CURRENT ISSUES UNDER THE CIVIL FALSE CLAIMS ACT: WORTHLESS SERVICES, OFF-LABEL USE, AND MORE

Prepared for American Health Lawyers Association

Fundamentals of Health Law Program

November 10, 2008

Elizabeth Carder-Thompson and Andrew L. Hurst

Reed Smith LLP Washington DC 202.414.9200

I. INTRODUCTION

A dizzying array of civil and criminal provisions address false or fraudulent representations made to, and false claims filed with, Medicare, Medicaid, and state and federal health care programs. This outline will briefly identify relevant criminal and civil provisions relating to these issues, and then focus more closely on recent uses of the civil False Claims Act ("FCA") in government investigations of health care providers, suppliers, and manufacturers, including a section on state false claims legislation. Finally, it will discuss the issue of distinguishing overpayments from false claims and provide information on the voluntary disclosure program of the Office of the Inspector General ("OIG") of the Department of Health and Human Services (HHS).

II. CRIMINAL STATUTES: OVERVIEW

A. Medicare and Medicaid Anti-Fraud and Abuse Amendments (42 U.S.C. §1320a-7b)

This section of the Social Security Act ("SSA") provides criminal penalties for engaging in certain activities involving Federal health care programs. Subsection (a) governs false statements and representations, and makes it a crime knowingly and willfully to:

1) make or cause to be made a false statement of a material fact in any application for any payment;

2) make or cause to be made a false statement of a material fact for use in determining rights to payment;

3) fail to disclose or to conceal an event affecting an individual or continued right to receive a benefit or payment;

4) converting benefits for personal use;

5) presenting claims by unlicensed physicians; and

6) counseling on asset transfer to permit Medicaid or other eligibility.

The government has argued that paragraph 3, above, makes it a felony to fail to disclose to Medicare and Medicaid the existence of an overpayment. A separate subsection (c) governs false statements or representations with respect to the condition or operation of facilities. Id. at §1320a-7b.

B. Mail or Wire Fraud (18 U.S.C. §§1341, 1343)

These provisions apply to use of the mails or wire for the purpose of executing any scheme or in furtherance of a plan to defraud or for obtaining money or property by means of false or fraudulent representations.

C. RICO (18 U.S.C. §§1961 *et seq*.)

The Racketeered Influence and Corrupt Organizations Act prohibits a person from receiving any income, directly or indirectly, from a pattern of racketeering activity, defined as committing a predicate act (e.g., mail or wire fraud) at least twice in ten years.

D. Money Laundering (18 U.S.C. §§1956-1957)

This statute prohibits knowingly engaging or attempting to engage in a "monetary transaction in criminally derived property" of value greater than $10,000 and derived from "specific unlawful activity" – which includes mail and wire fraud, theft or bribery in programs involving federal funds, or "any act or activity constituting an offense involving a federal health care offense."

E. False Statements (18 U.S.C. §1035)

Under the U.S. Criminal Code, a person can be subjected to a fine and/or imprisonment for up to five years when such a person, in any matter involving a health care program, "knowingly and willfully (1) falsifies, conceals, or covers up by a trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses a materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry."

F. False Claims (18 U.S.C. §287)

This section applies to false claims for payment submitted to the federal government, such as those for services not provided, or for unnecessary services.

III. CIVIL MONETARY PENALTIES (42 U.S.C. §1320a-7a)

The OIG has broad authority to impose civil monetary penalties (CMPs) for a wide variety of actions, including many involving false claims and representations. These include:

- Presenting a claim that the person knows or should know is false;[1]
- Presenting a claim for a service not provided as claimed;
- Engaging in a pattern or practice of upcoding; and
- Presenting claims for physician's services not rendered by a physician.

IV. THE FEDERAL CIVIL FALSE CLAIMS ACT

The federal civil False Claims Act, 31 U.S.C. §§3729, *et seq*. ("FCA" or the "Act"), is a civil statute whereby the United States can recover monetary damages from parties who file fraudulent claims for payment of funds by the federal government.[2] Originally enacted in 1863, the FCA was intended to combat fraud and price-gouging by government contractors during the Civil War. Little used for over one hundred years, the Act was extensively amended in 1986 to expand its scope of liability, increase monetary penalties and damages, and to strengthen the ability of private parties to bring actions on behalf of the government.[3] Since its amendment, the FCA has become one of the government's primary tools in combating fraud connected with the payment of government funds, particularly in connection with Medicare and Medicaid reimbursement. Because of the federal government's success in recovering funds

---

1 See 1320a-7a(i)(7): "should know" is defined as acting in deliberate ignorance or in reckless disregard of the truth or falsity of the information; there need be no proof of specific intent to defraud.

2 It is important to note that under certain circumstances, criminal and civil prosecution of the same circumstances creating a "false" claim may constitute impermissible double jeopardy. *See United States v. Halper*, 490 U.S. 435 (1989); *United States v. Mayers*, 957 F.2d 858 (11th Cir.), *cert. denied*, 504 U.S. 989 (1992).

3 *See* Pub. Law 99-562, § 2, Oct. 27, 1986, 100 Stat. 3153.

through the FCA, a number of states have enacted civil false claims statutes of their own to combat fraud in state programs.

As discussed below, the FCA and its state progeny create a very broad range of liability in connection with claims for payment from governmental entities, and provide for severe penalties and damages where liability is found. Moreover, these statutes allow civil actions on behalf of the government to be brought by "whistleblowers" -- private parties who then receive a portion of the government's recovery. The combination of these factors has resulted in an explosion of false claims litigation in the past two decades, making it vital for attorneys representing entities who deal with the government to understand the fundamentals of the federal and state false claims acts, and to keep abreast of the latest developments and strategies involved in false claims defense.

A. Liability Under the FCA

The FCA creates liability for false claims under seven circumstances:

(1) knowing presentation of a false or fraudulent claim to the federal government for payment or approval (31 U.S.C. § 3729(a)(1));

(2) knowing use or creation of a false record or statement to get a false or fraudulent claim paid by the federal government (31 U.S.C. § 3729(a)(2));

(3) conspiring to defraud the federal government to get a false or fraudulent claim paid (31 U.S.C. § 3729(a)(3));

(4) intentional failure to return all federal government money or property (31 U.S.C. § 3729(a)(4));

(5) intentional making and issuance of a receipt for more than what the federal government actually received (31 U.S.C. § 3729(a)(5));

(6) knowing purchase or receipt of property from a federal official who is not authorized to sell or deliver the property (31 U.S.C. § 3729(a)(6));

(7) knowing creation or use of a false record or statement to decrease a monetary obligation to the government (31 U.S.C. § 3729(a)(7)).

The overwhelming majority of cases brought under the FCA fall under either sections 3729(a)(1) or (2). Those sections are the focus of this presentation.

In order to establish liability under 31 U.S.C. §§ 3729(a)(1) or (2), a plaintiff bears the burden of showing: a) that the defendant submitted or caused the submission of a claim to the federal government; b) that the claim was false or fraudulent, or the defendant made or used false or fraudulent records or statements to obtain the claim's payment or approval; and c) that the defendant either had actual knowledge of the claim's falsity or acted in reckless disregard of the claim's validity. Because the FCA specifically creates liability for parties who not only directly submit claims to the government, but for parties who cause such submissions to be made as well, it is not necessary for the plaintiff to show that the person actually presenting the claim knew it to be false.

A “claim” for purposes of the FCA covers a wide range of transactions with the government. The Act defines a claim as:

> [A]ny request or demand which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient of any portion of the money or property which is requested or demanded.

31 U.S.C. §3729(c). Courts have interpreted this expansive definition to include a number of transactions which may not at first blush appear to be "claims."[4] However, a number of courts have refused to find submissions to the government to be "claims" where the submission is unrelated to the receipt of government funding.[5] Most courts have required an impact on the treasury[6] in some form for there to be an actionable "claim."[7]

Another issue that has arisen in terms of FCA liability is whether a claim must be directly "presented" to the federal government to trigger the Act. Many courts have required a claim that forms the basis of FCA liability to have been presented to the federal government directly, even if the applicable section of the statute does not

---

4 *See, e.g. United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196 (D.C. Cir. 1995), *cert. denied*, 516 U.S. 1068 (1996)(false reports relating to progress being made on contracted work are "claims"); *United States. v. Truong*, 860 F.Supp. 1137 (E.D.La. 1994)(redeemed illegally acquired food stamps are "claims").

5 *See, e.g. United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996), *cert. denied*, 117 S.Ct. 958 (1997)(finding no "claim" where forms submitted to state agency did not certify compliance with federal regulations, and any regulatory violations were unrelated to the receipt of federal funds).

6 In enacting the 1986 amendments to the Act, Congress made it clear that the FCA was targeted at fraud which impacted the government fisc: "The False Claims Act is intended to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services." S. Rep. No. 99-345, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.

7 *See, e.g. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) ("The False Claims Act at least requires the presence of a claim – a call upon the government fisc – for liability to attach."); *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) ("the statute attaches liability. . .to the 'claim for payment.'"); *Dookeran v. Mercy Hospital of Pittsburgh*, 281 F.3d 105 (3d Cir. 2002)(application to obtain designation as a clinical center containing false representations could not qualify as a "claim" for purposes of the Act).

explicitly contain such a requirement, as in the case of Sections 3729 (a)(2) and (a)(3).[8] Other courts had found presentment to be unnecessary, i.e., so long as government funds are involved, the Act applies.[9]

The Supreme Court settled the "presentment" issue in *Allison Engine*, finding that while the Act does not contain a specific "presentment" requirement, it does require a "direct link" between the fraudulent conduct in question and the loss to the federal government.[10] In so holding, the unanimous court also found that the Act requires a showing of the "materiality" of a false statement to a claim. In sum, if a false statement is the basis of liability, a plaintiff must show that the false statement was material to the actual payment of the claim – in other words, that the statement was a condition of the payment of the claim.[11] As a whole, the *Allison Engine* decision tightened the link between a defendant's conduct and the payment of money by the federal government, and shortened the reach of the Act.

The "falsity" of a claim is another potential issue to be litigated in an FCA complaint. In many FCA cases, falsity of a claim is based on an interpretation of a statutory or regulatory provision. Where the falsity of a claim rests on a legitimately disputed interpretation of a regulation or statute, courts will sometime refuse to find a

---

8 *See, e.g*. *United States ex rel. Totten v. Bombardier Corp*., 380 F.3d 488 (D.C. Cir. 2004)(requiring showing of presentment of claim directly to a government official in Section 3729(a)(2) action).

9 *See, e.g. United States ex rel. Thacker v. Allison Engine Company, Inc*., 471 F.3d 610 (6th Cir. 2006)(holding that presentation of claim to government unnecessary under FCA so long as government funds are used in the transaction in question).

10 *Allison Engine Co. v. United States ex rel. Sanders*, 07-214, 553 U.S. ____ (June 9, 2008).

11 *Id.*

claim "false" for purposes of the FCA.[12] In addition, some courts have found that an agency's determination as to the propriety of a submission to the government may be determinative as to the "falsity" of a claim.[13]

Perhaps the most hotly disputed area of FCA liability has been its requirement of intent. The statute itself attempts to clarify the standard, defining “knowingly” for purposes of the Act as actual knowledge of falsity, or deliberate ignorance or reckless disregard of the truth or falsity of the claim or statement.[14] While specific intent to defraud is not required, courts have made clear that the Act is "concerned with ferreting out wrongdoing," not punishing innocent mistakes or mere negligence.[15]

A case under the FCA cannot be brought later than six years after the violation was committed, or more than three years after the material facts were known or should have been known to the government, whichever is later, but under no circumstances more than ten years after the violation.[16]

B. Penalties and Damages Under the FCA

---

12 *See, e.g. Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir.), *cert. denied*, 117 S.Ct. 175 (1996)(refusing to find claim false where evidence did not support reasonable inference that the allocation of construction costs in connection with federal contract was false).

13 *See United States ex rel. Windsor v. Dyncorp, Inc.*, 895 F.Supp. 844, 851 (E.D.Va. 1995)(Department of Labor determination as to whether an employee's classification was improper could establish a claim's falsity in connection with contractual wages); *but see United States v. Cripps*, 460 F.Supp. 969, 974 (E.D.Mich. 1978)(HUD approval of alleged collusive bidding scheme did not vitiate liability because the authorizing party "exceeded his or her authority and the government is not bound by the unauthorized acts of its agents.")

14 31 U.S.C. § 3729(b).

15 *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992).

16 31 U.S.C. § 3731(b).

The FCA's large civil penalties and damages are the main reason for the Act's popularity with the government and private parties bringing actions under its provisions. The FCA calls for civil penalties in the amount of $ 5,500 to $11,000 *per false claim*, as well as damages totaling three times the amount of damage sustained by the government as a result of the false claims.[17]

Although courts have been divided as to whether the government must show the actual payment of funds sought by a false claim to establish FCA liability,[18] most courts have required a plaintiff to demonstrate some sort of impact on the federal treasury to establish money damages.[19] In fact, some courts have found that if the government receives a different or inferior product or service than it bargained for, but receives the same or equivalent benefit that it would have otherwise, the government is entitled to no damages award even if liability is established.[20]

Damages under the FCA are reduced to double the damages suffered by the government if a violator voluntarily discloses the existence of the false claims to the government within thirty days of their occurrence and prior to the initiation of any

---

17 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3.

18 *Compare United States v. Kensington Hospital*, 760 F.Supp. 1120, 1127 (E.D. Pa. 1991) (determination of "actual harm" unnecessary to establish FCA liability) *with Young-Montenay, Inc. v. United States*, 15 F.3d 1040 (Fed. Cir. 1994) (damages are required element for FCA liability).

19 *See United States v. Advance Tool Co.*, 902 F.Supp. 1011 (W.D. Mo. 1995), *aff'd*, 86 F.3d 1159 (8th Cir. 1996), *cert. denied*, 117 S.Ct. 1254 (1997) (government could not prove actual damages after receipt of counterfeit tools, and penalties were only appropriate remedy).

20 *See United States v. Collyer Insulated Wire Co.*, 94 F.Supp. 493 (D.R.I. 1950) (company providing non-specification materials not liable for damages where substandard material was used effectively by government despite flaws).

investigation regarding the claims.[21] At least one court has held that penalties should not be imposed upon a party that voluntarily discloses.[22]

Courts have found that the penalties and damages provided for by the FCA are, at least in part, punitive, and therefore subject to the Excessive Fines Clause set forth in the Eighth Amendment.[23] There appears to be no hard-line test for an excessive fine, and courts have examined FCA penalties and damages under the Eighth Amendment on a case by case basis.[24]

C. The Qui Tam Provisions of the FCA

The *qui tam* provisions of the FCA allow private persons, called "relators," to bring civil false claims actions on behalf of the government.[25] These provisions, otherwise known as the "whistleblower" provisions, are another reason for the recent explosion of FCA litigation.

Procedurally, the *qui tam* provisions operate in a unique manner. The relator is required to file its suit under seal and to serve the government with the complaint, along with disclosure of all material evidence and information in the possession of the relator in connection with the alleged false claims.[26] Once served with the complaint and

---

21 31 U.S.C. §3729(a).

22 *United States ex rel. Falsetti v. Southern Bel Tel and Tel. Co.*, 915 F. Supp. 308 (N.D. Fla. 1996).

23 *United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001).

24 *See United States v. Mackby*, No. 02-16778, 2003 WL 21911092 (9th Cir. Aug. 12, 2003)(fines and penalties of approximately $ 730,000 resulting from damages suffered by government of approximately $ 55,000 does not violate Eighth Amendment).

25 31 U.S.C. §3730(b)(1).

26 31 U.S.C. §3730(b)(2).

information, the government has a sixty-day period to investigate the complaint and to decide whether it wants to intervene in the action.[27] If the government chooses to intervene, it exercises primary responsibility for the case, and the relator has limited control over the action.[28] If the government declines to participate, the relator may pursue the action without the government's assistance.[29]

Substantively, a *qui tam* action is identical to a normal FCA action in that the same rules and standards regarding liability and calculation of damages and penalties apply. Upon a successful recovery by the government, a relator receives 15 to 25 percent of the total award if the government intervenes and 25 to 30 percent of the total award if the government does not intervene. 31 U.S.C. § 3730(d).[30] If the relator is involved in the false claim, the court may reduce or eliminate the award to the relator depending on the relator's culpability. 31 U.S.C. § 3730(d)(3).

The *qui tam* provisions contain jurisdictional bars which divest a court of jurisdiction over an FCA action under certain circumstances. 31 U.S.C. § 3730(e). One of the jurisdictional bars in particular, the bar to actions deriving from publicly disclosed information, has been the subject of extensive litigation and is one of the most commonly used defenses to a *qui tam* action.

---

27 *Id*.

28 31 U.S.C. §3730(c)(1). If the government proceeds with the action, it has the right to settle or dismiss the suit over the objections of the relator. 31 U.S.C. § 3730(c)(2). Moreover, the government may limit the participation of the relator in the suit upon a showing that full participation would be detrimental to the government's case. *Id*.

29 31 U.S.C. § 3730(c)(3).

30 If a court finds that the lawsuit is based primarily upon information disclosed in another forum, the relator can be awarded no more than 10 percent of the government's proceeds. 31 U.S.C. § 3729(d)(1).

The "public disclosure" jurisdictional bar to *qui tam* actions, perhaps the most widely litigated jurisdictional bar, reads as follows:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing, audit or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(a). Courts have applied a three part inquiry in deciding whether jurisdiction exists in public disclosure situations: (1) whether the allegations made by the plaintiffs were publicly disclosed; (2) if so, whether the disclosed information is the source or basis for the relator's suit; and (3) if yes, whether the relator is an original source of that information.[31] If the complaint is based upon publicly disclosed information, and the relator is not an original source, a court lacks jurisdiction to entertain the case. *Id*.

A court's inquiry seeks to determine whether the publicly disclosed information "could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing."[32] With the public disclosure bar, Congress sought to limit *qui tam* actions to those where the relator contributes significant independent information not already available to the United States.[33] Ultimately, the purpose of the FCA's public disclosure bar is to

---

31 *U.S. ex rel. Cooper v. Blue Cross and Blue Shield of Florida*, 19 F.3d 562, 565 (11th Cir. 1994).

32 *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994).

33 *Id.* at 653.

discourage opportunistic FCA suits by persons "without independent knowledge of fraud [who] use information already available to the government to reap rewards for themselves without exposing any previously unknown fraud."[34]

The first inquiry in applying the FCA's public disclosure bar is whether there has been a "public disclosure" of the "allegations or transactions." The FCA itself details the types of disclosures that are deemed "public."[35] In particular, the statute refers to administrative, including governmental, audits or investigations. Further, public disclosure includes criminal, civil, or administrative hearings – including criminal and civil trials.[36]

Additionally, there must be a public disclosure of "allegations or transactions." As the FCA's reference to allegations or transactions is in the disjunctive, the public disclosure must reveal either the allegations of fraud or the elements of the underlying fraudulent transaction.[37] The elements of a fraudulent transaction include both the misrepresented state of facts and the true state of facts.[38]

The second prong of the public disclosure question is whether the action is "based upon" the publicly disclosed allegations or transactions. The majority view is

---

34 *Seal 1 v. Seal A*, 255 F.3d 1154, 1158 (9th Cir. 2001).

35 *See* 31 U.S.C. § 3730(e)(4)(A).

36 *See United States ex rel. Mistick PBT v. Housing Auth. of City of Pittsburgh*, 186 F.3d 376, 387 (3rd Cir. 1999), *cert. denied*, 529 U.S. 1018 (2000)(finding that the section refers to both civil and criminal hearings and trials, as well as other court proceedings that are not described as "hearings" in standard usage).

37 *See United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 740 (3rd Cir. 1997).

38 *See Mistick*, 186 F.3d at 385.

that the phrase "based upon" is a slight misnomer. That is, the majority of circuits have held that "based upon" means having a "substantial identity [with]" or "supported by" the prior public disclosure, not directly deriving from the disclosure.[39]

The third inquiry in applying the public disclosure bar is whether the relator was the "original source" of the information. For purposes of this prohibition, "original source" is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action … based on the information." 31 U.S.C. § 3730(e)(4)(B).[40] To qualify as an original source, relators must prove that they: (1) have direct and independent knowledge of the information; and (2) voluntarily provided the information to the United States prior to filing suit.[41] The term "direct" is defined as "marked by absence of intervening agency," while "independent knowledge" is knowledge that is not dependent on public disclosure.[42]

---

39 *See, e.g. Mistick*, 186 F.3d at 387-388; *United States ex rel. Biddle v. Bd. of Trustees of Leland Stanford, Jr. Univ.*, 161 F.3d 533, 539-40 (9th Cir. 1998); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 682-84 (D.C. Cir. 1997), *cert. denied*, 522 U.S. 865 (1997); *Cooper v. Blue Cross & Blue Shield of Florida, Inc.*, 19 F.3d 562, 567 (11th Cir. 1994); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1158 (2nd Cir. 1993); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 552 (10th Cir. 1992), *cert. denied*, 507 U.S. 951 (1993); *Houck on Behalf of United States*, 881 F.2d 494, 504 (7th Cir. 1989).

40 The Supreme Court recently made clear that to be an original source, a relator must have knowledge of violations at the time of his or her employment, not just predictions that the defendant would eventually commit fraud through its conduct. *Rockwell International Corp. v. United States*, 127 S.Ct. 1397 (2007).

41 *See United States ex rel. Barth v. Ridgedale Electric, Inc.*, 44 F. 3d 699, 702-03 (8th Cir. 1995); *Stone*, 999 F. Supp. at 857.

42 *See id.*

The FCA also expressly prevents relators from bringing *qui tam* complaints based on the same underlying facts as those in actions previously filed, regardless of their disclosure. This "first to file" bar states that "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the potential action." 31 U.S.C. § 3730(b)(5).

Courts addressing the "first to file" bar have construed it broadly. In general, courts have applied a "material facts" test, whereby later-filed actions are barred "regardless of whether the allegations incorporate somewhat different details."[43] The Ninth Circuit provided a detailed analysis of the "first to file" bar to date, holding that "Section 3730(b)(5) bars later-filed actions alleging the same material elements of fraud … regardless of whether the allegations incorporate somewhat different details."[44]

D. Defendant Counterclaims and Costs Under the FCA

Counterclaims by a *qui tam* defendant may be brought against a relator so long as those claims are not dependent on the liability of the defendant. For a long time counterclaims were absolutely forbidden against *qui tam* relators in an effort to prevent retaliation against whistleblowers. In the last two decades, however, courts have

---

43 *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001).

44 *Lujan,* 243 F.3d at 1189. *See also Palladino v. VNA of Southern New Jersey, Inc.*, 68 F. Supp. 2d 455 (D.N.J. 1999) (dismissing claims even though the "'later' qui tam plaintiffs stated facts different from those stated by the 'original' plaintiffs – indeed, they described events occurring at different offices of SmithKline in different regions of the country. . ."); *United States ex rel. Capella v. United Technologies Corp.*, No. 3:94-CV-2063, 1999 WL 464536 (D. Conn. June 3, 1999)("[S]ection 3730(b)(5) precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action, even if the allegations cover a different time period or location within a company.")

allowed counterclaims which are not predicated on the liability of the defendant to be brought, reasoning that in many cases the *qui tam* action will be the exclusive forum in which these claims may be brought.[45]

A *qui tam* defendant may recover attorneys fees and expenses from a relator if the government declines to intervene in the case, the relator proceeds, and the defendant prevails in the action. First, the *qui tam* provisions themselves contain a section which allows the award of reasonable attorneys fees and expenses to a defendant if a court finds the claim to be "clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4). Second, costs may be recovered from a relator pursuant to Federal Rule of Civil Procedure 54(d)(4), which allows the award of costs other than attorneys fees from a prevailing party in federal litigation. Third, recovery of attorneys fees and expenses may be available against both the relator and the government under the Equal Access to Justice Act, 28 U.S.C. § 2412(d)(1)(D). This act allows a defendant to recover fees and expenses incurred in an action brought by the government where "the demand by the United States is substantially in excess of the judgment finally obtained. . .and is unreasonable when compared with such judgment." *Id.*

E. Constitutional Issues Connected to the FCA

---

45 *See, e.g. United States ex rel. Burch v. Piqua Engineering*, 145 F.R.D. 452 (S.D. Ohio 1992)(denying motion to dismiss counterclaims against relator for breach of contract, defamation and other claims because the counterclaims compulsory and failure to allow would deny due process); *United States ex rel. Madden v. General Dynamics,* 4 F.3d 827 (9th Cir. 1993)(counterclaims for breaches of duty, libel, and misappropriation of trade secrets are proper because the claims are independent of defendant liability, and failure to allow claims would result in waiver and not discourage frivolous *qui tam* suits).

One constitutional issue that has arisen in the last few years is whether states could be sued under the FCA. In May, 2000, a divided Supreme Court ruled in *Vermont Agency of Natural Resources v. United States ex. rel. Stevens* that states could not be held liable under the *qui tam* provisions of the FCA.[46] The Court held that the term "person" in the FCA did not include states for the purposes of FCA liability. The Court noted that there is a long-held presumption against including states in the definition of "person," and nothing in the text of the FCA explicitly refutes that presumption. Writing for the majority, Justice Scalia reasoned that if Congress wished to alter the traditional rule that states are not subject to such liability, it must clearly state its intention to do so.

On March 10, 2003, the Supreme Court ruled that, unlike states, local governments are included in the definition of "person" in the False Claims Act, and are therefore subject to liability under the Act.[47] In doing so, the Court resolved a circuit split regarding such local government liability.[48]

In *Chandler*, the Supreme Court affirmed the Seventh Circuit's ruling that municipal governments are persons within the scope of the FCA. The Court found that the FCA term "person" included local governments when the statute was first enacted, and no subsequent amendment had changed that definition. The Court reasoned that corporations, both municipal and private, have been subject to FCA liability since the

---

46 *Vermont Agency of Natural Resouces v. United States ex. rel. Stevens*. 529 U.S. 765, 120 S. Ct. 1858 (2000).

47 *Cook County v. United States ex. rel. Chandler*, 123 S. Ct. 1239 (2003).

48 *Compare United States ex. rel. Garibaldi v. Orleans Parish School Board*, 244 F.3d 486 (5th Cir. 2001)(finding punitive nature of statute was strong evidence that Congress did not intend FCA to apply to local governments) *and United States ex. rel. Dunleavy v. County of Delaware*, 279 F.3d 219 (3rd Cir. 2002)(same) *with United States ex. rel. Chandler v. Cook County*, 277 F.3d 969 (7th Cir. 2002)(local governments liable under FCA).

Act's passage in 1863. This sharply contrasted with the tradition of state government immunity discussed in *Stevens*. Therefore, while the legislative history of the 1986 amendments was found in *Stevens* to be insufficient to overcome the presumption that states fall outside the definition of a "person," the Court found the same legislative history to be evidence that Congress intended to continue the tradition of municipal government inclusion in that definition. Further, the Court found it unlikely that Congress would repeal such a provision by implication. The Court stated that the traditional rule that disfavors the repeal of provisions by implication outweighed any concerns about the punitive nature of FCA damages, especially considering the statutory limits on those damages. Even though Congress has the power to exclude local governments from the FCA, the Court stated that it would not assume that Congress did so "under its breath."

A more fundamental constitutional question appears on the face of the Act. The *qui tam* provisions of the FCA create what appears to be a quandary: how does a relator have constitutional standing[49] to bring a claim on behalf of the federal government, particularly when the government declines to participate in the case, when the relator is not the party suffering the "injury in fact"? That question was also answered in the *Vermont* case by the Supreme Court, which found that the relator's "bounty" makes it the partial assignee of a claim by the United States, and therefore provides the requisite standing.[50]

---

49 Article III of the Constitution limits federal courts to jurisdiction over "cases or controversies." In order for a suit to constitute a case or controversy, the plaintiff who brings the suit must have "standing," *i.e.*, he must be the person who suffered an injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

50 529 U.S. at 773-4.

F. State False Claims Acts

At least seventeen jurisdictions have enacted false claims statutes, including *qui tam* provisions, modeled on the FCA: California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Massachusetts, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, and Virginia. In addition to those statutes, six other states have enacted laws that apply specifically to types of health care fraud: Georgia, Louisiana, Michigan, New Hampshire, Texas and Wisconsin.[51]

The Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1, *et seq*. (the "VFATA") is typical of these false claims statutes. The VFATA was signed into law by Governor Warner on April 17, 2002, and became effective on January 1, 2003. *See* 2002 Va. SB 445. Modeled very closely on the FCA, the VFATA creates liability in an identical manner as the FCA (Va. Code Ann. §8.01-216.3), has an identical limitations period (Va. Code Ann. §8.01-216.9), and the same intent requirement. Like the federal statute, the VFATA provides for "civil investigative demands," unique discovery power which permits the Attorney General to make expansive inquiry into false or fraudulent claims. Va. Code Ann. §8.01-216.10. Although these civil investigative demands provide the Attorney General with far ranging power regarding false claims, they are governed by specific safeguards contained within the VFATA that provide recipients with some protection and specificity. *See* Va. Code Ann. §§8.01-216.11-.18. The VFATA contains "qui tam" provisions which are nearly identical to those contained in the FCA.

---

51 New Mexico and Tennessee have both types of fraud combating statutes.

The Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.001, *et seq*. (the "Texas Act") is an example of a statute that takes a different tactic than the FCA. While the FCA is designed to address fraud in connection with any federal program, the Texas Act addresses only fraud connected to the Medicaid program, and assigns liability for various behaviors in billing under the program. Tex. Hum. Res. Code Ann. § 36.002. The Texas Act also creates criminal liability for any violation of the Act.[52] The level of criminal culpability for the offense is determined mainly by the amount of funds involved in the offense. *Id.*

The civil penalty in Texas is $5,000 to $15,000 for each unlawful act committed by the person" that injures an elderly person, a disabled person, or a person younger than 18 years of age; otherwise, the penalty is $1,000 to $10,000 for each unlawful act. *Id.* at § 36.052(a)(3). Like the FCA, the Texas Act requires the payment of treble damages, and lessens it based on voluntary disclosure. *Id.* at §§ 36.052. The Texas Act also calls for the mandatory or permissive suspension or revocation of a person or entity's license, permit, certification, or service provider agreement upon a finding of liability, as well as a mandatory ten-year disbarment from the Medicaid program. *Id.* at § 36.005. Finally, the Texas Act specifically allows for the Attorney General to bring actions for injunctive relief to remedy unlawful acts. *Id.* at §36.051.

Like the FCA, the Texas Act allows for *qui tam* actions. The provisions are generally similar with one significant distinction: if the Texas attorney general opts not to take over the action, the court "shall" dismiss the action in its entirety. *Id.* at § 36.104(b). The attorney general may contract with a private attorney to represent the state if it elects to proceed with the action. *Id.* at § 36.105. Under the Texas Act, the

---

52 *Id* at § 36.131.

state is specifically authorized to pursue alternate administrative remedies to alleged behavior, with the private plaintiff having the same rights in the administrative proceeding as the person would have under the other provisions. *Id.* at § 36.109.

Like the FCA, the Texas Act contains a section authorizing broad investigative powers, including Civil Investigative Demands. *Id.* at §§ 36.053 and 36.054. The demand must state the rule or statute under which the conduct is being investigated as well as the general subject matter of the investigation. It must also describe the classes of documents to be produced along with a return date. *Id.* at § 36.054(a). The defendant's failure to comply with the demand is punishable as contempt. The Texas Act specifically authorizes stay of discovery in a civil case brought under the statute if the discovery would interfere with a criminal or civil matter or investigation arising from the same facts. Id. at § 36.108.

G. Federal Prosecution of Health Care False Claims Cases

Because the FCA is a federal statute enforced by the Department of Justice ("DOJ"), that agency's policies regarding prosecution of entities have become key to understanding government action on health care fraud.

In 1998, Deputy Attorney General, Eric H. Holder, Jr. issued a memorandum[53] (commonly known as the "Holder Memorandum") detailing DOJ policy regarding the prosecution of health care FCA actions. Specifically, the Memorandum discusses two subjects: 1) guidance as to when the DOJ should prosecute health care FCA actions; and 2) "national initiatives" in FCA prosecutions.

---

53 Memorandum From Eric. H. Holder, Jr., to All United States Attorneys *et al.*, re Guidance on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998).

The Memorandum required DOJ to make two findings to prosecute an FCA action. First, it had to find that a provider submitted false claims to the government. The Memorandum detailed issues that should be considered in making this finding, including: a) whether relevant statutory and/or regulatory provisions made the provider's submission false; b) whether the data upon which the DOJ relied was accurate and true; c) whether the falsity of claims needed to be verified through further investigation, and if so, that the investigation confirmed the falsity of the claims.

The Memorandum also discussed "national initiatives" in FCA prosecutions. In essence, a national initiative involves a nationwide effort by the DOJ and HHS to address a perceived failure to adhere to the government's interpretation of statutes and guidelines governing health care providers. The Memorandum mandated the creation of working groups within DOJ to coordinate and plan future national initiatives. The groups were required to: a) examine initiatives for factual and legal accuracy; b) prepare initiative-specific guidance for DOJ personnel; and c) establish a general investigative plan for the initiative. Moreover, all DOJ personnel were instructed to utilize "contact letters" to attempt to resolve issues prior to the institution of litigation.

In 2003, Deputy Attorney General Larry D. Thompson issued a new guidance memorandum[54] (commonly known as the “Thompson Memorandum”). The purpose of the memorandum was to provide criteria to federal prosecutors when deciding whether to charge a corporation, rather than or in addition to individuals within the corporation. The Thompson Memorandum set out nine factors that DOJ should consider in determining whether to charge a corporation. Several of these factors relate to

---

54 Memorandum from the U.S. Department of Justice, Office of the Deputy Attorney General, Principles of Federal Prosecution of Business Organizations, (Jan. 20, 2003).

corporate compliance and include: the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents, including, if necessary, the waiver of corporate attorney-client and work product protection; and the corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies.

Although the existence and adequacy of a pre-existing compliance program is an important factor according to the Thompson Memorandum, a "paper-program" is not sufficient. The critical factors in evaluating any compliance program are "whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct to achieve business objectives."

In December 2006, Deputy Attorney General Paul J. McNulty issued new corporate charging guidelines[55] for federal prosecutors. These new guidelines, known as the "McNulty Memorandum," superseded and replaced the Thompson Memorandum in a number of respects. The McNulty Memo also included a list of nine factors for federal prosecutors to consider when deciding whether to indict a corporation.

The McNulty Memo addressed the two controversial factors as to the determination of "cooperation" in the Thompson Memo that created some controversy: whether a company that would not waive the corporate attorney-client and work product

---

55 Memorandum from the U.S. Department of Justice, Office of the Deputy Attorney General, Principles of Federal Prosecution of Business Organizations, (Dec. 12, 2006).

protection would be viewed as cooperating, and whether a company that advanced attorneys' fees to employees or agents under investigation or indictment would be viewed as cooperating. First, the McNulty Memo stated that federal prosecutors are required to obtain written approval from the Deputy Attorney General before seeking a waiver of the attorney-client privilege. This waiver must only be sought under limited circumstances "where there is a legitimate need for the privileged information to fulfill … law enforcement obligations." The four factors that determine "legitimate need" are:

- the likelihood and degree to which the privileged information will benefit the government's investigation;
- whether the information sought can be obtained in a timely and complete fashion by using alternative means that do not require waiver;
- the completeness of the voluntary disclosure already provided; and
- the collateral consequences to a corporation of a waiver.

Second, the McNulty Memo stated that prosecutors generally should not take into account whether a corporation is advancing attorneys' fees to employees or agents under investigation and indictment. However, prosecutors may continue to weigh whether the corporation appears to be "protecting its culpable employees and agents." A corporation's promise of support to culpable employees or agents may be considered by the prosecutor in weighing the extent and value of a corporation's cooperation. For example, a corporation retaining the employees without sanction for their misconduct or through providing information to the employees about the government's investigation pursuant to a joint defense agreement is likely not to be seen as cooperating with the government's investigation.

On August 28, 2008, Deputy Attorney General Mark Filip issued a memorandum revising the guidelines for corporate prosecution.[56] The Filip Memorandum specifically addresses the concerns expressed by the business community over the cooperation "credit" and effective compliance plans, and changes the policies set forth in the McNulty Memo in many respects.

These changes in DOJ policy as a result of the Filip Memo are fundamental. First, cooperation in the corporate context will no longer be measured in terms of waiver of privileges, but in terms of disclosure of relevant evidence and information. Moreover, the information disclosed need not be the attorney work product and privileged information required by the McNulty Memo. Second, the corporation's actions regarding its employees, including retention of counsel for employees, or firing or discipline of its employees, do not come into play in evaluating cooperation. Finally, joint defense agreements are no longer permissible factors for consideration of cooperation.

Further, the Filip Memo attempts to include "good faith" as a factor in evaluating compliance programs and their role in prosecution decisions. The change recognizes the complaint from the corporate world that earnest attempts to modify behavior were not sufficiently recognized by the McNulty Memo.

This area of law, and DOJ policy, continue to evolve in response to the increased use of compliance programs, and continued emphasis on corporate culpability for criminal and fraudulent acts.

---

56 Memorandum from the U.S.Department of Justice, Principles for Federal Prosecution of Business Organizations, (August 28, 2008).

H. Whistleblower Retaliation Provision of the FCA

The FCA, and many state acts, contain a section designed to prevent retaliation against *qui tam* relators, or "whistleblowers," by their employers as a result of their reporting fraud. The whistleblower retaliation section of the FCA provides as follows:

> Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

31 U.S.C. § 3730(h).

To state a cause of action under Section 3730(h), a plaintiff must demonstrate that: "(1) he engaged in 'protected conduct,' (*i.e.*, acts done in furtherance of an action under § 3730) and (2) that he was discriminated against because of his 'protected conduct.'"[57] "Protected conduct" requires a "nexus with the 'in furtherance of' prong of [a False Claims Act] action," and involves determining whether a plaintiff "sufficiently furthered 'an action filed or to be filed under'" the False Claims Act.[58] While a plaintiff's conduct will be seen as "in furtherance of" a False Claims Act claim so long as litigation is a distinct or reasonable possibility based on the purported fraudulent behavior, it is important to note that "[m]ere grumbling to the employer about job dissatisfaction or regulatory violations does not constitute protected conduct in the first place."[59]

---

57 *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 187 (3d Cir. 2001).

58 *McKenzie v. BellSouth Telecomm.*, Inc., 219 F.3d 508, 515 (6th Cir. 2000).

59 *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 743 (D.C. Cir. 1998). The Third Circuit also made clear that the contemplated must be a viable one for the whistleblower provisions to be triggered. *Dookeran v. Mercy Hospital*, 281 F.3d 105 (3d Cir. 2002). In that case, the court found that the circumstances as pled could not have

Continued on following page

The scope of the damages that can be sought under Section 3730(h) is becoming clear as more cases are brought to verdict under this section of the Act. Damages have been given for lost wages, reimbursable costs, pre- and post-judgment interest, and reasonable attorneys' fees – all seen as meeting the Act's requirement of "mak[ing] the employee whole."[60] Most courts have found that punitive damages cannot be awarded under Section 3730(h).[61]

I. Recent Developments under the Federal Civil False Claims Act

(1) Proposed Legislation to Amend the Federal Civil False Claims Act

In September 2007, Senators Charles Grassley and Dick Durbin introduced the "False Claims Correction Act of 2007."[62] This piece of legislation is designed to strengthen the FCA in areas viewed by critics as weak aspects of the Act's application to contractor fraud.

The proposed legislation would change the FCA in many major and substantive respects. First, it would remove the Act's "presentment" requirement -- that false claims must be presented to a government employee for them to fall under the purview of the Act. Instead, any claim involving government money or property, no matter how

---

Continued from previous page

given rise to a viable FCA action as a matter of law, and that Section 3730(h) could not be invoked as a result. *Id*.

60 *E.g. In re Visiting Nurse Ass'n Serv*., 176 B.R. 748 (Bakr. E.D. Pa. 1993).

61 *See Hammond v. Northland Counseling Center*, 1998 U.S.Dist. LEXIS 9133 (D. Minn. Feb. 27, 1998); *and Neal v. Honeywell*, 995 F.Supp. 889 (N.D.Ill. 1995).

62 S. 2041, 110th Congress (Sept. 12, 2007). Companion legislation was introduced in the House of Representatives in the same year. *See* H.R. 4854, 110th Congress (Dec. 19, 2007).

tangentially, would be subject to the FCA. Such a change would expand the reach of the Act dramatically, and directly contravene the Supreme Court's holding in *Allison Engine* (discussed above).

Second, the proposed legislation would severely weaken, if not eliminate, the public disclosure bar of the FCA (discussed above). In essence, the proposed legislation would eliminate the requirement that a relator be the "original source" of the information upon which the suit is based. Further, it would narrow the definition of "public disclosure" such that most suits that are currently barred by the Act would no longer be. Finally, it would change the prohibition on such suits under the Act from a jurisdictional bar, to one that is enforced only upon motion of the United States.

Third, the proposed legislation would make the FCA cover not only United States funds, but non-U.S. government funds that are under the control of the United States.[63]

Fourth, the proposed legislation would specifically permit a government employee to serve as a qui tam relator under certain conditions (essentially where government inaction after reporting was alleged).

Finally, the proposed legislation would increase the statute of limitations of the Act from six to ten years, and expand DOJ's ability to investigate FCA claims through Civil Investigative Demands. There are a number of other additions to the FCA in both the Senate and House bills.

The False Claims Correction Act is viewed as a sweeping expansion of liability

---

63 This portion of the legislation is intended to address the holding in *United States ex rel. DRC, Inc. v. Custer Battles LLC*, 2006 WL 2388790 (E.D. Va. Aug. 16, 2006), which found that the FCA could not be applied to Iraqi funds that were being administered by the United States.

under the FCA. It is strongly supported by the relators' bar, and generally viewed as overly expansive by federal contractors and their counsel. The bill has been referred from committee,[64] enjoys broad bi-partisan support, and is likely to be enacted in the 111th Congress.

(2) Use of Breach of Compliance Agreements to Create FCA Liability

The DOJ has continued to utilize a new weapon in addressing health care fraud. In *United States v. Tenet Healthcare Corporation*, *et al*., No. 03-206 (C.D. Cal.), DOJ made separate allegations against the defendants of failures to comply with corporate integrity agreements ("CIAs") and to self-report fraud in a case nominally brought under the civil FCA. This marks a significant departure from the prior practices of DOJ and HHS, in that they have previously emphasized the use of corporate integrity agreements and self-reporting to *prevent* fraud, not to punish it.

The Complaint was brought in January 2003 by the DOJ against Tenet Healthcare Corporation, its predecessors in interest, and scores of subsidiary hospitals. In general, the Complaint alleged that Tenet submitted "upcoded" claims for inpatient services. Specifically, the Complaint alleged that Tenet knowingly utilized codes which would provide for a higher level of reimbursement than was appropriate. As such, the Complaint averred that all "upcoded" claims made by Tenet were false and subject to recovery, damages and penalties under the Act. This "upcoding" theory has been utilized in a number of cases brought under the Act.

The Complaint contained further allegations which are not typically used by the DOJ for FCA matters. Tenet purportedly made representations to the government that

---

64 See Sen. Judiciary Committee Report No. 110-507 (Sept. 25, 2008).

it was in material compliance with its CIA (and other federal statutes and requirements) -- representations it was required to make pursuant to the CIA. The Complaint alleged that Tenet discovered these fraudulent upcoding practices through an audit, and that it intentionally did not report its misconduct notwithstanding an affirmative duty to report the violations pursuant to the CIA, and that this failure to affirmatively report the allegations constituted criminal conduct pursuant to 42 U.S.C. §§ 1320a-7b(a)(3)(A) and (B).

It is possible that the DOJ included the allegations regarding the CIA and Section 1320a-7b in the Complaint to place pressure on Tenet and obtain leverage in settlement negotiations. According to published reports, the Complaint was brought after months of negotiations between DOJ and Tenet.[65] The DOJ may have added the CIA and Section 1320a-7b allegations to turn the case into a violation of specific agreements with the government and purportedly criminal behavior and not one of upcoding.

The allegations against Tenet and the related entities were settled in a global agreement in June 2006. Terms of the settlement included a nearly $800 million payment for the charge inflation allegations, $47 million related to alleged kickbacks, and $46 million related to upcoding.

These DOJ allegations could have an impact on future FCA cases and investigations for two main reasons. First, DOJ could utilize certifications of compliance to create a new class of "claim" for FCA purposes. In theory, each of these certifications could constitute a "false statement" actionable under Section 3729(a)(2) of

---

65 Taylor, Mark, A Question of Integrity: *Federal Prosecutors Question Tenet's Compliance With Integrity Agreement in a $323 Million False Claims Act Lawsuit*, Modern Healthcare, Vol. 33, No. 2 (1/13/03).

the Act. Each certification could subject the certifying party to a $5500 to $11,000 penalty for each, plus treble damages. False certifications of compliance alone could be the basis of a significant FCA case.

The damages under a false certification of compliance theory could be far reaching. Hypothetically, all claims which the government paid in reliance on the certification would constitute the damages incurred by the United States if the certification were found to be false. Similar theories have been presented in "implied certification" cases, and under certain conditions, have survived court scrutiny.[66]

Second, DOJ's allegations regarding Tenet's CIA obligations make clear its intention to use the FCA and other enforcement mechanisms to address corporate failure to self-report fraud. An increasing number of health care providers are entering into CIAs, either as part of settling fraud claims or as a means of working with the Department of Health and Human Services to proactively address fraud. Under DOJ's theory in Tenet, the corporation would not be held criminally liable for direct acts of fraud, but for the failure to report itself when it learned of false or fraudulent claims. In other words, should the corporation become aware at any time that any of its claims to

---

66 See cases discussed infra. Generally, a claimant makes a false statement under the FCA when he or she falsely certifies compliance with a statute only if the government has conditioned payment of a claim upon such certification. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Some courts have further limited false certification cases to situations where "the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *See United States ex rel. Mikes v. Straus,* 274 F.3d 687, 700 (2d Cir. 2001). *See also, U.S. ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F.Supp 2d 258, 264 (D.D.C. 2002). While the theory has gained general acceptance, it is important to note that some courts have expressed reservations about implied certification as a basis for FCA liability. *See, e.g., United States ex rel. Barmak v. Sutter Corp.*, 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. May 14, 2002); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).

the government were improper, it would be committing a crime by not reporting the impropriety to the United States Government.

(3) Use of Regulatory Violations as Basis of FCA Liability

There has also been an increased use by the government of violations of applicable regulations or other statutes by entities as the basis for separate FCA lawsuits. In one line of cases, the government has sought to use alleged violations of the federal anti-kickback statute, 42 U.S.C. § 1320(a)-7(b), as the basis for FCA liability. The anti-kickback statute establishes criminal penalties for knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or in return for purchasing, ordering or recommending or arranging purchasing or ordering of items or services for which payment may be made in whole or in part under federal health care programs. By violating the anti-kickback statue, i.e., in paying for patient referrals or the like, a Medicare provider would have failed to comply with all laws relevant to its agreement with Medicare, and would therefore have submitted a false claim to the government for any funds obtained in connection with the anti-kickback violation.

Courts have given this theory a mixed reception. Some courts have upheld the theory, finding that an anti-kickback violation could support a claim under the "implied certification" theory, where it is alleged that the government would not have reimbursed the claim had it known about the violation.[67] However, other courts have been more

---

67 *See, e.g. United States ex rel. McNutt v. Haleyville Medial Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005)(notice to defendants that they had to comply with all applicable law in order to participate in Medicare is basis for knowing submission of false claims where kickbacks were alleged); *United States ex rel. Pogue v. Diabetes Treatment Centers of Am., Inc.*, 238 F. Supp.2d 258 (D.D.C. 2002); *United States ex rel. Bidani v. Lewis*, No. 97C6502, 2003 U.S. Dist. LEXIS 3291 (N.D.Ill. Mar.5, 2003) (unreported supply discounts rendered Medicare claims fraudulent under AKS and therefore violated the FCA).

skeptical of the theory, and have refused to find that an anti-kickback violation constitutes an FCA claim.[68]

In a second line of cases, the government has sought to bring a variety of actions in the long-term care field, alleging that facilities failed to provide adequate care in accordance with regulatory requirements and therefore violated the FCA. The government and relators generally have advanced two theories when proceeding with this type of claim – an implied certification theory and a worthless services theory.

In pursing an implied certification theory, the government asserts that the provider violated the FCA because it "implicitly certified in its claims for reimbursement that it has provided care in a manner consistent with the prevailing standard of care."[69] The government has not had substantial success in relying on this theory to support FCA cases based on quality of care violations. Many federal courts have rejected such theories because quality of care laws and regulations are conditions of participation, and do not influence the government's payment decisions.

Alternatively, a worthless services theory has been alleged by asserting that the provider violated the FCA because "the performance of services is so deficient that for all practical purposes it is the equivalent of no performance at all."[70] These cases have

---

68 *United States ex rel. Barmak v. Sutter Corp.*, No. 95-CV7637, 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. May 14, 2002)(dismissing FCA claims based on AKS violation, expressing reluctance to use the FCA to reach "every kind of fraud practiced on the government").

69 See *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1154 n3 (W.D. Mo. 2001).

70 See *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

been alleged chiefly as implied certification[71] and worthless services[72] cases, both theories that have been viewed with skepticism by courts.[73]

(4) Off–Label Promotion Uses and the FCA

The use of off-label promotion by pharmaceutical and biotechnology manufacturers has set the stage for continued investigative and enforcement activity seeking to apply the FCA in unprecedented ways. It is estimated that there are well over 150 pending investigations of pharmaceutical and device companies for off-label promotion and other activities.

Under the provisions of the Food, Drug and Cosmetic Act ("FDCA"), once a drug or device is approved, the manufacturer may only market or promote the drug or restricted device for those uses specified in the product's approved labeling. Promotion or marketing of the product by the manufacturer for any use not specified on the label,

---

71 *See United States ex rel. Joslin v. Cmty. Home Health of Md., Inc.*, 984 F. Supp. 374, 385 (D. Md. 1997)(distinguishing between certifying compliance and conditions of payment and finding no implied certification took place); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034 (N.D. Ill. 1998), *cert. denied*, 528 U.S. 1038 (1999) (certification of compliance with lab regulations not tied to payment, and can't be basis of FCA complaint); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (rejecting implied certification theory where certification not tied to reimbursement); *United States ex rel. Swan v. Covenant Care, Inc.*, No. S-99-1891, slip. op. (E.D. Ca. Aug. 5, 2002)(implied certification that claims were not false cannot be taken from Medicare claims made in connection with long-term care facility)..

72 *See United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.*, 945 F. Supp. 1485 (W.D. Ok. 1996)(not providing safe environment in facility cannot lead to FCA claim for worthless services); .

73 *See, e.g. United States ex rel. Conner v. Salina Regional Health Center*, No. 07-3033, 2008 WL 4430668 (10th Cir., Oct. 2, 2008)(rejecting implied certification theory that alleged implied certification arose from signature of Medicare cost reports); *but see United States v. Borseau*, 531 F.3d 1159 (9th Cir. 2008)(affirming District court finding that cost reports were "material" to reimbursement decision and could be the basis of FCA claims).

referred to as an "off-label" use, may violate the FDCA.[74] As illustrated by the cases and settlements summarized below, the government has constructed a theory that a violation of the FDCA by a manufacturer ultimately triggers a violation of the FCA by "causing" health care providers to submit false claims for payment to federal health care programs.

United States ex. rel. Franklin v. Parke-Davis. In the first of a series of cases involving charges stemming from the off-label promotion of products, the federal government alleged in *United States ex. rel. Franklin v. Parke-Davis*,[75] that a pharmaceutical manufacturer violated the FCA by promoting off-label use of its anti-seizure drug, Neurontin. The allegations arose out of a *qui tam* lawsuit brought under the FCA by a former employee who claimed that the Parke-Davis division of Warner-Lambert orchestrated a comprehensive scheme to promote off-label use of the drug.

According to the former employee, Warner-Lambert engaged in a strategic marketing plan to actively promote Neurontin for the treatment of a variety of conditions not included on the drug's approved labeling. Additionally, the government alleged that Warner-Lambert promoted Neurontin as effective for treating bipolar disorder and for use as the sole drug in treating epileptic seizures, even after the FDA specifically determined that there was not sufficient scientific data to support the claims and thus rejected the request to include them on the product's labeling.

The government alleged that the company's off-label promotional activities not only violated the FDCA but also violated the FCA by harming state Medicaid programs.

---

74 *See generally* 21 U.S.C. 331(a) and 352(a), (n), (q) and (r).

75 *United States ex. rel. Franklin v. Parke-Davis*, Civ. No. 96-11651-PBS (D. Mass. Aug., 22, 1996).

Under the government's theory, Warner-Lambert's conduct reportedly caused physicians to write prescriptions for Medicaid patients to receive Neurontin even though Neurontin was not eligible for Medicaid reimbursement. Neurontin was supposedly not eligible for Medicaid reimbursement because Warner-Lambert fraudulently caused the physicians to write the prescriptions by providing them with false information regarding off-label uses and/or paying the physicians kickbacks in the form of trips and "consulting fees," thus making the drug not eligible for reimbursement.

In May of 2004, Warner-Lambert agreed to plead guilty and pay more than $430 million to resolve criminal charges and civil liabilities in connection with the off-label promotion of Neurontin.

U.S. v. Serono Laboratories, Inc. [76] The case arose from *qui tam* actions filed against the company by former sales representatives, alleging that Serono caused the filing of false and fraudulent Medicaid claims. In 1996, the FDA had granted accelerated approval of Serostim for use in treating AIDS wasting, then the leading cause of death for AIDS patients. At that time, there also came onto the market protease inhibitor drugs which, when used together as an "AIDS cocktail," dramatically curtailed proliferation of the virus. The prevalence of AIDS wasting declined, and demand for Serostim began to drop as a result. The charges included kickbacks to physicians for prescribing Serostim, illegal off-label marketing of the drug, and conspiring with a medical device manufacturer to increase the market for Serostim.

---

[76] *United States v. Serono Laboratories Inc.*,D. Mass., No. 05-cr-10282-RCL, 12/15/05 The CIA in Serono and the other cases cited herein are available on the OIG's website at http://www.oig.hhs.gov/fraud.asp

In October 2005, Serono pled guilty and agreed to pay a total of $704 million to settle criminal charges and civil liabilities in connection with activities to promote, market and sell its drug Serostim, which is used to treat AIDS wasting. Serono Labs was excluded from federal health care programs for five years, and all subsidiaries are subject to a five-year CIA. In July 2008, a medical director of Serono pleaded guilty to three misdemeanor counts for introducing the device into interstate commerce. [77]

U.S. v Schering Sales Corp. The portion of the case involving off-label activity related specifically to statements made to the FDA. In particular, in 2001, Schering received a letter from FDA alleging that Schering had promoted Temodar for unapproved uses and provided false and misleading efficacy information to visitors at a commercial exhibit hall booth during an American Society of Clinical Oncology meeting. Schering Sales responded in writing that the statements in the FDA's letter were "an isolated incident" and "certainly inconsistent the direction provided by the home office." According to the government's allegations, the company was engaged in widespread off label marketing of both Intron A and Temodar, including:

- The sales force was trained to seek off-label sales through training classes, ride-alongs with managers, district meetings, teleconferences, and sales meetings;
- The marketing department provided the sales force a plan of action that targeted off-label sales and provided them with clean copies of "for your information only" scientific articles and abstracts to use with physicians; and
- The sales force was required to create business plans that emphasized detailed promotional goals to obtain off-label sales and was compensated in large measure by their success in achieving sales in unapproved uses.

---

[77] *United States v. Muurahainen,* D. Mass., No. 08-cr-10182, *plea entered* 7/23/08.

In August of 2006, Schering agreed to pay a total of $435 million. Additionally, Schering Sales Corporation agreed to be permanently excluded from participation in federal health care programs to resolve criminal charges and civil liabilities in connection with the sales and marketing of Temodar for use in the treatment of brain tumors and metastases, and Intron A for treatment of superficial bladder cancer and hepatitis C. The matter also involved Medicaid price issues relating to Claritin RediTabs and K-Dur.[78]

U.S. v. InterMune, Inc. In the first off-label promotion case of its kind, DOJ announced in October of 2006 that, rather than requiring a criminal plea, it was entering into a deferred prosecution agreement ("DPA") with InterMune, Inc. to resolve allegations related to off-label promotion and marketing of its product, Actimmune®. Pursuant to the terms of the DPA, DOJ agreed to recommend to the court that the prosecution of InterMune be deferred for a period of two years, contingent upon: (1) payment of $36.9 million to resolve liabilities under the FCA; (2) the company's past and future cooperation in DOJ investigations; and (3) the company's continued efforts to implement comprehensive changes to its compliance policies in accordance with the terms of a five-year CIA with the OIG.[79]

The government alleged that although Actimmune was approved by the FDA for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis, the vast majority of sales over the course of a six month period were attributed to prescriptions for treatment of IPF, a debilitating, fatal lung disease for which there is no

---

[78] See http://www.usdoj.gov.usao/ma/schering-plough.html

[79] *United States v. InterMune Inc.,* D.N. Cal., No. 06-cr-0707, *deferred prosecution filed* 10/26/06

FDA-approved treatment. In fact, InterMune had conducted a Phase III clinical trial in an effort to obtain FDA approval for use of Actimmune for treatment of IPF but failed to establish statistically significant evidence that the drug benefits IPF patients. Despite this failure, InterMune issued an allegedly misleading press release in August of 2002 which stated that "Actimmune may extend the lives of patients suffering from this debilitating disease" and that "Actimmune is the only available treatment demonstrated to have clinical benefit in idiopathic pulmonary fibrosis (IPF), with improved survival data in two controlled clinical trials." The government alleged that this dissemination of information to physicians not only promoted off-label use but was misleading. This information caused the submission of false claims to federal healthcare programs by encouraging them to bill for Actimmune for use in treating IPF, even though the drug was not eligible for payment since it was being used in an off-label and/or unnecessary manner. Subsequently, the company's former CEO was indicted for his role. [80]

U.S. ex. rel. Marchese v. Cell Therapeutics, Inc. In April 2007, the DOJ announced that Cell Therapeutics, Inc. agreed to pay $10.5 million to resolve allegations that the company illegally marketed its anti-cancer drug, Trisenox.[81] According to the qui tam relator, Cell Therapeutics promoted to physicians that Trisonex could be used to treat various forms of cancer for which the drug was neither approved by the FDA nor had it been clinically proven to be safe or effective. As a result, Cell Therapeutics caused physicians to write off-label prescriptions and, thus, caused the submission of false claims to the Medicare program. In addition, the complaint alleged that the company entered into sham "consulting agreements" with physicians to pay the

---

80 *United States v. Harkonen,* N.D. Cal.,CR-08-0164, *indicted* 3/18/08

81 *United States ex rel. Marchese v. Cell Therapeutics Inc.*, W.D. Wash.,No. 2:06-cv-00168-MJP, *settlement announced* 4/17/07

physicians $500-$1,000 to attend dinners or conferences on the off-label uses of Trisenox that were held at expensive resorts and restaurants. Sunsequently, the court found that the qui tam relator's delays in reporting the alleged improper marketing activities entitled him to only 15 percent of the settlement. [82]

U.S. v. Pharmacia & Upjohn Company, Inc. Also in April 2007, the DOJ announced that Pharmacia & Upjohn Company, LLC, agreed to pay $15 million dollars and enter into a Deferred Prosecution Agreement for a term of 36 months arising out of an investigation into the illegal promotion and distribution of Genotropin. Genotropin is a human growth hormone product approved for treatment related to growth deficiencies including treatment of children who fail to grow due to inadequate secretion of endogenous growth hormone; treatment of pediatric patients with Prader-Willi Syndrome; and long-term replacement therapy for adults with growth hormone deficiency. The government alleged that Pharmacia engaged in the unlawful promotion of Genotropin for off-label uses including anti-aging, cosmetic use and enhancing athletic performance.

In September of 2008, the federal district court refused to dismiss the action saying that the plaintiff's amended complaint properly pleaded fraud under Fed. R. Civ. P. 9(b). [83]

U.S. v. Jazz Pharmaceuticals, Inc. On July 13, 2007, Jazz Pharmaceuticals, Inc. entered into a CIA with the OIG and a non-prosectuion agreement with the United States as part of a $20 million settlement related to the off-label promotion of the

---

82 *United States ex rel. Marchese v. Cell Therapeutics Inc.,* W.D. Wash., No. CV06-0168 MJP, 12/14/07

83 *United States ex rel. Rost v. Pfizer Inc.*, D. Mass., No. 03-11084-PBS, 9/18/08.

prescription drug Xyrem by its wholly-owned subsidiary, Orphan Medical Inc. ("Orphan"), which pled guilty to felony misbranding.[84] The civil and criminal investigations were initiated after a qui tam relator (a former Orphan sales representative) filed suit. Although Xyrem was approved only for cataplexy (a muscle condition associated with narcolepsy) and excessive daytime sleepiness, Orphan admitted that its sales personnel promoted Xyrem to physicians, for such unapproved uses as fatigue, insomnia, chronic pain, depression, bipolar disorders and movement disorders. The government alleged that Orphan sales personnel collaborated with a medical professional to instruct physician customers through speaking engagements on how to conceal the off-label prescriptions for reimbursement purposes, intentionally causing false claims.

United States ex rel. West v. Ortho-McNeil Pharmaceutical Inc. The relator in this case was a former sales representative who alleged that Ortho-McNeil (and its parent company, Johnson & Johnson) engaged in the fraudulent promotion of the drugs Levaquin and Ultram for non-FDA approved uses such that all claims for reimbursement for these drugs amounted to false claims. Specifically, West claimed that Levaquin was marketed for the non-FDA approved treatment of prostatitis and that Ultram was similarly marketed for osteoarthritis and diabetic neuropathy as well as in non-FDA approved doses. Because West's complaint did not specifically set forth who made false or misleading statements on behalf of Ortho-McNeil to cause the false claims, what the false or misleading statements were, or to whom they were made, his

84 *United States v. Orphan Medical,* E.D.N.Y., docket unavailable, *settlement* 7/13/07.

Complaint did not survive Rule 9(b) of the Federal Rules of Civil Procedure and was dismissed. [85]

United States ex rel. Piacentile v. Bristol-Myers Squibb Co. and Otsuka Pharmaceutical Co., Ltd. On March 27, 2008, Otsuka American Pharmaceutical Inc, the American subsidiary of Japanese pharmaceutical manufacturer Otsuka Pharmaceutical Co., Ltd., entered into a CIA with the OIG as part of a $4 million settlement related to off-label promotion of the prescription drug Abilify. Abilify has been approved by the FDA to treat adult schizophrenia and bi-polar disorder. The government alleged that Abilify sales representatives promoted the use of Abilify for pediatric patients and for geriatric patients suffering from dementia-related psychosis. However, at the time, the FDA had not approved Abilify for treatment of children nor had they determined that Abilify was safe and effective in the treatment of dementia-related psychosis. [86]

United States ex re. Paccione v. Cephalon Inc., and related cases On September 29, 2008, DOJ announced that Cephalon would enter a criminal plea and pay a total of $444 million to resolve claims of improper marketing of three drugs for uses not approved by the FDA. The guilty plea constituted a one count misdemeanor of "distribution of misbranded drugs: inadequate directions for use." The company entered separate settlements to resolve investigations by state attorneys general in Connecticut and Massachusetts, along with a five-year CIA with the OIG. The government's allegations involved the drugs Gabitril (approved by FDA for partial seizures in people

---

85 *United States ex rel. West v. Ortho-McNeil Pharmaceutical Inc.,* N.D. Ill., No. 03 C 8239, 7/20/07

86 *U.S. ex rel. Piacentile v. Bristol-Myers Squibb Co. and Otsuka Pharmaceutical Co. Ltd.,* D. Mass.,CV-05-10196-MLW,*settlement* 3/27/08

with epilepsy but allegedly promoted for insomnia, anxiety, and pain); Actiq (approved for breakthrough cancer pain but allegedly marketed for non-cancer patients to treat pain from migraines, injuries, sickle-cell pain crises, and more); and Provigil (approved for excessive sleepiness associated with narcolepsy and other specific conditions, but allegedly marketed for fatigue, lack of energy, and other conditions). [87]

The raft of off-label investigative and enforcement activity to date is troubling for many reasons. The FDCA itself does not contain a private right of action, and it is a huge leap to characterize an FDCA violation as a "false" claim. Many drugs and devices today are used in an off-label fashion as part of clinical research and to the benefit of patients; indeed, such uses are often reimbursable by Medicare and Medicaid. The sheer magnitude of the settlements to date, however, and the promise of more cases to come, may be enough to dissuade manufacturers from undertaking new research in critical areas, and to cause physicians to avoid prescribing for off-label uses.

The threat of *qui tam* actions is ever present for manufacturers today, especially as the headlines abound on multi-million dollar recoveries by relators, who range from sales representatives to company travel agents. Drug and device companies continue to be seen by relators and the government alike as deep pockets, but cases take years to develop – hence, off-label promotional activity taking place today may not come to light as part of an enforcement action for four, five, or even six years. These harsh

---

[87] Text of the civil settlement is available at http://www.usdoj.gov/usao/pae/News/Pr/2008/sep/cephalonsettlementagreement.pdf.

Text of the corporate integrity agreement is available at http://www.usdoj.gov/usao/pae/News/Pr/2008/sep/cephaloncorporateintegrityagreement.pdf.

Text of the guilty plea agreement and sentencing memo is available at http://www.usdoj.gov/usao/pae/News/Pr/2008/sep/cephalonguiltyplea.pdf on the Web.

realities make attention to risk reduction – including auditing and monitoring, and accurate documentation -- all the more pressing.

(5) FCA Cases Involving Integrity of Research

Although research misconduct allegations are generally addressed under the research misconduct regulations through the Office of Research Integrity ("ORI"), which is part of the Department of Health and Human Services ("HHS"), claims may be brought under the FCA as well.

On February 6, 2003, Northwestern University agreed to pay the United States $5.5 million to settle allegations that the school violated the FCA. A former employee of the University's Office of Research Sponsored Programs initiated the claims under the *qui tam* provision of the FCA. In the case, the government alleged that Northwestern overstated the percentage of its researchers' work effort that would be devoted to several federally-sponsored medical research grants. Additionally, the government alleged that the university knowingly failed to comply with the federal government requirements that a specified percentage of the researchers' efforts be devoted to the grant.

On April 14, 2005, a similar suit was settled by The University of Alabama at Birmingham and two related entities. The university and the entities agreed to pay $3.39 million to settle allegations that they violated the FCA. Two former employees of the university initiated the claims under the *qui tam* provision of the FCA. The allegations include: misleading the National Institutes of Health and other sponsors of federally-funded grants by overstating the percentage of work effort that the researchers were able to devote to the grant and unlawfully billing Medicare for clinical research trials that were also billed to the sponsor of research grants.

On March 17, 2005, Eric Poehlman, a researcher, pled guilty to making material false statements on numerous federal research grant applications. In most cases, Dr. Poehlman falsified and fabricated research data on grant applications in order to support the scientific basis for and his expertise in conducting the proposed research. Dr. Poehlman agreed to pay $180,000 to settle the *qui tam* action against him and agreed to pay $16,000 in attorney's fees to the *qui tam* relator, his former research assistant. Dr. Poehlman will be barred for life from seeking or receiving funding from any federal agency in the future.

V. OVERPAYMENTS

Once a provider becomes aware of conduct that may lead to a *qui tam* action, it has the option of taking action that will possibly preempt any action that may be filed. One option is to invoke the OIG's voluntary disclosure program. The guidelines for the program as it currently exists were announced by the OIG on October 30, 1998.[88] The purpose of the protocol is to provide guidance to health care providers that decide to voluntarily disclose conduct the provider believes may warrant an action under the FCA.[89] It is grounded in the OIG's belief that any repercussions of such action or behavior can be minimized by maintaining "open lines of communication with…[the OIG]."[90]

The initial step for a provider in determining whether a voluntary disclosure is necessary is to determine if there is a potential basis for an action under the FCA. If a provider determines that "reasonable, responsible government officials could deem the

---

88 Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998).

89 Id. at 58400.

90 Id.

conduct to be unlawful," the prudent approach, according to the OIG, would be to disclose the conduct. After determining that there is misconduct, the provider should first submit a voluntary disclosure to the OIG's Assistant Inspector General for Investigative Operations. As part of the disclosure process, the disclosing provider is expected to conduct an internal investigation regarding the matter reported and report the findings to the OIG.

A voluntary disclosure submission has both risks and benefits to a provider. The OIG is quite aware of the range of disclosure events and admits that it "cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will inure to the disclosing entity."[91] Indeed, in some cases, it would be wholly inappropriate for a provider to undertake a formal disclosure under the program, since a refund or other process may be preferable.

More recent guidance by the OIG was issued in Open Letters to Providers concerning the self-disclosure protocol in 2006 and 2008.[92]

---

91 Id. at 58401.

92 See http://oig.hhs.gov/fraud/selfdisclosure.asp