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Robert Salcido
Akin, Gump, Strauss, Hauer & Feld, L.L.P.

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INTRODUCTION

One of the more interesting events in 1996 was the development of a split in authority regarding whether the government may base a False Claims Act ("FCA")[1] action upon an alleged violation of the provisions of the Medicare/Medicaid Anti-Kickback Act ("Anti-Kickback Act"),[2] also referred to as the Anti-Kickback Statute. The ultimate resolution of the conflict will have a significant impact on the health care community.

The FCA and the Anti-Kickback Act are among the most powerful weapons the government has in its arsenal to combat health care fraud and abuse.[3] The FCA is the government's "primary litigative tool for combating fraud."[4] It imposes liability on those who, inter alia, "knowingly" present or cause to be

* Robert Salcido is an associate in the health industry practice group of Akin, Gump, Strauss, Hauer & Feld, L.L.P., in its Washington, D.C., office, where he concentrates his practice on health care fraud and abuse and health regulatory issues. From 1988 to 1993, Mr. Salcido was a Trial Attorney with the Civil Division of the United States Department of Justice, where he worked in the Department's Civil Fraud Unit, focusing primarily on prosecuting actions under the False Claims Act, including the Act's qui tam provisions, and handling cases arising under the Act's voluntary disclosure provisions. He received his bachelor's degree *summa cum laude* from Claremont McKenna College, and graduated from Harvard Law School.

1. 31 U.S.C. §§ 3729 to 3733 (1995).
2. 42 U.S.C. § 1320a-7b(b) (1995), *as amended by* the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"). *Compare* United States *ex rel.* Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996) (denying defendants' motion to dismiss the FCA action under Fed. R. Civ. P. 12(b)(6)), *with* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 938 F. Supp. 399 (S.D. Tex. 1996) (granting defendants' motion).
3. For an explanation of the sanctions that can be imposed for submitting false Medicare and Medicaid claims, see Timothy Stoltzfus Jost, *Medicare and Medicaid False Claims: Prohibitions and Sanctions*, 3 ANNALS HEALTH L. 41 (1994).
4. United States *ex rel.* Kelly v. Boeing Co., 9 F.3d 743, 745 (9th Cir. 1993) (quoting SENATE JUDICIARY COMMITTEE, FALSE CLAIMS AMENDMENTS ACT OF 1986, S. REP. NO. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266).

presented "a false or fraudulent claim for payment."[5] "Knowingly" is defined to mean, among other things, that the person acts in "deliberate ignorance" or in "reckless disregard" of the truth or falsity of the information.[6]

The FCA also allows for private enforcement. Under the Act's qui tam provisions, private persons, known as "relators," may enforce the statute by filing a complaint, under seal, setting forth allegations of fraud committed against the government.[7] The government, while maintaining the complaint under seal, investigates the allegations.[8] The Department of Justice ("DOJ") can intervene in the action and lift the seal from the complaint, thus assuming primary responsibility for prosecuting the claim.[9] If the government declines to intervene, the qui tam plaintiff may elect, but is not obligated, to prosecute the action.[10] If the government prevails on the merits, it is awarded treble damages plus a $5000 to $10,000 penalty for each false claim submitted to it; under most circumstances, the relator recovers fifteen to twenty-five percent of the government's recovery (depending upon the relator's contribution to the action), plus reimbursement of the relator's reasonable legal fees and expenses.[11] If the government does not intervene in the action, the relator's statutory recovery is between twenty-five and thirty percent of the government's recovery plus reimbursement of reasonable legal fees and expenses.[12]

The Anti-Kickback Act prohibits persons from paying or soliciting remuneration in order to induce another to refer business reimbursed under a federal health care program. The Anti-Kickback Act is unlike the FCA in three significant ways: (1) it

5. 31 U.S.C. § 3729(a)(1).

6. *Id.* § 3729(b).

7. *Id.* § 3730(b)(2). Qui tam "is an abbreviation for *qui tam pro domino rege quam pro se ipso*, which means 'he who [is] as much for the king as for himself.'" United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 647 n.1 (D.C. Cir. 1994) (citation omitted). For a discussion of the history and use of qui tam actions, see Robert Salcido, *Screening Out Unworthy Whistleblower Actions: An Historical Analysis of the Jurisdictional Bar to Qui Tam Actions Under the False Claims Act*, 24 Pub. Cont. L.J. 237 (1995); David J. Ryan, *The False Claims Act: An Old Weapon with New Firepower Is Aimed at Health Care Fraud*, 4 Annals Health L. 127 (1995).

8. 31 U.S.C. § 3730(b)(3).

9. *Id.* §§ 3730(b)(4) & (c)(1); *see, e.g.*, United States *ex rel.* Babcock v. Dole Citrus, Inc., 912 F. Supp. 1325 (E.D. Cal. 1995).

10. 31 U.S.C. § 3730(b)(4)(B).

11. *Id.* §§ 3729(a) & 3730(d)(1). Under section 3730(d)(1), if the relator's action is based upon primarily public information, the relator's recovery is capped at 10%.

12. *Id.* § 3730(d)(2).

is a criminal statute, (2) it requires that the violator act in a "knowing *and* willful" manner, and (3) it does not contain any provisions that would permit a private individual to enforce its provisions.[13]

The government's combined use of these statutes has proven to be deadly when aimed against specific providers. The argument is that a claim for payment for services based upon an illegally established referral is so tainted as to be a false claim.[14] Prior to 1996, the government's largest health care recoveries, the 1994 National Medical Enterprises $324 million civil settlement and the 1995 Caremark $161 million settlement, involved allegations that these companies had violated the Anti-Kickback Act and the FCA.[15] In both cases, the government was conducting both civil and criminal investigations. Each of these cases settled before the DOJ filed an action, and there is nothing to indicate whether the government would have alleged (1) violations of each statute or (2) that the parties' alleged violation of the Anti-Kickback Act constituted a violation of the FCA.

During the summer of 1996, any doubts regarding the DOJ's intentions were resolved when it intervened in a qui tam action alleging that the defendants violated the FCA because they had engaged in practices in violation of the Anti-Kickback Act. In *United States ex rel. Parker v. Apria Healthcare Group, Inc.*,[16] the government charged Apria with "submitting false Medicare claims for patients whose referrals it received through a kickback scheme . . . ."[17] The parties settled, and Apria agreed to (a) pay $1.65 million and (b) enter into a four-year corporate integrity agreement. Other defendants agreed to pay $346,000.[18]

In 1996, district courts split on the issue of whether an FCA action based upon a violation of the Anti-Kickback Act may be brought.[19] The resolution of this split is of tremendous significance to the health care community, for if such actions are permitted, the government and private persons will be able to avail

13. 42 U.S.C. § 1320a-7b(b)(1) & (2) (1995).

14. Ryan, *supra* note 7, at 146.

15. *See* Ronald H. Clark & Kendra L. Dimond, *Compliance Plan: A Drug Company's First Line of Defense Against Health Care Fraud Prosecutions*, 13 FOOD DRUG COSM. & MED. DEVICE L. DIG. 66 (May, 1996).

16. No. 1:95-CV-2142-FMH (N.D. Ga. amended complaint filed July 10, 1996).

17. *DME Supplier, Three Providers Settle Fraud Charges for $2 Million*, 8 BNA's MEDICARE REP. 133 (Feb. 7, 1997).

18. *Id.*

19. *See supra* note 2.

themselves of a civil statute (the FCA), which has produced more than three billion dollars in recoveries over the last decade, in order to enforce a broadly worded criminal statute (the Anti-Kickback Act).[20] The government has a strong interest in persuading courts to permit such actions, as such actions would (without the need for additional legislation) dilute the Anti-Kickback Act's "knowing *and* willful" standard into the FCA's "knowing" standard. In addition, if the government is successful in the action, it can obtain not only treble damages, but the massive civil penalties offered by the FCA. Whistle blowers also have an interest in combining the two statutes because the collapse of the two into one transforms an action based upon a statute that expressly does not permit a private right of action (the Anti-Kickback Act) to one that permits a private person not only to sue but also to become substantially enriched if the action is successful (under the FCA).

However, as explained below, courts should reject the government's and whistle blowers' requests to transform an action under the Anti-Kickback Act into one under the FCA. Each statute has a different standard of intent: It is possible for a party to act recklessly without having the malice of willfulness. In such a case, the two acts would conflict. When two acts conflict, the more specific, here the Anti-Kickback Act, governs. Moreover, amendments to the Anti-Kickback Act manifest congressional intent that the Act serve as the exclusive remedy when it is alleged that an individual was improperly paid or improperly solicited remuneration in exchange for program-related business. Finally, an overly broad interpretation of the Anti-Kickback Act will have a detrimental effect on beneficial changes occurring in the health care community.

I. The Anti-Kickback Act

The Anti-Kickback Act, in expansive language, prohibits any type of payment, whether paid "directly or indirectly, overtly or covertly, in cash or in kind," that is knowingly and willfully intended to induce someone to refer Medicare, Medicaid, or other state health program patients, or to order goods or services re-

20. *See Qui Tam Statistics*, 64 Fed. Cont. Rep. (BNA) 362 (Oct. 23, 1995). The government has recovered more than $1 billion as a result of qui tam actions, which is a subset of all FCA actions. One private group has estimated that the government will recover more than $21 billion over the next 10 years (1996-2006) under the FCA. *See False Claims Act*, 66 Fed. Cont. Rep. (BNA) 229 (Sept. 16, 1996).

imbursable under such programs.[21] Specifically, the Act, among other things, prohibits an individual from *soliciting or receiving* any remuneration from any person (1) "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program," or (2) "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . ."[22] Further, the Act prohibits an individual from offering or paying any remuneration to any person to *induce* such person to make these prohibited referrals or transactions.[23] These offenses are classified as a felony, punishable by fines of up to $25,000 and imprisonment for up to five years.[24]

An understanding of the legislative development of the Anti-Kickback Act is crucial in analyzing the relationship between it and the FCA. It clearly demonstrates Congress's manifest intent that the Act only operate against those who "knowingly *and* willfully" engage in the proscribed conduct. Further, given the all-encompassing nature of the Act's expansive language, Congress intended that the executive branch promulgate specific guidance so that health care providers could plan confidently and implement their commercial activities. The legislative history is explained below.

A. *The 1972 Legislation*

Congress initially passed the Anti-Kickback Act in 1972. As passed, the Act did not have a scienter (intent) requirement, and, unlike its current version, it did not define activities that were excluded from its statutory terms. Also, unlike the current version, a violation of the original statute constituted a misdemeanor, not a felony. Specifically, the Act prohibited one from (a) "furnish[ing] items or services to an individual for which

21. 42 U.S.C. § 1320a-7b(b)(1).

22. *Id.* § 1320a-7b(b)(1)(A) & (B) (emphasis supplied). For purposes of this statute, a federal health care program includes state health care programs, such as programs funded or receiving state allotments under Titles V, XIX, or XX of the Social Security Act, and "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the [Federal Employees Health Benefit Program]) . . . ." *Id.* § 1320a-7b(f) (Supp. 1997).

23. *Id.* § 1320a-7b(b)(1) & (2) (1995).

24. *Id.*

payment is or may be made under [federal law]," (b) soliciting, offering, or receiving a "kickback or bribe in connection with the furnishing of such items or services . . . ," (c) paying or receiving such payment, or (d) soliciting, offering, or receiving a "rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services . . . ."[25] Conviction brought with it a fine of up to $10,000 and/or imprisonment for up to one year.[26]

According to the House Ways and Means Committee Report, the statute primarily was directed toward outlawing referral activities that most professional organizations had considered to be unethical and activities that led to the inappropriate use of scarce federal funds. The committee felt that a "specific provision defining acts subject to penalty under the Medicare and Medicaid programs should be included to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions."[27]

25. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972) (codified as amended at 42 U.S.C. § 1395nn(b) (1995)). The Medicaid Act contained a parallel provision. *Id.* (codified as amended at 42 U.S.C. § 1396h(b)(1)).

26. *Id.*

27. H.R. REP. No. 92-231 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093. In interpreting this version of the statute, circuit courts differed in how strictly they defined the statutory terms. For example, the Second and Fifth circuits reversed convictions on the grounds that the terms "bribe" and "kickback" encompassed conduct requiring a breach of duty or law. *See* United States v. Zacher, 586 F.2d 912, 916 (2d Cir. 1978) (ruling that where the nursing home accepted payments in exchange for preferential admission, it did not violate the law because the conduct "did not increase the cost to the government of patient care, decrease the quality of patient care purchased by the government or involve the misapplication of government funds . . . ."); United States v. Porter, 591 F.2d 1048, 1054 (5th Cir. 1979) (reversing the defendants' conviction because the court believed that their conduct could not fairly be characterized as a bribe or kickback because it could not find any breach of "duty imposed upon any of these defendants by a statute or regulation, the violation of which would amount to a misapplication of federal funds"). The Seventh Circuit and Sixth Circuit focused their review on the dictionary definition of the term "kickback" rather than on whether defendants breached a known duty. *See* United States v. Hancock, 604 F.2d 999, 1001-02 (7th Cir. 1979) ("The term [kickback] is commonly used and understood to include 'a percentage payment . . . for granting assistance by one in a position to open up or control a source of income' . . . and we think it was used in the statute to include such a payment.") (quoting WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1966)); United States v. Tapert, 625 F.2d 111 (6th Cir.), *cert. denied*, 449 U.S. 982 (1980).

B. *The 1977 Legislation*

Congress broadened the Anti-Kickback Act in 1977. Rather than prohibiting acts involving "bribes" or "kickbacks," it chose to prohibit the payment of "remuneration" in exchange for referral. Further, it upgraded the penalty for a violation from a misdemeanor to a felony. However, in order to foster commercially beneficial transactions, it limited the broad application of the statute by creating statutory exceptions regarding the payment of discounts and payments made pursuant to a bona fide employment relationship.[28] Specifically, the revised statute first prohibited one from soliciting, offering, or receiving "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in exchange for *referring* an individual or *arranging* for the provision of any item or service paid for in whole or in part with federal funds or in exchange for actually participating in or recommending the purchasing, leasing, ordering, or arranging of "any good, facility, service, or item" paid for in whole or in part with federal funds.[29] One who violated the Act was guilty of a felony and subject to up to $25,000 in fines and/or imprisoned for up to five years. It also prohibited one from *offering* or *paying* remuneration of the same sort in exchange for the same activities.[30] The 1977 Act did not apply to "a discount or other reduction in price . . . if the reduction in price was properly disclosed and appropriately reflected in the costs claimed or charges made" nor "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services."[31]

The legislative history underlying the amendment is sparse. The House Ways and Means and the Interstate Commerce and Foreign Commerce committees' report on the Medicare and Medicaid Antifraud and Abuse amendments expressed three primary purposes in amending the statute. The first was to enhance deterrence by upgrading the penalty.

> Recent hearings and reports . . . indicate that such penalties [the misdemeanor provisions of existing law] have not proved adequate deterrents against illegal practices by some individu-

28. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1180-81 (1977). Congress used the same language quoted above to revise the Medicaid Anti-Kickback Act. 91 Stat. at 1182.
29. Pub. L. No. 95-142 at § 4(b)(1), 91 Stat. at 1180.
30. *Id.* § 4(b)(2), 91 Stat. at 1180.
31. *Id.* § 4(b)(3), 91 Stat. at 1181.

> als who provide services under Medicare and Medicaid. In addition, these misdemeanor penalties appear inconsistent with existing Federal criminal code sanctions which make similar actions punishable as felonies.[32]

The second purpose was to clarify ambiguous language.

> [The amendment] would make subject to the penalty provisions any person who solicits or receives any remuneration (1) in return for referring an individual to a person for the furnishing, or arranging for the furnishing of items or services; or (2) in return for purchasing, leasing, or ordering, or arranging for, or recommending the purchasing, leasing, or ordering of goods, facilities, or services. Also, any person who offers or pays any remuneration to any person to induce such person to do similar activities would be subject to the penalty provisions.
>
> The bill would define the term "any remuneration" broadly to encompass kickbacks, bribes, or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind (but would exclude any amount paid by an employer to an employee for employment in the provision of covered items or services).[33]

The amendment's third purpose was to identify activities that would not fall within the scope of the statute because they were good business practices resulting in program savings. For example, among other things,

> [t]he bill would specifically exclude the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under Medicare and Medicaid, but only if such discounts are properly disclosed and reflected in the cost for which reimbursement could be claimed. The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal. In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.[34]

C. The 1980 Amendments

In 1980, Congress amended the statute by including a mens rea element, clarifying that only those who "knowingly and willfully" engage in a prohibited act will suffer penalties under the

32. *See* H.R. Rep. No. 95-393, pt. 2, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3055.
33. 1977 U.S.C.C.A.N. at 3056.
34. *Id.*

statute.[35] Specifically, the House Budget Committee Report pointed out that the purpose of the revision was to ensure that those whose conduct may have been improper would nonetheless not be prosecuted unless they specifically intended to engage in the proscribed conduct.[36] This same element exists today.

D. *The 1987 Amendments*

In 1987, Congress again revised the statute to better define its scope and application. Specifically, Congress created additional statutory exceptions: one exception allowed the Secretary of Health and Human Services to exclude through regulations any payment practice, the so-called safe harbors, and another excluded the amounts paid by vendors to group purchasing organizations in exchange for the organization arranging for the purchase of items or services by those who furnish these health care items or services.[37] According to a Senate Finance Committee Report, the purpose of this provision was to address "uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed."[38] In order to clarify the uncertainty, it commanded the "Secretary of Health and Human Services ["HHS"], in consultation with the Attorney General, . . . [to] promulgate final regulations, specifying payment practices that shall not be treated as a criminal offense under [the statute] . . . and shall not serve as the basis for an exclusion" from participation in Medicare or the state health care programs under the Act.[39]

Furthermore, Congress amended the statute to create an administrative procedure under which the Secretary could exclude from the Medicare program persons who violated, among other things, the Anti-Kickback Act. Although the exclusion would initially be effected through an administrative proceeding, the intent requirement remained unchanged. Prior to issuing any exclusion, the Secretary had to afford the individual a hearing

35. *See* Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980) (codified as amended at 42 U.S.C. § 1395nn(b)(1)(1995)).

36. H.R. REP. NO. 96-1167, at 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572.

37. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, §§ 4 & 14, 101 Stat. 680, 688-89, 697-98 (1987) (codified as amended at 42 U.S.C. § 1320a-7b (1995)).

38. S. REP. NO. 100-109, at 27 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 707-08.

39. Pub. L. No. 100-93, §14(a), 101 Stat. at 697-98.

before an administrative law judge "because some of the grounds for exclusion under [the Act] may involve practices that require adjudication to determine whether the requisite criminal intent existed to 'knowingly and willfully' violate the standards."[40]

E. The 1996 Amendments

Recently, Congress enacted the HIPAA, which contains provisions bearing on the Anti-Kickback Act.[41] Specifically, to provide clear guidance to the health care community and assure that federal authorities would prosecute only those who deliberately engaged in prohibited conduct, Congress has commanded that the Secretary undertake three actions. First, the Secretary must publish for comment and consider for final ruling any appropriate modifications to existing safe harbors, as well as promulgating additional safe harbor provisions.[42] Second, the Secretary must issue advisory opinions explaining the meaning of remuneration, whether a transaction constitutes prohibited remuneration under the statute or regulations, what constitutes "an inducement to reduce or limit services" as prohibited by the Act, and whether an activity is subject to sanctions.[43] Third, the

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40. S. REP. 100-109, at 13, *reprinted in* 1987 U.S.C.C.A.N. at 693.

41. Pub. L. No. 104-191, 110 Stat. 1936 (1996). For a detailed explanation of the fraud provisions of HIPAA, see Colleen Faddick, *Health Care Fraud and Abuse: New Weapons, New Penalties, and New Fears for Providers Created by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")*, 6 ANNALS HEALTH L. 77 (1997).

42. Specifically the Act states:

> After considering [the public] proposal[,] . . . the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

Pub. L. No. 104-191, § 205 (to be codified at 42 U.S.C. § 1320a-7d(a)(1)(B)).

43. Specifically the Act states:

> (1) Issuance of Advisory Opinions
> The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.
> (2) Matters Subject to Advisory Opinions
> The Secretary shall issue advisory opinions as to the following matters:
> (A) What constitutes prohibited remuneration within the meaning of [the Anti-Kickback Act].
> (B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in [the Anti-Kickback Act] for activities which do not result in prohibited remuneration.

Inspector General must determine whether to issue special fraud alerts upon receipt of a public request.[44]

The House Ways and Means Committee stated that the purpose of these requirements was to ensure that existing law did not have a chilling effect on legitimate business arrangements. Congress believed that the Secretary's clarification of the statute would enable prosecutors to spend their time on the more egregious types of conduct. Congress reasoned that providers "want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them [and they] should be able to receive guidance from the government."[45]

Finally, Congress also created an exception to the Anti-Kickback Act to accommodate risk-sharing arrangements for providing services and items between a Medicare HMO or Competitive Medical Plan,[46] provided that the arrangement "places the individual or entity at substantial financial risk for the cost or utilization of the items or services . . . which the individual or entity is obligated to provide."[47]

F. Court Construction of the Intent Element

As noted previously, the Anti-Kickback Act requires that one *knowingly and willfully* perform a prohibited act to be found guilty of violating the statute. Circuit courts, however, have split on the precise meaning of "knowingly and willfully."

> (C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by regulations for activities which do not result in prohibited remuneration.
>
> (D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits . . . within the meaning of [the Anti-Kickback Act].
>
> (E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under [the exclusion, civil monetary penalties, or criminal penalties provisions].

Id. § 205 (to be codified at 42 U.S.C. § 1320a-7d(b)(2)).

44. The Act states:

> Upon receipt of a [public] request . . ., the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued [and] . . . [i]f appropriate, . . . issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

Id. § 205, 110 Stat. at 2003 (to be codified at 42 U.S.C. § 1320a-7d(c)(1)(B)).

45. H.R. REP. NO. 104-496, at 84-85 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1884-85.

46. *See* 42 U.S.C. § 1395mm (1995).

47. Pub. L. No. 104-191, § 216, 110 Stat. at 2007.

In *Hanlester Network v. Shalala*,[48] the Office of the Inspector General asserted that the *Hanlester* litigants had offered and paid remuneration to physician-investors to induce referrals of laboratory tests to the three laboratories owned by Hanlester Network, in violation of section 1320a-7b(b)(2) of the United States Code, and had solicited and received payments from Smithkline BioScience Laboratories in exchange for referrals, in violation of section 1320a-7b(b)(1).[49] The Ninth Circuit disagreed, ruling that the Act's "knowingly and willfully" standard requires that persons (1) know that the statute "prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law."[50] In applying this standard, the court ruled that the litigants had not knowingly and willfully paid or received payments for referrals because, among other things, the partnerships had not conditioned the purchase of shares on an agreement to order tests, conditioned the number of shares sold on the amount of business that the physicians agreed to refer, or authorized the ouster of partners who failed to refer business. Further, the partnerships did not believe that their arrangement contravened the law. Similarly, the court found that the litigants had not knowingly and willfully solicited and received remuneration in return for referrals because the nature of the management services agreements was common. They did not conceal their pay-

48. 51 F.3d 1390 (9th Cir. 1995). For an explanation of the implications of *Hanlester*, see William R. Kucera, Jr., Note, Hanlester Network v. Shalala: *A Model Approach to the Medicare and Medicaid Kickback Problem*, 91 Nw. U. L. Rev. 413 (1996).

49. 51 F.3d at 1394-95. The *Hanlester* litigants consisted of the Hanlester Network (the general partnership), the Keorle Corporation (the name of the Hanlester Network after its sale), Pacific Physicians Clinical Laboratory (a limited partnership of the Network), Omni Physicians Clinical Laboratory, Ltd. (a limited partnership of the Network), Placer Physicians Clinical Laboratory, Ltd. (a limited partnership of the Network), Kevin Lewand (President of the Network), Gene Tasha (a general partner in the Network and its Vice President of Operations), Melvin L. Hantsinger, M.D. (the Network's Medical Director), and Ned Welsh (a general partner in the Network). The limited partnership had entered into a laboratory management agreement with Smithkline under which the partnerships would provide a medical director and pay Smithkline a monthly management fee. This was the first time the government used the Anti-Kickback Act to sanction a self-referral arrangement. Kucera, *supra* note 48, at 452.

50. 51 F.3d at 1400. *See generally* Michael Tichon et al., *Compliance Issues Under the New Fraud and Abuse Rules*, 16 Whittier L. Rev. 1085, 1094 (1995) (Under the *Hanlester* decision, "unless someone subjectively believes that at the time of his or her conduct it was illegal, he or she did not violate the statute . . . .").

ments to Smithkline, and they did not believe that their arrangement was unlawful.[51]

The Eighth Circuit in *United States v. Jain*[52] reached a slightly different conclusion regarding the required intent under the Act. Dr. Jain and his corporation, Center for Mental Health Services, Inc., were convicted of receiving payments from a psychiatric hospital for referring patients to that hospital. Two former hospital administrators testified against Dr. Jain, who operated an outpatient therapy clinic, contending that he demanded payment from the hospital in exchange for his agreement to refer patients. Dr. Jain testified that the payments he received were for mental health workshops he provided; he denied ever requesting money for referrals, which he agreed would constitute "illegal," "unethical," and "wrong" conduct.[53]

In construing the meaning of the intent standard, the Eighth Circuit upheld the district court's jury instruction. The court ruled that the "*mens rea* standard should only require proof that Dr. Jain knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"[54] The Eighth Circuit distinguished the Ninth Circuit's ruling in *Hanlester*, noting that *Hanlester* "involved an administrative debarment proceeding."[55]

Whether subsequent courts follow the Ninth Circuit's formulation requiring that defendants know that they breached a legal duty or the Eighth Circuit's formulation requiring that defendants know that their conduct was wrongful, the government must prove, at a minimum, that defendants have "actual" knowledge that the conduct at issue is improper.

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51. 51 F.3d at 1400-01.

52. 93 F.3d 436 (8th Cir. 1996).

53. *Id.* at 438-39.

54. *Id.* at 439. The court further held:

> The parties assert radically different positions on this issue of statutory construction. Based upon the traditional principle that ignorance of the law is no defense, the government urges us to apply the general rule that "willfully" in a criminal statute "refers to *consciousness of the act but not to consciousness that the act is unlawful*." Defendants urge us to adopt the exception to that general rule that has long been applied in criminal tax cases—willfulness in a criminal tax statute means the "*voluntary, intentional violation of a known legal duty.*"

Id. at 440 (emphasis added). The Eighth Circuit also "instructed that 'good faith' was a defense to this charge, explaining that Dr. Jain acted in good faith if he believed he was being paid for promoting the hospital, and not for referring patients." *Id.*

55. *Id.* at 441.

The legislative underpinnings of the Anti-Kickback Act demonstrate Congress's manifest intent that the statute only be applied against those persons who acted with a specific intent to engage in prohibited conduct. As will be shown in the next section, this is a substantially higher intent standard than the "constructive" knowledge standard of the False Claims Act. Moreover, to the extent that Congress established an enforcement mechanism, it established that the Anti-Kickback Act shall be enforced through criminal prosecution or administrative action. It did not create a civil cause of action, whether brought by the government or a private individual.

II. The False Claims Act

The False Claims Act, passed in 1863 to halt contractor frauds against the Union Army during the Civil War, originally prohibited the "present[ation of] . . . any claim upon or against the Government . . . knowing such claim to be false, fictitious, *or* fraudulent," and imposed both criminal and civil penalties.[56] The FCA prohibited the "knowing" submission of false claims, but did not define the words "knowing" or "knowingly."[57] Because of the lack of a definition and the use of otherwise imprecise language, the circuits inconsistently interpreted the statute's intent standard.[58] The Fifth, Sixth, Ninth, and Eleventh circuits held that the FCA required proof that the defendant acted with the intent to deceive the government.[59] The Seventh, Eighth, and Tenth circuits and the Court of Claims held that an intent to deceive was not necessarily a requisite element of proof.[60] In 1986, Congress amended the statute to clarify that no "specific

56. Ryan, *supra* note 7, at 127-28. *See also* Act of Mar. 2, 1863, ch. 67, 12 Stat. 696 (emphasis added). In its current version, the word "fictitious" has been deleted.

57. *See* 31 U.S.C. § 3729 (1982) (superseded).

58. Because of its origin as a statute providing criminal penalties, some courts construed the provision to apply only to "fraudulent" conduct. Conversely, other courts, noting the use of the disjunctive in the statute—false or fraudulent—ruled that no specific intent to defraud was required and that the government need only prove that the person knew the claim was "false." Under this interpretation, one could be held liable under the statute without the government proving that the person had an illicit intent.

59. *See* United States v. Aerodex, Inc., 469 F.2d 1003, 1007 (5th Cir. 1972); United States v. Ueber, 299 F.2d 310 (6th Cir. 1962); United States v. Mead, 426 F.2d 118 (9th Cir. 1970); United States v. Davis, 809 F.2d 1509, 1512 (11th Cir. 1987).

60. *See* United States v. Hughes, 585 F.2d 284, 287-88 (7th Cir. 1978); Miller v. United States, 550 F.2d 17, 23 (Ct. Cl. 1977); United States v. Cooperative Grain and Supply Co., 476 F.2d 47, 56 (8th Cir. 1973); Fleming v. United States, 336 F.2d 475, 479 (10th Cir. 1964), *cert. denied*, 380 U.S. 907 (1965).

intent" is required to violate the statute.[61] Instead, Congress specified that those who act with "reckless disregard" or in "deliberate ignorance" of the facts can be held liable under the Act.[62]

A. *1986 Revisions to the FCA*

A study of the House and Senate committee reports analyzing the 1986 amendments clarifies the statute's intent standard. On June 26, 1986, the House Judiciary Committee issued a report on its bill to amend the FCA.[63] Acknowledging the problem in interpreting the knowledge requirement, the House Judiciary Committee described the parameters of the legislative amendment. "There is no doubt that actual knowledge of a claim's falsity will confer liability under the statute. However, courts have in the past reached different opinions in defining what type of 'constructive knowledge,' if any, will result in liability."[64] The House bill's definition of "knowing" and "knowingly" was almost identical to that actually passed. It required that the person have "actual knowledge" of the information in the claim or "deliberately choose to remain ignorant" of the truth or falsity of the information, or act in "reckless disregard of the truth or falsity of the information."[65] The Committee further reported:

> It is intended that persons who ignore "red flags" that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim should be held liable under the Act. This definition, therefore, enables the Government not

61. *See* S. Rep. No. 99-345, at 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5271-72:

> As a civil remedy designed to make the Government whole for fraud losses, the civil False Claims Act currently provides that the Government need only prove that the defendant knowingly submitted a false claim. However, this standard has been construed by some courts to require that the Government prove the defendant had actual knowledge of fraud, and even to establish that the defendant had specific intent to submit the false claim. . . . The Committee believes this standard is inappropriate in a civil remedy and presently prohibits the filing of many civil actions to recover taxpayer funds lost to fraud.

62. 31 U.S.C. § 3729(b) (1995).

63. *See* 132 Cong. Rec. H6474-88 (daily ed. Sept. 9, 1986) (statement of Rep. Glickman).

64. H.R. Rep. 99-660, at 20 (1986).

65. *Id.* Congress's sole amendment to this provision prior to passage was to affix the phrase "and no proof of specific intent to defraud is required" at the conclusion of the sentence that defined the statutory terms "knowing" and "knowingly."

only to effectively prosecute those persons who have actual knowledge, but also those who play "ostrich."[66]

Shortly after the House Judiciary Committee issued this report, the Senate Judiciary Committee issued its report[67] on the Senate's bill to amend the FCA. While the Senate's definition differed from that of the House, the Senate Judiciary Committee similarly described the scope of the provision in expansive terms.

> [S]ome courts . . . require that the Government prove the defendant had actual knowledge of fraud, and even to establish that the defendant had specific intent to submit the false claim, for example, *United States v. Aerodex, Inc.*, 469 F.2d 1003 (5th Cir. 1972). The Committee believes this standard is inappropriate . . . . Currently, in judicial districts observing an "actual knowledge" standard, the Government is unable to hold responsible those corporate officers who insulate themselves from knowledge of false claims submitted by lower-level subordinates. The "ostrich-like" conduct which can occur in large corporations poses insurmountable difficulties for civil false claims recoveries.
>
> The Committee is firm in its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence. But the Committee does believe the civil False Claims Act should recognize that those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate.[68]

Later in its report, the Committee noted that the exact scope of the person's "obligation" will differ depending upon the types of claims that are submitted.

The Senate's version defined "this obligation as 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim.' Only those who act in 'gross negligence' of this duty will be found liable under the False Claims Act."[69]

Prior to the introduction of the Senate's bill on the floor, the committee changed the definition of "knowing" and "know-

66. *Id.* Later, while discussing the bill's scienter standard on the House floor, the House's chief sponsor of the legislation, Representative Berman, pointed out that the FCA should be viewed as imposing an "affirmative obligation" on persons to ascertain the truthfulness of their claims. 132 CONG. REC. H6474-88 (daily ed. Sept. 9, 1986).

67. S. REP. NO. 99-345, *reprinted in* 1986 U.S.C.C.A.N. 5266.

68. *Id.* at 6-7, *reprinted in* 1986 U.S.C.C.A.N. at 5271-72.

69. *Id.* at 20, *reprinted in* 1986 U.S.C.C.A.N. at 5285.

ingly" to conform to the draft House bill, which ultimately was signed into law, with the proviso affixed that "no proof of specific intent is required."[70] In explaining the scope of the amendment, the Senate sponsor clarified the issue.

> The fundamental issue in designing a standard of knowledge is to reach not only defendants with actual knowledge of a false claim, but also defendants who insulate themselves from that knowledge which a prudent person should have before submitting a claim to the Government. It is this problem of defining constructive knowledge, or of dealing with the "ostrich"—the individual who ignores or fails to inquire about readily discoverable facts which would alert him that fraudulent claims are being submitted—that has led to various formulations of the standard of knowledge.
>
> * * *
>
> Our intent in returning to the reckless disregard standard is only to assure that mere negligence, mistake, and inadvertence are not actionable under the False Claims Act. In doing so, we reconfirm our belief that reckless disregard and gross negligence define essentially the same conduct and that under this act, reckless disregard does not require any proof of an intentional, deliberate, or willful act.[71]

House and Senate negotiators met to resolve pending differences in the bills passed by both bodies. These negotiators adopted the Senate's definition of "knowing" and "knowingly."[72] In summarizing the statutory mandate, the House's

70. *See* 132 CONG. REC. S11238 (daily ed. Aug. 11, 1986) (statement of Sen. Simpson).

71. *Id.* at S11243 (statement of Sen. Grassley). Senator Grassley elaborated on the Senate's choice of language to define the Act's intent standard:

> S. 1562, as considered by the Subcommittee on Administrative Practice and Procedure, contained a "reckless disregard" standard which the sponsors as well as the Department of Justice believed would cover those persons who insulate themselves by design from knowledge about the truth or falsity of a claim. The concern was raised, however, that some case law exists in which reckless disregard is construed as requiring an intentional, deliberate or willful act—a considerable escalation of the scienter requirement. To avoid the risk of such a misconstruction, the full Judiciary Committee then adopted a "gross negligence" standard which would appear to be less susceptible to this misinterpretation. The committee was aware that the two standards are very similar and in fact are often used to define each other, that is, reckless disregard often is defined as gross negligence and gross negligence frequently is said to require a reckless disregard.

Id.

72. 132 CONG. REC. S15018 (daily ed. Oct. 3, 1986) (statement of Sen. Stevens (for Sen. Grassley)). The only difference existing at this time in the respective bodies' definitions of "knowledge" was that the Senate's bill included the phrase "and no proof of specific intent to defraud is required."

chief sponsor, Representative Berman, pointed out that "[t]his section is intended to reach the 'ostrich-with-his-head-in-the-sand' problem where government contractors hide behind the fact they were not personally aware that such overcharges may have occurred."[73]

B. Case Law Construing the FCA's Intent Requirement Since the 1986 Amendments

Consistent with the legislative history and the plain language of the FCA, courts have construed the statute to reach instances in which the defendant did not act with a specific intent to defraud the government. In other words, they did not specifically know that the information on the face of the claim was false, but instead were merely reckless or deliberately ignorant of the facts. For example, in *United States v. Lorenzo*,[74] the district court imposed liability on the defendant based upon conduct that the district court found constituted, at a minimum, "reckless disregard" of the facts. Specifically, defendant dentist Dr. Lorenzo claimed to rely upon information he had learned at a seminar and from a carrier representative leading him to believe that he and his associated companies could bill Medicare for oral cancer examinations provided to nursing home residents. The court found that the governing statute and regulations clearly did not permit Dr. Lorenzo and his companies to bill for these services. Further, the court concluded that the carrier representative had furnished Dr. Lorenzo incomplete information because Dr. Lorenzo had failed to disclose to the representative that the attending physicians had not requested the oral cancer examinations and that the examinations were unrelated to specific medical problems.[75]

According to the court, Dr. Lorenzo received, but ignored, information that should have put him on notice that his claims were improper. Several employee dentists as well as the medical director of a group of nursing homes had challenged Dr. Lorenzo's right to bill Medicare for the oral cancer examinations. Additionally, one carrier routinely had denied the claims that he had submitted. Under these facts, the court determined that although Dr. Lorenzo denied that he knew that the claims were improperly coded, at the very least he "acted in reckless disre-

73. 132 CONG. REC. H9382, 9389 (daily ed. Oct. 7, 1986).
74. 768 F. Supp. 1127 (E.D. Pa. 1991).
75. *Id.* at 1129-30.

gard of the truth or falsity of the information."[76] Thus, under the FCA, the court found Dr. Lorenzo liable for $130,719.10 in damages, trebled to $392,157.30, and $18,415,000 in civil penalties.[77]

United States v. Krizek[78] also presents a situation where no direct proof of specific intent to violate the statute existed, yet the court imposed liability under the FCA. In *Krizek*, the court found that a physician had submitted claims recklessly when his billing staff used "rough approximations" of his time with patients and submitted claims without supervision. Specifically, the district court found that the staff assumed that the doctor had furnished a fifty-minute psychotherapy session unless they were told otherwise.[79] Such an approximation resulted in the physician's ability to bill for more than twenty hours of services within a twenty-four hour period. While the physician claimed that he was, at worst, merely "negligent" and emphasized the "ma and pa" nature of his small practice, the court nonetheless imposed liability, ruling that the physician "failed utterly in supervising [his] agents in their submissions of claims on his behalf . . . [furthermore] [t]hese were not 'mistakes' nor merely negligent conduct."[80] The circuit court agreed, holding that the facts supported the district court's finding that Dr. Krizek "acted with reckless disregard."[81]

Both the *Lorenzo* and *Krizek* cases demonstrate that courts apply the FCA in situations where defendants have no direct knowledge that their conduct is unlawful or wrongful. Thus, the scope of the FCA is substantially broader than that of the Anti-Kickback Act. Indeed, according to some of its legislative spon-

76. *Id.* at 1131-32. Apparently, Dr. Lorenzo also was aware the claims were false because he "advised his patients to write their Congressmen to urge Medicare coverage for dental services . . . ." *Id.* at 1131.

77. *Id.* at 1133.

78. 111 F.3d 935 (D.C. Cir. 1997).

79. 859 F. Supp. 5, 11 (D.D.C. 1994), *modified*, 909 F. Supp. 32 (D.D.C. 1995), *rev'd in part, aff'd in part, and remanded*, 111 F.3d 935 (D.C. Cir. 1997). The 50-minute session was the longest time-period the government reimbursed. *Id.* at 9. The physician's staff believed that the 50-minute session served as a "rough approximation" because while some sessions were for a shorter duration (and thus a 20- to 30-minute session code or some other code would be appropriate), some sessions were for a substantially longer period than 50 minutes and yet only the 50-minute code would be billed. *Id.* at 11.

80. *Id.* at 13-14.

81. 111 F.3d at 942. The District of Columbia Circuit Court explained the intent standard to be applied to FCA actions. *Id.* at 941-42. Specifically, the court concluded that "the best reading of the Act defines reckless disregard as an extension of gross negligence." *Id.* at 942.

sors, the FCA imposes liability on persons who are merely in a position to obtain knowledge, but ignore "red flags" (the "ostrich" situation); imposes liability on persons who do not have actual knowledge of the transaction; and creates an "affirmative obligation" on persons to "ascertain the truthfulness" of claims for reimbursement submitted to the government.[82]

III. The Government's Mistaken Attempt to Predicate an FCA Action on a Violation of the Anti-Kickback Act

The government's foray into combining the FCA with the prohibitions of the Anti-Kickback Act is of recent vintage. As noted in the Introduction, the DOJ settled cases with National Medical Enterprises and Caremark based on allegations that these companies violated both statutes, but both of these cases involved parallel criminal and civil investigations.

Further, recently relators and the United States Attorney's offices in some districts have litigated the issue.[83] In 1994, in a whistle-blower action in which the government did not intervene, the district court denied a motion to dismiss an FCA action based upon violations of the Anti-Kickback Act, although the court questioned the relator's ability to prove the FCA violation.[84] In *Shalala v. T^2 Medical, Inc.*,[85] the government simultaneously filed a complaint and settled the action in which it alleged that because the defendant had violated the Anti-Kickback Act, the defendant also had "caused false and fraudulent claims to be presented to the United States in violation of 31 U.S.C. § 3729(a)."[86] It was unclear whether the government had asserted, in fact, that it may predicate a civil FCA action upon a violation of the Anti-Kickback Act or whether the criminal investigation had unearthed alleged violations of the Anti-Kick-

82. *See* 132 Cong. Rec. at H6482 (daily ed. Sept. 9, 1986) (statement of Rep. Berman). For a more detailed account of the history and application of the Act's scienter standard, see Robert Salcido, *Applications of the False Claims Act "Knowledge" Standard: What One Must "Know" to be Held Liable Under the Act*, The Health Lawyer (ABA Forum on Health Law) (Mid-Winter 1996).

83. In 1991, the Eastern District of Pennsylvania allowed the government to pursue its FCA claim based upon an alleged kickback scheme, denying the defendant's motion to dismiss. United States v. Kensington Hosp., 760 F. Supp. 1120 (E.D. Pa. 1991).

84. United States *ex rel.* Roy v. Anthony, 914 F. Supp. 1504 (S.D. Ohio 1994).

85. Ga. No.1:94-CV-2549 (N.D. Ga. complaint filed Sept. 26, 1994).

86. *Id. See also Novel Use of False Claims Act Arises in T^2 Medicare Settlement*, 3 BNA's Health L. Rep. 1418 (Oct. 20, 1994).

back Act while the civil investigation had uncovered allegations of unrelated violations of the FCA.

In 1996, the courts had the opportunity to rule on the issue. District courts in *United States ex rel. Pogue v. American Healthcorp, Inc.*,[87] and *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*[88] split on the issue of whether a person may predicate a violation of the FCA upon a violation of the Anti-Kickback Act. Both of these actions were qui tam actions in which the Department of Justice had declined to intervene. Thus, these cases did not shed light on the DOJ's official view on this matter.[89] However, the DOJ unambiguously answered this question during the summer of 1996, when, in *United States ex rel. Parker v. Apria Healthcare Group, Inc.*, it intervened in a whistle-blower action, alleging that defendants had violated the FCA based upon an alleged violation of the Anti-Kickback Act.[90]

The remainder of this article reviews the opinions in *Pogue* and *Columbia/HCA,* as well as the DOJ's litigating position in *Apria.* Although the district court in *Columbia/HCA* correctly rejected the whistle blower's contention that a violation of the Anti-Kickback Act results in a violation of the FCA, the court based its decision on the plaintiff's failure to meet pleading requirements under Rule 9(b) of the Federal Rules of Civil Procedure and on the plaintiff's failure to show that the claims filed were in and of themselves fraudulent.[91] An alternative and more fundamental basis exists to reach the same correct result. Courts should conclude that the government (and private persons acting under the FCA's qui tam provisions) cannot base an FCA action upon an alleged violation of the Anti-Kickback Act because such an action creates a conflict between the intent standards under the two statutes. Given this conflict, courts

87. 914 F. Supp. 1507 (M.D. Tenn. 1996).

88. 938 F. Supp. 399 (S.D. Tex. 1996).

89. Although the United States Attorney's offices of various districts had predicated FCA prosecutions upon an alleged violation of the Anti-Kickback Act, the DOJ's Civil Division had not actively participated in those actions. This is significant because primary power to enforce the FCA resides with the Civil Division, and the government's general expertise with the statute resides in that office as well. *See* 28 C.F.R. pt. 0, subpt. Y, app. (1996). Thus, the Civil Division's intervention in a qui tam action alleging such a theory, or bringing an action in its own name, is significant because it signals that that office has approved the theory and will bring similar enforcement actions nationwide when it confronts similar facts.

90. United States *ex rel.* Parker v. Apria Healthcare Group, Inc., No.1:95-CV-2142-FMH (N.D. Ga. amended complaint filed July 10, 1996).

91. 938 F. Supp. at 406-07.

should recognize that the Anti-Kickback Act is the more specific statute and that Congress intended *it* to provide the exclusive remedy for an illegal kickback, thus denying litigants the chance to employ the FCA.

A. FCA Actions Based Upon a Violation of the Anti-Kickback Act

In *Pogue*, for the first time, a district court undertook an extended analysis of whether a person may allege a violation of the FCA upon alleging a violation of the Anti-Kickback Act. Pogue, the relator, had asserted that defendants "were involved in a scheme by which individual physicians would refer their Medicare and Medicaid patients" to a health care facility for treatment in violation of the Anti-Kickback Act.[92] The district court *initially* granted defendant's motion to dismiss the FCA claim on two grounds: "Pogue had failed to allege that any of the claims submitted by [the defendant] were themselves false . . . [and he] had failed to allege that the government suffered damages as a result of the submission of the claims."[93] The relator moved for reconsideration. Specifically, as to the ruling that the claims were not false, the relator contended that participants in any federal program impliedly certify "that the participant will abide by and adhere to all statutes, rules, and regulations governing that program . . . . [Therefore,] by submitting a claim for payment without complying with such statutes, rules and regulations, Defendants had submitted a fraudulent claim in violation of the FCA."[94]

The district court attempted to stake out a middle ground between a wholesale adoption of the relator's theory and a rejection of the contention that an alleged violation of the Anti-Kickback Act can form the basis for a violation of the FCA. First, it noted that one other district court had ruled that an alleged violation of the Anti-Kickback Act could form the basis

92. 914 F. Supp. at 1508.

93. United States *ex rel.* Pogue v. American Healthcorp, Inc., No. 3-94-0515, 1995 WL 626514, at *5 (M.D. Tenn. Sept. 14, 1995).

94. 914 F. Supp. at 1509. The district court reversed its prior ruling that a relator must allege that the government suffered damages in order to state a cause of action under the FCA. It pointed out that the Supreme Court in *Marcus v. Hess*, 317 U.S. 537 (1943), had affirmed, without discussion, a district court ruling that a failure to show actual damages would not prove fatal to the plaintiff's cause of action under the FCA. 914 F. Supp. at 1509 n.1.

for a violation of the FCA.[95] The court also pointed out that a body of FCA case law had broadly construed the statute to reach instances where a violation of the FCA was based upon a violation of another statute.[96] Finally, the court pointed to the legislative history of the FCA, which stated that "'each and every claim submitted . . . in violation of any statute or applicable regulation, constitutes a false claim.'"[97] The court concluded that Congress did not intend to limit the FCA to claims that are fraudulent on their face, but to include "fraudulent *acts* that cause the government to pay out sums of money to claimants it did not intend to benefit."[98]

If the district court had completed its analysis at this point, the case would have been a complete victory for the relator. However, the court cautioned that the FCA did not reach all fraud to which the government is exposed.[99] The court also pointed out that several other courts had in fact refused to apply

95. 914 F. Supp. at 1509 (citing United States *ex rel.* Roy v. Anthony, 914 F. Supp. 1504 (S.D. Ohio 1994)). The district court in *Roy* ruled that plaintiff's "vague assertion" that defendants "were engaged in continuing violations of the Fraud & Abuse Statute during—and in connection with—their submission of claims for Medicare/Medicaid payments" created "a tenuous connection between the Fraud & Abuse Statute and the False Claims Act, but the connection is sufficient to overcome the burden of a [Fed. R. Civ. P.] 12(b)(6) motion." *Roy*, 914 F. Supp. at 1506.

96. *Pogue*, 914 F. Supp. at 1510-11 (citing Ab-Tech Constr., Inc., v. United States, 31 Fed. Cl. 429 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995), and United States v. Incorporated Village of Island Park, 888 F. Supp. 419 (E.D.N.Y. 1995)).

In *Ab-Tech*, the plaintiff had obtained a Small Business Administration contract based upon its representation that it would adhere to program requirements that it would obtain advance approval of financial arrangements it had entered into with non-minority firms. The court ruled that although the claims were not false—the work had been performed—the claims were rendered false by plaintiff's failure to abide by the rules underlying the program. In *Island Park*, the court had found that defendants had engaged in a pre-selection scheme under which it gave preferential treatment to resident white applicants for housing in violation of regulations applicable to the grant funds it received. Further, the court found that the defendants, in obtaining the grant funds, falsely stated that persons would not be excluded from the program on the basis of race. From these facts it concluded that defendants had violated the False Claims Act by engaging in fraudulent conduct and making false statements that caused false claims for HUD-subsidized mortgages to be submitted to the government.

See also Ryan, *supra* note 7, at 144.

97. 914 F. Supp. at 1513, quoting S. Rep. 99-345, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. The court continued: "'[C]laims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program, or though payments on the Government loan are current, if by means of false statements the Government was induced to lend an inflated amount.'" *Id.* at 1511 (quoting S. Rep. 99-345, 1986 U.S.C.C.A.N. at 5274).

98. 914 F. Supp. at 1513 (emphasis added).

99. 914 F. Supp. at 1508 (citing United States v. McNinch, 356 U.S. 595 (1958)).

the FCA in particular situations even though the defendant had engaged in fraudulent conduct.[100] In its attempt to reconcile the case law, the court first concluded that Congress intended to reduce financial loss to the government, either through patently false claims or claims that "cause the government to pay out sums of money to claimants it did not intend to benefit."[101] Nevertheless, the court concluded that the FCA did not "operate as a stalking horse for enforcement of every statute, rule, or regulation" nor "punish every type of fraud committed upon the government."[102] Thus, the court concluded that a relator may bring his claim under the FCA "only if he can show that Defendants engaged in the fraudulent conduct with the purpose of inducing payment from the government."[103] Because the *Pogue* court found that the relator had in fact alleged "that Defendants concealed their illegal activities from the government in an effort to defraud the government into paying Medicare claims it would not have otherwise paid," he had stated a cause of action under the FCA.[104]

In *Columbia/HCA*, the district court arrived at a different conclusion. In this case, the relator contended that the defendants had created investment arrangements and provided financial inducements to physicians for patient referrals in violation of the Medicare Anti-Kickback Act and Stark laws, which, the relator contended, resulted in a violation of the FCA.[105] The

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100. 914 F. Supp. at 1511-12 (citing United States v. Shaw, 725 F. Supp. 896 (S.D. Miss. 1989) and United States *ex rel.* Weinberger v. Equifax, 557 F.2d 456 (5th Cir. 1997)). In *Shaw*, the district court rejected the government's contention that the use of a bribe to influence loan approval rendered the application for the loan false or fraudulent. In *Weinberger*, the Fifth Circuit held that even if plaintiff had properly alleged facts constituting a violation of the Anti-Pinkerton Act, 5 U.S.C. § 3108 (1995), which prohibits the government from employing an individual employed by a detective agency or similar organization, he had failed to state a claim under the FCA. The court stated: "Unless the government made it clear that it would not employ detective agencies when it contracted for the work, [the defendant's] application did not make a material misrepresentation, did not mislead the government, and thus did not defraud the government within the meaning of the False Claims Act." 557 F.2d at 461.

101. 914 F. Supp. at 1513.

102. *Id.*

103. *Id.*

104. *Id. See also* Kristen DeBry et al., *Health Care Fraud*, 33 AM. CRIM. L. REV. 815 (1996); Pamela H. Bucy, *Crimes by Health Care Providers*, 1996 U. ILL. L. REV. 589 (1996) (further discussing health care industry fraud against the government).

105. United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 938 F. Supp. 399, 401 (S.D. Tex. 1996). Stark I prohibited doctors from referring Medicare patients to an entity for clinical laboratory services if the referring doctor had a non-exempt financial relationship with such entity. 42 U.S.C. § 1395nn (1995). Stark II

defendants contended that the court should dismiss the relator's claim because the law of the Fifth Circuit prohibited an FCA action if the government did not pay out more on a claim than it would have paid but for the alleged fraud.[106] The district court concurred with the defendants, holding that the Fifth Circuit still required "that a claim itself be false or fraudulent in order for liability under the FCA to exist . . . . Allegations that medical services were rendered in violation of Medicare anti-fraud statutes do not, by themselves, state a claim for relief under the FCA."[107]

While the *Apria* case recently settled, the arguments made by the DOJ and defendants during the course of the litigation are instructive. In *United States ex rel. Parker v. Apria Healthcare Group, Inc.*,[108] the DOJ intervened in a qui tam action and amended the whistle blower's complaint to allege that Apria entered into a "consultant" agreement with defendants Georgia Lung Associates ("GLA") and Dr. Swartz, the "primary purpose" of which was to secure "patient referrals."[109] The government contended that Apria paid GLA an amount that exceeded the fair market value of any consulting services provided. Apria immediately filed a motion to dismiss asserting that the government could not base an FCA action upon a violation of the Anti-Kickback Act. Defendant pointed out that the underlying claims were truthful and, therefore, could not form the basis of an FCA action; that the FCA is not intended to be a "catchall" remedy for every type of alleged fraud against the government; and that the Anti-Kickback Act is a criminal statute with no provision for civil enforcement.[110]

The government, in opposing Apria's motion to dismiss, set forth three grounds upon which it believed its claim should survive.[111] First, it contended that the FCA reaches not just "false"

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expanded the scope of "designated health services" for which referrals are prohibited. *Id.* § 1395nn(a)(1).

106. 938 F. Supp. at 403 (citing for support United States *ex rel.* Weinberger v. Equifax, 557 F.2d 456 (5th Cir. 1977), and United States v. Shaw, 725 F. Supp. 896 (S.D. Miss. 1989)).

107. *Id.* at 405.

108. No. 1:95-CV-2142-FMH (N.D. Ga. amended complaint filed July 10, 1996).

109. Memorandum of Law in Support of Motion of Defendant Apria Healthcare Group, Inc. to Dismiss Complaint and Amended Complaint, at 4, *Apria* (No. 1:95-CV-2142-FMH) (memorandum filed July 25, 1996). The case was settled before the court ruled on the motion to dismiss.

110. *Id.* at 4-14.

111. Memorandum of the United States in Opposition to Apria Healthcare Group, Inc., Georgia Lung Associates, P.C. and Edward I. Swartz's Motions to Dis-

claims but all "fraudulent" attempts to obtain governmental funds. Second, it asserted that the defendants' actions were "fraudulent" because, contrary to their representations in provider agreements to abide by all program requirements, they had entered into a kickback scheme that violated the Anti-Kickback Act, thereby rendering their underlying Medicare claims false. Third, the government, relying primary upon the analysis contained in *Pogue*, argued that a number of cases as well as the FCA's legislative history supported the conclusion that an FCA action may be based upon the violation of another statute.[112]

Thus, there is no definitive resolution of the issue. As suggested below, the resolution that best conforms with the structure and policy of the Anti-Kickback Act is that an FCA action cannot be based upon an alleged violation of the Anti-Kickback Act because the two statutes, when applied together, conflict.

B. The Conflicts and Ill Effects of Using the False Claims Act to Prosecute Kickback Schemes

Courts should reject attempts to base FCA actions upon a violation of the Anti-Kickback Act for four reasons. First, the intent standards in the two statutes are in conflict. Second, the legislative histories of both acts reveal no intent on the part of Congress to use both to combat kickbacks in the health care industry. Third, Congress intended that the Anti-Kickback Act be the government's exclusive remedy when persons knowingly and willfully solicit or receive remuneration in exchange for the referral of program-related business. Last, these actions could have a chilling effect on beneficial changes occurring in the health care industry.

There is a conflict between the Anti-Kickback Act and the FCA when the government proposes to establish a violation of the FCA based upon a violation of the Anti-Kickback Act in a civil proceeding. Under the plain language of the FCA, the government need only prove that defendant acted with "reckless disregard" or "deliberate ignorance" of the facts in order to establish a violation of the FCA.[113] The Anti-Kickback Act, how-

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miss the United States' Amended Complaint, *Apria* (No. 1:95-CV-2142-FMH) (memorandum filed Aug. 22, 1996).

112. *Id.* at 14-16.

113. As was noted above, the Senate's chief sponsor of the amendments to the FCA pointed out that the Act does not require "proof of specific intent." 132 Cong. Rec. S11238 (daily ed. Aug. 11, 1986) (statement of Sen. Grassley). Further, in the House, Rep. Berman stated that the FCA may apply "where the submitted claims to

ever, mandates that the defendant "knowingly and willfully" engage in the prohibited conduct. Inevitably, when the government attempts to apply the lower intent standard to an illegal referral by alleging a violation of the FCA, a conflict is created. There will be a category of cases in which the defendant acted with recklessness or in deliberate ignorance of known facts but did not act "knowingly and willfully." To the extent the government attempts to penalize these individuals for illegal referrals, courts should dismiss the action.

The cases previously discussed underscore the type of conflict that may arise. As was noted, in *Lorenzo* and in *Krizek* the defendants claimed that they did not "know" that the claims they submitted were false claims. In these cases, the courts imposed liability because, under the circumstances, the defendants were "reckless" (the FCA standard) in not determining whether the factual basis of their claims was accurate. Conversely, as explained in section I(F) above, under the Anti-Kickback Act, defendants at a minimum must have actual knowledge that their conduct was improper. Recall that the Ninth Circuit held in *Hanlester* that defendants must know they have violated the law; their belief that their arrangements were lawful then provides a defense to the allegations. The Eighth Circuit in *Jain* held that the defendant must know his conduct is wrongful. If either court had applied the FCA intent standard, and thereby limited its analysis to whether the litigants were reckless in entering into the questioned arrangement, the analysis would have been substantially different, and, in the *Hanlester* case, the result may have been different as well.

When the Supreme Court has confronted situations in which two statutes may be applied but conflict in their application, it applies the more specific. "Where there is not clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment."[114] In the context of the Anti-Kickback Act, the specific resolution was to design a statute requiring a specific intent provision with a dual enforcement scheme, which permitted criminal prosecution or administrative enforcement. There was no clear intention to otherwise sanction an illegal kickback using the already avail-

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the Government are prepared in such a sloppy or unsupervised fashion" that it "result[s] in overcharges to the Government." 132 CONG. REC. H9389 (daily ed. Oct. 7, 1986).

114. Morton v. Mancari, 417 U.S. 535, 550-51 (1974).

able FCA. Therefore, where an application of the Anti-Kickback Act conflicts with the FCA, the specific provisions of the Anti-Kickback Act govern and provide the government with a means of relief.[115] Courts should refrain from reading the Anti-Kickback Act into the FCA because the histories of *both* the Anti-Kickback Act and the FCA demonstrate that Congress did not intend these statutes to be used in concert.

As explained in Section I, Congress has amended the Anti-Kickback Act at least four times to clarify and narrow its application to only those who "knowingly and willfully" engage in prohibited conduct. To assure compliance, Congress directed the Secretary of HHS to specify practices that were so inherently innocuous that they would not be subjected to prosecution. Most recently, Congress directed the Secretary to furnish the health care community with advisory opinions and, when appropriate, additional safe harbors and fraud alerts. The clearly stated goal was to avoid any chilling effect the Act might have on legitimate arrangements. To expand the otherwise clear boundaries of unacceptable practice and broaden them under the FCA flies in the face of congressional actions. Under these circumstances, not only will the most "deliberate cases" of a violation of the law be prosecuted either by the DOJ or whistle blowers, but so too will fringe cases. In direct contradiction to congressional intent, such an enforcement policy could easily have a "chilling effect" on legitimate transactions and impede "providers who are attempting to structure new and innovative health care delivery systems to contain health care cost."[116]

Congress's goals in amending the FCA likewise could be undermined. Congress specifically set forth the standard of intent applied in FCA actions—reckless disregard or deliberate ignorance. However, the government may only establish a violation of the Anti-Kickback Act by proving that the person acted with specific intent to violate the law, the explicit standard that Congress had rejected under the FCA but had embraced under the Anti-Kickback Act. The result would be two tracks in FCA litigation—litigation where the court must apply the intent standard of the FCA and a second set of prosecutions where the

115. *See also* McDonnell v. Cisneros, 84 F.3d 256, 261 (7th Cir. 1996) ("When Congress crafts particular remedies for particular wrongs, the presumption is that these are the exclusive remedies and that such limitations as they may embody are not to be circumvented by extending a more generally worded statute over the subject of the more specific one.") (citations omitted).

116. *Id.*

court must ignore the FCA intent standard and apply an intent standard of another statute, the Anti-Kickback Act. This result is contrary to Congress's intent that the FCA provide a "uniform" scienter standard to be applied in all FCA prosecutions.[117]

The second issue is perhaps the most troubling: the expansion of exclusive remedies. The Supreme Court has ruled that where it is clear from the legislative history that Congress intended one statute to provide an exclusive remedy, that statute must be applied even where the terms of another statute may operate.[118] Amendments to and debates on the Anti-Kickback Act, such as the imposition of an intent standard, clarification as to its application, and establishment of a dual (criminal and administrative) enforcement process, manifest the intent to fill the field in this area and establish an exclusive remedy under the Anti-Kickback Act. While courts have applied the FCA to violations of other statutes,[119] the key distinction is that the other statutes did not on their face encompass possibly innocent conduct.[120] For example, violations of the environmental laws, the Fair Housing Act, and the General Anti-Kickback Act are equally actionable whether the action is brought under those statutes or under the FCA because innocent conduct is not included within the confines of these statutes. To the contrary, as the Eighth Circuit pointed out in *United States v. Jain*, the Anti-Kickback Act may

117. *See* S. REP. NO. 99-345, at 6-7, *reprinted in* 1986 U.S.C.C.A.N. at 5271-72.

118. *See, e.g.*, Brown v. General Servs. Admin., 425 U.S. 820, 828-29 (1976) (finding that Congress intended "to create an exclusive preemptive administrative and judicial scheme for the redress of federal employment discrimination"); *see also* Jett v. Dallas Indep. Sch. Dist., 491 U.S. 701, 734 (1989) ("precisely drawn, detailed statute pre-empts more general remedies").

119. *See, e.g.*, United States v. Accudyne Corp., 880 F. Supp. 636 (W.D. Wis. 1995) (holding that the FCA was not preempted by environmental laws, such as the Clean Water Act, when the relator had contended a violation of the FCA predicated upon a violation of the environmental laws). *See also* United States v. Incorporated Village of Island Park, 888 F. Supp. 419 (E.D.N.Y. 1995) (holding that the FCA was not preempted by the Fair Housing Act ("FHA") when the government had asserted claims under the FCA rather than under the FHA).

120. The General Anti-Kickback Act, 41 U.S.C. §§ 51-58 (1995), generally prohibits the payment of compensation by a subcontractor to a prime contractor for the purpose of improperly obtaining favorable treatment in connection with a prime contract. Unlike the Medicare/Medicaid Anti-Kickback Act, it expressly permits the government to institute a civil cause of action based upon a demonstration that defendant "knowingly engages in conduct prohibited" by the law. *Id.* § 55. Thus, unlike the situation with the Anti-Kickback Act, there is no conflict between the General Anti-Kickback Act and the FCA because *both* statutes provide for civil relief upon a showing that the defendant "knowingly" violated the law. Under these circumstances, the rule permitting plaintiff to chose the remedies prevails because there is no conflict between statutes.

encompass within its broad sweep innocent conduct.[121] In addition, Congress has created statutory exceptions to the Anti-Kickback Act and now has mandated the Secretary to provide even more safe harbors, thereby protecting from Anti-Kickback Act sanctions what the government perceives as innocent conduct.[122] Additionally, if a party brings an action for a prohibited kickback under the FCA, with its lesser intent standard, there is a substantial risk that innocent persons would be prosecuted since, in the eyes of Congress, only those who "knowingly and willfully" pay or solicit remuneration are culpable under the Anti-Kickback Act.

Finally, courts should consider the policy implications of applying the FCA to activities proscribed by the Anti-Kickback Act. As has been well documented, the transformations occurring within the health care industry have required increased coordination of resources. Further, those compensated under capitation systems may be subject to guidelines regarding referrals that seek to reduce or eliminate unnecessary medical services. The necessity of such interconnectedness and adherence to such guidelines require exchanges that include the payment of remuneration, found acceptable under a safe harbor or statutory exception. An overly broad interpretation of the Anti-Kickback Act could have a chilling effect on cost-saving measures that could enhance patient care.[123]

Certainly, the use of the FCA to enforce another law is not unusual. What are unusual are the results explained above, which are not supported by the purposes or goals of the FCA and not supported by Congress's response to illegal kickbacks.

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121. 93 F.3d 436, 440 (8th Cir. 1996).

122. For example, the safe harbors to date have touched upon investment interest, rental fees for space and equipment, contracts for personal services and management, the sale of a practice, the use of referral agencies and services, warranties, discounts, payments to employees, payments to group purchasing organizations, issues facing health care providers and the home health industry, and services to residents at nursing facilities. 42 C.F.R. § 1001.952 (1996).

123. *See, e.g.*, David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861 (1989) (asserting that "[i]t is preposterous to attempt to prevent payments among health care providers, at least in an economic milieu that relies upon private behavior motivated by the promise of profit"). *See also* Andrea Tuwiner Vavonese, *The Medicare Anti-Kickback Provision of the Social Security Act—Is Ignorance of the Law an Excuse for Fraudulent and Abusive Use of the System?*, 45 CATH. U. L. REV. 943 (1996); John J. Farley, Note, *The Medicare Antifraud Statute and Safe Harbor Regulations: Suggestions for Change*, 81 GEO. L.J. 167 (1992).

CONCLUSION

The general FCA and the broadly worded Anti-Kickback Act provide the federal government with substantial power over any person who desires to furnish care to Medicare and Medicaid beneficiaries. However, both statutes were designed to address different concerns and problems. The government's attempt to mix the statutes results in an unwarranted dilution of the Anti-Kickback Act's intent standard, transforms a criminal law statute into a civil statute, imposes possibly enormous penalties, and converts a statute that does not provide for private relief into one that permits private causes of action. There is no evidence that Congress intended any of these results. Given this, courts should refuse to allow the government and whistle blowers to base their FCA actions upon an alleged violation of the Anti-Kickback Act.