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False Claims Act and *Qui Tam* Quarterly Review

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The *False Claims Act and Qui Tam Quarterly Review* is published by Taxpayers Against Fraud, The False Claims Act Legal Center (TAF). This publication provides an overview of major False Claims Act and *qui tam* developments including case decisions, DOJ interventions, and settlements.

TAF is a nonprofit public interest organization dedicated to combating fraud against the Federal Government through the promotion and use of the *qui tam* provisions of the False Claims Act (FCA). TAF's mission is both activist and educational. Established in 1986, TAF serves to: (1) collect and evaluate evidence of fraud against the Federal Government and facilitate the filing of meritorious FCA *qui tam* suits; (2) work in partnership with *qui tam* plaintiffs, private attorneys, and the Government to effectively prosecute *qui tam* suits; (3) inform and educate the general public, the legal community, and other interested groups about the FCA and its *qui tam* provisions; and (4) advance public, legislative, and government support for *qui tam.*

TAF is based in Washington, D.C., where it maintains a comprehensive FCA library for public use and a staff of lawyers and other professionals who are available to assist anyone interested in the False Claims Act and *qui tam.*

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Constitutionality of FCA/ Article II Take Care and Appointments Clauses

***Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 391 (5th Cir. May 25, 2001) (en banc)**

The en banc Fifth Circuit held that the *qui tam* provisions of the False Claims Act do not violate the Take Care and Appointments Clauses of Article II of the Constitution. The court ruled that the important role that *qui tam* lawsuits have played throughout American history provides very significant support for the Act's constitutionality. Because the Executive maintains significant control over FCA litigation pursued by a *qui tam* relator, the Act does not interfere with the President's constitutional duty to "take Care that the Laws be faithfully executed." Furthermore, because FCA relators are not "officers of the United States," the Act's *qui tam* provisions do not violate the Appointments Clause.

Joyce Riley, a former nurse at St. Luke's Episcopal Hospital, brought this action against the hospital and seven other defendants alleging that the hospital defrauded the Government by unnecessarily admitting patients, unnecessarily upgrading services, and allowing an unlicensed physician to perform services. The Government declined to intervene, and the defendants moved to dismiss on Article III standing grounds. The district court granted the motion, and Riley appealed to the Fifth Circuit. A divided Fifth Circuit panel held that although Riley had standing to sue, *qui tam* actions in which the Government does not intervene violate the doctrine of separation of powers and the Take Care Clause. *See* 196 F.3d 514 (5th Cir. 1999). On appeal, the Fifth Circuit granted rehearing en banc, but delayed the rehearing pending the Supreme Court's decision in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), 19 TAF QR 1 (July 2000).

In an eleven to two decision, the en banc court of appeals reversed the panel's decision. Judge Stewart, who had dissented from the original panel's decision, now wrote for the majority to uphold the constitutionality of the Act. Only the two judges who comprised the original panel majority continued to reject the Act as unconstitutional.

Historical Support for Constitutionality

The en banc court began by noting that *qui tam* lawsuits have been used to protect national treasuries throughout English and American history. In *Stevens*, the Supreme Court noted that this history was "well nigh conclusive" on the question of whether *qui tam* relators have Article III standing. The en banc court was persuaded that this history was similarly conclusive with regard to the Article II question. Although the historical record is not the sole definitive argument supporting constitutionality of the *qui tam* provisions under Article II, the court stated that it is certainly a "touchstone illuminating" their constitutionality.

Executive Retains Sufficient Control Over *Qui Tam* Actions

Although the Constitution requires the President to "take Care that the Laws be faithfully executed," the court ruled that it does not require Congress to prescribe litigation by the executive as the exclusive means of enforcing federal law. Moreover, the court noted that the executive retains significant control over *qui tam* suits under the FCA. If the Government initially declines to intervene, it may still intervene at a later date upon a showing of good cause. Even in cases where the Government never intervenes, it may request to be served with copies of pleadings and deposition

transcripts and may pursue alternative remedies. The Government may stay discovery in a *qui tam* action upon a showing that it would interfere with a government investigation or prosecution. The Government also retains the power to settle or dismiss an action over a relator's objections after an opportunity for a hearing. Finally, despite its non-intervention, the Government receives the bulk of any recovery.

The en banc court rejected the panel majority's reliance on *Morrison v. Olson*, 487 U.S. 654 (1988), in which the Supreme Court upheld the independent counsel provisions of the Ethics in Government Act (EGA). Although *Morrison* examined similar constitutional questions, the court held it was inapplicable for two reasons. First, while the EGA authorizes the independent counsel to act *as* the United States itself and to exercise all investigative and prosecutorial functions of the Government, the FCA only authorizes a *qui tam* relator to sue *in the name of* the United States. Second, in contrast to the independent counsel, who undertakes the functions of a criminal prosecutor, the *qui tam* relator is simply a civil litigant. Because of these differences, the EGA and the FCA require different types of executive control over the independent prosecutor and the *qui tam* relator respectively. Hence it was not appropriate for the panel majority simply to apply a "test" gleaned from *Morrison* to the facts in *Riley*.

If anything, the en banc court ruled, *Morrison* suggests that the Supreme Court would uphold the *qui tam* provisions of the FCA. Relators sue in civil capacities and wield far less executive power than independent counsels, who take on prosecutorial functions. Because the Supreme Court upheld the latter in *Morrison*, it seems likely that *a fortiori* it would uphold the former as well. Moreover, the en banc court noted, any intrusion by the *qui tam* relator into the executive's Article II power is comparatively modest when viewed in the broad context of the American judicial system, which permits much greater intrusions by the judiciary into the executive's prosecutorial authority even in the criminal context. For example, the court noted, once the executive brings an indictment, judicial approval is required for dismissal.

Qui Tam Provisions Do Not Violate Appointments Clause

The court rejected the defendants' argument, raised in the district court but not reached in the decisions below, that the *qui tam* provisions of the FCA violate the Appointments Clause of Article II, which vests appointment of "officers" of the United States in the executive. The court noted that Supreme Court precedent has established that the constitutional definition of "officer" encompasses, at a minimum, a continuing and formalized employment relationship with the Government. There is no such relationship between the Government and *qui tam* relators, who are not subject to the benefits or requirements associated with offices of the United States. For example, relators do not draw a government salary and are not required to establish their fitness for public service. Therefore, *qui tam* relators are not officers of the United States and the *qui tam* provisions of the FCA do not violate the Appointments Clause. Accordingly, the court reversed the panel decision and remanded to the district court for further proceedings.

Dissenters Argue FCA Violates Article II

In a lengthy dissent, the two judges who formed the original panel majority continued to insist that the FCA violates Article II because it "impermissibly undermines" the powers of the executive. The dissenters rejected the en banc majority's reliance on the continuous history of *qui tam* legislation dating back to the earliest years of the Republic. In the dissenters' view, this history is not dispositive because

Congress never undertook a "reasoned discussion" of the constitutional issues at stake. The dissenters argued that the FCA violates the Take Care Clause by stripping the executive of accountability for and control over law enforcement. They also argued that only "officers" of the United States may litigate on behalf of the Government, and therefore the Act violates the Appointments Clause.

Need for Economic Damages

Varljen v. Cleveland Gear Co., 250 F.3d 426 (6th Cir. May 17, 2001)

The Sixth Circuit held that recovery under the FCA is not dependent on a showing that the Government sustained economic damages. Failure to comply with government contract specifications can result in an FCA "injury" even if the supplied product is as good as the specified product, and the Government's inspection and acceptance of a product do not absolve a contractor of liability under the Act.

The relators in this action had a contract to build winches for the Defense Department, and subcontracted with the defendant Cleveland Gear to produce gears for inclusion in the winches. The subcontract required that Cleveland Gear submit the first batch of gears for inspection and, upon approval, that it produce subsequent batches by the same manufacturing process. The subcontract also required Cleveland Gear to notify the relators of any changes in the manufacturing process that would "affect fit, function, or service life of the item." The relators sued under the FCA, alleging that, after the approval of the initial batch, Cleveland Gear had changed the manufacturing process without notice in order to cut costs. The Government declined to intervene, and Cleveland Gear moved to dismiss. The district court granted the motion, ruling that the relators had failed to allege any injury to the United States, because the Government had inspected and approved the gears complained of. The relators appealed and the Government intervened in support of their appeal.

No Monetary Damages Required for Injury to Government

The court of appeals reversed. The court noted that recovery under the FCA is not dependent on a showing that the Government sustained monetary damages. Failure to comply with contract specifications can result in FCA "injury" to the Government even if the supplied product is as good as the specified product. Parties that contract with the government are held to the letter of the contract, and even the Government's knowledge of fraud does not necessarily absolve a contractor of FCA liability.

The relators alleged that the defendant's certification of compliance with the contract's quality assurance requirements was false. The court ruled that this amounted to an allegation that the defendant knowingly produced products that did not meet the contract's quality and corresponding safety requirements. It was immaterial whether this alleged noncompliance resulted in products with the same basic performance characteristics as the products specified. Government inspection and acceptance of the products in question could not absolve the defendant of liability for false certification.

Moreover, in an amended complaint that the district court did not permit them to file, the relators explicitly linked the alleged contractual noncompliance to serious risk of injury to Defense Department personnel. The amended complaint also alleged that had the government known of the manufacturing change, it would have rejected all of the gears produced after the initial batch. Although the court of appeals did not believe that it was necessary for the plaintiffs

to amend their complaint, it ruled that either the initial complaint or the amended complaint should have withstood the motion to dismiss.

Hutchins v. Wilentz, Goldman & Spitzer, 2001 WL 660936 (3d Cir. June 13, 2001)

The Third Circuit held that the False Claims Act only prohibits false claims that cause economic loss to the Government. The court also held that when bringing an FCA claim for retaliation, an employee who has been assigned the task of investigating and reporting fraud bears a heightened burden of proving both that he engaged in protected conduct and that he put the employer on notice of the distinct possibility of FCA litigation.

Charles Hutchins worked as a paralegal in the creditors' rights department of the law firm of Wilentz, Goldman & Spitzer. In 1995 Louis DeLucia, a partner in that department, asked Hutchins to investigate certain client bills, with particular attention to the high costs of computerized research. Hutchins investigated the matter and discussed it with his supervisor, Marie Henneberry, informing her of his concerns that the firm was overcharging clients by marking up the cost of computerized research and using paralegals to perform secretarial tasks. Hutchins then submitted a memorandum to DeLucia stating that the firm had a policy of billing clients for 1.5 times the actual cost of Westlaw and LEXIS expenses.

The next month, the firm's management summoned Hutchins to a meeting to discuss his continued employment. Hutchins contended that the firm wanted to fire him because of his "investigation" into its fraudulent billing practices. The firm claimed that it was upset over Hutchins' relationships with other employees. After further problems between Hutchins and other employees, the firm decided at the end of the week to fire Hutchins the following Monday. When Hutchins reported for work that Monday, he requested files from the accounting department detailing the firm's billing for Westlaw and LEXIS. The firm denied his request and two hours later informed him that he was fired.

Hutchins filed a pro se *qui tam* complaint under the FCA, alleging that the firm had violated § 3729 by submitting false billing statements to the United States Bankruptcy Court and had violated § 3730(h) by firing him because of his investigation into the firm's billing practices. The district court dismissed the § 3729 claim under Federal Rule of Civil Procedure 12(b)(6) and granted summary judgment to the firm on the § 3730(h) claim. Hutchins appealed.

Monetary Damages Required for FCA Claim

The Third Circuit noted that there was no dispute that inflating the research bills was unlawful. But the court insisted that monetary damages are required for an FCA claim and rejected Hutchins' assertion that the firm's submission of false claims was actionable even if it did not cause the Government to expend any money. The court stated that it had been unable "to find any case establishing that a false statement to the government which does not cause the government economic loss gives rise to False Claims Act liability." The court noted that the statutory definition of the term "claim" includes any request or demand to a recipient for money if the Government provides any portion of the money or will reimburse the recipient for the money. Therefore, the court held, "the submission of false claims to the United States government for approval which do not cause financial loss to the government are [sic] not within the purview of the False Claims Act. . . . Unless these claims result in economic loss

to the United States government, liability under the False Claims Act does not attach."

Employee Assigned to Investigate Fraud Faces Heightened Burden on Retaliation Claims

The court also rejected Hutchins' claim that the firm unlawfully retaliated against him in violation of § 3730(h) of the FCA. In order to make out a claim for retaliation, the court noted, a plaintiff must show that he was engaged in "protected conduct," that his employer was aware of that conduct, and that the employer discriminated against him because of that conduct. Hutchins based his claim that he was engaged in protected conduct on three things: his memorandum to DeLucia, his inquiry to Henneberry, and his request to the accounting department for billing documents.

The court ruled that where an employee was assigned the task of investigating fraud, the employee bears a heightened burden of proving that he was acting in furtherance of an FCA suit and not simply in accordance with his employment obligations. Hutchins' simple statement in his memorandum to DeLucia that Westlaw and LEXIS expenses were being marked up was not protected conduct, in the court's view, and did not put the firm on notice that an FCA suit was a "distinct possibility." The court noted that Hutchins did not threaten to report the firm's billing practices to the Government, did not indicate that he believed the practices were illegal or fraudulent, did not advise that corporate counsel become involved, and did not file suit until after he was fired.

Likewise, the court ruled, Hutchins' complaint to Henneberry about the assignment of secretarial tasks to paralegals did not suggest the possibility of an FCA suit. Hutchins merely told Henneberry that he thought this practice was unethical, not that it was illegal. In the court's view, his complaint was merely a "suggestion for improvement," not a "precursor to litigation." Finally, the court ruled, Hutchins' request to the accounting department for billing documents could not support a retaliation claim. Because the firm had already decided to fire Hutchins before he requested the documents, the firm did not retaliate against him "because of" this request.

Therefore, because Hutchins had failed to allege monetary harm to the government, the court affirmed the dismissal of Hutchins' *qui tam* claims. Moreover, because he failed to allege that he engaged in "protected conduct" and that he put the firm on notice of the "distinct possibility" of an FCA suit, the court affirmed the grant of summary judgment on Hutchins' retaliatory discharge claims.

FCA Liability/Causation

U.S. ex rel. Kulumani v. Blue Cross Blue Shield Ass'n, 2001 WL 563775 (N.D. Ill. May 23, 2001)

An Illinois district court dismissed a *qui tam* complaint premised on a defendant's failure to issue supplemental instructions to Medicare providers clarifying a government regulatory bulletin. The court held that the failure to issue supplemental instructions could not have caused the submission of false claims.

Sam Kulumani was employed as an auditor with the Blue Cross Blue Shield Association (BCBSA), which had contracted with the U.S. Health Care Finance Administration (HCFA) to handle Medicare cost audits. BCBSA subcontracted the work to various regional Blue Cross Plans (BCPs) across the country. In 1992, Kulumani distributed a government administrative bulletin explaining the HCFA regulations governing limited reimbursement available for equipment and facility purchase loans.

Subsequently Kulumani allegedly advised his superiors that the BCPs were confused by the regulations and needed further instructions on compliance. His superiors allegedly replied that the BCPs were not in compliance but that no further advisories would be issued. Kulumani brought an FCA action against BCBSA based on these allegations. The Government declined to intervene and BCBSA moved to dismiss for failure to state a claim.

Failure to Supplement Government Instructions Did Not Cause Submission of False Claims

The court granted BCBSA's motion, holding that Kulumani had failed to allege that BCBSA had presented, or caused another person to present, a false or fraudulent claim for payment or approval to the Government. According to the complaint, BCBSA did not itself submit any claims to the Government; it merely contracted with the Government to perform auditing functions and then subcontracted those functions to the BCPs. Moreover, the court ruled, BCBSA's mere failure to send additional advisories regarding compliance after previously having distributed one did not "cause" the BCPs to submit false claims. There was no allegation that BCSBA ever directed the BCPs to ignore the regulations or provided them with any conflicting information regarding the regulations. The only action that BCBSA took that could be interpreted as "causing" the claims to be filed was its distribution of the Government's own bulletin. The court ruled that it could not "deem providing government bulletins regarding regulations as activity 'causing' the submission of false or fraudulent claims."

No Facts Alleged to Support Allegations of False Claims

The court also ruled that apart from legally conclusory language, Kulumani had alleged no facts to show that the BCPs actually submitted false claims to the Government, or that BCBSA knew of the submission of false claims. Furthermore, the court noted, Kulumani had failed to allege specific damage to the Government. Accordingly, the court dismissed the complaint for failure to state a claim.

Section 3729(b) Knowledge Requirement

U.S. ex rel. Norbeck v. Basin Electric Power Cooperative, 248 F.3d 781 (8th Cir. Apr. 30, 2001)

The Eighth Circuit held that an electric power cooperative's overcharges of interest to a government agency could not give rise to FCA liability where there was no evidence that the cooperative actually knew or acted in reckless disregard of the possibility that the interest was actually charged to the Government. Furthermore, the court ruled, simple contract breaches and mere misinterpretation of a contact's terms do not provide evidence of a knowing violation.

Basin Electric Power Cooperative (Basin) contracted to sell excess electric power from the Antelope Valley Station (AVS) to a government agency at prices based on the cost of production. The contract provided that production costs would be calculated according to a formula that included interest on AVS debt as well as operational and maintenance costs. Basin then sold AVS to a group of investors and leased it back, paying a monthly lease cost instead of the interest on debt. Therefore, the contract was modified so that the Government's cost of power would reflect a pro rata share of lease costs rather than interest costs.

Basin's former chief auditor Robert Norbeck filed a *qui tam* action alleging that Basin violated the FCA in the manner in which it accounted for the sale and leaseback of AVS. The Government intervened to pursue breach of contract claims against Basin, but declined to intervene in Norbeck's FCA claims. Basin

admitted some overcharge occurred and returned $2.4 million to the Government before trial. However, the district court found at trial that the total overcharge was $15.5 million and that the overcharges violated the FCA. After offsetting for the prior payment and trebling damages the court entered a judgment of almost $36 million. Basin appealed.

Honest Accounting Mistakes and Contact Misinterpretations are Not "Knowing" Violations

The court of appeals reversed the district court's finding of a $15.5 million overcharge as unsupported by the evidence. Moreover, the court of appeals determined that Basin did not submit the admitted $2.4 million overcharge with the level of intent required for liability under the FCA. The court found no evidence that Basin knew or acted in reckless disregard of the possibility that any of the interest from pooled debt was being improperly charged to the Government. Moreover, there was no evidence that Basin auditors knew or acted in reckless disregard of the possibility that its accounting assumptions were incorrect. Finally, the court of appeals rejected the claim that "the myriad of small edges taken by Basin" in cost computation could provide evidence of a knowing violation of the Act. All of Basin's other overcharges were simple breaches of contract. The mere misinterpretation of a contract, or mere contract breaches, the court ruled, cannot provide evidence of a knowing violation. Because Norbeck failed to provide any evidence that Basin submitted its overcharges with the requisite reckless disregard for the truth, the court of appeals reversed the district court's FCA judgment against Basin.

Imputed Interest Charges Did Not Give Rise to FCA Claim

Norbeck also argued on cross-appeal that Basin violated the FCA by improperly charging the Government for imputed interest on a loan from Basin's general fund to the AVS project. Because this was an internal transaction, no actual interest was charged: rather, imputed interest is an accounting fiction representing the time value of the money transferred. The court of appeals affirmed the district court's dismissal of this claim. Although the relevant regulations did not provide for the charging of imputed interest, they did not prohibit it, and the court held that it was not unreasonable. Therefore, it could not support an FCA claim because Norbeck was unable to show that Basin knew that the imputed interest charges were false or acted with reckless disregard of their truth or falsity.

Section 3730(e)(4) Public Disclosure Bar and Original Source Exception

U.S. ex rel. Dhawan v. New York Medical College, 252 F.3d 118 (2d Cir. May 31, 2001)

The Second Circuit upheld a district court ruling that the relators in a *qui tam* action did not qualify as an "original source" as required to escape the public disclosure bar. The court held that where a third party is the source of the core information on which the relators' *qui tam* action is based, the relators cannot qualify as an original source even if they provided the initial impetus for the third party's investigation.

Surender Dhawan and Dennis Gowie were executives at a hospital owned and operated by the New York City Health and Hospitals Corporation (HHC). The New York Medical College (NYMC) entered into an annual affiliation agreement with HHC under which NYMC provided physician services and staffing to the hospital in exchange for a fee partially reimbursed by Medicare and Medicaid. The relators allege that they

repeatedly complained to HHC's management that the level of services provided by NYMC was not commensurate with the amounts billed. In 1993 HHC conducted an audit and concluded that NYMC had overcharged it by more than $2 million. HHC fired the relators, who brought a state court action against NYMC and HHC in 1993 and subsequently filed this federal *qui tam* action in 1995. In 2000 the district court granted NYMC's motion to dismiss pursuant to the public disclosure bar, and the relators appealed.

Initiation of Investigation Did Not Make Relators Original Sources

The court found that the relators' amended complaint clearly indicated that the source of the core information underlying the fraud allegations was the HHC audit. The complaint relied overwhelmingly on the confirmed and quantified findings of the audit rather than on the relators' own initial unconfirmed and unquantified suspicions of fraud. Therefore, the complaint was based upon public disclosures and subject to dismissal unless the relators qualified as "original sources" under § 3730(e)(4)(B). To qualify as an "original source," a relator must have "direct and independent knowledge of the information on which the allegations are based." Because they depended on the audit rather than their own "direct and independent knowledge," the relators could not qualify as original sources. Even if the relators' complaint had alleged that HHC would not have undertaken the audit but for the relators' requests for action, this would not make the relators original sources because they did not actually perform the audit themselves.

Source of Public Disclosure Is Not Necessarily Original Source

The court also rejected the relators' argument that they were original sources because they were responsible for the public disclosure by filing the state-court lawsuit. The court noted that publicly disclosing the information on which a *qui tam* lawsuit is based is not the same as being an original source of that information. Just because the relators may have been responsible for the disclosure of the information, it does not necessarily follow that they had "direct and independent knowledge" of the information. Because the relators failed to allege that they were original sources of the information on which their suit was based, the court of appeals affirmed the dismissal for lack of subject matter jurisdiction.

***U.S. ex rel. Nemani v. St. Louis University*, No. 4:98CV1996 (E.D. Mo. Apr. 30, 2001)**

A Missouri district court dismissed a *qui tam* action, holding that it was based on public disclosures obtained through FOIA requests and discovery in an earlier proceeding. The court held that a plaintiff whose *qui tam* action is based in any part upon publicly disclosed allegations or transactions is subject to the jurisdictional bar.

Rama Nemani, a former St. Louis University biochemist, brought this *qui tam* action against the university and one of his former colleagues, alleging that they submitted false statements to the Government in connection with applications for two scientific research grants. The defendants moved to dismiss based on the public disclosure bar.

Bar Applies to Action "Based in Any Part" on Publicly Disclosed Allegations

The court ruled that Nemani's action was based upon public disclosures obtained through FOIA requests and discovery in a prior state court action. In the Eighth Circuit, for the jurisdictional bar to apply, "the essential elements exposing the transaction as fraudulent must be

publicly disclosed." The court found that the essential elements of some, but not all of Nemani's allegations had been publicly disclosed. The public disclosures related to the alleged false statements to the Government, but not to the true state of affairs or to an allegation of fraud. The court adopted the approach of the Fifth, Sixth, and Tenth Circuits, which have held that a plaintiff whose *qui tam* action is based in any part upon publicly disclosed allegations or transactions is subject to the jurisdictional bar.

Relator Was Not Original Source

Moreover, Nemani was not an "original source" of the information and thus could not escape the bar. To qualify as an "original source" under § 3730(e)(4)(B), a relator must have "direct and independent knowledge of the information on which the allegations are based." Nemani's sources of information were FOIA reports and discovery in the state court action, rendering his knowledge secondhand. Ruling that Nemani did not qualify as an "original source," the court dismissed the case for lack of subject matter jurisdiction.

Section 3730(h) Retaliation Claims

Hutchins v. Wilentz, Goldman & Spitzer, 2001 WL 660936 (3d Cir. June 13, 2001)

See "Need for Economic Damages" above at page 4.

Statute of Limitations

U.S. v. Tech Refrigeration, 2001 WL 629705 (N.D. Ill. June 5, 2001)

An Illinois district court denied a motion to dismiss a false claims action pursuant to the statute of limitations, holding that there was a disputed issue of fact as to when the Government should have known of the alleged violation. The court held that in the FCA's tolling provision the phrase "official of the United States charged with responsibility to act" ordinarily refers to an official in the Department of Justice.

In June 2000 the Government sued Tech Refrigeration, its president, and its general manager for defrauding Amtrak through an overbilling and kickback scheme. The complaint alleged that the scheme extended from 1990 to 1995. The defendants moved to dismiss, arguing that the FCA's statute of limitations barred the action. Attached to the defendants' motion was a listing of the alleged kickback checks, which spanned the period from 1990 to 1994, and a copy of an administrative subpoena that Amtrak's Office of Inspector General served on Tech Refrigeration in 1996.

The FCA's statute of limitations, 31 U.S.C. § 3731(b), provides that a false claims action may not be brought—

> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
> (2) more than 3 years after the date on which facts material to the right of action are known or reasonably should have been known to the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
>
> whichever occurs last.

Based on the dates of the alleged kickback checks, all but two of the alleged false claims appeared to have been made more than six years before the suit was filed. Therefore, the Government could not rely on § 3731(b)(1)

and sought instead to rely on § 3731(b)(2). The defendants argued that the term "official of the United States charged with responsibility to act" covered Amtrak officials, and therefore the three-year clock of § 3731(b)(2) began to run in 1996, when Tech Refrigeration first produced documents to Amtrak's OIG in response to the administrative subpoena. The Government argued that the term refers only to officials of the Department of Justice, and therefore the clock did not begin to run until June 1997, when Amtrak officials supposedly first told the Department of Justice of their suspicion that the defendants had violated the FCA.

"Official of the United States" Refers to DOJ Official

The court noted that § 3731 does not define the term "official of the United States charged with responsibility to act." Although the Senate Report on the 1986 amendments indicates the tolling provision refers to an official within the Department of Justice, this report apparently referred to an earlier version of the proposed legislation with different wording. Therefore the legislative history is inconclusive. However, the court noted, the preceding section, 31 U.S.C. § 3731(b)(2), charges the Attorney General—not other government agencies—with responsibility for investigating and prosecuting FCA violations. Therefore, the court concluded, the term "official of the United States" in § 3731 refers to a pertinent official of the Department of Justice.

Imputed Knowledge Provision Applied Sparingly

However, the court noted, this does not mean that the statute of limitations begins to run only when the responsible Justice Department official actually knows the material facts. Rather, the statute says the clock begins to run when the facts "are known or reasonably should have been known." The court agreed with the conclusion of other courts that there may be circumstances where the knowledge of government agencies other than the Department of Justice could trigger the three-year clock. For example, a court might find that the Government failed to exercise due diligence if another agency had conducted an extensive investigation and disseminated its conclusions widely without specifically informing the Department of Justice. However, the court ruled, such a finding should be reserved for unusual situations. The scant legislative history indicates that the "should have known" language should be applied sparingly; moreover, the ten-year outside limit adequately protects defendants against inordinate delay.

Therefore, based on the record before it the court could not say that the Justice Department knew or should have known of the material facts more than three years before suit was filed. Accordingly, the court denied the defendants' motion to dismiss.

Personal Jurisdiction and Venue

U.S. ex rel. Attorneys Against American Apartheid v. City of Orlando, Civ. No. 99-2089 (D.D.C. June 4, 2001)

A District of Columbia district court ruled that because the False Claims Act provides for nationwide service of process, personal jurisdiction may be found anywhere in the United States. Although the court asserted personal jurisdiction, it ruled that the mere fact that the defendants sought funds from federal agencies in the District of Columbia was not sufficient to support venue there.

In 1994 and 1995, the City of Orlando obtained a grant of over a million dollars from the U.S. Department of Commerce Economic

Development Administration (EDA) to create a new entertainment district that would bring jobs to the predominantly black and economically depressed Parramore neighborhood. Orlando was to match the EDA grant with its own funds and bought a hotel that was to serve as the "entertainment district gateway." However, in 1996 the successful bidder on the project withdrew.

In 1994 Gabe Kaminowitz brought a *qui tam* action regarding the EDA grant against the city in a Florida district court. In 1996 the district court granted summary judgment to the defendants and in 1998 the Eleventh Circuit affirmed. Meanwhile, in 1997 the city sold the hotel and other Parramore properties to a private corporation, which demolished them to build garage space.

In 1999 Kaminowitz, proceeding pro se on behalf of Attorneys Against American Apartheid, filed a new *qui tam* action against the city in a District of Columbia district court, alleging that the city violated the Act by (among other things) illegally lobbying federal officials for the EDA grant despite an express certification that it would not do so; failing to construct the entertainment district and create any new jobs; diverting federal HUD money to use as local matching funds for the EDA grant; and selling the hotel for a profit and diverting the funds for unknown purposes. The defendants moved to dismiss for lack of jurisdiction and improper venue or alternatively to transfer venue to Florida.

FCA Provides Personal Jurisdiction Anywhere in United States

The court denied the defendants' motion to dismiss for lack of personal jurisdiction. It rejected the defendant's contention that it could exercise personal jurisdiction only pursuant to the D.C. long-arm statute, noting that the FCA contains its own jurisdictional provision, 31 U.S.C. § 3732, which provides that an FCA action may be brought "in any judicial district in which the defendant . . . can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." Moreover, § 3732 also provides for nationwide service of process. Therefore, the court ruled, personal jurisdiction may be found anywhere in the United States. In determining whether there are sufficient "minimum contacts" to satisfy constitutional due process when assessing jurisdiction in FCA cases, the defendant's contacts with the United States govern, not the defendant's contacts with the district in question. Because Orlando is located in the United States, and the mayor, who was named as a co-defendant, resides and works in the United States, the court held that it could exercise personal jurisdiction.

Venue in District of Columbia Was Improper

However, the court ruled that venue in the District of Columbia was improper, and transferred the case to the Middle District of Florida. The court rejected the notion that the only applicable venue provision was 28 U.S.C. § 1391, ruling that § 3732 of the FCA governs venue as well as personal jurisdiction. Nevertheless, the court rejected the plaintiffs' argument that venue was proper in the District of Columbia because the defendants submitted their claims to agencies located there, and therefore "act[s] proscribed by section 3729 occurred" there. The court concluded that all the relevant conduct occurred in Florida, and the fact that the government agencies from which the defendants sought funds are located in the District of Columbia was insufficient to satisfy § 3732 with regard to venue. Because the District is unique in that it is the seat of the Federal Government, the court ruled, to allow venue there simply because the defendant had contact with a federal agency would threaten to convert the District into a national judicial forum.

Venue Transferred to Florida

However, the court viewed dismissal for improper venue as unduly harsh in this case, and instead transferred the case to the Middle District of Florida. As an alternative basis for its ruling, the court stated that even assuming *arguendo* that the District was an appropriate forum under § 3732, the case should still be transferred to Florida. 28 U.S.C. § 1404 provides that even if a case is filed in a jurisdiction where venue is proper, the court may transfer the case to any other district where it might have been brought for "the convenience of the parties and witnesses." Because Florida was considerably more convenient for the parties, it was appropriate that the case be tried there. The court rejected the plaintiffs' assertion that they could not receive an impartial hearing in Florida simply because they had obtained an unfavorable result in their prior lawsuit. Accordingly, the court granted the defendants' alternative motion to transfer venue to Florida.

Rule 9(b)

U.S. ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048 (9th Cir. Apr. 2, 2001)

The Ninth Circuit affirmed a district court's ruling that a relator had failed to satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) by providing specific factual support for his fraud allegations. However, the court reversed the district court's denial of leave to amend where the complaint could be construed to allege a theory based on the fraudulent provision of medically worthless services to the Government.

Insoon Lee was a supervisor at a laboratory operated by SmithKline Beecham, Inc. (SmithKline). In 1995 Lee brought a *qui tam* action alleging that SmithKline falsified test results when the actual results fell outside acceptable standards of error. The complaint asserted that SmithKline billed Medicare for these worthless tests, falsely certifying the payment requests that it sent to the Government. The Government declined to intervene. SmithKline moved to dismiss Lee's amended complaint under Rule 9(b) for failure to plead fraud with particularity and under Rule 12(b)(6) for failure to state a claim. The district court dismissed with prejudice and Lee appealed.

Relator Failed to Supply Details of Alleged Fraud

The court of appeals upheld the dismissal for failure to comply with Rule 9(b). Although the Rule might not require Lee to allege all facts supporting each and every instance of fraud over a multi-year period, it did require at least enough detail to permit the defendant to defend against the charge. Lee failed to specify the types of tests implicated in the alleged fraud, the employees who performed the tests, or the dates, times, and places where the tests were conducted. The court rejected Lee's contention that the requirements of Rule 9(b) should be relaxed because the information supporting his claims was in the possession of the defendant. Because Lee worked as a supervisor at the laboratory for over twenty years, had knowledge of the allegedly falsified tests, and was employed at SmithKline at the time he filed suit, he could not fairly allege that the facts evidencing an FCA violation were in the sole possession of the defendant. Therefore, the district court properly dismissed his complaint pursuant to Rule 9(b).

District Court Erred in Denying Leave to Amend

However, the court of appeals held that the district court abused its discretion in denying leave to amend. Leave to amend should be granted unless the district court determines that the

pleading could not possibly be cured by the allegation of other facts. The district court had treated Lee's complaint as a "false certification" case based on submission of HCFA claim forms. Because the claim forms contained no certification language, the district court had denied leave to amend on the grounds that any amendment would be futile. However, the court of appeals ruled, the district court overlooked allegations in the complaint supporting a different theory—that SmithKline violated the FCA by seeking and receiving payment for medically worthless tests. Because this theory could provide a basis for an FCA action even absent any false certification, Lee should have been granted leave to amend. Therefore, the court of appeals remanded to the district court to allow Lee an opportunity to amend his complaint to satisfy the heightened pleading requirements of Rule 9(b).

U.S. ex rel. McCarthy v. Straub Clinic & Hospital, Inc., 140 F. Supp. 2d 1062 (D. Haw. Apr. 13, 2001)

In April 2001 a Hawaii district court denied the defendants' motion to dismiss for lack of personal and subject-matter jurisdiction and failure to plead fraud with particularity. Lillian McCarthy, who was employed beginning in 1992 as Manager of Cash Posting at the Straub Clinic and Hospital, Inc. (Straub), complained to the Government in 1994 that Straub had submitted false claims. After investigating, the Government entered into a settlement agreement under which Straub, without admitting wrongdoing, agreed to pay the Government $2.4 million and to execute a Corporate Integrity Agreement (CIA) governing its billing practices. McCarthy and her supervisor Katherine Manuel allegedly discovered that Straub continued to submit false claims and in 1999 filed this FCA action against Straub and its parent corporation PhyCor. The Government intervened and the defendants moved to dismiss.

Straub argued that the court lacked jurisdiction over the FCA claim because the plaintiffs alleged violations of the CIA, which had its own enforcement mechanism. Rejecting this argument, the court noted that the plaintiffs alleged violations both of the CIA and the FCA, and that allegations of CIA violations did not divest the court of jurisdiction under the FCA. The CIA did not in any way grant the defendants immunity from prosecution under the FCA.

Straub also argued that the relators failed to allege fraud with sufficient particularity as required by Fed. R. Civ. P. 9(b). The court noted that the Ninth Circuit had recently indicated in *United States ex rel. Lee v. SmithKline Beecham, Inc.*, *supra* p. 12, that in a fraud extending over several years the plaintiff was not required "to allege, in detail, all the facts supporting each and every instance" of fraud, and that the application of Rule 9(b) may be relaxed when the information supporting claims of fraud is in the hands of the corporate defendant. The court noted that the complaint furnished significant detail, alleging specifically who submitted the false claims, as well as how and when ("on a daily basis") they submitted them. The complaint also provided specific examples of the alleged false claims, albeit without specific names, times, and dates. The court did not expect the relators to remember the exact dates of all false submissions, because their employment had been terminated nearly two years earlier. The court held that the relators had provided enough detail to allege fraud with specificity and indicate that they were missing only those details that Straub could reasonably be assumed to hold.

The court also rejected Straub's argument that the relators failed to establish a claim for retaliation under the whistleblower protection section of the FCA, 31 U.S.C. § 3730(h). The court found that the relators had properly pleaded all three elements of such a claim: that they investigated the alleged fraud, that Straub knew of their investigation, and that Straub discriminated against them because of it. Straub argued that it was difficult to believe that an employer would wait five years before retaliating against whistleblowing employees. The court ruled that a motion to dismiss is not the appropriate context for such a credibility determination. On a motion by the defendants to dismiss, unless the relator's allegations are clearly frivolous, the court must take them to be true.

Finally, the court rejected PhyCor's motion to dismiss for lack of personal jurisdiction.

PhyCor, a company headquartered in Tennessee, argued that it lacked sufficient contacts with Hawaii to subject it to jurisdiction there. The relators had alleged that PhyCor provided health care services in Hawaii, and that it owned, managed and controlled Straub. The court found that PhyCor could reasonably expect to be haled into court in a state where it controlled a health care facility and conducted business. PhyCor had purposefully availed itself of the privilege of doing business in Hawaii, and the relators' cause of action arose out of PhyCor's management and control over Straub. Thus the relators had made a prima facie showing of personal jurisdiction over PhyCor.

***Nguyen v. City of Cleveland*, 138 F. Supp. 2d 938 (N.D. Ohio Apr. 4, 2001)**

In April 2001 an Ohio district court reaffirmed its prior ruling that an FCA retaliation claim is not subject to arbitration but certified the issue for review by the Sixth Circuit. Previously, in *Nguyen v. City of Cleveland*, 121 F. Supp. 2d 643 (N.D. Ohio 2000), 21 TAF QR 15, the court had ruled that the retaliation claim was not subject to a clause in an employment contract mandating that disputes be settled through arbitration. One of the defendants, Parsons Engineering (Parsons), moved for reconsideration of this ruling. Although the court agreed with Parsons that it had misapplied a non-binding precedent from another jurisdiction, it nonetheless remained convinced that its previous holding was correct. The court reiterated its view that the case of a *qui tam* relator is fundamentally different from that of others seeking to avoid arbitration, because the relator has acted for the public and not for himself. The court characterized its ruling as a recognition of a special conflict between the policies of the FCA and those of the Arbitration Act. Nevertheless, the court found that there was substantial ground for differences of opinion and that an immediate appeal might advance the ultimate resolution of the matter. Accordingly, the court certified its earlier ruling for interlocutory review by the court of appeals.

***U.S. ex rel. MacGregor v. Regents of the University of California*, 2001 WL 674249 (N.D. Cal. May 16, 2001)**

In May 2001 a California district court denied a relator's motion to establish his share of a purported settlement between the Government and a state agency. Roderick MacGregor and C. Anthony Hunt were researchers at the University of California. In 1999 MacGregor filed a *qui tam* complaint against Hunt and the University alleging that Hunt had diverted government funds for a university research project for private commercial purposes, and submitted false statements to conceal the diversion. According to MacGregor, the Government investigated the allegations while the complaint was still under seal and, in what MacGregor termed a "settlement," the University returned a portion of the overcharges to the Government. In 2000 the Government declined to intervene, and in February 2001 the University moved to dismiss pursuant to *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), 19 TAF QR 1 (July 2000). The court dismissed the University without prejudice to the Government. MacGregor then moved for a hearing to determine the adequacy of the "settlement" and an order establishing his share.

The court denied the motion, holding that because under *Stevens* MacGregor was not entitled to bring the action against the University in the first place, he was not a proper relator and was not entitled to any relator's share. Furthermore, the court held, MacGregor was not entitled to a fairness hearing because he had

no right to dictate the terms on which the University could be dismissed. The court ruled that MacGregor was asking to be treated as if he had a right to bring an FCA suit when in fact he had no such right.

U.S. ex rel. Sprys v. Winn Dixie Stores, Inc., No. 6:98-cv-1188-Orl-31DAB (M.D. Fla. June 4, 2001)

In June 2001 a Florida district court denied a defendant's motion for leave to file a counterclaim against an FCA relator based on theft of company property. The defendant Winn-Dixie Stores, Inc. alleged that a week after meeting with the Government to discuss fraud allegations, the relator Richard Sprys used a Winn-Dixie computer to create and print out reports to use in furtherance of his *qui tam* action. Winn-Dixie alleged that Sprys' actions violated his duty of confidentiality as well as Florida statutory and common law.

The court noted that in the context of *qui tam* actions many federal courts have prohibited as contrary to public policy any counterclaims that would offset the defendant's liability. These courts have held that permitting such counterclaims might facilitate retaliation and chill the reporting of fraud. Other courts have allowed defendants to assert compulsory counterclaims that seek independent damages rather than indemnification or contribution. These decisions reflect a concern that barring such compulsory counterclaims would violate the defendants' constitutional right to procedural due process.

The court noted that Winn-Dixie's proposed counterclaim did not allege that Sprys disclosed company documents to any third party other than the Government and the court. Moreover, the counterclaim did not allege any independent injury beyond Winn-Dixie's potential liability under the FCA. Rather, the counterclaim sought to make actionable Sprys' conduct in providing evidence of Winn-Dixie's violations to the Government. Therefore, the court ruled, allowing the counterclaim would be contrary to public policy and the legislative intent behind the FCA. Moreover, the court ruled, the damages Winn-Dixie sought in its proposed counterclaim were essentially those borne in defense of the FCA action. A defendant may recover such costs under § 3730(d)(4) if the court finds that the relator's claim was clearly frivolous, vexatious, or designed to harass. However, the court could find no authority permitting a counterclaim where the "independent damages" sought were comprised solely of the cost of defending an FCA action. Therefore, the court denied the defendant's motion.

U.S. ex rel. Franklin v. Parke-Davis, 2001 WL 740558 (D. Mass. June 25, 2001)

In June 2001 a Massachusetts district court granted in part and denied in part the defendant's motion to dismiss pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6) in a *qui tam* action against a pharmaceutical company. The complaint alleged that the defendant Parke-Davis engaged in an illegal and fraudulent scheme to promote the sale of its drugs Neurontin and Accupril for "off-label" uses (*i.e.* uses not approved by the FDA), which caused the submission of false Medicaid and Veterans Affairs claims. Federal law permits physicians to prescribe drugs for off-label uses but prohibits drug manufacturers from marketing or promoting drugs for such uses. Prescriptions for the off-label use of a drug are not reimbursable under Medicare (with certain enumerated exceptions).

David Franklin, a former "medical liaison" with Parke-Davis, filed this *qui tam* action in 1996. The complaint alleged that the "medical liaisons" were instructed to make false or exaggerated claims concerning the safety and efficacy of Parke-Davis drugs for off-label uses and in dosages much higher than those approved by the FDA. Parke-Davis allegedly encouraged the liaisons to misrepresent their scientific credentials and pose as research personnel, and rewarded doctors prescribing large quantities of its products with kickbacks in the form of sham research or consultancy fees, travel, and tickets to the Olympics. As a result of Parke-Davis' actions, the doctors allegedly submitted large numbers of false claims for off-label prescriptions to the Government for reimbursement. The complaint remained under seal until 1999 when the Government declined to intervene. Parke-Davis moved to dismiss the complaint under Rule 9(b) for failure to plead fraud with particularity and under Rule 12(b)(6) for failure to state a claim.

Turning first to Parke-Davis' Rule 9(b) motion, the court noted that the Rule requires the plaintiff to plead with particularity the time, place and contents of the false representations, as well as the identity of the person making the representations and what he obtained with them. Although Franklin's complaint lacked these details, he urged the court to consider his much more detailed and specific disclosure statement filed with the Government pursuant to 31 U.S.C. § 3730(b)(2), which he had referenced in the complaint and provided to the court and the defendant. The court agreed to consider the allegations in the disclosure statement for purposes of the motion to dismiss, but directed Franklin to amend his complaint to incorporate the required details.

Viewed in the light of the disclosure statement, the court ruled, the complaint's allegations that Parke-Davis fraudulently promoted off-label uses of Neurontin for Medicaid reimbursement were sufficiently specific to satisfy Rule 9(b). The disclosure statement identified the "who, what, where, when and how" of the alleged fraud, giving names of participants and specific examples. The court noted that in a case where the alleged scheme is complex and far-reaching, the relator is not required to plead every single instance of fraud. However, the court dismissed a count alleging fraudulent promotion of Accupril and another alleging fraud against the Department of Veterans Affairs, holding that these counts, even when read in light of the disclosure statement, were insufficiently specific under Rule 9(b).

The court also denied the Rule12(b)(6) motion with regard to the allegations of Medicaid fraud involving Neurontin. It rejected Parke-Davis' argument that because the Food, Drug, and Cosmetics Act (FDCA) does not provide for civil damages for marketing off-label drugs, the FDCA preempts an FCA action. It also rejected Parke-Davis' attempt to characterize the complaint as involving only a technical violation, noting that Franklin had clearly alleged that Parke-Davis knowingly made false statements to doctors that caused them to submit ineligible claims to Medicaid. The court declined Parke-Davis' invitation to rule that it was not the proximate cause of the submission of the alleged false claims on the grounds that the intervening actions of the prescribing physicians broke the chain of legal causation. The court noted that an intervening action breaks the causal connection only when it is unforeseeable, whereas when viewed in the light most favorable to Franklin, the physicians' actions were not only foreseeable, they were intended. Finally, the court rejected Parke-Davis' argument that its alleged false statements to the physicians were not material

to the Government's decision to pay for the prescriptions. The court noted that liability under the FCA is not limited to false statements or claims made directly to the Government, and that Franklin had adequately alleged that the statements were material because the Government would not have paid the claims if it had known the use for which they were being submitted.

Finally, the court dismissed two counts involving violations of the Medicaid anti-kickback provision and of FDA rules regarding clinical trials. The court ruled these violations are not per se violations of the FCA, and are actionable under the FCA only if the defendant fraudulently caused the submission of false claims. Because Franklin had failed to make such an allegation, the court dismissed these counts.

The Impact of the New Federal Privacy Rule on False Claims Act Cases

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INTRODUCTION

Under the authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[1] the federal Department of Health and Human Services (HHS) has at long last issued final Standards for the Privacy of Individually Identifiable Health Information (the "Privacy Rule" or "Rule"), which went into effect on April 14, 2001.[2] During the rule-making process, the Government examined whether health care providers and others should be able to disclose patient health records in connection with False Claims Act matters. A number of outside parties, including Taxpayers Against Fraud, provided comments during this process.[3] The issue of disclosure is very important for False Claims Act cases: patient-specific information is often critical to proving that defendants knowingly made false health care claims. For example, in the fee-for-service context, review of patient-specific information often is needed to determine whether a provider billed for services not provided, billed for medically unnecessary services, or engaged in improper duplicate billing or upcoding. In the managed care and prospective payment system context, patient-specific information ordinarily is highly relevant to claims involving the provision of inadequate care, the denial of medically necessary care, or the misrepresentation of patient status.

This article examines the impact of the new Privacy Rule on disclosures of patient-specific information in False Claims Act cases. The author concludes that the new Rule adequately protects the ability of *qui tam* plaintiffs to disclose health care fraud to the Government while curbing purely gratuitous disclosures.

OVERVIEW OF THE RULE

HHS's new Privacy Rule, which is accompanied in the Federal Register by hundreds of

pages of preamble,[4] governs the disclosure and use of individually-identifiable health information by health plans and health care clearinghouses, as well as health care providers that transmit health information in electronic form (collectively referred to in the Rule as "covered entities"). The Rule restricts the ability of covered entities to use and disclose individually-identifiable health information regardless of whether the information is transmitted orally or recorded in writing or in any other medium (for example, an electronic database).

For most purposes, the Rule requires health care providers to obtain a patient's authorization or consent before using or disclosing individually-identifiable health information. However, as a general matter, health care providers and their associates and employees will remain free to disclose patient records when reporting potential health care fraud to the appropriate authorities without having to obtain the patient's "authorization" or "consent" (terms which have distinct meanings for purposes of the Rule). Likewise, the Government will remain free to use and disclose patient records when investigating potential fraud. However, parties making such disclosures without patient consent in the health care fraud context must be careful to satisfy the special requirements of the new Rule, which are discussed below.

In addition to the new Privacy Rule, several federal laws and a Supreme Court opinion[5] already protect patient privacy with regard to discrete categories of health information. In addition, state laws impose a mishmash of requirements.[6] Preexisting federal restrictions that are not repealed by the Rule will continue to apply. Moreover, the Rule does not preempt state law that is stricter, that covers certain subject matters spelled out in the Rule, or that the Secretary of HHS has exempted from preemption upon special request.[7]

HIPAA imposes civil and criminal penalties on offenders.[8] In certain circumstances, the criminal penalties can be extremely stiff. For example, if a person violates the Rule with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a court may impose a fine of up to $250,000 and imprisonment of up to 10 years.

The Secretary has charged HHS's Office of Civil Rights (OCR) with responsibility for enforcing the regulation, a function that will include, among other things, "responding to questions," "providing interpretations and guidance," "seeking civil monetary penalties," and "making referrals for criminal prosecution."[9] OCR has already established a web site that provides key information concerning the Rule.[10] On July 6, 2001, HHS posted fifty pages of "Initial Guidance" in question and answer format on the OCR web site.[11]

It is very likely that HHS will modify aspects of the Rule during the next several years. HHS received over 11,000 comments in response to Secretary Thompson's request for supplemental comments. HHS is reviewing these comments, issuing clarifications

and guidance in response (available on the OCR web site), and has stated its intent to "issue proposed modifications as necessary in one or more rulemakings to ensure that patients' privacy needs are appropriately met."[12]

The Rule requires that most providers bring their practices into conformity with the new standards within two years of the April 14, 2001 effective date. Small providers are being given an extra year.[13]

This article focuses on those aspects of the Rule with the greatest implications for False Claims Act matters. It provides an overview of the prerequisites for different categories of disclosure of patient-specific information pursuant to False Claims Act suits. These categories include disclosures by persons not covered by the Rule; disclosures by covered entities to "health oversight agencies" and outside counsel; and disclosures by the Government and *qui tam* plaintiffs in judicial proceedings.

ANALYSIS

1. Threshold issues

In analyzing whether to obtain or disclose patient-specific information in connection with an action under the False Claims Act, *qui tam* counsel should first answer the following questions:

a) Is the disclosing party a "covered entity" as defined in the Rule? If the disclosing party is not a "covered entity,"[14] then any disclosures made without patient consent or authorization to counsel and the Government will likely be affected merely by the "whistleblower" or "business associate" provisions discussed in Section 2 below. On the other hand, if the disclosing party is a "covered entity", then the "health oversight" or "business associate" principles discussed in Sections 3 and 4 should govern.

b) Is it practicable and advisable to redact the records? Records that have been redacted in the stringent manner set forth in the Rule[15] will not trigger the protections of the Rule,[16] and consequently will eliminate the need for compliance with the Rule's disclosure and use requirements. In cases involving a small number of patient records, or a large number of records and a disclosing entity with the resources to perform the redacting, it may well be best to redact individually-identifiable health information following the procedures set forth in the Rule, using a key to link records relating to the same patient.

c) Can patient authorization for disclosure be obtained without undue effort? Under the Rule, a covered entity may disclose individually-identifiable information in conformity with the requirements of the Rule if the patient has so authorized.[17] If a valid patient authorization has been obtained, a *qui tam* plaintiff need not worry about

meeting the requirements of the other disclosure provisions, such as the requirement that self-initiated disclosures for "health oversight" include no more than the "minimum" information "necessary."

d) What other federal and state laws apply? Disclosures of certain categories of individually-identifiable health information, such as certain substance abuse records, psychotherapy notes, records in the files of government health plans, and clinical laboratory test records, are subject to the requirements of other federal statutes and case law. In addition, as noted above, the Rule does not preempt state laws that establish stricter privacy protections or cover certain specified subject matters. The Secretary also has the power to exempt certain categories of state law (including laws relating to fraud and abuse) from preemption. Accordingly, a careful search and analysis of other federal and state law is warranted before disclosing individually identifiable information in connection with a *qui tam* matter.

2. Disclosures by Non-Covered Entities

The first step for *qui tam* counsel in determining whether a client may disclose individually-identifiable information in connection with reporting violations of the False Claims Act is to determine whether the client falls outside the definition of a "covered entity" under the Rule.[18] Individuals working for health care providers, clearinghouses, and plans, and business associates of these entities, have often disclosed patient records to law enforcement to back up allegations that false claims have been submitted to government health care programs. In many instances, they have done so not as a representative of a health care entity, but rather in their individual capacities as plaintiffs under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

In the preamble to the Privacy Rule, HHS explained that individuals reporting fraud or other violations of law in their private capacity are *not* subject to the Rule. HHS noted that "[s]ince the HIPAA legislation only applies to covered entities, not their workforces, it is beyond the scope of this rule to directly regulate the whistleblower actions of members of a covered entity's workforce."[19]

However, although it does not "directly regulate" members of the workforces of covered entities, the Privacy Rule does regulate them *indirectly*, by requiring covered entities to sanction employees who violate the entities' privacy policies or procedures.[20]

The Rule also *indirectly* regulates business associates of covered entities. Business associates are persons who perform certain health care-related functions on behalf of a covered entity and who receive or use individually-identifiable information to perform these functions.[21] The indirect regulation of business associates is accomplished by provisions that (i) require a covered entity to enter into a contract or other arrangement

with its business associate that restricts the associate's ability to use and disclose patient-specific information, and (ii) require the covered entity to sanction the business associate if it violates material terms of the arrangement, and fails to take reasonable steps to cure the breach. The covered entity must sanction its associate by terminating the arrangement or reporting the violation to the Secretary of HHS.[22]

In light of this indirect regulation of employees and business associates, HHS took additional steps in the Rule to protect legitimate whistleblowers. Recognizing that covered entities might attempt to misuse the sanction requirements to retaliate against whistleblowers, the Rule expressly provides that employers are not liable under the Rule when employees and "business associates" engage in legitimate whistleblowing activity,[23] and are not required to impose on employees engaging in such activity the sanctions that otherwise would be required under the Rule.[24]

a. Good Faith Whistleblowing Disclosures Do Not Violate the Rule

The Rule's whistleblower provision, 45 C.F.R. 164.502(j), allows employees and "business associates" of the covered entity to disclose patient records in support of allegations of health care fraud, provided that the disclosure is made either:

(i) to appropriate government and accreditation agencies "for the purpose of" reporting activities that the whistleblower believes to be either unlawful, in violation of professional or clinical standards, or potentially dangerous to one or more patients, workers or the public; or

(ii) to an attorney retained by the employee or business associate for the purpose of determining "legal options" with regard to the potential misconduct.

To qualify for this safe harbor, the whistleblower must have a "good faith" belief in the allegations, a standard similar to that found in many federal and state statutes that protect whistleblowers from retaliation by their employers.

Disclosure to a government or accreditation agency must be made to a "health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity." [25]

The term "health oversight agency" is defined in the Rule broadly to include federal, state, local, Indian tribe, and U.S. territory government agencies and their agents and contractors that are "authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or

compliance, or to enforce civil rights laws for which health information is relevant."[26]

Importantly, provided that the requirements of this section are met (and assuming their actions comply with other federal and state law), employees and business associates of a covered entity may disclose individually-identifiable information under this section without patient consent or authorization, notwithstanding what the covered entity might have promised patients in its required "notice of privacy practices for protected health information."[27]

b. Good Faith Whistleblowing Disclosures are Exempt from Sanctions

Good-faith whistleblowing disclosures are also exempt from the provisions in the Privacy Rule that require covered entities to sanction employees for violations of privacy policies and practices. Thus, the Privacy Rule provides that covered entities are not required to sanction "a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j)[the whistleblower provision]."[28]

In her Response to Comments on Section 164.502(j), the Secretary noted that HHS's "purpose in including this provision is to make clear that we are not erecting a new barrier to whistleblowing, and that covered entities may not use this rule as a mechanism for sanctioning workforce members or business associates for whistleblowing activity."[29] Other federal and state laws affirmatively bar the employer from retaliating against employees for lawful actions taken in order to report fraud to the government.[30]

The protection from sanctions that the Rule provides to whistleblowing "business associates" is weaker than the protection provided to employee informants. This is because, pursuant to the Rule, a covered entity may only disclose patient records to a business associate that agrees not to use or further disclose the information beyond what is permitted or required by the contract or other arrangement entered into between the covered entity and the business associate, or as "required by law."[31] As noted above, covered entities must sanction business associates that do not make reasonable efforts to cure material breaches of these agreements, by terminating dealings, among other things. In contrast to whistleblowing by employees, the text of the Rule nowhere expressly exempts whistleblowing by business associates from this sanction requirement.

As a result, business associates who have signed contracts that do not expressly authorize disclosures for "health oversight," and who nonetheless voluntarily disclose patient records to the government, might face claims by covered entities that they are in material breach of their contract and are consequently subject to sanction under the Rule. Business associates would have a strong argument that any contractual provision prohibiting legitimate whistleblowing is void as contrary to public policy, particularly since the Secretary of HHS has indicated her intent that business associates not be sanctioned

for such conduct. However, this argument would not be without litigation risk. Accordingly, business associates should consider insisting on contracts that authorize them to disclose such records for "health oversight".

A business associate who does not obtain a contractual authorization to disclose patient records for health oversight can still get the evidence that underlies allegations of health care fraud into the hands of law enforcement pursuant to the contractual authorization to make disclosures "required by law."[32] The business associate may do so by informing government representatives of the nature of the alleged fraud (without revealing patient-specific information), and then producing the patient records in response to a government subpoena or civil investigative demand seeking the evidence that backs up the allegations. The business associate also should inquire into whether the "required by law" provision authorizes disclosure of patient-specific information to comply with the federal laws that require fraud to be pleaded with particularity (Federal Rule of Civil Procedure 9(b)), and that require *qui tam* plaintiffs to provide the Department of Justice with substantially all the material evidence and information supporting their False Claims Act allegations.[33] Elsewhere in the Rule, HHS expressly defines "required by law" to include: (i) the requirements of compulsory process, such as civil investigative demands and OIG subpoenas, and (ii) statutes requiring the production of "information." [34] In clarifications in the preamble to the Proposed Rule, which the Secretary has stated are incorporated in the text of the Final Rule,[35] the Secretary noted that the "required by law" provision authorizes disclosures made to comply with statutes and regulations requiring production of information justifying a claim.[36]

3. Disclosures by Covered Entities

A different analysis applies when the potential *qui tam* plaintiff is a *covered entity* alleging fraud by another provider based on an examination of individually-identifiable health information. For example, a physician practice participating in a managed care organization (MCO), or admitting patients to a hospital, might have grounds to believe that the MCO or hospital has violated the False Claims Act. The evidence of False Claims Act violations might consist of patient charts that, when viewed in tandem with the claims submitted to Medicare by the MCO or hospital, indicate that the MCO or hospital misrepresented the patients' condition or status. In these circumstances, disclosure may be made under the authority of the "health oversight" provision.

Provided certain requirements are met, the Privacy Rule authorizes covered entities, without patient consent or authorization, to disclose protected health information for a number of "public policy" purposes, including, *inter alia*, "health oversight."[37] The Rule authorizes disclosures to "health oversight agencies" for "health oversight activities", whether the disclosures are self-initiated, voluntary responses to government requests, or compelled responses to government demands.

a. "Health Oversight" is Defined Broadly

In the Preamble to the Final Rule, the Secretary of HHS indicated that health care fraud investigations, administrative proceedings, civil litigation and criminal prosecutions are health oversight activities conducted by health oversight agencies, regardless of whether they are performed by a program agency or law enforcement agency. The Secretary explained that agencies such as the FBI that are traditionally considered "law enforcement" will sometimes function as "health oversight agencies," and that investigation of potential health care fraud by an agency is a "health oversight activity" by a "health oversight agency."[38]

The Rule defines health oversight activities broadly by specifying only what they do *not* include. The Rule explains that health oversight does not include investigations and other activities that do not arise out of and are not directly related to: "(i) The receipt of health care; (ii) A claim for public benefits related to health; or (iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services."[39]

b. The Rule Authorizes Self-Initiated Reporting of Health Care Fraud

Significantly, the Rule authorizes disclosures for health oversight without patient consent or authorization even when such disclosures are self-initiated, *i.e.*, unaccompanied by a government request. The Rule's authorization of self-initiated reporting ensures that health care providers are able to make thorough disclosures when they first encounter potential health care fraud.

c. Covered Entities Must Comply with Substantive and Procedural Requirements

Like the whistleblowing provision, however, the health oversight provision does not provide a blanket permission for disclosures. *First*, the disclosure must be to a health oversight agency, as defined in the rule. The covered entity must verify the identity and authority of the public official to whom disclosure is made.[40] *Second*, unless the disclosure is required by law, *e.g.*, required by an OIG subpoena or civil investigative demand,[41] the covered entity must make "reasonable efforts" to limit the disclosed information to "the minimum necessary to accomplish the intended purpose."[42] In assessing what is the "minimum" amount of information needed to accomplish the health oversight purpose, a covered entity may rely on a public official's representation that the information requested is the minimum necessary for the stated purpose, but only if "such reliance is reasonable under the circumstances."[43]

d. Restrictions on Health Oversight Use in Notices of Privacy Practices

Providers, clearinghouses and plans that wish to preserve their ability to disclose patient-specific information as part of a self-initiated disclosure of potential health care fraud will need to exercise care in drafting their required notices of privacy practices to ensure that their notices do not preclude them from doing so. Covered entities may issue notices stating their intent to restrict their practices to a greater extent than does the Privacy Rule.[44] Once they have done so, however, the Rule requires them to adhere to this stated intent.[45] If covered entities agree in patient notices not to make disclosures for health oversight without patient consent or authorization, they may later conclude that they have unwisely complicated their ability to report a practice such as upcoding or billing for services not rendered that can be proved only by examining patient-specific information.

4. Disclosures by Covered Entities to Outside Counsel

When entities covered by the Privacy Rule hire outside counsel, consultants, and auditors to assist in the review of potential False Claims Act violations, they should bear in mind that these outside professionals may fall within the scope of the term "business associate," triggering the contractual and sanction provisions of the Rule.[46] The term "business associate" as defined in the Rule includes a person who "[p]rovides, other than in the capacity of a member of the workforce of such covered entity, *legal*, actuarial, accounting, [or] *consulting* . . . services to or for such covered entity . . . where the provision of the service involves the disclosure of individually identifiable health information from such covered entity . . . or from another business associate of such covered entity . . . to the person."[47]

Attorneys serving as "business associates" of covered entities should note that the Rule will require them to enter into contracts or other arrangements with their clients in which they agree to: (i) "[m]ake available the information required to provide an accounting of disclosures", and (ii) make their "internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance." [48] However, the Rule provides that "[p]rotected health information obtained by the Secretary [to investigate or review compliance] will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements . . . or if otherwise required by law."[49]

Nonetheless, to minimize the risk of waiver of privilege that might result from application of these provisions, when feasible counsel may wish to provide advice based only on health care information that has been redacted in the manner set forth in the Rule so that it does not identify the individual patient, and consequently is not protected by

the Rule. (See discussion in Section 1(b), above.) By doing so, counsel will not be subject to the restrictions of the "business associate" provisions.

5. Disclosures to the Government in Administrative and Judicial Proceedings

The government may rely on the broad "health oversight" authorization even when seeking patient records in judicial proceedings. While the more restrictive "judicial proceedings" provision of the Rule ordinarily would cover disclosure to the government in connection with a judicial proceeding, the Secretary has made clear that that provision supplements rather than restricts the authority granted in the "health oversight" provision.

The "judicial proceedings" provision[50] authorizes covered entities to disclose patient records in judicial and administrative proceedings only if certain potentially onerous procedural and substantive requirements are met. For example, disclosures may be made to a party to the proceeding in response to a subpoena from the party or a discovery request only if the covered entity receives "satisfactory assurance" that the party has made reasonable efforts either to notify the individual whose records are to be disclosed, or to secure a protective order.

However, the Rule provides that a health oversight agency in litigation may obtain patient-specific information under the "health oversight" provision[51] without having to comply with the stricter requirements of the "judicial proceedings" provision (42 C.F.R. § 164.512(e)).[52] Moreover, in the Background to the "judicial and administrative proceedings" subsection, the Secretary stated:

> We clarify that the provisions of this [judicial and administrative proceedings] paragraph do not supersede or otherwise invalidate other provisions of this rule that permit uses and disclosures of protected health information. For example, the fact that protected health information is the subject of a matter before a court or tribunal does not prevent its disclosure under another provision of the rule, such as . . . 164.512(d)[health oversight].[53]

Once a law enforcement or investigatory agency, such as HHS OIG or the Department of Justice, has obtained individually identifiable health information from a covered entity disclosing the information under the health oversight provision or otherwise, it may use such information for official purposes, including administrative and judicial proceedings, without being subject to any restrictions imposed by the Privacy Rule. By its terms, the Rule directly regulates only covered entities, *i.e.*, health care providers, plans and clearinghouses. It does not regulate law enforcement or investigatory agencies.

6. Disclosures to *Qui Tam* Plaintiffs in Non-Intervened Cases

The civil False Claims Act authorizes private *qui tam* plaintiffs to litigate their claims on their own if the United States declines to intervene.[54] Q*ui tam* plaintiffs in non-intervened cases may have to use traditional judicial discovery tools to obtain documents such as patient records from the defendant, since the Government may no longer be investigating the claims, or may not be willing or able to share evidence with the *qui tam* plaintiff. The new Privacy Rule imposes additional requirements on *qui tam* plaintiffs seeking protected health information in litigation, but these requirements should not prove overly burdensome.

Pursuant to the Privacy Rule, a covered entity may always produce protected health information to a *qui tam* plaintiff in response to a court order that expressly calls for production of the information.[55] In addition, covered entities may produce protected information in response to judicial subpoenas and discovery requests from *qui tam* plaintiffs that are unaccompanied by court orders, *provided that* the covered entity receives "satisfactory assurance," a term defined in the Rule, that the party seeking the information has made "reasonable efforts" *either* (i) "to ensure that the individual who is the subject of the protected health information . . . has been given notice of the request," *or* (ii) "to secure a qualified protective order that meets the requirements [of the Rule]."[56]

In order to provide "satisfactory assurance" that the individual has been given notice of the request, the party requesting the information must provide to the covered entity a written statement and accompanying documentation that (a) the party requesting the information has made a good faith attempt to provide notice to the individual; (b) the notice included sufficient information to permit the individual to raise an objection to the court; and (c) the time for such objection has elapsed and either no objection was filed or all objections have been resolved by the court.[57]

Providing "satisfactory assurance" that a qualified protective order has been requested is likely to be a preferable option for *qui tam* plaintiffs in cases involving the records of numerous patients. To provide satisfactory assurance that a qualified protective order has been requested, the party requesting disclosure need only show that both parties to the dispute have stipulated to an agreement that has been presented to the court, or that the party requesting disclosure has moved the court for an order, and that the agreement or proposed order:

> (A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.[58]

Significantly, the Rule does not require that the court enter the requested protective order before disclosure may be made.

A covered entity also may disclose protected health information to *qui tam* plaintiffs, in response to lawful process, if the covered entity itself makes reasonable efforts to notify the individual whose health information is to be disclosed, or to secure a qualified protective order.

CONCLUSION

The new Privacy Rule adequately protects the ability of *qui tam* plaintiffs and other informants to disclose health care fraud to the authorities, and leaves unaffected the ability of the federal government to investigate and prosecute alleged violations of the False Claims Act. Plaintiffs and others seeking disclosure of unredacted, individually-identifiable information will have to comply with new federal procedures. However, the Rule serves only to curb gratuitous disclosures; it should not hinder disclosures in connection with legitimate reporting of potential fraud. As in the past, counsel contemplating a disclosure will still need to consult other federal and state privacy laws, which may not be preempted by the Rule. Counsel should also determine whether HHS has modified any aspects of the regulatory provisions at issue through supplemental rulemaking, and obtain all pertinent judicial and administrative interpretations of the new Rule, including any that might be issued by HHS's Office of Civil Rights.

ENDNOTES

[1] Pub. L. No. 104-191, Section 262 (codified in scattered sections of 42 U.S.C.).

[2] 65 Fed. Reg. 82,798-82,829 (Dec. 28, 2000).

[3] HHS made significant changes in the Final Rule in response to the points made in comments submitted by TAF.

[4] *See* 65 Fed. Reg. 82,462-82,798 (Dec. 28, 2000).

[5] Other federal laws imposing restrictions on disclosure of health care information include, but are not limited to, the Clinical Laboratory Improvement Act Amendments, 42 U.S.C. § 263a, the Confidentiality of Substance Abuse Records statute, 42 U.S.C. § 290dd-2, and the Privacy Act, 5 U.S.C. § 552a (relevant for certain federal government health plans and contractors). See also Jafee v. Redmond, 518 U.S. 1 (1996) (recognizing psychotherapist-patient privilege under Fed. R. Evid. 501).

[6] In the preamble to the Rule, the Secretary noted that "[w]hile virtually every state has enacted one or more laws to safeguard privacy, these laws vary significantly from state to state . . . ." 65 Fed. Reg. 82,463 (Dec. 28, 2000).

[7] *See* 45 C.F.R. § 160.203 (2001).

[8] *See* 42 U.S.C. § 1320d-6 (2000).

[9] 65 Fed. Reg. 82,472 (Dec. 28, 2000).

[10] *See* http://www.hhs.gov/ocr/hipaa.

[11] *See* http://www.hhs.gov/ocr/hipaa/finalmaster.html.

[12] *Id.*

[13] *See* Final Rule: Correction of Effective and Compliance Dates, 66 Fed. Reg. 12,434 (Feb. 26, 2001).

[14] The definition of "covered entity" is set out at 45 C.F.R. § 160.103 (2001).

[15] *See id.* § 164.514(a) and (b).

[16] *Id.* § 164.502(d)(2).

[17] *See id.* § 164.508.

[18] *See id.* § 160.103.

[19] 65 Fed. Reg. 82,501-02 (Dec. 28, 2000).

[20] 45 C.F.R. § 164.530(e)(1) (2001).

[21] The Rule defines "business associate." *See id.* § 160.103.

[22] *Id.* §§ 164.502(e); 164.504(e).

[23] *Id.* § 164.502(j).

[24] *Id.* § 164.530(e)(1).

[25] *Id.* § 164.502(j)(1)(ii)(A).

[26] *Id.* § 164.501.

[27] *See id.* § 164.502.

[28] *Id.*

[29] 65 Fed. Reg. 82,636 (Dec. 28, 2000).

[30] *See, e.g.*, 31 U.S.C. § 3730(h) (2000).

[31] 45 C.F.R. § 164.504(e)(2)(ii)(A) (2001).

[32] *Id.*

[33] 31 U.S.C. § 3730(b)(2) (2000).

[34] 45 C.F.R. § 164.501 (2001).

[35] 65 Fed. Reg. 82,497 (Dec. 28, 2000).

[36] 64 Fed. Reg. 82, 497 (Nov. 3, 1999).

[37] 45 C.F.R. § 164.512(d) (2001).

[38] 65 Fed. Reg. 82,673 (Dec. 28, 2000).

[39] 45 C.F.R. § 164.512(d)(2) (2001).

[40] *Id.* § 164.502(b)(1).

[41] *See id.* § 164.502(b)(2)(iv).

[42] *Id.* § 164.502(b)(1).

[43] *Id.* § 164.514(d)(3)(iii)(A).

[44] *Id.* § 164.520(b)(1).

[45] *Id.* § 164.502(i).

[46] *Id.* §§ 164.502(e); 164.504(e).

[47] *Id.* § 160.103 (emphasis added).

[48] *Id.* § 164.504(e)(2)(ii)(G) and (H).

[49] *Id.* § 160.310 (c)(3).

[50] *Id.* § 164.512(e).

[51] *Id.* § 164.512(d).

[52] Clause 2 of the "judicial and administrative proceedings" subsection provides: "The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information." *Id.* § 164.512(e)(2).

[53] 65 Fed. Reg. 82,530 (Dec. 28, 2000).

[54] 31 U.S.C. § 3730(b)(4)(B) (2000).

[55] 45 C.F.R. § 164.512(e)(1)(i) (2001).

[56] *Id.* § 164.512(e)(1)(ii).

[57] *Id.* § 164.512(e)(1)(iii).

[58] *Id.* § 164.512(e)(1)(v).

ALLEGATION: FALSE CERTIFICATION OF DEFECTIVE PRODUCTS

U.S. ex rel. Ocampo v. Pacific Precision Metals, Inc. *(C.D. Cal. No. CV98-4710)*

In April 2001, DOJ intervened in a *qui tam* suit alleging that Pacific Precision Metals, Inc. (PPM) provided the U.S. Postal Service with defective and nonconforming mail drop units, mail sorting cases, and tables. According to the complaint, Medcab, a division of PPM, falsely certified that it complied with contract requirements, when in fact it failed to manufacture its products in accordance with specifications; failed to inspect its products prior to shipping; failed to calibrate measuring devices used to conduct inspections of its products; and failed to correct nonconforming and defective products prior to shipment. In addition, the complaint alleged that Medcab submitted falsified quality assurance records to induce acceptance of the defective products and to avoid detection. Relator George Ocampo, a former quality assurance inspector for PPM, filed the suit in December 1997. Phillip Benson (Orange County, Cal.) represents the relator. Assistant U.S. Attorneys Wayne Gross and Cathy Ostiller are representing the Government.

ALLEGATION: MEDICARE FRAUD

U.S. v. Bowen et al. *(D. Del. No. 01-280)*

In April 2001, the United States filed a False Claims Act lawsuit against Bowen Family Chiropractic Center, Inc. and its owner James Bowen, alleging that the defendants misrepresented patients' conditions in order to receive reimbursement from Medicare for chiropractic services. According to the complaint, the defendants sought reimbursement for medically unnecessary treatment and listed patients being treated for ongoing maintenance therapy as suffering from new, acute, or exacerbated conditions. The complaint lists 1,911 false bills totaling $30,966.18 in improper Medicare reimbursement. Assistant U.S. Attorney Maryanne Donaghy is representing the Government.

ALLEGATION: FILING FALSE COST REPORTS

U.S. v. Intrados/International Management Group et al. *(D.D.C. No. 1:01CV00769)*

In April 2001, the United States filed a False Claims Act suit against Intrados/International Management Group (Intrados) for allegedly defrauding the U.S. Agency for International Development (USAID). In 1994, Intrados was awarded a contract to provide technical assistance services in connection with USAID's efforts to privatize civilian and defense industries in the former Soviet Union. According to the complaint, Intrados submitted claims for nonbillable labor costs and personal expenses. The allegedly personal expenses reimbursed included payments for embryo transplant surgery, litigation, condominium rental, personal travel, home repairs, and personal compensation that exceeded the limits established in federal regulations. In total, the Government reimbursed $574,000 in allegedly unauthorized costs, which the defendants designated as salaries, overhead, or travel allowances. Assistant U.S. Attorneys Mark Nagle and Lydia Griggsby represent the Government.

ALLEGATION: MEDICARE FRAUD

U.S. v. Regional Development Behavioral Health Centers, Inc. et al. *(E.D. Pa. No. 01-CV-2143)*

In May 2001, the United States filed a False Claims Act lawsuit against five Pennsylvania mental health centers and their owners, alleging that the centers filed false Medicare claims for Partial Hospitalization Program services. The centers named as defendants are: Regional Development Behavioral Health Centers, Inc.; Shenandoah Behavioral Health Center; Schuylkill Haven Behavioral Health Center; Pocono Behavioral Health Center; and Turning Point Behavioral Health Center. The complaint alleges that the defendants overcharged the Government; admitted patients who did not meet the eligibility criteria; falsely certified that the centers met the requirements for Medicare Community Mental Health Centers; sought payment for worthless patient services; and billed for costs and services not covered by the program. Assistant U.S. Attorney Susan Shinkman is handling the case for the Government.

U.S. ex rel. Dienstag v. Interim Healthcare of Hollywood, Inc., No. 95cv7104 (S.D. Fla.)

In April 2001, DOJ announced that Interim Healthcare of Hollywood, Inc. (Interim) and its owner Bradley Hertz had agreed to pay the Government **$1.6 million** to settle a *qui tam* case alleging that Interim fraudulently shifted costs to Medicare by claiming reimbursement for unallowable costs. Interim was also alleged to have improperly shifted costs such as salaries and nonreimbursable expenses from its private home health agency to Medicare. In addition to the civil settlement, Hertz pled guilty to a criminal fraud charge and is serving one year in federal prison. The relators, Stephen Dienstag and Lee Kirschbrown, had worked as accountants for Interim before filing the *qui tam* suit in 1995. The relators' share is 20 percent or $320,000. Lainie Joan Simon of Hunt Cook Riggs Mehr & Miller (Boca Raton, Fla.) represented the relators. Assistant U.S. Attorney Laurie Rucoba represented the Government.

U.S. ex rel. Lindsey v. Trend Community Mental Services, Inc., No. 1:97cv311 (W.D.N.C.)

In April 2001, DOJ announced that Trend Area Mental Health, Developmental and Substance Abuse Services (Trend) had agreed to pay **$485,000** to settle a *qui tam* lawsuit alleging that the company submitted claims to Medicaid for services not performed. The suit also alleged that Trend failed to document services adequately and to oversee and manage contractor services properly. James and Jane Lindsey, the foster parents of a child entitled to services Trend was supposed to perform, filed the *qui tam* suit in 1997. Larry McDevitt, Michelle Rippon, and W. Carleton Metcalf of Van Winkle, Buck, Wall, Starnes & Davis, P.A. (Asheville, N.C.) represented the relators. Assistant U.S. Attorney Clifford Marshall handled the matter for the Government.

Sales and Marketing Services, Inc.

In April 2001, Sales and Marketing Services, Inc. (SMS), its President W. Richard Smith, its Vice-President Laura Johnson, and its Operations Manager Gregory Johnson agreed to pay the Government **$275,000** to settle allegations that they submitted false claims on a Department of Veterans Affairs (VA) contract to supply surgical instruments. Under the contract, SMS was to supply surgical instruments to the VA, but was prohibited from supplying instruments manufactured in Pakistan. According to the Government, SMS falsely represented that instruments made in Pakistan were made in Europe. SMS and Smith have agreed to permanent exclusion from government contracts and programs. In a related matter, Smith, Laura Johnson, and Gregory Johnson pleaded guilty to criminal charges of smuggling and introduction into interstate commerce of misbranded instruments. The U.S. Customs Service, the FDA Office of Criminal Investigations, and the VA OIG investigated the matter. Assistant U.S. Attorney S. Hollis Fleischer handled the civil case for the Government.

Milvets Technology Systems

In April 2001, DOJ announced that Milvets Technology Systems, Inc. (Milvets) had agreed to pay **$250,000** to settle allegations that the company falsely billed the Library of Congress and the Department of the Treasury for labor costs. Milvets provided labor for the maintenance of computer systems at the Library of Congress between 1993 and 1995. Under the terms of the contract, Milvets was required to supply workers with specified levels of experience in computer maintenance. The Government alleged that

Milvets provided workers without the experience specified, and in some instances provided workers with no computer maintenance experience whatsoever. Milvets also provided labor to the Department of the Treasury under a financial management service contract between 1995 and 1996. The Government claimed that Milvets billed the Treasury for outside consultants at an inflated rate that was only applicable to Milvets employees. The Library of Congress OIG and the Department of the Treasury investigated the matter. Assistant U.S. Attorney Charles Peters represented the Government.

U.S. ex rel. Hertz v. Delray Community Hospital, No. 96-8330 (S.D. Fla.)

In April 2001, Tenet Health Corporation agreed to pay **$175,000** to settle a *qui tam* lawsuit alleging that a Florida hospital overcharged Medicare patients for surgical outpatient pathology services. The hospital billed Medicare three times the allowed charge for pathology tests of tissue taken during colonoscopy examinations. The relator, a former patient, discovered the overcharges after reviewing his own records, and filed the *qui tam* suit in 1996. The relator's share was 21 percent or $36,750. Neil Getnick and Lesley Ann Skillen of Getnick and Getnick (New York City) represented the relator. Assistant U.S. Attorney Laurie Rucoba represented the Government.

U.S. ex rel. Koch v. Koch Industries et al., No. 91-CV-763 (N.D. Okla.)

In May 2001, Koch Industries reportedly agreed to pay the Government **$25 million** to settle a *qui tam* lawsuit alleging that from 1985 to 1989 the company underreported the amount and quality of oil purchased from federal and Indian leases. Bill Koch, the brother of Charles Koch, chairman of Koch Industries, filed the *qui tam* suit in 1991. During a 1999 jury trial, Koch Industries admitted that it received approximately $170 million in oil it did not pay for, but argued that the amount was small enough to fall within industry standards. However, the jury found that Koch Industries intentionally cheated oil producers on federal and Indian lands, and found actual damages of $553,504 and 24,587 false claims, exposing the company to potential liability in fines and treble damages in excess of $210 million. The complete terms of the settlement were not disclosed. However, the relator's share was reportedly 29.5 percent or $7.37 million. Roy Bell, Timothy Irving, and James Stubblefield of Ross Dixon & Bell, L.L.P. (San Diego) and James Sturdivant, David Keglovits, and Kristin Oliver of Gable & Gotwals (Tulsa, Okla.) represented the relator. Stephen Altman and Gordon Jones of the DOJ Civil Division handled the case for the Government.

U.S. ex rel. Goodwin v. Driscoll Children's Hospital, No. C-98-184 (S.D. Tex.)

In May 2001, Driscoll Children's Hospital (Driscoll) agreed to pay the U.S. Government and the State of Texas a total of **$14.5 million** to settle a *qui tam* lawsuit alleging false claims under the Disproportionate Share Hospital (DSH) program for uncompensated care. Driscoll received large DSH payments from Medicaid because it serves a disproportionate number of low-income patients. The complaint alleged that Driscoll falsified data in order to increase Medicaid reimbursements under the DSH program. In addition, Driscoll is alleged to have claimed reimbursement for unallowable lobbying expenses, and provided kickbacks to physicians for patient referrals. The Federal Government's share of the settlement is $7.64 million and the state's share is $4.68 million. The relator, William Goodwin, is the former CFO of Driscoll. The relator's share

of the federal settlement is 27 percent or $2.06 million. John Clarke of Goode Casseb Jones Riklin Choate & Watson (San Antonio), Glen Grossenbacher (San Antonio), Richard Tinsman of Tinsman & Houser (San Antonio), and Cage Wavell (Corpus Christi) represented the relator. Assistant U.S. Attorney Charles Wendlandt, Jr. and Stephanie Jackson of DOJ's Civil Division represented the Government.

U.S. ex rel. Baca v. Catholic Healthcare West, No. CIV-S-98-0569DFL (E.D. Cal.)

In May 2001, Catholic Healthcare West and its subsidiary Mercy Healthcare Sacramento reportedly agreed to pay a total of **$10.25 million** to the Federal Government and the State of California to settle a *qui tam* suit alleging that the companies submitted false claims to Medicare, Medi-Cal and TRICARE. California received $465,188 of the total settlement. The Government alleged that Catholic Healthcare West billed for nonreimbursable annual physical exams, upcoded routine doctor referrals to more highly reimbursable consultations, upcoded evaluations and management office visits, and billed for undocumented laboratory work and ancillary services. George Baca, the former executive director of patient services at Catholic Healthcare West, filed the *qui tam* lawsuit in 1998. The relator's share was approximately 17.6 percent or $1.85 million. Charles J. Stevens of Stevens & O'Connell (Sacramento) represented the relator. HHS OIG investigated the matter. Assistant U.S. Attorneys Michael Hirst and Adisa Abudu-Davis represented the Government.

U.S. ex rel. Hoefer v. Fluor Daniel Inc., No. SA SV 97-1008-GLT (C.D. Cal.)

In May 2001, DOJ announced that one of the nation's largest engineering and construction firms, Fluor Daniel, Inc. (Fluor), had agreed to pay **$8.2 million** to settle a *qui tam* lawsuit alleging that it submitted invoices on numerous government contracts that contained costs not allowed pursuant to the Federal Acquisition Regulation (FAR) or the federal Cost Accounting Standards (CAS). The improper charges consisted of overhead attributable to Fluor's Technology Operating Company (TOC), which discovers and evaluates new technology. The FAR, CAS, and the individual contracts required Fluor to distribute these overhead costs equitably among all private and government contracts that benefited from new technology. Fluor's business was only about 5 to 10 percent federal, but the company charged the bulk of the TOC overhead to federal contracts. Patrick Hoefer, Fluor's former director of Government Financial Compliance, filed the *qui tam* suit in 1997. The relator's share was approximately 22 percent or $1.8 million. Dean Pace of Pace & Rose (Los Angeles) represented Hoefer. The Department of Energy OIG, the DCIS, the Army Criminal Investigative Command, the Department of Transportation OIG and the DCAA investigated the matter. Assistant U.S. Attorney Gary Plessman represented the Government.

U.S. ex rel. Madrid v. HealthSouth Corp., No. CV-97-H-3206-S (N.D. Ala.)

In May 2001, HealthSouth Corporation agreed to pay **$7.9 million** to settle a *qui tam* lawsuit alleging that the company overcharged Medicare and TRICARE for equipment and supplies. The total amount consists of $7.2 million plus $683,000 associated with the abandonment of assets. HealthSouth bought the equipment and supplies that were the subject of the lawsuit from a corporation owned by the parents of the CEO of HealthSouth. The complaint alleged that HeathSouth billed the items at a price above the

supplier's costs, in violation of the rules governing transactions with related entities. In addition, HealthSouth allegedly overbilled the Government for rental payments and the costs of an abandoned computer system. Greg Madrid, a former billing clerk for HealthSouth, filed the *qui tam* lawsuit in 1997. Steve Echsner of Levin, Papantonio, Thomas, Mitchell, Green, Echsner & Proctor, P.A. (Pensacola, Fla.) represented the relator. The relator's share is 20 percent or $1.48 million. HHS OIG and DCIS investigated the matter. Assistant U.S. Attorney Jim Gann represented the Government.

U.S. ex rel. [Relator] v. Northeast Georgia Health System

In May 2001, Northeast Georgia Health System (NGHS) reportedly agreed to pay **$6.4 million** to settle a *qui tam* suit alleging that its former home health agency submitted claims to Medicare and Medicaid for services rendered to patients that did not meet home health care eligibility requirements. The billings at issue involved cases without adequate documentation as well as cases where a patient's condition was chronic, and therefore not reimbursable. In addition to the monetary settlement, NGHS will implement a five-year corporate integrity agreement. The *qui tam* suit was filed in May 1999 by a former employee of Hand in Hand, a home health agency formerly owned by NGHS. HHS OIG investigated the matter. Assistant U.S. Attorney Amy Kaminshine represented the Government.

U.S. ex rel. Woods v. Paracelsus Healthcare Corp., No. 98-4564 (C.D. Cal.)

In May 2001, Paracelsus Healthcare Corporation agreed to settle the Government's FCA claim as part of the company's bankruptcy reorganization. The total amount of the settlement of the Medicare fraud *qui tam* suit is approximately **$5.1 million**. However, the Government is only likely to recover between $2 and $3 million as the pro rata share of its bankruptcy claim. The suit alleged that Paracelsus gave Alliance Healthcare Corporation, a psychiatric services management company, free office space and inflated management and director fees to induce it to funnel patients to a Paracelsus hospital. In addition, Paracelsus is alleged to have billed Medicare for nonreimbursable items such as patient transportation. As part of the settlement, Paracelsus has agreed to implement a five-year corporate integrity agreement. Mark Kleiman (Los Angeles) represented the relator. HHS OIG investigated the matter. Assistant U.S. Attorney Kristine Blackwood represented the Government.

U.S. ex rel. Keehle v. Maryland Specialty Wire, Inc., No. 01-CR-0231 (N.D.N.Y.)

In May 2001, the Strandflex Division of Maryland Specialty Wire, Inc. agreed to pay **$1 million** to settle a *qui tam* lawsuit alleging that it failed to properly test steel cable for control systems of military aircraft. The cable at issue is used to connect cockpit controls to the engines, landing gear, rudder, and wing surfaces. According to the lawsuit, the defendants did not even own the testing materials required to detect flaws in the product. When apprised of the alleged failure to test, Air Force officials immediately tested the cables and found that they could only support half the load they were required to support. Patricia Keehle, a former quality assurance manager for Strandflex, filed the *qui tam* lawsuit in 1999. In addition to the civil settlement, the company agreed to pay a total of $600,000 in criminal fines and restitution. The relator's share was 21 percent or $210,000. Mark Polston (Washington, D.C.)

represented the relator. Assistant U.S. Attorney Gregory West represented the Government.

Marvin Balistocky, M.D.

In May 2001, Marvin H. Balistocky, M.D. agreed to pay **$531,026** to settle allegations that he submitted false claims to Medicare and Medicaid in connection with ophthalmological care. Among other things, the Government claimed that Dr. Balistocky submitted false claims for laser surgeries performed as part of post-cataract removal surgery by indicating that the surgeries were performed after the ninety day post-operative period; submitted claims for services that were either never rendered or upcoded; and submitted claims for two patient evaluation and management services per patient visit. In addition, Dr. Balistocky has been charged with two counts of criminal health care fraud. Assistant U.S. Attorney Margaret Hutchinson represented the Government.

Christus Schumpert

In May 2001, DOJ announced that Christus Schumpert, a Shreveport, Louisiana hospital, had agreed to pay **$125,000** to settle allegations that it improperly billed Medicare for patients transferred to other hospitals. Under Medicare's Prospective Payment System (PPS), the Government reimburses most hospitals with a fixed amount depending on the diagnosis, rather than on the actual cost of services. However, when a hospital admits but later transfers a patient to another PPS hospital, as Schumpert did, the transferring hospital is entitled to reimbursement based on a per diem rate rather than the higher fixed amount. The Government alleged that Schumpert intentionally submitted false claims for the full fixed payments for patients it had transferred to other hospitals. The settlement is part of a national initiative launched by HHS OIG, and is the fourth PPS case in the country to settle. Assistant U.S. Attorney Scott Newton represented the Government.

U.S. ex rel. Worner v. UroCor, Inc., No. 97-751C (W.D. Okla.)

U.S. ex rel. Moore v. UroCor, Inc., No. 98-1330R9 (W.D. Okla.)

U.S. ex rel. Turner v. UroCor, Inc., No. 99-143T (W.D. Okla.)

U.S. ex rel. Bailey v. UroCor, Inc., No. 99-00253L (W.D. Okla.)

In June 2001, UroCor, Inc. agreed to pay **$9 million** to settle four *qui tam* lawsuits alleging that it improperly charged Medicare and other federal health programs for lab tests. The Oklahoma City company serves approximately one-third of the office-based urologists in the United States, and specializes in conducting tests that detect bladder and prostate cancer. The suits alleged that UroCor billed the Government for unnecessary DNA analyses of cytology specimens and charged the Government higher prices than those charged for private patients. In addition to the monetary settlement, UroCor agreed to a 5-year Corporate Integrity Agreement. Three of the four relators received a share of the settlement. The first relator to file, Dr. Theresa Worner, received 7.7 percent or $690,000. Robert Vogel of Vogel & Slade (Washington, D.C.) represented Ms. Worner. Christine Moore's share is 5.5 percent or $460,000. Mary Louise Cohen of Phillips & Cohen (Washington, D.C.) represented Ms. Moore. Sandra Turner's share is 2.2 percent or $200,000. Charles Bailey of Greber & Simms (Baltimore) represented Ms. Turner. HHS OIG, the DCIS, and the FBI investigated

the matter. Patricia Davis of the DOJ Civil Division and Assistant U.S. Attorney Robert Troester represented the Government.

U.S. ex rel. Cosens v. Holy Cross Hospital

In June 2001, DOJ announced that seven hospitals had agreed to pay the Government **$5,476,637** to settle a *qui tam* lawsuit alleging that the hospitals improperly billed Medicare for surgical procedures that included unapproved experimental cardiac devices. According to DOJ, between 1986 and 1994 participating Medicare hospitals were advised that Medicare would not reimburse for procedures involving "investigational devices," that is, devices that had not received final approval for marketing from the FDA. Kevin Cosens, a former medical device salesman, filed the *qui tam* suit in 1994 against hospitals across the country. The hospitals involved in the current settlement are Holy Cross Hospital in Ft. Lauderdale; Green Hospital of Scripps Clinic in San Diego; Healthwest Regional Medical Center in Phoenix; West Florida Regional Center in Pensacola; and three Miami hospitals, the Miami Heart Institute, South Miami Hospital, and Mt. Sinai Medical Center. The relator's share is 20 percent or $1,095,327. Don Warren (San Diego) and Phillip Benson (Orange County, Cal.) represented the relator. HHS OIG, the DCIS, and the DOJ Civil Division investigated the matter.

U.S. ex rel. Krohn v. Sun West Services, Inc. et al., No. 97-0644 (D.N.M.)

In June 2001, Sun West Services, Inc. (Sun West) and its successor, Fine Host Corp., agreed to pay the Government **$275,000** to settle a *qui tam* suit alleging that the food service provider overbilled the National School Lunch and School Breakfast programs, which provide food to underprivileged students. The suit alleged that Sun West inflated operating costs of employee-related expenses and insurance in school districts in New Mexico and Arizona. John Krohn, a former employee of Sun West, filed the *qui tam* suit in 1997, and the Government declined to intervene. Also named as defendants were four former company officials, including former Sun West President William C. Smitherman, the former U.S. Attorney for Arizona. The relator's share was 30 percent or $82,500. Charles Purdy (Santa Fe) represented the relator. Assistant U.S. Attorney Howard Thomas represented the Government.

U.S. ex rel. Hass v. South Carolina State University, No. 98-CV-1568 (D.S.C.)

In June 2001, DOJ announced that South Carolina State University (SCSU) had agreed to pay **$140,000** to settle a *qui tam* lawsuit alleging that SCSU diverted U.S. Department of Agriculture (USDA) grant funds from one USDA grant program to another, in violation of the Food and Agriculture Act of 1977. Former SCSU contractor Jeffrey Hass filed the *qui tam* suit in June 1998. The relator's share is 15 percent or $21,000. Walter Bundy, Jr. of Smith Bundy Bybee & Barnett (Charleston, S.C.) and Henry Wall of Bruner Powell Robbins Wall & Mullins, L.L.C. (Columbia, S.C.) represented the relator. Assistant U.S. Attorney Deborah Barbier handled the case for the Government.

TAF News

FCA Conference Materials

- As part of its information clearinghouse activities, TAF has materials available for distribution at conferences and other programs. Information can be tailored to a legal or general audience. Resource material, including statistical information, is also available for those writing articles on the FCA.

Qui Tam Practitioner Guide

- The *TAF Qui Tam Practitioner Guide: Evaluating and Filing a Case* can be ordered at no charge by phone, fax, or mail. This "how to" manual includes sections on evaluating the merits and viability of a case, pre-filing and practical considerations, and preparing and filing the complaint.

TAF on the Internet

- TAF's Internet presence is designed to educate the public and legal community about the False Claims Act and *qui tam*. TAF's site is located at http://www.taf.org.

Previous Publications

- Back issues of the *Quarterly Review* are available in hard copy as well as on TAF's Internet site.

Quarterly Review Submissions

- TAF seeks submissions for future issues of the *Quarterly Review* (e.g., opinion pieces, legal analysis, practice tips). To discuss a potential article, please contact Staff Attorney Amy Wilken or Bret Boyce.

Anniversary Reports and Video

- To mark the anniversary of the 1986 FCA Amendments, TAF has available a variety of resources including a Tenth Anniversary Report, an Assessment of Economic Impact, and an educational video highlighting the effectiveness of the Act. These materials are available at no charge.

Call for Experts and Investigators

- In response to inquiries, TAF is working to compile a list of experts and investigators across an array of substantive areas. Please contact TAF with any suggestions you may have.

Qui Tam Attorney Network

- TAF is continuing to build and facilitate an information network for *qui tam* attorneys. For an Attorney Network Application or a description of activities, please contact TAF. Be sure to ask about TAFNET, our electronic mail system for Attorney Network members.

TAF Library

- TAF's FCA library is open to the public, by appointment, during regular business hours. Submissions of case materials such as complaints, disclosure statements, briefs, and settlement agreements are appreciated.

Acknowledgments

- TAF thanks the Department of Justice and *qui tam* counsel for providing source materials.