti-kickback and self-referral laws should remain solely with financially disinterested government prosecutors and the administrative bodies originally designated by Congress to administer these laws. This important antifraud effort should not be left to ad hoc common-law enforcement by financially interested public and private prosecutors proceeding under the FCA.

II. TAINTED CLAIMS AND THE COURTS: FALSE CLAIMS ACT PROSECUTIONS OF KICKBACK AND SELF-REFERRAL FRAUD

FCA prosecutions of anti-kickback and self-referral claims have superseded both the substantive requirements of the common law of fraud, and the substantive and procedural requirements of the Medicare and Medicaid antifraud statutes themselves.¹⁵ The elements of common-law fraud vary from one jurisdiction to the next. Generally, however, a prima facie case in any jurisdiction requires the plaintiff to show the defendant made a material misrepresentation, which the plaintiff relied upon to his detriment.¹⁶ Congress enacted the anti-kickback and self-referral prohibitions to prosecute fraud in health care, assuming a substantially similar definition of fraud.¹⁷ The tainted-claims approach to medical fraud, however,

15. For arguments that the FCA conflicts with underlying anti-kickback and self-referral laws, see Robert Salcido, *Mixing Oil and Water: The Government's Mistaken Use of the Medicare Anti-kickback Statute in False Claims Act Prosecutions*, 6 ANNALS HEALTH L. 105 (1997).

16. See 37 AM. JUR. 2D *Fraud and Deceit* § 12 (1968); see also RESTATEMENT (SECOND) OF TORTS § 525 (1977).

17. H.R. REP. NO. 95-393, pt. 2, at 48 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3050 ("H.R. 3 is designed to strengthen the ability of the Federal and State governments to find and correct abuse and to detect and prosecute fraud. Fraud involves an intentional deception or

circumvents both these bodies of common and legislative law. Medicare and Medicaid fraud prosecuted under the FCA requires neither a showing of materiality¹⁸ nor of any detriment or injury to the government in order to make out a prima facie case.¹⁹ Moreover, a plaintiff may state a colorable FCA claim where the defendant is guilty of a regulatory violation that involves no affirmative misrepresentation and upon which the government placed no reliance in making its decision to pay the claims alleged to be "false or fraudulent" under the Act.²⁰

Tainted claims prosecutions under the FCA are also distinguishable from cases prosecuting similar fraudulent conduct directly under the antifraud statutes themselves. Under the anti-kickback statutes, fraud prosecutors must show a mens rea of *knowing* participation in an illegal arrangement to exchange referrals for remuneration.²¹ To prove a felony under the anti-kickback law, prosecutors must show a violation occurred beyond a reasonable doubt. Even under the Civil Monetary Penalties Law,²² entities with which a physician has a prohibited financial relationship may be held liable only if prosecutors can show a *knowing* violation of the statutes.²³ In contrast, prosecutors proceeding under the FCA may satisfy the mens rea element of that statute merely by showing the defendant acted in "reckless disregard" or with "deliberate indifference" to the truth or falsity of the claim submitted.²⁴ Proof under the FCA need only be made by a preponderance of the evidence instead of by the higher criminal standard of proof of the anti-kickback law. Although plaintiffs in a tainted-claims action must prove the underlying statutory violation in order to sustain this derivative claim, using the FCA allows plaintiffs to bypass the administrative and criminal proceedings in favor of obtaining a civil tribunal's consideration of the underlying charge. There is no procedural or other mechanism requiring that the civil courts resolve these claims as the administrative law or criminal tribunals would have.

misrepresentation with the intent of receiving some unauthorized benefit for the individual engaged in fraud."); Physician Financial Relationship with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Reporting Requirements, 60 Fed. Reg. at 41,924-25 (stating that the Stark Law was passed to curb overutilization).

18. The Fourth Circuit, however, requires false statements to be material to be actionable under the FCA. *United States ex rel. Berge v. Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1459 (4th Cir. 1997).

19. For cases holding that no injury to the government is required to prove an FCA action, see *United States ex rel. Schumer v. Hughes Aircraft Co.*, 63 F.3d 1512, 1525 (9th Cir. 1995); *United States v. Ridglea State Bank*, 357 F.2d 495, 497 (5th Cir. 1966); *Toepelman v. United States*, 263 F.2d 697, 699 (4th Cir. 1959); *United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1127 (E.D. Penn. 1991). *But cf. Young-Montenay, Inc. v. United States*, 15 F.3d 1040, 1043 (Fed. Cir. 1994) (holding that under the FCA the government must establish the fourth element that "United States suffered damages as a result of the false or fraudulent claim").

20. *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1508-13 (M.D. Tenn. 1996).

21. Douglas A. Blair, *The Knowingly and Willfully Continuum of the Anti-kickback Statute's Scienter Requirement: Its Origins, Complexities, and Most Recent Judicial Developments*, 8 ANNALS HEALTH L. 1, 6 (1999).

22. 42 U.S.C. § 1320a-7a (1994 & Supp. IV 1998).

23. *Id.* § 1320a-7a(a).

24. 31 U.S.C. § 3729(b)(2)-(b)(3) (1994).

Finally, while the *qui tam* provision of the FCA creates a private cause of action allowing plaintiffs to share in the proceeds of damages defendant providers pay, neither the anti-kickback nor self-referral laws permit private enforcement.²⁵

The FCA imposes civil liability on anyone who knowingly presents or causes to be presented a false or fraudulent claim for payment to the U.S. government,²⁶ and upon anyone who knowingly makes or causes false statements to be made in order to cause false or fraudulent claims to be paid by the government.²⁷ The cost of violating the FCA is substantial. Civil penalties range between \$5500 and \$11,000 per false claim filed, plus *treble* damages equal to three times the proven losses to the government. Under the *qui tam* provision of the FCA, a private party plaintiff, acting as a “relator” or “private prosecutor,” may bring a claim on behalf of the U.S. government.²⁸ For their effort, the FCA awards private prosecutors a share in the trebled penalties and damages recovered from the defendants, plus costs and reasonable attorney fees. Although it was enacted as a part of the original FCA statute in 1863, the *qui tam* provision became especially attractive in 1986 when Congress amended the statute to increase the relator’s share in proceeds from litigation to fifteen percent and thirty percent, depending upon whether the government chooses to intervene in the action, or allow the relator alone to pursue the claim to its conclusion.²⁹ Predictably, once Congress increased the relator’s share, the number of *qui tam* cases filed increased significantly.³⁰ And also predictably, the fastest growing area of *qui tam* litigation is in the prosecution of health care fraud.³¹ Quite literally, for private plaintiff-relators, the FCA is “where the money is.”³²

25. *W. Allis Mem’l Hosp., Inc. v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988). Legislative history shows Congress did not intend to create a private right of action. The government, not private parties, is charged with the enforcement of the Medicare program. *Id.*; *Donovan v. Rothman*, 106 F. Supp. 2d 513, 516 (S.D.N.Y. 2000) (stating that there is no private cause of action to redress Medicare anti-kickback violations).

26. 31 U.S.C. § 3729(a)(1).

27. *Id.* § 3729(a)(2).

28. *Id.* § 3730(c).

29. For a full discussion of the procedural requirements and history of *qui tam*, see Lisa M. Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003 (1998).

30. See Taxpayers Against Fraud, *Qui Tam Statistics*, at <http://www.taf.org/taf/docs/qtstats99.html> (last visited Mar. 7, 2001). In 1987, only twelve percent of *qui tam* cases involved the Department of Health and Human Services as the client agency. By fiscal year 1998, the percentage of *qui tam* cases involving health fraud had climbed to sixty-one percent. *Id.*, at <http://www.taf.org/taf/docs/qtstats99.html> (last visited Mar. 7, 2001).

31. See Press Release, U.S. Dep’t of Justice, Justice Department Recovers over \$3 Billion in Whistle-Blowers False Claims Act Awards and Settlements (Feb. 24, 2000) (“[A]lmost half the *qui tam* filings, and more than half of the *qui tam* recoveries, involve health care fraud.”), available at <http://www.usdoj.gov/opa/pr/2000/February/079civ.htm>; see also Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57, 58 (1999).

32. 141 CONG. REC. 17,014 (1995) (statement of Rep. Stark) (introducing the Health Care Anti-Fraud and Abuse Initiative of 1995). “When Willie Sutton was asked why he robbed banks, he responded: ‘Because that’s where the money is.’ Today’s criminals continue to be attracted to where the money is—in health care.” *Id.*; see also BUCY ET AL., *supra* note 11, §

However, the tainted-claims approach to health care fraud is attractive to plaintiffs for reasons even beyond the obvious financial incentives. Plaintiffs have no standing to sue directly under the anti-kickback and self-referral statutes. The tainted-claims theory allows private prosecutors to allege violations of this body of antifraud law indirectly through the FCA. Further, using the tainted-claims theory of liability, plaintiffs premise a prima facie case of FCA liability not on evidence that satisfies the elements of the FCA statute itself,³³ but rather on the fact that the defendant's claim for payment is tarnished by the fact that the provider violated a separate underlying federal statute. Under the tainted-claims theory, the plaintiff does not allege that the claim for payment itself is false or fraudulent, but rather the falsity or fraud is supplied by the "taint" of an entirely separate, underlying violation. U.S. district courts in the Fifth, Sixth, and Ninth Circuits have approved differing approaches to the tainted-claims theory of recovery. After the theory first gained judicial acceptance in 1994, courts in Maryland,³⁴ Louisiana,³⁵ Massachusetts,³⁶ Pennsylvania,³⁷ and most recently Missouri³⁸ have also considered this approach. Certainly, private and public prosecutors alike are seeking to expand the tainted-claims approach.

This Part first reviews cases that have approved the tainted-claims arguments advanced by prosecutors to outline the parameters of the doctrine. Then, it summarizes the tainted-claims arguments presented in court that have failed to explore the limits of the doctrine. The cases reveal that private plaintiffs have led the way in advancing the tainted-claims theory, but the government has also joined the effort to extend the FCA's reach under this theory. The theories these prosecutors have advanced not only seek to federalize formerly state common-law actions but also to judicially replace the antifraud statutes Congress enacted with new federal rules. Part I concludes that the greatest danger of defining the tainted-claims approach in this case-by-case manner is that the doctrine's future application is unpredictable.

1.01[1].

33. While jurisdictions differ slightly in their formulations of a prima facie case under the FCA, it is generally agreed that a plaintiff must show that a defendant knowingly filed a false claim or statement for payment with the U.S. government. *See* 31 U.S.C. § 3729 (1994).

34. *United States ex rel. Joslin v. Cmty. Home Health, Inc.*, 984 F. Supp. 374, 383-84 (D. Md. 1997); *see also infra* notes 91-102 and accompanying text.

35. *United States ex rel. St. Lacorte v. Smithkline Beecham Clinical Labs., Inc.*, No. CIV.A.96-1380, 1999 WL 639683 (E.D. La. Aug. 19, 1999) (granting plaintiff's motion to amend complaint to state medical necessity claims with particularity as required by Federal Rule of Civil Procedure 9(b)).

36. *Massachusetts ex rel. Gublo v. Novacare, Inc.*, 62 F. Supp. 2d 347, 355 (D. Mass. 1999) ("[S]ubmission of false certification of compliance with the Stark Law in order to qualify for Medicare reimbursement can constitute a false claim under the FCA.").

37. *United States ex rel. Showell v. Phila. AFL, CIO Hosp. Ass'n*, No. CIV.A.98-1916, 2000 WL 424274 (E.D. Pa. Apr. 18, 2000).

38. *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000); *see infra* note 132.

*A. The Common-Law Origins and Development of
the Tainted-Claims Approach*

The district court in *United States ex rel. Roy v. Anthony*³⁹ was the first to consider the “interaction” between the FCA and the fraud and abuse statutes. In *Roy*, the plaintiff alleged that defendant-physicians referred patients for medical-imaging services (x-rays, cat-scans, MRIs, etc.) to laboratories operated by companies owned in part by defendant-physicians.⁴⁰ These defendant-physicians were then paid based on the number of referrals they sent to the defendant-laboratory. If proven, this conduct would clearly satisfy the actus reas element of a felony action under the Medicare and Medicaid anti-kickback law. The question of first impression before the *Roy* court, then, was whether the fact of the anti-kickback violation itself satisfied the elements of the FCA.⁴¹ The *Roy* court displayed considerable equipoise before ruling that it did.⁴²

According to the *Roy* Court, there are two ways the anti-kickback statutory violations could satisfy the elements of a FCA claim.⁴³ Either the plaintiff may show that the kickbacks themselves “somehow tainted” the claims for Medicare reimbursement, or the plaintiff may prove the claims were “constructively false or fraudulent” by virtue of the kickback violations.⁴⁴ Thus, the *Roy* decision marks the genesis of the tainted-claims cause of action where the taint of an anti-kickback violation alone may satisfy the four elements of the FCA.⁴⁵

Approximately one year later, a U.S. district court in Tennessee went further to refine the tainted-claims theory by inferring a false statement to hold the defendant-providers liable for fraud under the FCA. In *United States ex rel. Pogue v. American Healthcorp, Inc.*,⁴⁶ the private qui tam relator filed a FCA lawsuit against his former employer after his termination from the defendant’s employ.⁴⁷ The plaintiff-relator alleged defendant-physicians referred Medicare and Medicaid patients to defendant-medical centers for treatment notwithstanding their own financial interest in the medical centers.⁴⁸ The *Pogue* plaintiff could not prosecute this alleged violation of the anti-kickback or self-referral law directly, because neither statute creates a private cause of action.⁴⁹ However, the violations of the antifraud statutes, the plaintiff

39. 914 F. Supp. 1504 (S.D. Ohio 1994).

40. *Id.* at 1505.

41. *Id.* at 1506.

42. *Id.* (calling plaintiff’s claim “[a] vague assertion [that] creates . . . a tenuous connection between the Fraud & Abuse Statute and the False Claims Act”).

43. *Id.*

44. *Id.* at 1506-07. The court did not reveal whether the taint alone could independently satisfy the FCA, or whether both were required. Later courts, however, have premised FCA liability on either finding. *See, e.g., United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996).

45. *Roy*, 914 F. Supp. at 1506-07.

46. No. 3-94-0515, 1995 WL 626514 (M.D. Tenn. Sept. 14, 1995), *vacated by* 914 F. Supp. 1507 (M.D. Tenn. 1996).

47. *Id.* at *1.

48. *Id.*

49. *Id.*

alleged, were actionable under the FCA.⁵⁰ Initially, the district court rejected plaintiff's theory that anti-kickback statutory violations stated a prima facie case of FCA liability; the trial court dismissed plaintiff's complaint for failure to state a claim.⁵¹ Four months later, however, the same judge vacated that dismissal.⁵²

Upon reconsideration, the *Pogue* court concluded that while every kind of fraud was not within the purview of the FCA, the reach of the FCA extended "well beyond intentional false claims for the payment of money by the federal government."⁵³ In the absence of any expressly false statement or claim submitted to the federal government, the *Pogue* court supplied the falsity element of an FCA cause of action against defendant-medical providers in that case by implication.⁵⁴ The court approved the plaintiff's argument that by their participation in the federal Medicare and Medicaid programs, defendants had impliedly certified that they were in compliance with Medicare and Medicaid rules.⁵⁵ The *Pogue* court concluded the plaintiff had stated an actionable FCA claim because if this implied certification turned out to be false, then the defendants had filed a "false or fraudulent claim for payment" within the meaning of the FCA.⁵⁶ The *Pogue* court went on to explain that even if the claims themselves were not intentionally false, they "derived" from conduct intended to defraud the government.⁵⁷ According to *Pogue*, claims for payment are false if the defendant-providers have engaged in any conduct, even if that conduct occurred prior to submitting those claims, with the purpose of fraudulently inducing payment from the government.⁵⁸ In *Pogue*, the court was willing to imply falsity based upon the qui tam plaintiff's allegation that the defendants hid their anti-kickback violations from the government in order to obtain Medicare reimbursements, provided the plaintiff could show that the defendant acted intentionally.⁵⁹ Reasoning that the government otherwise would not have paid the Medicare reimbursements if it had known of the defendants' conduct, the court held that the plaintiff's allegations were sufficient to fulfill the falsity and intent elements of the FCA.⁶⁰

50. *Id.*

51. *Id.* at *6 (holding plaintiff's allegations of anti-kickback violations were insufficient to satisfy the falsity and injury elements of the FCA).

52. *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996).

53. *Id.* at 1511 (emphasis added).

54. *Id.* at 1509, 1513.

55. *Id.* at 1509.

56. *Id.* at 1513.

57. *Id.*

58. *Id.* at 1513.

Therefore, Pogue may bring his claim under the False Claims Act only if he can show that Defendants engaged in the fraudulent conduct with the purpose of inducing payment from the government. If Defendants' fraudulent conduct was not committed with the purpose of inducing payment from the government, that conduct does not operate to taint their Medicare claims and render the claims false or fraudulent under the False Claims Act.

Id.

59. *Id.* at 1513.

60. *Id.*

The *Pogue* decision, therefore, takes the tainted-claims theory several steps beyond *Roy*. *Pogue* creates a rather incredible theory of implied liability. Under *Pogue*, a truthful claim is rendered false or fraudulent under the FCA by two implications.⁶¹ First, the court may imply FCA falsity from proof of a separate statutory violation by reasoning that the defendant impliedly certified that no such violation existed when the defendant requested payment from the government—even in the absence of any express certification whatsoever.⁶² The second implication is the more startling. *Pogue* holds that a court may imply a defendant acted “knowingly” within the meaning of the FCA, even in the absence of any evidence that the defendant had any knowledge of the underlying statutory violation, by reasoning that when the defendant filed a claim for Medicare payment that should not have been paid, the defendant *intentionally hid* the violation from the government in order to obtain reimbursement.⁶³ Together, these two implications allow the court to conclude the defendant’s otherwise truthful claims are fatally “tainted” as a result of the defendant’s intentionally fraudulent conduct.

The Fifth Circuit refined *Pogue*’s impliedly false, impliedly tainted claims approach in *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*⁶⁴ The *Thompson* court⁶⁵ defined three distinct types of tainted-claims actions that are viable in the Fifth Circuit: (1) “Stark-II-based” tainted claims, (2) false-certification claims, and (3) “generic” tainted claims.⁶⁶ *Thompson*’s first two types of tainted-claims actions are distinguishable from the *Pogue* approach in two ways. First, the *Thompson* court based its finding that the subject claim was false under the FCA on the claimants’ express, not implied, certification that they had complied with antifraud laws they in fact had violated.⁶⁷ Second, in the first two actions, the *Thompson* court required an express, not implied, finding that the government had relied on the claimants’ conduct before concluding that a statutory violation was actionable under the FCA.⁶⁸ The *Thompson* court’s third, “generic” tainted-claims cause of action, however, is difficult to distinguish from the *Pogue* approach to tainted claims.

The first and easiest variety of tainted claims the Fifth Circuit approved are those premised upon a violation of the Stark II express prohibition against billing Medicare or Medicaid for physician self-referrals.⁶⁹ Under *Thompson*, claims submitted by

61. *See id.* at 1509-13.

62. *Id.* at 1511, 1513.

63. *Id.* at 1513.

64. 125 F.3d 899 (5th Cir. 1997), *remanded to* 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

65. This section discusses the tainted-claims theory as it has emerged collectively from the Fifth Circuit and Texas district court opinions taken together. The Fifth Circuit approved only the first two tainted-claims actions discussed herein. *Thompson*, 125 F.3d at 902. The third cause of action was created by the Texas district court on remand. *Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1049 (S.D. Tex. 1998). Although the *Thompson* tainted-claims approach is discussed as a unified doctrine, where appropriate, each court’s separate contribution to the tainted-claims theory is cited separately.

66. *Thompson*, 125 F.3d at 901-03.

67. *Id.* at 903.

68. *Id.*

69. The Stark II express prohibition is codified at 42 U.S.C. § 1395nn(a)(1) (1994), which

providers while in violation of Stark II are per se actionable as “false or fraudulent claims” under the FCA, first because Stark II expressly prohibits submission or payment of claims by violators of that statute, and second because a defendant-provider acts knowingly when submitting a claim to the government for that payment which the provider is ineligible to receive.⁷⁰ The Stark-II-based tainted claims approved in *Thompson* represent an improvement over *Pogue*’s impliedly tainted claims because here, an express statutory violation renders the defendant’s otherwise truthful reimbursement claims “false or fraudulent,” rather than an implied legal fiction. However, *Thompson* is no less troublesome in its implication that a defendant violated Stark II *knowingly*.⁷¹ The “taint” that makes Stark-II-based FCA claims actionable, then, is not merely the statutory violation, but defendant’s knowing submission of claims while in violation of Stark II despite the statute’s prohibition against noncompliant providers filing claims for Medicare or Medicaid payment.⁷² However, the *Thompson* court also concluded that Stark II tainted claims do not require showing any loss or injury to the United States since defendant-providers in these cases would be liable for penalties under the FCA, even if not for damages.⁷³

The second category of tainted claims *Thompson* addressed were false-certification claims.⁷⁴ These claims were based on the evidence in the case that the *Thompson* defendants had violated anti-kickback and self-referral prohibitions while providing the medical services claimed for, despite express statements on their annual cost reports that certified the defendants understood and complied with all Medicaid and

provides in pertinent part as follows:

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

Id.

70. *Thompson*, 20 F. Supp. 2d at 1047.

71. The examination of Stark II’s ambiguity (regulatory ambiguity), *see infra* Part III.A.2, demonstrates the tremendous weakness in this assumption.

72. On remand the *Thompson* district court explained:

The Columbia defendants fail to appreciate this central difference between FCA damages and penalties and the fact that the mere presentation of Columbia’s Medicare claims for patients referred in violation of the Stark laws give rise to civil penalty liability under the FCA where that presentation is explicitly prohibited by §1395nn(a)(1), for a claim that the defendant knows he is unauthorized to present because it is false, fictitious, and fraudulent.

Thompson, 20 F. Supp. 2d at 1034.

73. *Id.* at 1034.

74. To the extent that false-certification claims are based upon Stark II, the Fifth Circuit also approved a second cause of action under the FCA for this conduct under 31 U.S.C. § 3721(a)(2) (1994), the “false statements” provision of the FCA. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997), *remanded to* 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

Medicare regulations.⁷⁵ Under *Thompson*, the defendants' claims for Medicare reimbursement, though truthful in themselves, were tainted by the falsity of the defendants' express certifications.⁷⁶

Thompson's holding is similar to *Pogue's* in that the Fifth Circuit held a defendant-provider is liable under the FCA where the defendant submitted claims for payment after falsely certifying compliance with the Medicare and Medicaid laws and regulations. However, unlike *Pogue*, the *Thompson* court did not *imply* a false certification to show the claim was "false or fraudulent," but instead relied upon defendants' express statements of compliance in their annual cost reports to satisfy the falsity element.⁷⁷ Moreover, unlike *Pogue*, the *Thompson* court limited actionable false-certification claims to those in which the plaintiff can show that the government relied upon the express false certification as a condition of payment.⁷⁸

Thompson's third category of tainted claims is an aggressive creation of the U.S. district court, fathomed after remand of this case from the Fifth Circuit.⁷⁹ The Court of Appeals for the Fifth Circuit did not specifically address the *qui tam* plaintiff's tainted claims premised upon violations of statutes other than Stark II.⁸⁰ However, on remand, the district court did.⁸¹ Thus, the district court created a third category of tainted claims: those in which the "taint" that renders the defendant's claim false derives from a finding that the defendant at some point violated some other statute, law, or regulation.⁸² Apparently, the violated provision need not have borne any relationship to the provision of medical services.⁸³ In this category, *any* noncompliance with *any* statute or requirement will taint a claim and make it actionable under the FCA.⁸⁴ These are "generic tainted claims" because no specific statutory violation need support the FCA liability.⁸⁵

Although the *Thompson* court begins its analysis of this third category of tainted claims by mentioning claims based upon anti-kickback statutory violations, the court's analysis does not depend on this particular antifraud statute providing the underlying basis for the FCA claim.⁸⁶ This generic nature of the underlying statutory violation is clear because of the important distinctions between the anti-kickback

75. *Id.* at 902.

76. *Thompson*, 20 F. Supp. 2d at 1049.

77. *Thompson*, 125 F.3d at 902.

78. *Id.*; *Thompson*, 20 F. Supp. 2d at 1035.

79. *Thompson*, 20 F. Supp. 2d at 1049.

80. While the plaintiff's claims in this case were premised upon statutory violations of both Stark II and the Medicare and Medicaid anti-kickback statutes, the Fifth Circuit's discussion of both statutory-violation and false-statement claims centered *exclusively* on the Stark II violations. In fact, the court recognized the viability of the plaintiff's false-statement claims *only* if the district court was able to find a violation of the Stark Law on remand. *Thompson*, 125 F.3d at 902.

81. *Thompson*, 20 F. Supp. 2d at 1049.

82. *Id.* at 1047.

83. *Id.* at 1047-48.

84. *Id.*

85. *Id.*

86. *Id.* at 1047.

statute⁸⁷ and Stark II.

The anti-kickback statute is distinguishable because it contains no express provision prohibiting reimbursement if its terms are violated. This is an important distinction because without such a prohibitive provision, the court is left with no concrete basis upon which to conclude either that the defendant's claim was false, or that it was filed with an intent to defraud the government. The gravamen of premising a false claims action on a defendant's violation is the presumption that the defendant was not entitled to receive—indeed the government would not have paid—the reimbursement claim had the defendant's violation been known. Where there is no prohibition against submitting or paying claims in the face of a particular violation, the defendant may in fact have been entitled to the federal payment claimed notwithstanding the noncompliance. And, since the court may not conclude a provider is necessarily ineligible to receive reimbursement just because it was not in compliance with a particular anti-kickback provision, the defendant's claim may not have necessarily been false within the meaning of the FCA. Moreover, without an express prohibition, the implication that the defendant *knowingly* overlooked its ineligibility to receive reimbursement to submit Medicare or Medicaid claims, loses its force. Finally, without an express prohibition, the *Thompson* court's findings that tainted claims are based on statutory violations opens the door for prosecutors to pursue FCA liability against medical providers for any type of statutory violation. Although the statute at issue in *Thompson* was the anti-kickback law,⁸⁸ there is, under this theory, no principled reason why a defendant-provider would not be held liable under the FCA for submitting a claim while its building violated an inspection code; its employees failed to comply with Occupational Safety and Health Act regulations; or its physicians ran afoul of some Title VII requirement while interviewing a new prospective office worker. The chances for abuse, then, are greatest under this third category of tainted claims, where claims may be tainted by *any* generic statutory or regulatory violation by which the government requires a broad certification of compliance as a condition of payment.

In their article, John Boese and Beth McClain have aptly identified several pragmatic flaws in the reasoning and outcome of the *Thompson* approach to tainted claims. Citing the unworkable breadth of the "blanket" certification of compliance on which the false certification claims rested, Boese and McClain adopt the arguments of then Judge Breyer to explain the practical flaws in this decision: where "compliance is inordinately difficult, turning nearly everyone into a rule violator . . . permit[ting] the agency to pick and choose when and where to enforce the rule, [it] is obviously undesirable. It destroys in practice the very hope of rational[ity] . . . that the rulemaking process promises in principle."⁸⁹ Judge Breyer's arguments apply with even greater force to the irrational breadth of prosecutorial discretion exercised

87. 42 U.S.C. § 1320a-7b(a) (1994).

88. *Thompson*, 20 F. Supp. 2d at 1047-48 (stating "[w]hile there is a dearth of case law on point, Relator makes a persuasive argument under *Peterson* . . . and in light of the . . . purpose of the FCA that submission of [ineligible claims for payment] constitutes a false claim within the ambit of the FCA").

89. John T. Boese & Beth C. McClain, *Why Thompson Is Wrong: Misuse of the False Claims Act to Enforce the Anti-kickback Act*, 51 ALA. L. REV. 1, 42 (1999) (quoting *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992)).

by both government and qui tam enforcers of the fraud and abuse laws. This is further compounded by the regulatory ambiguity that makes compliance not only “inordinately difficult” but in fact not even expected by the government, which has said in recent advisory opinions that it will not prosecute “technical violations” of the anti-kickback and self-referral rules.⁹⁰

In fact, the problems of irrational prosecutorial discretion, statutory ambiguity, and unworkable breadth are merely the tip of the iceberg. The fundamental substantive legal problem with tainted claims under the FCA, such as those approved by the courts in *Thompson* and *Pogue* is that they are premised on the presumption that the FCA may serve as a mechanism to federalize any conduct that violates another federal, state, or local statute, regulation, or common law. In short, *Thompson* permits the FCA to replace existing law, with a newly created body of federal general common law. Although qui tam plaintiffs and government prosecutors have thus far been unsuccessful, they have pursued increasingly aggressive arguments under the tainted-claims approach, seeking to extend the FCA’s reach to encroach indiscriminately on state common law, regulatory provisions, and other federal provisions.

B. Current Judicial Limits of the Tainted-Claims Approach

As currently conceived by the courts, there is no substantive legal limit to the application of the tainted-claims theory of recovery. The theory is amorphous and the terms of the FCA are flexible so that the tainted-claims approach can be used to displace virtually any body of existing statutory or common law. For example, in *United States ex rel. Joslin v. Community Home Health, Inc.*,⁹¹ the FCA was used to prosecute an alleged violation of state certificate of need regulations.⁹² There, the qui tam relator alleged the defendant-home health care provider was liable for penalties and damages under the FCA because it had submitted Medicare claims while in violation of certification-of-need (“CON”) requirements that affected the defendant’s eligibility for licensing under the state home health care licensing rules.⁹³ Medicare rules require participating providers to comply with state licensing laws. Therefore, the *Joslin* relator based his FCA claim on allegations that the defendant violated Maryland’s CON requirements applicable to licensed HMO’s. Despite the plaintiff’s invocation of the FCA, there was nothing federal in the nature of the claim or interests raised by this case.⁹⁴ The *Joslin* case was, at its core, a state licensing-law claim.⁹⁵

The licensing issues raised in *Joslin* turned on questions of ownership and control of the defendant’s board of directors, on the composition of defendant’s enrollee population, and on the retroactive effect of Maryland’s repealed CON requirements

90. *Id.* at 28; see also Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 855, 916 (1989) (unfair for criminal antifraud statute to provide little guidance).

91. 984 F. Supp. 374 (D. Md. 1997).

92. *Id.* at 377.

93. *Id.*

94. *Id.*

95. *Id.*

for HMO's.⁹⁶ Yet, the *Joslin* plaintiff did not pursue his allegations directly under the Maryland state licensing and CON laws, but instead alleged a federal FCA violation to address his state licensing claims.⁹⁷ The Maryland district court's FCA ruling turned on whether the defendant's corporate restructuring triggered notice or other requirements under Maryland state law.⁹⁸ Notably, the *Joslin* court was not sitting in diversity and therefore had no obligation to apply Maryland law, even to the several issues that arose in the case but had never been decided by a Maryland court.⁹⁹

The *Joslin* court rejected the qui tam relator's multiple charges that the defendant's Medicare claims were tainted.¹⁰⁰ The plaintiff's allegations invoking the FCA included arguments that the defendants submitted claims for payment while one defendant was in violation of 42 U.S.C. §1395bbb(a)(5) (a statute which requires participating home health agencies to comply with state laws); that the form the defendant used to submit Medicare bills falsely implied regulatory compliance; and that merely by operating the home health service without a CON, the defendant had submitted a false claim.¹⁰¹ The *Joslin* court dismissed all the relator's claims in that case, declining the invitation to "seriously undermine" the intended role of the FCA.¹⁰²

Another far-reaching extension of the FCA was suggested by the qui tam relator in *United States ex rel. Mikes v. Straus*.¹⁰³ Dr. Mikes, a pulmonologist, alleged the defendants were liable under the FCA for knowingly allowing inappropriate and improper spirometry tests¹⁰⁴ to be performed, using improperly calibrated instruments, and inadequately trained personnel.¹⁰⁵ Dr. Mikes alleged the defendants' spirometer tests failed to meet standards set by the American Thoracic Society ("ATS").¹⁰⁶ Here, the FCA was merely a statutory vehicle by which the plaintiff attempted to prosecute a state medical malpractice claim in federal court.¹⁰⁷ Dr.

96. *Id.* at 379-80.

97. *Id.* at 377.

98. *Id.* at 380.

99. It does appear, however, that the court applied Maryland law. *Id.* at 381 ("[A] federal court will attempt to determine what the state's highest court would hold if confronted with the same issue.").

100. *Id.* at 385.

101. *Id.* at 377.

102. *Id.* at 384. The court declined

to hold that the mere submission of a claim for payment, without more, always constitutes an "implied certification" of compliance with the conditions of the government program . . . by permitting FCA liability potentially to attach every time a document or request for payment is submitted to the Government, regardless of whether the submitting party is aware of its non-compliance.

Id.

103. 84 F. Supp. 2d 427 (S.D.N.Y. 1999).

104. A spirometer is a medical device used to measure a patient's ability to exhale. STEDMAN'S MEDICAL DICTIONARY 1652-53 (26th ed. 1995).

105. *Mikes*, 84 F. Supp. 2d at 431.

106. *Id.* at 430.

107. *Id.* The plaintiff in *Thompson* made a similar attempt, which the Fifth Circuit dismissed. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901-02

Mikes's FCA argument rested on the "false implied certification" theory of tainted claims.¹⁰⁸ She argued that in order to qualify to participate in the Medicare program under 42 U.S.C. §1320c-5(a), the defendants were required to "assure" they would provide a certain quality of medical service.¹⁰⁹ When defendants failed to meet the ATS standards, Dr. Mikes argued the defendants' assurance was false and thus tainted their claims for Medicare reimbursement, which were then also per se false under the FCA.¹¹⁰ The *Mikes* court adopted the Seventh Circuit view, "squarely reject[ing]" this argument,¹¹¹ and concluding that the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."¹¹² The *Mikes* court did not, however, preclude the possibility that future medical malpractice claims could be brought under the FCA. The infirmity of that particular plaintiff's case might be corrected by a future qui tam litigant resulting in what the *Mikes* court called one of "those exceptional circumstances where the claimant's adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the Government, or, in more practical terms, where the Government would have refused to pay had it been aware of the claimant's non-compliance."¹¹³ This is a patently unhelpful standard. It is unlikely that the government would agree that it was willing to pay claimants who are noncompliant with *any* regulation whatsoever. Therefore, by this standard, no regulation would fail to "lie at the core" of an agreement with the government.¹¹⁴

The most recent reported attempt by a qui tam relator to extend the tainted-claims law is perhaps the most far fetched. In *United States ex rel. Showell v. Philadelphia AFL, CIO Hospital Ass'n*,¹¹⁵ a qui tam plaintiff sought to use the tainted-claims approach in an apparent medical malpractice action, challenging the record keeping and medical decisions of a hospital and physician-defendants who treated his mother.¹¹⁶ The Pennsylvania district court granted summary judgment to the defendants where the qui tam plaintiff had not ever been present when his mother received the treatment in question, did not know for what condition his mother was being treated, had no evidence of his mother's dissatisfaction with her treatment, had no expert evidence the treatment was inadequate, and based his entire "fourteen-

(5th Cir. 1997), remanded to 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

108. *Mikes*, 84 F. Supp. 2d at 434.

109. *Id.* at 433.

110. *Id.*

111. *Id.*; see also *Lamers v. City of Green Bay*, 168 F.3d 1013 (7th Cir. 1999); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034 (N.D. Ill. 1998), *aff'd*, 183 F.3d 730 (7th Cir. 1999). Although it has not been litigated fully, this argument has also failed in the Fifth Circuit. *Thompson*, 125 F.3d at 903. *But cf.* *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs., Inc.*, 945 F. Supp. 1485 (W.D. Okla. 1996).

112. *Mikes*, 84 F. Supp. 2d at 435-36 (quoting *Lamers*, 168 F.3d at 1020).

113. *Id.* at 435.

114. See *United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992).

115. No. CIV.A.98-1916, 2000 WL 424274, at *1 (E.D. Pa. Apr. 18, 2000). The *Showell* relators primarily alleged direct violations of the FCA. Once the Pennsylvania court determined the relators failed to make out a prima facie claim under the FCA, the court also dismissed the tainted-claims allegations. *Id.* at *4.

116. *Id.* at *2, *4.

count, two hundred twenty-five paragraph Amended Complaint” on his own lay reading of the medical record.¹¹⁷

The *Showell* plaintiff had undertaken virtually no discovery and retained no expert.¹¹⁸ Therefore, he took the stand himself as the primary witness in the summary judgment hearing.¹¹⁹ The *Showell* court appropriately dismissed this FCA case but not before significant judicial and medical resources had been expended in defense of the qui tam plaintiff’s claims. The *Showell* case is evidence that plaintiffs may not be able to resist the invitation to file poorly investigated and unsupported tainted-claims cases. The allegations are easy to make and the potential “payoff” is great. As long as the tainted-claims doctrine persists in its current form, plaintiffs will file cases like *Showell*.

Public officials have also been zealous in using the tainted-claims approach.¹²⁰ In *United States ex rel. Aranda v. Community Psychiatric Centers*,¹²¹ the government successfully stated an FCA claim based on allegations the defendant-psychiatric hospital had failed to provide its patients with “a reasonably safe environment.”¹²² At bottom, the government alleged a medical malpractice claim.¹²³ Yet, the government argued the defendant-hospital had “implicitly certified” its compliance, not only with Medicaid regulations but with numerous other federal regulations as well by participating in the Medicaid reimbursement program.¹²⁴ The government’s FCA claim, then, rested on charges that the defendant’s patient treatment failed to

117. *Id.* at *2.

118. *Id.*

119. *Id.* at *4.

120. See, e.g., Michael Mustokoff et al., *The Government’s Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Ingenuity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANNALS HEALTH L. 137 (1997).

121. 945 F. Supp. 1485 (W.D. Okla. 1996).

122. *Id.* at 1487.

123. For a summary of numerous unreported medical malpractice cases brought against nursing homes under the FCA, showing the “vast scope of conduct that may be encompassed by extending the FCA to quality of care claims,” see Kathleen A. Peterson, *First Nursing Homes, Next Managed Care?: Limiting Liability in Quality of Care Cases Under the False Claims Act*, 26 AM. J.L. & MED. 69, 74 (2000). See also John R. Munich and Elizabeth W. Lane, *When Neglect Becomes Fraud: Quality of Care and False Claims*, 43 ST. LOUIS U. L.J. 27, 47 (1999) (advocating government prosecutors add state unjust enrichment, breach of contract, conversion, fraud, constructive trust and disgorgement and mistake of fact claims to FCA actions against “unscrupulous providers . . . tempted to seek reimbursement without rendering quality or adequate care”). These cases are often settled by consent decree or result in exclusion of the provider from the Medicare program. See Peterson, *supra*, at 74-78. But for an argument that the FCA is an important statute for “[t]he protection of our older adults residing in nursing homes,” see David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANNALS HEALTH L. 147, 147 (1997). See also John T. Boese, *When Angry Patients Become Angry Prosecutors: Medical Necessity Determinations, Quality of Care and the Qui Tam Law*, 43 ST. LOUIS U. L.J. 53, 59 (1999) (noting the attractiveness of FCA prosecution for disgruntled patients of managed care organizations whose medical malpractice claims are preempted under the Employee Retirement Income Security Act).

124. *Aranda*, 945 F. Supp. at 1487.

meet the requisite standard of care.¹²⁵

The *Aranda* court, in adjudicating this FCA-based malpractice case, declined to consider anything other than Medicaid regulations or requirements to articulate the requisite standard of care since the alleged FCA violations were based on Medicaid claims.¹²⁶ The court rejected the government's attempt to base FCA liability on impliedly false certification of compliance with other federal programs as well.¹²⁷ Nothing requires this restraint, however. In fact, the tainted-claims approach in *Aranda* permits FCA liability based on breaches of anything from one of the 100,000 Medicare and Medicaid regulations,¹²⁸ to standards set by state licensing boards¹²⁹ or professional trade organization standards.¹³⁰

The most recent tainted-claims cases brought by the government prosecutors continue to enlarge the tainted-claims theory in much the same way that *Showell*,¹³¹ the most recent qui tam case, broadens the application of this doctrine.¹³² In *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*,¹³³ for example, the court approved an FCA action based upon the defendants' certification, the fact that the procedures they performed were medically necessary,¹³⁴ and upon their implied certification that the procedures were "provided economically."¹³⁵ The *Kneepkins* court extends the tainted-claims, implied-certification theory even further than the *Pogue* decision. Here, the defendants operated a dialysis laboratory, performing

125. *Id.* The few details provided in the reported case suggest a particularly egregious set of facts prevailed at this psychiatric hospital. Perhaps the government was on the moral high ground in prosecuting the defendants in this case. Nevertheless, the adage "bad cases make bad law" comes to mind in reviewing the government's decision to prosecute an unlimited array of federal regulations as an FCA case.

126. *Id.* at 1488.

127. *Id.*

128. *Id.* at 1487.

129. *E.g.*, *United States ex rel. Sanders v. E. Ala. Healthcare Auth.*, 953 F. Supp. 1404, 1411 (M.D. Ala. 1996) ("Knowing submission of a claim that falsely represented attainment of state licensing requirements is enough to constitute a false claim.").

130. *See, e.g.*, *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 433 (S.D.N.Y. 1999) (referring to standards of professional trade organization for administration of particular type of medical test).

131. *United States ex rel. Showell v. Phila. AFL, CIO Hosp. Ass'n*, No. CIV.A.98-1916, 2000 WL 424274, at *1-*3, *4 (E.D. Pa. Apr. 18, 2000); *see supra* notes 115-19 and accompanying text.

132. *See United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000) (disapproving use of the FCA to prosecute where government merely disagrees with provider's reasonable medical care, but allowing government to recover where it proves patients did not receive the "quality of care which promotes the maintenance and the enhancement of the quality of life").

133. 115 F. Supp. 2d 35 (D. Mass. 2000).

134. *Id.* at 41-42. This certification was in accordance with 42 U.S.C. § 1395y(a)(1)(A) (1994), which requires that services billed to Medicare must be reasonable and medically necessary.

135. *Kneepkins*, 115 F. Supp. 2d at 42-43. Under 42 U.S.C. § 1320c-5(a)(1), services must be "provided economically."

blood tests on end stage renal disease (“ESRD”) patients.¹³⁶ The government intervened in this *qui tam* case to allege that the defendants were liable under the FCA because their partnership agreement allowed below cost testing in exchange for referrals, thus violating the anti-kickback law.¹³⁷ Further, the government alleged the defendants were liable under the FCA because their blood tests were not provided “economically.”¹³⁸ Instead of submitting one set of blood tests for reimbursement, the defendant-laboratory split the relevant blood tests into two groups or “panels,” billing nonroutine panels on a fee-for-service basis, while routine panels were submitted to the government under a composite billing.¹³⁹ It is important to note that the government and the court recognized that all of the blood tests themselves were reasonable and medically necessary to treat ESRD patients.¹⁴⁰ Moreover, the *Kneepkins* court conceded that there was no rule which “command[ed] providers to structure their tests in any particular manner.”¹⁴¹ Finally, the court acknowledged that the defendant’s claims for payment contained no express certification that the blood tests were provided as cheaply as possible.¹⁴² Yet, after acknowledging that it had no case precedent upon which to rely, the court agreed to allow the government to proceed on its theory that “extended this [implied certification] principle to claims that supposedly violate §1320c-5’s economical care requirement.”¹⁴³

Expansion of the tainted-claims theory appears currently driven by *qui tam* and public prosecutors’ creativity. The limits of the theory have been drawn by courts on a case-by-case basis.

The reasons various courts have approved or declined to find FCA liability in tainted-claims cases cannot be reconciled and therefore yield no clear instruction for future conduct in light of these decisions. In *Mikes*, the court concluded the falsity element of the FCA was not satisfied by plaintiff’s tainted-claims arguments.¹⁴⁴ In *Thompson* the plaintiff’s claim failed for lack of specificity,¹⁴⁵ while in *Joslin* the

136. *See Kneepkins*, 115 F. Supp. 2d at 37.

137. *Id.* at 42.

138. *Id.*

139. *Id.* at 37-38.

140. *Id.* at 41.

141. *Id.* at 41 n.3. The court analyzed the so-called “50/50 Rule,” which is deemed an interpretive rule that requested blood tests to be submitted in groups or “panels” comprised of roughly fifty percent routine and fifty percent of more expensive, nonroutine tests. The court concluded that the

interpretive rules such as the 50/50 Rule, by their nature, do not impose affirmative duties upon providers. Hence, the 50/50 Rule does not command providers to structure their tests in any particular manner, and, despite the government’s contrary suggestion, measures taken to avoid the application of the Rule are not necessarily illegitimate.

Id.

142. *Id.* at 42 (“More troubling, however, is the fact that the Chem 7 claims contain no express certification that the tests were economically provided.”).

143. *Id.*

144. *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 436 (S.D.N.Y. 1999).

145. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

court concluded the plaintiff failed to show the defendants manifested the requisite intent—knowledge—to be held liable under the FCA.¹⁴⁶ In *Showell*, the court pointed to the plaintiff's inadequate factual foundation.¹⁴⁷ The variety in courts' approaches is not limited to cases brought by private qui tam plaintiffs. The government has demonstrated that it was equally willing to aggressively pursue the extension of FCA-based claims in *Aranda* and *Kneepkins* as qui tam relators have been in *Joslin* and *Showell*. The tainted-claims approach in its current form may be used to transform any common law, regulatory, or administrative antifraud claim into a federal FCA case. The inherent uncertainty of this approach is exacerbated when the FCA is applied to prosecute anti-kickback and self-referral fraud.

III. THE STATUTORY PROBLEM: MARRYING THE FALSE CLAIMS ACT AND MEDICAL ANTIFRAUD LAWS

The tainted-claims cases based upon violations of the Medicare anti-kickback statute and the self-referral laws present a special case. First, because these specialized antifraud laws embody such a significant level of ambiguity in themselves, the application of the FCA to these laws raises questions of consistent and predictable statutory interpretation. Second, these antifraud laws regulate the complex details of economic activity among health providers. The FCA, by contrast, is a broad enforcement tool that sets out general principles to govern contractual relationships with the government. Forcing these two very different approaches together may do more harm than good in the effort to reduce waste due to fraud. Third, the self-referral and anti-kickback statutes both have intricate administrative procedures that are incompatible with the judicial controls that operate under the FCA. This Part reviews the basic structure of the anti-kickback and self-referral laws, looking closely at the safe harbor and statutory exclusions that exempt certain health care transactions from their purview. Next, this Part reviews the intended scope of the FCA and its application to health care fraud cases. This Part concludes that the tainted-claims cases, as currently conceived by public and private prosecutors, displaces a congressionally mandated public-enforcement regime with a body of common law driven largely by self-interested prosecutors.

A. The Antifraud Statutes—an Overview

The self-referral prohibition and the anti-kickback law are industry- and conduct-specific statutes. They address health care fraud exclusively, and they address this area with a level of detail that aims specifically at commercial interactions unique to the health care industry. These antifraud statutes regulate a wide range of complex economic behavior by individual categories of participants in the health care market. Each statute includes an administrative enforcement structure tailored to address the prohibited conduct. The antifraud laws create a statutory scheme under which

146. United States *ex rel.* *Joslin v. Cmty. Home Health, Inc.*, 985 F. Supp. 374, 385 (D. Md. 1997).

147. United States *ex rel.* *Showell v. Phila. AFL, CIO Hosp. Ass'n*, No. CIV.A.98-1916, 2000 WL 424274, at *2 (E.D. Pa. Apr. 18, 2000).

Congress contemplated experienced prosecutorial and administrative control. Yet the government and plaintiffs suing on its behalf have virtually abandoned direct enforcement of these statutes in favor of using the FCA.¹⁴⁸ Historically, the statutes most precisely tailored to address kickbacks, false claims, and self-referral fraud in medicine have not proven to be prosecutorial “weapons of choice.”¹⁴⁹ This section reviews the basic structures of the antifraud laws and the FCA to determine whether this prosecutorial choice is consistent with Congress’s intent for the antifraud laws.

1. The Medicare and Medicaid Anti-kickback Law

The criminal sections of the Medicare and Medicaid Antifraud Act¹⁵⁰ are the core of what is commonly called the anti-kickback law.¹⁵¹ In fact, this statute can be

148. JOHN T. BOESE, *CIVIL FALSE CLAIMS AND QUI TAM ACTIONS* app. H, at H-1 (2d ed. Supp. 2000); U.S. GEN. ACCOUNTING OFFICE, *MEDICARE FRAUD AND ABUSE: DOJ’S IMPLEMENTATION OF FALSE CLAIMS ACT GUIDANCE IN NATIONAL INITIATIVE VARIES 16* (1999) (stating that the FCA is one of the Department of Justice’s most important “weapons in the fight against health care fraud”); Pamela H. Bucy, *Crimes by Health Care Providers*, 1996 U. ILL. L. REV. 589, 606 (1996).

149. See Bucy, *supra* note 90, at 883 (listing criminal statutes used to prosecute medical fraud); *Fraud: New Civil Anti-kickback Offense Added by Fraud Section of Budget Bill*, 6 Health Law Rep. (BNA) No. 34, at D-1 (Aug. 21, 1997) (stating that the government does not bring many anti-kickback cases because of the difficulty in proving guilt beyond a reasonable doubt); see also Durin B. Rogers, Note, *The Medicare and Medicaid Anti-kickback Statute: “Safe Harbors” Eradicate Ambiguity*, 8 J.L. & HEALTH 223, 228 (1993-94).

150. See *supra* note 4.

151. The Medicare and Medicaid Antifraud Act also includes a civil provision called the Civil Monetary Penalty Law. 42 U.S.C. § 1320a-7a (1994 & Supp. IV 1998). This discussion excludes the CMPL because that statute is seldom used. Its prohibitions are similar to the FCA, while it presents more difficult proof problems for prosecutors. It sets forth a range of substantive offenses in two subsections. *Id.* § 1320a-7a(a), (b). Those subsections define “improperly filed” or false-claims violations and violations in the form of payments to induce improper reductions or limitations of services to beneficiaries. *Id.* These substantive offenses cover primarily what has been called “raw” fraud—upcoding, claiming reimbursement for medically unnecessary services or services never provided, and filing claims while unlicensed or excluded from participation in federal health programs. *Id.* § 1320a-7a(a). The statute also punishes hospitals and physicians who pay or accept payments to limit or increase the medical services provided to a beneficiary, for which the beneficiary would otherwise have been eligible to receive. *Id.* § 1320a-7a(b). Beyond these substantive provisions, the statute lays out detailed procedural and evidentiary rules, outlining the due process protections available to alleged violators. *Id.* § 1320a-7a(c). Three sanctions are available to the Secretary of the Department of Health and Human Services (the “Secretary”) after a final determination is entered, pursuant to an administrative hearing. The Secretary may (1) impose civil monetary fines of \$50,000 per violation, plus (2) assess the underlying remuneration, which may be trebled at the discretion of the Secretary, and (3) exclude a provider from participating in Medicare and Medicaid. *Id.* § 1320a-7a(a); see also William A. Sarraille & Robert E. Wanerman, *Safe Harbors Reflect Limited Acceptance of Provider Changes*, 8 Health Law Rep. (BNA) No. 49, at 2022 (Dec. 23, 1999).

Importantly, the CMPL lodges significant discretionary authority in the Secretary. In

divided into two sections. The first section sets forth the criminal false-claims prohibitions,¹⁵² and the second contains the anti-kickback provisions.¹⁵³ Under the anti-kickback law's false-claims section, the government must show the defendant (1) knowingly and willfully (2) made or caused to be made (3) a false statement or representation (4) of material fact in an application for payment under a federal health program.¹⁵⁴ The two anti-kickback provisions make it illegal to knowingly (1) solicit or receive any remuneration, or (2) offer or pay any remuneration in return for or in order to induce referrals for services or goods paid for by a federal health care program.¹⁵⁵ On their face, these sections criminalize many common business practices including paying inducements to recruit medical personnel,¹⁵⁶ consulting fee agreements, and brokerage, partnership, or joint venture agreements between providers and various support service entities. Thus, Congress has sought to limit the reach of the anti-kickback law, by enacting a series of statutory exemptions. The Department of Health and Human Services ("DHHS") has promulgated a series of safe harbors. Congress has also attempted to mitigate the harshness of the criminal provisions by enacting a civil penalty section to broaden the sanctions available to the government for anti-kickback violations.¹⁵⁷ These provisions exclude specific business practices from criminal prosecution under the broad law.

a. The Statutory Exceptions

The breadth of the main provisions of the anti-kickback law reflects the government's self-articulated view that the statute's main purpose is "curtailing the corrupting influence of *money* on health care decisions."¹⁵⁸ Although the statute begins from the apparent premise that financial incentives necessarily corrupt health care delivery, within the main body of the law Congress enacted five statutory exemptions designed to mitigate the chilling effect of the anti-kickback law.

The anti-kickback law's prohibitions "shall not apply to" (1) discounts or price reductions, (2) payments to bona fide employees, (3) payments by a group purchasing agent, (4) co-insurance waivers for subsidized beneficiaries, or (5) safe harbors issued pursuant to the Medicare and Medicaid Patient and Program

addition to the authority to preside over the administrative hearing, the statute spells out the Secretary's discretionary powers to determine the amount and scope of any civil penalty to impose, based on the nature of the offense, the degree of culpability and the requirements of justice. 42 U.S.C. § 1320a-7a(d).

152. *Id.* § 1320a-7b(a).

153. *Id.* § 1320a-7b(b)(1)-(2).

154. *Id.* § 1320a-7b(a).

155. *Id.* § 1320a-7b(b)(1)-(2).

156. See John A. Bourdeau, Annotation, *Illegal Remuneration Under Medicare Anti-kickback Statute*, 132 A.L.R. FED. 601, 601 (1996).

157. 42 U.S.C. § 1320a-7a(a) (providing a civil monetary penalty equal to \$50,000 per violation plus up to triple the underlying remuneration). However, since its enactment, this provision has been seldom used.

158. Office of Inspector General, Office of Public Affairs, Fact Sheet, Federal Anti-kickback Law and Regulatory Safe Harbors (Nov. 1999) (emphasis added), <http://www.dhhs.gov/progorg/oig/ak/safefs.htm> [hereinafter OIG Fact Sheet].

Protection Act of 1987.¹⁵⁹ Therefore, remuneration given or received in the context of these five exemptions is not subject to prosecution under the act. The reason for each of these exemptions varies.

Congress recognized that discounts, price reductions, and waivers often represent savings to the federal health programs, and that it is good business practice to allow health care providers and suppliers to seek these without the threat of criminal or civil prosecution.¹⁶⁰ The employee exemption is a pragmatic one, recognizing that the incentive effects of offering remuneration to an employee do not carry the potential for program abuse that the statute prohibits.¹⁶¹ The exemption pertaining to group purchasing agents codifies the fact that the practice of collective volume purchasing is likely to reduce program costs. The waiver of co-insurance exemption encourages plans to offer favorable incentives to enrollees. Finally, the fifth statutory exemption merely incorporates the safe-harbor regulations promulgated by the Office of Inspector General ("OIG") as exemptions.

b. The Regulatory Safe Harbors

In 1987, as part of the Medicare and Medicaid Patient and Program Protection Act, Congress instructed the DHHS to clarify the pervasive impact of the anti-kickback law's influence. The congressional mandate required the DHHS to promulgate regulations specifying those payment practices that will not be subject to criminal prosecution or provide a basis for exclusion.¹⁶² In response, the DHHS's OIG published eleven regulatory safe harbors in 1991;¹⁶³ two additional safe harbors in 1992;¹⁶⁴ and seven new, plus one revised, safe-harbor provisions in 1993.¹⁶⁵ In 1996,

159. 42 U.S.C. § 1320a-7b(b)(3).

160. See S. REP. NO. 95-453, at 12 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

161. *Id.*

162. Act of Aug. 18, 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 697, *reprinted in* 42 U.S.C. § 1320a-7b app. (1994).

163. These eleven broad safe-harbor areas protected (1) investment interests, (2) space rentals, (3) equipment rentals, (4) personal-services agreements and management contracts, (5) sales of practices, (6) referral services, (7) warranties, (8) discounts, (9) employees, (10) group-purchasing organizations, and (11) waivers of beneficiary co-insurance payments and deductibles. See OIG Anti-kickback Provisions, 56 Fed. Reg. 35,952, 35,984-87 (July 29, 1991) (codified as amended at 42 C.F.R. § 1001.952(a)-(k) (2000)); see also BUCY ET AL., *supra* note 11, § 2.13[1][c], at 2-113 to -128 (combining the 1991 and 1992 safe harbors, which were finalized on the same date, to total thirteen initial safe harbors).

164. The two additional safe-harbor areas excepted (1) certain incentives offered by health plans to enrollees—such as increased coverage, reduced cost sharing, or reduced premium amounts—and (2) price reductions offered to health plans by contract providers. Safe Harbors for Protecting Health Plans, 57 Fed. Reg. 52,723, 52,729-30 (codified at 42 C.F.R. § 1001.952(l)-(m) (2000)). Also in 1992, the OIG expanded the protection for co-insurance waivers, creating a safe harbor for Medicare SELECT insurers and providers. *Id.* at 52,729 (amending 42 C.F.R. § 1001.952(k)(1)(iii) (2000)).

165. The seven new safe harbors, and an eighth safe harbor clarifying the sale-of-practice rule, all proposed in 1993 and made final in 1999, were for (1) investment interests in rural areas, (2) ambulatory surgical centers, (3) group-practice investments, (4) practitioner recruitment, (5) obstetrical-malpractice insurance subsidies, (6) referral agreements for

as part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"),¹⁶⁶ Congress enacted the twenty-first new safe harbor protecting shared-risk agreements¹⁶⁷ and instructed DHHS to promulgate regulations in accordance with that new provision.¹⁶⁸ On November 19, 1999, the OIG published two new safe-harbor provisions to cover shared-risk arrangements.¹⁶⁹ Most recently, the OIG issued a notice of proposed rulemaking, announcing a new safe-harbor provision designed to protect hospitals that restock ambulances with medical supplies and drugs.¹⁷⁰ Currently, there are a total of twenty-three anti-kickback safe harbors that have been promulgated since 1987.¹⁷¹

c. Congress's Attempt to Limit the Reach of
the Anti-kickback Law

It is important to understand the nature of these safe-harbor provisions, and how they shield providers from criminal or administrative sanctions under the anti-kickback law. Safe harbors reflect the fact that the anti-kickback law does not on its face describe a comprehensive range of illegal activities. Instead, they describe the elements that must be satisfied for conduct to be deemed illegal. Because it is a general description of illegal conduct, standing alone, the reach of the anti-kickback law is broad. According to the OIG, the purpose of safe-harbor provisions is "to limit the reach of the [anti-kickback] statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements."¹⁷² Precise

specialists, (7) cooperative hospital service organizations, and (8) clarification of the sale-of-practice rule. Additional Safe Harbor Provisions Under the OIG Anti-kickback Statute, 58 Fed. Reg. 48,008, 49,013-15 (proposed Sept. 21, 1993) (codified at 42 C.F.R. § 1001.952(a), (e), (n)-(s) (2000)). Later, in 1994, the OIG published clarification for six other existing safe harbors—investment interests, space rentals, equipment rentals, personal-services and management contracts, referral services, and discounts—and withdrew a "sham contract" safe harbor it had proposed earlier. Clarification of the OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Anti-kickback Provisions, 59 Fed. Reg. 37,202, 37,203 (proposed July 21, 1994) (to be codified at 42 C.F.R. pt. 1001).

166. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

167. 42 U.S.C. § 1320a-7b(b)(3)(F) (Supp. IV 1998).

168. Act of Aug. 18, 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 697, *reprinted in* 42 U.S.C. § 1320a-7b app. (1994).

169. *See* Statutory Exception to the Anti-kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63,504, 63,513-15 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952(t)-(u) (2000)). The two new shared-risk safe harbors protect (1) managed-care arrangements paid on a capitated basis and (2) financial arrangements between managed-care plans and individuals or entities reimbursed on fee-for-service basis where the providers are at substantial financial risk for the cost or utilization of items furnished to program beneficiaries. 42 C.F.R. § 1001.952(t)-(u) (2000).

170. Ambulance Restocking Safe Harbor Under the Anti-kickback Statute, 65 Fed. Reg. 32,060, 32,064-65 (proposed May 22, 2000) (to be codified at 42 C.F.R. pt. 1001).

171. OIG Fact Sheet, *supra* note 158, <http://www.dhhs.gov/progorg/oig/ak/safefs.htm>.

172. Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-kickback Statute, 64 Fed. Reg. 63,518, 63,518 (Nov.

compliance with the narrow terms of any given safe harbor will shield a provider from prosecution under the statute. However, given how narrowly drawn the safe harbors are, many transactions will not fit their requirements exactly. Nevertheless, failure to comply precisely with a safe harbor does not automatically result in a criminal prosecution or exclusion under the statute.¹⁷³ Transactions that do not fit an established safe harbor may be outside the purview of the anti-kickback statute entirely and not subject to its provisions. On the other hand, noncompliant transactions may be clear violations of the anti-kickback statute.¹⁷⁴ Most likely, transactions that do not fit safe-harbor parameters are technical violations of the broad provisions of the statute; however, they are not necessarily actionable based on the government's assessment of the risk of fraud posed by the arrangement. In this instance, the OIG and the Department of Justice ("DOJ") must exercise prosecutorial discretion—based on a number of factors including the seriousness of the violation, the degree of risk of loss to the federal programs, and the intent of the parties—to decide whether to prosecute each transaction that comes to their attention on a case-by-case basis.¹⁷⁵

As a practical matter, the OIG bases its decision to craft a new safe harbor largely on its estimate of the types of transactions that are frequently being structured in the health care marketplace without the blessing or protection of an express safe harbor. In other words, the safe-harbor rules-promulgation process is not an a priori exercise, but rather an ex post response to innovations in the market as providers seek new financial arrangements to allow them to compete successfully. For example, the newest safe harbor, a provision protecting hospital restocking of ambulances, covers a limited practice that came to the OIG's attention when several hospitals involved in ambulance "replenishing arrangements" submitted requests for advisory opinions. Once the OIG has seen a number of similar transactions and becomes convinced that these transactions involve relatively little risk of fraud against the federal health programs, then the process of issuing a proposed rule, soliciting comments, and ultimately promulgating a final rule begins as it has in this instance. There may currently be numerous other financial arrangements in existence in the market, which

19, 1999) (codified at 42 C.F.R. § 1001.952 (2000)) (quoting 56 Fed. Reg. 35,952 (July 29, 1991)).

173. *Id.* at 63,521.

174. A very similar legislative approach is taken under securities law. For example, section 3(a)(11) of the Securities Act of 1933 defines an exemption or "safe harbor" from the broad registration requirements of that statute. 15 U.S.C. § 77c(a)(11) (1994). The breadth of the core statute and the imprecise language of the exemption has led the administrative body, the Securities and Exchange Commission, to promulgate a clarifying rule, Rule 147. 17 C.F.R. § 230.147 (2000). While persons are exposed to possible civil and administrative sanctions if they do not meet the exact requirements of the exemption, liability is not assured since the administrative body is charged also with interpreting the application of Rule 147 to each transaction. See J. William Hicks, *Intrastate Offerings Under Rule 147*, 72 MICH. L. REV. 463 (1974).

175. One author has advocated a rule-of-reason analysis to permit courts to analyze correctly the distinctions and benefits of various business arrangements that may be implicated under the anti-kickback law. See Timothy J. Aspinwall, *The Anti-kickback Statute Standard(s) of Intent: The Case for a Rule of Reason Analysis*, 9 ANNALS HEALTH L. 155, 182-92 (2000).

are more deserving and needy of the protection that an explicit safe harbor provides, and they may represent bigger cost savings for the Medicare and Medicaid programs. Nevertheless, ambulance restocking is the practice that has almost randomly come to the OIG's attention and therefore it is the protected conduct.

James F. Blumstein has already noted the civil-liberties problems with this approach to criminal lawmaking.¹⁷⁶ He explains that banning kickback and referral fees is either unnecessary at best, and most often economically counterproductive. These laws work at cross-purposes with facilitating a financially healthy health care market. First, there is no conceivable way the OIG can anticipate the infinite number of possible financial arrangements that could be structured to deliver health care but that may implicate the broad prohibitions of the anti-kickback statute. Therefore, under the ad hoc transactional model the OIG has adopted,¹⁷⁷ providers in the marketplace must *always* be in a position of negotiating and structuring financial interactions in an environment of uncertainty. Providers must continually expose themselves to the significant risk of criminal prosecution and civil liability in order to remain competitive, while hoping for the regulatory law to "catch up" with the market. Moreover, even once a limited safe harbor has been fashioned, providers who depart from the specific terms of the safe harbor risk the presumption that they have violated the law. These problems are helped some by the guidance the OIG provides to providers through the advisory-opinion procedure and the publication of special alerts. These warn providers of the parameters of permissible transactions and give guidance concerning other transactions providers might consider. However, the fact remains that not only does the government have considerable and largely unpredictable discretion to prosecute under the anti-kickback and self-referral statutes, but the application of the FCA's *qui tam* provisions, as approved by *Pogue*, *Thompson*, and other tainted-claims cases, also allows private parties to enjoy unlimited prosecutorial discretion in their efforts to sue health care providers. The legislative record does not anywhere reveal that congress intended to enforce the antifraud statutes through this virtual "free for all."

2. The Self-Referral Prohibitions

The self-referral prohibitions are actually contained in two separate enactments, called Stark I¹⁷⁸ and Stark II.¹⁷⁹ The self-referral laws prohibit physicians from

176. James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 218 (1996).

177. See Mark A. Hall, *Making Sense of Referral Fee Statutes*, 13 J. HEALTH POL., POL'Y. & L. 623, 625 (1988).

178. Enacted as part of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (codified as amended in scattered sections of 42 U.S.C.). For a discussion of the popular terms used to refer to these acts, see *supra* note 7.

179. Enacted as part of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (codified as amended in scattered sections of 42 U.S.C.). On January 9, 1998, the Health Care Financing Administration published a proposed rule amending the Stark II section of the self-referral laws. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 63 Fed. Reg. 1659 (proposed Jan. 9, 1998) (to be codified at 42 C.F.R. pts. 411, 424, 435, 455). That proposed rule seeks to clarify the scope of the self-referral

referring Medicare or Medicaid patients to a clinical laboratory, or for other types of "designated health services" if the referring physician, or someone in her immediate family, has a "financial relationship"¹⁸⁰ with the entity receiving the referral.¹⁸¹ A "financial relationship" is defined as an ownership or investment interest.¹⁸² The Stark Law, also known as the Ethics in Patient Referrals Act, imposes civil penalties of up to \$15,000 per violation, and up to \$100,000 for any arrangement considered to have been entered to circumvent the statute's self-referral ban.¹⁸³

Originally enacted in 1989, the Stark I provision was refined by regulations promulgated under the act in 1992¹⁸⁴ and was amended in 1993.¹⁸⁵ The 1993 amendments extended the coverage of Stark's provisions to physical therapy, radiology, and diagnostic-services facilities, and a total of thirteen categories of providers.¹⁸⁶ In 1995, the statute was further refined by additional regulations to revise reporting requirements and other miscellaneous provisions under the law.¹⁸⁷ These statutes were introduced in response to a spate of studies and reports that revealed a large percentage of physicians had ownership interests in clinical laboratories and those physicians tended to refer their patients for laboratory services more frequently than other physicians. In short, the self-referral law is intended to curb costly physician overutilization by prohibiting physicians from making referrals that serve their own financial self-interest.

Like the anti-kickback law, the core prohibitions of the self-referral law reach broadly. Congress, therefore has enacted a number of detailed statutory and regulatory exceptions to the ban on self-referrals.¹⁸⁸ Many of the self-referral

ban and is currently being considered for implementation. *Id.* The new final rule is scheduled for September 2000 publication. *See Stark II Rule Could Be Out by Late Summer*, 9 Health L. Rep. (BNA) No. 26, at 1016 (June 29, 2000).

180. They also prohibit referrals to clinical laboratories pursuant to a compensation agreement.

181. 42 U.S.C. § 1395nn(a)(1) (1994). For full review of the Stark Law's legislative history, see Am. Bar Ass'n, *Stark I Final Regulations: Implications for Health Care Providers and Suppliers*, HEALTH LAW., Aug. 1995 (Special ed.), at 1, 3-4.

182. 42 U.S.C. § 1395nn(a)(2)(A).

183. *See* 42 U.S.C. § 1395nn(g)(3)-(4).

184. Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services, 57 Fed. Reg. 8588 (proposed Mar. 11, 1992) (to be codified at 42 C.F.R. pt. 411).

185. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993) (codified as amended in scattered sections of 42 U.S.C.).

186. *See id.*

187. Physician Financial Relationships with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41,914, 41,978-82 (Aug. 14, 1995) (codified at 42 C.F.R. pt. 411).

188. 42 U.S.C. § 1395nn(b) includes the three general exceptions: physician services, in-office ancillary services, and prepaid plans. On the other hand, the statute includes a general exception for referrals where the Secretary determines the relationship between the physician and entity do not pose a risk of program or patient abuse. *Id.* § 1395nn(b)(4). Finally, the Stark Law lists several "permissible" exceptions including ownership or investment in securities, certain hospitals, space and equipment rentals, employment relationships, personal-service arrangements, physician incentive plans, physician recruitment, group-practice

exceptions are similar to the statutory exemptions and regulatory safe harbors Congress enacted under the anti-kickback statute. These highly technical exceptions apply to group practices; prepaid plans; rural providers; hospital investors; office space and equipment rental agreements; bona fide employment relationships; personal service arrangements; physician incentive plans; and other miscellaneous transactions. Although private parties have no right to enforce the self-referral law,¹⁸⁹ the government can obtain civil monetary penalties under the self-referral law's strict-liability standard more easily than under the false-claims provisions, which require a showing of intent.¹⁹⁰

The self-referral law is further distinguishable from the anti-kickback statute in four important ways. First, the self-referral ban applies only to physicians, while the anti-kickback statutes are aimed at curbing overutilization and improper financial consideration by all types of health care providers and suppliers of medical goods and services. Second, the self-referral laws prohibit referrals outright so that a prohibited transaction is per se illegal under these statutes, while the anti-kickback statute looks at providers' intent to determine whether the subject remuneration was prohibited under that act. Third, the self-referral law is a civil statute which includes no criminal provisions, unlike the anti-kickback law, which contains criminal prohibitions. Finally, the self-referral law contains an express prohibition against submitting a claim for reimbursement of services rendered in violation of its provisions, while the anti-kickback law contains no analogous prohibition.¹⁹¹ Thus, as the Court held in *Thompson*, submitting a claim for payment to an entity violating the self-referral law is arguably a per se FCA cause of action.¹⁹² The question remains, however, whether the FCA generally, and the qui tam provision specifically is, in fact, an appropriate enforcement vehicle for violations of the medical antifraud statutes.

B. The Intended Scope of the Civil False Claims Act

The intended and prudent reach of the FCA is an important and confusing question; even the U.S. Supreme Court has directly contradicted itself on this issue.¹⁹³

arrangements and group practices that satisfy the parameters of the exception. *Id.* § 1395nn(c)-(e).

189. See *West Allis Mem'l Hosp., Inc. v. Bowen*, 852 F.2d 251 (7th Cir. 1988) (holding that there is no private cause of action under the Stark Law).

190. See TIMOTHY P. BLANCHARD, *MEDICARE AND MEDICAID FALSE CLAIMS: LEGAL COMPLEXITIES AND DEVELOPING ISSUES* (Nat'l Health Lawyers Ass'n, Legal Analysis Plus: Monograph Series, 1996).

191. 42 U.S.C. § 1395nn(g)(1).

192. See *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998).

193. In *United States v. McNich*, 356 U.S. 595 (1958), the Supreme Court said, "It is equally clear that the False Claims Act was *not designed to reach every kind of fraud* practiced on the Government." *Id.* at 598 (emphasis added). However, ten years later in *United States v. Neifert-White Co.*, 390 U.S. 228 (1967), the Supreme Court reviewed the legislative history of the FCA to conclude:

Debates at the time suggest that the Act was intended to reach *all types of fraud*,

Following the Supreme Court's leadership, the federal courts have also "staked out" entirely irreconcilable views of the FCA's application to anti-kickback and self-referral cases. In *Pogue*, the district court cautioned that the FCA "was *not intended to operate as a stalking horse for enforcement of every statute, rule, or regulation.*"¹⁹⁴ In *Luckey v. Baxter Healthcare Corp.*,¹⁹⁵ the Seventh Circuit ruled that "technical violations of a federal regulation on which a claim is based do not make the claim 'false.'"¹⁹⁶ Yet, in *Thompson*, the trial court citing the Fifth Circuit said, "While there is a dearth of case law on point, Relator makes a persuasive argument . . . [that] *the FCA reaches 'all fraudulent attempts to cause the Government to pay out sums of money.'*"¹⁹⁷

This is an especially troubling contradiction in light of the possibility that at least some of the FCA-based fraud litigation initiated against health care providers is the result of the lure of receiving a share of the lucrative damages and penalties payable to private and public prosecutors under the qui tam provisions of the FCA and the Control Account.¹⁹⁸ And yet the impact of failing to limit the scope of the FCA, at least where certain medical fraud prosecutions are concerned, may be to completely swallow the preexisting federal and state law, statutory as well as common, to replace existing law with an "all purpose" tool for creating a new body of federal general common law of fraud.

The FCA requires no showing of specific intent to prove falsity or fraud.¹⁹⁹ A

without qualification, that might result in financial loss to the Government. In its present form the Act is broadly phrased to reach any person who makes or causes to be made 'any claim upon or against' the United States In the various contexts in which questions of the proper construction of the Act have been presented, the Court has consistently refused to accept a rigid, restrictive reading, even at the time when the statute imposed criminal sanctions as well as civil.

Id. at 232 (footnotes omitted) (emphasis added).

194. *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (emphasis added).

195. 183 F.3d 730, 733 (7th Cir. 1999) (rejecting plaintiff's FCA claim based on allegation that defendant was liable for using ineffective test for plasma).

196. *Id.*

197. *Thompson*, 20 F. Supp. 2d at 1047 (quoting *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (emphasis added)). Both the *Pogue* and *Thompson* cases are discussed in depth in Part II.A.

198. 42 U.S.C. § 1395i(k) (Supp. IV 1998).

199. *See, e.g., United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) ("[A]n FCA violation may be established without reference to the subjective intent of the defendant."). *But see United States v. Bay State Ambulance and Hosp. Rental Serv.*, 874 F.2d 20, 29-30 (1st Cir. 1989) (holding that intent is an element of an anti-kickback violation); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) ("[R]equiring the jury to find 'beyond a reasonable doubt that one of the material purposes of the solicitation was to obtain money for the referral of services'"); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) ("We also hold that the materiality of utterances charged to be within the false statement statute is an essential element of the crime"). The level of intent required varies. In *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), the Ninth Circuit required specific intent—the defendant must have known the conduct was illegal and must have acted with the intent to violate the law—to be held liable under the anti-kickback law. *Id.* at 1400. However, in *United*

prima facie case under the FCA does not require any showing that the government was injured by the alleged violation of the act.²⁰⁰ And most jurisdictions²⁰¹ require no causal link between the alleged fraud or falsity and the government's decision to make a payment from the public fisc. There are, therefore, doctrinal reasons for a public or private prosecutor to prefer the FCA over the self-referral or anti-kickback statutes. However, even beyond the substantive issues that make the FCA an attractive enforcement tool, the application of the FCA to medical fraud prosecutions is expanding in such a way that other motives and justifications deserve examination.

The tainted-claims approach applying the FCA to kickback and self-referral cases raises a "red flag" because of the disparity between the prosecutorial theories advanced against defendants in FCA cases and those advanced against providers charged directly under the antifraud statutes or under the common law. While there is clearly no prohibition against using the more general FCA rather than the specific antifraud statutes as a prosecutorial tool,²⁰² and no colorable preemption argument precludes this application of the FCA,²⁰³ the fact that a separate and somewhat contradictory body of fraud law is developing under the auspices of the FCA makes this trend one that deserves attention. Moreover, the fact that the law makes substantial financial incentives available to both private plaintiffs (under the *qui tam* provision of the FCA) and to government prosecutors (under the Control Account established by HIPAA)²⁰⁴ raises the question of whether there is an extent to which this expansion of the law is fueled by self-interest and whether that self-interest is consistent with the public's interest.

Robert Salcido has observed that the use of the FCA as a tool to enforce the Medicare and Medicaid anti-kickback law, "a broadly worded criminal statute," is "powerful."²⁰⁵ The FCA, as amended in 1986, is itself a potent enforcement tool. The penalties, which attach to each individual claim for payment filed by a defendant, together with the treble damages structure under this Act provide what one writer has called a "bounty" to motivate government and private enforcers alike.²⁰⁶

States v. Jain, 93 F.3d 436 (8th Cir. 1996), the court held that only intent to defraud was required. *Id.* at 441; *see also* *United States v. Neufeld*, 908 F. Supp. 491, 496 (S.D. Ohio 1995) ("Resort to the statutory language does not lend support to the definition of 'willful' in the Anti-Kickback statute as requiring a knowledge of illegality.").

200. *See, e.g.*, *United States ex rel. Pogue*, 914 F. Supp. 1504, 1512-13 (M.D. Tenn. 1996).

201. For examples of cases requiring a causal link between the injury and the false statement, *see* *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (4th Cir. 1996); *United States ex rel. Schwelt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *United States v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981); *United States v. Hibbs*, 568 F.2d 347, 351-52 (3d Cir. 1997). But for examples of cases not requiring a causal link, *see* *United States v. First Nat'l Bank*, 957 F.2d 1362, 1374 (7th Cir. 1992); *United States v. Entin*, 750 F. Supp. 512, 519 (N.D. Fla. 1990).

202. *But cf.* *Brown v. Gen. Serv. Admin.*, 425 U.S. 820, 834 (1976) (stating that a more specific statute preempts application of a general one).

203. *United States v. Gen. Dynamics Corp.*, 19 F.3d 770, 777 (2d Cir. 1994) (finding that the anti-kickback law does not preempt FCA remedies).

204. *See* 42 U.S.C. § 1395i(k)(2)(c)(ii) (Supp. IV 1998).

205. Salcido, *supra* note 15, at 108.

206. *See* Phelps, *supra* note 29, at 1009.

Blumstein has observed that the Medicare and Medicaid anti-kickback statutes are broad, and the regulatory safe harbors intended to insulate legitimate business arrangements from their reach are narrow.²⁰⁷ To the extent that Stark I and II limit the inflationary effects of self-referrals, the statutes have required four clarifying amendments and a morass of regulatory explanation in order to target the illegal activity that Congress intended to prohibit.²⁰⁸ When combined for enforcement purposes with the Medicare and Medicaid anti-kickback and self-referral prohibitions, the FCA becomes not just a powerful but perhaps a lethal tool.

The tainted-claims approach to applying this complex network of anti-kickback and self-referral laws through the FCA is flawed in at least three important respects. First, the tainted-claims approach misunderstands the economic reality of the health care market. Second, FCA enforcement of self-referral and anti-kickback statutes is inconsistent with Congress's decision not to create a private cause of action under either of these laws. Third, public and private prosecutors in tainted-claims cases are subject to financial incentives that taint the exercise of prosecutorial discretion required to correctly apply the underlying antifraud statutes. The next three sections will consider each of these problems in turn.

IV. THE ECONOMIC PROBLEM: DEFINING "INAPPROPRIATE" FINANCIAL CONSIDERATIONS IN THE HEALTH CARE MARKET

The tainted-claims approach to prosecuting medical fraud rests on simplistic assumptions about the economic impact of kickbacks and referral fees. The anti-kickback and self-referral laws themselves, however, reflect a much more comprehensive view of the problem with these provider fees. While the self-referral and anti-kickback statutes reflect Congress's considered attempt to accommodate the complex and changing structure of the market for health care delivery, the tainted-claims approach errs by eliminating the opportunity for beneficial transactions to escape the prohibitive sweep of the FCA's general provisions. This Part first summarizes the familiar distinctive features of the health care market and then employs a microeconomic model to describe theoretical errors in the tainted-claims approach.

Patients come to health care providers in the hope of improving their personal, physical, or mental condition.²⁰⁹ Providers similarly enter into relationships with patients in the hope of improving the patient's condition. In most cases, the provider's hope of improving a patient's condition is at least partly, perhaps even largely, altruistic. However, the relationship between patient and provider is also an economic one. Providers receive economic remuneration in exchange for providing

207. Blumstein, *supra* note 176, at 205-06.

208. Christian D. Humphreys, Comment, *Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?*, 30 SAN DIEGO L. REV. 161, 164-67 (1993).

209. Some patients come unwillingly, but if they themselves do not hope for improvement in their condition, the actor who required their relationship with a health care provider usually does (e.g., cases of involuntary commitment or hospitalization of terminal patients hoping only for marginal improvement).

health care. Moreover, in today's market, virtually all medical services are delivered as a result of the collective activity of numerous providers and suppliers. Frankford has observed that the relationships facilitating collective activity in health care necessarily involve remuneration as they would in any other industry.²¹⁰ Numerous market imperfections raise the concern that providers' financial self-interest may unnecessarily inflate the cost or compromise the quality of health care delivery.

The tainted-claims approach to enforcing anti-kickback and self-referral prohibitions is aimed at completely prohibiting providers from accepting any referral fees, under the assumption that all fees are solely self-interested.²¹¹ Tainted-claims enforcement is intended to eliminate the providers' ability to act in their own self-interest in order to control inflation and maintain an acceptable level of quality in health services. However, the economic problem with this approach in a nutshell is that it assumes that providers' financial self-interest is entirely inconsistent with the goals of cost containment and quality maintenance. This is simply untrue. While the market for health care is distinguishable from the market for other goods, the tainted-claims approach ignores those differences and penalizes rational, efficient behavior along with fraudulent conduct, as though the two were identical.

Timothy Stoltzfus Jost and Sharon Davies have evaluated the deterrent function of fraud and abuse sanctions for various categories of medical fraud.²¹² Understanding that complete deterrence is appropriate only where a victim's loss exceeds the wrongdoer's gain from illegal conduct, Jost and Davies correctly conclude this should not be the goal of laws that address kickbacks and self-referrals.²¹³ Rather, because some remuneration arrangements result in gains rather than losses to the government and to society, Jost and Davies conclude these socially beneficial transactions should be exempt from antifraud enforcement.²¹⁴ The tainted-claims

210. David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1865 (1989); see also Mark V. Pauly, *The Ethics and Economics of Kickbacks and Fee Splitting*, 10 BELL J. ECON. 344, 352 (1979).

211. Using the deterrence analysis heuristic defined by Timothy Stoltzfus Jost and Sharon Davies, tainted-claims enforcement errs in attempting to accomplish "complete deterrence." Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 273-77 (1999). Jost and Davies argue convincingly that complete deterrence is inappropriate to address bribes, kickbacks, and self-referral fraud. *Id.*

212. It is outside the scope of Jost and Davies's work to look at the effect of the tainted-claims approach to antifraud enforcement, but their analytical tools are useful in this area as well. Jost and Davies conclude that "society does not suffer . . . if penalties are set high enough to completely deter bribes and kickbacks regardless of whether the service is necessary." *Id.* at 274. Here their conclusion ignores the cost of over-deterrence. This is particularly relevant in the tainted-claims context in which the rules set penalties to completely deter all forms of remuneration arrangements by penalizing certain conduct regardless of whether the government suffers any loss in paying for medically necessary services billed at appropriate levels. The tainted-claims approach thus results in discouraging economically efficient conduct by providers, who seek to avoid the excessive penalties that would result if their behavior was mistakenly penalized as fraudulent.

213. *Id.* at 277.

214. *Id.* at 276.

approach fails to make this important distinction between socially beneficial and truly fraudulent transactions. Tainted-claims penalties are set indiscriminately high so that they not only deter costly remuneration agreements, but socially beneficial transactions as well.²¹⁵ To borrow a phrase from Jost and Davies, the tainted-claims approach belongs to that category of sanctions that “make no sense.”²¹⁶

A. Health Care Market Imperfections

The legal and economic literature on the health market thoroughly documents the salient market imperfections that may adversely affect health provider decisions. First, because of the third-party-payer system, providers do not receive cost containment cues directly from their patients. The fact that providers are paid primarily by third-party insurers adds to the risk that the providers’ financial self-interest may supersede the public interest, not only in maintaining the quality of patient care, but also in containing the cost of providing patient care. Second, patients’ utilization decisions are not informed by the cost of the goods or services they consume. Also, physicians are primarily responsible for prescribing the treatments and are thus responsible for utilization rates of the services they provide.

Third, for many reasons, the financial rewards paid to providers in exchange for patient care are not directly dependent upon the quality of patient outcomes. While in some cases the expected outcome resulting from the delivery of medical services may be predicted with sufficient certainty to be guaranteed, more often the differences in patients, treatment modalities, approaches to care, and numerous other variables make objective measurement of the quality of services difficult to assess. Therefore, the providers’ self-interest in financial remuneration is not directly aligned with the patients’ interest in improving their condition.²¹⁷ Moreover, the cost of the patient care is not directly imposed on the patient with whom the provider is in a relationship. Therefore, by increasing the burden of those charges, the provider does not directly compromise the quality of the patient relationship from the provider’s perspective.²¹⁸

215. See Stanley A. Twardy & Michael P. Shea, *Anti-kickback Anxiety: How a Criminal Statute Is Shaping the Health-Care Business*, BUS. L. TODAY, May-June 2000, at 18, 20 (describing transactions being altered or avoided because of FCA prosecutions of health providers), available at <http://www.abanet.org/buslaw/blt00May-kickback.html>.

216. Jost & Davies, *supra* note 211, at 274-75.

Some of these remuneration arrangements result in the more efficient provision of goods and services, which in turn results in gains to society or even to the government health care programs. . . . It would make no sense to use the fraud and abuse laws to attempt to deter these arrangements at all, much less to deter them completely.

Id.

217. Over the long run, however, a provider’s reputation and, therefore, prospect for obtaining future business are dependent upon patient outcomes to the extent that alternative providers are available for patients to choose those providers who may have better records for improving their patients’ conditions.

218. This does not mean patients cannot experience stress, which affects their likelihood of recovery, from a difficult relationship with the third-party insurer, but it is possible for provider

Anti-kickback and self-referral prohibitions are directed at controlling providers who stand to benefit from the increased utilization of goods or services that they are in control of prescribing. However, the anti-kickback and self-referral laws themselves contain intricate safe harbors and exceptions that allow enforcers to carefully consider whether the effect of fees on utilization rates and costs is actually detrimental.²¹⁹ The many statutory and regulatory exceptions to the core provisions of each antifraud statute reflect Congress's understanding that many transactions that appear to present fraud problems in fact provide efficiencies and savings for the Medicare and Medicaid program and its beneficiaries, precisely because the health care market is unique. The network of safe harbors and exceptions is unwieldy and cumbersome. However, it is superior to the tainted-claims approach because the existing legal framework permits enforcers to consider the beneficial economic effect of collaborative and fee-sharing arrangements that are completely overlooked when the antifraud statutes are enforced through the FCA.

B. Defining "Inappropriate" Financial Considerations

Thomas Bulleit and Joan Krause have described the primary objective of the anti-kickback statutes as preventing "inappropriate financial considerations from influencing the amount, type, cost, or selection of the provider of medical care received by a federal health care program beneficiary."²²⁰ This is consistent with the concerns legislators expressed when enacting the antifraud legislation.²²¹ Bucy notes further that the dangers of "inappropriate financial considerations" include costly overutilization of unnecessary medical services, subsidization of marginal medical providers, and the deterrence of competitors' entry into the marketplace.²²² All

and patient to align themselves against the third-party payer in a way that preserves, and may in fact enhance, the perceived quality of the relationship between provider and patient.

219. Jost & Davies, *supra* note 211, at 275. Express exemptions under the anti-kickback and self-referral laws accommodate the "reality" that referral fees are not all bad. *Id.* at 275. The existing laws' safe harbors and exemptions "plainly reflect the judgment of Congress and the HCFA that some remuneration agreements are socially beneficial and thus are to be encouraged." *Id.* at 276.

220. Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies or Cost-Effectiveness?: Application of the Medicare Anti-kickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 *FOOD & DRUG L.J.* 279, 282 (1999).

221. See, e.g., *Issues Related to Physician "Self Referrals": Hearings on H.R. 939 Before the Subcomm. on Health and the Subcomm. on Oversight of the House Comm. on Ways and Means*, 101st Cong. 27-28 (1989) (statement of Rep. Stark, Chairman, Subcomm. on Health, Comm. on Ways and Means).

222. BUCY ET AL., *supra* note 11, § 2.13, at 2-90; see also Pamela H. Bucy, *Health Care Reform and Fraud by Health Care Providers*, 38 *VILL. L. REV.* 1003, 1012 (1993) (stating that physicians use kickbacks as a way to increase volume); Gregory D. Jones, *Primum Non Nocere: The Expanding "Honest Services" Mail Fraud Statute and the Physician-Patient Fiduciary Relationship*, 51 *VAND. L. REV.* 139, 155-66 (1998) (stating that a kickback is a breach of the physician's fiduciary duty); Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 *TENN. L. REV.* 455 (1998); Daniel Melvin, *Suspect Financial Arrangements Between Hospitals and Hospital-Based*

financial considerations by health care providers, however, are not "inappropriate." In fact, even financial considerations due to referral fees or payments may be appropriate because they may encourage more cost efficient and higher quality medical care. While the antifraud laws are structured to accommodate this economic reality, the tainted-claims approach is not. This section uses a microeconomic model to describe this difference.

1. "Inappropriate" Assumptions of the Tainted-Claims Approach

The tainted-claims approach appears to assume that the market for health care is a simple, competitive one.²²³ Further, it assumes that health care is a pure economic good that can be defined as a bundle of goods and services that society has determined will meet the minimal needs of each of its members. Under these assumptions, health care providers will supply and consumers will demand the optimal amount of health care services, at the optimal price, simply by finding the intersection of the demand and supply curves that describe the health care market.

However, as several commentators have documented, a unique feature of the health care market is that the demand for health goods and services is largely influenced by the suppliers, the health care providers.²²⁴ The demand for health services is not solely consumer driven, but, because of information asymmetries between providers and their patients, providers induce demand by their diagnosis and treatment decisions.²²⁵ The tainted-claims approach focuses exclusively on this feature of the market and attempts to control the demand providers create for health care. The objective of the tainted-claims approach, therefore, is to protect against distortions in the demand for health care services.

The distortion assumed by the tainted-claims approach is that all self-referral and kickback fees shift the demand curve to the right. Put another way, under the tainted-claims assumption, if providers are allowed to receive increased fees for their referrals, the providers will artificially increase the demand for those referral services in an effort to increase their personal income.²²⁶ This increased demand is assumed

Physicians, 1 DEPAUL J. HEALTH CARE L. 183 (1996); Alycia C. Regan, *Regulating the Business of Medicine: Models for Integrating Ethics and Managed Care*, 30 COLUM. J.L. & SOC. PROBS. 635 (1997).

223. I have argued elsewhere that the market for health care is in fact a natural monopoly. Dayna B. Matthew, *Doing What Comes Naturally: Antitrust Law and Hospital Mergers*, 31 HOUSTON L. REV. 813 (1994). Others have shown that the health care market is an oligarchy. *Id.* at 833-37. In any event, because of the unique market imperfections described in Part IV.A.1 above, no serious argument can be made that the health care market is one of perfect competition.

224. For a comprehensive description of the market for healthcare, see ALAIN C. ENTHOVEN, *HEALTH PLAN THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE* (1980).

225. *Id.* at 21-23.

226. *But see* John C. Fletcher & Carolyn L. Engelhard, *Ethical Issues in Managed Care: A Report of the University of Virginia Study Group on Managed Care*, 122 VA. MED. Q. 152, 165 (1995).

to be fraud, and it is represented below in Figure 1 as a rightward shift in the demand curve. The tainted-claims approach assumes the difference between consumer demand (D_1) and "inappropriate" demand (D_2) is fraud. See Figure 1 below:

FIGURE 1. THE DEMAND SHIFT ASSUMED UNDER THE TAINTED-CLAIMS APPROACH

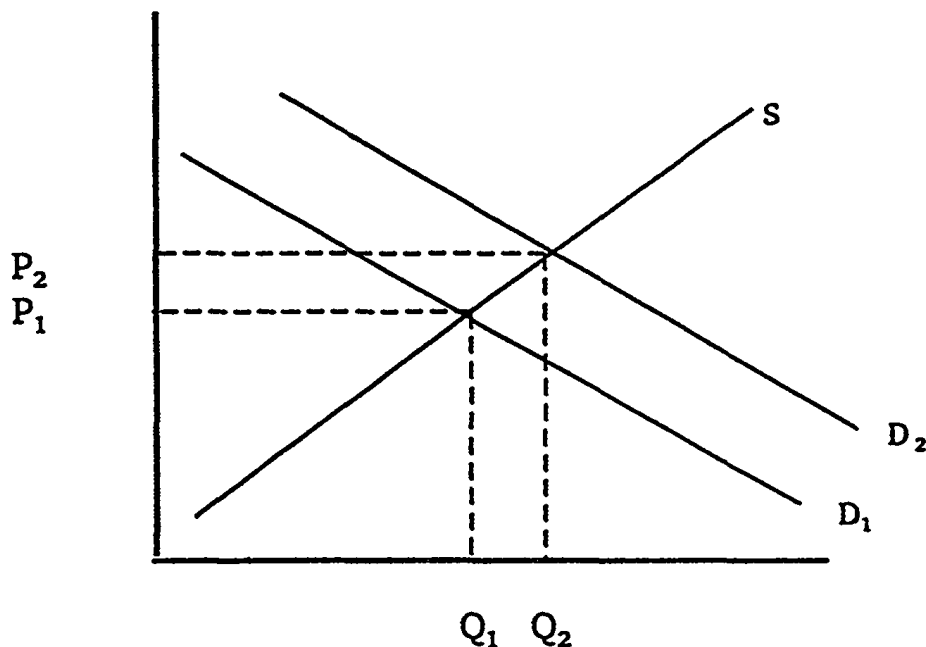


Figure 1 graphically represents the tainted-claims assumption that when providers are permitted to collect additional fees in excess of P_1 , the price of health care is inflated to P_2 . The tainted-claims approach regards efforts to obtain increased fees at the level of P_2 as "inappropriate financial considerations."²²⁷ Moreover, this view contends that once demand is artificially inflated, the market will find a new, suboptimal equilibrium not only increasing the price of medical services from P_1 to P_2 , but also increasing the quantity of health care supplied from Q_1 to Q_2 .

The tainted-claims approach seeks to protect against four possible consequences of this demand shift. First, it seeks to contain the increased cost of medical services that would result from artificially inflated demand for medical services.²²⁸ Second,

227. Under the tainted-claims approach, the effort to obtain fees through receipt of kickbacks, bribes, and self-referral fees are considered "inappropriate financial considerations" because these payments do not bear relationship to the value of the health care goods and services provided, but rather reflect wealth transfers to providers seeking to augment their incomes over and above the true value of the medical services they provide. Therefore, this theory presumes that payments to providers in the form of self-referral fees or kickbacks artificially shift the existing demand curve for medically necessary health services to the right, increasing the demand to include medically *unnecessary* health care services. See *supra* Figure 1.

228. Blumstein, *supra* note 176, at 207 (discussing potential for overutilization and moral hazard stemming from the difference between the cost to the patient and the actual cost of

it seeks to exclude inefficient providers who, at P_2 , would remain in the market, buoyed by the excess income they receive from illegal remunerations. Third, the tainted-claims approach seeks to prevent potential barriers to entry, which are created by an artificially high demand for medical services at price levels inflated by illegal payments, that may deter competing providers from entering the market. Fourth, the approach is intended to discourage providers from utilizing lesser quality medical goods and services, based on referral and other fees that will benefit them, but that will not serve the best interest of the patient. By controlling excess payments to providers, the tainted-claims theory claims to assure that the level of health services provided equals the *actual* level of need—presumably undistorted demand—for health services, rather than a level inflated by the providers' desire for extra income. While the anti-kickback and self-referral statutes share these same four objectives,²²⁹ the effort under these laws encourages, rather than discourages, economically efficient behavior.

2. Appropriate Financial Considerations Under the Antifraud Laws

The antifraud laws do not regard all increases in demand due to referral fees as fraudulent or inappropriate. Although referral fees may increase demand, such increases may be economically efficient under some circumstances.²³⁰ Referral fees may be appropriate either where the fees encourage efficiencies or where the fees purchase goods and services that add value to the consumer-patient.²³¹

In the first instance, referral fees may positively influence the supply of medical goods and services.²³² These fees may actually decrease prices and increase the quantity of health care provided if, for example, more efficient care results from financial relationships that improve providers' ability to serve a greater number of patients for small marginal cost increases. In the latter case, while referral fees may increase the price of health care, the increased price would correctly reflect the value of additional convenience to patients, improved technology or other added benefits not possible without the economic alliances from which the appropriate referral fees

health services).

229. H.R. REP. NO. 104-496, at 69 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1869 ("In order to address the problem of health care cost inflation and make insurance more affordable, it is important to focus on key sources affecting levels of the underlying health care costs. Two key sources of excessive cost are medical fraud and abuse . . .").

230. Kaz Kikkawa, *Medicare Fraud and Abuse and Qui Tam: The Dynamic Duo or the Odd Couple?*, 8 HEALTHMATRIX 83, 106 (1998) ("Moreover, while many providers are in technical violation of the statute, their violations sometimes result in actual savings to the Medicare and Medicaid programs, more efficient delivery of health care, or an increase in the quality of health care.").

231. Blumstein, *supra* note 176, at 222; Frankford, *supra* note 210, at 1869-74; Theodore N. McDowell, Note, *The Medicare-Medicaid Anti-fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 726-27 (1987).

232. These changes would be represented graphically by a rightward shift in the supply curve and no change in the demand curve. As the supply curve shifts outward, the cost of care actually decreases and the quantity of health care increases.

arise. In either case, by excepting a variety of potentially beneficial referral fee transactions from the statutory broad prohibitions, the antifraud statutes acknowledge the economic fact that several provider relationships may result in a price for medical goods and services (P_n), which includes *appropriate* rather than *inappropriate* referral fees.²³³ Two hypothetical examples will demonstrate this point.

The first example involves referral fees that are “appropriate” because they result in efficiencies that actually reduce the variable cost at which health care may be delivered. Such a fee may motivate a general practice physician to refer a patient to a specialist in internal medicine within his same group practice. The group may benefit financially from this referral and the fee may increase the absolute dollar cost of a particular medical service to the patient. However, the increased payment to the group, which is equal to the higher absolute dollar cost of that service to the patient, may facilitate higher quality medical care at a lower cost per patient than referrals made outside the group practice. The internal medicine specialist within the group may offer certain efficiencies, such as the ability to realize economies of scope and scale based on the volume of patients seen within the group and reduced transaction costs that are based on proximity and similarities in practice styles within the group. Put another way, the referrals may increase revenues within the group, but may also reduce the cost of treating each additional patient. As Pauly has noted, then, the law should allow the general practitioner and the internist to self-refer as long as they set their marginal revenues equal to marginal costs.²³⁴

The anti-kickback and self-referral laws themselves attempt to do this by recognizing certain exceptions to the broad prohibitions both laws contain. In the example above, for instance, the group practice exception is intended to allow the general practitioner and internist to refer patients without fear of liability under certain conditions. The antifraud laws recognize that increased demand may in fact be neither artificial nor excessive. The tainted-claims approach, however, leaves no room for the possibility that the kickback and referral fees either represent services of value added to the patient or fair market rates for good.

The second example of an “appropriate” referral fee is one that represents a reasonable price set for the provision of complimentary or additional goods and services that facilitate the provision of medically necessary health care.²³⁵ For example, referral fees between two provider groups may purchase expedited or

233. The tainted-claims argument also does not explain the economic effect of banning appropriate referral fees. This section describes some economic benefits that result from certain referral fee transactions, which are exempted from the antifraud prohibitions. Therefore, it follows that the banning of fees in these cases, as the tainted-claims approach seeks to do, will result in a detrimental economic effect. For example, the blanket prohibition represented by the tainted-claims approach may act as an excessive penalty, similar to a punitive damages award in a tort case that ultimately discourages productive behavior as market participants seek to avoid incurring the unreasonably high cost of punitive damages.

234. Pauly, *supra* note 210, at 351-52.

235. This change in assumptions would be shown graphically by a change in the slope or shape of the supply curve, but again, no change in the demand curve. In this case, the slope of the supply curve might increase as the quality of care improves. The same quantity of care may cost more, but the quality of the care provided is different and inferior to the quality of care that would be available in the absence of these appropriate referral fees.

higher quality care as a result of the consistent and longstanding relationship between the referrer and the referred. Discounted real estate rates, which are offered by hospitals to physician groups, may purchase convenience, proximity, and perhaps greater patient compliance as the effort to obtain follow-up care becomes easier through a physician group located in or near the hospital. In this case, the financial considerations introduced by referral fees are not “inappropriate” because they represent an agreed-upon price for services that add value to the patient.

To protect “appropriate” financial considerations from prosecution, the self-referral and anti-kickback statutes have carved an intricate list of exceptions and regulatory safe harbors to allow health care providers to negotiate cost-effective agreements for the delivery of health care services. On the other hand, the law seeks to punish and deter “inappropriate” considerations. The difficulty, of course, is in determining those financial considerations that are “appropriate” and those that are not.

At least two problems arise. First, as discussed above, it is not necessarily true that financial incentives such as referral fees or other forms of remuneration are simply excess payments for the provision of excess medical goods and services. Where these payments reflect the added value placed on other services or efficiencies that providers bring to the market—such as the economies of scope and scale that result from referrals within a group—the statutes create safe harbors. An example is the space and equipment leasing exceptions and safe harbors under the self-referral and anti-kickback laws.²³⁶ There, referral fees may encourage savings resulting from space or equipment leases between hospitals and physician groups, allowing physician providers to serve hospital patients more economically on site than if the same patients had to travel to an alternate location not subsidized by the hospital.

In fact, the exercise of distinguishing what is an “appropriate” financial consideration from an “inappropriate” one is not an objective enterprise. At one end of the ideological spectrum, some hold the view that *any* financial incentive or consideration in delivering medical care is inappropriate. This view is naive because it suggests that medical care, which is a scarce resource, can be delivered in unlimited quantities to meet unlimited demand without any regard to cost.²³⁷ A health care provider who does not consider the costs of the services that she provides, acts irresponsibly with respect to conserving both individual patient and societal resources. Although this view is now widely discounted, its pervasiveness, along with the visceral distaste for acknowledging any link between cost and health care, remain as underpinnings of the anti-kickback and self-referral laws today.

At the other end of the spectrum, it is an equally troublesome view that imagines financial considerations should alone direct the allocation of medical resources.²³⁸ The confusing structure and legislative history of the anti-kickback and self-referral

236. 42 U.S.C. § 1395nn(e)(1) (1994) (self-referral exceptions); 42 C.F.R. § 1001.952 (2000) (anti-kickback safe harbors).

237. *E.g.*, Uwe Reinhardt, *Uncompensated Hospital Care*, in UNCOMPENSATED HEALTH CARE: RIGHTS AND RESPONSIBILITIES 1, 1-15 (Frank A. Sloan et al. eds., 1986) (discussing notion that health care is a right).

238. *See generally* ENTHOVEN, *supra* note 224 (suggesting health care reform by creating a system of health plan competition with built-in incentives for consumer satisfaction and cost control); *see also* Blumstein, *supra* note 176, at 218.

statutes reflect the difficulty of finding a policy equilibrium between these two market realities.

On the one hand, the cost-containment mechanisms that are most effective in the managed-care model are those that attach financial incentives to encourage efficient, cost-effective choices in health care delivery. For example, in order to encourage providers to limit their consumption of health resources, managed-care companies offer financial incentives to limit utilization of expensive specialists outside their immediate network. The basic managed-care model is to equip providers with a financial "stake" in their medical delivery system in order to influence their medical decisions. At the same time, the antifraud law seeks to limit the extent to which providers' medical decisions are influenced by financial self-interest. In its most general terms, therefore, the job of the anti-kickback and self-referral laws is contradictory; the laws both constrain the behavior of market participants, while at the same time the laws seek to allow providers the freedom to compete in a market that demands efficiency and innovativeness to survive.

While the simplistic tainted-claims approach is unable to accommodate these conflicting goals,²³⁹ the legislative structure of the antifraud laws accommodates this conflict more precisely. The anti-kickback and self-referral laws are each comprised of sweeping prohibitions followed by enormously complex transactional exceptions that legislatively distinguish "appropriate" from "inappropriate" considerations. This is the balance that the antifraud laws attempt to strike. However, because the basic premise of the tainted-claims approach does not include any provisions to tailor or limit the breadth of the false-claims approach to controlling medical fraud, this approach stands at direct odds with the reality of the market-driven medical economy. The antifraud laws are far from perfect in their approach. However, Congress, recognizing the difficulty and importance of the balance that these statutes strike, has limited enforcement under the anti-kickback and self-referral laws to the government agencies with experience and expertise in the health care market. The next Part explores the wisdom of this congressional judgment.

V. THE POLICY PROBLEM: ABANDONING PUBLIC ENFORCEMENT OF THE ANTIFRAUD STATUTES

The legislative history of the antifraud laws²⁴⁰ confirms Congress's intent to set forth an *exclusively public* administrative enforcement structure for the antifraud laws. That Congress contemplated solely public enforcement of the medical antifraud laws is obvious both from the plain language of each of the statutes and from the supporting Congressional documents. This Part explores this legislative history and concludes that the *qui tam* tainted claims pursued under the FCA are a significant departure from public enforcement of the anti-kickback and self-referral laws that

239. Kikkawa, *supra* note 230, at 106 (describing the simplistic common-law approach as "naïve" in its failure to distinguish "good violators" from "bad violators" who deliberately break the anti-kickback provisions with the primary intention of lining their own pockets).

240. BUCY ET AL., *supra* note 11, § 2.13[1], at 2-93 to -102; Durin B. Rogers, *The Medicare and Medicaid Anti-kickback Statute: "Safe Harbors" Eradicate Ambiguity*, 8 J.L. & HEALTH 223, 227-30 (1993-94).

Congress originally designed. The analysis in this Part concludes that by operating outside the administrative enforcement provisions conceived by the drafters of the antifraud statutes, tainted-claims prosecutors have entirely changed the public enforcement mechanisms enacted by Congress. These changes may ultimately impair the health care market, rather than contribute to the efficiency and cost-containment goals that Congress seeks to serve under the Medicare and Medicaid antifraud laws.

*A. The Legislative History of the Government's
Criminal Enforcement Authority Under
the Medical Antifraud Laws*

The anti-kickback statute, as first enacted by the Ninety-second Congress in 1972,²⁴¹ was a narrow provision, buried in a virtual tome of major legislative revisions to the Medicare, Medicaid, and federal welfare systems.²⁴² It punished as misdemeanors any bribes or kickbacks paid or received in connection with goods or services reimbursed by Medicare or Medicaid. Enforcement authority over the criminal provisions rested then, as it does today, with the DOJ.

Congress passed the first amendment broadening the anti-kickback statute in 1977.²⁴³ That legislation expanded the scope of prohibited criminal conduct under the Act to include “any remuneration” paid in exchange for referrals, including the bribes, kickbacks, and rebates specifically covered in the prior statute. The 1977 amendments also increased the criminal penalties under the law from misdemeanors to felonies, punishable by up to five years in prison and/or \$25,000 in fines.²⁴⁴ The expressed purpose of these 1977 amendments was to “strengthen the capability of the *Government* to detect, prosecute and punish fraudulent activities under the medicare and medicaid programs.”²⁴⁵ Similarly, with each successive amendment to the anti-kickback statute—whether the substantive purpose was to broaden the “any remuneration” language, to increase criminal penalties, or add a mens rea element—all have been focused on enhancing the authority of the federal and state government in administering the law. Although it has considered revisions, refinements, and amendments to the statute almost every year since its enactment, Congress has never considered ceding enforcement of the antifraud and abuse law

241. Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) (Medicare), 242(c) (Medicaid), 86 Stat. 1329, 1419 (1972) (codified as amended at 42 U.S.C. § 1320a-7b(b) (1994 & Supp. IV 1998)).

242. H.R. REP. NO. 92-231 (1972), reprinted in 1972 U.S.C.C.A.N. 4989, 4989-5400. The 1972 anti-kickback law was introduced with little explanation. In the legislative history of the bill, the law received only brief treatment; its discussion was less than one page out of the four hundred eleven pages dedicated to explaining that year's Social Security Act amendments. *Id.*

243. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179-83 (1977) (codified as amended at 42 U.S.C. § 1320a-7b(b) (1994 & Supp. IV 1998)).

244. Today, these criminal penalties have been rendered moot by the Federal Sentencing Guidelines which require/permit up to \$250,000 in penalties. U.S. SENTENCING GUIDELINES MANUAL § 2F1.1 (1998).

245. S. REP. NO. 95-453, at 1 (1977); H.R. REP. NO. 95-393, at 1 (1977) (emphasis added), reprinted in 1977 U.S.C.C.A.N. 3039, 3040.

to private citizens.

It is clear that Congress intended to delegate the job of controlling medical fraud and abuse primarily to the government, not to private individuals. For several reasons, this is a rational approach. Perhaps most importantly, centralizing enforcement of these statutes allows the government to coordinate civil and criminal enforcement provisions contained in the various antifraud statutes. Congress anticipated and legislated so that the civil and criminal enforcement efforts within the government would coordinate and not duplicate efforts to control fraud.²⁴⁶ For example, in 1977, Congress provided that until the DOJ had reviewed the claim for six months and declined to initiate criminal proceedings, the OIG was to refrain from civil prosecution of any claim referred from the DHHS. Only then might civil proceedings begin. As the health care industry has changed, the civil and criminal authorities delegated to the government have changed as well. These changes belie the wisdom of government oversight where anti-kickback and self-referral fraud cases are concerned.

First, the illegal activity at which the antifraud statutes are aimed is often and increasingly complex; fraudulent behavior is difficult to distinguish from legitimate business practices.²⁴⁷ Distinguishing illegal kickback arrangements from payment structures common to the intricate integrated delivery systems in today's market may turn only on details of separate fees earned and paid for different goods and services in a single transaction; a study of the fair market rates for similar goods and services in a given locale; or an examination of the parties' intent by reviewing each document involved in the transaction.

As originally enacted, the Secretary of the DHHS ("Secretary") had the authority to investigate thoroughly, the discretion to prosecute where transactions warranted, and the authority to tailor appropriate remedies and penalties in each case. The Secretary has sole authority to determine questions of fact, sanction procedural and evidentiary misconduct, and serve process. Finally, the statute provides judicial review of the Secretary's decisions, which may be directly appealed to the appropriate federal circuit court of appeals. Unbiased governmental discretion is essential to avoid prosecuting or chilling economically advantageous behavior in the health care market.

A second reason why governmental authority is appropriate to the task of prosecuting medical fraud is the public nature of the job. Originally, the objectives of the antifraud statutes were clearly to protect the public interest, both on behalf of program beneficiaries and to protect against the misuse of taxpayers' money.²⁴⁸ The

246. S. REP. NO. 95-453, at 43 (coordinating Department of Health, Education, and Welfare referral of suspects with DOJ authority to initiate criminal proceedings and the OIG's later residual authority to initiate civil proceedings).

247. Both the Senate and House committee reports spoke at length about the bills' aim to address practices of "factoring" (providers selling accounts receivables for collection by nonmedical providers); percentage lease arrangements; and other program abuses less clearly defined ("wherein providers, practitioners and suppliers of services operate in a manner inconsistent with accepted, sound medical or business practices resulting in excessive and unreasonable financial cost to either Medicare or Medicaid"). H.R. REP. NO. 95-393, at 48, *reprinted in* 1977 U.S.C.C.A.N. at 3050.

248. H.R. REP. NO. 95-393, at 44, 49, *reprinted in* 1977 U.S.C.C.A.N. at 3046-47, 3051-52

public nature of the enforcement task was reflected in the legislative history of the anti-kickback statutes. Moreover, the public nature was reflected in the fact that the enforcement effort was originally conceived as one which would work cooperatively with the medical profession in order to serve the best interests of patients. For example, when drafting early antifraud legislation, Congress placed a great deal of reliance on the fact that the medical profession itself had identified fraudulent business practices among its own members, deeming them “unethical” even before they became illegal.²⁴⁹ Additionally, governmental oversight of the prosecutorial effort reflects that Congress also anticipated coordination between federal and state enforcement authorities.²⁵⁰

As originally conceived, the objectivity of government enforcement efforts provided a third reason to prefer public over private enforcement of the antifraud laws. The enforcement effort was more likely to be focused on the public welfare rather than self-interested.²⁵¹ Finally, the original and early anti-kickback legislation made use of a wide variety of enforcement options available to the government. These options included disclosure and review controls imposed by professional-standards-review organizations, civil monetary penalties, criminal incarceration, and exclusion. The 1977 amendments not only broadened the substantive reach of the anti-kickback statute, but also strengthened the procedural provisions so that the state and federal authorities might effectively coordinate their antifraud activities to protect the public interest.²⁵² By 1977, the anti-kickback statute had evolved into a comprehensive arsenal of tools for experienced, public servants who were committed to protecting the public fisc and interest.

Two years later, in 1980, Congress actually narrowed the scope of the criminal anti-kickback statute by adding a mens rea requirement that changed the law from a strict liability provision to one requiring proof that defendants acted “knowingly and willingly” in order to impose liability.²⁵³ By this amendment, legislators sought to assure that inadvertent error would not be prosecuted as illegal activity under the anti-kickback statute.²⁵⁴ Also, in adding the mens rea requirement, Congress acknowledged that it was possible to violate the complex Medicare and Medicaid provisions without engaging in criminal conduct, and possibly without even engaging in conduct deemed actionable under the civil antifraud provisions. Nevertheless, Congress’s primary intent under the anti-kickback and civil antifraud statutes was to evaluate each case in light of its effect on the public fisc and the health care industry itself.

The 1980 amendments to the anti-kickback law, contained in the Omnibus

249. *E.g.*, 135 CONG. REC. 2035, 2036 (1989) (statement of Rep. Stark) (referring to the *New England Journal of Medicine*’s editor-in-chief’s criticism of self-referrals as well as similar pronouncements by the American Medical Association).

250. H.R. REP. NO. 95-393, at 50-51, *reprinted in* 1977 U.S.C.C.A.N. at 3052-54.

251. However, when HIPAA was enacted in 1996, the Control Account established by that legislation seriously compromised this objectivity. *See infra* Part VI.

252. Several reasons have been advanced to argue that private enforcement of the antifraud statutes is necessary. *See, e.g.*, Bucy, *supra* note 222, at 1020-22.

253. Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (codified at 42 U.S.C. § 1320a-7b(b) (1994)).

254. H.R. REP. NO. 96-1167, at 234 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5672.

Reconciliation Act, aimed principally at restraining growth in federal spending, eliminating the budget deficit, and controlling inflation.²⁵⁵ Congress amended the anti-kickback statute's mens rea requirement and enacted an array of other statutory provisions that enhanced the government's enforcement effort against medical fraud. These enhancements included disclosure and reporting requirements;²⁵⁶ authority to withhold future reimbursements;²⁵⁷ authority to conduct coordinated audits of providers;²⁵⁸ broader power available to DHHS officials to exclude violating providers and suppliers from all federal health programs;²⁵⁹ and federal matching funds to establish state Medicaid fraud control units.²⁶⁰ The 1980 amendments, therefore, not only addressed the scope of the government's penal authority, but went further to give the federal government's investigatory powers a variety of intermediate sanctions to combat Medicare and Medicaid fraud and a coordinated enforcement relationship with the states.

Congress next amended the anti-kickback statute in 1987. This amendment made three important changes to the core anti-kickback law that, in large part, remains much the same to date. First, Congress instructed the DHHS to promulgate guidelines called "safe harbors" that define which business practices are permissible under the statute and will not subject providers to prosecution or exclusion.²⁶¹ Next, Congress significantly broadened the offenses for which the exclusion sanction is available to the Secretary as an alternative to the Act's criminal penalties.²⁶² Thus, as of 1987, the OIG has both mandatory and discretionary authority to exclude a violator from participation in Medicare, Medicaid, and certain other federal block-grant social-services programs. Third, Congress combined the Medicare and Medicaid anti-kickback provisions into one statute.²⁶³

The legislative history of the anti-kickback law confirms Congress's intent to delegate the complex job of enforcing this statute to the DHHS, the OIG, and the U.S. Attorney, but not to private individuals. Therefore, private enforcement of the anti-kickback laws using the tainted-claims approach contradicts congressional intent.

255. *Id.* at 1, reprinted in 1980 U.S.C.C.A.N. at 5527.

256. *Id.* at 59-60, reprinted in 1980 U.S.C.C.A.N. at 5572-73.

257. *Id.* at 60, reprinted in 1980 U.S.C.C.A.N. at 5573.

258. *Id.* at 63-64, reprinted in 1980 U.S.C.C.A.N. at 5576-77.

259. *Id.* at 142, reprinted in 1980 U.S.C.C.A.N. at 5593.

260. *Id.* at 152, reprinted in 1980 U.S.C.C.A.N. at 5942.

261. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (codified as amended at 42 U.S.C. § 1320a-7b(b)(3)(E) (Supp. IV 1998)); S. REP. NO. 100-109, at 4-14 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 707-708.

262. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 2, 101 Stat. 680, 680 (codified as amended at 42 U.S.C. § 1320a-7 (1994 & Supp. IV 1998)) (adding mandatory exclusion provisions for nonprogram offenses, violation of state Medicaid provisions, and other criminal convictions, and also adding permissive exclusions for fraud and controlled-substance or obstruction-of-investigation convictions); S. REP. NO. 100-109, at 4-14, reprinted in 1987 U.S.C.C.A.N. at 685-695.

263. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 4(a), 101 Stat. 680, 689 (codified as amended at 42 U.S.C. § 1320a-7b(b) (1994 & Supp. IV 1998)); S. REP. NO. 100-109, at 17, reprinted in 1987 U.S.C.C.A.N. at 698.

The analysis of the self-referral laws is similar to that of the anti-kickback statutes. Congress enacted the self-referral laws in 1989. These new rules passed as an addition, refinement, and correction to perceived loopholes in the existing anti-kickback statute.²⁶⁴ Therefore, the self-referral rules were intended as an addendum to the government's existing antifraud weapons. The same administrative structure and enforcement tools that were in place for civil enforcement under the anti-kickback law were to apply to the newly enacted self-referral law.

Representative Stark introduced the self-referral legislation by first recalling the "sweeping law" that made payment of kickbacks illegal.²⁶⁵ Although the anti-kickback law was ten years old at the time, it reflected what Representative Stark called "a firm resolve that patients should not be bought or sold."²⁶⁶ Yet, the anti-kickback law had failed to address self-referrals. According to Representative Stark, "the Ethics in Patient Referrals Act, [was intended to] close these loopholes once and for all."²⁶⁷ The self-referral law was intended to ease the prosecutorial burden associated with the mens rea element of the anti-kickback law. Representative Stark introduced the self-referral law as a solution to the "enormous difficulty" of investigating and proving deliberateness under the anti-kickback statute.²⁶⁸ Importantly, Representative Stark made specific reference to the practical limitations the government faced in fighting medical fraud. Representative Stark acknowledged that the value and complexity of self-referral arrangements were well beyond the enforcement capability of the OIG's nationwide staff of 225 individuals.²⁶⁹ Yet, despite this shortcoming, two things are notable. First, Representative Stark did not mention or seek to resort to any other enforcement authority, even in light of the personnel shortage the government faced in 1989. Second, when Congress crafted a solution to the problem of being outnumbered, it did not enlist the help of private prosecutors. Congress did not create a private cause of action under either the self-referral or anti-kickback law, even when it realized the government needed help to prosecute these laws. Instead, Congress decided that by passing clear, unequivocal civil standards with substantial civil penalties, the self-referral law would draw a "bright line" rule to guide physicians. Representative Stark announced, "if the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law."²⁷⁰ From the outset, Congress's considered judgment was not to enlist the aid of private prosecutors to enforce the antifraud laws.

The anti-kickback and self-referral laws have both been amended numerous times since their enactment.²⁷¹ Most recently, Congress reformed the health fraud laws in

264. 135 CONG. REC. 2035 (1989).

265. *Id.*

266. *Id.*

267. *Id.*

268. *Id.*

269. *Id.*

270. *Id.*

271. By June 2001, the DHHS is expected to announce a final rule refining the Stark II self-referral law. *Rulemaking: Stark II Final Rules Expected Shortly, BBA Rules Still in Pipeline Agenda Says*, 9 Health Law Rep. (BNA) 1820 (Dec. 7, 2000). Although that regulatory announcement is expected to clarify the self-referral rules, it does not appear to include any

1996 with the HIPAA. The HIPAA establishes what Congress has called a "national health care fraud and abuse control program."²⁷² Congress described the purpose of this new program: "to coordinate Federal, State and local law enforcement to combat health care plan fraud."²⁷³ Congress elaborated:

A multiplicity of Federal, State and local law enforcement agencies, as well as private health insurers and health plans, are involved in various aspects of the investigation and prosecution of health care fraud. It is crucial that these efforts be as coordinated as possible in order to detect, prevent, and successfully prosecute health care fraud and abuse.²⁷⁴

This language again reiterates the very public nature and priority placed on the government's administrative enforcement of the antifraud laws. While private insurers contribute investigative support to the enforcement effort, no other private parties are mentioned.

The HIPAA expanded the administrative responsibilities of the government, adding, for example, the duty to maintain a national fraud data bank²⁷⁵ and new obligations to educate providers by publishing advisory opinions, special fraud alerts, guidelines and interpretive opinions.²⁷⁶ The 1996 Act also enhanced the government's enforcement capability with broader investigatory and audit authority²⁷⁷ and an expanded range of intermediate sanctions and monetary penalties for a wide variety of providers and situations.²⁷⁸ Importantly, through the HIPAA, Congress amended the intent standard in the Civil Monetary Penalties Law to conform that law to the FCA.²⁷⁹

Without question, the congressional intent in 1996 was to widen and coordinate the government's various efforts to combat medical fraud. However, it is most notable that in all the discussion of statutory revision, even the amendment that specifically referred to the FCA, Congress made no mention and did not even acknowledge a place for private-party enforcement of the antifraud statutes.

It is important to note that with each successive amendment to the antifraud statutes, not only the government's enforcement authority has been expanded, but also its responsibility to educate and communicate with the health care community. Congress has conceived a medical antifraud program that requires more than the

reference to any private cause of action under this statute. *Id.*

272. H.R. REP. NO. 104-496, at 67 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1866.

273. *Id.*

274. *Id.* at 79, *reprinted in* 1996 U.S.C.C.A.N. at 1878-79.

275. *Id.* at 92-93, *reprinted in* 1996 U.S.C.C.A.N. at 1892-94.

276. *Id.* at 84-85, *reprinted in* 1996 U.S.C.C.A.N. at 1884-85.

277. *Id.* at 79-80, *reprinted in* 1996 U.S.C.C.A.N. at 1879-80.

278. *Id.* at 89-90, *reprinted in* 1996 U.S.C.C.A.N. at 1889-90.

279. *Id.* at 95-96, *reprinted in* 1996 U.S.C.C.A.N. at 1896-97.

The current standard of "knows or should know" is inconsistent with the Civil False Claims Act which applies to all other federal programs.

. . . The requirement that a person "knowingly" presents a claim or "knowingly" makes a false or misleading statement which influences discharge would prevent charging persons who inadvertently perform these acts.

Id. at 96, *reprinted in* 1996 U.S.C.C.A.N. at 1896-97.

simple “cookbook” statutory application. The complexity and flexibility of these laws particularly make enforcement of the health care antifraud provisions first and foremost the purview of the state and federal government. At no time has Congress sanctioned private enforcement of these statutes. To the extent that the tainted-claims approach does so, it is contrary to Congress’s intent.

*B. The Government’s Primary Jurisdiction over
Kickback and Self-Referral Cases*

The government agencies that Congress intended to control enforcement of the anti-kickback and self-referral laws have lost control. They no longer control the selection of targets, extent of investigations, terms of settlement, theories of recovery, and other aspects of case management. These decisions have been ceded to private parties under the *qui tam* provisions of the FCA. The result is a chaotic departure not only from Congress’s original objectives in enacting fraud and abuse law—making the application of these laws expensive both in financial and administrative terms—but also, perhaps more seriously, a departure from well-settled principles that allocate the balance of power between the judiciary and administrative agencies.

The doctrine of primary jurisdiction instructs that where an agency’s determination lies at the heart of Congress’s assignment to the agency; where the agency’s expertise is required to decide intricate, technical facts; and where an agency’s determination would materially aid the court, then the court should defer—or at least stay—its proceedings until the controlling agency has resolved a commercial dispute delegated by Congress to that administrative procedure.²⁸⁰

The civil enforcement of the Medicare and Medicaid antifraud statutes lies at the heart of the mission delegated to DHHS’s OIG. The OIG was created in 1972, during the same year and as a part of the same legislation as the Medicare and Medicaid anti-kickback statutes themselves.²⁸¹ A presidential appointee, the Inspector General (“IG”) originally had only general oversight responsibility for the federal health programs and authority to temporarily suspend providers’ inefficient or uneconomic activities.²⁸² Today, however, Congress has significantly expanded the OIG’s

280. The requirement that parties “exhaust all administrative remedies” before proceeding to litigation is distinguishable from the doctrine of primary jurisdiction. The former applies where a claim is cognizable in the first instance by an *administrative agency* alone; judicial interference is withheld until the administrative process has run its course. “Primary jurisdiction,” on the other hand, applies where a claim is originally cognizable in the *courts*, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views. . . .

United States v. W. Pac. R.R. Co., 352 U.S. 59, 63-64 (1956) (emphasis added).

281. See H. R. REP. NO. 92-231, at 66 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4889, 5382-83.

282. “The Inspector General . . . would be responsible for reviewing and auditing the Social Security health programs on a continuing and comprehensive basis to determine their

authority through the Secretary. With the Secretary's approval, the IG has the authority to serve process on providers under the Federal Rules of Civil Procedure 4,²⁸³ conduct administrative hearings to determine whether violations have occurred, and administer a wide range of administrative sanctions from fines to exclusion.²⁸⁴ At the heart of the IG's mission is the responsibility to determine whether the civil provisions of the anti-kickback statute and the self-referral provisions have been violated.

The transactional approach²⁸⁵ that Congress has taken to regulating Medicare and Medicaid fraud has resulted in an intricate and highly technical network of safe-harbors, statutory exemptions, and exceptions to the anti-kickback and self-referral prohibitions. These rules describe transactions that appear on their face to involve a straight-forward application of contract and commercial law. However, under current law, they can expose participants to felony convictions and significant sanctions if those participants fail to comply with the precise terms of safe-harbor or exclusionary provisions. Certainly, the expertise of the agencies to which Congress delegated authority to prosecute kickback and self-referral fraud is essential to the proper resolution of each case and to the continued development of a competitive market for health care. An illustration will be instructive.

Assume that a cardiologist is treating an elderly Medicare patient's heart arrhythmia. Assume further that this physician belongs to a large, integrated network of physicians and hospital providers. She wants to refer her patient to a cardiothoracic surgeon within the same group practice to be considered for possible in-patient surgery at the network hospital. Assume also that the cardiologist wishes to refer to this network surgeon because she believes that he will provide the highest quality, most cost-effective care for her patient. These two physicians have developed a working relationship because the surgeon stays current on medical developments, incorporates new techniques into his practice, communicates with referring physicians easily, interacts well with families, and participates actively in the postoperative care of his patients. In short, assume this surgeon provides superior care.

However, to avoid criminal and civil penalties for this referral, the cardiologist must comply with the statutory exclusion for investments in group practices under the anti-kickback statute and with both the "group practice" and "in-office ancillary services" exceptions under the self-referral law. These regulations implicate two entirely separate bodies of statutory, regulatory, and common law; each must be satisfied independently to avoid liability. This one patient referral will implicate virtually every conceivable aspect of the cardiologist's and surgeon's practices.

The practice patterns of each physician must comply with the self-referral law. Group members must provide a full range of professional service within their group. No less than seventy-five percent of the group's services must be provided by the members themselves. All other services must be supervised by a member of the

efficiency, economy and consonance with the Statute and Congressional intent." *Id.*

283. 42 U.S.C. § 1320a-7a(c)(1) (1994).

284. *See supra* note 151.

285. Hall, *supra* note 177, at 626 (calling the exceptions that list narrow individual transactions as exempt from a blanket prohibition as the "transactional approach").

group. The group's handling of its real property, personnel, and assets must comply with the law. Each member must share office space, equipment, and personnel. Moreover, the hospital where the surgery is performed must be a place that also provides services unrelated to those the hospital provides to the group. The providers' billing procedures and financial management must follow the self-referral law's requirements. The group must use a single Medicare billing number and must have collectively established their income and expense distribution methods. Certainly, no group member's compensation may depend in any way upon volume or number of referrals.²⁸⁶

The cardiologist must also be sure that her investment in the integrated group practice meets the criteria set forth in the anti-kickback statute. All equity interests in the group must be held by licensed professionals practicing in the group and must be held in the group itself, not in a subdivision. Also, profit distributions must derive only from "in-office ancillary services" as defined under the self-referral law.²⁸⁷ If the cardiologist fails to satisfy any one of these requirements and yet files a request for Medicare reimbursement for services to this patient, then under *Pogue*,²⁸⁸ *Thompson*,²⁸⁹ and their progeny, the cardiologist is at risk for being named a defendant in a tainted-claims lawsuit under the FCA and faces possible civil penalties, administrative fines, exclusion, or jail time. Moreover, since the majority of physicians deliver medical services within group practices such as the one in this example, the treatment this one transaction receives could have far-reaching effects in the marketplace. Arguably, in light of the breadth of the core anti-kickback and self-referral statutes, the complexity of the relevant network of rules that limit their reach, the enormous degree of prosecutorial discretion the current law requires, and the special factual considerations unique to the health care market and each transaction within it, no court should entertain a tainted-claims case until after the OIG or the DOJ has first exercised primary jurisdiction under the criminal and administrative provisions of the prevailing antifraud laws.²⁹⁰

286. See 42 U.S.C. § 1395nn (1994 & Supp. IV 1998)

287. Clarification of the Initial OIG Safe Harbor Provisions Under the Anti-kickback Statute, 64 Fed. Reg. 63,518, 63,540 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952 (2000)) (describing group practice investment safe harbor).

288. United States *ex rel.* Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507, 1509-13 (M.D. Tenn. 1996); see *supra* text accompanying notes 46-63 and accompanying text.

289. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 900-03 (5th Cir. 1997); see *supra* notes 64-90 and accompanying text.

290. As another example, suppose a drug manufacturer seeks to offer a volume discount to make itself an attractive supplier to a large, integrated network of health providers who serve Medicare and Medicaid beneficiaries. The network of antifraud provisions that control this discount is mind-boggling. First, to avoid a felony conviction, the manufacturer must conform its discount to the statutory exemption under 42 U.S.C. § 1320a-7b(b)(3)(A) (1994 & Supp. IV 1998). The discount must be prospective, not retrospective, although the industry practice might be otherwise. *Id.* § 1320a-7b(b)(2), (3)(C)(i). The discount must not be tied to the volume of product the purchaser prescribes to patients, although, if carefully constructed, the discount may vary with the amount of drugs the purchaser buys. *Id.* § 1320a-7b(b)(3)(C)(i). The manufacturer must determine whether its purchaser will buy directly from the manufacturer or through a group purchasing contract. In either event, the manufacturer must file disclosures

Although the anti-kickback and the self-referral laws are comprehensive, nothing in the plain language or legislative history of either statute reveals an express congressional intent to make these statutes the exclusive remedies for the fraudulent conduct they regulate.²⁹¹ Neither does the congressional record appear to support any argument that the more precisely drawn antifraud statutes preempt the more general remedies available under the FCA.²⁹² Therefore, the salient question is not whether the FCA can be used to prosecute medical fraud cases, but how to properly allocate shared administrative and judicial authority over anti-kickback and self-referral cases.

The doctrine of primary jurisdiction supplies the answer. In *United States v. Western Pacific Railroad Co.*,²⁹³ the U.S. Supreme Court explained that the primary jurisdiction doctrine “‘allocat[es] the law-making power over certain aspects’ of commercial relations. It transfers from court to agency the power to determine some of the incidents of such relations.”²⁹⁴ In *Western Pacific* three railroad companies sued to recover higher tariffs from the U.S. government, which had transported aerial bomb cases filled with napalm gel.²⁹⁵ The dispute centered on whether the

in compliance with reporting rules under 42 U.S.C. § 1320a-3 and § 1320a-3a, also known collectively as the “Medicaid Rebate” statute. That law, and its accompanying regulations, require the manufacturer to pay the state Medicaid program a rebate, each quarter, in order for a state to receive federal funds to pay for prescription drugs purchased for Medicaid beneficiaries. *Id.* §§ 1320a-3, 1320a-3a. If the network uses a group purchasing agent, then the manufacturer’s discount must be pursuant to a written contract, which specifies the value of the purchase by each entity or individual in the network, *id.* § 1320a-7b(b)(3)(C)(i), and must otherwise comply with the group purchasing exception to the anti-kickback statute contained in 42 U.S.C. § 1320b-7b(b)(3)(C). To the extent that the purchasing network includes physicians, they will, of course, comply with 42 U.S.C. § 1395nn to assure no financial relationship exists between themselves and the manufacturer in our example.

291. *See, e.g.*, *United States v. Gen. Dynamics Corp.*, 19 F.3d 770, 770 (2d Cir. 1994) (holding that the anti-kickback act of 1986 does not preempt the government’s FCA action to recover cost of kickbacks that tainted construction differential subsidy applications). Although the underlying statute is not identical to those in the Medicaid/Medicare fraud cases, the government in that case bypassed the underlying kickback statute in favor of prosecuting under the FCA. Defendants argued that the FCA’s application was preempted by the anti-kickback act. The court rejected this claim for reasons that would similarly apply to a Medicare/Medicaid anti-kickback or self-referral case prosecuted under the FCA. *See, e.g.*, *United States ex rel. Mikes v. Straus*, 78 F. Supp. 2d 223, 224-26 (S.D.N.Y. 1999) (denying a motion to reconsider the holding that antifraud remedies under the Social Security Act preempt FCA liability); *see also United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485, 1489 (1996) (declining to hold that the comprehensive antifraud regulatory scheme precludes an FCA suit).

292. *But cf. Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 828-29 (1976) (holding that the legislative history of section 717 of the Civil Rights Act of 1964 indicated Congress’s intent “to create an exclusive, pre-emptive administrative and judicial scheme for the redress of federal employment discrimination”).

293. 352 U.S. 59 (1956).

294. *Id.* at 65 (quoting Louis L. Jaffe, *Primary Jurisdiction Reconsidered*, 102 PA. L. REV. 577, 584 (1954)).

295. *Id.* at 60.

government should have paid the higher tariff rate for “incendiary bombs” or the lower rate for gasoline.²⁹⁶ Holding that the issues of tariff construction and the reasonableness of tariffs were matters for the Interstate Commerce Commission to determine, the Court reasoned that where the tariff in question required technical interpretation of extrinsic evidence, and where the inquiry required the expert agency’s exercise of discretion in technical matters, then the doctrine of primary jurisdiction required the federal courts to stay their proceedings until the issue first went to the controlling agency.²⁹⁷

A similar deference to administrative primary jurisdiction applies even in *qui tam* cases brought under the FCA. In *United States ex rel. Plumbers and Steamfitters Local Union No. 342 v. Dan Caputo Co.*,²⁹⁸ the Ninth Circuit held that a district court should have stayed its proceedings in a dispute over employee wages.²⁹⁹ In that case, the court cited a Virginia district court’s decision to hold that the issue of wage classification under the Davis-Bacon Act is properly within the purview of the Department of Labor under the doctrine of primary jurisdiction.³⁰⁰ Relying upon cases analogous to the medical antifraud cases, the *Caputo* court reasoned that “[t]o permit [plaintiff’s] claim to go to a jury would result in bypassing the carefully crafted administrative scheme for resolving Davis-Bacon Act classification disputes.”³⁰¹

The U.S. Supreme Court decision in *United States Navigation Co. v. Cunard Steamship Co.*³⁰² is also instructive. There, the plaintiff shipping company sought an injunction against defendant-corporations, alleging they violated the Sherman Antitrust Act’s prohibitions against unfair restraints on trade.³⁰³ The plaintiff in *Cunard* had not, however, raised the matter before the administrative agency—the U.S. Shipping Board—authorized by Congress under the Shipping Act to determine what trade practices were unfair or discriminatory.³⁰⁴ The Supreme Court held in *Cunard* that the doctrine of primary jurisdiction required the district court to defer reaching any conclusion on the plaintiff’s antitrust claims until after the Shipping Board had exercised its “exclusive preliminary jurisdiction”³⁰⁵ to consider the alleged unfair practices at bar. The *Cunard* Court explained:

Whether a given agreement among such carriers should be held to contravene the [Shipping] act may depend upon a consideration of economic relations, of facts peculiar to the business or its history, of competitive conditions in respect of the shipping of foreign countries, and of other relevant circumstances, generally unfamiliar to a judicial tribunal, but well understood by an administrative body especially trained and experienced in the intricate and technical facts and usages

296. *Id.* at 66-68.

297. *Id.* at 66, 70.

298. 152 F.3d 1060 (9th Cir. 1998).

299. *Id.* at 1061-62.

300. *Id.* at 1062.

301. *Id.* at 1062 (quoting *United States ex rel. Windsor v. DynCorp., Inc.*, 895 F. Supp. 844, 852 (E.D. Va. 1995)).

302. 284 U.S. 474 (1932).

303. *Id.* at 478.

304. *Id.* at 478-79.

305. *Id.* at 485.

of the shipping trade; and with which that body, consequently, is better able to deal.³⁰⁶

The *Cunard* Court's reasoning applies with equal weight to the health care transactions in kickback and self-referral cases. In both instances, facts peculiar to the competitive conditions in a unique market, as well as technical terms under an industry-specific statute, make the government's administrative officials better able to construe and enforce the law.

More recently, in *Ricci v. Chicago Mercantile Exchange*,³⁰⁷ the Supreme Court again applied the primary jurisdiction doctrine to dismiss a claim brought by the government against the Chicago Mercantile Exchange and a trading company until administrative officials had the opportunity to act.³⁰⁸ *Ricci* is particularly instructive because it involves the interaction between two federal statutes, one broad in its reach and another more narrow. This statutory relationship is similar to the broad health care antifraud statutes and the narrow exceptions that limit them.

In *Ricci*, the Sherman Antitrust Act³⁰⁹ contained the relevant broad controlling prohibitions. The *Ricci* plaintiff alleged the defendants violated the Sherman Antitrust Act by conspiring to remove the plaintiff from the Chicago Mercantile Exchange.³¹⁰ However, another act of Congress—the Commodity Exchange Act³¹¹—contained narrow regulations that, in some instances, immunized certain trade agreements from prosecution under the antitrust law. Congress had delegated the administration of these regulations to the Commodities Exchange Commission (“CEC”). The Supreme Court approved the issuance of a stay to suspend the antitrust case, pending administrative proceedings before the CEC to resolve issues within that agency's primary jurisdiction.³¹² For its holding, the Court cited three reasons that also apply to anti-kickback and self-referral claims under the FCA.

First, in these cases where the general prohibitions of the anti-kickback and self-referral laws may immunize certain commercial conduct by health providers from prosecution, “it [is] essential for the [fraud and abuse] court to determine whether the [safe harbors or statutory exceptions] are ‘incompatible with the maintenance of [a FCA] action.’”³¹³ Second, Congress has placed some facets of the antifraud effort squarely within the statutory jurisdiction of the DHHS and the DOJ.³¹⁴ Third, agency adjudication of the anti-kickback and self-referral disputes will materially aid in resolving the question of whether an FCA violation has occurred. In fact, no tainted-claim action exists apart from a prior finding that the underlying fraud statute has been violated. The U.S. Supreme Court has said, in a case analogous to those at issue here, that the primary jurisdiction to make that prior finding rests with the agencies,

306. *Id.* at 485.

307. 409 U.S. 289 (1973).

308. *Id.* at 302.

309. 15 U.S.C. §§ 1-7 (1994).

310. *Ricci*, 409 U.S. at 291.

311. Commodity Exchange Act, ch. 369, 42 Stat. 998 (1922) (codified as amended at 7 U.S.C. §§ 1-25 (1994)).

312. *Ricci*, 409 U.S. at 302.

313. *Id.* (quoting *Silver v. N.Y. Stock Exch.*, 373 U.S. 341, 358 (1963)).

314. *See supra* Part III.

not with the courts.³¹⁵

Some have argued that the doctrine of primary jurisdiction complicates and increases the cost of settling disputes and deprives citizens of access to the courts.³¹⁶ These arguments, if persuasive, are properly made before Congress in urging it to repeal the intricate administrative structure and authority embodied in the anti-kickback and self-referral statutes and regulations.³¹⁷

Perhaps the most persuasive reason in favor of honoring Congress's intent to delegate antifraud enforcement to the DOJ and DHHS would be the simplest. By virtue of the training and expertise of its personnel, the government is better positioned to examine the economic details of each transaction and to interpret the nuances of each regulatory exception as it applies in each case. This approach is preferable to the "one size fits all" tainted-claims rules courts such as *Pogue* and *Thompson* have devised; their rule results in a creative but erroneous body of law.

Having established the government's primary jurisdiction over fraud and abuse claims, one important problem remains. Even if exclusive authority to enforce the antifraud laws was returned to the government, current laws still expose public officials to financial incentives that significantly distort the exercise of prosecutorial and administrative discretion. The next Part explores this ethical problem.

315. See *Far E. Conference v. United States*, 342 U.S. 570, 573 (1952) (dismissing an antitrust suit brought by the government to give the Federal Maritime Board the primary opportunity to grant immunity for defendants' conduct under the Shipping Act, 46 U.S.C. app. §§ 801-842 (1994)). Courts in both civil and criminal medical fraud cases should defer to the DHHS to apply the network of exceptions, exclusions, and safe harbors to medical transactions before proceeding against providers in kickback and self-referral cases. That agency's specialization and experience better equip it to evaluate transactions in the health care industry and to determine its true economic effect.

316. See *Ricci*, 409 U.S. at 320 (Marshall, J., dissenting).

317. Similarly, other objections to application of the primary jurisdiction doctrine are either inapposite to these antifraud cases, or are more properly put before the legislative branch that granted primary jurisdiction to the agencies in the first place. Cf. *United States ex rel. Johnson v. Shell Oil Co.*, 34 F. Supp. 2d 429, 433 (E.D. Tex. 1998) (denying defendant's motion to dismiss because primary jurisdiction deferral would unnecessarily prolong resolution of dispute); *United States ex rel. Haskins v. Omega Inst., Inc.*, 11 F. Supp. 2d 555, 561 (D.N.J. 1998) (denying deferral where qui tam plaintiff would have no alternate recovery if proceeding was deferred to Department of Education); *United States v. Inst. of Computer Tech.*, 403 F. Supp. 922, 924-25 (E.D. Mich. 1975) (denying deferral where real party in interest in judicial proceeding was the agency before whom a deferred case would be heard).

VI. THE ETHICAL PROBLEM: FINANCIAL INCENTIVES TO
PROSECUTE MEDICARE AND MEDICAID FRAUD
UNDER THE FALSE CLAIMS ACT

Significant financial incentives for private prosecutors are built into the qui tam provisions of the FCA. Similarly, substantial financial incentives are available to government prosecutors from the Control Account.³¹⁸ The FCA pays private plaintiffs a percentage share of the damages and settlements collected from defendant-providers. That share can be as large as thirty percent of collected funds. Government prosecutors can access a percentage share of the damages and settlements they collect to finance their future antifraud enforcement efforts from the FCA. Whether it is the qui tam relator's share of damages under the FCA or the public prosecutor's interest³¹⁹ in being credited with depositing funds into the Control Account, both interests represent financial incentives that have the potential to distort exercises of public and private prosecutorial discretion. These financial incentives are of particular concern where the FCA is used to prosecute kickbacks or self-referral fees because the incentives themselves are "kickbacks" payable to prosecutors for targeting medical providers. Ironically, these financial incentives arguably pose the same threat to prosecutorial discretion, as prosecutors claim self-referral fees pose to providers' medical judgment. This Part explores the effect of financial incentives first on public and then on private prosecutors proceeding against health care providers in the tainted-claims cases.

A. The Health Care Fraud and Abuse-Control Account

Title II of the HIPAA³²⁰ represents, by far, the most comprehensive and far-reaching amendment to the government's authority to combat health care fraud and abuse. The HIPAA Fraud and Abuse Control Program ("Program") brought important and much needed resources to the government's effort to combat health care fraud. The Program introduced by the 1996 law has resulted in increased cooperation and coordination between state, local, and federal government agencies. It has also given the government access to potent investigatory tools, broader

318. This fund, created as part of the HIPAA, allows government prosecutors to reap financial benefits from the penalties and settlements providers pay as the result of fraud and abuse actions. The fund is financed with penalties, settlements, and forfeitures collected from providers investigated and/or prosecuted by the government. *See* 42 U.S.C. §§ 1320a-7a, 1395(j)(5)(3)(ii) (1994 & Supp. IV 1998). Prosecutors do not directly spend the same dollars collected from enforcement on future enforcement efforts. Enforcement collections are first deposited into the Trust Fund, along with millions of other revenue dollars. This intermediate step, however, is unlikely to "purge" the collected funds of their taint before they are sent to fund the Control Account. The fact remains, that prosecutors may draw from the Control Account to fund their future prosecutorial efforts.

319. Public prosecutors do not have a direct personal interest in funds deposited into the Control Account from their prosecutorial effort, but they do have an interest in the size of the Control Account as a measure of their professional success and as a source of financing for future professional endeavors.

320. 42 U.S.C. § 300gg (Supp. IV 1998).

sanction and penalty provisions, and more open lines of communication between the government and industry. Importantly, the Program has also brought substantial financial resources to bear on the problem of health care fraud.

Congress created the Control Account as part of the HIPAA legislation that introduced the Program.³²¹ Beginning in fiscal year 1997, HIPAA now requires the government to deposit the proceeds from criminal fines, judgments, settlements, and forfeitures in health fraud cases into the Trust Fund, which in turn finances the Control Account. In addition to appropriations from the nation's general revenue fund, the Control Account itself is financed with "monies derived from the coordinated health care anti-fraud and abuse programs; from the imposition of civil money penalties, fines, forfeitures, and damages assessed in criminal, civil, or administrative health care cases; along with any gifts or bequests would be transferred into the [Control Account]."³²² The Control Account's funds are shared each year, with appropriations available for the Secretary, the Attorney General, the FBI, and state Medicaid fraud control units. Put succinctly, the more the government collects, the more it has to spend.³²³

The ironic query, of course, is whether the Control Account exposes those in the government who prosecute the broad anti-kickback and self-referral laws, to the same "corrupting influence[s] of money"³²⁴ as the government is seeking to "curtail" in the health care industry. The empirical evidence strongly suggests that the answer to this question is "yes."

B. The Effects of Financial Incentives on Public Prosecutors in Health Fraud Cases

The Control Account creates a significant ethical problem. By establishing the Control Account, Congress has exposed the government's antifraud enforcement officials to the same financial incentives that have driven private qui tam plaintiffs to expand the law in order to serve their financial self-interest. The amount of money

321. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 201(b), 110 Stat. 1936, 1993 (codified as amended at 42 U.S.C. § 1398i (1994 & Supp. IV 1998)).

322. See 42 U.S.C. 1395i(k) (Supp. IV 1998).

323. While Congress has set the amounts appropriated to the Control Account under HIPAA in 42 U.S.C. § 1395i(k)(2), not only are these appropriations funded by the government's antifraud efforts, but the government tracks each enforcement agency's contributions into the Trust Fund, publishing each year's "Monetary Results" and accomplishments for each enforcement agency right next to each agency's appropriated allocation for the year. See 1999 FRAUD ANNUAL REPORT, *supra* note 12. Moreover, Congress has specified the amounts annually appropriated to fund future enforcement efforts through fiscal year 2002. See 42 U.S.C. § 1395i(k)(3). Certainly if the DOJ, OIG, and other government prosecutors failed to raise sufficient funds from antifraud cases, then deposits from the Trust Fund into the Control Account would fall short and Congress would have to look elsewhere to meet this statutory obligation. However, as long as the government's prosecutorial effort continues to be profitable, under this statute, it is also self-funded.

324. OIG Fact Sheet, *supra* note 158, <http://www.dhhs.gov/progorg/oig/ak/safefs.htm>.

at issue in the Control Account annually is not insignificant;³²⁵ thus, the extent of the financial incentives is great. The result is that the government has lost the objectivity that peculiarly equipped it to enforce the complex antifraud statutes. The influence of these financial incentives on government prosecutors does, however, explain two otherwise puzzling aspects of the government's recent antifraud enforcement efforts. First, the presence of financial incentives offers an explanation for the reason the government is pursuing increasingly aggressive and arguably questionable theories of recovery against health care providers in anti-kickback and self-referral cases.³²⁶ Second, these financial incentives shed light on the peculiar alliance between government prosecutors and qui tam relators. This section considers each of these issues respectively.

The tainted-claims approach initially appeared to be the creation of private plaintiffs. However, more recently, government officials have cooperated in and even initiated cases based upon this distorted theory of recovery.³²⁷ The financial incentives created by the Control Account explain the government's role in the tainted-claims quagmire.

These incentives influence public prosecutors to advance increasingly aggressive theories of recovery because of the prospect of sharing in the financial reward of such cases. For example, the OIG recently announced that its antifraud enforcement will extend beyond billing and coding issues into challenging providers' "medical necessity" decisions.³²⁸ The danger presented by applying the tainted-claims theory to medical necessity cases is that government law enforcement officials, with no medical training, will aggressively seek to criminalize and penalize health care providers' medical-treatment decisions, motivated in part, at least, by their interest in increasing deposits into the Control Account. This effort will significantly compromise the quality of medical decisionmaking in most cases.

The effect of financial incentives on government officials is empirically demonstrable. Under the HIPAA, the DHHS must report annually on the status of the Control Account.³²⁹ The annual report for the fiscal year of 1999 reveals the

325. For fiscal year 1999, the respective "draws" from the Control Account by agency were reported as follows: DHHS, \$90 to \$100 million; DOJ, \$32 million; FBI, \$66 million; and Health Care Financing Administration, \$550 to \$560 million. Jost & Davies, *supra* note 211, at 239.

326. Certainly, the presence of financial incentives is not the only explanation for the government's interest in pursuing these claims. For other explanations, including the lower burden of proof under the FCA, deeper pockets making actions against health care providers "viable" and the help from "insiders" that comes from qui tam relators in prosecuting complex medical fraud cases, see Bucy, *supra* note 31, at 58.

327. See *supra* Part III.

328. To date, these medical necessity claims have been unsuccessful in tainted-claims cases. See *United States ex rel. Thompson v. Columbia HCA/Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997). *But see* Ken Blickenstaff, *Strong Medicine: The Evolution of Healthcare Fraud Enforcement*, *ADVOCATE*, Sept. 1999, at 16 (discussing the government's new investigative methods). Blickenstaff concludes "providers should take note that doctors' orders are no longer considered sacred ground." *Id.*

329. Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320a-7c (Supp. IV 1998).

productive use to which the Control Account funds have been put and the success of the Program. However, the report also sheds light on a perplexing mystery: the anomalous relationship between public and private enforcers of the antifraud laws. Given that the plain language and legislative history of the antifraud statutes provide clear evidence that Congress did not intend private enforcement of the anti-kickback and self-referral laws, it is unclear why the government continues to support qui tam enforcement of these statutes under the FCA.

Several explanations are possible. Perhaps government needs the help of private prosecutors in identifying cases of fraud.³³⁰ This is possible but unlikely. The United States declines to intervene in the vast majority of health care fraud cases brought by qui tam relators, and the vast majority of those cases pursued by qui tam plaintiffs alone are dismissed.³³¹ It appears, therefore, that the government views much of the help that it receives from qui tam relators in uncovering actionable fraud as not very helpful at all. Another possibility is that the government regards qui tam relators as cooperative colitigants who bring much to the table in fraud cases. However, the increasing amount of litigation between the government and relators betrays the conflict of interest between these private and public prosecutors.

Borrowing some concepts from public-choice theory helps to explain this peculiar alliance. Generally, public-choice theory takes what Farber and Frickey have called a "jaundiced view of legislative motivation."³³² Government actors are not presumed to work for the public good under this view, but rather "government is merely a mechanism for combining private preferences into a social decision."³³³ The theory contends that legislators seldom, if ever, act solely to serve either the public will or the public good. Instead, they work to serve their own self-interest.

Although public-choice theory is a model about legislative processes, it also sheds light on problems in political systems. In this section, the theory proves to provide the most likely explanation for the government's continued tolerance of the influence qui tam relators exert over anti-kickback and self-referral law enforcement.³³⁴ Despite the detrimental effect private prosecutors have had in creating an expansive theory of tainted-claims recovery, the fact is that the qui tam relators serve the government prosecutors' self-interest. This section contends that public prosecutors' zeal for the tainted-claims approach is based on their rent-seeking desire to increase the size of the Control Account, as well as their reputational interests that flow from this achievement, rather than on the desire to serve the public good.³³⁵

330. This is what the government says publicly. *See, e.g.*, U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD REPORT FOR FY 1998 (1999), <http://www.usdoj.gov/dag/pubdoc/health98.htm> (last visited Apr. 5, 2001) [hereinafter 1998 FRAUD REPORT].

331. On the other hand, the DOJ reports that in excess of half of the \$480 million the department was awarded in the fiscal year of 1998 came at least partially from suits involving qui tam claims. *Id.*

332. DANIEL A. FARBER & PHILIP P. FRICKEY, LAW AND PUBLIC CHOICE 22 (1991).

333. *Id.* at 44.

334. For other explanations, see Bucy, *supra* note 31, at 58-59 (discussing the lower burden of proof under the FCA, that deeper pockets make actions against health care providers "viable," and the help from "insiders" that comes from qui tam relators in prosecuting complex medical fraud cases).

335. For a general discussion of the effect of financial incentives on criminal prosecutions,

When qui tam relators recover damages or settlements from defendant-providers, so does the government. The government can add these recoveries to the Control Account via the Trust Fund, and report these collections in each year's annual report. These are financial interests. Once the collections of qui tam relators are added to the government's coffers, the legislators and public officials can announce that great progress has been made in the fight against fraud. In this way, private qui tam plaintiffs serve a political interest. Herein lies the taint of prosecutorial financial incentives even on government efforts to combat kickbacks, bribes, and self-referrals in health care.

The recovery of money in the antifraud effort makes good press. It makes good press for legislators as the policymakers boast about the number of dollars recovered in FCA settlements and judgments against health care providers, as if those numbers represent a commensurate reduction in the incidence of fraud in the health care industry.³³⁶ It makes good press for the executive branch. The Clinton administration has taken advantage of the high profile granted to its "Operation Restore Trust" effort.³³⁷ It makes good press for private attorneys, who can claim that the lucrative settlements and recoveries by qui tam plaintiffs have deterred fraud.³³⁸ And, indeed, it makes good press for the judicial branch of the federal government.

The DOJ reported in January 2000 that "the federal government won or negotiated more than \$524 million in judgments, settlements, and administrative impositions in health care fraud cases and proceedings" in 1999.³³⁹ In 1998, the DOJ either negotiated or was awarded \$480 million from health care providers.³⁴⁰ The report goes on to exclaim that "[t]he Department has recovered \$2 billion in matters

see Eric Blumenson & Eva Nilsen, *Policing for Profit: The Drug War's Hidden Economic Agenda*, 65 U. CHI. L. REV. 35 (1998).

336. See White House Fact Sheet: President Clinton Announces Unprecedented Progress in Fighting Medicare Fraud and Abuse (Jan. 24, 1998), http://www.the-institute.com/resources/1998-ORT_Progress.html.

THE PRESIDENT ANNOUNCED: A Justice/HHS Report Which Cites Nearly \$1 Billion in One Year in Savings for the Medicare Trust Fund. . . . [The report] shows remarkable progress in rooting out health care fraud and abuse. In FY 1997 alone, the first full year of anti-fraud and abuse funding under HIPAA, nearly \$1 billion was returned to the Medicare Trust Fund, the largest amount ever.

Id. (emphasis in original), http://www.the-institute.com/resources/1998-ORT_Progress.html; see also U.S. Dep't of Health & Human Servs., HHS Fact Sheet: A Comprehensive Strategy to Fight Health Care Waste, Fraud and Abuse 1 (Feb. 10, 1999) [hereinafter HHS Fact Sheet].

Since 1993, the Clinton Administration has focused unprecedented attention on the fight against fraud, abuse and waste in the Medicare and Medicaid programs. . . . In February 1999, the Office of the Inspector General announced that improper Medicare payments to doctors, hospitals, and other health care providers declined 45 percent from FY 1996 to FY 1998.

Id.

337. See, e.g., Press Release, Office of Inspector General, Secretary Launches New "Operation Restore Trust" (May 20, 1997) (on file with author).

338. See generally 1999 FRAUD ANNUAL REPORT, *supra* note 12.

339. *Id.*

340. 1998 FRAUD REPORT, *supra* note 330.

involving alleged fraud against [D]HHS since 1986.”³⁴¹ On the other hand, little is reported in these documents about the actual incidence of fraud, and whether the increased collections indeed represent inversely decreasing occurrences of fraud.³⁴² The problem is that collections are touted as though they represent directly proportional reductions in the incidence of fraud itself.³⁴³ Clearly this cannot be the case. The money collected from health care providers may indeed represent some level of fraud reduction and deterrence. The amounts paid in damages and settlement may provide some empirical information concerning reductions in the level of fraudulent activity. To the extent it does, however, it does so no more precisely than the amount of damages and settlements paid in automobile accident cases indicates how many people have stopped driving recklessly.³⁴⁴ It is not news that the amounts a defendant population may pay to compromise a claim, or even discharge a judgment, are neither measures nor admissions of any extent of liability. In truth, at least some of the funds recovered from health care defendants and deposited into the Control Account represent providers’ economic decisions to pay rather than incur the cost of defending document-intensive, highly complex fraud allegations in litigation. It is likely that these payments by defendants also reflect their interest in avoiding other costs that often accompany prolonged fraud and abuse litigation, such as the costs of bad publicity and slowed productivity as personnel and other resources are dedicated to mounting legal defenses, rather than to the core business of delivering health care.

Nowhere is this more likely the case than with tainted-claims cases. These cases first involve such intricate transactions and ambiguous regulations and require such a sophisticated understanding of the health care market that litigation is highly unlikely to properly distinguish “appropriate” from “inappropriate” and, therefore, actionable financial considerations on the part of health care providers. Yet, the rhetoric implying the contrary—from policymakers, lawyers, and government bureaucrats—suggests otherwise.

It does not serve the best interest of public officials to candidly discuss the limited information that is actually contained in the monetary results of antifraud enforcement. Instead, since 1996, the government has reported annually on the total

341. *Id.*

342. *See, e.g.,* William L. Stringer, *THE 1986 FALSE CLAIMS ACT AMENDMENTS: AN ASSESSMENT OF ECONOMIC IMPACT 35* (1996) (estimating actual fraud based on recoveries and concluding that FCA deterred \$148 billion of fraud in the ten years since the 1986 Amendments to the False Claims Act).

343. *See, e.g.,* HHS Fact Sheet, *supra* note 336, at 1 (stating enforcement actions returning fines to Medicare Trust Fund, which in turn funds the Control Account, “have saved taxpayers more than \$38 billion” since 1993).

344. Presumably, a rational, guilty defendant or target in a fraud investigation will pay an amount to stop litigation that bears some relation to the benefit he received from engaging in the prohibited activity. For these defendants, the damages and settlements they pay may, in part, reflect the size of the fraud they had been committing. However, it is first erroneous to assume that every target and defendant is, in fact, guilty. Moreover, it is erroneous to assume that the damages and settlements paid even by guilty defendants does not reflect other savings—cost of avoiding litigation, bad publicity, productivity losses—that influence the amount of damages and settlement offers defendants are willing to pay.

deposits made into the Control Account as a measure of its effectiveness in the fight against fraud. Each line item reported announces that a health care provider paid money "back" and, by faulty inference, that a provider was stopped from perpetuating fraud upon the government in like amount. For example, the 1999 report showed the following results:

TABLE 1: TOTAL TRANSFER/DEPOSITS BY RECIPIENT 1999³⁴⁵

DEPARTMENT OF THE TREASURY	
HIPPA Deposits	
Gifts and Bequests	\$ 2,500.00
Criminal Fines	\$ 36,006,432.00
Civil Monetary Penalties	\$ 4,797,073.00
Penalties and Multiple Damages	\$ 73,559,143.00
HEALTH CARE FINANCING ADMINISTRATION	
OIG Audit Disallowances-Recovered	\$ 50,002,122.00
Restitution/Compensatory Damages	\$ 209,567,402.00
RESTITUTION/COMPENSATORY DAMAGES TO FEDERAL AGENCIES	
Office of Personnel Management	\$ 9,286,426.00
Other Agencies	\$ 5,408,372.00
Treasury Miscellaneous Receipts	\$ 14,793,185.00
DHHS—Other Than HCFA	\$ 42,993,069.00
REALTORS' PAYMENTS (QUI TAM)	\$ 44,418,028.00
TOTAL	\$ 490,466,482.00

Moreover, each line item inferentially announces what agency should be credited with the greatest success in fighting health care fraud. Lawmakers benefit greatly from the exposure generated by these types of "facts and figures." Private attorneys and private attorneys general also reap significant rewards, both financially and reputationally, for their apparent success in fighting fraud. The most telling report is the summary of qui tam cases and recoveries.³⁴⁶ The criminal and civil enforcement statistics demonstrate the extent to which the government has relied upon qui tam prosecutors in health care fraud cases generally. Below, Table 2 summarizes the comparative enforcement efforts of public and private prosecutors under the FCA.

345. 1999 FRAUD ANNUAL REPORT, *supra* note 12, at 4.

346. For a complete report, see 1998 FRAUD REPORT, *supra* note 330.

TABLE 2: CIVIL HEALTH CARE FRAUD CASES ³⁴⁷
 COMPARING PUBLIC TO PRIVATE PROSECUTION RESULTS

	FY 1996	FY 1997	FY 1998
HEALTH CARE FRAUD CASES FILED (U.S. Attorneys)	90	89	107
QUI TAM HEALTH CARE FRAUD CASES FILED (Private)	176	306	273
QUI TAM HEALTH CARE FRAUD JUDGMENTS/SETTLEMENTS (in millions of dollars)	\$66	\$608	\$261
TOTAL HEALTH CARE FRAUD JUDGMENTS/SETTLEMENTS (in millions of dollars)	\$136	\$961	\$300
PERCENTAGE OF TOTAL HEALTH RECOVERY FROM QUI TAM	48.5%	63.2%	87%

The qui tam relator is the primary “breadwinner” in civil fraud cases. She is increasingly important as a contributor to the politically and publicly important Control Account, and as such, the private prosecutor has become increasingly important to those who benefit from enhancing the myth that financial collections from health care providers actually reduce kickback and self-referral fraud. This financial role has insulated the qui tam enforcement role from serious scrutiny. So far, the political and economic contributions made by private prosecutors have overshadowed the fundamental inappropriateness of their role in controlling kickback and self-referral fraud. The problem, however, may be that the beneficial contributions the qui tam relator makes in the short term may in the long term prove costly, especially in the anti-kickback and self-referral cases where the relator’s role is to discard completely the administrative enforcement mechanisms Congress has carefully crafted for almost thirty years.

VII. A PROPOSED SOLUTION TO THE PROBLEMS OF TAINTED-CLAIMS LITIGATION

Since 1972, Congress has attempted to find and articulate a balance between allowing freedom of competition and growth in the health care industry and constraining costly overutilization and inflation due to fraud. The anti-kickback and self-referral laws are the result of that effort. They include a network of safe harbors and regulations that promises to grow increasingly more complex as the health care economy also grows more intricate. The tainted-claims litigation represents a significant departure from Congress’s intent under these laws and from settled

347. *See id.*

principles of administrative law and statutory construction. The core problem with tainted-claims litigation, however, is that enforcing the anti-kickback and self-referral laws in their current structure simply should not be left to financially self-interested parties through the common-law process.

A. A More Reasoned Approach

The problem of fraud and abuse in that market is both real and great. Yet, the tainted-claims approach is a dangerously inappropriate tool with which to address this problem. The congressionally fashioned approach to kickback and self-referral fraud is far from perfect.³⁴⁸ Yet, these statutes set out a more carefully crafted and reasoned approach to the kickback and self-referral problem than the tainted-claims approach. To correct the substantive, economic, and ethical problems posed by the tainted-claims approach, the evidence compiled in this Article mandates a return to the administrative structure of the existing anti-kickback and self-referral laws.

First, the primary enforcement of anti-kickback and self-referral fraud should return exclusive government enforcement, as Congress originally intended. Ideally, the anti-kickback and self-referral laws should be entirely exempt from qui tam enforcement. At minimum, after filing a qui tam complaint under seal that alleges or implicates anti-kickback or self-referral law violations, the private relator should be required to defer further proceedings until the government has intervened. If, after its investigation of the qui tam claims, the government declines to intervene, the case should be dismissed.³⁴⁹ If the government does intervene, then the myriad of prosecutorial and policy decisions will be directed throughout the case by lawyers and public officials whose expertise and judgment will comport with the policy judgments Congress intended to delegate to the government.

Second, the Control Account legislation should be revised. Funds collected from antifraud enforcement should be deposited into a general revenue account, similar to that used for criminal forfeiture receipts. These funds should be applied to nation wide law enforcement, not exclusively for medical fraud. This will eliminate the cause-and-effect relationship of current accounting methods that have distorted the government's prosecutorial judgments.

348. While it is outside the scope of this Article to suggest revisions to the antifraud laws themselves, this possibility should not be overlooked by Congress. Moreover, many of the reforms the HIPAA put into place to enhance the enforcement capabilities of government investigators and lawyers represent positive additions to the law that could even be extended.

349. See Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 141 (1999) (arguing to preclude qui tam relators from proceeding under the FCA in cases based on alleged Nursing Home Reform Act violations where that statute creates no private cause of action).

B. Conclusion

The foregoing analysis compels the conclusion that the Medicare and Medicaid anti-kickback statute and the self-referral laws should each be exempt from qui tam enforcement under the FCA. Alternatively, no qui tam relator should be permitted to enforce the medical antifraud laws under the FCA without the government exercising primary jurisdiction over the claim. Moreover, the empirical evidence makes clear that government officials must regain their objectivity in the fight against medical fraud by eliminating the financial incentives available to public prosecutors that the current law permits.

These highly technical and specialized statutes require a level of expertise and an exercise of prosecutorial discretion that Congress has rightly assigned to administrative specialists. Congress's effort to fashion a comprehensive and coordinated approach to control this area of medical fraud is corrupted by the presence of private enforcers. Private prosecutors threaten to destroy the development of a uniform, cohesive, and well-reasoned body of common law construing the anti-kickback and self-referral statutes. And as long as they are influenced by their own financial self-interest, government prosecutors threaten to do the same. It is difficult to detect and prosecute the sophisticated fraudulent conduct at which the anti-kickback and self-referral laws are aimed. However, the answer to these difficulties lies in strengthening the underlying substantive criminal- and administrative-law provisions as Congress has done in some parts of the HIPAA, and not in creating a "bounty" incentive for prosecutors as Congress has done in other parts of the HIPAA.

The tainted-claims theory of recovery under the FCA is replacing an extensive administrative structure designed to address kickback and self-referral fraud with a brand new body of unpredictable, federal common law, generated through litigation by private parties and government attorneys with a questionable degree of coordination and/or foresight from either. This is a substantive legal concern. The tainted-claims approach rests on a faulty economic assumption that all referral fees are harmful. The FCA is a particularly imprecise tool for distinguishing the appropriate from inappropriate financial incentives built into health care transactions. Moreover, the resulting uncertainty introduced by prosecuting kickback and self-referral fraud under this faulty assumption is likely to have a significant and adverse impact on the structure of health providers' business arrangements in the future. This is an economic concern. Finally, the FCA approach to prosecuting kickback and self-referral fraud presents an ethical concern in that this litigation appears to be more effective at serving the financial self-interest of both government and private enforcers than at actually reducing the incidence of fraud. As a policy matter, the financial incentives that now motivate government and private qui tam medical fraud prosecutors under the FCA, appear to suffer from at least the same criticisms of self-dealing and tainted judgment as the financially self-interested behavior that the anti-kickback and self-referral statutes are intended to address. The solution to these concerns is remarkably simple: enforce the current antifraud statutes as written and as intended. Nothing more is needed, and nothing less.

