



## **HCCA's 2005 Annual Compliance Institute**

# **FRAUD & ABUSE/FALSE CLAIMS ACT DEVELOPMENTS**

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## **§ 1.01 INTRODUCTION**

This chapter examines the Federal False Claims Act (the “FCA”) and its application in the health care industry. Fraud and abuse actions represent one of the fastest growing and complex areas of compliance within the industry. Since 1986, the Department of Justice reports that over \$10 Billion has been awarded in civil verdicts under the FCA.<sup>1</sup> While the FCA was primarily established to combat fraud perpetrated by military contractors, it is now commonly applied to health related services. In 1987, FCA actions involving the Department of Health and Human Services represented only twelve percent of the total number of FCA cases. By 1998, health related FCA actions totaled more than sixty percent of the 470 FCA actions filed. Experts project that the escalation of health care related FCA actions will continue throughout the decade.

The following chapter provides a unique look into the enforcement of FCA actions, primarily through the eyes of the judiciary. It is intended to provide the reader with an understanding of the law and its application in the court system. The chapter begins with a brief history of the origins of the FCA and its evolution into the powerful enforcement tool it is today. The second part will provide an explanation of the law and its procedural aspects. Third, this chapter will examine some of the categories of FCA actions and provide case analysis of its application. The fourth part will examine the growing trend of state false claim legislation. This chapter concludes with a brief review of the trends in FCA actions.

## **§ 1.02 HISTORY**

The primary function of the FCA is to prohibit an individual or entity from filing a false or fraudulent claim with the United States Government. Its origin can be traced back to the Civil War Era, when the government sought an effective recoupment tool in response to the fraudulent billing practices of the Union Army’s suppliers. In 1863, at the urging of President Abraham Lincoln, congress enacted legislation that empowered the government, as well as individuals with knowledge of fraud, to take action. Lincoln envisioned the FCA as a way to ferret out false claims by encouraging whistleblowers to take action on behalf of the government.<sup>2</sup> Lincoln was of the opinion that offering individuals economic incentives was the most effective way to promote private enforcement of federal legislation. Throughout the years, the government has used the FCA as a collection instrument, but it was not until the 1986 amendments, that the FCA evolved into the government’s primary tool to recover economic loss due to fraud.

## **§ 1.03 THE FALSE CLAIMS ACT**

### **[A] OVERVIEW**

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<sup>1</sup> Eric S. Askanase, *Qui Tam Provisions of the FCA are a Serious Threat to American Industry, and they are Subject to Constitutional Challenges on Several Grounds*, DEF. COUNS. J. (October 2003). For a list of the top 50 FCA settlement please see Appendix A.

<sup>2</sup> Id.

The FCA works by attaching liability to those who “knowingly” submit, or cause to be presented, “a false or fraudulent claim for payment or approval.”<sup>3</sup> While 31 U.S.C. 3729(a) lists seven liability provisions, only four are commonly enforced. The four include (i) making, or assisting an individual to make a false claim; (ii) making or assisting an individual to make a false statement related to a false claim; (iii) conspiracy to make or submit a false claim; and (iv) submission of a false claim in order to conceal, avoid, or decrease an obligation to pay a debt.<sup>4</sup> The imposition of liability under the FCA is unique because it is not in response to the underlying fraudulent activity or to the government’s wrongful payment, but rather the claim for payment itself.<sup>5</sup>

The scope of the FCA’s enforcement is far reaching. Although the FCA was born out of the need to combat fraud brought about by military contractors, its greatest impact may be felt in the health care industry. It appears that no field or specialty is out of the reach of the FCA. In the past, health care targets have included hospitals, physicians, researchers, home health agencies, long-term care facilities, suppliers, and billing services just to name a few.<sup>6</sup> In addition to the traditional government/relator actions against an individual wrongdoer, the government has also used the FCA as an enforcement tool for national investigations focusing on particular sectors of the industry in an effort to combat fraud.<sup>7</sup>

The FCA is not just limited to monetary transactions. The FCA may also be applied to fraudulent claims inducing the government into delivering property or services. A violation of the FCA can result in civil liability in the amount of \$5,500 to \$11,000 per occurrence.<sup>8</sup> Additionally, the individual is liable for three times the amount of damages which the government sustains as a result of the violation.<sup>9</sup> The penalty shall be determined by the judiciary and is evaluated on a facts and circumstance analysis of the violators’ acts.

## **[B] FCA ELEMENTS**

A successful FCA claim must allege three basic elements. First, the defendant submitted or caused another person to submit a claim for payment to the federal government. By definition, a claim is “any request or demand, whether under a contract

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<sup>3</sup> 31 U.S.C. § 3729(a)(1).

<sup>4</sup> 31 U.S.C. § 3729(a)(1)–(3);(7). The final three enforcement provisions impose liability for individuals who (i) are entrusted with federal money and fail to deliver or return the total amount, (ii) authorized to certify a receipt of property without actually knowing the verifying information contained within, (iii) knowingly buy or obtain property from a governmental employee who has no legal authority to sell such property. *Id.* at §3729a(4)–(6).

<sup>5</sup> *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995).

<sup>6</sup> Robert Salcido, *The Government’s Increasing Use of the False Claims Act Against the Health Care Industry*, J. LEGAL MED. 457 (December 2003).

<sup>7</sup> Such national investigations have included the 72-Hour Window Project, which focused on hospital billing practices concerning outpatient services, and the Lab Unbundling Project, which focused on the billing for multiple test that could have completed by a single procedure. *See Salcido, supra* note 6 at 459.

<sup>8</sup> 31 U.S.C § 3729(a).

<sup>9</sup> *Id.* The judiciary has the discretion to lower the treble damages if the court finds the individual furnishes all information relating to the false claim, cooperates with the government, and the cooperation must not be in response to a criminal or civil action. *Id.* at §3729(a)(A)–(C).

or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.”<sup>10</sup> While a false claim may take many forms, the most common are claims submitted for goods or services that violate contract terms or state or federal regulations.<sup>11</sup> Regardless of its form, the broad definition of “claim” will encompass almost any demand or request made for federal funds.

Second, the claim was false or fraudulent and/or the defendant made or used a false or fraudulent record or statement to obtain payment or approval of the false or fraudulent claim.<sup>12</sup> Unfortunately, the terms “false” and “fraudulent” are not defined within the FCA. The task of determining whether the claim was false or fraudulent lies with the judiciary. While the terms false and fraudulent are open to interpretation, the courts have definitively ruled that a claim will not be deemed false if it is submitted pursuant to a reasonable interpretation of vague statutory language.<sup>13</sup>

Lastly, the person submitting the claim had actual knowledge of its falsity, or acted in reckless disregard of its falsity.<sup>14</sup> “Knowingly,” for purposes of the FCA, means that a person, with respect to information either “has actual knowledge of the information”; “acts in deliberate ignorance of the truth or falsity of the information”; or “acts in reckless disregard of the truth or falsity of the information.”<sup>15</sup> No proof of specific intent to defraud is required to bring forth a FCA action. In 1998, the Justice Department released a memorandum concerning the handling of health care false claims cases. The list enumerated a series of factors that should be evaluated in determining whether a claim was made “knowingly.”<sup>16</sup> Most challenges to the FCA are brought

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<sup>10</sup> 31 U.S.C. § 3729(c)(2004).

<sup>11</sup> S. Rep 345, 99<sup>th</sup> 2d Sess. 25, reprinted in 1986 U.S.C.C.A. 526, 5274; *See Shaw v. AAA Engineering & Drafting, Inc.*, 213 F.3d 519, 531–2 (10th Cir. 2000).

<sup>12</sup> *United States v. Adler*, 623 F.2d 1287, 1289 (8th Cir. 1980)

<sup>13</sup> *Id.*

<sup>14</sup> *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986).

<sup>15</sup> 31 U.S.C. § 3729(b).

<sup>16</sup> Eric. J. Holder, Jr., Deputy Attorney General, *Guidance on the Use of the False Claims Act in Civil Health Care Matters* (June 3, 1998). The list included:

(1) Notice to the Provider. Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?

(2) The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?

(3) The Pervasiveness and Magnitude of the False Claims. Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?

(4) Compliance Plans and Other Steps to Comply with Billing Rules. Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?

(5) Past Remedial Efforts. Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?

(6) Guidance by the Program Agency or its Agents. Did the provider directly contact either the program agency (e.g., CMS) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of

under second prong dealing with the claims “falsity” or the third prong dealing with “knowledge” requirements.

### [C] QUI TAM PROVISION

One of the unique features of the FCA is that anyone may initiate the law suit on behalf of the government. The FCA is sometimes referred to as the “Informer’s Act” or the “Qui Tam Statute” because of its liberal standing requirements. Qui tam is an abbreviation for the Latin term “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,” meaning, “*who pursues this action on our Lord the King's behalf as well as his own.*”<sup>17</sup> Qui tam provisions allowed for individuals to bring suit on behalf of the monarch or sovereign.<sup>18</sup> Today’s qui tam provision can be traced back centuries and is deeply rooted in Anglo-Saxon jurisprudence.

The qui tam provision allows a private plaintiff, with evidence of fraud against federal programs or contracts, to sue the responsible party on behalf of the government. The original FCA qui tam provisions guaranteed the individual initiating the suit a fifty percent share of the outcome. While the percentages have been altered over time, the current legislation allows the whistleblower to collect between fifteen and thirty percent of the recovered funds.<sup>19</sup>

Procedurally, all qui tam suits require government review before the defendant is served. The relator, when initiating a qui tam action, must first serve the complaint upon the government, where it remains sealed for a period of sixty days. During this time, the government will review the allegations contained within the complaint and elect whether to intervene or not. If the government elects intervention, they assume the claim and adopt the action of the relator. If the government does not exercise its right to intervene, the relator may still proceed by serving the complaint on the wrongdoer. If the government intervenes the relator is entitled to between fifteen and twenty percent, whereas, if there is no intervention the relator stands to receive between twenty-five and thirty percent.

Detractors of the FCA, specifically the qui tam provision, often criticize the motives and intentions of the relator. While some relators may be legitimately interested in preventing the waste of public funds, more often than not, the relator’s motives can be traced to the possibility of a financial windfall. A review of qui tam actions will reveal that relators are typically competitors, disgruntled employees, or public interest watch groups interested in advancing a set agenda. Additionally, critics of the FCA are

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all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?

(7) Have There Been Prior Audits or other Notice to the Provider of the Same or Similar Billing Practices?

(8) Any Other Information That Bears on the Provider's State of Mind in Submitting the False Claims.

Id.

<sup>17</sup> United States *ex rel.* S. Prawer & Co. v. Fleet Bank, 24 F.3d 320, 324 n. 7 (1st Cir. 1994).

<sup>18</sup> This individual or third party litigating on behalf of the crown became known as the “Relator.” *What is the False Claims Act?*, The Qui Tam Online Network, at <http://www.quitamonline.com/whatis.html> (last visited July 27, 2004).

<sup>19</sup> *What is Qui Tam?*, The False Claims Act Legal Center, at <http://www.taf.org/whatis.htm> (last visted July 27, 2004).

concerned about the possibility of relators filing frivolous lawsuits in the hopes of landing a significant payday.

In an effort to combat the filing of frivolous and meritless claims, the judiciary has required relators bringing suit under the FCA to have a particular or unique knowledge of the fraud. The FCA precludes a federal court from exercising jurisdiction over allegations in a qui tam suit that are based upon publicly disclosed information, unless the relator is the original source of that information.<sup>20</sup> An individual will be deemed an original source if they have “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 under this section which is based on the information.”<sup>21</sup>

#### **[D] RULE 9(b): The Particularity Requirement**

Procedurally the first step in a FCA action is to file a complaint with the government. As indicated earlier, the complaint shall remain sealed for a period of sixty days while the government reviews the allegations and determines if intervention is prudent. Historically, plaintiffs drafted their complaints with factual detail and particularity that was unique to the cause of action. The heightened pleading standards imposed by the early courts established a difficult burden that most plaintiffs were unable to meet in the early stages of litigation. Typically, the plaintiff, who was without the benefits of discovery or initial fact-finding, had limited access to the relevant and determinative facts, which were usually controlled by the defendant.<sup>22</sup> Over the past century, the courts have shifted away from the strict pleading requirements to a much more liberal approach. Today, the Federal Rules of Civil Procedure require a pleading to include a short and plain statement concerning jurisdiction, claim for relief, and judgment sought.<sup>23</sup>

While a short and plain statement is sufficient in most law suits, the court had carved out an exception for cases involving fraud and mistake. A claim surrounding fraud and mistake require more specific allegations, and is therefore governed by a different rule. Rule 9(b) governs the more specific pleading requirements and provides:

[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.<sup>24</sup>

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<sup>20</sup> 31 U.S.C. § 3730(e)(4)(a).

<sup>21</sup> Id. at 3730(e)(4)(b).

<sup>22</sup> Elaine M. Korb and Richard A. Bales, *A Permanent Stop Sign: Why Courts Should Yield to the Temptation to Impose Heightened Pleading Standards in § 1983 Cases*. 41 BRANDEIS L.J. 267 (Winter 2002).

<sup>23</sup> FED R. CIV. P. 8(a). Rule 8(a) states:

(1) a short and plain statement of the grounds upon which the court’s jurisdiction depends, unless the court already has jurisdiction and the claim needs no new grounds of jurisdiction to support it, (2) a short and plain statement of the claim showing that the pleader is entitled to relief, and (3) a demand for judgment for the relief the pleader seeks.

Id.

<sup>24</sup> Id. at 9(b).

Rule 9(b) requires that a plaintiff set forth specific facts including the time, place, and content of the alleged false or fraudulent representations. The intent behind the more specific requirements is to give notice of the plaintiffs' claim, to protect the defendant from meritless claims of fraud, to discourage "strike suits," and to prohibit relators hoping to uncover fraud via discovery.<sup>25</sup> Additionally, the Rule 9(b) requirement provides the government the benefit of examining the particulars of the allegations, thereby aiding the intervention decision. The courts application of Rule 9(b) is best exemplified by the following case law.

[1] *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*<sup>26</sup>

John Karvelas worked as a respiratory therapist at Melrose-Wakefield Hospital in Massachusetts from 1982 to 1997. He filed a qui tam action against the hospital in 2001 alleging that between the years 1994 and 1997, the hospital knowingly submitted false claims to the United States Government in order to obtain Medicare and Medicaid payments in violation of the FCA. Specifically, Karvelas alleged sixteen different fraudulent schemes that wrongfully billed the government, for services that were performed either improperly or not at all. The district court dismissed the case with prejudice opining the plaintiff did not meet the particularity requirements of Rule 9(b).

The issue before the First Circuit Court of Appeal was whether the district court erred in dismissing the Relators complaint on the grounds that it failed to plead fraud with particularity as required by Rule 9(b). Karvelas argued that the FCA was not a fraud statute and should therefore not be governed by Rule 9(b). Additionally, Karvelas argued a pleading under the FCA need not comply with the more stringent requirements of Rule 9(b). Rather, his contention was that, if Rule 9(b) was applicable to a FCA action, the particularity requirement should be relaxed.

The Court did not agree with Karvelas interpretation of the FCA. The court took the position that the FCA is in fact a "fraud statute" and should therefore be governed by the pleading requirements of 9(b). The court

reject[ed] Karvelas's argument that the False Claim Act is not a "fraud" statute because, under the statute, "liability depends on the defendant's knowledge, not on his fraud," and therefore only the second clause of Rule 9(b), which allows knowledge of fraud to be averred generally, applies. Under the FCA, liability depends on the defendant's acts (presentation of a false or fraudulent claim to the United States government) and mental state (knowledge, or deliberate ignorance or reckless disregard for the truth of falsity of the information presented). That Rule 9(b) allows "[m]alice, intent, knowledge, and other condition of mind of a person [to be] averred generally" does not mean that particularity requirements do no apply to FCA claims. Rather, it simply means that a qui tam relator need not plead with particularity allegations concerning defendants' knowledge, reckless disregard, or deliberate ignorance of the submission of false claims. The characterization of a state of mind, after all, does not lend itself to detailed pleading. On the other hand, the details of actual presentation of false or fraudulent claims to the government can and must be pled with particularity in

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<sup>25</sup> Doyle v. Hasbro, Inc. 103 F.3d 186 (1st Cir 1996).

<sup>26</sup> 360 F.3d 220 (1<sup>st</sup> Cir. 2004)

order to meet the requirements of Rule 9(b). Finally, every circuit court that has addressed this issue has concluded that the heightened pleading requirements of Rule 9(b) apply to claims brought under the FCA.<sup>27</sup>

Kravelas contended that even if the FCA was a fraud statute, the particularity requirement of rule 9(b) should be relaxed because the information necessary to plead the specifics was within the possession and control of the defendant. Additionally, Kravelas argued that requiring a qui tam to specify the particulars of the fraud was inconsistent with the goals of the FCA. A relaxation of Rule 9(b) would allow a party to plead generally at the outset, and later amended the complaint to include the particulars uncovered via discovery. Unfortunately, there is no bright line rule that indicates when the relaxation of the particularity requirement is warranted.

This is the first time the First District Court of Appeal had to determine if the relaxation should be applied to cases arising under the FCA. While some courts have discussed the possibility of the relaxation of particulars for FCA claims in the abstract, few court have actually applied it to a qui tam action.

The FCA requires a relator to provide the government with a “copy of the complaint and written disclosure of substantially all material evidence and information the person possesses.”<sup>28</sup> This provision seems to indicate that allowing a relator to plead in general terms at the outset of the allegation and amend the particulars after discovery seems to contradict the FCA’s procedural aspects for filing a qui tam action. The courts reluctance in relaxing the pleading requirements in a FCA claim stems from their unwillingness to allow a qui tam to use discovery as a pretext for uncovering unknown wrongs. In light of the procedural aspects, and the necessity for pleading the particulars, the court held that a “a relator may not present general allegations in lieu of the details of actual false claims in the hope such details will emerge through subsequent discovery.”<sup>29</sup>

Lastly, Karvelas argued that his complaint satisfied the particularity requirement of Rule 9(b). In the ninety-three page complaint, Karvelas outlined a total of sixteen schemes, each amounting to a FCA violation while failing to present evidence of the actual false claim. The presentation of a false and fraudulent claim is the one element that every FCA violation must have. Underlying schemes and other wrongful activities by themselves are not FCA violations. Pleadings concerning fraudulent schemes are inadequate unless they are linked to allegations of a false claim submitted to the government and pled with particularity.

[D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification number, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claim with particularity.<sup>30</sup>

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<sup>27</sup> Id. at 228.

<sup>28</sup> 31 U.S.C. § 3730(b)(2) (2004).

<sup>29</sup> Id. at 231

<sup>30</sup> Id. at 233.

The court noted that it is not necessary to satisfy all the particulars indicated above. This list is not to be viewed as a checklist of fraudulent activities, nor is it exhaustive. However, a pleading which includes some of these activities will carry the presumption of compliance with Rule 9(b).<sup>31</sup>

After review of the arguments presented by the Relator, the court was unpersuaded and upheld the district court's decision. Despite the serious nature of the alleged violation, the allegations standing alone unsupported by particulars are insufficient to support a claim under the FCA.

**[2] *United States ex rel Clausen v. Laboratory Corporation of America*<sup>32</sup>**

In this FCA action, Jeffery Clausen ("Clausen") filed a qui tam suit against Laboratory Corporation of America, Inc. ("LabCorp") for billing practices relating to testing provided to long-term care facilities ("LTCFs"). LabCorp serviced over 100 LTCFs between the late 1980's and 1998, primarily providing services to nursing homes. LabCorp submitted claims for reimbursement for certain tests to Medicare and Medicaid.

Clausen alleged that LabCorp was engaging in classic billing fraud actions including unauthorized, unnecessary or excessive medical testing. Specifically, Clausen alleged that LabCorp engaged in six schemes to defraud the government including (i) the administration of standing orders to conduct specific tests without the need for a physicians order, (ii) patient screening, (iii) duplicative and unnecessary testing of patients, (iv) unbundling, (v) duplicative billing for blood draws, and (vi) duplicative billing of trip charges.<sup>33</sup>

Clausen filed his original complaint with the United States Government in early 2000. Upon review, the government chose not to intervene, leaving Clausen to proceed on his own. Concerned that the original complaint would be barred by Rule 9(b), Clausen filed an amended complaint alleging more particular information including information on fraudulent practices obtained from LabCorp employees, descriptions and codes for medical tests, and the testing history of three patients.<sup>34</sup> Accompanying the complaint were exhibits used to support the claim including documents relating to patient and testing information, a roster of employees who may have particular knowledge of the fraudulent billing practices, a sales brochure, "standing order reports, test results, and physician orders."

Despite the evidence included, the district court moved to dismiss the complaint because the Relator failed to satisfy the particularity requirement of Rule 9(b). The district court opined that the particularity requirement does apply to FCA claims, the standard should not be relaxed, and Clausen failed to allege the particulars regarding the actual submission or timing of the false claim. While the court acknowledges the detailed evidence included with the complaint, it still only amounted to conclusory allegations regarding fraudulent conduct. The complaint failed to state a single claim arising from the schemes. However, the court allowed Clausen to amend his complaint in order to comply with the particularity requirement.

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<sup>31</sup> Id.

<sup>32</sup> 290 F.3d 1301 (2002).

<sup>33</sup> Id. at 1303.

<sup>34</sup> Id. at 1303.

Clausen's second amended complaint explained the schemes in greater detail. Included was evidence relating to the electronic forms submitted to generate the Medicare and Medicaid claims. Clausen proffered that the blank electronic forms provide an example of how a fraudulent claim would have been submitted by LabCorp. Despite the more particular information, Clausen still failed to identify any particular fraudulent charge, date, bill, or billing practice that was false. The district court again rejected Clausen's complaint for failure to state particulars of the fraud in compliance with 9(b).

On appeal, Clausen argued that Rule 9(b)'s particularity requirement was improperly applied to his FCA action. Additionally, he contended that the court has never "squarely addressed" the issue, and the particularity requirement should not apply, because the FCA only creates liability for false, not necessarily fraudulent claims.

The Court, in examining his argument observed that "Rule 9(b) prevents 'speculative suits against innocent actors for fraud,' and explained that under Rule 9(b), allegations of fraud 'must include facts as to time, place, and substance of the defendant's fraud.'" The court upheld the decision of the lower court, holding that it is well settled law that the FCA is a fraud statute and is thus governed by the Rule 9(b)'s particularity requirement.

#### **§ 1.04 CATEGORIES OF FCA CASES BASED UPON IMPROPER REIMBURSEMENT**

FCA cases based on improper Medicare Part B reimbursement claims fall into one of three major categories. These categories include (i) the "classic" false claim, (ii) the "standard of care" false claim, and (iii) the "tainted" claim.<sup>35</sup> The traditional "classic" false claim theory centers on the direct submission of a claim. The FCA was originally enacted to impose liability for this type of claim. However, in recent years the "standard of care" and "tainted" claims have evolved out of the FCA. These types of claims are predicated on issues other than the actual claims themselves. Liabilities for these claims are rooted in either an expressed or implied compliance with another law, statute, or regulation.

An expressed false claim is one in which the individual submitting the claim certifies compliance of the procedure and the billing practices with a particular law or regulation. The expressed certification is required as a prerequisite for payment.<sup>36</sup> If the individual fails to make the certification, the government will not reimburse the individual for the claim. An implied false claim is centered on the notion that by simply submitting the claim, the individual or entity is ensuring that it complied with all rules and regulations regarding conditions of payment from a federally funded program. Under this theory the government is essentially "looking to get what it paid for." The government's position is that if the services are not performed up to a certain standard, it

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<sup>35</sup> The "tainted" claims cases will be discussed in the subsequent sections concerning the Stark law and the Anti-kickback statute.

<sup>36</sup> United States *ex rel* Mikes v. Straus, 274 F.3d 687, 698 (2d Cir 2001).

is as if the work was not performed, thereby making the claim false. This subsection will provide a brief description of each claim followed by case law application.<sup>37</sup>

### **[A] Classic False Claim**

“Classic” false claims are those where services for which reimbursement is sought are predicated on a facially fraudulent claim submission. Under these circumstances, “[n]o certification, implied or otherwise, is necessary when the liability stems from the [d]efendants’ activities of billing for procedures which they did not perform. This would plainly constitute fraud.”<sup>38</sup> Examples of classic false claims include:

billing for services not provided, billing for unnecessary services, misrepresenting services that were provided, misrepresenting Medicare eligibility of patients, billing Medicare for services provided when the provider was excluded from Medicare, including non-reimbursable items in a cost report submitted to Medicare, filing a claim for which the services billed were actually provided, but the purported provider did not actually render or supervise the service..., submitting a code that receives a higher level of reimbursement than the appropriate code for the service actually provided, and submitting claims to Medicare for patients who are required to pay a certain amount before coverage applies, where the patient threshold amount was not paid by the patient.<sup>39</sup>

### **[B] “Standard of Care” False Claim Cases**

In recent years, the FCA has evolved into a compliance tool regulating the quality of care provided to patients. The justification for the expansion is based in part on the rationale that the submission of the claim certifies that the provider is in substantial or full compliance with Medicare and Medicaid quality of care requirements.<sup>40</sup> These claims are premised on compliance with applicable standards of care, and are therefore called “standard of care” false claims. The government’s position is that because the provider’s services fell below the quality standard of care, it is as if the care was never provided, and therefore the claim is false.<sup>41</sup>

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<sup>37</sup> Due to the well established case law surrounding the “classic” false claim no case law will be provided for cases pertaining to the “classic” false claim please see: (1) *United States v. Krizek*, 111 F.3d 934 (D.C. Cir. 1997); (2) *United States v. Cabrera-Diaz*, 106 F. Supp.2d 234 (D.P.R. 2000); (3) *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001).

<sup>38</sup> *United States v. NCH Health Care Corp.*, 163 F. Supp.2d 1051 (W.D. Mo. 2001).

<sup>39</sup> ROBERT FABRIKANT ET AL., *HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE* §4.01[d] (2004) [citations omitted].

<sup>40</sup> Robert Fabrikant and Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L REV. 105, 125 (Fall 1999).

<sup>41</sup> *United States v. NHC Health Care*, 115 F. Supp.2d 1449 (W.D. Mo. 2000).

In 1996, the courts first acknowledged that the imposition of liability for non-compliance with quality of care standards was a viable theory under the FCA.<sup>42</sup> Traditionally, quality of care cases focused on nursing homes, however experts opine that an expansion into other health care sectors is almost inevitable.

There has been a great deal of debate surrounding the expansion of the FCA to include the quality of care standard. Critics commonly cite to the vague language regarding the minimum level of care provided for in the Medicare statutes. The statutes speak in general terms regarding the quality of care, such as “promoting maintenance or enhancement of the quality of life of each resident,”<sup>43</sup> allowing for a wide range of interpretation.<sup>44</sup> Critics claim the quality of care issue is far too subjective because Medicare and Medicaid fail to provide clear care standards. Yet despite the criticism, the FCA continues to act as a quality of care enforcement tool.<sup>45</sup> The following cases will demonstrate the judiciary’s enforcement of the FCA via the standard of care theory.

**[1] *United States ex rel Aranda v. Community Psychiatric Ctrs. Of Okla., Inc.***<sup>46</sup>

In *United States ex. rel Aranda v. Community Psychiatric Ctrs. of Okla., Inc.*, the court first addressed the issue of FCA enforcement regarding the quality of care. In *Aranda*, the Government brought an FCA action on behalf of a psychiatric patient who was under the care of the Defendant. The Government alleged that the Defendant knowingly failed to provide a reasonably safe, secure and quality environment for its residents and yet impliedly certified that it did by way of submitting bills to Medicare when it had previously agreed to abide by all statutes, rules, and regulations required under the Medicare programs.<sup>47</sup> The hospital submitted a Motion to Dismiss, which was denied by the court, stating that the failure of the hospital to meet recognized professional standards could conceivably constitute a FCA violation.<sup>48</sup> Thereafter, the case was settled and the Government’s theory was never challenged on a fully developed set of facts.

**[2] *United States ex. rel Luckey v. Baxter Healthcare Corp.***<sup>49</sup>

*United States ex. rel Luckey v. Baxter Healthcare Corp.*, involved a qui tam action brought by the plaintiff, a former laboratory technician, against her former employer (“Baxter”).<sup>50</sup> The Plaintiff alleged that she had communicated to Baxter that its failure to test colorless blood plasma samples for saline contamination created a risk of inaccurate results that were later transmitted to the Food and Drug Administration (the

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<sup>42</sup> See *United States ex. rel. Aranda v. Community Psychiatric Centers*, 945 F. Supp. 1485 (W.D. Okla. 1996).

<sup>43</sup> 42 U.S.C. § 1396r(b) (2004).

<sup>44</sup> John H. Krause, *Medical Error as False Claim* 27 Am. J. L. and Med. 181, 188 (1999).

<sup>45</sup> See *Generally* 65 Fed. Reg. 14289, 14295 n.49 (2000).

<sup>46</sup> 945 F. Supp. 1485 (W.D. Okla. 1996).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 1488.

<sup>49</sup> 183 F.3d 730 (7th Cir. 1999).

<sup>50</sup> *Id.*

“FDA”). Raising an implied certification theory, the plaintiff argued that Baxter’s non-compliance with the regulatory standard of care put the defendant in violation of federal statutes and regulations.<sup>51</sup> In effect, the Plaintiff argued that every time Baxter submitted a claim to the federal government, it impliedly claimed adherence to those regulations, and therefore, its claims were necessarily fraudulent.

The court declined to accept this argument stating that “[e]quating ‘imperfect tests’ with ‘no tests’ would strain language past the breaking point.”<sup>52</sup> In addition, according to the record, there was no indication that the Government was anything less than 100% satisfied with the product or the representations made in relation to the sale.<sup>53</sup> Moreover, there is nothing in the record to even suggest that Baxter had the required scienter to deceive the Government.<sup>54</sup> The record simply indicates that there is a dispute as to “whether Baxter’s testing protocols could be improved.”<sup>55</sup> Accordingly, the court was unwilling to apply the FCA under an implied certification theory and granted Baxter’s motion for summary judgment.

### [3] *United States ex rel. Mikes v. Straus*<sup>56</sup>

This quality of care case involved a qui tam action brought by a former physician employee of defendant Straus’ medical group practice. The Plaintiff alleged that the Defendant violated the FCA by submitting Medicare payments for spirometry tests which did not meet the standard of care.<sup>57</sup> It was alleged that the Defendant knew the machinery was not calibrated correctly and yet nonetheless conducted and billed the federal health care program for the tests. Based on the submission for Medicare reimbursement, the Plaintiff alleged that the claims were false under the FCA.<sup>58</sup> The district court entered summary judgment for the defense, stating that FCA liability pertaining to the certification of compliance with regulatory and industry standards could only exist, as a matter of law, where “the claimant’s adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the Government....”<sup>59</sup> Additionally, the court provided that the submission of a claim for a service that was not provided in accordance with the relevant standard of care does not necessarily make the claim per se false.

The district court determined that the Plaintiff failed to establish that Medicare reimbursement was in any way tied to compliance with §1320c-5(a) of the Social Security Act (the “SSA”). By opining that the claim was not false under the FCA implied certification theory, the court adopted the *Luckey* rationale and granted summary judgment for the Defendants.

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<sup>51</sup> *Id.* at 731.

<sup>52</sup> *Id.* at 732.

<sup>53</sup> *Id.* at 733.

<sup>54</sup> *Luckey*, 183 F.3d at 733.

<sup>55</sup> *Id.*

<sup>56</sup> 84 F. Supp. 2d 427 (S.D.N.Y. 1999).

<sup>57</sup> Spirometry is an easy-to-perform pulmonary function test used to detect lung diseases.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 435.

The district court's decision to grant summary judgment was affirmed on appeal.<sup>60</sup> In evaluating the Plaintiff's claim of implied false certification, the appeals court examined the interplay between §1395y(a)(1)(A) of the Medicare Act together with §1320c-5(a) of the SSA, to identify if the payment was contingent upon compliance. Section 1395y(a)(1)(A) of the Medicare statute states that "no payment may be made under [the Medicare statute] for items or services which...are not reasonable and necessary...." Since there is an expressed condition of payment—that is, "no payment may be made"—it explicitly links Medicare payments to the requirement that the particular item or service be "reasonable and necessary."<sup>61</sup> The Plaintiff contended that the submission of the claim forms implicitly certified that the procedures were "reasonable and necessary."

However, §1320c-5(a) of the SSA contains no such expressed condition of payment. Instead, §1320c-5(a) simply states that "it shall be the obligation" of a practitioner who provides a medical service "for which payment may be made...to assure" compliance with the section. Therefore, §1320c-5(a) appears to act prospectively, setting forth obligations to which a provider must adhere to in order to be eligible to participate in the Medicare program.<sup>62</sup>

Accordingly, the court reasoned that § 1320c-5(a) of the SSA is a condition of participation in the Medicare program and does not create an expressed condition of payment upon compliance with its terms. Thus, the Defendants' certifications on the Medicare reimbursement forms are not legally false. Consequently, the Defendants did not submit impliedly false claims by requesting reimbursement for tests that allegedly were not performed according to the recognized standards.<sup>63</sup>

The Plaintiff also alleged that the Defendants violated the FCA by submitting claims for worthless services. A worthless claim is not predicated on an expressed or implied certification theory, but rather that the services lack any medical value. A worthless services claim, for all practical purposes, is the equivalent of no performance at all.<sup>64</sup>

The court stated that the "requisite intent is the knowing presentation of what is known to be false," not simply the result of negligence or innocent mistake.<sup>65</sup> Mere allegations that the Defendants submitted Medicare claims knowing they did not conform to the ATS guidelines were alone insufficient to satisfy the standard for a worthless services claim. The idea of presenting a claim known to be false does not mean the claim is incorrect as a matter of accounting, but rather that it is a lie.<sup>66</sup>

Overwhelming evidence of the Defendant's genuine belief that their services had real medical value caused the court to conclude, as a matter of law, they did not submit their claims with the requisite scienter. Therefore, the court concluded, The Defendants did not violate the FCA and there was no issue of fact sufficient to bar summary judgment.<sup>67</sup>

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<sup>60</sup> United States *ex rel.* Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001).

<sup>61</sup> *Id.* at 700.

<sup>62</sup> *Id.* at 701.

<sup>63</sup> *Id.*

<sup>64</sup> *Straus*, 274 F.3d at 702.

<sup>65</sup> *Id.* at 703.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 704.

**[4] In *United States ex rel. Swafford v. Borgess Medical Center*<sup>68</sup>**

The relator, Jack Swafford, was a registered vascular technologist employed by the Defendants. Swafford participated in venous ultrasound studies ordered by the Borgess Medical Center ("Borgess") and observed their practices regarding the submission of Medicare/Medicaid reimbursement forms.

Borgess typically order venous ultrasound studies for patients suspected of suffering from specific risk factors associated with blood clotting. Using ultrasound, the patient's venous system would be examined to determine the presence or absence of certain "normal" characteristics for five blood clot risk factors. Typically, the procedure would be performed by either a technician or a technologist, who would then indicate the presence or absence of the five factors on a worksheet. The technician/technologist was assigned to determine either the presence or absence of the characteristics, and to indicate either "positive" or "negative" for each factor.

Borgess' physicians would review the worksheets, and then prepare a final report setting forth their findings and conclusions. Afterward, the physicians signed the following statement prior to submitting the results for reimbursement: "I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction."

Swafford alleged that the physicians did not review any hard copy data (video tape results) generated by the studies. Instead, Swafford contends the physicians merely reworded the technician's or technologist's "worksheet" to prepare a physician's ultrasound report. The medical center then billed the government for these "interpretations" which, according to Swafford, constituted mere plagiarism of the worksheet prepared by the technician/technologist.

Borgess sought summary judgment from the district court claiming that there was no issue of material fact, and that they should prevail as a matter of law. To succeed under a FCA theory, a plaintiff must establish at least three elements: first, that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; second, that the claim was false or fraudulent; and third, that the defendant knew the claim was false or fraudulent.

The parties did not dispute that Borgess presented "claims" as defined under the FCA by submitting Health Care Financing Administration (HCFA) 1500 forms seeking reimbursement from Medicare. Therefore, there is no genuine issue of material fact as to the first element of the FCA claim.

As to the second element of the FCA claim, Swafford argued that Borgess' practices fell short of the standard of care by (1) failing to review the underlying data of the ultrasound studies--the photographs, prints or videotape of the ultrasounds taken by the technologist/technician; (2) assuming the accuracy of the worksheet information provided by the technician/technologist, a number of whom lack working knowledge of physics; and by (3) failing to perform an independent review of either the hard-copy data, thus increasing the risk of unnoticed interpretative error. Therefore, by submitting claims for reimbursement that represent sub-standard care, Swafford contends that Borgess impliedly presented false claims under the FCA.

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<sup>68</sup> 24 Fed. Appx. 491 (6th Cir. 2001).

Despite these contentions, the court concluded that no genuine issue of material fact with respect to false claims under the FCA existed, even if Swafford could demonstrate the failure to conform to the applicable standard of care. The court agreed with the Seventh Circuit decision in *Luckey v. Baxter Healthcare Corp.*,<sup>69</sup> when it stated that “[e]quating ‘imperfect tests’ with ‘no tests’ would strain language past the breaking point.” Consequently, the court found no genuine issue of material fact regarding the falsity of the claim.

The court next considered the third element of the FCA claim, the issue of scienter. To succeed under the FCA, a relator need not demonstrate specific intent to defraud the government. The FCA’s scienter requirement, set forth in § 3729(b), requires either “‘actual knowledge’ that one is submitting a false or fraudulent claim for payment or approval, acts in deliberate ignorance of the truth or falsity of one’s false claim, or ‘acts in reckless disregard of the truth or falsity of the claim.’”

Accordingly, the plaintiff must demonstrate more than mere innocent mistakes or negligence on the part of the Defendants. Furthermore, “what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or simply false. The requisite intent is the knowing presentation of what is known to be false.” Swafford conceded that on at least three occasions Borgess contacted the HCFA seeking any “published guidelines” specific to the procedures in dispute. The answer from HCFA was that no such published guidelines existed. The court concluded that this evidence demonstrated that defendants evinced concern and investigated the question of what procedures were required to submit a proper claim for reimbursement. Consequently, the court ruled that there was no genuine issue of material fact as to scienter.

Finding no genuine issues of material fact at issue in the case, the court ruled in favor of the Defendants motion for summary judgment. On appeal, the Sixth Circuit Court of Appeals affirmed the lower court decision finding no FCA violation.

**[5] *United States v. NHC Health Care Corp.***<sup>70</sup>

In this implied certification case, the Government brought a FCA claim against NHC Health Care Corp. (“NHC”), a long-term care facility in Missouri, for submitting false or fraudulent bills to Medicare and Medicaid for services that were not provided to the facility’s patients. During trial, the government brought forth evidence to show that the facility had billed the government for services it knowingly did not render. Included in the evidence were: (i) reports of extreme staff shortages at the facility which precluded the facility from delivering appropriate care, 2) reports of neglect and lack of care through numerous accounts of surveyors and patient’s family members testifying to the unclean conditions at the facility and other observations concerning the poor treatment of patients, 3) direct evidence regarding two patients in the facility who were not being bathed nor assisted to the restroom resulting in a general omission of care, and 4) reports of regulatory non-compliance conducted by experts.

NHC argued that summary judgment was proper because the government’s action was barred, based on the theory of implied certification of compliance. NHC’s defense

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<sup>69</sup> 183 F.3d 730 (7th Cir. 1999).

<sup>70</sup> 164 F.Supp.2d 1051 (W.D. Mo. 2001).

was based on the same theories used in *Straus, Borgess, and Baxter*. The court rejected this argument, stating that implied certification is not relevant since the facility is not being sued for violating the standard of care, but is accused of actually failing to provide the services for which they had billed the government. The court explained that at some point a health care provider can cease to maintain a standard of care by failing to perform minimum necessary care activities to promote the patient's quality of life. When a provider reaches such a point, it has committed fraud and any billing certifications are unimportant. In this case, the court created an exception to the implied certification defense, indicating that service may fall so far below the minimum level of care, that reimbursement for these services is false. Thus, if the care reaches this level, the claim is akin to those brought under the classic false claim theory.

The Court denied the defendant's motion, holding that the evidence presented a genuine issue of material fact and that a jury might conclude that the facility knowingly submitted false claims through the lack of care and reckless indifference provided to patients of the facilities.

**[6] *United States ex rel. Swan v. Covenant Care, Inc.*<sup>71</sup>**

In *United States ex rel. Swan v. Covenant Care, Inc.*, a relator alleged that Covenant Care, Inc. ("CCI") falsified patient records in order to conceal evidence of substandard care. Ila Swan, an advocate for nursing homes, alleged that CCI routinely falsified patient records in order to conceal staffing and funding shortages in violation of the FCA. Swan claims that CCI was so understaffed that patients often were denied routine care such as feeding, turning, and bathing.<sup>72</sup> She alleged that despite the lack of services, CCI employees "back charted" patient files to indicate to reflect that the work had been completed. One employee stated that almost ninety percent of all forms had been doctored.<sup>73</sup>

CCI claimed that Swan was not entitled to bring a qui tam action because she discovered the allegations from public documents. The FCA provides for "limit[at]ions] on qui tam jurisdiction to those cases where the relator played a role in exposing a fraud of which the public was previously unaware."<sup>74</sup> In this case, Swan uncovered most of her allegations based on a civil lawsuit filed prior to her action.

The court found that the "essential elements of...[the] claim were previously disclosed in *Bretz*, and Swan is not an original source of the *Bretz* disclosures, therefore the court lacks subject matter jurisdiction over her suit and must dismiss her FCA claim under § 3730(e)(4)(A)."<sup>75</sup>

However the court still proceeded with the FCA liability analysis as if Swan was not jurisdictionally barred. The majority of Swans allegations focus on the failure to provide adequate care and the falsification of patient documents in violation of federal regulations. However, the court was quick to point out that "the FCA is not a vehicle for

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<sup>71</sup> 279 F. Supp. 2d 1212 (E.D. Cal. 2002).

<sup>72</sup> Id. at 1216.

<sup>73</sup> Id.

<sup>74</sup> Id at 1215.

<sup>75</sup> Swan, F. Supp.2d at 1220.

ensuring regulatory compliance,”<sup>76</sup> The court stated that liability may only be imposed for the submission of the false claim and not the underlying fraudulent activity.

The court held that Swan allegations failed under the false certification theory as well. The court acknowledged that some courts impose FCA liability for statutory quality of care standards,<sup>77</sup> however, the Ninth Circuit has failed to adopt that standard. “The prevailing law is that ‘regulatory violations do not give rise to a viable FCA action’ unless government payment is expressly conditioned on a false certification of regulatory compliance.”<sup>78</sup> Swan failed to introduce any evidence that CCI expressly certified compliance with any Medicare quality of care provision. Thus, Swan failed to demonstrate a regulatory violation under the FCA, and CCI would have been entitled to summary judgment had Swan satisfied subject matter jurisdiction.

[7] *United States ex rel. Holder v. Special Devices, Inc.*<sup>79</sup>

In *United States ex rel. Holder v. Special Devices, Inc.*, the United States sued Special Devices, Inc. (SDI) on behalf of Charles Holder for violating the FCA. The Defendant moved for a motion to reconsider after the court denied his motion for summary judgment. Holder, a former employee, alleged that SDI filed false claims in a series of government contracts by failing to adhere to the contractual obligations concerning various environmental, health and safety regulations. The defendant relied on *United States ex rel. Hopper v. Anton*,<sup>80</sup> arguing that the contracts must contain a provision requiring certification of compliance to be held liable under the FCA. *Hopper* stood for the principle that violating the law does not create a cause of action under the FCA unless there has been an expressed certification of compliance.<sup>81</sup>

The court rejected SDI’s reliance on *Hopper* because that case lacked a relationship between regulatory compliance and the receipt of funding from the government. In *Hopper*, it was alleged that the school district did not comply with the regulatory guidelines because federal funds were assigned based on a per student basis, while California apportioned the funds based on personnel and other factors. The *Hopper* Court rejected the Plaintiff’s claim of non-compliance because the school district was not required to file any certifications for the funding.

In the case at hand, the court pointed out that it was clear that there was a relationship between the subject matter of the false statement and the event triggering the government’s loss. The contract provided that SDI would comply with any and all laws. When SDI failed to comply, the government suffered a loss in the form of increased pollution. Additionally, the court distinguished this case from the *Hopper* ruling because *Hopper* failed to address false implied certification. This was a crucial conclusion since FCA liability based on a false certification of compliance with a government contract,

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<sup>76</sup> *Id.*

<sup>77</sup> See *United States v. NCH Healthcare Corp.*, 115 F.Supp. 1149; *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla.*, 945 F.Supp. 1485 (W.D. Okla. 1996).

<sup>78</sup> Swan, 297 F.Supp. 2d. at 1221.

<sup>79</sup> 296 F.Supp.2d 1167 (C.D. Cal. 2003).

<sup>80</sup> *United States ex rel. Hooper v. Anton*, 91 F.3d 1261(9th Cir. 1996).

<sup>81</sup> *Id.* at 1266–67.

whether express or implied, is consistent with the legislative history of the FCA.<sup>82</sup> Therefore, Defendant's motion was subject to a FCA violation.

### [C] Tainted False Claim Cases

The third major category of FCA liability comes from what is known as a "tainted" claim. Under the tainted claim theory, the defendant's FCA liability arises from the violation of another law. For example, if a defendant has violated the Stark law regarding self-referrals, then all subsequent claims submitted to Medicare would be tainted, and thus subject to FCA action.<sup>83</sup> Typically, these cases involve claims made to the Medicare Program which are entirely proper (i.e. "medically necessary and reasonable"), except for the fact that the referral of these services are the result of an illegal kickback, remuneration, or self-referral arrangement. Although the goods or services provided are legitimate, the information used to obtain them was false. Thus, the initial falsity "taints" an otherwise legitimate claim.<sup>84</sup>

The tainted claim theory originated from traditional bid-rigging cases, in which a party would fraudulently submit high or low bids to induce the government into awarding contracts.<sup>85</sup> Initially, the tainted claim theory applied to health care providers who falsified their information in order to enroll in a federally funded health care program.<sup>86</sup> Currently, there is a growing trend to apply this theory to regulatory violations that occur in the provider's course of business. However, as of today, there is no bright line rule of whether arrangements prohibited by law automatically give rise to liability under the FCA.

The expansion of the "tainted" false claim has resulted in a situation in which the violation no longer arises in the initial information stage, but rather is the result of statutory noncompliance. Therefore, any regulatory violation could potentially render all subsequent claims per se false.<sup>87</sup> The evolution of the false claim theory to the level of per se tainted creates a precarious situation. The nexus between the regulatory violation and the subsequent claim may be much attenuated, while the services may have been wholly appropriate.<sup>88</sup> Therefore, the reimbursement will be denied regardless of the fact the claim was false or not. Critics are of the opinion that the FCA should not be the enforcement vehicle for administrative regulations.

Additionally, the tainted claim theory expands beyond the context of Stark and Anti-Kickback legislation. FCA liability may be imposed on any provider who certifies that a claim complies with a specific regulatory scheme. Under this theory, the claimant must abide by all program rules and regulations in order to receive a federal payment.<sup>89</sup>

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<sup>82</sup> Shaw v. AAA Engineering & Drafting Inc., 213 F.3d 519, 531–32 (10th Cir. 2002).

<sup>83</sup> Michael E. Clark, *Whether the False Claims Act is a Proper Legal Tool for the Government to use for Improving the Quality of Care in Long-Term Care Facilities*, 15 No. 1 HEALTH LAW 12, 15 (September 2002).

<sup>84</sup> Joan H. Krause, *Medical Error As False Claim*, 27 Am. J.L. and Med. 181 (2001) (quoting JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 1-1 to 1-38 (Supp. 1999)).

<sup>85</sup> Id.

<sup>86</sup> S. Rep 345, 99th 2d Sess. 25, reprinted in 1986 U.S.C.C.A. 526, 5274.

<sup>87</sup> Krause, *supra* note 84 at 185.

<sup>88</sup> Clark, *supra* note 83, at 15.

<sup>89</sup> Krause, *supra* note 84 at 188.

Before providing tainted claim case analysis, a brief summation of the Anti-Kickback Statute and Stark regulation is warranted to provide the reader a better understanding of the tainted claim case law.

### [1] **Anti-Kickback Statute, 42 U.S.C. §1320A-7B**

In 1972, Congress enacted the Anti-Kickback Statute laying the foundation for what some call “one of the most potent weapons in the government’s arsenal”<sup>90</sup> to combat health care fraud. The statute provides criminal sanctions against anyone who knowingly and willfully offers payment, solicitation, or remuneration in an effort to induce a referral of business that is paid for by a federally funded program. In essence, the Anti-Kickback legislation prohibits anything of value from being offered or received to induce the referral of patients or business paid for in whole or in part by Federal health care programs.<sup>91</sup>

The penalties for such violations include (i) felony charges with the possibility of five years imprisonment and/or a \$25,000 fine, (ii) the loss of Medicare and Medicaid provider status, (iii) potential financial liability for damages and penalties under the FCA or Civil Money Penalties Law, or (iv) parallel adverse ramifications on state licensure, hospital privileges, and managed care participation.

In the process of passing the Medicare and Medicaid Patient and Program Protection Act of 1987, Congress expressed concerns that the Anti-Kickback Statute was overly broad and that its application to legitimate health care practices might result in the entire industry being deemed illegal. As a result, Congress ordered the Office of the Inspector General (OIG) to promulgate safe harbor regulations to shelter business relationships that would not be prosecuted under the statute. In response, the OIG created safe harbors, coined “safe harbors for toy boats” by the industry. Over the years the legislature has continued to create safe-harbors. The goal of the safe harbors is to make certain arrangements per se lawful and immune from prosecution. For the relationship to escape prosecution, the OIG has stated that substantial as opposed to complete compliance with a safe harbor is not sufficient to offer protection.<sup>92</sup> If the activity falls within one of the enumerated safe harbors, there is a presumption that the claim is no

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<sup>90</sup> Stanley A. Twardy and Michael P. Shea, *Anti-kickback Anxiety: How a Criminal Statute is shaping the Health-Care Business*, BUS. L. TODAY May/June 2000.

<sup>91</sup> Other activities that are prohibited include: Remuneration to purchase, lease, order or arrange for the purchase, lease, or order of any good, facility, service, or item for which payment may be made, in whole or in part under a Federal health care program.

<sup>92</sup> The government’s perspective on the failure to comply with a safe harbor was clearly stated at 56 Fed. Reg. 35952 (July 29, 1991) as meaning one of three things:

1. The arrangement does not fall within the ambit of the statute, as no intended to induce the referral of business reimbursable under Medicare or Medicaid.
2. The arrangement could be a clear statutory violation
3. The arrangement may violate the statute in a less serious manner with the degree of risk depending on a fact-specific inquiry, including whether the parties made a good-faith effort to comply; the arrangement is innocuous, or there is no applicable safe harbor. In these circumstances, the OIG may review the arrangement on a case-by-case basis to determine whether, based upon the totality of facts and circumstances, it poses a risk of fraud and abuse under the statute.

56 Fed. Reg. 35952 (July 29, 1991).

longer tainted.<sup>93</sup> While the failure to fit within a safe harbor does not make the arrangement per se illegal, there is a presumption that the arrangement violates anti-kickback laws.

## [2] Stark Self-Referral Law

The Stark law primarily governs the relationship between physicians and health care providers. Broadly speaking, the Stark Self-Referral law prohibits physicians from referring federal health care beneficiaries to an entity in which the physician has either a direct or indirect relationship. In the 1993, Congress enacted the Stark legislation with the passing of Section 13562 of the Omnibus Budget Reconciliation Act of 1993. Stark I and II laws seek to regulate physicians who have a financial relationship with a health care entity by extending the physician self-referral prohibition to include Medicare and Medicaid patients, and a self-referral ban on designation health services (DHS).<sup>94</sup>

The Stark law prohibits referrals for specific DHS's, prohibits billing for those services, and prohibits Medicare from paying for such services, when the referring physician has a financial relationship with the entity providing the service, and that relationship does not fall within one of the specified statutory or regulatory exceptions.<sup>95</sup>

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<sup>93</sup> The List of Safe Harbors Include:

- a. Investment interest in large publicly-traded entities or certain small entities
- b. Space Rentals
- c. Equipment Rentals
- d. Personal Service and Management Contracts
- e. Sale of Practice
- f. Referral Services
- g. Warranties
- h. Discounts
- i. Employees
- j. Group Purchasing Organizations
- k. Certain Medicare Part A waivers of coinsurance and deductibles
- l. Increase Coverage, Reduced Cost-Sharing, or reduced premium amounts offered by certain health plans (Managed Care).
- m. Price Reductions offered to certain health plans (managed care)
- n. Investment interest in underserved areas
- o. Investment interests in surgeon-owned single-specialty, multi-specialty and hospitals
- p. Investment interests in group practices composed exclusively of active investors who are licensed health care professionals
- q. Rural practitioner recruitment incentives
- r. Referral agreements for specialty services
- s. Obstetrical malpractice insurance subsidies
- t. Cooperative hospital service organizations
- u. Ambulance Replenish Arrangements.

<sup>94</sup> DHS services include:

- a. Clinical Laboratory Services
- b. Physical Therapy, Occupational therapy, and speech-language pathology services
- c. Radiology and certain other imaging services
- d. Radiation therapy services and supplies
- e. Durable Medical Equipment and Supplies
- f. Parenteral and enteral nutrients, equipment and supplies
- g. Prosthetics, Orthotics, and Prosthetic devices and supplies.
- h. Home Health Services
- i. Outpatient prescription drugs
- k. Inpatient and outpatient hospital services

<sup>95</sup> See 42 U.S.C. § 1395nn(a),(g).

Under the Stark Law, referrals include not only actual referrals, but also referrals concerning the ordering of a good or service in which the physician receives direct or indirect financial gain.

Stark law violators face penalties including denial of payment, mandatory refund of any payment previously received, civil money penalties up to \$15,000 per referral, \$100,000 for “circumvention schemes,” and exclusion from the Medicare program. In the context of Medicaid, the federal government will not pay federal matching funds to state Medicaid programs for services that are provided pursuant to a referral that would violate the Stark law if those services had been provided to a Medicare patient.

The Stark Law, like the Anti-Kickback safe harbors, provides for certain exempt activities. The statutory exceptions include (i) personal physician services by member of a group, (ii) in-office ancillary services, (iii) prepaid health plans, and, and (iv) certain enumerated services. Additionally, the Stark Laws established two primary categories of “financial relationships,” important for purposes of identifying applicable exceptions. These relationships are divided into either compensation arrangements<sup>96</sup> or ownership/investment interest.<sup>97</sup> If the physician/entity relationship falls into either category, the referral is not prohibited, regardless of the financial relationship between the two parties.

These so called “tainted” claims are primarily based on the alleged violation of the Federal Anti-Kickback Statute and/or the Federal Stark Law. The following case law may provide more insight into application of the tainted claim theory.

### **[3] “Tainted Claims” Theory of Liability Cases Under the FCA**

#### **[a] *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*<sup>98</sup>**

In *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.* (“HCA”), the relator, James M. Thompson, M.D., alleged that HCA submitted false or fraudulent claims under the FCA by submitting Medicare claims for services rendered in violation of the Anti-Kickback Statute and self-referral statutes. Specifically, Thompson alleged that HCA violated the Medicare anti-kickback statute by inducing physicians to refer Medicare patients to Columbia/HCA hospitals. He further alleged that the Defendants made false statements in support of the false claim by certifying the company’s annual

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<sup>96</sup> Compensation Exceptions include:

1. Rental of space and equipment, and provision of personal services.
2. Bona fide employment arrangements
3. remuneration from hospital unrelated to DHS
4. Physician recruitment plans
5. Isolated transaction
6. Certain group practice arrangements with a hospital
7. Payments by a physician for items and services

<sup>97</sup> Ownership/Investment Exception

1. Certain Publicly traded securities and mutual funds
2. Investment in rural, Puerto Rican or “entire” hospital facilities.

<sup>98</sup> 20 F. Supp.2d 1017 (S.D. Tex. 1998). [Hereinafter Thompson I]

report indicating that the services were performed in compliance with all laws and regulations.<sup>99</sup>

On remand from the Fifth Circuit Court of Appeals, the district court denied the HCA's motion to dismiss and motion for summary judgment. First, the court concluded that Thompson had stated legitimate FCA violations regarding HCA's alleged false certification of services identified in the annual cost reports. The alleged prohibited financial relationships among defendants and referring physicians made the certifications false. In addition to highlighting expressed statements in the relevant statutes and the Health Care Finance Administration (HCFA) form 2552, Thompson provided evidence that HCFA relied on the certifications in determining issues of payment, retention of payment, as well as continued eligibility in the Medicare program. The evidence established a clear nexus between the certifications and the injury to the government.<sup>100</sup>

The second issue is whether the Stark Law's expressed prohibition on payment for services rendered in violation of their own terms makes such alleged violations actionable under the FCA.

The Court concluded that it does. The Court ruled that Thompson had successfully stated a claim under the FCA for violation of the expressed terms of § 1395nn. Thompson alleged that the government was injured by HCA's submissions for Medicare payments. Payments which they knew they were statutorily prohibited from receiving because they arose out of an illegal self-referral. While the court stated that a pecuniary injury to the public is not required for an FCA action, the government did expend money resulting from investigative and administrative expenditures.<sup>101</sup>

The court further found that Thompson had also stated a claim for a violation of the FCA based on the alleged scheme of self-remuneration in violation of the Anti-Kickback statute. The statute prohibits the making of any false statements, failing to disclose material information, or making false statements or representations to qualify as a certified Medicare provider in applying for Medicare payments.<sup>102</sup>

Thompson alleged that the explicit certifications of compliance with relevant healthcare laws and regulations were false and fraudulent and provided evidence that the government conditioned its approval, payment, retention of payment funds on those certifications. The court found that the government was in fact injured and alleged that it would not have paid the claims submitted by HCA, had it had knowledge of the self-referral and kick-back violations.

The Thompson court cited *United States ex rel. Pogue v. Am. Healthcorp, Inc.* concluding that the FCA "was intended to include not only situations in which a claimant makes a false statement or submits a false record in order to receive payment but also those situations in which the claimant engaged in fraudulent conduct in order to receive payment."<sup>103</sup> Thus, it concluded "that the False Claims Act was intended to govern not only fraudulent acts that create a loss to the government[,] but also those fraudulent acts

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<sup>99</sup> *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 900-901 (S.D. Tex. 1997). [Hereinafter Thompson II].

<sup>100</sup> *Thompson I*, 20 F. Supp.2d at 1046

<sup>101</sup> *Id.* at 1047.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 1048 (citing *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1511 (M.D. Tenn. 1996)).

that cause the government to pay out sums of money to claimants it did not intend to benefit."<sup>104</sup> Consequently, the court denied the defendant's motion to dismiss.

**[b] *United States ex rel. Pogue v. Am. Healthcorp, Inc.***<sup>105</sup>

In this qui tam action, the plaintiff, Scott Pogue, alleged that his former employer, Diabetes Treatment Centers of America ("DTCA"), its parent company American Healthcorp, Inc. ("AHC"), its partner West Paces Medical Center ("West Paces"), five individual physicians; and a number of unnamed hospitals and physicians violated certain provisions of the FCA.

Pogue alleged that Defendants were involved in a scheme by which individual physicians would refer their Medicare and Medicaid patients to West Paces for treatment, thereby violating federal anti-kickback and self-referral statutes. Pogue contends that the Defendants submitted false and fraudulent claims to the government, in violation of the FCA.<sup>106</sup>

The defendants filed a motion to dismiss for failure to state a claim upon which relief can be granted. The court ruled that Pogue failed in his complaint to allege either actual damages or that defendants' conduct was fraudulent with the purpose of inducing payment from the government. Consequently, the district court granted the defendants motion to dismiss.<sup>107</sup>

Upon reconsideration, the court vacated its earlier order to dismiss, holding that the plaintiff need not allege actual damages or actual false claims in order to recover under the False Claims Act, but rather that defendants' conduct was fraudulent with the purpose of inducing payment from the government.

Pogue relied on the decision in *Ab-Tech Constr., Inc. v. United States*,<sup>108</sup> wherein the Government brought a counterclaim under the FCA against a company that had been awarded a government construction contract pursuant to the Small Business Administration's minority program ("SBA"). The purpose of the SBA program was to assist minority-owned businesses in gaining the skill and experience necessary to be competitive in the marketplace. The SBA required approval of any management agreement, joint venture, or other agreement relevant to the performance of a subcontract formed under the SBA program. The Government alleged that the plaintiff had entered into a financial arrangement with a non-minority-owned enterprise without getting SBA approval, and thereby submitted false claims in the form of payment vouchers for services performed. The court agreed finding that "the payment vouchers represented an implied certification by the plaintiff of its continuing adherence to the requirements for participation in the SBA program."<sup>109</sup> Stating that the FCA reaches beyond monetary claims that fraudulently overstate the amount due, the court reiterated that the FCA extends "to all fraudulent attempts to cause the Government to pay out sums of money."<sup>110</sup>

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<sup>104</sup> *Id.* at 1048–9.

<sup>105</sup> 914 F. Supp. 1507 (M.D. Tenn. 1996).

<sup>106</sup> *Id.* at 1508.

<sup>107</sup> *Id.* at 1512.

<sup>108</sup> *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

<sup>109</sup> *Id.* at 434.

<sup>110</sup> *Id.* at 433.

By deliberately withholding the non-minority-owned enterprise, the plaintiff not only dishonored the terms of its agreement with that agency but also, more importantly, caused the Government to pay funds in the mistaken belief that it was furthering the aims of the SBA program. In effect, “the Government was duped” by the plaintiff’s active concealment of a fact vital to the integrity of the program. The withholding of such information—information critical to the decision to pay—is the essence of a false claim.<sup>111</sup>

Pogue argued that the *Ab-Tech* rationale governed in this case as well. The payment vouchers at issue in *Ab-Tech* were not themselves false because the work was performed according to specification and the government was properly billed. Rather, the court found that the plaintiff’s assertion that he had complied with the regulations governing the SBA program rendered the payment vouchers false. Similarly, Pogue argued that although there is no allegation that defendants overcharged Medicare or charged it for services not rendered, defendants’ failure to comply with Medicare laws prohibiting kickbacks and self-referrals rendered the Medicare claims false or fraudulent. The court agreed.

Secondly, Pogue did not allege that the government suffered any loss due to Defendants’ alleged illegal activities. Pogue’s complaint did not assert that the alleged kickbacks or self-referral profits were improperly included, nor was there anything else that would suggest that the claims were somehow tainted. The government would have paid the claim regardless of who performed the services and regardless of the reason the patients chose the provider.

Nonetheless, the court in *Ab-Tech* and in the related case of *United States v. Incorporated Village of Island Park*,<sup>112</sup> found that the defendants had violated the FCA despite a lack of risk to government funds. In *Ab-Tech*, the court noted that the government had suffered no loss because it still received a building built to specifications.<sup>113</sup> In *Island Park*, the government would have paid the same amount for subsidized housing regardless of who eventually occupied those homes. In its ruling, the court said that the FCA “is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.”<sup>114</sup> Therefore, Pogue alleged, the FCA clearly prohibits fraudulent acts even if they do not cause a loss to the government.

The court concluded that the FCA was intended to govern not only fraudulent acts that create a loss to the government but also those fraudulent acts that cause the government to pay out sums of money to claimants it did not intend to benefit.<sup>115</sup>

Consequently, in order to bring his claim under the FCA, Pogue had to show that the Defendants engaged in the fraudulent conduct with the purpose of inducing payment from the government. If the Defendants’ fraudulent conduct was not committed with the

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<sup>111</sup> *Id.* at 434.

<sup>112</sup> *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 439 (E.D.N.Y. 1995).

<sup>113</sup> *Ab-Tech*, 31 Fed. Cl. at 434.

<sup>114</sup> *Inc. Village of Island Park*, 888 F. Supp. at 439.

<sup>115</sup> *Pogue.*, 914 F. Supp. at 1513.

purpose of inducing payment from the government, that conduct does not operate to taint their Medicare claims and render the claims false or fraudulent under the FCA.<sup>116</sup>

In the present case, Pogue sufficiently alleged that the government would not have paid the claims submitted by defendants if it had been aware of the alleged kickback and self-referral violations. Thus, Pogue alleged that defendants concealed their illegal activities from the government in an effort to induce government payment for Medicare claims it would not have otherwise paid.<sup>117</sup> Thereafter, the court granted Pogue's Motion to Reconsider and vacated its earlier decision dismissing the case.<sup>118</sup>

The *Pogue* case was later transferred to the United States District Court for the District of Columbia. The Defendants again raised defenses similar to the ones earlier raised before the United States District Court for the Middle District of Tennessee. The court rejected these defenses and made it clear in its decision that the violation of the Medicare Anti-kickback and self-referrals laws can form the basis for a violation of the False Claims Act.<sup>119</sup> The District of Columbia Court's opinion went to great lengths to demonstrate that the "implied certification" theory of liability under the False Claims Act has not been rejected by the other Courts. The Court concluded that this theory of liability was viable where compliance with laws such as the Anti-Kickback statute and the Stark Law would affect the government's decision to pay on claims to the Medicare and Medicaid programs.

**[c] *United States ex rel. Barmak v. Sutter Corp.***<sup>120</sup>

In *United States ex rel. Barmak v. Sutter Corp.*, the Relator, David Barmak brought an FCA claim against Sutter alleging it fraudulently obtained Medicare overpayments by waiving co-payments for sales of exercisers equipment, forging certificates of medical need, and paying kickbacks to hospitals and doctors for patient referrals.<sup>121</sup> As a result of a six year investigation by the United States Attorney's Office, the government decided to intervene only on the claims regarding waiver of co-payment.

On Sutter's Motion to Dismiss, the court ruled that the complaint was so vague and over-broad that it failed to meet the specificity requirements of Federal Rule of Civil Procedure 9(b), which states that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."

In addressing the plaintiff's attempt to claim violations of the anti-kickback statute as a basis for a FCA claim, the court stated that it was "not convinced that a *qui tam* Plaintiff can use the FCA as a vehicle for pursuing a violation of the anti-kickback statute in this Circuit." The court went on to state that it was "aware that some courts have permitted it, but that it remains a hotly disputed and controversial area of the law."<sup>122</sup>

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<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> See *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, 2002 WL 31856364 (D.D.C.).

<sup>120</sup> 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y 2002).

<sup>121</sup> *Id.* at \*1.

<sup>122</sup> *Id.* at 17–18 See *supra Pogue* and *Thompson*

First and foremost, the court pointed out that the anti-kickback statute is a criminal felony statute. As such, the court claimed that there is absolutely no private right of action provided, and the statute is to be enforced by the Department of Justice (the “DOJ”). Furthermore, the court stated that it has “no reason to believe, nor have the parties provided any, that Congress intended to subvert the DOJ’s exclusive jurisdiction over the anti-kickback statute by grafting the FCA’s *qui tam* provisions onto it.” This is a strong departure from the earlier decisions in *Pogue* and *Thompson* discussed above. Most importantly, the court indicated that it was “unwilling to presume...that a violation of the anti-kickback statute is *ipso facto* a violation of the FCA.”<sup>123</sup>

In this particular case, assuming a right of action, the Plaintiff failed to plead a causal relation between the violation of the anti-kickback statute and violation of the FCA. As stated by the court, the Plaintiff had “not alleged any certification of compliance with the anti-kickback statute, or that the Government relied on such certification in making payments to Defendants.”<sup>124</sup> Consequently, the court dismissed Plaintiff’s FCA action based on the violation of the anti-kickback statute.

***[d] United States ex rel. Bidani v. Lewis***<sup>125</sup>

In this declined *qui tam* case, the relator, Anil Bidani alleged that the Defendants violated the FCA by submitting claims for dialysis supplies and equipment that had been tainted by illegal discounting in violation of the anti-kickback statute.

The court began by recognizing that a claim made in violation of statutory or regulatory requirements may be deemed “false” under the FCA where compliance with such requirements is a condition of payment. As in *Pogue*, the court then re-characterized the test as one of “materiality” (*i.e.*, was the alleged kickback violation material to the government’s treatment of defendants’ Medicare claims). The court then distinguished outcome materiality (that the falsity affects the actual decision to pay the claim) from claim materiality (that the falsity was material to the defendant’s claim of right) and determined that the more stringent outcome test applied. The court continued:

[s]ince there was no disclosure, how the government would have treated defendants’ individual claims is a hypothetical question. So we turn instead to the inquiries of whether compliance with the AKS [Anti-Kickback Statute] was so important to the Medicare reimbursement process or so central to Medicare reimbursement agreements that compliance with the AKS was a condition of reimbursement so that failure to disclose non-compliance resulted in wrongful payments.<sup>126</sup>

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The government has entered a statement of interest in this case, arguing that since the AKS is a critical provision of the Medicare statute, compliance with it is material to the government’s treatment of claims for reimbursement. [The court agreed]. The AKS criminalizes receiving remuneration intended to affect

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<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> 264 F. Supp.2d 612 (N.D. Ill. 2003)

<sup>126</sup> *Id.* at 615.

decisions to purchase supplies for which payment may be made under Medicare. Those convicted under the AKS are barred from participating in Federal Health Care Programs. Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place. Reimbursing a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact. This situation exemplifies the “inducing wrongful payment” test for determining materiality contemplated in *Luckey*.<sup>127</sup>

The court agreed with the government’s contentions, holding that the kickback violation was material to the issue of reimbursement. Thus as a matter of law, the motion was denied and the case was remanded to the lower court to determine whether the Defendant’s actions violated the Anti-kickback statute, and in turn the FCA.

[e] ***United States ex rel. Urbanek v. Laboratory Corporation of America Holdings, Inc.***<sup>128</sup>

This *qui tam* complaint alleged that defendant, Laboratory Corporation of America (LabCorp), paid kickbacks to physicians in order to obtain the referral of clinical lab services. LabCorp provided the physician with (i) free gloves, gowns, centrifuges, alcohol swabs, gauze speculums, spatulas, pap smear brushes and brooms, and other medical supplies (ii) free computers, printers, printer ribbons, and similar office equipment and supplies, (iii) a phlebotomist inside a physician’s office; (iv) “professional courtesy” discounts to doctors and their families and (v) waiver of out-of-network charges to managed care patients referred by a physician.

The Court stated in its decision that the Second Circuit has concluded that there is some merit in the “implied certification theory,” but notes that “caution should be exercised not to read this theory expansively and out of context.”<sup>129</sup> The Court went on to say that the Second Circuit also stated in its decision that “implied false certification” is appropriately applied only when the underlying statute or regulation relied upon by the relator expressly states the provider must comply with that statute in order to be paid. In other words, the Court found that in order for a violation of the False Claims Act to be based on a violation of another statute that the statute must expressly preclude payment because of non-compliance by the defendant.

The *Urbanek* court, therefore, concluded that the existence of a false certification can only be based when such certification is a prerequisite to obtaining a government benefit. The Court went on to conclude that the Anti-Kickback Statute does not expressly state that a provider must comply with this law in order to be paid and, therefore, FCA liability cannot be based on “implied certifications” of compliance with the Anti-Kickback Statute. The Court, however, stated that the Stark Law was a different matter and is a statute which is expressly connected to claims for payment. Accordingly, the court concluded that since the Stark Law expressly states that a provider must comply in order to be paid, the implied certification theory of liability can be appropriately

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<sup>127</sup> Id. at 615–616.

<sup>128</sup> Case No. 00-CV-4863 (E.D. Pa., August 14, 2003).

<sup>129</sup> See *United States ex. rel. Mikes v. Straus*, 274 F.3d, 687, 698 (2d Cir. 2001).

applied to that statute and be the basis for FCA liability. This decision clearly limits the application of “implied certification” liability under the FCA.

[F] *United States ex rel. Schmidt v. Zimmer, Inc.*<sup>130</sup>

In this case, Richard Schmidt, (Schmidt), an orthopedic surgeon brought forth a *qui tam* action alleging that Zimmer, Inc. (“Zimmer”), a manufacturer and seller of orthopedic implants, violated the FCA by indirectly causing fraudulent cost reports to be submitted as a claim for payment. The Relator based the theory of fraud on an alleged kickback scheme in which Zimmer contracted to provide discounts and incentives to hospitals purchasing Zimmer products. In turn, the hospital would then submit the cost reports to Medicare without disclosing the discounts, in potential violation of the Anti-Kickback Statute.

Schmidt asserted an implied false certification theory based on the notion that the hospitals certification of compliance with federal laws and regulations were false because it failed to account for the discount. Schmidt alleged that Zimmer was liable for this falsity because it knowingly caused a false claim to be presented for payment. The District Court dismissed the case against Zimmer stating that Schmidt had failed to state a cause of action. The trial court dismissed the cause of action holding that Zimmer could not be liable because it did not submit, review, approve, or receive the cost reports.<sup>131</sup> Traditionally, a third party could only be responsible for a false claim if they “duped or tricked” another party into submitting a false claim.<sup>132</sup>

Third Circuit Court of Appeal was asked to resolve whether it was possible for Zimmer to knowingly assist in the hospitals false certification.<sup>133</sup> The critical issue is not the knowledge of the party submitting the claim, but rather the knowledge and conduct of the party that caused the claim to be submitted.<sup>134</sup> The court proffered that Zimmer created a marketing scheme that it knew would, if successful, result in the submission of a false certification of adherence to federal law.<sup>135</sup> The targets of this Anti-Kickback scheme were health care providers that Zimmer knew to be enrolled in the Medicare program. The court inferred that Zimmer’s knowledge of the providers Medicare enrollment status and knowledge that the providers would submit claims to Medicare was pivotal, if not essential, to providing the discounts and incentives. Therefore, it was possible to infer that, “Zimmer must have known [the hospital] could not purchase its implants, receive kickbacks, and share those kickbacks with its physicians, in the manner provided by the contract unless [the hospital] falsely certified itself to be in compliance with federal law.”<sup>136</sup>

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<sup>130</sup> 286 F.3d 235 (3d Cir. 2004).

<sup>131</sup> *Id.* at 240.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 243.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 244.

<sup>136</sup> *Id.*

However, the court stated that it was unsure if Zimmer knew that the hospitals were submitting false claims.<sup>137</sup> In fact, the provider contract required that the hospitals were responsible for disclosing the dollar value of the discounts or reduction in price. However, the court failed to make a definitive finding that the appearance or possibility that a party may submit a false claim in excess of what it paid could subject the third party to liability under an implied certification theory. “[M]ere awareness that another may, or even has, chosen to make such a claim does not alone constitute “causing a false claim to be presented.”<sup>138</sup> The court held that “assuming...a jury were to conclude that Zimmer’s marketing scheme was a substantial factor in bringing about [the hospitals] filing and that the filings [were] a normal consequence of the situation created by the scheme, Zimmer could be found to have caused, and thus responsible for, that filing.”<sup>139</sup> The case was reversed and remanded to the District Court to determine if Zimmer was in violation of the anti-kickback law.

This case is unique in that it extends the implied false certification theory to a third party. Here, the court found the possibility of a sufficient nexus between the inducement of purchase and the submission of a false claim. While this case ultimately addressed a causation issue, the court seemed to embrace an implied false certification theory where the underlying statute or law did not directly relate to the payment of a claim.

**[G] *United States ex rel. Quinn v. Omnicare, Inc.***<sup>140</sup>

In this FCA case, Thomas Quinn, a regional comptroller for Pompton Nursing Home Suppliers (Pompton) brought forth a *qui tam* action against his employer and its parent company Omnicare, Inc.<sup>141</sup> Pompton is a New Jersey based pharmacy servicing patients at local long-term care facilities. The underlying factual basis for the allegations centered on the redispensing of a return medication. In some instances, the medications, which Pompton submitted and received full reimbursement from Medicaid, were returned by the patient or facility.<sup>142</sup> In these situations, Pompton returned fifty percent of the cost to Medicaid and retained the remaining fifty percent to cover expenses relating to the restocking, repacking, and redispensing the medication.

Quinn asserted four theories of FCA liability relating to the practice of refunding and redispensing the medication. First, he asserts an implied certification theory of liability alleging that Pompton submitted false claims by failing to adjust the initial claim when the medications were returned.<sup>143</sup> Under this theory, the initial claim becomes false for failing to void or adjust the payment after the medication was returned. However,

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<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at 245.

<sup>139</sup> *Id.* 244-45.

<sup>140</sup> 382 F.3d 432 (3d Cir. 2004).

<sup>141</sup> *Id.* at 434.

<sup>142</sup> *Id.* at 435. “New Jersey Pharmacy regulations allow Medicaid provider pharmacies to recycle returned unit dose packaged medications if they have been stored properly and the seal and control numbers remain intact.” *Id.* citing N.J.A.C. § 13:39-9.15.

<sup>143</sup> *Id.* at 437.

there is no express language contained in the claim submission form that indicated medications cannot be returned. In the absence of this language, the court was unwilling to extend the notion of an implied false certification for the failure to void or adjust a payment.

Additionally, the court questioned “whether a claim, which is not ‘false’ or ‘fraudulent’ when initially, submitted, can later be rendered so if the medication is returned.”<sup>144</sup> The court opined that in this particular circumstance, the initial claim did not contain any intentional misrepresentation. Additionally, Pompton had no way of knowing if a medication was to be returned upon submitting the claim. Therefore, Pompton lacked the necessary knowledge requirement that the initial claim be obtained by false or fraudulent conduct.

Next, Quinn asserted that Pompton double-billed Medicaid when it re-sold medication that was previously returned.<sup>145</sup> Quinn claimed that by refunding half of the cost to Medicaid and submitting a new claim for the same medication, Pompton subsequently double-billed and fraudulently represented the cost of the services provided on the second claim submission. However, Quinn was unable to point to any evidence that the same medication was the subject of two separate Medicaid claims.<sup>146</sup> The court noted that the relator carries the burden to establish that a specific drug had been paid for by Medicaid, returned, and subsequently redispensed and rebilled to Medicaid.<sup>147</sup> Quinn attempted to prove the billing occurred by offering evidence that Medicaid patients accounted for roughly sixty percent of Pompton’s sales. The court was unwilling to accept a theory that some claims “must have been” submitted simply based on the percentage of the pharmacy’s sales paid for by Medicaid. Moreover, the court noted that New Jersey law allows pharmacy’s to recycle and redispense medication. Thus, even if the relator identified a specific drug that had been billed, returned, and redispensed, FCA liability was improper because the act was not prohibited by State or Medicaid Law.<sup>148</sup>

Third, Quinn re-alleged liability under an implied false certification theory based on Pompton’s acknowledgement that the submission of a claim required certification that the “services covered by [the] claim and the amount charged was in accordance with... [Medicaid] regulations.”<sup>149</sup> Quinn argued that Pompton was in violation of the State regulation requiring pharmacies to comply with all New Jersey Board of Pharmacy Regulations. The district court adopted a *Mikes* rationale by limiting the application on the implied false certification theory to cases where the underlying statute or regulation expressly required compliance prior to reimbursement. The court dismissed the argument, opining that the regulations may provide grounds to disqualify a pharmacy from program participation, but adherence to the regulations was not a condition of payment.<sup>150</sup>

On appeal, Quinn stated the claim submission form required providers to expressly certify that the organization complied with all Medicaid regulations, which incorporated the Board of Pharmacy Regulations. The Third Circuit Court of Appeals found that the argument contained some merit. The court stated that even though the

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<sup>144</sup> *Id.* at 438.

<sup>145</sup> *Id.* at 339.

<sup>146</sup> *Id.* at 439.

<sup>147</sup> *Id.* at 439.

<sup>148</sup> *Id.* at 441.

<sup>149</sup> *Id.* at 442.

<sup>150</sup> *Id.* at 442.

regulations did not expressly condition payment on compliance with its terms, it is not irrelevant to the government's decision regarding payment of the claim. Yet, the court went on to say,

even if Pompton does not qualify for Medicaid reimbursement if it dispenses an improperly recycled medication to a Medicaid patient, we cannot say that, in this case, Pompton has made any false certifications in connection with a Medicaid claim. The reason we come to this conclusion is because of the impossibility of proving from the numbers alone that a claim was made by Pompton to Medicaid for an improperly recycled medication.<sup>151</sup>

While this allegation was dismissed because of a lack of proof, the court appeared to entertain the possibility that a party may violate the FCA under an implied false certification theory even if the underlying statute did not expressly condition payment upon compliance with its terms.

Lastly, Quinn alleged that Pompton violated the FCA by failing to credit 100% of the total payment to Medicaid. Under this reverse false claim theory of liability, Quinn alleged that Pompton was required to credit back 100% of the cost of the medication upon the return of the drug.<sup>152</sup> However, the court dismissed the claim because New Jersey Law did not expressly include an obligation to credit Medicaid for the returned medication. In closing, the court avowed that it was a lack of regulation that allowed Pompton to retain half of the cost of the medication and “Congress and/or the New Jersey legislature might serve Medicaid well if this lack of regulation were corrected.”<sup>153</sup>

## **[D] Recent Settlements**

### **[1] *United States ex. rel. Sal Barbara v. Amisub, Inc.***<sup>154</sup>

This relator action was brought against a Tenet hospital in Ft. Lauderdale, Florida, based on claims arising from valuations and acquisitions of physician practices by the hospital during 1993 and 1994. In its order denying relator's motion for summary judgment, the Court nevertheless indicated that the facts created a “strong inference” that referrals were taken into account in setting compensation, which, if established, would support a violation of the Stark II statute. The Court also stated that clarity was needed on the precise meaning of the phrase “taking into account” as applied to Stark II violations.

The Court did dismiss a portion of the case against the defendant as it related to the acquisition of a retiring physician's practice, holding that letters sent by the retiring

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<sup>151</sup> *Id.* at 443.

<sup>152</sup> *Id.* at 445.

<sup>153</sup> *Id.* at 447.

<sup>154</sup> Case No. 97 CV-6590 (U.S. Dist. Ct., S. Fla.)

physician urging his patients to see his remaining partners did not constitute a “referral” for Stark or kickback purposes. The case was settled in December, 2003.

**[2] *United States ex rel. Rauh v. McLeod Regional Medical Center of Pee Dee, Inc.***<sup>155</sup>

This *qui tam* action alleged that McLeod had purchased physician practices at far above fair market value, and billed for services referred by the physicians involved. The relator and the government alleged that such bills constituted false claims under the False Claims Act. The case was settled in October 2002 for \$15,485,000. The relator did not receive a portion of the settlement amount.

**[3]. *United States ex rel. Johnson-Porchardt v. Rapid City Regional Hospital***<sup>156</sup>

In a complaint filed in March 2001, a *qui tam* relator alleged that the Hospital and an oncology group committed Stark II and anti- kickback violations by being parties to a below-market lease for Hospital space. The complaint also alleged upcoding for certain procedures by the oncology group. On December 19, 2002 the case was settled for a payment by the Hospital of \$6,000,000 and by the group of \$525,000. In a February 2003 ruling, the *qui tam* relator was awarded 24% of the settlement amount. In making this award, the Court noted that the relator had diligently attempted to obtain resolution of the issue internally for a three-year period.

**[4] *Columbia HCA Physician Settlement.***

HCA agreed to pay \$225.5 million to resolve lawsuits alleging that HCA hospitals and home health agencies unlawfully billed Medicare, Medicaid and TRICARE for claims generated by the payment of kickbacks and other illegal remuneration to physicians in exchange for referral of patients. In 2001, Columbia Management Companies, Inc., pled guilty to one count of conspiracy to pay kickbacks and other monetary benefits to doctors in violation of the Medicare Anti-kickback Statute and paid a \$30 million criminal fine. Dr. James Thompson, a doctor who filed suit against the company in 1995, will receive \$41.5 million as his statutory share of the settlement. Gary King, a former HCA employee, will receive \$5 million and Ann Mroz, a former HCA nurse, will receive a share of \$837,500.

**[5] *Gambro Healthcare Settlement***

In late 2004, Gambro Healthcare (Gambro) agreed to pay criminal and civil penalties in excess of \$350 million to settle allegations of Medicare and Medicaid fraud. Additionally, Gambro Supply Corporation (“Gambro” Supply), a subsidiary, agreed to plead guilty to criminal charges, admit to its participation in a fraudulent scheme, pay \$25

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<sup>155</sup> Civ. Act. No. 3-98-3178 (D.S. Car.).

<sup>156</sup> U.S.D. Ct. S.D. (Western Div.) 01-CV-5019.

million in fines, and accept permanent exclusion from participation in the Medicare program.<sup>157</sup>

The specific allegations charged Gambro with creating a shell corporation to defraud Medicare. The Department of Justice alleged that Gambro Supply provided medical equipment to patients via a shell medical equipment company, resulting in Gambro receiving a higher reimbursement than it would have if it submitted the claims directly.<sup>158</sup> The Government also alleged that Gambro billed for supplies that were never provided. Moreover, Gambro was alleged to have engaged in the “hard coding” of diagnostic codes and submitting false statement made to induce payment for medically unnecessary test.<sup>159</sup> According to the United States Attorney’s Office, Gambro defrauded the Government out of millions of dollars of federal insurance money for the unnecessary tests.

The Government also contended that Gambro engaged in practices that violated the Anti-Kickback Statute. The complaint proffered that Gambro hired physicians as medical directors for its dialysis clinics and compensated them based on the number of patient referrals made to its clinics. Often these remunerations were in excess of the fair market value of the services.<sup>160</sup> Additionally, the complaint alleged that Gambro provided illegal remunerations to its joint venture physician partners in exchange for patient referrals to its clinics. This was one of the largest healthcare settlements ever reached by the Department of Justice.

## **[E] Restitution Regarding FCA And Receipt Of Referral Fees**

In 2001, the Eleventh Circuit Court of Appeals reviewed a criminal conviction regarding the district court’s decision ordering a physician to pay restitution to Medicare for monies received in exchange for patient referrals in violation of the federal anti-kickback statute. The issue on appeal was whether a physician receiving remuneration for making patient referrals should be ordered to pay restitution in the amount of the illegal remuneration.

In *United States v. Liss*,<sup>161</sup> CCL, a Florida laboratory, and its employees developed a scheme to defraud Medicare by paying doctors to refer their Medicare patients in return for kickbacks. CCL created a scheme of consulting agreements with doctors acting as Testing Review Officers ("TROs"). The agreements allowed the doctors to authorize lab work for an individual without the need to seek authorization from the individuals own physician. As such, the TRO agreements served to disguise the kickbacks that were given in return for the patient referrals.<sup>162</sup>

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<sup>157</sup> Press Release, United States Attorney’s Office Eastern District of Missouri, Gambro Healthcare Agrees to pay over \$350 Million to resolve Civil and Criminal Allegations in Medicare Fraud Case (Dec. 2, 2004) available at <http://www.usdoj.gov/usao/moe>.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* Hard Coding “results in the submission of false statement and bills being submitted for ancillary medications and services which were not medically necessary.” *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> 365 F.3d 1220 (11th Cir. 2001)

<sup>162</sup> *United States v. Liss*, 265 F.3d 1220, 1224 (11th Cir. 2001).

In August 1996, CCL signed a TRO agreement with a co-defendant physician named Michael Spuza, in which Spuza was paid \$600 a month. Between August 1996 and April 1998, CCL paid \$12,000 to Spuza under the TRO agreement. In addition, CCL made 28 equipment sublease and office rental payments on behalf of Spuza totaling \$55,371.36. Medicare reimbursed CCL \$269,004.73 as a result of the referrals made by Spuza for clinical laboratory work. The Court found that all the associated referrals were made for legitimate medical reasons.<sup>163</sup>

The government claimed that according to the anti-kickback statute Spuza was required to pay the full amount of remuneration it had been paid by CCL for the referrals. The court agreed with the government's argument, but failed to make any findings of fact on the issue. Accordingly, Spuza was ordered to pay \$55,371.36 in restitution.<sup>164</sup>

On appeal, Spuza contended that the district court erred in ordering him to pay restitution because the government offered no evidence to suggest that the Medicare program suffered any loss attributable to the illegal remuneration from CCL. Spuza argued that because the referrals made to CCL were medically necessary and because he was not involved in fraudulent billing, it was error for the court to assume that Medicare suffered a loss which was attributable to his receipt of remuneration.<sup>165</sup>

According to *United States v. Martin*,<sup>166</sup> an award of restitution must be based on the amount of loss actually caused by the defendant's conduct. The government bears the burden of proving the amount of the loss.<sup>167</sup>

In Spuza's case, the government offered no evidence to prove that the Medicare program suffered any loss attributable to Spuza's receipt of remuneration. The amount paid by Medicare to CCL was not affected by what CCL did with the money it received. Although CCL may owe restitution if it fraudulently billed for the services allegedly referred by Spuza, billing fraud is not a part of Spuza's offense conduct.<sup>168</sup>

The court found there was no basis for such an assumption of loss to Medicare because the medical necessity of the referrals is unquestioned. Accordingly, the court vacated the district court's restitution order.<sup>169</sup>

## **§ 1.05 STATE FALSE CLAIMS ACTS**

In light of the success of the FCA on the Federal level, several states have enacted similar statutes in an effort to combat fraud on a local level. The state false claim acts, as its name suggests, imposes liability on false or fraudulent claims submitted to state agencies. Several states have codified their own versions of the False Claim Act including: Arkansas, California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Michigan, New Mexico, Nevada, North Carolina, Oklahoma, Tennessee, Texas, Utah, Virginia, and District of Columbia.<sup>170</sup> As the success of the federal FCA increases, more and more states are likely to follow suit.

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<sup>163</sup> *Liss*, 265 F.3d at 1224-25.

<sup>164</sup> *Id.* at 1231.

<sup>165</sup> *Id.*

<sup>166</sup> 195 F.3d 961, 968 (7th Cir. 1999).

<sup>167</sup> 18 U.S.C. § 3664(e); *United States v. McIntosh*, 198 F.3d 995, 1003 (7th Cir. 2000).

<sup>168</sup> *Liss*, 265 F.3d at 1232.

<sup>169</sup> *Id.*

<sup>170</sup> [www.taf.org/statefca.htm](http://www.taf.org/statefca.htm). The State False Claims acts may be found at:

These state false claim statutes typically mirror the federal legislation. However, it is important to note that each state has enacted subtle differences. Some of the differences include expanded liability to include individuals with knowledge who fail to disclose the fraudulent submission, variations in the qui tam provisions, liability imposed on a broader scope of conduct, jurisdiction issues, and variations within the penalty and damage provisions. While it is not practicable to list all the differences here, the reader should note that just because an act would presumptively escape liability under the FCA that does not necessarily ensure the action would escape state liability. Providers in states with codified a false claims act should consult the particular legislation regarding specific inquires.

### **§1.06 Conclusion**

The FCA continues to remain a forceful tool in the area of health care compliance. While FCA health care actions have leveled off in recent times, there will continue to be a steady volume of cases. It is important for providers to remain conscious of the continuation of the quality of care and tainted claim theories of liability under the FCA. So long as there remains the possibility of a whistleblower bringing forth an action on behalf of the government under a state or federal FCA, the risk of liability is simply something that providers cannot afford to ignore.

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Arkansas: ARK. CODE ANN § 20-77-901 (Michie 2004) (Medicaid Only)  
California: CAL. GOV'T CODE § 12650 (Deering 2004).  
Delaware: DEL. CODE ANN., tit. 6, § 1201 (2004).  
Florida: FLA STAT. § 68.081 (2004).  
Hawaii: HAW. REV STAT § 661-21 (2004)  
Illinois: 740 ILL. COMP. STAT 175/1 (2004).  
Louisiana: LA. REV. STAT. ANN § 46:437.1 (West 2004)  
Massachusetts: Maa Gen Law Ann. ch 12 §§ 5-50  
Michigan: MICH COMP. LAWS ANN. §§ 400.601 (Wst 2004)  
New Mexico:  
Nevada: NEV. REV. STAT. 357.010  
North Carolina: N.C. Gen. Stat. § 108A-7016.  
Oklahoma: 21 OKLA. STAT ANN § 358  
Tennessee: TENN. CODE ANN. § 71-5-181 (2004) (Medicaid Only)  
Texas: TEX. HUM. RES. CODE § 36.00436.117 (Vernon 2004)  
Utah: UTAH CODE ANN. § 26-20-1 (2004)  
Virginia: Va. Code. Ann. §§ 8.01-216.1  
Washington: Wash. Rev. Code § 48.010-900 (2004)  
District of Columbia: D.C. Code Ann § 1-1188.13 (2004)

Id.

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