False Claims Act & Qui Tam

Quarterly Review

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

The TAF Education Fund is a nonprofit charitable 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). The TAF Education Fund serves to inform and educate the general public, the legal community, and other interested groups about the FCA and its *qui tam* provisions.

The TAF Education Fund 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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FROM THE EDITOR

"Those of us who manage the public's dollars will be held to account—to spend wisely, reform bad habits, and do our business in the light of day—because only then can we restore the vital trust between a people and their government."

–President Barack Obama,
January 20, 2009

I feel fortunate to have attended college and law school in Washington, D.C., and to still work and live in the seat of our federal government. I first arrived in Washington, D.C., over fifteen years ago, and during my time here, I've experienced my share of historical and memorable events, including countless protests and marches, the aftermath of the September 11th terrorist attacks, the anthrax scare, the random violence of the Washington, D.C., snipers, a drug-addicted mayor, and even the impeachment of a president. Very little surprises or impresses people in this town anymore. However, I was completely overwhelmed by the historical significance of January 20, 2009—the day Barack Obama was inaugurated as the 44th President in United States history. As an African American man, I felt especially fortunate to have a ticket to attend the inauguration ceremony and I, along with about 2 million of my newest friends, braved sub-freezing temperatures for several hours, in order to witness the historic event "in person." As I listened to President Obama's first speech, I was immediately struck by the sentence quoted above. It reminded me that President Obama is a former False Claims Act attorney, having represented Janet Chandler in her *qui tam* action, against Cook County, Illinois. That case resulted in the U.S. Supreme Court's monumental holding that local governments are "persons" subject to liability under the False Claims Act.

I realized that January 20, 2009, is a significant day for our entire community. As we are all dedicated to the preservation, enforcement, and proper interpretation of the False Claims Act, we are all fortunate to have Barack Obama as our president, regardless of our individual politics. With unprecedented "bailout" funds being distributed throughout corporate America, a massive stimulus package on the horizon, a new Department of Justice taking shape, and False Claims Act legislation pending before Congress, we need a president who understands the pressing need for government oversight of federal funds, as well as for a strong False Claims Act to prosecute those who defraud the government and steal from taxpayers. President Obama is off to a good start, having expressed general support for the efforts of whistleblowers, and specific support for a stronger False Claims Act, both while on the campaign trail and through his transition team's website, www.change.gov. I hope that he continues in his

efforts to "restore the vital trust between [the] people and [our] government," and I welcome him to my city with open arms.

As always, I would love to hear from you, so feel free to email me with your comments, ideas, articles, and criticisms. I look forward to hearing from you.

Happy New Year!
Cleveland Lawrence III
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Recent False Claims Act & *Qui Tam* Decisions

OCTOBER 1, 2008–DECEMBER 31, 2008

FALSE CLAIMS ACT LIABILITY

A. Violations of the Anti-Kickback Statute and/or Stark Law

U.S. ex rel Fry v. The Health Alliance of Greater Cincinnati, 2008 WL 5282139 (S.D. Ohio Dec. 18, 2008)

The relator filed a *qui tam* action against an integrated health care delivery system and other corporations providing services for heart and vascular diseases, alleging violations of the Anti-Kickback Statute, false certification, conspiracy, reverse false claims, and retaliatory discharge from employment. The government elected to intervene and brought claims for payment under mistake of fact, unjust enrichment, and disgorgement. The defendants jointly moved to dismiss the complaint for failure to state a claim and failure to plead fraud with particularity. The United States District Court for the Southern District of Ohio concluded that the plaintiff adequately alleged that the defendants operated a cross-referral scheme to cause the government to pay and also sufficiently identified the false claims in detail. The defendants' motion was accordingly denied.

Relator was a doctor affiliated with the defendants. He alleged that the defendants assigned time to doctors in the hospital's heart station in proportion to the number of referrals made by the doctors. This arrangement was allegedly a "pay to play" scheme that violated the Anti-Kickback Statute, the Stark Law, and the FCA. After the relator complained about the system, he was allegedly terminated in retaliation, and the defendants took steps to conceal the scheme.

Failure to State a Claim

The defendants argued that the time assigned to the cardiologists in the heart station did not amount to remuneration, and therefore, the complaint failed to state a violation of Anti-Kickback Statute. The court, however, found that the term "remuneration" was to be read expansively and that time in the heart stations was essentially money because it provided the doctors with an opportunity to bill for services. Accordingly, the court found that the government adequately pled a referral scheme that violated the Anti-Kickback Statute. Furthermore, the court noted that the complaint properly alleged knowing and willing participation in the scheme, because the defendants knowingly took steps to conceal the referral system.

The defendants also argued that they lacked the *mens rea* to violate the FCA, because it was objectively reasonable for them to believe their conduct was legal. The court found that it was common knowledge that remuneration for referrals

was illegal and that their referral scheme had been challenged by doctors. Furthermore, the court held, the question of intent was for a jury to decide.

The defendants also contended that the complaint failed to sufficiently allege that the claims submitted were false or that they were material to the government's decision to pay, that there was no conspiracy, and that FCA claims do not attach to Medicaid, since Medicaid claims are submitted to the state, not the federal, government. The court noted that certification of compliance with the Anti-Kickback Statute was a necessary condition for payment by the government and therefore, was material to the government's decision to pay. It also found that the conspiracy claim was properly pled because it included more than one actor and dismissed the defendants' argument that Medicaid claims were not actionable under the FCA, finding that "Medicaid claims submitted to the state are also claims to the federal government under the FCA." Accordingly, the court held that the FCA claims were properly pled, and denied the motion to dismiss.

Particularity Requirement

The defendants argued that the complaint failed to identify any specific false claims and failed to describe how new patients were obtained as a result of heart station assignment time. The court, however, held that the complaint satisfied Rule 9(b)'s particularity requirement, as it identified not only the parties involved in the alleged fraud, but also the allegedly false claims. In particular, the complaint identified claims that were made under the referral scheme and the relevant diagnostic resource group codes of each false claim. Accordingly, the motions to dismiss were denied.

U.S. ex rel. Thomas v. Bailey, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008)

The relator filed a *qui tam* action against a neurosurgeon, surgical device manufacturers and other corporate entities, alleging that the defendants engaged in sham consulting agreements that were actually unlawful kickbacks under Anti-Kickback Statute. Specifically, the relator alleged that physicians entered into sham consulting agreements in which they were given kickbacks in return for the usage of the defendant surgical device manufacturer's products. The complaint provided specific facts of this scheme regarding one particular neurosurgeon and more generally alleged that the scheme was in place nationwide. The complaint further alleged that this scheme violated the Anti-Kickback Statute and caused submission of false claims to the government. The government declined to intervene. A settlement agreement was reached with the neurosurgeon and two other defendants. The relator then filed a second amended complaint that included allegations of a na-

tionwide corporate policy of the same conduct. The defendants moved to dismiss for failure to state a claim. The United States District Court for the Eastern District of Arkansas held that the second amended complaint stated a claim to the extent it alleged that the corporate defendants knowingly caused the neurosurgeon to submit false claims to the government, but failed to state a claim regarding the remaining allegations. The defendants' motion was accordingly granted in part and denied in part.

Violation of the Anti-Kickback Statute

The court first addressed whether or not the relator pled the alleged fraud under the Anti-Kickback Statute with sufficient particularity. It held that the allegations of fraud relating to the neurosurgeon in the first complaint were pled with particularity because the relator provided the "who, what, where, when, and how" of the alleged kickback scheme. However, the court held that the allegations of a nationwide corporate policy of kickback arrangements were not pled with sufficient particularity, since the relator failed to identify who adopted the alleged policy, where was it adopted and how was it implemented.

Submission of False Claims

The court then analyzed whether the relator sufficiently pled that false or fraudulent claims were submitted to the government. The relator alleged that, while a sham consulting agreement was in place, the claims for surgical device reimbursement submitted by the hospitals for surgeries involving defendants' products constituted either an express or implied false certification of compliance with the Anti-Kickback statute, and subjected the defendants to liability under the FCA. The court noted that false certification of compliance with the Anti-Kickback statute could trigger liability under the FCA, and then determined that the hospital's act of submitting a claim impliedly certified the hospital's compliance with the Anti-Kickback Statute. However, the court observed, this was different from the hospital certifying a physician's compliance with the Anti-Kickback Statute. Hence, since the alleged sham consulting agreements were with the physicians and not directly with the hospitals, and since hospitals are not required to certify that physicians are in compliance with the Anti-Kickbacks statute, the court found the relator's allegations to be lacking as against the hospital. Furthermore, the court concluded that the relator's complaint did not plead that the hospitals knew that there were allegedly improper kickbacks. The relator, however, also contended that the hospital expressly certified the physicians' selection of devices while submitting their annual cost reports to the government. More broadly, the relator alleged that this certification by the hospital certified every physician's compliance with the relevant regulations. The court found that not only was this certification impossible and beyond the certifier's knowledge but it was also not required by regulation. Accordingly, the

court held that the allegations regarding false or fraudulent claims submitted by hospitals were not pled properly and claims based on those allegations were dismissed.

Notably, however, the court held that the amended complaint did state a claim to the extent it alleged that the defendants knowingly caused the neurosurgeon to submit false claims to the government. It found that when a physician submits a claim to Medicare, he or she impliedly certifies the claim is in compliance with the Anti-Kickback Statute.

Particular FCA Claims

Lastly, the court discussed whether or not the relator adequately pled the remaining claims under sections 3729(a)(1), (2) and (3). The court found that the claim under subsection (a)(1) was properly pled because it alleged that the defendants engaged in a scheme that they knew would violate the Anti-Kickback Statute and result in the submission of false or fraudulent claims to the government. However, the claim under subsection (a)(2) was dismissed because the relator identified no false record that was presented to the government for payment. The subsection (a)(3) claim was also dismissed because the relator did not allege a specific intent to defraud the government.

Accordingly, the court only allowed the relator to maintain his claim under section 3729 (a)(1) of the FCA, which alleged that the defendants caused the neurosurgeon to submit false or fraudulent claims to the government for payment.

***See U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 2008 WL 4430668 (10th Cir. Oct. 02, 2008), at page 21.**

B. What Constitutes a False Claim

U.S. v. Eghbal, 2008 WL 5101943 (9th Cir. Dec. 5, 2008)

The government filed an FCA action against two individuals, alleging that they made false statements to procure home mortgage insurance from the Department of Housing and Urban Development (HUD). The defendants were accused of violating the FCA by falsely certifying that they had complied with various HUD regulations, which state that HUD will not insure mortgage loans for buyers who cannot cover their own down payments, and which include the condition that HUD will not agree to insure a buyer's mortgage loan unless the seller signs a document certifying that he/she did not provide any portion of the buyer's down payment. The government alleged that the defendants violated those regulations by buying 200 HUD-foreclosed homes, reselling them for profit to buyers with mortgage loans insured by HUD, providing their own funds to help buyers cover their respective down payments, and falsely certifying to HUD that they did not assist buyers with their down payments. As a result of the defendants' actions, many of the buyers defaulted on their mortgage loans, triggering the HUD mortgage insurance.

The defendants had previously pled guilty to criminal charges of making false statements to the government, and the government's FCA case sought to recover about $2.8 million that HUD paid out to cover balances owed on 27 properties on which buyers had defaulted. The district court granted summary judgment in favor of the government, and awarded nearly $6 million in damages and penalties (The court reached that figure by trebling the government's actual damages of $2.8 million and then subtracting from that amount the $2.7 million the government recouped by selling the 27 properties. In addition, the court imposed the minimum civil penalties for each of the 27 false certifications, which totaled about $148,000.) The United States District Court for the Central District of California granted the motion. The defendants appealed to the Ninth Circuit, contesting both their FCA liability and the district court's damages award. The Ninth Circuit affirmed the decision of the district court, holding that the allegedly false statements made by the defendants caused the government to approve the false claims and that the district court's damages calculation was proper.

Liability for Making False Claims

The defendants contended that they were not liable under the FCA because their false statements to HUD were not "claims," but were merely fraudulent inducements to get HUD to insure mortgage loans that it otherwise would not have insured. They argued that the actual claims on HUD funds were made

by the mortgage holders who defaulted on their loans, and that they—the defendants—played no role in causing those mortgage loan defaults. The Ninth Circuit, applying the Supreme Court's recent decision in the *Allison Engine* case, noted that "FCA liability attaches to a false statement that has a 'material effect' on the Government's eventual decision to pay a claim." Hence, the defendants were liable under the FCA because government's commitment to pay for the mortgage insurance claim was based on the defendants' false statements to HUD. Furthermore, the appeals court found a causal link between the defendants' admittedly false statements and HUD's payment and approval of the mortgage loan insurance claims, stating that "the false statements at issue here bore directly upon the likelihood that the buyers would be unable to make their mortgage payments, and thus, the misrepresentations had a causal connection to the subsequent defaults sufficient to support FCA liability." Hence the court held the defendants violated the FCA.

Calculating Damages

With respect to the district court's calculation of damages, the defendants conceded that the district court calculated damages properly. However, they argued that the damages award violated the Eighth Amendment's excessive fines provision. The circuit court disagreed, finding that the district court's award was justified, as the district court made specific factual findings in determining that the award was not grossly disproportionate to the offenses, including finding that the defendant's false claims were related to other illegal activities, that even greater penalties could have been imposed but were not, and that the harm caused by the defendants' scheme was far-reaching. The circuit court agreed with this assessment, and added to those factors the fact that the defendants' "systematic and ongoing scheme . . . undermines the integrity of the programs and erodes the public confidence in the Government's ability to manage and fund such programs." Thus, the Ninth Circuit affirmed the district court's judgment on and damages.

JURISDICTIONAL ISSUES

A. Section 3730(B)(5) First-to-File Bar

Her v. Regions Financial Corp., 2008 WL 5381321 (W.D. Ark. Dec. 22, 2008)

The relators filed separate *qui tam* actions against two banks, alleging false certification and submission of false claims to the government, based on the defendants' alleged misrepresentation of compliance with federal regulations in order to obtain guarantees on non-viable farm loans, and their alleged submission of false claims to the government in order to obtain payments related to those guarantees. The defendants moved for dismissal contending that the court lacked jurisdiction under the first-to-file bar because they were defendants to a prior action filed by a different relator, which was based on the same alleged fraudulent scheme. The plaintiffs argued that the prior action involved false certifications regarding the feasibility of the loans and the adequacy of the collateral, whereas their claims involved false certifications that the defendants would not charge excessive interest rates or loan fees. The United States District Court for the Western District of Arkansas found that all three cases were materially based on the same underlying facts and that the two later-filed actions only alleged different aspects of the same fraudulent scheme. The court further observed that in all three actions, the defendants allegedly made false statements to induce the government to make payments on the fraudulently obtained guaranteed loans. Hence, the court found that the first-to-file bar applied and the defendants' motion to dismiss was granted.

U.S. ex rel. Bane v. Life Care Diagnostics, 2008 WL 4853599 (M.D. Fla. Nov. 10, 2008)

The relator brought a *qui tam* action against a laboratory service provider alleging that the defendant conspired with other health service providers to file fraudulent Medicare claims. The defendant moved to dismiss the second amended complaint for lack of subject matter jurisdiction under the first-to-file bar. The defendant contended that it had not been included in a previous *qui tam* action filed by the relator, which essentially described the same alleged scheme of defrauding the government. The magistrate who considered the motion recommended that the motion be granted and the United States District Court for the Middle District of Florida adopted the magistrate's recommendation. The court held that the first-to-file doctrine barred the relator's claim because that claim was based upon the same fraudulent scheme alleged in an earlier FCA action. The court found that the core facts, general

allegations and the fraudulent scheme described in the present action and in the previous action were almost identical, and that only a couple of nuances and fine distinctions to the alleged scheme to defraud were added in the latter action. Furthermore, the court noted that although the defendant was not included as a party in the previous action, it was mentioned twelve times in the previous complaint. The court then found that the relator's claim under the Anti-Kickback Statute was also based on the same underlying facts as the previous claim. Accordingly, the court granted the motion to dismiss.

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

U.S. ex rel. Davis v. District of Columbia, 2008 WL 5332817 (D.D.C. Dec. 23, 2008)

The plaintiff filed a *qui tam* action against the District of Columbia and its school system, alleging that the defendants failed to comply with the statutory requirements of maintaining financial documents regarding their claims to the federal government for Medicaid reimbursement. The government declined to intervene. The defendants moved to dismiss for lack of subject matter jurisdiction, failure to plead with particularity and failure to state a claim. The United States District Court for the District of Columbia observed that though the suit was based on publicly disclosed information, the plaintiff qualified as an original source. The court also found that the plaintiff had adequately alleged false representation and stated a valid claim. However, the court held that the plaintiff had not alleged any damages to the government and therefore, the motion to dismiss the claim for treble damages was granted. The motion to dismiss the conspiracy claim was also granted.

The plaintiff was an executive of a company (D&A) that developed and implemented Medicaid reimbursement plans. The defendants contracted with D&A to create a reimbursement plan for its special education program. When D&A's contract with the defendants expired at the end of 1998, the defendants did not renew it, and chose to contract with a different company. Nevertheless, D&A prepared a 1998 Medicaid reimbursement claim for the defendants of $60 million, and created the necessary supporting documentation. This claim was more than $50 million higher than the claim the defendants initially submitted to the federal government—a claim that was prepared by the defendants' new company. D&A informed the defendants that they were due more money, and alerted the defendants to the $60 million claim it had prepared. However, D&A refused to provide the defendants with the supporting documentation. The applicable regulations required that an entity seeking reimbursement maintain supporting documentation. Subsequently, the defendants submitted a revised cost claim for $60 million, without the supporting documentation from D&A, and the claim was paid by the government. After notifying the Department of Health and Human Services and the Department of Justice, the plaintiff brought this *qui tam* action, contending that the defendants' claim for $60 million was a false claim because they failed to maintain the necessary supporting documentation.

Public Disclosure Bar

In its motion to dismiss, the defendants contended that the court lacked subject matter jurisdiction because of the public disclosure bar. First, they argued that a discrimination suit arising out of the same relationship between the parties

was a public disclosure. The court, though, found that the discrimination suit was filed after the *qui tam* action and therefore was not a public disclosure. The defendants also argued that a prior state audit of Medicare reimbursement revealed that, in 1998, the defendants had submitted claims for Medicare reimbursement without supporting documentation. The defendants argued that this report constituted a public disclosure. Although the court was aware of the possibility that the U.S. Supreme Court might rule that state audit reports (as opposed to federal audit reports) may not qualify as public disclosures, the court determined that the state audit was a public disclosure but that the plaintiff was as an original source of the information, since he had direct and independent knowledge that in 1998 the defendants submitted claims for Medicare reimbursement without supporting documentation. The court noted that the plaintiff alleged that D&A was the only entity that could have created the necessary documentation. The plaintiff further alleged that he only disclosed his allegations to the relevant government agencies and did not divulge the documentation to anyone else, including the defendants. Therefore, the public disclosure bar did not apply and the court had subject matter jurisdiction over the plaintiff's *qui tam* action.

Particularity Requirement

The defendants argued that the plaintiff failed to allege with particularity when the fraud occurred. The court found that the allegation that the fraud occurred "in or about the Spring of 2002" was pled with particularity because it was not an open-ended allegation without definite starting or ending points. Furthermore, the court found that the plaintiff's personal disclosure statement contained factual allegations sufficient to support his claims and that he adequately alleged the time of the allegedly false representation in his personal disclosure statement. Accordingly, the court held that the plaintiff pled fraud with sufficient particularity.

Failure to State A Claim

The defendants also argued that there was no submission of a false claim. They contended that they were in possession of the supporting documentation because, by contract, D&A was an agent of the defendants. However, the court found that in a separate suit, the defendants had persuaded another member of the court that the contract with D&A was void. Hence, the court found, the plaintiff had properly alleged fraud. However, the court found that plaintiff failed to allege that the government had overpaid the Medicaid reimbursement because the complaint alleged that the defendants were, in fact, entitled to the $60 million claim amount. Accordingly, the court found that the plaintiff had only alleged the submission of a false claim and was only entitled to statutory penalties. The plaintiff's claim for treble damages was dismissed, as was his conspiracy claim.

U.S. ex rel. Radcliffe v. Purdue Pharma, L.P., 2008 WL 4587783 (W.D. Va. Oct. 14, 2008)

The relator filed a *qui tam* action against his former employer, a pharmaceutical company, as well as related entities. He alleged that the defendants had misrepresented the potency of OxyContin and that, as a result, the government reimbursed OxyContin prescriptions at a fraudulently higher rate, which, he alleged, constituted a false claim. The government declined to intervene. The defendants moved to dismiss, arguing a prior public disclosure of the alleged false claims, the relator's execution of a pre-filing general release, and the relator's failure to plead fraud with particularity. The United States District Court for the Western District of Virginia held that there had not been a public disclosure of the alleged fraud and that the relator's pre-filing release did not bar the *qui tam* suit. However, the court granted the motion to dismiss, finding that the complaint failed to plead fraud with particularity, and granted the relator leave to amend.

The relator was a former employee of the defendant pharmaceutical company. During his employment, he allegedly found that the defendants misrepresented the potency of OxyContin through oral representations or assurances made by the defendants' salespeople and in the OxyContin package insert. Consequently, physicians allegedly prescribed the defendants' medicine more frequently because it was purportedly both stronger and cheaper. The relator also alleged that government reimbursements for OxyContin were incorrect because they were based on the misrepresented potency. Hence, he alleged that OxyContin prescriptions submitted for government reimbursement constituted false claims. Prior to the *qui tam* action, the relator brought his concerns to the defendants. Eventually, he signed a severance agreement that included a general release of all claims. At that point, however, he had neither notified the government of the defendants' alleged fraud nor filed his *qui tam* suit. Meanwhile, the government was also investigating the defendants' marketing of OxyContin, among other things. The government then requested and was granted a stay in the *qui tam* action to continue that investigation. When the stay was lifted, the government brought criminal charges against the defendants for actions unrelated to the *qui tam* action, and also declined to intervene in the relator's suit.

There Was No Prior Public Disclosure of Information

The defendants argued that the relator's claims should be dismissed because of the public disclosure bar. Specifically, they claimed that published scientific articles and reference materials and the OxyContin package insert constituted public disclosures of the alleged fraud. The court held that scientific articles and reference materials were publicly disclosed in the news media. The court also found the packet insert, which was included in OxyContin packages and

published on the defendants' website, was publicly disclosed because the internet posting was either a corporate report or a press release. However, the court found that these materials were not public disclosures under the FCA because the disclosures only revealed scientific debate over the appropriate way to measure the potency of OxyContin and did not reveal any fraudulent intent by the defendant. Thus, the defendants' motion was denied on this issue.

Claim Was Not Barred by a Pre-Filing General Release

The defendants argued that the general release contained in the severance agreement between the pharmaceutical company and the relator barred the relator's claims. The court adopted the reasoning of the Ninth Circuit in determining whether a general release is enforceable to bar a subsequent *qui tam* action. The court held that, in general, pre-filing releases are unenforceable unless the government has full knowledge of the allegations and an opportunity to investigate prior to the release. It then found that since the government had not completed its investigation of the defendants in this case, the pre-filing release was not enforceable for public policy reasons. In particular, the court found that enforcing this agreement would hamper the ability of relators to supplement governmental enforcement of the FCA and would discourage relators from disclosing information to the government.

Particularity Requirement Regarding Fraud Not Met

The court granted the defendants' motion to dismiss, finding that the relator failed to plead fraud with particularity under Fed.R.Civ.P. Rule 9(b). It found that the relator's complaint did not describe even one instance in which a physician was influenced to prescribe OxyContin based on the defendants' misrepresentations, resulting in a false claim for payment being made by the physician to the government. However, the court granted the relator leave to file an amended complaint.

U.S. ex rel. Ondis v. City of Woonsocket, R.I., 2008 WL 4547495 (D.R.I. Oct. 08, 2008)

The relator brought a *qui tam* action against a city and its mayor alleging that the defendants made false statements to the Department of Housing and Urban Development (HUD) while applying for federal funds. The relator alleged that although the defendant received grants from HUD to create affordable housing for low-income households, through FOIA requests, the relator discovered nine incidents of the defendants' bias against affordable housing. The government declined to intervene. The defendants moved to dismiss, arguing that the FCA's public disclosure bar applied, since all but one of the alleged incidents had been reported in local newspapers or disclosed in a suit involving the city and two housing partnerships. The United

States District Court for the District of Rhode Island agreed with the defendants and held that it lacked subject matter jurisdiction because the action was based upon publicly disclosed information and the relator was not an original source of that information. Consequently, the court granted the motion to dismiss.

The Claims Were Based on Publicly Disclosed Information

The defendants argued that the court did not have jurisdiction because the relator's claims were based on publicly disclosed information. The court found that information appearing in newspapers, even if they are legal notices and classified advertisements—and even if the relator was unaware of their existence—was publicly disclosed. Furthermore, the fact that the plaintiff received information through an FOIA request was also evidence of a public disclosure. Accordingly, the court found a public disclosure within the meaning of FCA. The court then grouped the single incident not previously disclosed with the rest, finding that it was dependent on the publicly disclosed information. In addition, the court noted that the relator had conceded that he did not have any first-hand knowledge of the facts alleged, and therefore, he could not have been the original source of the information. Consequently, the court granted the defendants' motion to dismiss, on public disclosure grounds.

FALSE CLAIMS ACT RETALIATION CLAIMS

U.S. ex rel. Cassaday v. KBR, Inc., 2008 WL 5273496 (S.D. Tex. Dec. 16, 2008)

The relator brought a *qui tam* action against his former employer and other affiliate corporations, alleging the submission of false claims to the government and retaliatory discharge. The government declined to intervene. The defendants moved to compel arbitration of the relator's retaliation claims pursuant to his employment contract with the defendant. The United States District Court for the Southern District of Texas held that the retaliation claims fell within the scope of the arbitration clause because the relator's claims related to his employment and termination from the defendant. The court granted the defendants' motion to compel arbitration. The retaliation claim was thus severed and stayed pending adjudication.

Arbitrability of FCA Retaliation Claims

The relator asserted that FCA retaliation claims are not subject to arbitration because arbitration conflicts with the text of the FCA, the FCA's public disclosure provision, and the legislative history of the FCA, and creates inherent conflicts with the FCA. First, the court held the text of the FCA does not mandate that retaliation claims are not subject to arbitration. The court observed that other courts have not found any congressional intent in the statutory text that precludes arbitration. Second, the court found that the relator's public disclosure argument was unfounded. The relator argued that if arbitration proceedings could constitute a public disclosure under the FCA, employers could effectively immunize themselves from liability in similar situations. The court, however, found that since the FCA does not require that retaliation claims be filed prior to other claims, relators can avoid the public disclosure bar by simply filing the retaliation claims with or after the *qui tam* claims. Third, the court found that the relator's arguments that arbitration could cause a relator to improperly notify a defendant of a pending *qui tam* suit was unfounded because arbitration could be stayed pending the resolution of the other claims. Fourth, the court held that there was no specific language in the legislative history of the FCA that indicates that it precludes arbitration of retaliation claims. Finally, the court found that arbitration of FCA retaliation claims does not create an inherent conflict with the FCA's underlying purposes, finding that other federal claims have been held to be arbitrable and no federal statute or policy rendered the claims non-arbitrable. In sum, the court held that the relator's FCA retaliation claims fell within the scope of the arbitration provision because the relator's

claims related to his employment agreement with the defendant. The defendants' motion to compel was granted and the retaliation claim was severed and stayed pending arbitration.

McKinney v. Apollo Group, Inc., 2008 WL 5179110 (S.D. Cal. Dec. 10, 2008)

A *pro se* plaintiff filed an action against his former employer, a university, and other individual defendants, alleging retaliatory termination from employment in violation of the FCA and other claims. The complaint alleged that the defendants violated the Higher Education Act by using sales quotas to determine the pay of enrollment counselors. The plaintiff asserted that by notifying his employer of the alleged illegal activities, he performed a lawful act under the FCA's anti-retaliation provision. The defendants contended that apart from mentioning his concerns to his superiors, the plaintiff did not allege any facts indicating that he performed any investigation or other action in furtherance of an existing *qui tam* action. The defendants also asserted that the claim was barred as they were already involved in an ongoing *qui tam* action with the government regarding identical facts. The United States District Court for the Southern District of California found that the plaintiff failed to bring his FCA claim in the name of the government which was grounds for dismissal. The court also found that neither expressing mere dissatisfaction with one's treatment on the job nor simply investigating noncompliance with regulations was sufficient to state a FCA claim. The court then found that the complaint was devoid of any other facts supporting the alleged retaliatory termination. The court accordingly held that the plaintiff failed to state a claim under the FCA and dismissed the claim.

Mann v. Heckler & Koch Defense, Inc., 2008 WL 4551104 (E.D. Va. Oct. 07, 2008)

The plaintiff brought an original *qui tam* action against his former employer, a rifle manufacturer, alleging a violation of the FCA as well as a defamation claim under state law. The plaintiff alleged that the defendant improperly attempted to induce the U.S. Secret Service to enter into a contract to supply rifles, which in fact, did not meet the government's specifications. The complaint further alleged that after the plaintiff investigated the alleged FCA violation and alerted the defendant about what he had discovered, he was sent home from work for a few weeks and then harassed when he returned. Within weeks after the original complaint had been filed, the defendant suspended the plaintiff without pay, and eventually terminated his employment. The plaintiff then filed an amended complaint, and added and additional retaliation count, alleging that the defendant wrongfully termi-

nated his employment in response to the filing of his original complaint. The defendant moved to dismiss arguing that the plaintiff did not engage in protected activities under the FCA.

The United States District Court for the Eastern District of Virginia held that the plaintiff's investigation and internal complaints were protected activity, particularly since the plaintiff's investigation and internal complaints reasonably notified the defendants about a possible FCA action. The court also found it relevant that the plaintiff complained outside of the chain of command, informed a number of officers and directors about the alleged wrongdoing and took his concerns outside of the company. The fact that an internal investigation resulted from the plaintiff's complaints also supported the plaintiff's contention. Thus, the court denied the defendant's motion to dismiss with respect to the plaintiff's first count of retaliation. However, relying on the U.S. Supreme Court's decision in *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 545 U.S. 409 (2005), the district court found that the filing a complaint for retaliatory discharge under the FCA is not, in and of itself, a protected activity, since section 3730(h) only refers to retaliation for engaging in protected activities under the FCA's substantive provisions—sections 3730(a) and (b)—and does not refer to retaliation for engaging in activities under section 3730(h) itself. Accordingly, the court dismissed the retaliation claim based upon the filing of the plaintiff's original complaint.

U.S. ex. rel. Ellis v. Sheikh, 2008 WL 4761875 (W.D.N.Y. Oct. 31, 2008)

The relator filed a *qui tam* action against her former employer, a medical practitioner, and others. She alleged that the defendants had defrauded the government by using inappropriate billing codes for payment under Medicare and Medicaid. The relator also alleged that her termination by the defendants was in retaliation for her investigation of the defendants' activities. The defendants filed a motion to dismiss for failure to plead fraud with particularity and for failure to state a claim. The United States District Court for the Western District of New York held that the relator had sufficiently pled fraud with particularity. It found that the complaint described the fraud in detail and provided specific illustrative instances. In particular, the court found that the relator's allegations of short and frivolous medical appointments and her allegations of billing statements that included inaccurate billing codes but did not detail the services provided, were sufficient to plead fraud. The court also held that the relator had sufficiently pled that her termination was in retaliation for protected activity. The court observed that the relator, after investigating the defendants' activities, notified her

supervisor regarding the alleged fraud. She then allegedly spoke to government investigators and was subsequently terminated. The court found these facts were sufficient to allege that the defendants were aware of the relator's engagement in protected activity and she was terminated in retaliation.

COMMON DEFENSES TO FCA ALLEGATIONS

A. Not a Condition of Payment

U.S. ex rel. Lobel v. Express Scripts, Inc., 2008 WL 5083115 (E.D. Pa. Dec. 1, 2008)

The relator brought a *qui tam* action against his former employer, a pharmacy benefit manager, alleging that the defendant falsely certified compliance with relevant federal regulations when seeking payment from the government for prescriptions. The government declined to intervene. The defendant moved to dismiss. The United States District Court for the Eastern District of Pennsylvania held that the complaint did not allege that any of the prescriptions were fraudulent or that the government was billed for any unfilled prescriptions. Furthermore, the relator failed to allege that payment was conditioned upon regulatory compliance or that the alleged regulatory violation was material to the government's decision to pay. The court granted the defendant's motion and dismissed the complaint.

U.S. ex rel. Conner v. Salina Regional Health Center, Inc., 2008 WL 4430668 (10th Cir. Oct. 02, 2008)

The relator, an eye doctor, alleged that the medical center he'd worked for violated the FCA by certifying in its annual cost reports that it had complied with all Medicare statutes and regulations, when in fact, it had not. As a result, the relator contended, all of the defendant's Medicare claims were false. The relator also alleged that the defendant medical center violated the FCA and the Anti-kickback statute by encouraging him to hire his own scrub staff when he was dissatisfied with the center's staff, and by agreeing to renew his contract and reappoint him to the medical staff only if he consented to certain conditions—he did not agree, and he was not reappointed. The government declined to intervene in the case and the defendant moved to dismiss under Fed.R.Civ.P. 12(b)(6). The U.S. District Court for the District of Kansas dismissed the relator's FCA allegations, finding that the relator failed to state an FCA claim. The relator appealed to the Tenth Circuit. The Tenth Circuit affirmed the dismissal of the FCA claims, finding that the relator did not allege a recognizable false claim or a kickback under Anti-kickback statute.

Non-Compliance with Medicare Laws Does Not Constitute an FCA Violation

The relator asserted that the defendant's annual cost reports certified that the defendant had complied with the applicable Medicare statutes and regulations, when it had not. This certification, the relators argued, mandated that any failure by defendant to comply with any underlying Medicare statute or regulation rendered the certification false. As a result, any related reimbursement would be fraudulent. Under this theory, the relator alleged over $100 million dollars in damages per year to the government. The Tenth Circuit rejected this argument and noted that none of the Medicare statutes and regulations at issue condition payment upon compliance. Although the defendant's cost reports themselves included language that explicitly condition payment on compliance, the court stated that that language was too general to actually require perfect compliance, at all times, with all Medicare statutes and regulations. The court stated that if it accepted the relator's view, then "any failure by [the defendant] to comply with any underlying Medicare statute or regulation during the provision of any Medicare reimbursable service renders this certification false, and the resulting payments fraudulent." The court determined that such an interpretation stretched the FCA too far, since it did not account for the various Medicare agencies' discretion to determine whether an instance of non-compliance with the Medicare statutes and regulations was material to the agencies' respective decisions to make Medicare payments—if non-compliance does not affect an agency's decision to pay, then it is immaterial and not actionable under the FCA. The court also distinguished conditions of payment from conditions of participation, and determined that "although the government considers substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition to receiving Medicare *payments* for services rendered. (emphasis in original)" The court concluded that the language contained in the defendant's annual cost reports constituted a condition of participation, which is enforceable through administrative means, including removal from the Medicare program. As such, it did not give rise to an FCA claim, since it did not establish that the defendant's claims were false.

Failure to State a Claim Under the Anti-Kickback Statute

The circuit court reached a similar conclusion with respect to the relator's argument that the defendant violated the FCA by violating the Anti-Kickback statute, holding that the relator failed to properly allege a kickback under the Anti-Kickback statute. The relator had argued that the defendant violated the Anti-Kickback statute by forcing him to hire his own scrub staff in exchange for hospital privileges, including Medicare patient referrals. The court rejected this argument, however, finding that the relator was not forced to hire his own staff, since the defendant did not refuse to provide a staff to him. Rather than solicit

a kickback, the defendant merely offered a compromise to the relator, in the face of his growing dissatisfaction with the medical center's scrub staff. The court further rejected the relator's argument that the defendant violated the Anti-Kickback statute by imposing certain conditions that had to be met before the relator would be reappointed to the center's medical staff. The court held that this arrangement did not violate the Anti-Kickback statute because the center's decision not to reappoint the relator treated Medicare patients the same as non-Medicare patients, as it prevented the relator "from operating on any patient at [the defendant's center], not just Medicare patients referred by the hospital or another doctor. It applied equally to a patient paying out of pocket or with private insurance." Since the defendant's actions "involved only [the relator's] underlying appointment on the hospital's medical staff, and not his right to receive Medicare referrals," there was no solicitation of a kickback, no violation of the Anti-Kickback statute, and thus, no violation of the FCA.

Therefore, the Tenth Circuit affirmed the district court's decision to dismiss the relator's FCA claims.

B. Government Knowledge Inference

U.S. ex rel. Burlbaw v. Orenduff, 2008 WL 5046814 (10th Cir. Nov. 28, 2008)

Two relators, former employees of a state university, initially brought a *qui tam* action against the university, alleging that it falsely certified itself as a minority institution eligible for government set aside contract grants. The relators' allegations pertained to grants and contracts that funded a program at the school, through a Department of Defense set-aside program for minority institutions. The relators alleged that the school was not a minority institution, but falsely certified that it satisfied the criteria to be eligible for the set-aside program. In light of Supreme Court precedent clarifying that state agencies—such as state universities—are not considered "persons" under the FCA, the relators amended their complaint and, in lieu of filing suit against the university, sued (in their individual capacity) the high-ranking university employees who applied for benefits under the Department of Defense set-aside program. The court allowed this amendment over the defendants' objection that the Eleventh Amendment barred suits against state officers for performing conduct in the scope of their employment. The government declined to intervene in the case and the defendants moved for summary judgment, contending that qualified immunity protected them from the suit, and also arguing that, based on the facts, no reasonable jury could find that they had violated the FCA. The district court agreed on both fronts, and granted summary judgment in the defendants' favor. The relators appealed, arguing that qualified immunity did not apply to state officials in their individual capacities under the FCA and that there was sufficient evidence in the record to defeat the summary judgment motion. In a 60-page opinion, the Tenth Circuit affirmed the judgment of the district court, holding that the relators failed to produce sufficient evidence of the requisite scienter.

The facts show that the Department of Education maintained a list of minority institutions, which was based on enrollment data furnished by the institutions. Pursuant to a regulatory scheme, the Department of Defense relied on the DoE's list when determining eligibility for its set-aside program. Although it appears that the university did not in fact satisfy all of the criteria for minority institution status, New Mexico State University regularly appeared on the DoE's list of minority institutions. The relators argued that the defendants either had knowledge that the university did not qualify as a minority institution or were without sufficient knowledge to make that determination. Thus, the relators concluded, the defendants submitted false claims when they applied for the set-aside program. While the district court acknowledged that the defendants signed various documents certifying that the university qualified for minority institution status, its found that just as the DoD relied on the DoE's list of minority institutions, so did the defendants—so when the defendants

certified to the Department of Defense that the university was a minority institution, they were merely repeating what the Department of Education had already said. Therefore, the district court opined, even if the defendants submitted false claims based on false certifications, the relators could not demonstrate that they did so knowingly. The district court reasoned that the defendants' failure to independently verify the university's status was likely negligence, but did not constitute a knowing violation of the FCA.

The relators appealed to the Tenth Circuit, which agreed that the relators' FCA claims failed as a matter of law, and affirmed the trial court's grant of summary judgment in favor of the defendants.

Lack of Evidence of Scienter

The appeals court found that the relators could not contradict the district court's conclusions that both the Department of Defense, as well as the defendants, relied on the Department of Education's list of minority institutions, and that the defendants' negligence in not investigating the university's status themselves did not rise to the level of a knowing FCA violation. The court found it significant that the relators did not identify any deposition testimony from any defendant relevant to the issue of scienter. Furthermore, the documents offered as proof by the relators did not support an inference of scienter because they did not show knowledge of possible ineligibility. Accordingly, the court found that the record failed to create an issue of material fact.

Government Knowledge Inference

The court also found that, even if there were issues of fact regarding scienter, the government knowledge inference would preclude the *qui tam* action. The court found that there was both government knowledge of the facts surrounding the alleged fraud and government cooperation in the submission of the alleged false claim. The circuit court determined that the Department of Education had full access to the university's pertinent information, and still repeatedly and consistently determined that the university qualified as a minority institution. Furthermore, the court observed that, pursuant to the statutory/regulatory scheme in place, the Department of Defense blindly relied on the Education Department's determinations and consequently invited the university to apply for its set-aside program. Moreover, the court noted that the relators produced no evidence showing that the defendants provided inaccurate or incomplete information to the Department of Education. Thus, the court concluded, both the Education Department and Defense Department "were aware of the same universe of facts to which defendants were aware when defendants certified [the university's] minority institution eligibility." Accordingly, the appeals court concluded that there was a government knowledge inference that created a strong presumption that the defendants did not knowingly submit false claims, and held that the district court's grant of summary judgment in the defendants' favor was proper.

Qualified Immunity

Since the Tenth Circuit was able to determine that the relators' allegations failed as a matter of law, the court found it unnecessary to decide the defendants' cross-appeal, in which they argued that, as state officials being sued in the individual capacity, they, like the university, are not "persons" under the FCA, and that the Eleventh Amendment bars the relators' claims against them, since the university was the real party in interest in the case. As a result, the court left the qualified immunity issues for another day.

In re Pharmaceutical Industry Average Wholesale Price Litig., 2008 WL 4823968 (D. Mass. Nov. 5, 2008)

The government brought an FCA case alleging that the defendant pharmaceutical company fraudulently caused the government to overpay for drugs under the Medicare and Medicaid Programs. In particular, the government alleged that the defendant inflated prices for certain drugs in a pricing compendium used to set Medicare and Medicaid reimbursement rates. During discovery, the government asserted deliberative privilege on a number of documents relating to the government's knowledge of the alleged inflated pricing. The defendant moved to compel the production of these documents. The United States District Court for the District of Massachusetts issued a margin order regarding the discovery dispute and then referred the matter to a magistrate judge after both parties objected. The magistrate conducted an *in camera* review of the documents. After review, the court ordered production of the documents relevant to the defendant's government knowledge defense.

Government Knowledge

The defendant asserted that documents regarding the government's knowledge were relevant to whether the government justifiably relied on the defendant's prices and whether the government was misled. The government contended that the documents were privileged and that the defense of government knowledge was applicable only if the government had communicated its knowledge to the defendant. The court first held that there are exceptions to the government's deliberative privilege and that courts should employ a balancing test to determine when to compel disclosure. It then held that the government's prior knowledge of the alleged misrepresentation could be a defense to the FCA claims. Specifically, knowledge could be relevant to determine the falsity element of the claim as well as the defendant's state of mind. The court also found that the knowledge would be relevant to the government's common law fraud claim. Accordingly, the court held that the defendant was entitled to the discovery of the documents to ascertain the extent of the government's prior knowledge of the alleged fraud.

C. Statute of Limitations

U.S. ex rel. Sanders v. North American Bus Industries, Inc., 2008 WL 4793577 (4th Cir. Nov. 5, 2008)

The relator filed a *qui tam* action against his former employer—a manufacturer of transit buses—as well as the company's accountant. He alleged that the company falsely certified that its buses were eligible for federal "Buy America" subsidies and falsely described its imported bus shells for reclassification under the Harmonized Tariff Schedule of the United States (HTSUS). The relator also alleged retaliatory discharge. The government declined to intervene. The United States District Court for the District of Maryland granted summary judgment in favor if the defendants, holding that the claims regarding alleged false certification, false description for reclassification, and wrongful discharge were time barred. The district court also found that the relator failed to establish his claim of underpayment of duties. The relator did not oppose the dismissal of the retaliatory discharge claim, but appealed the other causes of action to the Fourth Circuit. The circuit court affirmed the lower court's decision, and held that the ten year limitations period under Section 3731(b)(2) only applied in cases where the federal government is a party. It also found that the defendants' alleged misrepresentations were not material to the reclassification under the HTSUS.

Claims Barred by the Statute of Limitations

The relator argued that the ten-year limitations period under Section 3731(b)(2) applied to all civil actions under the FCA. The Fourth Circuit disagreed, holding that the limitation period was extended to ten years only in cases where the government itself was a party. The court found that any other interpretation of the statute would be problematic. Specifically, it found that the relator's argument would produce a bizarre scenario in which the limitations period would depend on the knowledge of a nonparty to the action. The court also noted that the relator's interpretation would also allow relators to sit on their claims in order to allow more false claims to occur, thereby increasing their potential recovery. This delay would render the six-year limitations period under Section 3731(b)(1) superfluous and possibly cause the government to lose its ability to prosecute fraud under 18 U.S.C. §§ 287, 3282. Moreover, the court stated that the phrase "a civil action" in Section 3731(b)(2) does not encompass all FCA claims. Relying on *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 545 U.S. 409 (2005), the court found that when "a civil action" is read in context with the whole statute, it becomes clear that the extended limitations period only applies in actions where the government is a party. Accordingly, the district court's opinion was affirmed.

Failure to State a Claim

The relator alleged that the defendants fraudulently caused the government to reclassify their imported bus shells, allowing the defendants to obtain duty free treatment. Specifically, he alleged that the defendants misrepresented information in the protest filed to change the company's classification under HTSUS. The court found, however, that the relator failed to state a valid claim because the alleged misrepresentations were not material to the government's reclassification decision. Specifically, since the government took a holistic view in making its determination, the court found that the minute alleged misrepresentations could not have materially influenced its decision. Accordingly, the court affirmed the grant of summary judgment on those claims.

Finally, the relator contended that the defendants did not include engineering and technological services fees in the value of the bus shells and therefore, underpaid its duties. The court held that since the government determined that the bus shells qualified for duty free treatment, the relative value of the bus shells was immaterial as no duty was due under either value. The relator also creatively argued that since the defendants could not recover all of the duties paid under the earlier classification due to the limitations period, the government suffered a loss in the additional amount it would have received and kept under the unrefunded duties. The court rejected this argument because the defendants actually had no obligation to pay any duty. It held that the fact that the government did not receive an additional windfall in the unrefunded duties could not be the basis for an FCA claim and affirmed the grant of summary judgment.

FEDERAL RULES OF CIVIL PROCEDURE

A. Rule 9(b) and Pleading Fraud with Particularity

U.S. ex rel. Rafizadeh v. Continental Common, Inc., 2008 WL 5265188 (5th Cir. Dec. 19, 2008)

The plaintiff filed a *qui tam* action, alleging that the defendant property owners and managers overcharged the Louisiana Departments of Social Services and Health and Hospitals (the "Departments") under several lease agreements. The relator argued that since the Departments submitted budgets that included the lease agreements to the federal government for funding, they caused false claims to be submitted to the federal government for payment. The government declined to intervene. The defendants moved to dismiss, arguing that the complaint inadequately pled presentment and failed to plead fraud with particularity. The United States District Court for the Eastern District of Louisiana granted the motion to dismiss. The district court then denied the defendants' motion for attorneys' fees. Both parties appealed. The Fifth Circuit affirmed, holding that the complaint failed to identify the particulars of the alleged false statements and any impact on the government's decision to pay. The Fifth Circuit also affirmed the denial of attorneys' fees because the plaintiff's action was not clearly vexatious or brought only for the purpose of harassing the defendant.

Particularity Requirement

The court first held that the complaint failed to plead presentment with particularity. It found that the plaintiff failed to describe the allegedly false statements, failed to identify who prepared the budgets, and failed to state the role the budget played in obtaining funding. Further, it found that the mere incorporation of false claims into a budget did not satisfy Rule 9(b)'s pleading requirements. Accordingly, the court upheld the dismissal of the FCA claims.

Attorneys' Fees

After the district court dismissed the plaintiff's complaint, the defendants moved for attorneys' fees. The defendants argued that the plaintiff had previously filed four suits against them, that the plaintiff had threatened revenge against the defendants, and that the complaint was frivolous, as it was based on vague factual allegations. The Fifth Circuit, however, affirmed the district court's denial of attorneys' fees, noting that the *qui tam* issues had not been raised in the earlier

state suits. Further, the court held that although the plaintiff had failed to plead with sufficient particularity, the *qui tam* claims in the present action were non-frivolous.

U.S. ex rel. Kennedy v. Aventis Pharmaceuticals, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008)

The relators brought a *qui tam* action against a pharmaceutical company, alleging the illegal marketing of Lovenox for off-label uses not approved by FDA. The government declined to intervene. The defendant moved to dismiss the complaint. The United States District Court for the Northern District of Illinois granted the motion in part and the relators filed a second amended complaint. The defendant again moved for dismissal. The court then allowed discovery by the relators to identify specific false claims. After completion, the relators filed a third amended complaint. This complaint alleged violations of the Anti-Kickback Statute and that the defendant's marketing scheme caused hospitals to submit false claims to the government for reimbursement of off-label uses of Lovenox. The relators also alleged that cost reports submitted to the government amounted to false records used to get fraudulent claims paid by the government. The defendant moved for dismissal for failing to allege fraud with particularity. The court dismissed the complaint, holding that the relators failed to identify specific instances supporting their allegations. The motion to dismiss was accordingly granted.

Falsity Element

The relators alleged that the defendant's marketing scheme caused the hospitals to submit false claims for reimbursement. Though the relators identified specific prescriptions for off-label uses, they did not qualify as false claims because they were immaterial to the government's decision to pay. The reimbursements paid by the government were based on a fixed prospective payment system based on national average for the costs of treating a particular illness. Hence, individual charges on a patient bill were immaterial to the government's decision to pay. The court accordingly held that the relators failed to properly allege fraud.

The relators also alleged that the hospitals claimed compensation above the fixed Medicare payment for patients with extraordinarily costly treatments in cases where Lovenox was prescribed. While the court acknowledged this could be a false claim, it held that the relators failed to allege the claim with particularity. After allowing the relators discovery on this claim, the court found that the relators had failed to identify any particular instance of this claim or even any off-label uses of Lovenox.

The court then addressed the allegation that the defendant had caused fraudulent cost reports to be submitted to Medicare. The court held that submission of a cost report was too attenuated to be a false claim because a cost

report would only be used to set future reimbursement rates and that an individual cost report is only a small part of the data used to calculate Medicare reimbursement. The court also found that the relators failed to identify a particular cost report containing an off-label use of Lovenox. Accordingly, it dismissed this claim because it was not pled with particularity.

Lastly, the relators alleged that the defendant violated the Anti-Kickback Statute by inducing hospitals and doctors to prescribe Lovenox for off-label uses. The court held that the relators failed to identify any specific false certification of compliance by the hospital as a result of receiving kickbacks from the defendant. The court also noted that the relators were unable to identify any link between the allegedly false certification of compliance with the Anti-Kickback Statute and the payments made by the government. The complaint was accordingly dismissed for failure to meet the particularity standards.

U.S. ex rel. Shurick v. Boeing Co., WL 5054739 (M.D. Fla. Nov. 21, 2008)

The relator filed a *qui tam* action against his employer, a manufacturer of commercial and military aircraft, alleging that the defendant did not provide properly fitted respirators to its employees during the performance of a government contract. The government declined to intervene. The defendant moved to dismiss on the grounds of failure to plead fraud with particularity and failure to plead actual submission of false claims. The United States District Court of the Middle District of Florida held that the relator could not state a claim for relief under the FCA on a theory of alleged safety violations. The defendant's motion to dismiss was granted and the case was dismissed with prejudice.

The relator alleged that the defendant entered into a contract with NASA for various services. While providing services under the contract for the defendant, the relator allegedly was exposed to anhydrous ammonia, a toxic substance. The relator alleged that, as a safety measure, the defendant was to provide fitted respirators to certain employees, and that it failed to do so, in violation of the applicable safety regulations. The relator claimed that the safety violations created a false claim because the government did not obtain the safe and lawful services which were required under the contract.

Particularity Requirement

The court found that there was no allegation that the defendant failed to deliver the services under the contract or that the defendant improperly billed the government for any services. Instead, it found that the relator only alleged that the defendant's practices were allegedly unsafe to some of its employees in violation of certain government regulations. The court observed that the relator did not allege the submission of any claims that expressly conditioned payment on a certification

that the services were performed in compliance with any safety regulations. Furthermore, the court noted that even if the defendant's conduct amounted to a breach of contract, it did not give rise to an FCA claim based on a theory of alleged safety violations. Thus the defendant's motion to dismiss was granted.

Barys ex rel. U.S. v. Vitas Healthcare Corp., 2008 WL 4768856 (11th Cir. Nov. 3, 2008)

The relators filed a *qui tam* action against hospice service providers. They alleged submission of false claims and fraudulent certification of patients for the Hospice Medicare Benefit (HMB). The amended complaint was dismissed with prejudice by the United States District Court for the Southern District of Florida for failure to plead fraud with particularity. The relators appealed to the Eleventh Circuit. The Eleventh Circuit held that the conclusory allegations in the complaint were not supported by any factual allegations and affirmed the district court's decision. The court also held that the relators were not entitled to a relaxed pleading requirement.

Particularity Requirement

The relators alleged that the defendants fraudulently certified that patients were eligible to receive HMB. In particular, they alleged lengthy hospice stays, aggressive discouragement of decertification of non-terminally ill patients, promotion of HMB certification of patients without a physician's judgment, willful blindness to information regarding eligibility for HMB, and managerial instruction that patients not be discharged from HMB. The Eleventh Circuit, however, found that the facts offered by the relator failed to explain how the allegations caused fraudulent activity. Specifically, the defendants' training guide that directed physicians to be cognizant of good symptoms in their diagnosis did not suggest that any specific prognosis was fraudulent. Similarly, the court found, requiring an extra layer of physician review after an initial assessment, which allegedly caused extended hospice stays pending assessment, did not amount to fraudulent recertification. The court also held that the relators failed to allege any instances of how cash bonuses for maintaining high patient populations caused fraud. Accordingly, the court affirmed the dismissal.

Relaxed Pleading Requirement

The relators alternatively contended that a relaxed pleading standard should apply, because they did not have access to the medical records required to specifically demonstrate the fraudulent re-certifications. The court disagreed because the relators alleged that they had first-hand knowledge of the fraudulent activity but still failed to allege the factual basis for their claims. Thus, the court held that the relators were not entitled to a relaxed pleading standard.

Unterschuetz v. In Home Personal Care, Inc., 2008 WL 4572512 (D. Minn. Oct. 14, 2008)

The relator filed a suit against her former employer, a home care service provider, its owner, and the accountant of the company. The complaint alleged, among other things, FCA violations, accusing the defendants of receiving overpayments from the government by fabricating records of reimbursable services. The complaint also alleged that, as a result of the relator's discovery, she was terminated from her job. The defendants moved to dismiss the FCA claims. The United States District Court for the District of Minnesota dismissed the FCA claims after finding that the claims were not pled with particularity. Specifically, the court observed that none of the relator's FCA claims contained any specific details of fraud. The relator did not identify specific timecards alleged to be falsified, failed to specify the dates or presentment of false billings, the sum allegedly obtained by fraud, or any specific instances where the defendant failed to refund the government. Thus, the FCA claims did not meet the particularity requirements of Fed.R.Civ.P. 9(b), and were dismissed.

B. Rule 12(b)(6) Failure to State a Claim upon which Relief Can Be Granted

U.S. ex rel. Brown v. Aramark Corp., 2008 WL 5386445 (D.D.C. Dec. 29, 2008)

The relator, who became the substitute plaintiff, litigated a *qui tam* action originally filed by her husband, who died before the case was unsealed. The complaint was filed against a contract food service provider and its healthcare support service, and alleged that the defendants contracted with an acute care hospital to manage their food service department. The complaint further alleged that the defendants violated the FCA by improperly billing the federal government for recycled food and resources used at private functions unrelated to Medicare, and that the defendants created fraudulent and inflated cost reports and submitted false claims to the hospital, which were ultimately submitted to the government for reimbursement as Medicare and Medicaid related expenses. The complaint also alleged that the food service provider terminated the original relator from his employment, in violation of the FCA's anti-retaliation provision. The government declined to intervene. The defendants moved to dismiss for failure to state a claim. The relator sought a stay of decision on the retaliation claim, pending discovery. The United States District Court for the District of Columbia held that the relator failed to plead fraud with particularity and hence failed to state a claim. The court also concluded that the relator's complaint, on its face, "failed to allege facts sufficient to state a viable claim for retaliation under section 3730(h) of the FCA." Accordingly, the defendants' motion was granted.

Failure to State a Claim

The court held that the relator's complaint failed to plead fraud with particularity as required by Fed.R.Civ.P. 9(b). It noted that the complaint did not identify a single cost report containing false information or any specific instance of submission of a fraudulent cost report seeking payment from the government. Furthermore, the complaint failed to allege the date of cost reports or their submission, the names of employees involved in the alleged fraud, the content of the reports, or an actual presentation of false claims to the government for payment. The court observed that although the complaint alleged fraud, it failed to identify the circumstances necessary to state a claim. Accordingly, the court dismissed the claims under Section 3729(a)(1) and (2) of the FCA.

Anti-Retaliation Claim

The court also dismissed the retaliation claim, and held that the original relator's claim that he refused to participate in the defendants' allegedly illegal conduct did not amount to "protected activity" under the FCA. The court held that

the complaint failed to demonstrate that the original relator investigated the alleged fraud or that the defendants had the knowledge of his alleged investigatory activities. Accordingly, the court rejected the request to stay decision on the retaliation claim and held that the complaint failed to allege facts sufficient to state a claim for retaliation.

U.S. ex rel. Sanders v. American-Amicable Life Ins. Co. of Texas, 2008 WL 4724719 (3rd Cir. Oct. 29, 2008)

The relator filed a *qui tam* action against an insurance company and bank that sold life insurance policies to military personnel. The relator had been employed as an insurance agent for the insurance company, and alleged that the defendants violated the False Claims Act by engaging in an illegal scheme to sell life insurance policies, disguised as "savings plans," to military personnel. The suit specifically alleged that the defendants misused the military's allotment system, a method of direct deposit, so that once a military service member agreed to participate in the plan, the defendant bank would withdraw funds from the person's military paycheck to be directly deposited with the defendant insurance company. The relator's complaint alleged that the defendants' program was disguised as a savings program as a means to circumvent various military regulations, including regulations governing the use of the military's allotment system to pay insurance premiums. The complaint concluded that the defendants violated the FCA by preparing false claims—the military allotment forms—and causing various members of the military to submit those false claims to the U.S. Government, which in turn diverted various amounts of military salaries (alleged to be millions of dollars) to the defendants. The government declined to intervene, but did sue the insurance company under the Fraud Injunction Statute, alleging the same facts as those alleged by the relator. That suit resulted in a $10 million settlement to the defrauded military personnel and an agreement by the insurance company to change the way it marketed to members of the military. The defendants moved to dismiss for failure to state a claim and that motion was granted by the United States District Court for the Eastern District of Pennsylvania. The relator filed an appeal. The Third Circuit affirmed the decision of the district court because the relator failed to allege a claim against government money or property.

Failure to Establish a False Claim

The district court held that the relator did not plead the existence of a false "claim," since the defendants' alleged conduct could not possibly have caused an economic loss to the United States. The Third Circuit affirmed, finding that the relator did not show that a claim had been submitted to the Government, since the defendants did not make, and did not cause anyone else to make, a request

for Government money. The court determined that the defendants did not make a claim against federal funds, but merely sought funds that were released by the Government to pay its military employees' salaries. The court noted that "it was the defrauded military personnel who furnished or made money available to the defendants—and not the federal government—because it was those personnel who decided to participate in the fraudulent 'savings programs.'" Although the circuit court made no explicit statement, it appears that the court's rationale was that government employees' salaries are private funds, and not "government money or property," for FCA purposes. Simply stated, no federal funds were expended because the allotment payments were not made on behalf of the government. Since the circuit court found that the relator did not allege a "claim," he could not maintain an FCA action. Therefore, the court held, the relator's complaint did not state a claim for relief and was properly dismissed.

***See U.S. ex rel. Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 2008 WL 5411717 (3rd Cir. Dec. 30, 2008), at page 37.**

***See U.S. ex rel. Sanders v. North American Bus Industries, Inc.*, 2008 WL 4793577 (4th Cir. Nov. 5, 2008), at page 27.**

LITIGATION DEVELOPMENTS

A. Appellate Issues

U.S. ex rel. Rodriguez v. Our Lady of Lourdes Med. Ctr., 2008 WL 5411717 (3rd Cir. Dec. 30, 2008)

The relators, filed a *qui tam* action against the medical center that had formerly employed them as nurses, alleging that the defendant operated federally funded medical services programs for the homeless, poor and uninsured, and that beneficiaries of the programs could have prescriptions filled by persons who were not licensed pharmacists under New Jersey law. The relators contended that this practice amounted to a false certification of compliance with state law, and thus, a violation of the FCA. The government declined to intervene in the case, and the defendants moved to dismiss, under Federal Rules of Civil Procedure 12(b)(6) and 9(b). The district court granted the motion, finding that the relators failed to allege a violation of the FCA, presumably because they did not identify any instances of false claims being submitted. The relators appealed to the Third Circuit, arguing that they adequately pled an FCA violation under an implied false certification theory by alleging that the defendant received payments without disclosing that it had violated New Jersey law.

The Third Circuit first noted that the relators' appeal was filed 56 days after the district court entered judgment. Thus, the circuit court initially needed to determine whether the relators' appeal was timely, pursuant to Federal Rule of Civil Procedure 4(a)(1), which provides for a general 30-day appeals period and only extends that period to 60 days when the United States is a party. The Third Circuit noted that the Fifth, Seventh and Ninth Circuits apply the 60-day deadline even when the government does not intervene, while the Second, and Tenth Circuits apply the 30-day deadline under those circumstances. The Third Circuit agreed that the 60-day deadline should apply, because even if the government does not intervene, it is still the "party" to the action, as the government's name is still on the caption, the government retains the right to stay involved in the litigation and settlement of the case, and the government is entitled to at least 70 percent of any recovery. The court also observed that applying the 60-day period avoids confusion.

The court then determined that the district court failed to acknowledge the relators' theory of liability—that the defendant falsely certified that it complied with applicable state law in connection with its receipt of federal funds. The court noted, though, that the false certification theory of FCA liability—both express and implied—has not been adopted by the Third Circuit. The

court also stated that even if the false certification theory had been adopted in the Third Circuit, the relators' case still should have been dismissed, finding that the relators failed to assert that the defendant's receipt of federal funds was conditioned on—or at least relevant to—its compliance with the regulations governing pharmacists' licenses. Consequently, the Third Circuit affirmed the district court's dismissal of the relators' complaint for failure to state a claim.

U.S. ex rel. Shutt v. Community Home and Health Care Services, Inc., 2008 WL 5220273 (9th Cir. Dec. 16, 2008); *U.S. ex rel. Shutt v. Community Home and Health Care Services, Inc.*, 2008 WL 5233478 (9th Cir. Dec. 16, 2008)

The relator brought a *qui tam* action against a home health service provider and its owner, alleging Medicare fraud. The government also brought a criminal action arising out of the same fraud, in which the owner entered a guilty plea and agreed to pay full restitution. Subsequently, the government intervened in the *qui tam* action. The United States District Court for the Central District of California granted the government's motion for summary judgment and trebled the damages admitted by the owner in her plea agreement. The government's non-FCA claims were dismissed without prejudice. The district court, however, retained jurisdiction over the issue of relator's share. The defendant appealed the district court's summary judgment ruling to the Ninth Circuit, arguing that the district court's judgment subjected her to double jeopardy and was an excessive fine under the Eighth Amendment. The Ninth Circuit first determined that the district court's judgment was final and appealable, notwithstanding the fact that the district court retained jurisdiction over the issue of relator's share. The circuit court then affirmed the district court's judgment with respect to damages under the FCA.

Appeal When District Court Retains Jurisdiction over Collateral Issues

Although neither party disputed appellate jurisdiction, the Ninth Circuit's opinion focused primarily on whether it had jurisdiction to hear the appeal. The circuit court recognized that the district court's grant of summary judgment was final and appealable, but noted that the district court still retained jurisdiction over the relator's share issue. It noted that the issue of a relator's share involved distinct factual inquiries than the main action and that the relator's share guidelines are generally not relevant to a defendant's FCA liability. The Ninth Circuit also observed that relator's share issues might become moot if the appeals court determines that the underlying FCA claim should have been dismissed or that summary judgment should have been granted in the defendant's favor. Hence, the court decided that the issue of a relator's share was collateral to

the main action and held that the judgment on the merits of an FCA claim is a separate, final and appealable decision even when the issue of a relator's share is still pending. Finally, without further explanation, the circuit court stated: "[w]e therefore reach the merits of this appeal and affirm the district court's grant of summary judgment for the reasons stated in an *unpublished memorandum disposition* filed herewith."

Caluclation FCA Damages

In the unpublished memorandum disposition, the Ninth Circuit noted that, prior to the FCA litigation, the owner pled guilty to various health care fraud charges, and agreed to make restitution. On appeal, the owner challenged the district court's judgment in the FCA case on the grounds that the FCA case subjected her to double jeopardy, in violation of the Fifth Amendment, and both defendants argued that the district court's judgment violated the "excessive fines" provision of the Eighth Amendment. The circuit court observed that the owner's plea agreement—which she said she voluntarily agreed to after carefully discussing the matter with her attorney—specifically stated that she agreed "not to make any double jeopardy challenge to any administrative or civil forfeiture or civil fraud action arising out of the course of conduct that provides the factual basis for the [criminal] information." The court further held that a defendant cannot maintain a claim for double jeopardy, simply because she did not know the severity of the civil penalties against her at the time of her plea agreement. The court stated that this defendant "need not have been aware of all the possible circumstances that might ensue from the waivers obtained in the plea agreement for the waivers to be knowing and voluntary." In addition, with respect to the defendants' argument that the damages and penalties assessed by the district court were excessive, the circuit court found that the single $5,500 civil penalty and the $1.8 million in treble damages were not grossly disproportionate to the offense, as the district court found that the government's actual damages due to false claims were considerably higher than what was agreed to as part of the criminal plea agreement and may have even exceeded the treble damages award in the civil case, especially once the government's costs of investigating and litigating the fraud are factored in. Even if the district court's damages award exceeded the government's actual damages, the Ninth Circuit continued, "[g]iven the seriousness of the offense, the resulting non-pecuniary harm caused to the government, and the need to deter difficult-to-detect fraudulent claims, Congress's decision to impose a penalty that may sometimes substantially exceed actual damages is not unreasonable." Finally, the court found that the civil and criminal proceedings could have resulted in a maximum penalty of over $2 million and ten years in prison. Therefore, the damages and penalties assessed were below the statutory maximum, and thus, not excessive. Accordingly, the court affirmed the district court's summary judgment decision.

B. Calculating Damages and Civil Penalties

U.S. v. Incorporated Village of Island Park, 2008 WL 4790724 (E.D.N.Y. Nov. 3, 2008)

The FCA claim arose from the alleged misuse of HUD funds in a Community Development Block Grant Program and a section 235 Housing Program. The government's motion for summary judgment on its FCA claims was granted. The matter was then referred to a magistrate judge, who issued a report and recommendations regarding money damages and penalties. Specifically, the magistrate recommended that the government was entitled to double the amount of damages before deducting any compensatory payments. The Village of Island Park then filed a motion for reconsideration of the original order granting summary judgment. It also objected to the magistrate judge's damages calculation, arguing that it violated the Eight Amendment's Excessive Fines Clause and that it improperly calculated which damages should have been doubled. The court denied the motion for reconsideration, concluding that there was no equitable consideration in favor of it. It then denied the motion objecting to the damages calculation because it found the damages were completely remedial in nature. In particular, the court held that double damages under the FCA were remedial because the additional damages were necessary in order to make the government whole. Hence, the double damages did not violate the Eighth Amendment's Excessive Fines Clause. The court then held that the magistrate correctly calculated the damages. It held that the make-whole purpose of the Act was best served by doubling the government's damages before deduction of any compensatory payments. Accordingly the court denied the defendant's objection and adopted the magistrate judge's report and recommendations.

***See U.S. v. Eghbal*, 2008 WL 5101943 (9th Cir. Dec. 5, 2008), at page 7.**

***See U.S. ex rel. Shutt v. Community Home and Health Care Services, Inc.*, 2008 WL 5220273 (9th Cir. Dec. 16, 2008); *U.S. ex rel. Shutt v. Community Home and Health Care Services, Inc.*, 2008 WL 5233478 (9th Cir. Dec. 16, 2008), at page 38.**

C. Costs and Attorney's Fees

U.S. ex rel. Woodruff v. Hawaii Pacific Health, 2008 WL 5115051 (D. Haw. Dec. 5, 2008)

The plaintiffs filed a *qui tam* action against their former employers, alleging submission of false claims for procedures performed by unauthorized nurses or without the required physician supervision. The plaintiffs also alleged anti-retaliatory termination from their employment. The government declined to intervene. The defendants' motion for summary judgment was granted and, pursuant to Fed.R.Civ.P. 54(d)(1). The defendants filed a bill of costs. The plaintiffs objected to the bill of costs, arguing that the FCA, in anti-retaliation claims, precluded the award of costs under Fed.R.Civ.P. 54(d)(1) to defendants. The United States District Court for the District of Hawaii, however, noted that the plaintiffs' action was dominated by *qui tam* claims, and held that, while section 3730(d)(4) references "reasonable attorneys fees and expenses," nothing in section 3730(d)(4) precludes or displaces awards of costs under Fed.R.Civ.P. 54(d)(1). Thus, the court held that the defendants were entitled to costs to the extent they prevailed on the *qui tam* claims.

U.S. ex rel. Marchese v. Cell Therapeutics, Inc., 2008 WL 4950938 (W.D. Wash. Nov. 18, 2008)

After settling a *qui tam* action against a biopharmaceutical company, the relator filed a motion for reasonable attorney fees and costs. Although the United States District Court for the Western District of Washington granted the relator's motion, it denied many of the relator's claimed costs and fees. The court first noted that although the relator's primary counsel was from a different jurisdiction, the relator hired local counsel to assist in his representation. Consequently, the court required the relator to use the local counsel's billing rates to calculate attorney's fees. The court also held that the relator was not entitled to attorney fees that were not related to the issues on which the relator prevailed. As a result, the court denied fees that (1) were incurred after the settlement with the defendant; (2) related to prosecution of defendants not included in the settlement; and (3) related to the relator's employment claims against the settling defendant. Moreover, the court found that the costs the relator claimed for retaining co-counsel were excessive, since the relator's original counsel already had extensive litigation experience. For this reason, the court also determined that the claimed costs incurred for retaining an outside trial consultant were unreasonable. Additionally, the court capped all travel costs at the per diem rate allowable for government attorneys, since the case was a *qui tam* action. Furthermore, the court found the relator's requested fees related to preparing the fee motion

at issue were intolerably high, and held that the substance of the motion did not justify the number of hours claimed—the parties were ordered to meet and confer in order to recalculate the fees associated with filing the fee motion. Finally, the court did allow fees for time spent in defending the relator against criminal liability, noting that those efforts related to the *qui tam* action and that the relator "was required to present his position to the government and demonstrate that he should not be considered a target of the investigation in order to assist the government in its prosecution."

***See U.S. ex rel. Rafizadeh v. Continental Common, Inc.*, 2008 WL 5265188 (5th Cir. Dec. 19, 2008), at page 29.**

D. *Pro Se* Relators

Jones v. The Park at Lakeside Apartments, 2008 WL 4820083 (S.D. Tex. Nov. 5, 2008)

The relators filed a *qui tam* action acting as *pro se* litigants. The government declined to intervene. The United States District Court for the Southern District of Texas held that in a *qui tam* action the actual party in interest is the government. It found that even when the government declines to intervene, it is still bound by the outcome of the action. Accordingly, the court held that relators could not bring their FCA claims *pro se* because government interests were still at risk.

E. Identifying Federal Government Funds

U.S. v. Midwest Transport, Inc., 2008 WL 4981076 (S.D. Ill. Nov. 24, 2008)

The government brought an action against a transport company alleging that the defendant submitted fraudulent fuel certification forms to the United States Postal Service. Specifically, the government alleged that the defendant's payment certification forms failed to disclose certain discounts the defendant obtained for fuel purchases. The government also asserted common law claims of payment by mistake and unjust enrichment. The defendant moved to dismiss, arguing that the FCA does not apply to claims submitted to the U.S. Postal Service. The defendant asserted that the Postal Reorganization Act specifically exempts the Postal Service from FCA coverage and that Postal Service funds are distinct from U.S. Treasury funds, making the FCA inapplicable. The United States District Court for the Southern District of Illinois denied the defendant's motion, and held that the Postal Service is not exempted from the FCA. The court found that, notwithstanding its quasi-commercial nature, the Postal Service is still a federal agency, and that Postal Service funds are not distinct from the U.S. Treasury. Therefore, the court concluded that the U.S. Postal Service is protected by the FCA, and the defendant's motion to dismiss was denied.

Judgments & Settlements

OCTOBER 1, 2008–DECEMBER 31, 2008

Armor Holdings Products LLC (D.D.C. October 7, 2008)

To resolve allegations that they intentionally and deceptively defrauded the United States, Armor Holdings Products LLC has agreed to pay the United States $30 million. The United States alleged that Armor Holdings manufactured and sold substandard Zylon bullet-proof vests despite its knowledge that Zylon material had rapid degradation qualities. Additionally, the United States alleged that these bullet-proof vests were unsuitable for ballistic use. The two types of Zylon vests sold by Armor Holdings to the United States had been produced by Toyobo Co. Ltd., who had previously been sued by the United States for similar allegations. Thus, the $30 million settlement is part of a larger, more pervasive investigation into the practice of the body armor manufacturing industry. Three previous settlements total roughly $16 million for similar allegations against Zylon body armor manufacturers. The allegations and ultimate settlement were brought about by an ongoing investigation by the Justice Department's Civil Division, the General Services Administration Office of the Inspector General, the Department of Homeland Security Office of Inspector General, the Defense Criminal Investigative Service, the Air Force Office of Special Investigations, the Department of Energy Office of the Inspector General, the U.S. Agency for International Development Office of the Inspector General, among other agencies.

West Jefferson Medical Center (E.D. La. October 17, 2008)

West Jefferson Medical Center has agreed to pay the United States and the State of Louisiana $3.3 million to settle allegations that the hospital fraudulently billed Medicaid programs. The allegations put forth by the United States suggested that Western Jefferson Medical Center had deceived the Medicaid program into believing that its Pediatric Intensive Care Unit (PICU) could treat patients with specific critical care services, when it realistically could not. This alleged behavior took place between March of 1998 and October of 2003 and resulted in the collection of illegitimate reimbursements by the Medicaid program on the part of Western Jefferson Medical Center. The allegations were initially filed by Leslie Klemm, the relator, who served as a nurse in Western Jefferson. Klemm will receive a total of $627,000 as her share of the settlement between the United States, Louisiana, and West Jefferson. The investigation was led in a cooperative fashion by the Justice Department's Civil Division, HHS-OIG, the Office of the U.S. Attorney in New Orleans and the Louisiana Attorney General's Medicaid Fraud Control Unit.

Cooper University Hospital and St. Joseph Healthcare System Inc. (D.N.J. October 21, 2008)

Cooper Hospital and St. Joseph's Healthcare System Inc. agreed to pay the United States $3.85 million and $1.75 million respectively to settle allegations that both defendants falsely inflated Medicare and Medicaid patient charges. The alleged result was excessive outlier reimbursements from the United States government in violation of the False Claims Act. Cooper Hospital is a major teaching hospital in Southern New Jersey and St. Joseph Healthcare System Inc. manages a number of medical facilities across northern New Jersey. The defendants allegedly accepted and applied outlier inflation schemes devised by Besler Consulting and Shusko Consulting; the implementation of which purportedly resulted in the excess payment of millions of dollars to which the defendants were not entitled. Besler Consulting previously settled allegations in March 2008 for devising the previously mentioned schemes. The relator, Anthony J. Kite, served as an independent hospital consultant in New Jersey and filed the qui tam suit in 2005. He received $654,000 from Cooper Hospital and $481,250 from St. Joseph's Hospital as his share stipulated in the settlement agreements. A number of other hospitals in New Jersey and Pennsylvania who allegedly implemented similar schemes from Besler and Shusko have settled these allegations for more than $22 million thus far. Investigations were handled by the Justice Department's Civil Division, Commercial Litigation Branch; the U.S. Attorney's Office for the District of New Jersey, Affirmative Civil Enforcement Unit; the U.S. Attorney's Office for the Eastern District of Pennsylvania; the Department of Health and Human Services, Office of Inspector General and Office of Counsel to the Inspector General; the Centers for Medicare and Medicaid Services; and the FBI.

Washington Savannah River Company (D.S.C. October 31, 2008)

Washington Savannah River Company (WSRC) recently resolved allegations of submitting false claims to the United States by agreeing to pay approximately $2.4 million. Throughout the course of negotiations between WSRC and the Department of Energy (DOE) over employee pensions at their Savannah River Site, there were allegedly considerable estimated increases which would require additional input to the WSRC pension fund. WSRC allegedly failed to inform the DOE and following the establishment of the contract, WSRC received over $1 million in equitable adjustments. DOE purportedly believed that WSRC was unaware that they would need such adjustments and thus granted the equitable adjustments. As anticipated, the requirements for WSRC's pension fund contribution continually increased until ultimately WSRC requested another equitable adjustment of almost $36 million. Another stipulation within the settlement terms was that WSRC drop the pending $36 million equitable ad-

justment request. The allegations were grounded in the belief that WSRC had specific knowledge of the predicted rise in necessary contribution to pension funds. Had the rise in cost of pension funds been wholly unanticipated by both parties, there would have been no legal basis for allegation against the WSRC. The investigation of these allegations which ultimately resulted in the settlement was undertaken by the DOJ, the DOE's Office of the Inspector General, the U.S. Attorney's Office in Columbia, SC, and the DOE's Savannah River Operations Office.

Eagle Global Logistics (E.D. Tex. November 4, 2008)

Eagle Global Logistics (EGL Inc.) recently settled allegations that they violated the False Claims Act and knowingly defrauded the United States by agreeing to pay $750,000. EGL supposedly provided gifts and gratuities as an attempt to incentivize KBR employees to administer a government subcontract. KBR is a major contractor for logistical support for the U.S. Army's overseas operations and employees of KBR allegedly received sport tickets and meals among other gifts for the securing administration of EGL's subcontract. The complaint alleged that EGL provided these gifts between March 2003 and March 2005, and stood in violation of both the False Claims Act and the Anti-Kickback Act. The two relators in these allegations, David Vavra and Jerry Hyatt, received $157,500 for their role in exposing these allegations. EGL is no stranger to alleged False Claims Act violations as they have also recently settled two separate sets of allegations for $4 million and $30,000 respectively. The FBI and the Defense Criminal Investigative Service investigated these allegations as part of the National Procurement Fraud Initiative.

NCS Pearson Inc. (D. Minn. November 19, 2008)

NCS Pearson Inc., a Minnesota corporation, recently settled allegations of false claims by paying the Transportation Security Administration (TSA) $5.6 million. The TSA was born out of the Aviation and Transportation Security Act and established in the wake of September 11th. One of the central purposes of the TSA was to identify areas where airport security personnel were needed, and then recruit, train, and deploy these personnel. TSA partially subcontracted these services to NCS Pearson Inc. The complaint against NCS Pearson alleged that the corporation knowingly billed the TSA incorrect and excessive rates for the subcontracted work. The investigation resulting in the $5.6 million settlement was carried out by the DOJ's Civil Division, the Defense Contract Audit Agency, TSA, and the Office of Inspector General for the Department of Homeland Security.

RBC Mortgage (N.D. Ill. November 25, 2008)

RBC Mortgage Company recently settled allegations in violation of the False Claims Act by agreeing to pay the United States $10.71 million. RBC, a Canadian corporation with offices within the United States, held the status of a pre-approved mortgage lender with the ability to initiate and process Federal Housing Administration (FHA) loans without prior review of the loan application by the U.S. Department of Housing and Urban Development (HUD). This status is known as "Direct Endorsement Authority" and is subject to a number of stipulations. For instance, with "Direct Endorsement Authority" RBC was accountable for verifying each borrower's qualifications and performing due diligence in providing the loans. The intended purpose of direct endorsement and specifically FHA loans is to reduce processing costs of mortgage loans for low income families. The government's allegations against RBC state over a four year period between 2001 and 2005, RBC did not proceed with due diligence in underwriting certain loans and submitted loans for HUB endorsement which fell outside of the eligibility criteria for FHA insurance. In total, the government alleged that RBC violated the False Claims Act in submitting 219 federally insured loans for low-income family mortgages to the FHA and HUD. The $10.71 million settlement resolving these allegations was reached through investigations by the U.S. Attorney's office for the Northern District of Illinois, HUD's Office of Inspector General, and the Justice Department's Civil Division.

Bayer Healthcare LLC (S.D. Fla. November 25, 2008)

In a recent $97.5 million settlement, Bayer Healthcare LLC resolved allegations that they incited 11 separate diabetic suppliers to submit false Medicare claims thereby violating the False Claims Act. Bayer, a Tarrytown-based business, supposedly provided financial incentive to these 11 suppliers to switch their customers from products of Bayer's competition to Bayer products. The alleged cash-for-patient system that Bayer had with diabetic medical suppliers dealt with equipment such as glucose monitors and diabetic self-testing supplies. The 11 direct-to-patient suppliers submitted Medicare reimbursement claims following the distribution of these products. The greatest alleged payment from Bayer to a supplier was roughly $2.5 million to Liberty Medical Supply Inc. The ten other suppliers were allegedly paid $375,000 in an attempt to convert diabetic patients and those testing for diabetes to Bayer products. In order to conceal these kickbacks, Bayer supposedly made these payments under the guise of advertising payments. The fraudulent kickbacks with Liberty Medical Supply allegedly took place between 1998 and 2002, while the FCA violations with the ten other suppliers purportedly occurred from 1998 until 2007. The terms of the Settlement Agreement stipulated that Bayer Healthcare enter into a corpo-

rate integrity agreement with the Office of Inspector General for the Department of Health and Human Services (HHS). The investigation was carried out by the FBI, the U.S. Attorney's Office for the Southern District of Florida and the Justice Department's Civil Division, Commercial Litigation Branch.

Jackson-Madison County General Hospital and Milan General Hospital (W.D. Tenn. December 1, 2008)

Both Milan General and Jackson-Madison County General Hospitals agreed to pay the United States $5.3 million and $2.6 million respectively to settle a variety of allegations of Medicare fraud in violation of the False Claims Act. As an additional stipulation within the Settlement Agreement, the Jackson-Madison County General entered into a Corporate Integrity agreement with the Office of Inspector General for the U.S. Department of Health and Human Services. The government alleged that Milan General Hospital fraudulently admitted Medicare patients to the psychiatric unit, in an attempt to falsely bill for unnecessary services. Furthermore, the United States contended that Milan General billed for Medicare patients whose lengths of stay in the hospital surpassed their Medicare coverage. Jackson-Madison General allegedly failed to adhere to Medicare's documentation and medical necessity criteria for non-emergency transportation for Medicare patients. The almost $8 million cumulative settlement was reached as a result of investigative efforts by the U.S. Attorney's Office for the Western District of Tennessee and the U.S. Department of Health and Human Services, Office of Inspector General.

MedQuist Inc. (D. Mass. December 3, 2008)

MedQuist Inc., a medical transcription service provider based out of Mount Laurel, NJ, recently agreed to pay the United States government $6.6 million to resolve allegations that it fraudulently billed a number of its federal government clients in violation of the False Claims Act. The federal government clients stated in the complaint include the Department of Defense, the Public Health Service, and the Department of Veterans Affairs. The medical transcription industry has a billing standard set forth for specific federal government contracts called the "AAMT line", while non-governmental contracts have different billing standards. From roughly 1998 through 2004, MedQuist Inc. purportedly billed transcription fees in excess of the AAMT line for the services rendered to their federal government clients. These allegations came to the knowledge of the United States from two relators; Christopher Foley and Susan Purdue. Foley and Purdue will receive $450,000 and $144,000 respectively for their roles in breaking the allegations against MedQuist Inc.

Condell Health Network and Medical Center (N.D. Ill. December 1, 2008)

Condell Medical Center and parent corporation Condell Health Network agreed to pay a sum total $36 million to the United States and the state of Illinois. To avoid a costly litigation process and the admittance of liability, Condell voluntarily disclosed a variety of False Claims Act, Stark Law, and Anti-Kickback Statute violations from 2002 through 2007. These violations included the improper rental and leasing of office space to referring physicians and reimbursing physicians who failed to submit required written agreements after performing certain patient services. Additionally, Condell disclosed providing doctors with loans that violated the Anti-Kickback Statute and Stark Laws. The loans were also provided without due assessment of community need for the physicians services, and often given to doctors who were already practicing in the hospital's service area. Condell would then bill the doctors paying off the loans at a rate higher than fair market value of the services being rendered. In addition to improper loans, incentive bonuses were paid to physicians in an attempt to provide financial incentive for physicians to refer Medicare and Medicaid patients to Condell Medical Center, a 238-bed facility located in Libertyville, IL. As a result of Condell's voluntary disclosure of these activities, a settlement was reached whereby the United States receives $33.12 million and the State of Illinois receives $2.88 million. While the False Claims Act typically holds a standard of treble damages plus civil penalties for each violation of the False Claims Act, the settlement was formulated on double damages plus $5,000–$11,000 for civil penalties for each violation because of Condell's voluntary disclosure. Assistant U.S. Attorney Linda A. Wawzenski, deputy chief of the U.S. Attorney's Office Civil Division represented the United States in the Northern District of Illinois.

L-3 Communications Corp. (N.D. Ga. December 8, 2008)

L-3 Vertex Aerospace and L-3 Communications Corporation recently resolved allegations that they submitted false claims to the United States government on a military contract with the United States Army in Iraq. L-3 Communications agreed to pay $4 million to the United States for allegedly improperly billing and overbilling the Army for work done by L-3 employees on its government contract at Camp Taji, Iraq. As stipulated by contracted, L-3 was responsible for providing helicopter maintenance services and military operations support. L-3 allegedly submitted outright false records of hours worked and exaggerated other hours worked by its employees. As part of the Settlement Agreement, the relator Henry W. Roderigas received $720,000 for his role in uncovering the allegations against L-3. The settlement was reached, at least in part, by efforts

related to the National Procurement Fraud Initiative and Task Force, which was established in October 2006 and intended to enhance the United States government's ability to detect, prevent, and prosecute fraud connected with the elevated quantity of government subcontracts for national security purposes.

HMS Diagnostics Inc. (S.D. Tex. December 16, 2008)

HMS Diagnostics Inc., HMS Diagnostics LLC, and Health Management Services Inc. (collectively referred to as HMS) have recently settled allegations of fraud in violation of the False Claims Act by paying $550,000 to the United States. As an Independent Diagnostic Testing Facility (IDTF) that focuses on the treatment of sleeping disorders, HMS is required to have technicians administering sleep diagnostic tests to have certification to receive Medicare reimbursement. HMS is also required by Medicare and Medicaid rules and regulations to provide the names of licensed technicians. Additionally, Medicare and Medicaid must be notified periodically of changes in licensed personnel. HMS was alleged to have neglected all of the above requirements while requesting Medicare and Medicaid reimbursements for nearly 5 years from 2002 until August of 2007. As a result of the settlement, HMS agreed to pay the United States $4 million but did not admit liability for the allegations as part of the agreement. Furthermore, HMS entered into a corporate integrity agreement that will last for the next five years with the intent of encouraging closer adherence to Medicare and Medicaid guidelines.

Yale University (D. Conn. December 23, 2008)

Yale University recently entered into a settlement agreement to pay the United States $7.6 million which resolved allegations of misuse in federally-funded research grants violating the False Claims Act. There were two primary charges of misuse which both ran counter to the common standard that federal grant recipients may only charge the grants for expenses directly related to the objective of the grant, otherwise known as "allocable" costs. The first allegation stated that certain researchers would spend grant funds on non-allocable expenses as the time limit for their grant was running out. The incentive being that any remaining grant money at the expiration date must by law be returned to the federal government. The second set of allegations dealt with federally-funded grant researchers billing their grants for hours worked on projects that fell outside of the terms of certain grants. This allegedly occurred throughout summer months during which Yale University researchers were not paid their academic year salary, thereby creating monetary incentive for these researchers to bill non-allocable grant hours to the federal government. The U.S. Attorney's Office noted Yale's full cooperation and efforts to improve their federal grant management throughout the investigation process. The False Claims Act violations

supposedly occurred between 2000 and 2006 spanning six year. The settlement agreement was a result of investigative and joint efforts by the Department of Health and Human Services, the National Science Foundation, the Department of Energy, and numerous other government agencies.

Spartan Motors (D.S.C. December 23, 2008)

Spartan Motors and Spartan Chassis recently settled allegations of illegal kickbacks by paying the United States $1.7 million. In its complaint, the United States claimed that Spartan Motors and Spartan Chassis paid roughly $100,000 to an employee of Force Protection Inc. in order to receive a subcontract with the United States Military. In return, it was alleged that Force Protection Inc. agreed to purchase truck chassis's used for Marine Corps and Army Mine Resistant Ambush Protected vehicles from Spartan. The payment of $1.7 million resolves allegations of both the Federal False Claims Act as well as the Anti-Kickback statute. The case was brought forth through the National Procurement Fraud Initiative and investigated in joint effort by the Department of Defense's Defense Criminal Service Office, the Army's Criminal Investigation Command's Major Procurement Fraud Unite and the Defense Contract Audit Agency. As stipulated by the settlement agreement, Spartan accepts no liability for the allegations.

Legal Analysis

Off-Label Marketing as a Predicate for False Claims Act Liability

OFF-LABEL MARKETING AS A PREDICATE FOR FALSE CLAIMS ACT LIABILITY

*David S. Stone, Esq.**

Liability under the False Claims Act ("FCA"), 31 U.S.C. § 3729-33, can arise when pharmaceutical manufacturers market their drugs for uses that are not specifically approved by the U.S. Food and Drug Administration ("FDA"). Once a new drug is approved under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, the FDA does not preclude doctors from exercising their professional judgment by prescribing it for indications other than those approved by the FDA, commonly referred to as "off-label" uses. Manufacturers, however, are prohibited from marketing or promoting a drug for off-label uses. 21 U.S.C. §§ 331(d), 355(a) and (d). Even if the information is truthful and the drug's use beneficial to the patient, off-label promotion by a manufacturer is generally illegal and may subject the manufacturer to an enforcement action, civil liability, or criminal and civil penalties, including penalties under the FCA and various state false claims acts.

I. CONTOURS OF AN "OFF-LABEL" CASE.

A. The Basics.

When a pharmaceutical manufacturer unlawfully markets its drugs to physicians for off-label use, it presumably does so knowing that some of the prescriptions generated will result in claims for reimbursement being submitted to a governmental entity, such as Medicare or Medicaid. For example, as explained below, Medicaid does not normally reimburse off-label prescriptions. Medicaid's exclusion, combined with the prohibition against manufacturers promoting off-label uses, generated the seminal case of *U.S. ex rel. Franklin v. Parke-Davis*, which recognized that a claim pursuant to the FCA may be predicated on a manufacturer's illegal off-label marketing of a drug that resulted in submissions of false claims for payment to Medicaid. 147 F. Supp. 2d 39, 52–53 (D. Mass. 2001).

Medicaid's exclusion of off-label prescriptions is contained in Medicaid's definition of "covered outpatient drugs." First, it broadly defines "covered outpatient drugs" as any drug with an FDA approval, 42 U.S.C. § 1396r-8(k)(2)(A)(i), but then limits the definition to exclude drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). In turn, the statute defines a "medically accepted indication" as an indication that

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is either FDA approved or is included in any of the compendia described in 42 U.S.C. § 1396r-8(g)(1)(B)(i). 42 U.S.C. § 1396r-8(k)(6). At least one court has interpreted the "supported by citations in the compendia" language to hold that states cannot overlay additional requirements, such as the existence of a favorable double-blind clinical study, because "Congress has already stamped its imprimatur on these compendia" and, thus, "applying a more stringent test . . . is effectively denying coverage for those drugs [the state] is legally required to cover." *Edmonds, et al. v. Levine*, 417 F. Supp. 2d 1323, 1339, 1341 (S.D. Fla. 2006).

Accordingly, a typical off-label FCA case alleges that the manufacturer violated the FDA rule against promoting a drug for an off-label use, which induced physicians to prescribe the drug for an off-label purpose that they otherwise would not have, and that certain of those prescriptions were submitted to a governmental entity, such as Medicaid, for reimbursement. For instance, Eli Lilly & Company recently settled a FCA case involving the off-label marketing of Zyprexa for $1.42 billion. The United States[1] alleged that Eli Lilly caused claims for payment for off-label prescriptions of Zyprexa to be submitted to the Medicaid Program, the TRICARE program, and the Federal Employees Health Benefits Program, and caused purchases to be made by the Departments of Defense, Labor, and Veterans Affairs, the Bureau of Prisons, and "Public Health Service Entities." *See* Settlement Agreement at 3, *U.S. ex rel. Rudolph, et al. v. Eli Lilly & Co.*, Civ. Action No. 03-0943 (E.D. Pa. Jan. 15, 2009). The United States contended that

> Eli Lilly knowingly promoted the sale and use of Zyprexa to . . . health care professionals . . . for certain uses for which the [FDA] had not approved . . . and these unapproved uses were not medically accepted indications for which the United States and State Medicaid programs provided coverage. . . . As a result of the foregoing alleged conduct . . . contends that Eli Lilly knowingly caused false and/or fraudulent claims to be submitted to the United States . . . for these unapproved uses.

Id. at 4.

Such a case presumes, and the defendant cannot dispute, that the government would not have paid for the off-label prescription if it had known that the physician's prescribing decision was improperly influenced by the manufacturer's illegal conduct. *Parke-Davis*, 147 F. Supp. 2d at 53. While most off-label FCA cases are based on this basic premise, in practice the cases are far more complicated and, as discussed below, often include allegations that the manufacturer paid illegal kickbacks as part of its off-label marketing efforts.[2]

1. The United States intervened in *U.S. ex rel. Rudolph, et al. v. Eli Lilly & Co.*, which was the consolidation of four actions filed by relators.

2. Despite a relator's choice of forum, a FCA case may be transferred to a multidistrict litigation ("MDL") for consolidated pre-trial discovery. *See, e.g., California ex rel. Vicente v. Eli Lilly and Co.*, No. C 07-04911 (N.D. Cal.) (involving the off-label marketing of Zyprexa). *But see U.S. ex rel. West v. Ortho-McNeil Pharmaceutical*, No. 03 C 8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007) (involving FCA allegations regarding Levaquin and Ultram,

B. Off-Label Marketing Schemes and Safe Harbors.

The method through which manufacturers deliver unlawful off-label promotional messages is fairly consistent across offending manufacturers, although the particular design and implementation may vary. The media of delivery includes printed materials, journal articles, "detailing" visits to physicians by sales reps, and lectures in various settings—from luncheons to destination seminars—delivered to prescribers by influential peers. The content of the materials is nearly always carefully crafted by the manufacturer to convey the off-label message without attracting regulatory scrutiny, often using colloquialisms and other subtleties, such as referring to "expanded" or "emerging" uses, which are, in reality, euphemisms for off-label uses. The mode of delivery is itself often carefully chosen to provide a veneer of unbiased legitimacy and conceal the manufacturer's role in crafting the message and funding its delivery.

For a number of years, a "safe harbor" existed for manufacturers that complied with the FDA Modernization Act of 1997 ("FDAMA"), 21 U.S.C. § 360aaa. The FDAMA set forth limited ways in which manufacturers could provide journal articles and publications to physicians about unapproved uses of approved products. The safe harbor provided that, as long as a manufacturer complied with the FDAMA, the FDA would not use its dissemination of such materials as evidence of the manufacturer's intent that the product be distributed for an off-label use. In *U.S. ex rel. Franklin v. Parke-Davis*, No. Civ. A. 96-11651-PBS, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003), the court explained that even truthful off-label marketing that is ineligible for federal safe harbor protection would support a claim for causing false claims to be presented under 31 U.S.C. § 3729(a)(1).

On September 30, 2006, the FDAMA was allowed to sunset and, on January 13, 2009, the FDA issued new guidance on manufacturers' dissemination of publications on unapproved uses of approved drugs to healthcare professionals and entities. *See* Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, at *2, *available at*, http://www.fda.gov/oc/op/goodreprint.html. While the guidance provides no legally binding assurance of a safe harbor, it states:

> if a manufacturer follows the recommendations described in Section IV of this guidance, FDA does not intend to consider the distribution of such medical and scientific information in

and noting the off-label marketing claims were remanded from the MDL court). These cases are sometimes transferred because allegations that a manufacturer made false or misleading statements about the safety and efficacy of a drug are frequently at issue in personal injury, products liability, and securities fraud actions, all of which may give rise to MDLs. In fact, while there are no off-label allegations at issue, a FCA action currently being prosecuted by this author against Bayer for claims involving Baycol has recently been transferred to a products liability MDL. *See U.S. ex rel. Simpson v. Bayer*, Civil Action No. 08-cv-5758 (D. Minn.) (transferee court); Civil Action No. 06-cv-4796 (D.N.J.) (transferor court).

> accordance with the recommendations in this guidance as establishing intent that the product be used for an unapproved new use. However, if a manufacturer engages in other conduct that unlawfully promotes an unapproved use of a medical product . . . such other conduct may result in enforcement action.

Id. at *5–6. It is clear from the guidance's stated purpose that the FDA finds value in the distribution of credible medical information that is distributed in accordance with its guidance. *Id.* at *2. Yet, the FDA reminds the industry that any deviation from the guidance, even if the underlying information is truthful, may result in a civil or criminal action.

C. The Problematic Nature of a FCA Case Based on Third-Party Reimbursements.

Manufacturers' false statements regarding a drug's safety and efficacy, which are designed to induce physicians to prescribe a drug for an off-label purpose, can support claims under 31 U.S.C. § 3729(a)(2) for making false statements in order to get a false claim paid or approved. However, claims brought under 31 U.S.C. § 3729(a)(2) now require an assessment of the potential application of *Allison Engine Co. v. U.S. ex rel. Sanders*, __ U.S. __, 128 S. Ct. 2123 (2008). *Allison Engine* was a FCA case involving subcontractors' that submitted invoices, seeking payment for work that was not performed in accordance with specifications, which were submitted to shipbuilders contracted by the United States Navy. *Id.* at 2126-27. In holding that the subcontractors' invoices, which falsely certified that they complied with Navy specifications, did not constitute false claims to the government, the U.S. Supreme Court grafted a new intent requirement into subsection (a)(2), at least in some circumstances, stating that "a subcontractor violates § 3729(a)(2) if the subcontractor submits a false statement to the prime contractor intending for the statement to be used by the prime contractor to get the Government to pay its claim." *Id.* at 2130. Thus, (a)(2) requires proof "that the defendant made a false record or statement for the purpose of getting 'a false or fraudulent claim paid or approved by the Government.'" *Id*. The defense bar argues that this holding applies beyond subcontractors and applies to all § 3729(a)(2) claims involving entities that do not directly submit claims to the Government. Hence, any time such a claim is asserted against a drug manufacturer that did not sell products directly to the government (*i.e.*, where prescriptions are reimbursed through a governmental entity such as Medicare or Medicaid), such a defense is likely to be raised.

But, a drug manufacturer's misconduct is different in nature than a false certification of compliance with specifications that gives rise to a § 3729(a)(2) claim against a subcontractor. The drug manufacturer is not in a subcontractor role of filling an advance order for specific goods, but rather an independent actor in the stream of prescription drug commerce whose intentional miscon-

duct taints the reimbursement claims submitted by downstream actors such as physicians and pharmacists. *See Parke-Davis*, 2003 WL 22048255, at *5; *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943) (as to potential FCA liability of upstream actor in bid-rigging scheme, the court found a claim was stated because the "fraud did not spend itself with the execution of the contract. . . . Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the P.W.A. . . ."); *Parke-Davis*, 147 F. Supp. 2d at 52 (FCA claim properly stated against drug manufacturer predicated on off-label promotion); *In re Pharmaceutical Average Wholesale Price Litigation*, 491 F. Supp. 2d 12, 16 (D. Mass. 2007) (FCA claim properly stated by allegations that drug manufacturer manipulated average wholesale price upon which government calculated drug reimbursement).

The physician's freedom to write prescriptions for off-label indications raises the question: how can there be liability against the manufacturer when there is an intervening free agent? The answer is that the government has successfully wielded a presumption that the manufacturer's illegal promotion of the off-label use unduly influenced the physicians to write a greater number of off-label prescriptions than they otherwise would have. In the seminal case of *U.S. ex rel. Franklin v. Parke-Davis*, the court denied the defendant's motion for summary judgment on those grounds, holding that "'the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.'" 2003 WL 22048255, at *5 (quoting *Parke-Davis*, 147 F. Supp. 2d at 52–53).

Such a presumption is justified because the offending manufacturers typically promote off-label uses through various methods disguised as educational in nature and purport to impart unbiased scientific fact, when, in reality, they are carefully crafted marketing campaigns. Indeed, drug company marketing departments often analyze the success of these efforts, for example, by tracking the targeted physicians' prescribing levels and comparing them to marketing expenditures (including arguable kickbacks such as consulting fees, conventions, and honoraria). This information enables marketers to refine these campaigns to improve their effectiveness at generating off-label prescriptions.

There is also the puzzling question of just how are "false" claims being submitted in the first place, since an accurately completed reimbursement form would reflect off-label usage and would simply be disallowed as non-qualifying. The very fact that the prescriptions are being paid, however, reflects the reality that the claim form does not require sufficient information to identify the off-label nature of prescriptions that were the result of illegal marketing practices. *See Parke-Davis*, 2003 WL 22048255, at *4.

Rather than delving into the details of particular claim submissions, courts have instead focused on the conduct of the manufacturers and presumed that their conduct caused a significant percentage of claims to be "false," and that a significant percentage of those claims were in fact submitted to the government.

In *U.S. ex rel. Kennedy v. Aventis Pharmaceuticals, Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007), the court denied a Rule 9(b) motion to dismiss, finding that "specific facts . . . regarding particular claims were and are not likely within relators' reach" and, moreover, that "[g]iven the significant proportion of medical care in this country that is financed by Medicare and Medicaid, relators have drawn a reasonable inference that claims for reimbursement regarding off-label uses of Lovenox were submitted to the federal government or the State of Illinois for payment." Likewise, in *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007), the relator alleged that a significant percentage of Genotropin prescriptions were for off-label uses. The First Circuit stated that it was "not irrational to infer that, given the large percentage of children and the elderly who are insured under federal health programs, some false claims for Genotropin reimbursement were submitted to the government." *Id.* However, the strength of that inference was undercut by the criminal information that acknowledged "[i]n most, if not all, instances, patients taking Genotropin [for off-label uses] paid . . . out-of-pocket without reimbursement from any public or private third-party payors." *Id.* Consequently, without any government reimbursement, the First Circuit concluded the complaint did not adequately particularize that false claims were submitted to the government. *Id.*

D. Additional Allegations that Arise in Off-Label Cases.

1. Kickback Claims.

Manufacturers engaging in illegal off-label marketing often use incentives, in various forms, to induce physicians to attend educational presentations, participate in consulting arrangements, and review clinical materials, all of which are basically thinly veiled off-label promotions. Such incentives can constitute kickbacks and form an independent basis for liability under the FCA; however, such claims bring with them another layer of thorny issues.

For example, in *Parke-Davis* the court dismissed kickback claims that accompanied off-label allegations on the basis that the relator failed to allege the requisite false certification of compliance with the anti-kickback statute. 147 F. Supp. 2d at 53–54. Simply violating the federal anti-kickback statute is not itself "a *per se* violation of the FCA. In order for the anti-kickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon the claimant's certification of compliance with the anti-kickback provision." *Id.* at 54.

In *U.S. ex rel. Franklin v. Pfizer, Inc.* the court denied a motion to add FCA claims predicated on kickbacks because of undue delay and prejudice, and because the allegation that a manufacturer paid "kickbacks to physicians who wrote prescriptions to patients who submitted the prescriptions to pharmacists who submitted reimbursement claims to state and federal Medicaid agencies"

was too "attenuated" a chain of causation to establish a claim under the FCA. No. Civ. A. 96-11651-PBS, 2002 WL 32128635, at *1 (D. Mass. Feb. 6, 2002). The court did recognize that a viable claim might arise when the "kickbacks were coupled with express certifications." *Id*.

2. Misbranding Claims.

Manufacturers engaged in illegal off-label marketing may also be found to have violated regulations against "misbranding." FDA regulations prohibit "labeling" (a term broadly defined to cover many forms of manufacturer communications) that provides inadequate directions for use, contains false or misleading information, or includes information about unapproved uses. 21 U.S.C. §§ 331(a), 352(a) and (f); 21 C.F.R. § 202.1; *see also Parke-Davis*, 147 F. Supp. 2d at 44. Drugs with such labeling are considered "misbranded," and the sale of misbranded drugs is expressly prohibited. 21 U.S.C. § 333. Allegations of misbranding are typically based on two grounds: (1) that a product promoted for off-label use is misbranded because its directions are inadequate for the unapproved intended use, 21 U.S.C. 352(f); and/or (2) that the manufacturer disseminated "false and misleading" information regarding the product, 21 U.S.C. 352(a). *See* George S. Craft, Jr., *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 Hous. J. Health L. & Pol'y 103, 108 (2007) (citing Sentencing Memorandum of the United States, *U.S. ex rel. Warner-Lambert Co. LLC*, Crim. No. 04-10150 RGS, at 4–5 (D. Mass., filed June 2, 2004)); *see also* U.S.D.O.J. Press Release concerning settlement with Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc., *available at*, http://www.usdoj.gov/usao/nye/pr/2007/2007jul13a.html (describing the defendant's guilty plea for felony misbranding, which was based upon its off-label promotions).

II. RECENT OFF-LABEL SETTLEMENTS.

Recent civil recoveries and criminal fines and restitution in off-label cases have been quite substantial. Settlements have ranged from $9.8 million against Medicis Pharmaceutical Corp. for off-label promotion of Loprox to a record $1.42 billion against Eli Lilly for illegally marketing Zyprexa for off-label use. In addition, significant criminal fines suggest that the government takes a strong interest in these cases and views them as serious violations of the law.

Case	Juris-diction	Drug(s)	Settlement
U.S. ex rel. Franklin v. Pfizer, Inc. and Parke-Davis (96-cv-11651)	D. Mass.	Neurontin Accupril	5/13/04: $430 million settlement ($152 million for FCA)
U.S. v. Serono Labs	D. Mass.	Serostim	10/17/05: $704 million settlement ($136.9 million was for a related criminal fine)
U.S. v. Schering Plough	D. Mass.	Temodar Intron-A K-Dur Claritin RediTabs	8/29/06: $435 million settlement ($180 million was for the criminal plea)
U.S. v. InterMune Inc. (06-cr-0070)	N.D. Cal.	Actimmune	10/26/06: $36.9 million to settle criminal allegations
U.S. v. Pharmacia & Upjohn Co. LLC	D. Mass.	Genotropin	4/2/07: criminal fine of $15 million for off-label and $19.7 million settlement for kickbacks
U.S. ex rel. Marchese v. Cell Therapeutics Inc. (06-cv-0168)	W.D. Wash.	Trisenox	4/16/07: $10.5 million settlement
U.S. ex rel. Mulqueen v. Medicis Pharmaceutical Corp. (04-cv-2389)	D. Kan.	Loprox	5/8/07: $9.8 million settlement
Purdue Pharma		OxyContin	5/8/07: $19.5 million settlement with states
U.S. ex rel. Lauterbach v. Orphan Medical, Inc. (05-cv-0387; 07-cr-0531)	E.D.N.Y.	Xyrem	7/13/07: over $20 million to settle civil and criminal cases
Bristol-Myers Squibb[3]*	D. Mass. S.D. Fla.	Abilify and several others	9/07: $515 million settlement ($328 million for FCA)
*U.S. v. Cephalon Inc. (03-cv-6268; 03-cv-6277; 04-cv-4401; 05-cv-1904)**	E.D. Pa.	Actiq Gabitril Provigil	9/29/08: $375 million to settle FCA claims
U.S. ex rel. Rudolph, et al. v. Eli Lilly & Co. (03-cv-0943; 06-cv-2909; 06-cv-5526; 07-cv-1791)	E.D. Pa.	Zyprexa	1/15/09: $1.42 billion to settle civil suits and end a criminal investigation ($800 million to federal and state governments)

3. This settlement resolved multiple *qui tam* actions. *See U.S. ex rel. Richardson v. Bristol Myers Squibb*, Civil Action No. 06-11821 (D. Mass.); *U.S. ex rel. Piacentile v. Bristol-Myers Squibb Co.*, Civil Action No. 05-10196 (D. Mass.); *U.S. ex rel. Forden v. Bristol-Myers Squibb Co.*, Civil Action No. 04-11216 (D. Mass.); *U.S. ex rel. Cokus v. Bristol Myers Squibb*, Civil Action No. 01-11627 (D. Mass.); *U.S. ex rel. Barlow v. Bristol-Myers Squibb*, Civil Action No. 04-11540 (D. Mass.); *U.S. ex rel. Ven-A-Care of the Florida Keys, et al. v. Apothecon, et al.*, Civil Action No. 00-10698 (D. Mass.); and *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Bristol Myers Squibb Co.*, Civil Action No. 95-1354 (S.D. Fla.); *see also* Department of Justice press release, *available at*, http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html.

* This author was counsel to one or more relators in these matters.

III. CONCLUSION.

As is evident from this article, manufacturers that engage in unlawful off-label marketing will be discovered and will be subjected to civil and/or criminal actions that can bring with them sizable recoveries, penalties, and fines. The False Claims Act is one path through which governments and whistleblowers can hold manufacturers accountable for their off-label marketing schemes and prevent them from marketing drugs for uses that have not been approved by the FDA.