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.

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FROM THE EDITOR

I have been entrusted with the daunting task of succeeding my mentor and friend Jim Moorman as the Executive Director of TAF and TAF Education Fund. Jim arguably is the person to whom the county is most indebted for the long-term success of the False Claims Act. Without his relentless energy, industry, and unyielding determination, Pharma would have gutted the Act in the last legislative session, the IRS Whistleblower provision would have remained merely a "good idea," and double taxation would have deterred countless potential relators.

Jim is truly a tough act to follow, but you have my commitment, both as a fellow citizen and as a *qui tam* attorney, that I will do my best to serve our cause and our community with honor and integrity.

I take great comfort in knowing that I am not alone. We all have the good fortune of practicing law in the most honorable of legal practices. Through the FCA *qui tam* provisions, the federal government has enlisted us, private citizens, to stand in its shoes and to prosecute those who steal from the American people. What an awesome responsibility! Now, with the enactment of the IRS Whistleblower provision and the growth of State FCAs, our obligations as a legal community have greatly increased. During this time, more than ever, we need to come together into a true community of consequence, consolidating our strengths into one body against fraud.

In this spirit of unity, we will be announcing a number of initiatives in the coming months, which are geared toward highlighting the unique expertise of our member law firms, leveraging our collective voice, and uniting us behind a renewed effort to protect the Act. Please embrace these endeavors, as we look to move our community forward into the next twenty years of FCA enforcement.

Thank you so much for your continued support!

Yours truly,

Jeb White
Editor & Executive Director

Recent False Claims Act & *Qui Tam* Decisions

JANUARY 1–JUNE 30, 2007

**__EDITOR'S NOTE:__ The number of published opinions has tripled over the last three years. To better assist you in digesting this mounting caseload, we have summarized all of the district court decisions and limited our more extensive case summaries to landmark circuit court and Supreme Court decisions. In addition, the actual opinions and underlying legal documents are now available via our new, improved online version of the Quarterly Review. To obtain a copy of this version, please email Asher Alavi at aalavi@taf.org.*

STATUTORY INTERPRETATIONS

A. Section 3729(A) Damages and Civil Penalties

Coleman v. Hernandez, 2007 WL 1515163 (D.Conn. May 24, 2007)

Upon entry of a default judgment, a Connecticut district court was faced with the issue of how to calculate damages sustained by the government, where a person supplied adequate housing under a HUD program but erroneously tacked on an additional $60 per month charge to the rent. The court, rejecting the government's suggested calculation of assessing the entire rental payment plus the additional charges, limited the damages calculation to the amount of the additional erroneous payments.

United States v. Rinaldi, 2007 WL 1498856 (C.D. Ill. May 21, 2007)

After entering a default judgment in a civil FCA action, an Illinois district court assessed statutory damages in the amount of $65,054.67 and found that the government was entitled to civil penalties in the amount of $170,000.00. Notably, in this suit alleging that the defendant-dentist submitted 246 fraudulent claims involving 34 Medicaid beneficiaries, the government requested the minimum penalty for each of the 34 beneficiary numbers billed, rather than for each of the 246 claims.

United States v. Eghbal, 2007 WL 581463 (C.D. Cal. Feb. 14, 2007)

A California district court, analyzing a fraudulent scheme violating various HUD regulations, reduced the legal inquiry to whether the government would have guaranteed the home loans "but for" the defendant's false statements. Concluding that the government would not have otherwise guaranteed the loans, the court ruled that this determination was sufficient to establish a causal relationship between the false statements and FCA violations. In turn, the court granted the government's motion for summary judgment.

B. Section 3730(b)(2) Seal Provision

U.S. ex rel. Permison v. Superlative Technologies, Inc., 2007 WL 1880964 (E.D. Va. June 26, 2007)

A Virginia district court refused to reseal a *qui tam* complaint that was unsealed after the government declined to intervene. The court ruled that the relator's concerns for his career and the reputation of the defendant-employer did not outweigh the public's interest in access to court documents.

U.S. ex rel. Howard v. Lockheed Martin Corp., 2007 WL 1513999 (S.D. Ohio May 22, 2007)

Noting that FCA Section 3730(b)(2) only contemplates the unsealing of the *qui tam* complaint, an Ohio district court, faced with a defendant's motion to unseal the entire record, balanced the need of the defendants for the documents against the potential harm the disclosure would have on ongoing government investigations. Seeking the government's input, the court ordered the government to participate in an in camera review of the sealed documents.

U.S. ex rel. Pacific v. Doctors Care Health Services, Inc., 2007 WL 1140934 (S.D. Fla. April 17, 2007)

A Florida district court, noting that the FCA only contemplates sealing the underlying legal documents in a case for a limited time, ruled that the entire case record must be unsealed when the government declines to intervene in a *qui tam* suit, unless the government provides "ample justification" for keeping the documents under seal. Because the government failed to provide any reason why the documents should remain under seal, the court unsealed the entire record of the case.

C. Section 3730(c)(3) Government "Good Cause"

U.S. ex rel. Lam v. Tenet Healthcare Corp., 481 F. Supp. 2d 689 (W.D. Tex. March 28, 2007)

A Texas district court ruled that the federal government has Section 3730(c)(3) "good cause" to intervene in a previously declined *qui tam* action, where the relator sought to challenge the government's global settlement with the same defendant. The court also found that the government had waived any Rule 9(b) objections, for it filed its motion to dismiss a full year after declining to intervene and on the eve of the discovery deadline. Despite the fact that the defendant had recently signed the global settlement involving the same allegations raised in the relator's complaint, the court denied the defendant's motion to dismiss, highlighting that the relator's sufficiency challenge might ultimately prove that the global settlement did not fully and finally resolve all issues.

D. Section 3730(d)(1) Reasonable Attorneys' Fees

U.S. ex rel. Educational Career Development, Inc. v. Central Florida Regional Workforce Development Board, Inc., 2007 WL 1601747 (M.D. Fla. June 1, 2007)

FCA Section 3730(d)(1) permits a successful relator to recover "reasonable attorneys' fees and costs." A Florida district court, in assessing the "reasonableness" of the relator's counsel's proposed fees, ruled that the time spent "getting up to speed" about the prin-

ciples of *qui tam* actions, which "does not advance the case" and was not a result of the defendants' actions, are not recoverable under Section 3730(d)(1).

E. Section 3730(d)(2) Judicial Review of Settlement

U.S. ex rel. Parikh v. Premera Blue Cross, 2007 WL 1461165 (W.D. Wash. May 16, 2007)

After the parties of an FCA action agreed to dismiss the FCA allegations and to settle the Section 3730(h) anti-retaliation allegations, a Washington district court refused to dismiss the FCA suit and ordered the parties to reveal the terms of the anti-retaliation settlement agreement. According to the court, this disclosure was necessary for the court to fulfill its duties under FCA Section 3730(d)(2), which states that the court must determine whether the settlement is reasonable. Notably, the parties argued, to no avail, that this section does not apply to settlements under the FCA anti-retaliation provision.

JURISDICTIONAL ISSUES

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

Rockwell International Corp. v. United States, 127 S.Ct. 1397 (U.S. March 27, 2007)

In reversing the Tenth Circuit, a split U.S. Supreme Court decision ruled that a relator does not qualify for the FCA public disclosure bar's original source exception where the allegations in his original *qui tam* complaint do not match the allegations ultimately proven at a government-intervened FCA trial. The Court held that the public disclosure bar inquiry is a question of jurisdiction, which the relator must clear at all stages of the litigation. The Court also held that the relator must have "direct and independent knowledge" of the information in his complaint, as opposed to the information in the publicly disclosed allegations that triggered the public disclosure bar. Lastly, the Court ruled that the government's intervention does not provide an independent basis of jurisdiction with respect to the relator.

James Stone worked at a nuclear facility operated by Rockwell in the 1980s. In 1986, Stone was laid off, and in June of 1987 he went to the FBI, alleging that a number of environmental crimes were committed at the facility while he worked there, and providing the FBI with 2,300 pages of documents related to these charges. Among the documents was a 1982 engineering report containing Stone's assessment of a proposed waste treatment process that Rockwell was considering. In short, the process was called "pondcrete," and involved mixing hazardous waste sludge with concrete into a mixture that was sufficiently solid that it could be stored and disposed of in blocks. Back in 1982, Stone had raised concerns that the proposed piping system used to make the pondcrete would be ineffective and fail.

It turned out that there were problems with the pondcrete, but of a different nature. After Stone was laid off at Rockwell, the company learned that pondcrete blocks were insolid, and by 1988 the Department of Energy also learned of this, when several blocks began leaking waste, which in turn led to the revelation that there were thousands of insolid blocks at the facility. By the spring of 1988 the media had reported these findings, and it was the media's explanation that the root of the problem was "Rockwell's reduction of the ratio of concrete to sludge in the mixture," not the piping system that Stone had raised concerns about.

"Based in part on information allegedly learned from Stone," the FBI and EPA raided the Rockwell facility on June 6, 1989. The affidavit in support of the search warrant alleged, *inter alia*, that Rockwell had used an "inadequate waste-concrete mixture" in the pondcrete blocks, rendering many insolid, and the media reported this allegation. In July of the same year, Stone filed a *qui tam* suit under the FCA, alleging that Rockwell was obligated to comply with certain environmental laws, that it

had failed to do so, and that in order to induce the government to make payments to Rockwell under its contract, the company had presented false and fraudulent claims. Of the 26 environmental and safety issues mentioned in the complaint, one involved pondcrete, and reiterated Stone's claim that after his 1982 review of the design for the pondcrete process, he had predicted that the piping system would lead to problems.

After the government intervened, Stone and the government filed an amended complaint, which maintained the allegation that Rockwell violated environmental laws by storing leaky pondcrete, but dropped the allegation that it was due a piping system defect. These allegations were refined even further in a statement of claims that superseded the amended complaint, which added further details of events that allegedly gave rise to liability for the pondcrete problem, all of which, the Court point out, occurred after Stone left Rockwell's employ, and none of which involved his previous piping system allegations.

The jury returned a verdict finding Rockwell liable for claims covering the pondcrete allegations, which spanned from April 1, 1987 to September 30, 1988, and found for Rockwell on all other claims. After the verdict, Rockwell moved to dismiss under § 3730(e)(4). After bouncing back and forth between the district court and court of appeals on various issues, the Tenth Circuit finally held that Stone survived the FCA public disclosure bar. Rockwell filed a cert petition with the U.S. Supreme Court, which the Court granted.

Public Disclosure Bar Is a Question of Subject Matter Jurisdiction

As an initial matter, the Court skipped the first step of the inquiry—whether the public disclosure bar was triggered—for the parties had conceded that the suit was based upon publicly disclosed allegations. Then, the Court, stressing that it had to walk through the original source analysis because the public disclosure bar is matter of "subject matter jurisdiction, reversed the Tenth Circuit's decision.

"Original Source" Must Have "Knowledge" of Information in Complaint, Not Public Disclosure

First, the Court ruled that "the 'information' to which subparagraph [3730(e)(4)](B) speaks about is the information upon which the relators' allegations are based," means that the inquiry should not focus on whether the relator was the source of the public disclosure, but rather whether he is a source of the information underlying his own suit.

Relator Must Clear Public Disclosure Bar Hurdle At All Stages of Litigation

The Court next grappled with the phrase "information on which the allegations are based," holding that "the term 'allegations' is not limited to the allegations of the original complaint." Because the statute only speaks of the relator's "allegations *simpliciter*," it is not limited to the allegations in the original complaint, so that "new allegations re-

garding a fundamentally different fraudulent scheme require reevaluation of the court's jurisdiction." In other words, jurisdiction must be evaluated as to each distinct claim in a suit, and each must be capable of surviving if brought as a stand-alone action.

The Court then proceeded to a determination that Stone failed to qualify as an original source. As Stone and the government had alleged in the case they tried, during the relevant time period, Stone did not work at Rockwell, and therefore did not *know* anything about the problems that occurred there, with pondcrete or anything else. His "prediction" that the pondcrete process would not work because of a piping system flaw did not qualify as "direct and independent knowledge." Stone "did not *know* that the pondcrete failed; he *predicted* it," and "[e]ven if a prediction can qualify as direct and independent knowledge in some case (a point we need not address), it assuredly does not do so when its premise of cause and effect is wrong."

The Court found Stone's knowledge to be deficient because the flaw he predicted in the piping system never came to pass; the system worked, and it was a different problem, unforeseen by Stone, that led to the leaky pondcrete.

Government Intervention Does Not Cure 3730(e)(4) Concerns

Stone argued that because he was an original source as to some of the claims that went to trial, the court had jurisdiction over all of them, including the pondcrete claims. The Supreme Court rejected that argument, holding that § 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim. We, along with every court to have addressed the question, conclude that § 3730(e)(4) does not permit such claim smuggling. *Citing United States ex rel. Merena v. Smithkline Beecham Corp.*, 205 F.3d 97 (3d Cir.2000) (Alito, J.); *Hays v. Hoffman*, 325 F.3d 982, 990 (8th Cir.2003); *United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412, 1415-1416 (9th Cir.1992)).

Accordingly, the Court reversed and remanded the decision to the Tenth Circuit.

U.S. ex rel. Atkinson v. Pennsylvania Shipbuilding Co., 473 F.3d 506 (3d Cir. Jan. 12, 2007)

The Third Circuit, in affirming a lower court's summary judgment dismissal of an FCA *qui tam* action, agreed that a relator *may* not qualify for the FCA public disclosure bar's original source exception when the relator's knowledge depends on a review of public information, even when that public information does not qualify as a "public disclosure" within the meaning of the FCA public disclosure bar. However, instead of embracing a blanket rule that consultation with public documents automatically disqualifies a relator from being an original source, the court stressed that the "direct and independent knowledge" inquiry turns on "the availability of the information and the amount of labor and deduction required to construct the claim."

U.S. ex rel. Winslow v. PepsiCo, Inc., 2007 WL 1584197 (S.D.N.Y. May 31, 2007)

A New York district court ruled that the FCA public disclosure bar does not apply when the government requests additional information from a defendant, *unless* the governmental request reveals allegations or suggestions of fraud. Nevertheless, because the court was unsure of the proper regulation interpretation, the court deferred the action under the Doctrine of Primary Jurisdiction to give the U.S. Customs and Border Patrol Agency an opportunity to review the allegations.

U.S. ex rel. Ward v. Commercial Metals Company, 2007 WL 1390612 (S.D. Tex. May 9, 2007)

A Texas district court ruled that the FCA public disclosure bar precluded a relator from moving forward with a *qui tam* action where the relator learned of the underlying fraud from the legal proceedings of a previous civil action. The court rejected the relator's argument that he qualified for the original source exception where it was his original idea to use the disclosed facts to pursue a cause of action under the FCA. Borrowing from another Circuit, the court explained: "A relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation have already been disclosed."

U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corporation, 2007 WL 1279462 (D. Colo. May 2, 2007)

After a Colorado district court ruled that the FCA public disclosure bar precluded a relator from moving forward with a non-intervened FCA suit, the court ruled that it lacked jurisdiction to even enter judgment on behalf of the federal government, even though a jury in the relator's *qui tam* action had already found the defendant liable under the FCA.

U.S. ex rel. Lowman v. Hilton Head Health Systems, L.P., 2007 WL 1455819 (D.S.C. April 24, 2007)

Applying the controlling case law, which says that the FCA public disclosure bar only applies when the relator's actions are actually "derived from" the public disclosure, a South Carolina district court refused to dismiss an FCA *qui tam* action where the relator demonstrated that his knowledge of the fraud pre-dated the public disclosure. However, measuring the FCA Section 3731(b)(2) statute of limitations tolling period from the time the relator became aware of the fraud, the court ruled that the *qui tam* action was untimely.

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 851865 (D.D.C. March 14, 2007)

A District of Columbia district court ruled that a relator qualified for the FCA public disclosure bar's original source exception, for the information in his original complaint led to the discovery of the additional claims that formed the basis of later amendments to the complaint. The key for the court was that the relator had averred in his original complaint the *essential elements* of the previously unknown scheme upon which the new allegations were based. In turn, the court ruled that the relator qualified for the exception, for "but for" his efforts in uncovering and reporting the fraudulent scheme involving one government contract, the fraudulent claims arising out of two other contracts would not have been available.

U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corporation, 2007 WL 987538 (D. Colo. March 30, 2007)

While a Colorado district court stressed that federal government employees are not categorically barred from being *qui tam* relators, it ruled that they cannot satisfy the "voluntariness" prong of the FCA public disclosure bar's original source exception when there has been a "public disclosure" and their job duties include investigating and reporting fraud on the government. The court also ruled that a Section 3730(e)(4)(A) "public disclosure" occurs when a federal government investigator emails information about fraud to a state investigator. In turn, in dismissing the suit, the court found that a federal auditor-relator could not proceed with a *qui tam* action after a fellow federal auditor had emailed information about the alleged fraud to a state auditor.

U.S. ex rel. Vuyyuru v. Jadhav, 2007 WL 951851 (E.D. Va. March 28, 2007)

Noting the close similarities between the allegations raised in a previously published newspaper article and the relator's *qui tam* complaint, a Virginia district court concluded that the relator's allegations were actually "derived from" the article and that he had no "independent knowledge" of the allegations. In turn, the court ruled that the FCA public disclosure bar precluded the relator from proceeding with the action.

FALSE CLAIMS ACT RETALIATION CLAIMS

U.S. ex rel. Parikh v. Premera Blue Cross, 2007 WL 1585089 (W.D. Wash May 23, 2007)

After reviewing the parties' settlement of an FCA anti-retaliation action and proposed order dismissing the underlying FCA *qui tam* allegations, a Washington district court concluded that the settlement agreement was reasonable. In turn, the court approved the agreement and dismissed the FCA suit with prejudice as to the relator and without prejudice as to the government.

U.S. ex rel. Kersulis v. Rehabcare Group, Inc., 2007 WL 294122 (E.D. Ark. Jan. 29, 2007)

An Arkansas district court granted an FCA defendant's summary judgment motion after determining that the defendant-healthcare provider's system of commingling overflow patients did not violate any applicable laws or regulations. The court also dismissed the relator's FCA Section 3730(h) anti-retaliation suit, for the defendant-hospital employer demonstrated that the relator would have been terminated due to budget constraints even if the relator had not engaged in protected activity.

U.S. ex rel. Conner v. Salina Regional Health Center, Inc., 2007 WL 38403 (D. Kan. Jan. 5, 2007)

A Kansas district court rejected a Section 3730(h)-plaintiff's argument that his action was timely filed under a "continuing violation doctrine," which alleged that the defendant-hospital continued to "blackball" him in retaliation for his *qui tam* action for years after his termination. The court rejected the plaintiff's application of the "continuing violation doctrine" in this case. The court ruled that whether retaliatory post-employment conduct was actionable under the FCA does not impact the statute of limitations calculation of this case, for the complaint merely alleged retaliatory *discharge*.

COMMON DEFENSES TO FCA ALLEGATIONS

A. Time-Barred

U.S. ex rel. Sanders v. North American Bus Industries, 2007 WL 1860655 (D.Md. June 26, 2007)

A Maryland district court, rejecting a recent District of Columbia decision, held that the Section 3731(b)(2) three-year tolling provision does not apply to non-intervened *qui tam* actions. In turn, the court determined that the *qui tam* action at bar fell outside of the FCA statute of limitations period.

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 1723545 (D.D.C. June 14, 2007)

After ruling that the FCA Section 3731(b)(2) three-year tolling provision applies to relators measured by the time of the government's knowledge, a District of Columbia district court was faced with determining when the fraud at issue was known or reasonably should have been known by the government. The court, faulting the Justice Department's Civil Division for not seeking information from the Antitrust Division's criminal investigation, ruled that no reasonable jury could find that the government exercised proper due diligence in discovering the fraud. In turn, with the clock starting sooner than the parties anticipated, the court found that all of the relator's claims against this particular defendant were untimely.

U.S. ex rel. Parikh v. Premera Blue Cross, 2007 WL 1031724 (W.D. Wash. April 3, 2007)

A Washington district court ruled that the appropriate date for calculating whether allegedly false claims fell within the FCA limitations period is the date the original complaint was filed, as opposed to the date it was unsealed. The court also ruled that the Section 3731(b)(2) three-year tolling provision applied to non-intervened *qui tam* actions, measured by the date the relator discovered the fraud. Applying this standard, the court allowed allegations involving those claims filed within ten years of the original filing date.

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 842081 (D.D.C. March 19, 2007)

A District of Columbia district court ruled that the *jury* should decide whether the government had sufficient knowledge of the material facts of the alleged fraud to warrant the running of the Section 3731(b)(2) three-year tolling provision.

B. Lack of Falsity

U.S. ex rel. Laird v. Lockheed Martin Engineering & Science Services Co., 2007 WL 1830743 (5th Cir. June 27, 2007)

The Fifth Circuit affirmed the dismissal of a fraud-in-the-inducement FCA *qui tam* action after finding no nexus between the contractor's original underbid for the government contract and any subsequent request for payment that the contractor would not have been entitled to absent the contract. In addition, the court did not fault the defendant for failing to meet the terms of the contract, for the government, not the contractor, established the "doomed from the start" terms of the contract. Moreover, the allegedly false cost projection reports submitted during the course of the contract were not "material" under the FCA, for these projections were not utilized by the government to determine payment.

During the course of his employment as a Lockheed Martin cost specialist, James Mayfield became concerned that his employer was submitting fraudulent cost projections to the federal government. Specifically, Mayfield raised concerns that that his employer's proposal to obtain a NASA research contract greatly underestimated the actual cost of labor needed to complete the project. After voicing his concerns to his superiors, he was fired in February 1995.

Subsequently, he filed an FCA *qui tam* action against Lockheed Martin, alleging a fraud-in-the-inducement theory of FCA liability, which alleged that the company fraudulently induced the government into awarding it the contract by intentionally undervaluing its projected costs. The lower court dismissed the suit under Rule 12(b)(6) for failing to plead an actionable FCA claim. Mayfield appealed the decision to the Fifth Circuit.

Complaint Lacked Requisite Nexus Between Underbid and Subsequent Payment Requests

According to the Fifth Circuit, in order to succeed under the fraud-in-the-inducement theory under the FCA, Mayfield had to prove (1) that Lockheed had no intention to perform the research contract according to the terms of its proposed bid; and (2) that Lockheed obtained payments under the research contract to which it was not legitimately entitled.

For FCA liability, the court required a nexus between the underbid and a request for payment that Lockheed would not have been entitled to absent the contract. That nexus was absent in this case.

In reaching its conclusion, the court highlighted that the research contract was doomed to run over-budget from the start. Moreover, the overarching terms of the project were instituted not by Lockheed but by NASA. Indeed, NASA officials admitted that a sizeable portion of the cost overruns were specifically "government directed."

In addition, the Fifth Circuit also found that Mayfield could not demonstrate that Lockheed used the research contract to dupe NASA out of payments that it could not have obtained absent the contract. In other words, there was no evidence Lockheed finagled additional fees that it had no right to under the research contract. The payments Lockheed received were exclusively research contract-based.

False Cost Projections Were Not "Material" to Government's Decision to Pay

Moreover, the court found that subsequent cost projections submitted during the course of the contract period were not actionable, for the government did not use these projections to calculate Lockheed's pay.

The Fifth Circuit then laid out the existing case law addressing the proper standard for assessing the materiality of a false statement under the FCA. The Department of Justice filed an *amicus curiae* brief suggesting that a material statement need only have "potentially affected" the decision to pay. The court, however, noted that most lower court decisions in the circuit have suggested that the false statements must "actually affect" the government's decision to pay.

The Fifth Circuit, taking a pass on adopting a particular standard, ruled that the cost projections were immaterial under either standard. According to the court, the projections were not submitted nor used for the purpose of calculating Lockheed's payment, rather, by their terms they were for planning purposes only. Instead, NASA calculated Lockheed's payment solely based on its past performance, not on its cost projections. Thus, these cost projections could not have affected (or potentially affected) Lockheed's fee.

Accordingly, the Fifth Circuit affirmed the lower court's dismissal of Mayfield's *qui tam* action.

Trafalgar House Construction, Inc. v. United States, 2007 WL 1266924 (Fed. Cl. April 30, 2007)

In an FCA action brought by the government against a road contractor, the U.S. Court of Federal Claims ruled that the government failed to prove that the contractor's claims for additional money were false, for there were no evidence that the contractor was aware of the additional, costly road construction obstacles when it originally placed its bid. The court also ruled that the government had failed to establish that the contractor's original bid was submitted with "reckless disregard" of its truth or falsity.

C. Lack of Intent

M.A. DeAtley Construction, Inc. v. United States, 75 Fed. Cl. 812 (Fed. Cl. March 30, 2007)

The U.S. Court of Federal Claims determined that genuine issues of material fact precluded summary judgment, where facts exists that, at least, inferred fraudulent intent. According to the Federal Circuit, "misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was fraudulent intent."

U.S. ex rel. Lockyer v. Hawaii Pacific Health, 2007 WL 1153036 (D. Hawaii April 17, 2007)

A Hawaii district court granted an FCA defendant-hospital's motion for summary judgment, for the relator-physician failed to provide any evidence of the defendant's scienter when the defendant billed for services using provider numbers of physicians who were not present in the office suite. The court also dismissed the relator's Section 3730(h) anti-retaliation claim, for when he demanded his employee records from his employer-hospital, his stated reasoning was to challenge his pay decrease, not to investigate the hospital for fraud against the government.

San Francisco Bay Area Rapid Transit District v. Spencer, 2007 WL 911851 (N.D. Cal. March 29, 2007)

A California district court held that although a prime contractor did not take an active role in violating the California FCA, it was still liable for the fraud committed. The court found that if it had "diligently and competently managed" the government-funded program it would have discovered the subcontractor's FCA violations before they came to fruition.

D. Government Knowledge Defense

San Francisco Area Rapid Transit District v. Spencer, 2007 WL 1450350 (N.D. Cal. May 14, 2007)

In refusing to reopen a jury verdict against a government subcontractor, a California district ruled that, based on the evidence presented at trial, a reasonable jury could find the defendant liable under the California FCA. The court also ruled that its rejection of an explicit "government knowledge" jury instruction was appropriate, for nothing in the jury instructions prevented or discouraged the defendants from arguing to the jury that the government's knowledge of the defendant's actions negated the knowledge or falsity requirements of the Act. The court stressed that government knowledge, while relevant, is not a stand-alone defense to an FCA claim.

E. *Pro Se* Relator

U.S. ex rel. Brooks v. Lockheed Martin Corporation, 2007 WL 627372 (4th Cir. Feb. 23, 2007)

The Fourth Circuit, in an unpublished decision, dismissed in part and affirmed in part the dismissal of an FCA and FCA anti-retaliation suit brought by a *pro se* relator. The court dismissed the FCA *qui tam* allegations, because the federal government is the real party in interest and "the need for adequate legal representation of the United States counsels against permitting *pro se* suits." While the court agreed that a plaintiff could, however, proceed *pro se* in an FCA anti-retaliation suit, the court determined that the action at bar was not timely filed.

U.S. ex rel. Timpson v. Sampson, 2007 WL 1471963 (M.D. Fla. May 18, 2007)

A Florida district court, in granting the government's motion to dismiss a *qui tam* complaint, held that a relator could not proceed *pro se* with a *qui tam* action. The court stressed that the government would face claim and issue preclusion were the relator allowed to proceed with the litigation.

F. Venue Concerns

Giles v. United States, 2007 WL 788350 (Fed. Cir. March 13, 2007)

In an unpublished *per curiam* decision, the Federal Circuit agreed that the Court of Federal Claims does not have jurisdiction over FCA actions, for FCA Section 3732(a) confers exclusive jurisdiction to the district courts. In turn, the court affirmed the dismissal of an FCA *qui tam* suit filed with the Court of Federal Claims.

U.S. ex rel. Roop v. Arkray USA, Inc., 2007 WL 844691 (N.D. Miss. March 19, 2007)

After weighing several public and private factors, including the location of key witnesses, a Mississippi district court granted a defendant's motion to transfer an FCA *qui tam* action to the District of Minnesota.

U.S. ex rel. Ondis v. City of Woonsocket, Rhode Island, 480 F. Supp. 2d 434 (D. Mass. March 28, 2007)

After weighing the public and private factors, including the location of key witnesses, a Massachusetts district court granted an FCA defendant's motion to transfer a *qui tam* action to the District of Rhode Island.

State of Wisconsin v. Amgen, Inc., 2007 WL 92622 (W.D. Wis. Jan. 16, 2007)

Because the court found that the defendant-pharmaceutical company had not met its burden of showing that it may remove a *state* law case pursuant to federal FCA Section 3732(b) venue provision, a Wisconsin district court granted the relator's motion to remand and its request for costs and attorneys' fees.

G. Not a Condition of Payment

U.S. ex rel. Woodruff v. Hawaii Pacific Health, 2007 WL 1500275 (D. Hawaii May 21, 2007)

A Hawaii district court dismissed an FCA *qui tam* action, which alleged that the defendant-hospital violated several Medicaid conditions of participation. The court, in ruling that the relator did not state a claim under the FCA, stressed that the alleged violations were not actionable under the Act, unless the conditions were also prerequisites to receiving payment from the government. Finding that the conditions did not meet this threshold, the court dismissed the suit.

U.S. ex rel. Tyson v. Amerigroup Illinois, Inc., 2007 WL 781729 (N.D. Ill. March 13, 2007)

An Illinois district court, rejecting an FCA defendant's motion to overturn a jury verdict, ruled that violations of conditions of participation are actionable under the FCA, for "a condition of participation is a condition for payment." The court also found that the conditions for participation in the matter at bar were "material" to the government's decision to pay the defendant, for evidence was presented that the government would not have paid the claims unless the defendant had promised to comply with the conditions. Moreover, the court ruled that the number of civil penalties found by the jury did not violate the Eighth Amendment's Excessive Fines Clause, especially since it did not exceed the maximum penalty available under the FCA or other statutes.

U.S. ex rel. Yannacopoulos v. General Dynamics, 2007 WL 495257 (N.D. Ill. Feb. 13, 2007)

An Illinois district court, reviewing the controlling case law of whether violations of internal agency guidelines can give rise to an FCA action, stressed that compliance with relevant statutes, regulations or guidelines must be a condition of payment to be actionable under the FCA. Here, the court found that compliance was not a condition of payment, for the internal agency guidelines, which had not gone through the Administrative Procedure Act approval process, lacked the necessary force of law. However, the court noted that guideline compliance could still have been actionable if this requirement was expressly drafted into the controlling contract, but this did not occur in the matter at bar.

U.S. ex rel. DRC, Inc. v. Custer Battles, LLC, 2007 WL 316839 (E.D. Va. Feb. 2, 2007)

A Virginia district court granted a defendant's motion for summary judgment in an FCA *qui tam* action, alleging that the defendant-defense contractor fraudulently entered into and breached a contract to provide a certain number of security personnel to guard the Baghdad Airport. Upon further inspection, the court found that the contract did not require a fixed number of security personnel, so any false promises to supply a certain number of personnel was not material.

H. Lack of Presentment

In re Pharmaceutical Industry Average Wholesale Price Litigation, 2007 WL 1334496 (D. Mass. May 8, 2007)

A Massachusetts district court denied a defendant-pharmaceutical company's motion to dismiss an FCA action, which alleged that the company violated the FCA and the Anti-Kickback Statutes (AKS) by fraudulently inflating the "average wholesale price" that it reported to drug pricing compendia. The court ruled that an actionable FCA claim was raised, for the inflated prices *caused* provider reimbursement claims for the company's drugs to be false. Moreover, while the court avoided the question of whether the defendant's inflated reporting violated the AKS, the court allowed the AKS allegations to proceed, for the complaint also alleged that the company directly offered illegal kickbacks to healthcare providers.

U.S. ex rel. Arnold v. CMC Engineering, 2007 WL 442237 (W.D. Pa. Feb. 7, 2007)

Alluding to the reasoning behind the controversial D.C. Circuit Court's *Totten* decision, a Pennsylvania district court dismissed a Section 3729(a)(2) and (a)(3) action because the relator failed to establish that a false claim or statement was ever presented or made to a federal government employee. Notably, the court conceded that the allegedly false claims were paid solely with federal government funds.

I. Lack of Government Funds

U.S. ex rel. McCandliss v. Sekendur, 2007 WL 551567 (N.D. Ill. Feb. 20, 2007)

An Illinois district court, faced with the issue of whether an FCA defendant lied to the Social Security Administration (SSA) or the Federal Aviation Administration, determined that a viable action could only arise if the defendant lied to the SSA, for only the SSA was capable of paying funds to the defendant. Based on the evidence presented at trail, the court ruled that the defendant indeed fraudulently obtained payments from the SSA.

U.S. ex rel. SNAPP, Inc. v. Ford Motor Company, 2007 WL 420721 (E.D. Mich. Feb. 1, 2007)

A Michigan district court dismissed an FCA *qui tam* action, which alleged that a prime contractor misled the government about the percentage of minority-owned subcontractors it used, all in an attempt to qualify to bid on future government contracts. The court ruled that these allegations were not sufficient to give rise to an actionable FCA claim, for the relator did not identify any government contracts that the defendant received as a result of being wrongly qualified or a single payment made by the government because of the defendant's approved status.

J. Employee Release

U.S. ex rel. El-Amin v. The George Washington University, 2007 WL 1302597 (D.D.C. May 2, 2007)

A District of Columbia district court denied a defendant's motion to dismiss an FCA *qui tam* action, even though the relator signed a release distinguishing all causes of action against the defendant. The court concluded that the release, which became effective two days after she filed her *qui tam* complaint, was unenforceable because it violated key FCA public policy concerns, including allowing the government to fully investigate *qui tam* allegations under the protection of the FCA seal.

U.S. ex rel. Longhi v. Lithium Power Technologies, Inc., 481 F. Supp. 2d 815 (S.D. Tex. March 23, 2007)

A Texas district court denied an FCA defendant's motion for summary judgment, where the relators had executed a release agreeing not to sue the defendant and to indemnify the defendant if he did. The court found the release to be unenforceable, because the public policy and language of the FCA suggests that a release entered into during the seal period unduly interferes with the government's right to evaluate whether to join in an FCA *qui tam* action.

K. Liability for Employee's Actions

U.S. ex rel. Shackelford v. American Management, Inc., 2007 WL 1174892 (E.D. Mich. April 19, 2007)

A Michigan district court, faced with the controversial issue of whether to hold an FCA defendant-corporation liable for the actions of its employees, held that the principal-corporation is vicariously liable whenever its agent-employees act within the scope of their employment or with apparent authority regardless of the employers' knowledge or culpability. As such, the court held the defendant liable for the actions of its employees, even though the fraudulent scheme was only for employees' financial benefit.

L. Counterclaims Against Relator

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 851823 (D.D.C. March 14, 2007)

In light of the potential confusion of the jury, prejudice to the plaintiffs, and in the interest of judicial economy, a District of Columbia district court stayed and bifurcated an FCA defendant's counterclaims against the relator.

FEDERAL RULES OF CIVIL PROCEDURE

A. Rule 9(b) Failure to Plead Fraud with Particularity

U.S. ex rel. Howard v. Lockheed Martin Corporation, 2007 WL 1893215 (S.D. Ohio June 28, 2007)

An Ohio district court denied in part and granted in part a defendant's Rule 9(b) motion to dismiss an FCA *qui tam* action, which alleged violations of Section 3729(a)(1), (a)(2) and (a)(3). The court, reading Section 3729(a)(1) to require proof that a false claim was actually presented to a federal government employee, dismissed all (a)(1) allegations for failing to present evidence of actual presentment. However, citing the recent Sixth Circuit *Sanders* decision, which held that presentment is not required for 3729(a)(2) or (a)(3) liability, the court ruled that these allegations survived Rule 9(b).

U.S. ex rel. Smith v. Boeing Co., 2007 WL 1650924 (D. Kan. June 5, 2007)

A Kansas district court, denying a motion to dismiss a *qui tam* action, ruled that a relator satisfies the Rule 9(b) particularity requirements when the allegations, taken as a whole, put the defendants on notice of the basis of the FCA claims. Notably, the court stressed that at the pleading stage, a relator does not have to identify any particular invoice or claim that was actually submitted by the defendants. Instead, an allegation identifying a particular *type* of invoice or claim that was submitted by the defendant is sufficient to provide the notice required under Rule 9(b).

U.S. ex rel. Landrith v. Pekin Memorial Hospital, 2007 WL 1438582 (C.D. Ill. May 15, 2007)

An Illinois district court, in dismissing an FCA *qui tam* action, ruled that the complaint failed to satisfy the Rule 9(b) particularity requirements, for the complaint did not identify the individuals by name that were involved in the underlying fraudulent scheme.

U.S. ex rel. Jorgenson v. Alan Ritchey, Inc., 2007 WL 1287932 (W.D. Wash. April 27, 2007)

A Washington district court, granting in part and denying in part a defendant's motion to dismiss an FCA *qui tam* action, ruled that the complaint satisfied Rule 9(b), even though the relators did not identify a particular false claim that was actually submitted to the government. The court, swayed by the relators' lengthy work experienced with the defendant, ruled that the detail provided in the complaint sufficiently outlined the

allegations. However, because the relators were not intimately familiar with the inner workings at the defendant's *other* locations, the court rule that the allegations involving these locations could not survive Rule 9(b). Applying the heightened Rule 9(b) requirements to the relator's FCA Section 3729(a)(3) conspiracy allegations, the court found that these allegations did not sufficiently allege a conspiratorial agreement.

U.S. ex rel. Brinlee v. AECOM Government Services, Inc., 2007 WL 1232205 (W.D. La. April 25, 2007)

A Louisiana district court, in dismissing an FCA *qui tam* action under Rule 9(b), found that the complaint failed to include the "requisite" evidence that a false claim was actually presented to the government. However, the court permitted the relators' Section 3730(h) anti-retaliation action to proceed, especially since the defendant fired the relator soon after the government informed the defendant that the relator was actively cooperating in an investigation involving claims of fraud.

In re Pharmaceutical Industry Average Wholesale Price Litigation, 478 F. Supp. 2d 164 (D. Mass. March 22, 2007)

In an FCA action alleging that thirty-nine pharmaceutical companies violated the California False Claims Act by disclosing inflated average wholesale prices to the drug pricing publications used by the government to calculate reimbursements, a Massachusetts district court ruled that the complaint satisfied Rule 9(b) by stating the specific drugs sold by each defendant, by alleging the fraudulent scheme, by specifying the alleged fraudulent prices for each drug, and by attaching exhibits to the complaint that demonstrated the price spread for each drug. The court also rejected the defendants' argument that the resulting inflated reimbursement claims submitted by physicians were not false because the pricing information was not detailed on the individual claims. The court responded that although the claims themselves might not have contained the fraudulent price, it was predicated on an underlying fraudulent pricing scheme perpetrated by the defendants. In addition, the court concluded that the federal Anti-Kickback Statute does not preempt the state law, for the comparable California statute does not severely conflict with the federal statute.

U.S. ex rel. Absher v. Momence Meadows Nursing Center, 2007 WL 685693 (C.D. Ill. March 2, 2007)

An Illinois district court ruled that a relator's FCA *qui tam* complaint survived Rule 9(b), even though the complaint did not point to the specific dates on which the defendant submitted the allegedly false claims. The court found that, nevertheless, the complaint provided enough information to allow the defendants to respond to the allegations.

U.S. ex rel. Lafortune v. Beacon Ambulance Service, Inc., 2007 WL 580343 (W.D. Wis. Feb. 21, 2007)

A Wisconsin district court ruled that a complaint satisfied Rule 9(b), even though it lacked proof that an actual claim was submitted to the government. The court found that the complaint described in sufficient detail the process by which the defendant falsely billed the government. The court ruled that this level of detail permitted effective responsive pleading by the defendant.

U.S. ex rel. Heater v. Holy Cross Hospital, 2007 WL 521931 (S.D. Fla. Feb. 15, 2007)

A Florida district court ruled that a *qui tam* complaint satisfied Rule 9(b), even though the relator offered no proof that the defendant-hospital actually submitted a false reimbursement claim to Medicare or Medicaid. The court ruled that the relator's personal experience with the hospital's billing process provided sufficient "indicia of reliability" that the false claims were actually submitted to the government.

U.S. ex rel. Turner v. Michaelis Jackson & Associates, L.L.C., 2007 WL 496384 (S.D. Ill. Feb. 13, 2007)

An Illinois district court ruled that a complaint failed to satisfy the particularity requirements of Rule 9(b), for the relators failed to link their allegations of fraud to any particular claim that was actually submitted to the government. The court also ruled that the relator could not overcome this deficiency by providing statistical evidence that a claim *must have been* submitted.

U.S. ex rel. Berglund v. The Boeing Company, Inc., 2007 WL 473757 (D. Or. Feb. 5, 2007)

An Oregon district court denied a defendant's Rule 9(b) motion to dismiss an FCA *qui tam* action because he had not "proven" at the pleading stage that a false claim was actually submitted to the federal government. The court stressed that the relator's burden under Rule 9(b) was simply to set forth specific allegations so that the defendant had notice of the particular misconduct that was alleged. The court ruled that the relator in this case had met this burden.

B. Rule 11 Sanctions

U.S. ex rel. White v. Apollo Group, Inc., 2007 WL 870367 (5th Cir. March 22, 2007)

In an unpublished *per curiam* decision, the Fifth Circuit affirmed the lower court's decision to enter Rule 11 sanctions against a relator for "vexatious and frivolous litigation," where the *pro se* relator re-filed a previously dismissed *qui tam* suit, despite two previous court warnings about the possibility of sanctions. The court held that the relator waived any argument respecting Rule 11 sanctions on appeal, for his notice of appeal was untimely.

C. Rule 15(c) Relation Back Doctrine

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 851855 (D.D.C. March 14, 2007)

Rejecting the recent Second Circuit *United States v. Baylor University Medical Center* decision, a District of Columbia district court ruled that the government's complaint-in-intervention related back to the filing date of the original *qui tam* complaint under Rule 15(c) for the purposes of the FCA statute of limitations provision. Moreover, the court ruled that the FCA Section 3729(a)(3) conspiracy claims were timely, even though the conspiratorial agreement occurred outside the six-year limitations period, for at least some of the overt acts occurred within the limitations period.

Miller v. Holzmann, 2007 WL 710134 (D.D.C. March 6, 2007)

A District of Columbia district court held that the statute of limitations for FCA conspiracy claims begins to run anew upon the submission of each allegedly fraudulent or false claim, as opposed to beginning to run upon the formation of the conspiracy. The court also ruled that the government's claims involving a different contract than the one mentioned in the original *qui tam* complaint can "relate back" under Rule 15, for the relator originally asserted that the alleged conspiracy went beyond a single contract. As such, the court found that the government's additional claims were timely, for the claims on the additional contracts constituted the same "conduct, transaction, or occurrence" as the conduct alleged in the relator's original complaint.

DISCOVERY RULES

A. Motion to Compel Production of Disclosure Statement

U.S. ex rel. Singh v. Bradford Regional Medical Center, 2007 WL 1576406 (W.D. Pa. May 31, 2007)

A Pennsylvania district court denied an FCA defendant's motion to compel production of the relators' disclosure statement and information about the relators' financial relationship with area healthcare providers. The court ruled that the disclosure statement was protected as work product, for it was prepared "in anticipation of litigation" and the defendants failed show that they could not obtain substantially the same information without undue hardship. The court, in refusing to compel information about the relators' own possible illegal referrals, stressed that the case at bar was focused on the defendants' alleged misactions, not the actions of the relators.

Miller v. Holzmann, 2007 WL 313566 (D.D.C. Feb. 2, 2007)

A District of Columbia district court concluded that at the time the relator disclosed information to the government, the relator and the government shared a common interest in the prosecution of the *qui tam* case and the existence of that interest means that the disclosures were not a forfeiture of the attorney-client privilege. In turn, the court denied the defendant's motion to compel production of the documents.

B. Motion *in Limine*

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 851868 (D.D.C. March 14, 2007)

A District of Columbia district court granted a relator's motion *in limine* to exclude evidence of reference to the court's duty to treble damages and assess civil penalties under the FCA. The court determined that there was little probative value in educating the jury about trebling damages and civil penalties, but there was real risk that the jury might reduce its damages figure or number of violations in order to offset the effect of penalties and trebling.

C. Attorney-Client Privilege

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 915235 (D.D.C. March 27, 2007)

A District of Columbia district court found that notes prepared by the relator that were later provided to the Antitrust Division of the U.S. Department of Justice were subject to the attorney-client and "common interest" privileges and, therefore, did not have to be produced during discovery.

D. *Toughy* Regulations

U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, 2007 WL 404260 (D.D.C. Feb. 7, 2007)

A District of Columbia district court granted the government and the relator's motion to strike the expert report of a former federal government official for failing to comply with the agency's *Toughy* regulations, which require a party to first seek agency approval before attempting to secure testimony of a current or former agency employee. In addition, the court ruled that relators may utilize the Section 3731(b)(2) three-year tolling provision, measured from the time the government knew or should have known of the alleged fraud. Applying this interpretation to the case at bar, the court determined that the action was timely.

LITIGATION DEVELOPMENTS

A. Exception to Automatic Bankruptcy Stay

In re Health Essentials Solutions, Inc., 2007 WL 1453018 (Bkrtcy. W.D. Ky. May 17, 2007)

A Kentucky bankruptcy court, in denying the government's motion to rule that an FCA action is excepted from an automatic 11 U.S.C. § 362(a)(1) stay, noted that, in this particular case, the defendants were no longer in business, so the government's primary concern was merely to improve its financial stake in the debtor's estate, not to stop fraud. The court determined that if an action was instituted merely to protect the government's pecuniary interest in the debtor's property, the action was not excepted from the automatic stay.

B. Motion to Stay

U.S. ex rel. Westrick v. Second Chance, 2007 WL 1020808 (D.D.C. March 31, 2007)

In denying an FCA defendant's motion to stay, a District of Columbia district court highlighted that a criminal indictment did not appear to be imminent and that pre-indictment stays are not favored. The court stressed that if a criminal indictment was returned, the defendant could then refile its motion.

C. Issue Preclusion

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc., 2007 WL 851857 (D.D.C. March 14, 2007)

A District of Columbia district court denied an FCA plaintiff's motion to preclude a convicted defendant from contesting liability. The court noted that the defendant was previously convicted of *conspiring* to defraud the government, whereas the bulk of the case at bar was under 31 U.S.C. 3729(a)(1) and (a)(2), which required proof that the defendant did more than just simply conspire to defraud the government.

D. Court Deadlines

U.S. ex rel. Brunson v Narrows Health & Wellness, LLC, 2007 WL 102881 (N.D. Ala. Jan. 4, 2007)

After an Alabama district court granted a *qui tam* relator's motion to leave to amend a complaint, the relator sought an extension of the deadline on the date the amendment was due. The court, noting that the relator failed to provide a reason for the delay, denied the request and dismissed the action with prejudice.

Counsel Index

I. Statutory Interpretations

A. Section 3729(A) Damages and Civil Penalties

- ***Coleman v. Hernandez*, 2007 WL 1515163 (D.Conn. May 24, 2007)**

Catherine L. Williams, Frederic S. Brody, Richard L. Tenenbaum, CONNECTICUT LEGAL SERVICES, CT, for Plaintiff.

- ***United States v. Rinaldi*, 2007 WL 1498856 (C.D. Ill. May 21, 2007)**

Elizabeth L. Collins, Eric I. Long, U.S. Attorneys., Bradley Kent Hart, Illinois Attorney General, IL, for Plaintiffs.

Thomas M. Dawson, KS, for Defendant.

- ***United States v. Eghbal*, 2007 WL 581463 (C.D. Cal. Feb. 14, 2007)**

Lawrence C. Ecoff, ECOFF LAW & SALOMONS, Michael D. Nasatir, NASATIR, HIRSCH, PODBERESKY, & GENEGO, William J. Genego, NASATIR, HIRSCH, PODBERESKY, & GENEGO: counsel for defendant Morteza Eghbal and Marilyn Sylvia Trujillo

B. Section 3730(B)(2) Seal Provision

- ***U.S. ex rel. Howard v. Lockheed Martin Corp.*, 2007 WL 1513999 (S.D. Ohio May 22, 2007)**

Gerald Francis Kaminski, U.S. Attorney, OH, Michael F. Hertz, Russell B. Kinner, U.S. DEPARTMENT OF JUSTICE, CIVIL/COMMERCIAL LITIGATION BRANCH, Janet Louise Larkin, Jennifer Marie Verkamp, Frederick Mason Morgan, Jr.,VOLKEMA, THOMAS, MILLER, BURKETT, SCOTT, & MERRY, OH, Kevin Weimer, Stephen Thomas LaBriola, FELLOWS, JOHNSON, & LABRIOLA, LLP, GA, Michael Bothwell, BOTHWELL & HARRIS, PC, GA, for Relators.

Glenn Virgil Whitaker, VORYS SATER SEYMOUR & PEASE, OH, Douglas W. Gilfillan, Jessica J.M. Hagen, KING and SPALDING, GA, Gary G. Grindler, King and Spalding, for Defendants.

- ***U.S. ex rel. Pacific v. Doctors Care Health Services, Inc.*, 2007 WL 1140934 (S.D. Fla. April 17, 2007)**

Craig Marc Rappel, Robert Rappel, RAPPEL & RAPPEL, FL, Allison Cendali, UNITED STATES DEPARTMENT OF JUSTICE, Mark Alan Lavine, UNITED STATES ATTORNEY'S OFFICE, FL, for Plaintiff.

C. Section 3730(C)(3) Government "Good Cause"

• *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 689 (W.D. Tex. March 28, 2007)

Mitchell L. Weidenbach, Assistant United States Attorney, TX, Antonio V. Silva, LAW OFFICES OF ANTONIO V. SILVA, TX, Mark Nagle, PHILLIP, MICHAEL, TROUTMAN, & SANDERS, LLP, for Plaintiffs.

Joseph L. Hood, Jr., SCOTT, HULSE, MARSHALL, FEUILLE, FINGER & THURMOND, P.C., TX, Katherine Lauer, LATHAM & WATKINS, CA, for Defendant.

D. Section 3730(D)(1) Reasonable Attorney's Fees

• *U.S. ex rel. Educational Career Development, Inc. v. Central Florida Regional Workforce Development Board, Inc.*, 2007 WL 1601747 (M.D. Fla. June 1, 2007)

Michael F. Hertz, Patricia R. Davis, Ryan P. Fayhee, U.S. DEPT. OF JUSTICE, Samuel D. Armstrong, U.S. ATTORNEY'S OFFICE, Middle District of Florida, Daniel N. Brodersen, BEUSSE WOLDER SANKS MORA & MAIRE PA, FL, for Plaintiff.

Charles W. Sell, LAW OFFICES OF CHARLES W. SELL, Frank George Finkbeiner, LAW OFFICE OF FRANK G. FINKBEINER, FL, Jeffrey Alan Albinson, ALBINSON & CORSMEIER PA, FL, for Defendants.

E. Section 3730(D)(2) Judicial Review of Settlement

• *U.S. ex rel. Parikh v. Premera Blue Cross*, 2007 WL 1461165 (W.D. Wash. May 16, 2007)

Peter Angus Winn, U.S. ATTORNEY'S OFFICE, David S. Vogel, LAW OFFICES OF DAVID S. VOGEL, WA, James B. Helmer, Jr., Julie W. Popham, Paul B. Martins, HELMER MARTINS RICE & POPHAM, OH, John Timothy Keller, ASCHEMANN KELLER, IL, for Plaintiff.

Barbara Van Gelder, Kathryn Bucher, WILEY REIN LLP, Washington, DC, Harold Malkin, Yarmuth Wilsdon Calfo, Karen F. Jones, RIDDELL & WILLIAMS, WA, for Defendant.

II. Jurisdictional Issues

A. Section 3730(E)(4) Public Disclosure Bar and Original Source Exception

• *Rockwell International Corp. v. United States, 127 S.Ct. 1397* (U.S. March 27, 2007)

Maureen E. Mahoney, for Petitioner. Maria T. Vullo, for Respondent James S. Stone.

Malcolm L. Stewart, for Respondent the United States.

Christopher J. Koenigs, Michael B. Carroll, SHERMAN & HOWARD L.L.C., CO, Maureen E. Mahoney, J. Scott Ballenger, Matthew K. Roskoski, Barry J. Blonien, Nathan H. Seltzer, LATHAM & WATKINS LLP, for Petitioners.

Hartley David Alley, LAW OFFICES OF HARTLEY D. ALLEY, CO, Maria T. Vullo, Evan Norris, Doris F. Bernhardt, Paul, Weiss, RIFKIND, WHARTON & GARRISON LLP, NY, Attorneys for Respondent James S. Stone.

Paul D. Clement, Solicitor General, Peter D. Keisler, Assistant Attorney General, Edwin S. Kneedler, Deputy Solicitor General, Malcolm L. Stewart, Assistant to the Solicitor General, Douglas N. Letter, Peter R. Maier, Michael D. Granston, for the United States.

• *U.S. ex rel. Atkinson v. Pennsylvania Shipbuilding Co.*, 473 F.3d 506 (3d Cir. Jan. 12, 2007)

John G. Harkins, Elanor M. Illoway, and David W. Engstrom, HARKINS CUNNIGHAM: counsel for Appellee Sun Ship Inc.; Thomas H. Lee II, Veronica B. Rice, DECHERT LLP and Joseph O. Click, BLANK ROME LLP: counsel for appellee P.A. Shipbuilding Co.; Joseph G. DeRespino and Robert J. Dougher , DERESPINO & DOUGHER: counsel for appellee Fidelity Bank; William N. France, Healy & Baillie LLP: counsel for appellant

• *U.S. ex rel. Winslow v. PepsiCo, Inc.*, 2007 WL 1584197 (S.D.N.Y. May 31, 2007)

Mark Paul Carey, CAREY & ASSOCIATES P.C.: counsel for the U.S. ex rel. Scott Winslow; Jonathan H. Beemer, WHITE & CASE LLP, Karen M. Asner, WHITE & CASE LLP, Todd A. Gluckman, WHITE & CASE LLP, George James Terwilliger, WHITE & CASE LLP: counsel for Pepsico, Inc.

- ***U.S. ex rel. Ward v. Commercial Metals Company*, 2007 WL 1390612 (S.D. Tex. May 9, 2007)**

David Alton Sibley, Attorney at Law, TX, for Plaintiffs/Defendant.

A. Michael Warnecke, Sarah Rae Teachout, HAYNES and BOONE, TX, for Defendant.

- ***U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corporation*, 2007 WL 1279462 (D. Colo. May 2, 2007)**

Michael S. Porter, Atty. at Law, CO, Richard C. Lafond, LAFOND & SWEENEY, LLC, CO, for Plaintiffs.

Gregory E. Goldberg, Scott S. Barker, Danielle Renee Voorhees, Holland & Hart, LLP, Denver, CO, Charles D. Tetrault, VINSON & ELKINS LLP, Marie R. Yeates, VINSON & ELKINS LLP, TX, Spikes Kangerga, VINSON & ELKINS LLP, TX for Defendant.

- ***U.S. ex rel. Lowman v. Hilton Head Health Systems, L.P.*, 2007 WL 1455819 (D.S.C. April 24, 2007)**

Andrew D. Gowdown, Richard S. Rosen, ROSEN ROSEN AND HAGOOD, SC, Jennifer J. Aldrich, U.S. ATTORNEY'S OFFICE, SC, Andrew M. Beato, Gerard E. Mitchell, Robert F. Muse, STIEN MITCHELL AND MEZINES, for Plaintiffs.

E. Douglas Pratt-Thomas, PRATT-THOMAS PEARCE EPTING AND WALKER, SC, Brian R. Stimson, William H. Jordan, ALSTON AND BIRD, GA, Hutson Sanford Davis, Jr., MCNAIR LAW FIRM PA, SC, Andrew G. Melling, MCNAIR LAW FIRM, SC, for Defendants.

- ***U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 851865 (D.D.C. March 14, 2007)**

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, Keith V. Morgan, U.S. DEPT. OF JUSTICE, Michael F. Hertz, DEPARTMENT OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN & SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus DRINKER BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik TROUTMAN SANDERS

LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

- ***U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corporation*, 2007 WL 987538 (D. Colo. March 30, 2007)**

Michael S. Porter, Michael S. Porter, Atty At Law, Wheat Ridge, CO, Richard C. Lafond, Lafond & Sweeney, LLC, Denver, CO, for Plaintiff.

Gregory E. Goldberg, Scott S. Barker, Danielle Renee Voorhees, Holland & Hart, LLP, Denver, CO, Charles D. Tetrault, Vinson & Elkins, LLP, Washington, DC, Marie R. Yeates, Vinson & Elkins, LLP, Houston, TX, Spikes Kangerga, Vinson & Elkins, LLP, Austin, TX, for Defendant.

- ***U.S. ex rel. Vuyyuru v. Jadhav*, 2007 WL 951851 (E.D. Va. March 28, 2007)**

Thomas Hunt Roberts, THOMAS H. ROBERTS & ASSOCIATES PC, VA, for Plaintiff.

William Benjamin Pace, Martin A. Donlan, Jr., Nathan Adam Kottkamp, John William Boland, MCGUIREWOODS LLP, Rita Poindexter Davis, HUNTON & WILLIAMS LLP, VA, Charles William Mcintyre, Jr., MCGUIREWOODS LLP, for Defendants.

III. False Claims Act Retaliation Claims

• *Brock v. Presbyterian Healthcare Services, Inc.*, 2007 WL 915080 (10th Cir. March 28, 2007)

James P. Lyle, LAW OFFICES OF JAMES P. LYLE P.C., NM, for Plaintiff-Appellant. Scott D. Gordon, RODEY, DICKASON, SLOAN, AKIN & ROBB, NM, Pearson N. Bownas, Richard G. Stuhan, Sean P. Costello, JONES, DAY, REAVIS & POGUE, OH, Gregory M. Luce, JONES DAY REAVIS & POGUE, D.C., for Defendant-Appellee.

• *U.S. ex rel. Parikh v. Premera Blue Cross*, 2007 WL 1585089 (W.D. Wash May 23, 2007)

Peter Angus Winn, U.S. ATTORNEY'S OFFICE, David S. Vogel, LAW OFFICES OF DAVID VOGEL, WA, James B. Helmer, Jr, Julie W. Popham, Paul B. Martins, HELMER, MARTINS, RICE, & POPHAM, OH, John Timothy Keller, ASCHEMANN KELLER, IL, for Plaintiffs.

Barbara Van Gelder, Kathryn Bucher, WILEY REIN LLP, Harold Malkin, Yarmuth Wilsdon Calfo, Karen F. Jones, RIDDELL & WILLIAMS, WA, for Defendant.

• *U.S. ex rel. Kersulis v. Rehabcare Group, Inc.*, 2007 WL 294122 (E.D. Ark. Jan. 29, 2007)

Benjamin David Brenner, WILLIAMS & ANDERSON LLP, Charles A. Banks, BANKS LAW FIRM PLLC, Robert L. Vogel, VOGEL & SLADE LLP, Shelley R. Slade, VOGEL & SLADE LLP, Joshua King, BANKS LAW FIRM PLLC: counsel for plaintiffs Gregory Kersulis and Jimmie Wilson; Brian B. Lavine, TROUTMAN SANDERS LLP, Eric A. Richardson, TROUTMAN SANDERS LLP, Pamela Moseley Roberts, RELIANCE HEALTHCARE MANAGEMENT INC. Rick T. Beard, MITCHELL, WILLIAMS, SELIG, GATES & WOODYARD, John Keeling Baker, MITCHELL, WILLIAMS, SELIG, GATES & WOODYARD: counsel for defendant Rehabcare Group Inc.

• *U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 2007 WL 38403 (D. Kan. Jan. 5, 2007)

Douglas L. Carter, LAW OFFICES OF DOUGLAS L. CARTER, Michael W. Thompson, MITCHELL, KRISTL, & LIEBER P.C.: counsel for plaintiff Brian E. Conner; James D. Griffin, BLACKWELL SANDERS PEPER MARTIN LLP, Lorie J. Sellers, BLACKWELL SANDERS PEPER MARTIN LLP, Stephen J. Torline, BLACKWELL SANDERS PEPER MARTIN LLP, Neely L. Fedde, SHOOK, HARDY, & BACON LLP, John W. Mize, CLARK, MINE, & LINVILLE, CHTD: counsel for defendant Salina Regional Health Center Inc.

IV. Common Defenses to FCA Allegations

A. Time-Barred

• *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 1723545 (D.D.C. June 14, 2007)

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

• *U.S. ex rel. Parikh v. Premera Blue Cross*, 2007 WL 1031724 (W.D. Wash. April 3, 2007)

David S. Vogel, DAVID S. VOGEL, James B. Helmer, HELMER, MARTINS, RICE, & POPHAM, John Timothy Keller, ASCHEMANN KELLER, Julie W. Popham, HELMER, MARTINS, RICE, & POPHAM, Paul B. Martins, HELMER, MARTINS, RICE, & POPHAM: counsel for plaintiff Garish Parikh; Barbara Van Gelder, WILEY REIN LLP, Harold Malkin, YARMUTH WILSDON CALFO, Karen F. Jones, RIDDELL & WILLIAMS, Kathryn Bucher, WILEY REIN LLP

• *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 842081 (D.D.C. March 19, 2007)

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE

& REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

B. Lack of Falsity

• *Trafalgar House Construction, Inc. v. United States*, 2007 WL 1266924 (Fed. Cl. April 30, 2007)

Norman T. Daniels, Jr. and Carl L. Fletcher, Jr., DANIELS LAW FIRM, PLLC, West Virginia, Counsel for Plaintiff.

Brian S. Smith, UNITED STATES DEPARTMENT OF JUSTICE, CIVIL DIVISION, Counsel for Defendant.

C. Lack of Intent

• *M.A. DeAtley Construction, Inc. v. United States*, 75 Fed. Cl. 812 (Fed. Cl. March 30, 2007)

John C. Black, WA, counsel of record for Plaintiff.

Leslie C. Ohta, Trial Attorney, UNITED STATES DEPARTMENT OF JUSTICE CIVIL DIVISION, COMMERCIAL LITIGATION BRANCH, counsel of record for Defendant, with whom were Peter D. Keisler, Assistant Attorney General, David M. Cohen, Director, and Bryant G. Snee, Assistant Director.

• *U.S. ex rel. Lockyer v. Hawaii Pacific Health*, 2007 WL 1153036 (D. Hawaii April 17, 2007)

Arleen D. Jouxson, Rafael G. Del Castillo, JOUXSON-MEYERS & DEL CASTILLO LLLC, Wahiawa, HI, Harry Yee, OFFICE OF THE UNITED STATES ATTORNEY, Janice P. Kim, Honolulu, HI, for Plaintiffs.

Clarissa Y. Malinao, John-Anderson L. Meyer, Kenneth S. Robbins, ROBBINS & ASSOCIATES, Sharon V. Lovejoy, Stephanie E.W. Thompson, STARN O'TOOLE MARCUS & FISHER, Honolulu, HI, Edwin D. Rauzi, DAVIS WRIGHT TREMAINE LLP, WA, Harry R. Silver, PATTON BOGGS LLP, for Defendants.

- ***San Francisco Bay Area Rapid Transit District v. Spencer*, 2007 WL 911851 (N.D. Cal. March 29, 2007)**

David L. Norman, SAN FRANCISCO CITY ATTORNEY'S OFFICE, Eduardo G. Roy, Daniel T. Balmat, Denise A. Smith, Evan Nadel, Rodney R. Patula, SQUIRE, SANDERS, & DEMPSEY LLP, CA, for Plaintiff.

LeCarie Shalece Whitfield, MCIERNEY & DILLON P.C., CA, for Defendants.

D. Government Knowledge Defense

- ***San Francisco Bay Area Rapid Transit District v. Spencer*, 2007 WL 1450350 (N.D. Cal. May 14, 2007)**

David L. Norman, SAN FRANCISCO CITY ATTORNEY'S OFFICE, Eduardo G. Roy, Daniel T. Balmat, Denise A. Smith, Evan Nadel, Rodney R. Patula, SQUIRE, SANDERS, & DEMPSEY LLP, CA, for Plaintiff.

LeCarie Shalece Whitfield, MCIERNEY & DILLON P.C., CA, for Defendants.

E. *Pro Se* Relator

- ***U.S. ex rel. Brooks v. Lockheed Martin Corporation*, 2007 WL 627372 (4th Cir. Feb. 23, 2007)**

Kenneth P. Brooks, Appellant Pro Se. Glenn V. Whitaker, VORYS, SATER, SEYMOUR & PEASE, Cincinnati, Ohio, for Appellees.

- ***U.S. ex rel. Timson v. Sampson*, 2007 WL 1471963 (M.D. Fla. May 18, 2007)**

John Timson, FL, pro se.

Shannon Kelly Rosser, WICKER SMITH O'HARA MCCOY GRAHAM & FORD P.A., FL, for Defendants.

F. Venue Concerns

- ***Giles v. United States*, 2007 WL 788350 (Fed. Cir. March 13, 2007)**

Diane P. Giles, of India, pro se.

Claudia Burke, Trial Attorney, Commercial Litigation Branch, CIVIL DIVISION, UNITED STATES DEPARTMENT OF JUSTICE, for defendant-appellee. With her on the brief were Peter D. Keisler, Assistant Attorney General; David M. Cohen, Director; and Todd M. Hughes, Assistant Director.

- ***U.S. ex rel. Roop v. Arkray USA, Inc.*, 2007 WL 844691 (N.D. Miss. March 19, 2007)**

Jim D. Waide, III, WAIDE & ASSOCIATES PA, Richard Shane McLaughlin, McLaughlin Law Firm, Tupelo, MS, for United States of America.

L.F. Sams, Jr., Margaret Sams Gratz, Mitchell, McNutt & Sams, Tupelo, MS, for Defendant.

- ***U.S. ex rel. Ondis v. City of Woonsocket, Rhode Island*, 480 F. Supp. 2d 434 (D. Mass. March 28, 2007)**

Leon A. Blais, Blais, Parent & Quinn, Mansfield, MA, Patricia M. Connolly, United States Attorney's Office, Boston, MA, for Relator.

Justin P. O'Brien, Michael B. Galvin, Thomas E. Dwyer, Jr., Dwyer & Collora, LLP, Boston, MA, Howard R. Croll, Fontaine & Croll, Ltd., Woonsocket, RI, for Defendants.

- ***State of Wisconsin v. Amgen, Inc.*, 2007 WL 92622 (W.D. Wis. Jan. 16, 2007)**

Charles Barnhill, MINER, BARNHILL, & GALLAND: counsel for plaintiff State of Wisconsin; William M. Conley, FOLEY & LARDNER, Joseph H. Young, HOGAN & HARTSON LLP: counsel for Amgen Inc.; Lynn M. Stathas, REINHART, BOERNER, VAN DEUREN S.C., Allen C. Schlinsog, Jr. REINHART, BOERNER, VAN DEUREN S.C., James R. Daly, JAMES R. DALY: counsel for defendants Abbott Laboratories & TAP Pharmaceutical Products Inc.; Brian E. Butler, STAFFORD ROSENBAUM, LLP, D. Scott Wise, DAVIS POLK & WARDWELL: counsel for defendant AstraZeneca Pharmaceuticals LP; Stephen P. Hurley, HURLEY, BURISH & STANTON, S.C., Michael L. Koon, SHOOK, HARDY & BACON: counsel for defendant Aventis Pharmaceuticals Inc.; Bruce A. Shultz, COYNE SCHULTZ BECKER & BAUER, Merle M. Delancey, DICKSTEIN, SHAPIRO, MORION & OSHINSKY: counsel for defendants Baxter Healthcare Corporation; Patrick J. Knight, GIMBEL, REILLY, GUERIN & BROWN, Helen E. Witt, KIRKLAND & ELLIS LLP: counsel for defendants Ben Venue Laboratories Inc,

Boehringer, Ingelheim Pharmaceuticals, Inc., Boehringer, Ingelheim Roxane, Inc. Roxane Laboratories, Inc; James R. Clark, FOLEY & LARDNER, Stephen M. Edwards, HOGAN & HARTSON LLP: counsel for defendant Bristol Myers Squibb Co.; John W. Markson, BELL, GIERHART, & MOORE, S.C., Christopher Palermo, KELLEY DRYE & WARREN LLP: counsel for defendant Dey Inc.; Michael R. Fitzpatrick, BRENNAN, STEIL & BASTING, David J. Burman, PERKINS COIE LLP: counsel for defendant Immunex Corporation; Stephen P. Means, MICHAEL BEST & FRIEDRICH, LLP, Philip F. Ackerman, SONNENSCHEIN NATH & ROSENTHAL LLP, JohnMarc P. Buffa, SONNENSCHEIN NATH &

ROSENTHAL LLP: counsel for defendants Ivax Corporation and Ivax Pharmaceuticals, Inc., Donald K. Schott, QUARLES & BRADY, William Cavenaugh Jr., PATTERSON, BELKNAP, WEBB & TYLER LLP: counsel for defendants Johnson & Johnson, Inc; Michael P. Crooks, PETERSON, JOHNSON & MURRAY, S.C, John M.Townsend, HUGHES, HUBBARD & REED, LLP: counsel for defendant Merck & Company; David J. Harth, HELLER EHRMAN LLP, William A. Escobar, KELLEY DRYE & WARREN LLP: counsel for defendant Mylan Pharmaceuticals Inc; Kim Grimmer, SOLHEIM, BILLING & GRIMMER, S.C., Jane W. Parver, KAYE SCHOLER LLP: counsel for defendant Novartis Pharmaceutical Corporation; Beth J. Kushner, VON BRIESEN & ROPER, S.C.. John C. Dodds, MORGAN, LEWIS & BOCKIUS, LLP: counsel for defendants Pfizer Inc. and Pharmacia; Wayne A. Cross, WHITE & CASE LLP, Shannon Allen, FRIEBART, FINERTY & ST. JOHN: counsel for defendant Sandoz, Inc; Earl H. Munson, BOARDMAN, SUHR, CURRY, & FIELD, Brien T. O'Connor, ROPES & GRAY LLP, Patrick J. Drescher, ROPES & GRAY LLP: counsel for defendants Schering-Plough Corporation & Warrick Pharmaceuticals Corporation; Lester A. Pines, CULLEN, WESTON, PINES & BACH, T. Reed Stephens, SONNENSCHEIN, NATH & ROSENTHAL, LLP, Frederick G. Herold, DECHERT LLP, Mark D. Seltzer, HOLLAND & KNIGHT LLP: counsel for defendants Sicor Inc., & Teva Pharmaceuticals U.S.A. Inc., Daniel W. Hildebrand, DEWITT, ROSS & STEVENS, Mark H. Lynch, COVINGTON & BURLING: counsel for defendant Smithkline Beecham Corporation; Douglas B. Farquhar, HYMAN, PHELPS & MCNAMARA, Ralph A. Weber, GASS WEBER MULLINS, LLC: counsel for defendants Watson Pharma Inc & Watson Pharmaceuticals Inc.; Clifford Joe Cavitt, HURLEY, BURISH & STANTON, S.C.: counsel for defendants Aventis Behring LLC & ZLB Behring

G. Not a Condition of Payment

• *U.S. ex rel. Woodruff v. Hawaii Pacific Health*, 2007 WL 1500275 (D. Hawaii May 21, 2007)

Arleen D. Jouxson, Rafael G. Del Castillo, JOUXSON-MEYERS & DEL CASTILLO LLLC, Wahiawa, HI, Harry Yee, OFFICE OF THE UNITED STATES ATTORNEY, Honolulu, HI, for Plaintiffs.

Harry R. Silver, PATTON BOGGS LLP Kenneth S. Robbins, ROBBINS & ASSOCIATES, Honolulu, HI, for Defendants.

• *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 2007 WL 781729 (N.D. Ill. March 13, 2007)

Frederick H. Cohen, David Joel Chizewer, Chad A. Blumenfield, Ann Chen, GOLDBERG, KOHN, BELL, BLACK, ROSENBLOOM, & MORITZ LTD. IL, David Jamison Adams, Anne Renee Kuper Reader, ILLINOIS ATTORNEY GENERAL'S OFFICE, Michele Marion Fox, Samuel B. Cole, U.S. ATTORNEY'S OFFICE, IL, for Plaintiffs.

Daniel John Voelker, Catherine A. Miller, Garry L. Wills, Gia Fonte Colunga, Hillard M. Sterling, Jeffrey Lawrence Dorman, Kellye L. Fabian, FREEBORN & PETERS LLP, IL, Daniel J. Riley, Robert J. Wagman, Jr., BAKER BOTTS LLP, Theodore B. Olsen, Tulumello S. Andrew, GIBSON, DUNN, & CRUTCHER LLP, for Defendants.

- ***U.S. ex rel. Yannacopoulos v. General Dynamics*, 2007 WL 495257 (N.D. Ill. Feb. 13, 2007)**

Bradley Scott Weis, LAW OFFICE OF BRADLEY SCOTT WEIS, Thomas R. Meites, MEITES, MULDER, MOLLICA, & GLINK, Ann Louise Lugbill, LAW OFFICE OF ANN LOUISE LUGBILL, JAMIE S. FRANKLIN, MEITES, MULDER, MOLLICA, & GLINK, Jeffrey Irvine Cummings, MINER, BARNHILL, & GALLAND, Judson Hirsch Miner, MINER, BARNHILL, & GALLAND, Nancy L. Maldonado, MINER, BARNHILL, & GALLAND, Shona B. Glink, MEITES, MULDER, MOLLICA & GLINK: counsel for plaintiff; Linda L. Listrom, JENNER & BLOCK LLC, David J. Winters, JENNER & BLOCK LLP, Matthew Thomas Albaugh, JENNER & BLOCK LLP, Susan Cohen Levy, JENNER & BLOCK LLC: counsel for defendant General Dynamics.

- ***U.S. ex rel. DRC, Inc. v. Custer Battles, LLC*, 2007 WL 316839 (E.D. Va. Feb. 2, 2007)**

Alan Mark Grayson, GRAYSON & KUBLI PC, Bernard Joseph DiMuro, DIMURO, GINSBERG, & MOOK PC, Mark Robert Mann, GRAYSON & KUBLI PC, Mary Elizabeth Harkins, GRAYSON & KUBLI PC: counsel for plaintiffs DRC Inc, Robert J. Isakson, and William D. Baldwin; Deneed J. Melander, FRIED FRANK HARRIS SHRIVER & JACOBSON, Edward Scott Rosenthal, RICH GREENBERG ROSENTHAL & COSTLE LLP, James J. McCullough, FRIED FRANK HARRIS SHRIVER & JACOBSON, Lana Marie Manita, RICH GREENBERG ROSENTHAL & COSTLE LLP, Jennifer Jo Illingworth PORTER WRIGHT MORRIS ARTHUR: counsel for defendants Custer Battles LLC, Secure Global Distribution, Middle East Leasing, Custer Battles Levant, Scott Custer, and Michael Battles.

H. Lack of Presentment

- ***In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2007 WL 1334496 (D. Mass. May 8, 2007)**

Michael J. Sullivan, United States Attorney, George B. Henderson, II, Assistant U.S. Attorney, MA, R. Alexander Acosta, United States Attorney, Southern District of Florida, Mark A. Lavine, Ana Maria Martinez, Ann St. Peter-Griffith, Special Assistant U.S. Attorneys, Miami, FL, Peter D. Keisler, Assistant Attorney General, Michael F. Hertz, Joyce R. Branda, Renee Brooker, Justin Draycott, Gejaa T. Gobena, CIVIL DIVISION, COMMERICAL LITIGATION BRANCH, for United States.

James R. Daly, Daniel E. Reidy, JONES DAY, Chicago, IL, Mark P. Schnapp, Sabrina R. Ferris, GREENBERG TRAURIG P.A., Miami, FL, for Abbott Laboratories, Inc. and Hospira, Inc.

Sherrie R. Savett, Susan Schneider Thomas, Gary L. Azorsky, BERGER & MONTAGUE P.C., Philadelphia, PA, James J. Breen, Alison Simon, THE BREEN LAW FIRM, P.A., Miramar, FL, Jonathan Shapiro, STERN, SHAPIRO, WEISSBERG, & GARIN, MA, for Ven-A-Care of the Florida Keys, Inc.

• *U.S. ex rel. Arnold v. CMC Engineering*, 2007 WL 442237 (W.D. Pa. Feb. 7, 2007)

James A. Ashton, JAMES A. ASHTON, Jon Pushinsky, JOHN PUSHINSKY, William James Helzlsouer, WILLIAM JAMES HELZLSOUER: counsel for plaintiff United States ex rel. August W. Arnold; Jonathan K. Hollin, POWELL, TRACHTMAN, LOGAN, CARRLE, BOWMAN, & LOMBARDO, Paul A. Logan, POWELL, TRACHTMAN, LOGAN, CARRLE, BOWMAN, & LOMBARDO: counsel for defendant CMC Engineering

I. Lack of Government Funds

• *U.S. ex rel. McCandliss v. Sekendur*, 2007 WL 551567 (N.D. Ill. Feb. 20, 2007)

Glen McCandliss, LAW OFFICES OF GLEN A. MCCANDLISS: counsel for relator Glen McCandliss; Thomas Day Decker, THOMAS D. DECKER AND ASSOCIATES LTD: counsel for Batur C. Sekendur

• *U.S. ex rel. SNAPP, Inc. v. Ford Motor Company*, 2007 WL 420721 (E.D. Mich. Feb. 1, 2007)

E. Powell Miller, THE MILLER LAW FIRM, Melissa Wojnar-Raycraft, THE MILLER LAW FIRM: counsel for plaintiff SNAPP Inc.; Kenneth J. McIntyre, DICKINSON WRIGHT, L.Pahl Zinn, DICKINSON WRIGHT, Michelle L. Alamo, DICKINSON WRIGHT: counsel for defendant the Ford Motor Company

• *U.S. ex rel. El-Amin v. The George Washington University*, 2007 WL 1302597 (D.D.C. May 2, 2007)

Alan M. Grayson, Victor Aronoff Kubli, GRAYSON, KUBLI & HOFFMAN, P.C, for Plaintiffs/Relators.

Thomas Blaisdell Smith, ROPES & GRAY, Jonathan Lee Diesenhaus, William David Nussbaum, HOGAN & HARTSON LLP, Washington, DC, for Defendant.

- ***U.S. ex rel. Longhi v. Lithium Power Technologies, Inc.*, 481 F. Supp. 2d 815 (S.D. Tex. March 23, 2007)**

Andrew A. Bobb, US ATTORNEY'S OFFICE, TX, Mitch Kreindler, KREINDLER & ASSOCIATES P.C., TX, for Plaintiffs.

David C. Holmes, SOLOMON LAW FIRM PC, TX, for Defendants.

J. Liability For Employee's Actions

- ***U.S. ex rel. Shackelford v. American Management, Inc.*, 2007 WL 1174892 (E.D. Mich. April 19, 2007)**

Carolyn Bell Harbin, U.S. ATTORNEY'S OFFICE, MI, Justin C. Ravitz, Patricia A. STAMLER, SOMMERS, SCHWARTZ, MI, for Plaintiff-Relator.

Harold Z. Gurewitz, GUREWITZ & RABEN, MI, C. Frederick Robinson, MI, for Defendants.

William Heard, MI, pro se.

K. Counterclaims Against Relator

- ***U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 851823 (D.D.C. March 14, 2007)**

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

VI. Federal Rules of Civil Procedure

A. Rule 9(b) Failure to Plead Fraud With Particularity

• *U.S. ex rel. Smith v. Boeing Co.*, 2007 WL 1650924 (D. Kan. June 5, 2007)

Corlin J. Pratt, SHERWOOD, HARPER, DAKAN, UNRUH, & PRATT, Dean S. Rauchwerger, CLAUS MILLER P.C., Terry L. Unruh, SHERWOOD, HARPER, DAKAN, UNRUH, & PRATT, William J. Skepnek, SKEPNEK, FAGAN, MEYER, & DAVIS P.A.: counsel for plaintiffs Taylor Smith, Jeannine Pruitt, and James Ailes; Boyd A. Byers, FOULSTON SIEFKIN LLP, James M. Armstrong, FOULSTON SIEFKIN LLP, Jeffrey A. Jordan, FOULSTON SIEFKIN LLP, Steve Y. Koh, PERKINS & COIE: counsel for defendant, the Boeing Company;

• *U.S. ex rel. Landrith v. Pekin Memorial Hospital*, 2007 WL 1438582 (C.D. Ill. May 15, 2007)

Donald K. Birner, IL, James A. Lewis, Eric I. Long, U.S. Atty., IL, for Plaintiff.

L. Lee Smith, Danielle A. Lippens, HINSHAW & CULBERTSON, IL, for Defendant.

• *U.S. ex rel. Jorgenson v. Alan Ritchey, Inc.*, 2007 WL 1287932 (W.D. Wash. April 27, 2007)

John R. Scannell, Paul H. King, LAW OFFICE OF PAUL KING, David Reese Jennings, Peter Angus Winn, U.S. ATTORNEY'S OFFICE, WA, for Plaintiffs.

Brian K. Keeley, Medora A. Marisseau, BULLIVANT HOUSER BAILEY, WA, Paul Lee Myers, SRASBURGER & PRICE, TX, for Defendants.

• *U.S. ex rel. Brinlee v. AECOM Government Services, Inc.*, 2007 WL 1232205 (W.D. La. April 25, 2007)

Albert G. Alec Alexander, III, U.S. Attorneys Office, Lafayette, LA, Paul J. Wogaman, U.S. Dept of Justice, Washington, DC, Delbert G. Talley, Covington, LA, for Plaintiffs.

Timothy Stephen Babcock, Babcock Law Firm, Baton Rouge, LA, Jon W. Burd, Richard B. O'Keeffe, Jr., William A. Roberts, III, Wiley Rein et al., Washington, DC, for Defendant.

- ***In re Pharmaceutical Industry Average Wholesale Price Litigation*, 478 F. Supp. 2d 164 (D. Mass. March 22, 2007)**

Julie B. Brennan, MANCHEL & BRENNAN P.C., MA, for United Healthcare, Inc. & United HealthCare Insurance Company.

Charles Barnhill, MINER, BARNHILL, & GALLAND, WI, for Commonwealth of Kentucky, and State of Illinois.

Steven E. Bizar, BUCHANAN INGERSOLL P.C., Philadelphia, PA, for AmerisourceBergen Corporation.

Jeffrey B. Aaronson, BELL, BOYD, & LLOYD, Anthony J. Anscombe, SEDGWICK DETERT MORAN & ARNOLD, Violeta I. Balan, MAYER, BROWN, ROWE, & MAW LLP, Melanie Matison Brown, SEDGWICK DETERT MORAN & ARNOLD, IL, Marc E. Ackerman, HARRIS BEACH LLP, Kevin N. Ainsworth, MINTZ, LEVIN, COHN, FERRIS, GLOVSKY and POPEO, P.C., Melissa Aoyagi, DAVIS POLK & WARDWELL, Jennifer Aurora, SEDGWICK DETERT MORAN & ARNOLD LLP, Edwin Baum, PROSKAUER ROSE LAW FIRM, Sheila L. Birnbaum, SKADDEN, ARPS, SLATE, MEAGHER, & FLOM, Elise M. Bloom, PROSKAUER ROSE LAW FIRM, William P. Campos, SEDGWICK DETERT MORAN & ARNOLD LLP, William F. Cavanaugh, Jr., PATTERSON, BELKNAP, WEBB, & TYLER LLP, New York, NY, Joseph G. Adams, SNELL & WILMER LLP, Neil Alden, BOWMAN & BROOKE LLP, Martin A. Aronson, MORILL & ARONSON, Curtis Bergen, BOWMAN & BROOKE LLP, Donald Wayne Bivens, MEYER HENDRICKS & BIVENS PA, AZ, Pamela Zorn Adams, SHERIN and LODGEN LLP, Christopher K. Barry-Smith, OFFICE OF THE ATTORNEY GENERAL, Jessica Vincent Barnett, FOLEY HOAG LLP, Brandon L. Bigelow, BINGHAM MCCUTCHEN LLP, Scott A. Birnbaum, BIRNBAUM & GODKIN LLP, Robert P. Blood, GOODWIN PROCTER LLP, Michael P Boudett, FOLEY HOAG LLP, Douglas S. Brooks, KELLY, LIBBY & HOOPES, PC, Brett R. Budzinski, WILMER CUTLER PICKERING HALE and DORR LLP, MA, Kenneth W. Africano, HARTER, SECREST LAW FIRM, Mitchell J. Banas, Jr., JAECKLE FLEISCHMANN & MUGEL LLP, Elizabeth M Bergen, GIBSON, MCCASKILL LAW FIRM, Ann M. Campbell, BROWN & TARANTINO, Marco Cercone, RUPP, BAESE, PFALZGRAF & CUNNINGHAM, , NY, Justin S. Antonipillai, ARNOLD & PORTER, Pamela J. Auerbach, KIRKLAND & ELLIS LLP, Scott A. Barbour, MCNAME, LOCHNER, TITUS & WILLIAMS, NY, Steven F. Barley, HOGAN & HARTSON, LLP, MD, S. Paul Battaglia, BOND, SCHOENECK & KING PLLC, NY, Jon Steven Baughman, ROPES & GRAY LLP, Stacy D. Belf, ROPES & GRAY LLP, Jason Bruno, DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP, JonMarc P. Buffa, SONNENSCHEIN NATH & ROSENTHAL LLP, Michelle L. Butler, HYMAN PHELPS & MCNAMARA PC, Thomas C. Chabanis, SHOOK HARDY & BACON LLP., Ryan Beckett, BUTLER, SNOW, O'MARA, STEVENS, & CANNADA, Neville H. Boschert, WATKINS, LUDLAM, WINTER, & STENNIS, P.A., Felix Lee Bowie, III, DAVIDSON, BOWIE

& SIMS, PLLC, Roy D. Campbell, III, Bradley, ARANT, ROSE & WHITE, LLP, MS, Lawrence D. Berger, BALLARD SPAHR, ANDREWS & INGERSOLL, LLP, PA, Mark A. Berman, HARTMANN DOHERTY ROSA & BERMAN, LLC, NJ, Sam B. Blair, Jr., BAKER, DONELSON, BEARMAN, CALDWELL, & BERKOWITZ P.C., TN, Lynn M. Blake, FREIDMAN, HIRSCHEN LAW FIRM, NY, Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT, & TUNNELL, DE, George Ian Brandon, Sr., SQUIRE SANDERS & DEMPSEY LLP, AR, Raymond L. Brown, BROWN, BUCHANAN, & SESSOMS, PA, MS, Daniel Jerome Buckley, VORYS SATER SEYMOUR & PEASE, James Eugene Burke, KEATING MUETHING & KLEKAMP, OH, Richard O. Burson, FERRIS, BURSON & ENTREKIN, PLLC, MS, Kathleen T. Carter, WARD NORRIS HELLER & REIDY, NY, Tod S. Cashin, BUCHANAN INGERSOLL PC, NJ, Brent Caslin, KIRKLAND & ELLIS LLP, CA, for Defendants/Consolidated Defendants.

C. Jarrett Anderson, TX, Gary L. Azorsky, BERGER & MONTAGUE, PC, Terrianne Benedetto, Susan Aaronson, KLINE & SPECTER, P.C., Anthony Bolognese, BOLOGNESE & ASSOCIATES, Philadelphia, PA, Rebecca Bedwell-Coll, MASCONE, EMBLIDGE & QUAUDRA, CA, Steve W. Berman, HAGENS BERMAB SOBOL SHAPIRO LLP, Jeniphr Breckenridge, HAGENS BERMAN SOBOL SHAPIRO LLP, WA, David J. Bershad, MILLBERG WEISS BERSHAD HYNES & LERACH LLP, Michael M. Buchman, MILLBERG WEISS BERSHAD HYNES & LERACH LLP, Chris Chapman, WEITZ & LUXENBERG, James P. Carroll, Jr., KIRBY MCIERNEY & SQUIRE, NY, Ali Bovingdon, MT, James J. Breen, THE BREEN LAW FIRM, P.A., GA, Thomas W. Breidenstein, BARRETT & WEBER, Stanley M. Chesley, WAITE, SCHNEIDER, BAYLESS & CHESLEY CO., LPA, OH, Charlie Bridgmon, MCCUTCHEN, BALNTON, RHODES, & JOHNSON, Susan F Campbell, MCCUTCHEN, BLANTON, JOHNSON, & BARNETTE, SC, John Anthony Bruegger, SIMMONS COOPER, IL, Nicole Y. Brumsted, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP, MA, William F. Burns, GLASSMAN EDWARDS WADE & WYATT, PC, TN, Robert B. Carey, HAGENS, BERMAN, SOBOL, SHAPIRO PLLC, AR, Clinton C. Carter, BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES PC, AL, for Plaintiffs/Consolidated Plaintiffs.

Susan Hughes Banning, HEMENWAY & BARNES, MA, for Movant.

- ***U.S. ex rel. Absher v. Momence Meadows Nursing Center,* 2007 WL 685693 (C.D. Ill. March 2, 2007)**

Jullia F. Callahan, Michael F. Hertz, Polly A. Dammann, US Dept. of Justice, Washington, DC, Robin B. Potter, Robin Potter & Associates, Chicago, IL, Ronald E. Osman, Ronald E. Osman & Associates Ltd., Marion, IL, James A. Lewis, US Attorney, Springfield, IL, for Plaintiffs.

Howard M. Hoffmann, Amy E. McCracken, Nicholas J. Lynn, Duane Morris LLP, Chicago, IL, Keith E. Emmons, Meyer Capel PC, Champaign, IL, for Defendants.

- ***U.S. ex rel. Lafortune v. Beacon Ambulance Service, Inc.*, 2007 WL 580343 (W.D. Wis. Feb. 21, 2007)**

David L. Haron, FRANK, HARON, WEINER & NAVARRO, MI, Stephen E. Ehlke, Assistant U.S. Attorney, WI, for Plaintiff.

Nathan A. Fishbach, WHYTE HIRSCHBOECK DUDEK S.C., WI, for Defendant.

- ***U.S. ex rel. Heater v. Holy Cross Hospital*, 2007 WL 521931 (S.D. Fla. Feb. 15, 2007)**

Michael F. Hertz, U.S. DEPARTMENT OF JUSTICE, Stephanie I.R. Fidler, U.S. ATTORNEY'S OFFICE, Mark Gereon Bodner, ATTORNEY GENERAL OFFICE, DEPT. OF LEGAL AFFAIRS, FL, Wayne Lamprey, GOODIN MACBRIDE SQUERI RITCHIE & DAY LLP, CA, Carl Cory Mauro, EDWARDS ANGELL PALMER & DODGE LLP, FL, for Plaintiffs.

Daniel A. Miller, BROAD & CASSEL, FL, for Defendants.

- ***U.S. ex rel. Turner v. Michaelis Jackson & Associates, L.L.C.*, 2007 WL 496384 (S.D. Ill. Feb. 13, 2007)**

Ronald E. Osman, RONALD E. OSMAN & ASSOCIATES: counsel for plaintiffs Marsha Turner and Carolyn Swartos, Theodore J. McDonald Jr., BURROUGHS HEPLER, Michael L. Young, BURROUGHS HEPLER: counsel for defendants Michaelis Jackson & Associates and Michaelis Billy Jackson

- ***U.S. ex rel. Berglund v. The Boeing Company, Inc.*, 2007 WL 473757 (D. Or. Feb. 5, 2007)**

David J. Hollander, HOLLANDER, LEBENBAUM, & GANNICOTT, Frederick M. Morgan, VOLKEMA THOMAS LPA, Robert Rice, HELMER, MARTINS, RICE, & POPHAM Co. L.P.A: counsel for relator Cliff Berglund; Calvin L. Keith, PERKINS COIE LLP, Steve Y. Koh PERKINS COIE LLP, Renee E. Starr PERKINS COIE LLP

B. Rule 11 Sanctions

- ***U.S. ex rel. White v. Apollo Group, Inc.*, 2007 WL 870367 (5th Cir. March 22, 2007)**

Leeland O. White, TX, pro se.

Gerald F. Giordano, SNELL & WILMER, AZ, for Defendants-Appellees.

C. Rule 15(c) Relation Back Doctrine

- ***U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.,* 2007 WL 851855 (D.D.C. March 14, 2007)**

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

- ***Miller v. Holzmann*, 2007 WL 710134 (D.D.C. March 6, 2006)**

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

VI. Discovery Rules

A. Motion to Compel Production of Disclosure Statement

• *U.S. ex rel. Singh v. Bradford Regional Medical Center*, 2007 WL 1576406 (W.D. Pa. May 31, 2007)

Andrew M. Stone, STONE & STONE, Paul E. Skirtich, U.S. ATTORNEY'S OFFICE, PA, Gregory M. Simpson, SIMPSON LAW FIRM, GA, for Plaintiffs.

Daniel M. Mulholland, III, HORTY, SPRINGER & MATTERN, Carl J. Rychcik, Jay D. Marinstein, FOX ROTHSCHILD, PA, for Defendants.

• *Miller v. Holzmann*, 2007 WL 313566 (D.D.C. Feb. 2, 2007)

Robert B. Bell, WILMER HALE LLP, Gregory B. Reece, WILMER, CUTLER, PICKERING, HALE, & DORR, Howard M. Shapiro, WILMER, CUTLER, & PICKERING, Jennifer M. O'Connor, WILMER, CUTLER, PICKERING, HALE, & DORR, Jonathan Goldman Cedarbaum, WILMER HALE, Kevin Michael Henry, SIDLEY AUSTIN LLP, Matthew B. Baumgartner, WILMER, CUTLER, PICKERING, HALE, & DORR, Michael J. Gottlieb, WILMER, CUTLER, PICKERING, HALE, & DORR, Monya Monique Bunch, WILMER, CUTLER, PICKERING, HALE, & DORR, Robert D. Cultice, WILMER, CUTLER, PICKERING, HALE, & DORR: counsel for plaintiff Richard Miller; John H. Shenefield, MORGAN, LEWIS, & BOCKIUS LLP, Philip Craig Zane, BAKER, DONALSON, BEARMAN, CALDWELL, & BERKOWITZ PC: counsel for defendant Philip Holzmann

B. Motion in Limine

• *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 851868 (D.D.C. March 14, 2007)

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills,

Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

C. Attorney-Client Privilege

• *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 915235 (D.D.C. March 27, 2007)

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

VII. Litigation Developments

A. Exception to Automatic Bankruptcy Stay

• *In re HealthEssentials Solutions, Inc.*, 2007 WL 1453018 (Bkrtcy. W.D. Ky. May 17, 2007)

John L. Smith, KY, Jeffrey L. Zackerman, OH, for Debtor.

B. Issue Preclusion

• *U.S. ex rel. Westrick v. Second Chance*, 2007 WL 1020808 (D.D.C. March 31, 2007)

Stephen M. Kohn, David K. Colapinto, KOHN KOHN & COLAPINTO, P.C., Alicia J. Bentley, Callie R. Owen, U.S. DEPT. OF JUSTICE, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, for Plaintiff.

Konrad L. Cailteux, Michael J. Lyle, WEIL, GOTSCHAL, & MANGES LLP, NY, James S. Brady, Monica L. Cook, LAW FIRM OF MILLER JOHNSON, MI, William James Cople, III, SPRIGGS & HOLLINGSWORTH, Stephen Robert Spivack, Eric A. Frechtel, Bradley ARANT, ROSE, & WHITE, LLP, Drew William Marrocco, Joshua G. Berman, SONNENSCHEIN NATH & ROSENTHAL, LLP, David Schertler, Lisa Freiman Fishberg, SCHERTLER & ONORATO, L.L.P., Arden R. Pathak, Christopher W. Weller, George L. Beck, Jr., Terrie S. Biggs, AL, for Defendants.

• *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*, 2007 WL 851857 (D.D.C. March 14, 2007)

Robert B. Bell, Gregory B. Reece, Howard M. Shapiro, Jennifer M. O'Connor, Jonathan Goldman Cedarbaum, Matthew B. Baumgartner, Michael J. Gottlieb, Monya Monique Bunch, WILMER CUTLER PICKERING HALE AND DORR LLP, Kevin Michael Henry, SIDLEY AUSTIN LLP, Carolyn Gail Mark, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, Keith V. Morgan, U.S. ATTORNEY'S OFFICE, Michael F. Hertz, DEPT. OF JUSTICE, for Plaintiffs.

Charles Anthony Zdebski, June Ann Sauntry, TROUTMAN SANDERS LLP, Barry Coburn, TROUT CACHERIS PLLC, Charles Samuel Leeper, Jeffrey J. Lopez, Michael Reilly Miner, Elizabeth Ewert, Michael J. McManus, DRINKER, BIDDLE & REATH, Alan William Hugh Gourley, CROWELL & MORING LLP, David Schertler, SCHERTLER & ONORATO, LLP, Andrew Lawrence Hurst, Stephen Printiss Murphy, REED SMITH LLP, Brian P. Watt, Bryan B. Lavine, James J. Mills, Timothy J. Kozik, TROUTMAN SANDERS LLP, Charles C. Murphy, Jr., Ellen G. Schlossberg, VAUGHAN & MURPHY, GA, for Defendants.

C. Motion to Stay

• *U.S. ex rel. Brunson v. Narrows Health & Wellness, LLC*, 2007 WL 102881 (N.D. Ala. Jan. 4, 2007)

John D. Saxon, JOHN D SAXON PC, Redding Pitt, JOHN D SAXON PC, Stephen J. Austin, PORTERFIELD HARPER MILLS & MOTLOW PA, Carolyn Ngoc Lam, JOHN D SAXON PC, Lisa D. Davis, WILMER & LEE PA, Russell P. Parker, JOHN D SAXON PC: counsel for plaintiffs Denise Brunson and Michell Ronk; Daniel J. Burnick, SIROTE AND PERMUTT PC, Kyle T. Smith, SIROTE & PERMUTT PC: counsel for defendant Narrows Health & Wellness LLC.

Judgments & Settlements

JANUARY 1-JUNE 30, 2007

compiled by Asher Alavi

U.S. v. Robert I. Bourseau, et al., 03-cv-907-BEN (S.D. Cal. Sept. 29,2006)

September 29, 2006—Judge Robert Benitez of the U.S. Southern District Court of California ruled that hospital operators Robert I. Bourseau and Dr. Rudra Sabaratnam and their single-employee corporations, RIB Medical Management Services and Navatkuda Inc., were liable for more than $23 million dollars in damages for submitting false claims to Medicare. According to the verdict, Bourseau and Dr. Sabaratnam knowingly claimed false interest reimbursement from Medicare in the yearly cost reports of Bayview Hospital, which they controlled through their ownership of California Psychiatric Medical Services (CMPS). Numbering in the millions of dollars, these cost reports included CMPS bankruptcy fees, a fabricated lease expense, and unused square footage in the hospital. This judgment stemmed from a complaint filed in May of 2003 by the U.S. Government on behalf of the Department of Health and Human Services, Centers for Medicare and Medicaid Services. The case is currently on appeal in the Ninth Circuit Court of Appeals. Assistant U.S. Attorney Robert Ciaffa of the Southern District of California handled the case for the U.S along with trial attorneys Robert McAuliffe and Geeja Gobena of the U.S. Department of Justice's Civil Division.

U.S. ex rel Lee v. Horizon West Inc. et al., C-00-2921-SBA (N.D. Cal. Sept. 26, 2006)

September 26, 2006—California-based healthcare company, Horizon West Inc. and its subsidiary Horizon West Healthcare Inc., agreed to pay the U.S. Government $14.7 million to settle allegations of fraud brought under the False Claims Act. Horizon West, which runs nursing home facilities throughout California and Utah, was accused of falsely inflating nursing hours spent on Medicare patients in a *qui tam* complaint filed in 2000 by Julia Lee, a former director of nursing at a facility which was acquired by Horizon. Under terms of the settlement, Horizon will identify and pay unallowable costs it submitted for reimbursment, as well as the overcharges and interest from these costs. The case was investigated by the U.S. Department of Health and Human Services, Office of the Inspector General and the FBI. Lee's share of the settlement is currently being negotiated and Horizon will pay $99,693 to cover her attorney's fees and costs. TAF member Donald R. Warren of Warren-Benson Law Group represented Julia Lee. Sara Winslow and Steven J. Saltiel of the U.S. Attorney's Office for the Northern District of California and Suzette E. Gordon of the U.S. Department of Justice's Commercial Litigation Branch, Civil Division represented the Government.

U.S. v. Rogan 02-C-3310 (N.D.Ill. Sept. 29, 2006)

September 29, 2006—Judge John W. Darrah of the U.S. Northern District Court of Illinois ruled against Edgewater Hospital owner Peter Rogan, ordering him to pay more than $64 million in damages to the federal government for submitting false claims of reimbursement to Medicare and Medicaid in violation of the Stark law and

Anti-Kickback Statute. Darrah found Rogan guilty of giving kickbacks and bribes to physicians in exchange for referrals to his hospital and of disguising these kickbacks as legitimate payments eligible for reimbursement under Medicare and Medicaid. Additionally, Rogan engaged in the practice of hospitalizing patients without medical necessity and charging for medically unnecessary services to increase the amount of reimbursement he would be eligible to receive from Medicare and Medicaid. For these violations of the False Claims Act, Darrah imposed treble damages on Rogan, bringing the total to $64,259,032.50. Assistant U.S. Attorney Linda A Wawzenski handled the case.

American Medical Response Settlement (S.D.Tex. Oct. 5, 2006)

October 5, 2006—American Medical Response (AMR), one of the largest ambulance providers in the country, agreed to pay $9 million dollars to resolve charges that it defrauded the government by violating the Anti-Kickback Statute and the False Claims Act. The allegations stem from two *qui tam* cases filed in 2000 and 2001: *U.S. ex rel. Block v. Laidlaw Medical Transport* and *U.S. ex rel. Wightman v. Laidlaw Inc. et al.* Both of these suits assert that American Medical Response offered or provided financial kickbacks to hospitals to obtain their business. One such kickback scheme involved 'swapping arrangment' contracts, in which AMR would offer discounts to hospitals for standard emergency facility transport services in exchange for their non-emergency, discharge transport business. Relators Daniel Block and Adam Wightman will split a $1,6200,000 relator's share and will be reimbursed by AMR for their legal fees which amount to $122,455.07. The civil division of the Justice Department, the U.S. Attorney's Office for the Southern District of Texas, the Office of the Inspector General for the Department of Health and Human Services, and the FBI investigated this case. TAF members Glenn Grossenbacher and John E. Clark of Goode Casseb Jones Ricklin Choate and & Watson represented Adam Wightman and TAF member Anthony DeWitt of Bartimus Frickleton Robertson Gorny represented Daniel Block. Assistant U.S. Attorney Kevin Aiman handled the case along with Michael F. Hertz, Polly A. Damman, Jamie Ann Yavelberg, and Suzette Gordon of the U.S. Department of Justice, Civil Division.

U.S. ex rel. Diaz v. Lourdes Perez et al. (S.D. Cal. Oct. 16, 2006)

October 16, 2006—Lourdes Perez, the owner and operator of Provident Home Health Services Inc. (PHHS), was sentenced to 46 months in prison for defrauding Medicare and was required to make payments of $6,127,374 to Medicare and $874,336 to the IRS to settle civil charges filed under the False Claims Act. Marietta Diaz, a former payroll clerk at Provident Home Health Services, filed a *qui tam* complaint in 2003 that alleged that Perez had hired marketers to recruit patients for her home health service without regard to medical necessity and then billed Medicare for the services provided. Additionally, Diaz indicated that Perez had provided illegal kickbacks to doctors to get more referrals for PHHS. Although few patients actu-

ally visited PHHS, Perez billed Medicare and Medicaid regularly for their visits. In little more than 18 months, Perez defrauded the government of over $40 million. This sentencing resolves the criminal charges against Perez. The civil charges were already settled in 2003, when Perez agreed to pay the government $33.8 million. Assistant U.S. Attorney Wendy L. Weiss handled the settlement agreement. TAF member Michael P. Brown of Phillips and Cohen represented Marietta Diaz. The investigation of PHHS is still ongoing and is being coordinated by the FBI's Health Care Fraud Unit, the Criminal Investigation Division of the IRS, and the Department of Health and Human Services' Office of the Inspector General.

Michael Cox ex rel. People of the State of Michigan v. Specialized Pharmacy Services Inc., Omincare Inc., et al. 06-1039-CZ (Circuit Court for the 30th Judicial Circuit, Ingham County, Oct. 5, 2006)

October 5, 2006—Specialized Pharmacy Services Inc. and its parent company Omincare Inc. agreed upon a record $52.5 million dollar settlement with the State of Michigan to settle charges brought under the Michigan Medicaid False Claims Act. Specialized Pharmacy Services, a Michigan corporation which sells and distributes pharmaceutical products to hospitals and care facilities, signed a Unit Dose Agreement with the Michigan Medicare/Medicaid program in 1999, agreeing to only bill Medicaid for the actual quantity of pharmaceuticals used by patients. According to a complaint filed by Michigan Attorney General Mike Cox in 2006, Specialized Pharmacy Services defrauded Michigan's Medicaid program by deliberately overbilling the State for quantites of medications not consumed and by billing for prescriptions dispensed after a patient's death. The $52.5 million settlement was the largest False Claims settlement ever in the State of Michigan. In addition, SPS will enter into a Corporate Integrity Agreement to ensure its compliance with Medicare/Medicaid regulations. The Attorney General's Health Care Fraud Division conducted the investigation of SPS, with the assistance of Michigan's Department of Community Health, the FBI, and the U.S. Department of Health and Human Services. Michigan Attorney General Michael A. Cox and Assistant Attorney General Mark Matus of the Health Care Fraud Division handled the case for the state of Michigan.

U.S. ex rel. Hicks v. Oracle Corporation & PeopleSoft Inc., PJM-03-422 (D. Md. Oct. 10, 2006)

October 10, 2006—Oracle Corporation agreed to pay $98.5 million to settle False Claims Act allegations made against its recently acquired subsidiary, PeopleSoft Inc. Relator James A. Hicks, a former employee of PeopleSoft, filed a complaint alleging that PeopleSoft had failed to disclose its Multiple Product Price Reduction (MPPR) discount, which it offered to commercial customers in its negotiation with agencies of the federal government under the General Services Administration Multiple Award Schedule program (GSA-MAS). Accruing over the time period between 1997 and 2005, the overcharges numbered in the tens of millions. The $98.5 million dollar set-

tlement is the largest amount of money ever acquired by the government in a False Claims Act case involving the GSA-MAS program. Hicks will receive $17,730,000 for his efforts. Mark London and TAF member Christopher B. Mead of London & Mead in Washington D.C. represented James Hicks. Assistant U.S. Attorney Michael A. DiPietro and David J. Leviss of the U.S. Department of Justice's Commercial Litigation Branch, Civil Divison represented the government.

U.S. ex rel. Burns et al. v. Northside Hospital Inc. et al. 1:04-CV-0501 (N.D. Ga. Oct. 20, 2006)

October 20, 2006—Northside Hospital in Atlanta and two physician-owned groups: Blood and Marrow Transplant Group of Georgia (BMTGA) and Atlanta Blood Services (ABS), will pay a total of $6.37 million dollars to settle charges raised in a *qui tam* lawsuit. Former CEO Cheryl Burns and former billing officer Janine Slaughter filed a complaint under the False Claims Act against these three groups in 2004, claiming that Northside Hospital had violated the Stark Law by referring patients to ABS and BMTGA despite having a financial relationship with both. Additionally, Northside allegedly paid kickbacks to physicians in exchange for referrals to Northside Hospital including the provision of free employees to the physicians the purchasing of various products from the physicians at inflated prices. In the settlement agreement, Northside Hospital agreed to pay $5.72 million and BMTGA and ABS agreed to pay $650,000. Ms. Burns and Ms. Slaughter will split a $1.2 million share of the settlement. The U.S. Department of Health and Human Services, the Office of the Insepctor General, and the FBI headed the investigation. Assistant U.S. Attorney Mina Rhee represented the U.S. TAF member Marlan B. Wilbanks and Tyrone M. Bridges of Harmon, Smith, Bridges, and Wilbanks and Scott C. Withrow of Withrow, McQuade, and Olsen represented Cheryl Burns and Janine Slaughter.

U.S. ex rel. Hunt et al. v. Medco Health Solutions Inc. and Merck & Co. Inc., 00-V-737 (E.D.Penn. Oct. 23, 2006)

October 23, 2006—Medco Health Solutions agreed to pay $155 million dollars plus interest to the government to settle allegations of two False Claims suits and a civil investigation that it received illegal kickbacks from physicians in violation of the Anti-Kickback Statute and submitted false claims for reimbursement from Medicare and Medicaid. Relators Walter Gauger and George Hunt, both ex-employees of Medco Health Solutions Inc, alleged that Medco had offered kickbacks to health plans in exchange for their business, received kickbacks from pharmaceutical companies in exchange for using their drugs, and destroyed and canceled valid patient prescriptions. Their suit was consolidated with another False Claims suit brought by Joseph Piacentile, a prescription consultant for Ramp Corp., who accused Medco of withholding millions of dollars obtained in rebate agreements with pharmaceutical companies, and of deliberately switching and relabeling patients' prescriptions to cheaper or less effective drugs. Piacentile will receive $3 million of the relator's share while Gauger and

Hunt will split a $20.16 million share. TAF members Marc S. Raspanti of Miller, Alfano, & Raspanti and David S. Stone of Boies, Schiller, & Flexner represented the relators along with Allison M. Duncan, Philip E. Kessler, and Patrick H. Haggerty of Porter, Wright, Morris, & Arthur. Assistant U.S. Attorney M. Catherine Frye represented the U.S.

U.S. ex rel. Pittelli v. Keystone Mercy Health 01-CV-2379 (E.D.Penn. Oct. 26, 2006)

October 26, 2006—Keystone Mercy Health Plan agreed to pay $5 million dollars to resolve allegations brought under the False Claims Act that it failed to report its coordination of benefits (COB) recoveries and overpayments received from third party healthcare providers to the Pennsylvania Department of Public Welfare. As the operator of a managed-care health plan for Medicaid recipients in Southeast Pennsylvania, Keystone Mercy Health was required to hand over certain recoveries to DPW if these recoveries were made after a certain time period. Relator Lorraine A. Pittelli, however, filed a *qui tam* lawsuit against Keystone Mercy Health Plan in 2001, accusing KMHP of failing to submit these funds to the government. The U.S. intervened in this case after an investigation coordinated by the U.S. Attorney's Office of the Eastern District of Pennsylvania and the Pennsylvania Department of Public Welfare. Ms. Pittelli will receive $780,000 as her share of the recovery. Assistant U.S. Attorneys Virginia A. Gibson and Joseph Trautwein and Associate U.S. Attorney James G. Sheehan represented the U.S. Howard Bruce Klein and Bruce J. Goldstein of represented Lorraine Pitelli.

U.S. ex rel. Joan Gallagher v. InterMune Inc. 04-CV-3249 (E.D.Penn. Oct. 26, 2006)

October 26, 2006—California-based bio-pharmaceutical company, InterMune Inc., agreed to pay $37 million and enter into a deferred prosecution agreement with the government to settle civil and criminal charges that it illegally marketed its drug, Actimmune, for the treatment of idiopathic pulmonary fibrosis (IPF). The monetary settlement resulted from a *qui tam* suit filed in 2004 by Joan Gallagher, a former employee of InterMune. In her complaint, Gallagher alleged that InterMune made unlawful claims for reimbursement from Medicare and Medicaid by illegally prescribing Actimmune for a medically unapproved use. Although the FDA did not approve off-label uses of the drug, most of Actimmune's sales were for the off-label treatment of IPF. Intermune was able engineer this off-label use by publishing a press-release stating that Actimmune would benefit the survival of patients with IPF. This press release was deliberately misleading, as Actimmune's clinical trial was a failure. A two-year investigation by the FBI, the FDA's Office of Criminal Investigations, the Department of Health and Human Services' Office of the Inspector General, the Veterans Administration's Office of Investigation, and the Office of Personnel Management's Office of Investigations substantiated the claims made by Gallagher. As part of the settlement, Intermune signed a five-year Corporate Integrity Agreement with the Office

of Inspector General for the Department of Health and Human Services, to insure its compliance with federal regulations. The criminal prosecution against Intermune will be deferred for a period of two years, depending on Intermune's cooperation with the compliance policies stipulated in the agreement. Under separate settlement agreements, Intermune will pay $6.7 million to state Medicaid programs for its fraudulent practices regarding Actimmune. Relator Joan Gallagher will receive $5,748,160 as her share of the recovery. Assistant U.S. Attorneys Ioana Petrou and Alex Tse of the Northern District of California and Attorney Andy Mao of the Fraud Section of Civil Division oversaw the investigation and settlement of the case. John A. Beranbaum of Beranbaum Menken Ben-Asher & Bierman LLP represented Gallagher.

U.S. et al. ex rel. Lisitza v. Omnicare Inc. 01-c-7433 & U.S. et al. ex rel Kammerer v. Omincare Inc. 04-C-2074 (N.D.Ill. Nov. 14, 2006)

November 14, 2006—Omincare Inc., the nation's largest provider of pharmacy services to nursing home facilities, settled two False Claims lawsuits by agreeing to pay $49.5 million to the U.S. federal government and 43 state governments. According to allegations in both *qui tam* suits, Omnicare switched Medicare patients on three separate drugs to more expensive alternatives to obtain the higher reimbursement rate from Medicare and Medicaid. Omnicare often carried out this scheme without informing the patient's doctor of the purpose behind the switch or by providing misleading information concerning the affordability or effectiveness of the more expensive drug. The U.S. Attorney's Office and the National Association of Medicaid Fraud Control Units headed the investigation. The settlement was the largest ever in the Northern District of Illinois. Relator Bernard Lisitza will receive $6,443,204 for his part in the case and relator David Kammerer will receive $792,593. TAF member Michael Behn, of Behn & Wyetzner in Chicago, represented Bernard Lisitza. Charles Atkins of Weisser and Wolf in Cincinnati and TAF member Shelly Slade of Vogel & Slade in Washington D.C. represented David Kammerer. Linda A. Wawzenski, the deputy chief of the U.S. Attorney's Office Civil Division, represented the United States.

U.S. ex rel. Heckenkemper v. Integris Baptist Medical Center, Inc. & Integris Health, Inc., 3:03-CV-1619-L (W.D. Ok. Nov. 28,2006)

November 28, 2006—Non-profit health organization, Integris Baptist Medical Center, Inc. (IBMC) and its parent company, Integris Health, Inc. agreed to pay $12.2 million to resolve a False Claims Act case alleging that IBMC falsely inflated its costs relating to Integris' organ transplant department. Relator Frank Heckenkemper, a former contractor of Integris, filed a *qui tam* complaint against them in 2003, claiming that Integris knowingly submitted ineligible claims for Medicare/Medicaid reimbursment and billed Medicare/Medicaid for patients who were not covered by these programs. The U.S. Attorney's Office, the Department of Justice, and the Department of Health and Human Services began a joint investigation of Integris in response to this *qui tam* action. Mr. Heckenkemper will receive $2.3 million for his share of the recovery. TAF

member Peter W. Chatfield of Phillips & Cohen LLP in Washington D.C. represented the relator. Assistant U.S. Attorney Sean R. McKenna represented the U.S.

KBR Settlement

November 29, 2006—Halliburton subsidy, KBR, has agreed to pay the government $8 million to settle allegations that it overbilled the army for its services in the 1999 construction of Camp Bondsteel in Kosovo. The accusations, brought under the False Claims Act, allege that KBR double-billed for supplies and shipped non-conforming products from foreign suppliers for use in the construction of Camp Bondsteel. Additionally, KBR was accused of price inflating and failing to ensure competitive procurements. The U.S. Army Criminal Investigation Division and the Defense Criminal Investigative Service investigated the case. It is one of several defense-related, False Claims Act cases pending against KBR and Halliburton.

U.S. v. Jack Jacobo Michel M.D. et al. 1:04-cv-21579 (S.D.Fla. Nov. 30, 2006)

November 30, 2006—Larkin Community Hospital and its current and previous owners have agreed to pay $15.4 million to settle allegations brought under the False Claims Act that they had engaged in unlawful kickback schemes with physicians and had conspired to provide medically unnecessary services to patients to increase their reimbursment from both federal and Florida Medicaid/Medicare. Owners Dr. Jack Jacobo Michel M.D., Dr. James Desnick M.D., Morris Esformes, and Philip Esformes along with ex-employees Frank Palacios and Claudia Pace and 34 related companies were all part of the settlement. The settlement rose out of a compliant filed by the federal government in 2004 against Larkin which alleged that the hospital had paid kickbacks to physicians in exchange for patient referrals and had deliberately admitted patients into the hospital for treatments which were medically unnecessary. Florida joined the suit later in 2004. The U.S. Department of Health and Human Services, the FBI, and the Florida Medicaid Fraud Control Unit investigated the case. Assistant U.S. Attorneys Mark Lavine and Magda Lovinsky handled the case along with Michael F. Hertz, Polly A. Damman, and Alicia J. Bentley of the U.S Department of Justice's Commercial Litigation Branch.

U.S. ex rel. Kaczmarczyk et al. v. SCCI Health Services Corporation, 4:99-cv-01031 (S.D.Tex. Jan. 5, 2007)

January 5, 2007—SCCI Health Services Corporation and its subsidiary SCCI Hospital Ventures agreed to pay $7.5 million to settle allegations that they violated the Stark Law and the False Claims Act by engaging in prohibited financial relationships with physicians while receiving financial reimbursment from Medicare/Medicaid. SCCI, a nationwide medical service provider, was accused of making illegal financial payments to a number of physicians in violation of the Stark Act and of committing other fraudulent activities including false billing by a number of ex-employees who

filed a joint complaint in 1999. The U.S. intervened in 2002 after the Justice Department and the U.S. Attorney's Office for the Southern District of Texas conducted an investigation into the practices of SCCI. Relators Daryl Kaczymarczyk, Patricia Rocha, Michelle Pate, Michael Brigle, and Theresa Taylor will split $1.7 million as their share of the recovery. TAF members Jennifer Verkamp and Rick Morgan of Volkema Thomas; James Helmer of Helmer, Martins, Rice, & Popham, Co. L.P.A; and Donald Patrick McKenna and Scott Powell of Hare, Wynn, Newell, and Newton represented the relators along with John Green of Bloodworth & Green. Assistant U.S. Attorney Michelle Zingaro of the Southern District of Texas and Patricia L. Hanower and Suzette E. Gordon of the Department of Justice's Commericial Litigation Branch, Civil Divison represented the U.S.

U.S. ex rel. Moore v. East Tennessee Heart Consultants, 3:03-CV-577 (E.D.Tenn. Jan. 11, 2007)

January 11, 2007—East Tennessee Heart Consultants (ETHC), a group of 42 cardiologists, agreed to pay a total of $2.9 million dollars to the federal government, the state of Tennessee and a number of patients and insurance companies to settle allegations that they had failed to refund overpayments to Medicare, Medicaid, and the TennCare. The allegations arose from a False Claims Act suit filed in 2003 by two former employees of ETHC: Kristi Moore and Valarie Byrd. In their complaint, the relators alleged that ETHC had an intentional policy of retaining credit balances made by Medicare, Medicaid, and TennCare and of concealing the balances of these overpayments in order to submit more claims. Both civil and criminal investigations were conducted by the U.S. Attorney's Office for the Eastern District of Tennessee as well as other state and local authorities. Moore and Byrd will each receive $334,287 as their share of the recovery. TAF member David A. Burkhalter and Ronald A. Rayson of Burkhalter, Rayson, & Associates represented the relators. U.S. Attorney James R. Dedrick represented the U.S.

U.S. ex rel. Tyson v. Amerigroup Illinois Inc. 1:02-cv-06074 (N.D.Ill. Mar. 13, 2007)

March 13, 2007—U.S. Judge Harry Leinenweber (N.D. IL) pronounced a $190 million civil penalty on Amerigroup Corporation and Amerigroup Illinois, bringing the total judgment against the HMO to more than $334 million. This judgment came after an October verdict in which a federal jury found Amerigroup liable for 18,130 false claims and $144 million in damages to the U.S. government and the State of Illinois under the False Claims Act. The jury found that Amerigroup deliberately avoided insuring late-term pregnant women and other people with a high health-risk status to inflate its profits. As a result, less than half of the $243 million dollars it received from its managed care contract with Medicaid was used to provide health services to low-income people in Illinois, despite its promise to provide services to all indigent persons regardless of health-status. The judgment stemmed from a *qui tam* suit filed

in 2002 by Cleveland Tyson, a former vice president of governmental relations with Amerigroup. Tyson will receive between 15-25% of the total damages. Amerigroup denied any wrongdoing and plans to appeal the judgment. Assistant U.S. Attorneys Samuel B.Cole and Michele Fox represented the U.S. and Assistant Attorneys David J. Adams and Anne R.K. Reader represented the State of Illinois in the prosecution. TAF members Fred Cohen and David Chizewer of Goldberg, Kohn represented Cleveland Tyson.

Raritan Bay Medical Center Settlement

March 15, 2007—Raritan Bay Medical Center, of Perth Amboy, New Jersey, agreed to pay $7.5 million to the federal government to resolve claims made in three separate *qui tam* cases that it defrauded Medicare in violation of the federal False Claims Act. As alleged in the three complaints, Raritan Bay Medical Center falsely inlated its reimbursement from Medicare's outlier payment system by fraudulently increasing the charges of inpatient/outpatient care from 1998 to 2005. Raritan Bay also agreed to enter into a Corporate Integrity Agreement with U.S. Dept. of Health and Human Services to ensure compliance with Medicare regulations. TAF members Erika A. Kelton and Larry P. Zoglin of Phillips & Cohen LLP and Jonathan S. Berck LLC represented Anthony Kite, the relator in one major case against Raritan Bay Medical Center. Information about the other two cases is not available. Assistant U.S. Attorney Stuart Minkowitz and Daniel Spiro of the Department of Justice handled the case for the U.S. The case was investigated by the Justice Department 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, Offie of the Inspector General; the Centers for Medicare and Medicaid Services; and the FBI.

U.S. ex rel. McCaslin v. Harris County Hospital District, H-03-4438 (S.D. Tex. Mar. 27, 2007)

March 27, 2007—Harris County Hospital District in Texas agreed to pay close to $15.5 million to settle charges that it defrauded Medicare/Medicaid by knowingly submitting ineligible reimbursment claims. Relator Robert McCaslin, a former patient-account representative with Harris County Hospital District (HCHD), filed a *qui tam* suit in 2003, after learning that his division had been routinely submitting claims which were not allowed under Medicare/Medicaid regulations. Specifically, McCaslin recognized that HCHD had failed to comply with the Medicare as Secondary Payer (MSP) regulation which requires health care providers to bill private insurance coverage before seeking restitution from Medicare/Medicaid. In addition to flouting this regulation, HCHD would bill Medicare/Medicaid for medical servies provided to patients who were in the custody of law enforcement—an unlawful practice under Medicare/Medicaid regulations. TAF members Mitch Kriendler of Kriendler & Associates and Mary Louise Cohen of Phillips and Cohen LLP represented McCaslin. For his efforts, McCaslin will receive $2,780,842.85 of the settlement agreement.

U.S. ex rel. Reilly v. Catskill Regional Medical Center, 1:00-cv-7906 (S.D. N.Y, Mar. 28, 2007)

March 28, 2007—Cabrini Medical Center, a non-profit medical center in New York, paid $3.2 million to the federal government to settle charges that it defrauded Medicaid in violation of the False Claims Act and the Anti-Kickback Statute. The settlement arose from a *qui tam* suit filed by relator John F. Reilly in 2000 that alleged that Cabrini had participated in a referral scheme in which it would pay kickbacks out of funds received from the Medicaid program to AppliedCaseManagement Inc. in exchange for referrals to its detoxification program. Cabrini also entered into a fraudulent agreement with AppliedCaseManagement in which Applied was to provide administrative services for the Cabrini detoxification unit. These services were never used or were not needed by Cabrini, however, and merely served as an excuse for Cabrini to pay AppliedCaseManagement for referrals and bill Medicaid for the cost of these referrals. Although Cabrini denied any wrongdoing, it entered into a corporate integrity agreement with the Office of Inspector General of the Dept. Health and Human Services to ensure conformity with federal regulations. Reilly will receive $680,000 as his share of the recovered funds. TAF member Timothy J. McInnis of the Law Office of Timothy J. McInnis represented the relator with the assistance of TAF member David Koenigsberg of Menz Bonner & Komar LLP. Assistant U.S. Attorney Heidi A. Wendel handled the case.

Strozdas v. Environmental Management Inc., 5:04-cv-0093-HE (W.D. Ok. Mar. 31, 2007)

March 31, 2007—Environmental Management Inc, an environmental management company based in Guthrie Oklahoma, agreed to pay $850,000 to settle allegations made in a 2004 False Claims Act suit. David Strozdas, a former employee of Environmental Management Inc, claimed in his *qui tam* suit that EMI had defrauded the government by overbilling for services in its contract to clean up illegal methamphetamine labs. According to Strozdas, EMI not only used false overtime and expense invoices and fraudulent vacation allowances, but it also paid its employees below the market wage to keep the extra funds received in the contract for itself. Additionally, Strozdas indicated in his complaint that EMI improperly disposed of chemicals used in the clean up of the meth labs. EMI agreed to pay $700,000 immediately under the terms of the settlement agreement and to pay an additional $200,000 by February of 2008. Strozdas' share of the settlement agreement has not been disclosed. Kenneth N. McKinney and Connie M. Bryan of McKinney and Stringer and Cheryl A Vaught of Vaught & Conner represented David Strozdas.

U.S. ex rel. Marchese v. Cell Therapeutics Inc., et al., 06-0168-MJP (W.D.Wash. Apr. 17, 2007)

April 17, 2007—Cell Therapeutics, a pharmaceutical company based in Seattle, agreed to pay $10.5 million to settle allegations that it paid illegal kickbacks to physicians in violation of the Anti-Kickback Statue and the False Claims Act. Relator James

Marchese, a former oncology account manager with Cell Therapeutics Inc, filed a *qui tam* complaint in 2006 against his former company, alleging that CTI had improperly marketed its cancer drug, Trisenox, for unapproved uses through an unlawful kickback scheme. To induce doctors to prescribe its drug to potential patients, CTI provided them with substantial monetary payments as well as other incentives such as free food, entertainment, and travel. Additionally, CTI knowingly made false statements to the physicians by telling them that Trisenox was approved for certain off-label uses. The result of this kickback scheme was the payment of millions of Medicare/Medicaid dollars for the medically unproven use of a drug. Marchese's share of the settlement is still under negotiation. Robert G. Chadwell of McKay Chadwel PLLC represented James Marchese. Assistant U.S. Attorney Peter A. Winn and Alan Gale of the U.S. Department of Justice's Commercial Litigation Branch, Civil Division represented the United States.

Loma Linda Behavioral Medical Center

April 25, 2007—The Loma Linda Behavioral Medical Center (BMC) agreed to pay more than $2 million dollars to settle charges that it defrauded the government by overbilling Medicare in violation of the False Claims Act. The charges rose from a *qui tam* suit filed in 1998 by a former employee of Healthcare Financial Avisors (HFA), the consulting firm that assisted a number of hospitals in defruading the government. In this suit, the relator accused a number of these hopsitals, including Loma Linda BMC, of submitting false cost reports for Medicare reimbursement. With the assistance of HFA, Loma Linda BMC had filed fraudulent cost reports to Medicare, seeking reimbursement for unrelated expenses such as outpatient meals, and an unrelated employee assistance program. Although Loma Linda BMC agreed to pay $2,049,451.30 to settle these allegations, it did not admit any wrongdoing. Since the suit was filed in 1998, a number of hospitals named in the suit have settled with the government, the most recent being Jackson Memorial Hospital in Miami, which agreed upon a $14.25 million settlement last December. The Department of Health and Human Services, Office of the Inspector General investigated the case. The U.S. Attorney's Office for the Central District of California and the State of California Attorney General'S Office negotiated upon the settlement.

U.S. et al. ex rel. Mulqueen et al. v. Medicis Pharmaceutical Corp., 2:04-cv-02389 (D. Kan. May 8, 2007)

May 8, 2007—Arizona-based Medicis Pharmaceutical Corporation agreed to pay $9.8 million to settle allegations that it violated the False Claims Act. The settlement arose from a *qui tam* case filed in 2004 by several former Medicis sales representatives who alleged that Medicis had promoted the off-label use of its skin ointment, Loprox, to physicians as a treatment for diaper rash despite the fact that the drug was unapproved for use on children under the age of ten. According to the complaint filed by the relators, the Medicis sales team was given a memorandum by the Medicis

management that stated that Loprox was safe to use for diaper rash, citing a fictitious 'Japanese study' as proof of its safety. Medicis' management covered up this scheme by instructing its sales team to not leave paper copies of brochures describing this off-label use. The end result of these fraudulent, off-label prescriptions for Loprox was the loss of millions of dollars by the Medicaid program. Medicis' pediatric sales unit was sold off in 2004. Relators Debbie Mulqueen, Lisa Altazan, Cynthia Hamilton, and Julia Laib will receive $1,078,000 as their share of the settlement. Carrie Mulholland Brous and Tammie L. Horn of Brous Horn LLC represented the relators. AUSA Laurie Karhs represented the U.S. The FDA's Office of Criminal Investigations and the State of Kansas Attorney General's Office investigated the case and the U.S. Attorney's Office for the District of Kansas and the Civil Division of the Department of Justice handled it.

U.S. ex rel. American Fiber Systems Inc. v. Kansas City, Missouri School District and AT&T Inc., 06-0389-CV-W-NKL (W.D. Mo. May 8, 2007)

May 8, 2007—The Kansas City, Missouri School District (KCMSD) agreed to drop $13.6 million in federal reimbursement claims and to pay the United States an additional $66,000 to settle charges that it filed false claims on the FCC's E-Rate program from 2002 to 2006. Under the E-Rate program, disadvantaged schools in low-income areas are eligible to receive federal funding to set up and provide Internet access. KCMSD's settlement arose from a *qui tam* complaint filed in May 2006 by American Fiber Systems Inc., which alleged that KCMSD had submitted false claims for E-Rate reimbursement by not complying with the required competitive bidding process, for seeking payments from contracts that had been cancelled, and for unlawfully extending contracts to avoid rebidding. As part of the settlement, KCMSD agreed to disallow three employees and the school district's consultant, Dietrich Lockard Group, who previously handled the school's E-Rate applications, from participating in the school district's E-Rate application process. The Justice Department's Civil Division, the U.S. Attorney's Office for the Western District of Missouri, and the FCC's Office of the Inspector General conducted the investigation. Juliet A. Cox of Sonnenschein, Nath, & Rosenthal LLP represented the relator and Assistant U.S. Attorney Lucinda S. Woolery represented the United States.

From the Frontlines

"Off-Label" Marketing & The False Claims Act

"Off-Label" Marketing & The False Claims Act

by Shelley R. Slade[1]

Pharmaceutical companies and doctors often market drugs, and physicians often prescribe drugs for uses other than those specified on the product labels approved by the Food & Drug Administration (FDA). This so-called "off-label" distribution of medicine can expose drug manufacturers and doctors to liability under federal and state false claims laws when the drugs are paid for by a government health plan. This is because government health programs generally do not cover "off-label" uses of medications unless the off-label use has been authoritatively determined to be safe and effective.

After providing background on the facts and law that give rise to liability in such circumstances, this article discusses the federal government's willingness to aggressively use the federal False Claims Act (FCA) in cases involving off-label promotional activity, and offers suggestions on assessing potential legal action. The author observes that while the government has yet to pursue physicians for false claims based on their off-label marketing or prescription activity, it could do so under the existing statutory scheme, and might be inclined to do so if the physician's conduct was particularly egregious.

I. THE STATUTORY REMEDY

Although it is the pharmacies, and not the drug manufacturers and prescribing physicians who submit drug claims to government health plans such as Medicaid, the manufacturers and physicians can still be liable for such claims when they are false. This is because the federal False Claims Act imposes triple damage liability on any person who, among other things, knowingly *causes* the submission of false claims to the federal government for payment or approval.[2] As of this writing, twenty states have enacted analogous false claims law legislation that also imposes liability for the causation of false claims.[3] Accordingly, if the circumstances show that a pharmaceutical company or a physician knowingly has taken actions to cause a pharmacy to submit false claims, they need to be concerned about liability under the false claims laws.

Since liability for drug companies and doctors will arise under the "causation" prong of the false claims laws when pharmaceuticals are billed, it is useful to think of these laws as requiring a plaintiff suing a pharmaceutical manufacturer or a doctor for false drug claims to establish the following elements:

- a claim that is false because it seeks payment for off-label services not covered by the health plan

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2. *See* 31 U.S.C. § 3729(a)(1).

3. As of May 29, 2007, the District of Columbia and the following states have enacted false claims laws with *qui tam* provisions: California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, New Hampshire, New Mexico, New York, Nevada, Oklahoma, Tennessee, Texas and Virginia.

- [that the defendant] knowingly
- caused to be
- submitted for payment or approval by the government
- with compliance with the FDA label being material to the government's payment decision.

If plaintiff seeks damages as a result of the misconduct, he will also need to establish that these violations of the false claims law "caused" damages.

The following discussion analyzes how a drug company's off-label promotion of a drug and a physician's off-label marketing or prescribing activity can lead to misconduct that violates each of these elements.

A. The False Claim

1. Promoting Drugs for Unapproved Uses is Illegal

Stories abound of the ways in which the pharmaceutical industry is betraying the trust of the public. One of the more egregious examples of this betrayal is the industry's willingness to aggressively promote its products for uses that the FDA has not yet determined to be safe and effective—so-called "off-label uses." The FDA has the authority to approve the marketing of a drug only for uses that the FDA has judged to be both safe and efficacious through clinical trials or otherwise.[4] Drug manufacturers are prohibited from commercially marketing drugs for non-FDA-approved indications.[5]

The FDA oversees multi-stage, manufacturer-conducted, clinical trials to determine the safety and efficacy of drug products when used in a specified manner to treat particular illnesses or conditions. Once the FDA agrees with the manufacturer that a given drug has been shown through such trials to be safe and effective for particular uses, the FDA will work with the manufacturer on a product label that appropriately describes these uses. The label is supposed to reflect the uses that the FDA has found to be "safe and effective"; conversely, any use not listed on the label is presumptively one that the FDA has not yet found to be safe and effective.[6]

Despite the prohibitions in U.S. law, many drug manufacturers nonetheless promote a product off-label. They do so through a variety of techniques, such as:

- Making sales calls on physicians with practices exclusively dedicated to a class of patients for whom the drug is not yet indicated (*e.g.*, pediatricians in the case of a drug not yet found to be safe and effective for children);

4. 21 U.S.C. § 355(d).

5. 21 U.S.C. § 331(a) and (d); 21 U.S.C. § 333(a)(2); 21 C.F.R. § 312.7.

6. If the FDA concludes that medical studies indicate a significant risk of serious or even life threatening adverse effects from a particular use of a drug, the FDA will require the manufacturer to include a warning on the label inside a box with heavy black borders. This warning is referred to as a "black box warning."

- Urging physicians to develop a protocol for use of the drug in a non-indicated manner;
- Distributing or causing the distribution of non-peer reviewed "studies" of dubious scientific value that support the off-label use; and,
- Asserting in oral or written communications that the use is advisable, desirable, or recommended.

Pharmaceutical manufacturers often carry out such sales efforts by methods that compromise the independence and quality of medical decision-making. For example, drug companies often corrupt medical decision-making by coupling their off-label promotional activity with financial inducements to doctors, such as sizeable payments in exchange for completion of drug-related "questionnaires" or "consultations," grant money for studies of dubious scientific value, or honoraria for "speaking" about the benefits of the drug. These payments are often nothing more than disguised rewards to the doctors for prescribing a drug; the payment to the doctor far exceeds the cost of the minimal work that the drug company asks the doctor to perform, and, furthermore, the requested work has little if any legitimate value for the manufacturer.[7]

In addition, pharmaceutical sales representatives often impact the quality of medical decision-making by feeding false or misleading information about a drug to doctors. For example, manufacturers have been known to falsely suggest that a drug has been found to be safe and effective for a given use when it has not been.

Physicians are busy and overwhelmed with paperwork, and generally rely on drug company representatives for information about the proper use of their products. Receiving false or misleading information from sales representatives consequently can cause doctors to prescribe a drug based on an incorrect understanding of the outcome of clinical trials.

2. Government Programs Pay for Safe & Effective Treatments Only

As discussed below, Government health programs generally do not cover drug products unless their use in the circumstances is reasonable and necessary, which the programs have determined requires that the drugs be used in a safe and effective manner. These programs tend to rely on FDA determinations of what is safe and effective, as well as conclusions in authoritative medical compendia. If a particular use clearly is not indicated on the FDA-approved product label, and if the use also has not been

7. When a pharmaceutical company provides financial remuneration to a physician as a quid pro quo for the doctor increasing his off-label prescriptions of the company's drug, the company and the doctor may violate federal anti-kickback law as well as FDA marketing rules. The Federal Health Care Program Anti-Kickback Statute, enacted as Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b, prohibits persons from paying, soliciting, or receiving illegal remunerations in order to induce business reimbursable under federal or state health care programs. 42 U.S.C. § 1320a-7b(a). The types of remuneration covered specifically include kickbacks and bribes, whether made directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C. § 1320a-7b(b). The prohibited conduct includes remuneration intended to induce the prescription and ordering of medications to be paid for by federal, state, or municipal health care programs. *Id*. Several states contain analogous anti-kickback statutes. *See, e.g.*, Florida Stat., Ch. 409.920(2)(e).

determined to be safe and effective in authoritative studies, then the government likely will consider a claim for such use a "false" claim.

Medicaid

For example, the federal rules governing Medicaid—the jointly funded, federal-state program for individuals with low incomes—define "covered" outpatient prescription drugs to be those used for a "medically accepted indication."[8] The term "medically accepted indication" is a term of art in Medicaid law, and is defined as either an FDA-approved use or a use supported by citations included, or approved for inclusion in the American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information (or its successor publications), or the DRUGDEX Information System.[9] The federal rules further provide that a state Medicaid program may restrict coverage of covered outpatient drugs when the prescribed use is not for a medically accepted indication.[10] The state Medicaid programs have enacted varying rules on whether, and if so, when off-label, non-compendium uses will be covered.[11]

Medicare Part D

The new Medicare Part D program, which is a voluntary pharmaceutical benefit for seniors, the blind and the disabled, adopts the coverage criteria in the Medicaid statute, and likewise, only covers a drug if it is used for a FDA-approved use or supported by a citation in one of the medical compendia relied upon by the Medicaid program.[12]

Medicare Part B

Similarly, the Medicare Part B program, which covers drugs which cannot be self-administered and several other narrow categories of medications, such as those used in connection with organ transplants, will pay for a drug only if the use is "reasonable and necessary" in the circumstances.[13] To determine whether a drug use is "reasonable and necessary," the Medicare rules look to whether the use is "safe and effective."[14] Medicare considers a drug use to be "safe and effective" when the use is within the scope of

8. 42 U.S.C. § 1396r-8(k)(3).

9. 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i).

10. 42 U.S.C. § 1396r-8(d)(1)(B). Some argue that this statutory provision is superfluous in light of the statutory definition of "covered outpatient prescription drug," while others take the position that this provision effectively nullifies that definition by giving states the discretion to cover off-label, non-compendia uses.

11. Compare the Commonwealth of Massachusetts' Mass. Health Pharmacy Manual, 130 CMR 406.413(C)(4) (rev. 07/01/06)("The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence") and Pennsylvania's Medical Assistance Manual, 55 § 1121.54 (rev. Oct. '05) ("Payment will not be made to a pharmacy for the following services and items . . .Drugs and devices not approved by the FDA or whose use is not approved by the FDA.")

12. *See* 42 C.F.R. § 423.100, referencing the definition of "medically accepted indication" in the Medicaid statute.

13. 42 U.S.C. 1395y(a); 42 C.F.R. § 411.15(k); Medicare Benefit Policy Manual, Pub. 100-02, Ch. 16, § 20.

14. Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, § 50.4.1.

the indications specified on the FDA-approved label or when a Medicare carrier has affirmatively determined the use to be "medically accepted" in the circumstances in question, "taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[15]

CHAMPUS/TRICARE

The rules of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and its managed-care counterpart, TRICARE, are similar. With certain exceptions for experimental cancer drugs, these programs for civilian employees of the Department of Defense generally will pay for the costs only of "proven" drugs, *i.e.*, drugs that have been found to be "safe and effective" by the FDA.[16] Moreover, CHAMPUS/TRICARE will pay for off-label use of an FDA-approved drug only if the use is determined to a "medical necessity" and if the program can determine through a review of medical literature, national organizations, or technology assessment bodies that the off-label use is "safe and effective and in accordance with nationally accepted standards of practice in the medical community."[17] CHAMPUS/TRICARE will not pay for a pharmaceutical drug use unless "reliable evidence shows that the medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis."[18] The CHAMPUS/TRICARE rules make clear that "reliable evidence" of such studies does *not* mean physician opinion, anecdotal evidence or general practice within the medical community.[19]

* * * * *

How can one determine whether a use that the FDA has not approved for inclusion on the product label is nonetheless considered by a government payer to be "safe and effective"? While the manufacturer of the drug will almost certainly know this information, it often will be difficult to ascertain from readily available public sources. A good starting point is a review of the government health program's local and national coverage determinations, along with discussions of the drug's indications in the various medical compendia referenced above. If Medicaid is the payer, individual state policies must be researched.

Accordingly, a claim to Medicare, Medicaid, or CHAMPUS/TRICARE will be deemed a "false claim" if it seeks payment for a use of a drug that has not been deter-

15. Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, § 50.4.2.

16. 32 C.F.R. § 199.4(g)(15)(i)(A).

17. *Id.*

18. 32 C.F.R. § 199.4(g)(15)(i)(C).

19. *See* 32 C.F.R. § 199.2(b), definition of Reliable Evidence: "Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice."

mined to be safe and effective. If the manufacturer promoted the product for such use, then the manufacturer as well as the doctor would be exposed for having "caused" the submission of false claims to a government health program.

3. Alleging the Particulars of Individual "False Claims"

Every circuit court that has considered the issue has held that False Claims Act complaints must comply with Federal Rule of Civil Procedure 9(b)'s requirement that averments of fraud must be plead with particularity.[20] Moreover, most of these courts have held that pleading an FCA case with particularity requires plaintiff to plead the specifics of individual false claims, such as the claim number, date of submission, type of good or service for which reimbursement was sought, and/or name of the individual presenting the claim.[21]

Meeting this particularity requirement should be a fairly straightforward matter when a complaint is filed by a *qui tam* plaintiff who has access to individual patient or claims data or by a governmental entity with access to claims data. It may be more challenging, however, in a declined *qui tam* case in which the *qui tam* plaintiff, although an insider to the off-label marketing misconduct, lacks access to individual patient charts or billing data.

Indeed, just this past year, two U.S. district courts in the 1st Circuit dismissed two off-label marketing cases based on the *qui tam* plaintiff's inability to allege the particulars of specific false claims.[22] In each case, the *qui tam* plaintiff was a former employee of the defendant pharmaceutical company with detailed information on the

20. *See, e.g., U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 227-228 (1st Cir.), *cert. denied* 543 U.S. 820 (2004); *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 562-63 (6th Cir. 2003); *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308-09 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *U.S. ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 551-52 (D.C. Cir. 2002), *cert. denied* 544 U.S. 1032 (2005); *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999); *U.S. ex rel.LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227, 234 (3rd Cir. 1998); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997); *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995), *cert. denied* 517 U.S. 1213 (1996).

21. *See U.S. ex rel. Joshi v. St. Luke's Hospital, Inc.*, 441 F.3d 552, 559 (8th Cir.), *cert. denied* 127 S. Ct. 189 (2006); *U.S. ex rel. Sikkenga v. Bluecross Blueshield*, 472 F.3d 702, 727-28 (10th Cir. 2006); *Sanderson v. HCA-The Healthcare Co.* , 447 F.3d 873, 877 (6th Cir.), *cert. denied* 127 S. Ct. 303 (2006); *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., supra*, 360 F.3d at 232-33; *In re Genesis Health Ventures, Inc.*, 112 Fed. Appx. 140, 144 (3rd Cir. 2004); *U.S. ex rel. Clausen v. Lab Corp. of Am., supra*, 290 F.3d at 1311.

22. *See U.S. ex rel. McDermott v. Genentech, Inc.*, 2006 U.S. Dist. LEXIS 90598 (D. Maine, December 14, 2006) (" . . .a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity") ; *U.S. ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, 27-28 (D. Mass. 2006) ("Plaintiff's complaint fails to identify one actual false claim that was submitted to the government for the reimbursement of an off-label prescription of Genotropin. Plaintiff instead speculates that Defendants' marketing activities must have caused physicians to prescribe Genotropin for off-label uses and that some of these prescriptions were inevitably reimbursed by federal and state government health care programs. No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities. Without specific details of even one actual false claim that was submitted to any federal or state government, Plaintiff fails to satisfy Fed. R. Civ. P. 9(b)'s heightened pleading requirements.") *Cf. U.S. ex rel. Hess v. Sanofi-Synthelabo Inc.*, 2006 U.S. Dist. LEXIS 22449 (E.D. Missouri, April 21, 2006) (claims regarding the drug Elitek dismissed because plaintiff did not allege the specifics of the illegal promotional activity, the false representations regarding the drug or the nature or content of the false claims).

off-label marketing activity, but without access to claims data. In a footnote in one of these cases, the district court expressly rejected the relator's argument that a relaxed pleading standard was justified by the impossibility of relators' obtaining individual claims data:

> Even if it were 'impossible' to bring a *qui tam* FCA claim based on claims for reimbursement for the use of Rituxan to treat rheumatoid arthritis, that outcome could well be due to the language used by Congress in drafting the applicable statutes or to the uniform interpretation of that language by the federal courts. Neither reason for such an outcome necessarily means that the statutory language or the case law should be disregarded as a matter of public policy, as McDermott seems to suggest.[23]

It is unclear whether the law developing in the 1st Circuit will be followed elsewhere. If a *qui tam* plaintiff can plead particulars relating to the off-label promotional conduct, and also can allege a reasonable factual basis to infer that this misconduct led to false claims being submitted to a government program, such a stringent application of Rule 9(b) would appear to be unwarranted. Nonetheless, in light of the trend in the case law, a *qui tam* plaintiff bringing a case of this nature would be well served to make all possible efforts to obtain specific information on individual claims for off-label services paid by a government health program.

B. "Knowing" Misconduct

The federal False Claims Act, like the state false claims laws, only imposes liability for "knowing" misconduct. The law defines the term "knowingly" to include situations not only in which someone has "actual knowledge" of the falsity of their claim, but also those situations in which someone recklessly disregards, or acts with deliberate ignorance concerning the truth or falsity of a claim. Accordingly, if a drug manufacturer has "reason to know" that a given drug use is not covered by a government payer, that its employees are promoting that use, and that this promotional activity will cause submission of claims to government programs, then that company can be considered to have "knowingly" caused the submission of false claims. Likewise, if a doctor has "reason to know" that a given drug use is not covered, and that his prescribing of the drug will cause submission of claims to government programs, then that doctor can be considered to have "knowingly" caused the submission of false claims.

C. "Causation"

Drug manufacturers and physicians ordinarily are not the ones who submit claims to government health plans for pharmaceutical drug benefits. Pharmacies ordinarily submit such claims. When a False Claims Act case is brought against a drug manufacturer or a physician because of a pharmacy's charges to a government health program

23. *U.S. ex rel. McDermott, supra*, 2006 U.S. Dist. LEXIS 90586 at note 7.

for off-label use, the theory is that the manufacturer or doctor took certain steps—*e.g.*, marketing the drug off-label—that kick-started a chain of events leading to the submission of a claim to the government for a non-covered treatment.

If it can be said that the promotional steps of a manufacturer or the prescriptions of a physician were a "substantial factor" in producing "foreseeable" false claims for off-label use of a drug, then, according to at least one U.S. district court, the manufacturer or the physician will have "caused" the false claims as that term is used in the False Claims Act.[24] The U.S. district court for the District of Massachusetts has ruled that the foregoing common law standard for determining "causation" applies equally in the False Claims Act context.[25]

D. Submission to the Government for Payment or Approval

Since the inception of the new Medicare Part D pharmaceutical benefit in 2006, it can safely be said that the government pays for a significant percentage of the prescriptions of every medication with a large sales volume. Accordingly, if there is high volume usage of a drug off-label, it is just about guaranteed that the government is paying for some of that usage. The rough percentage of sales paid for by government payers will be known to the manufacturer, and can be approximated by an outsider by determining the extent to which the drug treats a condition found among the elderly or the indigent.

E. Materiality, "Condition of Payment" & Causation of Damages

Having established the elements of liability listed above, a False Claims Act plaintiff must next establish a firm connection between: (i) the government's decision on whether to pay the claim, and (ii) the certification, performance or compliance requirement at issue. The False Claims Act restricts liability to false statements made to "get" false claims paid, and restricts damages to losses "caused" by violations of the Act.[26]

The courts variously describe this inquiry as one looking into: (i) whether the subject of the representation or the compliance requirement was "material" to the government's payment decision;[27] (ii) whether the subject of the representation or the

24. *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *11-*12 (D. Mass. Aug. 22, 2003); *but see U.S. ex rel. Hess, supra*, 2006 U.S. Dist. LEXIS 22449 at *23 (in dictum, court sets forth "but for" causation standard.)

25. *United States ex rel. Franklin v. Parke-Davis, supra*, at *11-*12.

26. *See* 31 U.S.C. § 3729.

27. *See, e.g. U.S. ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1204 (10th Cir. 2006); *U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 442, 445 (6th Cir.), *cert. denied*, 546 U.S. 1063 (2005); 126 S. Ct. 797, 163 L.Ed. 2d 630 (2005); *U.S. v. Southland Management Corp.*, 326 F.3d 669, 679 n.3 (5th Cir. 2003) (Jones J., concurring); *Harrison v. Westinghouse Savannah River Co., supra*, 176 F.3d at 784; *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., supra*, 125 F.3d at 902; *U.S. v. Data Translation, Inc.*, 984 F.2d 1256, 1267 (1st Cir. 1992); *U.S. ex rel. Wilkins v. North Am. Constr. Corp.*, 173 F. Supp 2d 601, 618-30 (S.D. Tex. 2001). Those courts that have used the term "materiality" to describe this inquiry have generally adopted the standard adopted by the Supreme Court in interpreting statutes similar to the False Claims Act, looking to see whether the representation of compliance had a "natural tendency to influence" the Government's funding decision. *See, e.g., U.S. v. Southland Management Corp., supra; Harrison v. Westinghouse Savannah River Co. supra,* 326 F.3d at 676, *citing U.S. v. Wells, 519 U.S. 482, 489 (1997).* The courts disagree on whether to require "outcome based materiality," or, in other words, a showing that disclosure of the misconduct or false certification would have changed the government's funding situation in the case at hand. *Id.* at 676 and n.12.

compliance requirement was a "condition of payment" imposed by the government;[28] and/or (iii) whether the misrepresentation or misconduct "caused" damages.[29]

In off-label False Claims Act cases, this requirement, variously stated as set forth above, likely will result in the Department of Justice and the courts focusing on two chief issues:

1. To what extent did the off-label use present such an unreasonable and serious risk to patient health that by any objective standard the misconduct would have been "material" to the payment decision? For example, did the product label contain a black box warning or other serious warnings advising against the use, or was the off-label use little more than a technical violation?

2. Did the government health program act in a manner that was consistent with the position that the program did not cover the off-label use?

II. USE OF THE FALSE CLAIMS ACT TO REDRESS OFF-LABEL PROMOTION

Over the course of the last four years, the U.S. Department of Justice and the U.S. Department of Health & Human Services have shown a growing determination to use the federal False Claims Act to fight off-label marketing of drugs billed to the government. Federal officials are concerned not only about the taxpayer funds that are squandered on unsafe or ineffective drugs, they are also worried about the significant threat of patient harm posed by such conduct. As Deputy Attorney General Paul J. McNulty stated in announcing a recent False Claims Act off-label settlement:

> It is vital to public health and safety that pharmaceutical companies are deterred from improperly marketing their drugs to doctors and patients to treat . . . illnesses that these drugs are not approved to treat.[30]

The federal government's concern for patient harm means that the government will be particularly interested in pursuing off-label marketing under the False Claims Act when the promotional activity has caused patient harm, as indicated by numerous, serious adverse events following upon the off-label use and/or a black box warning on the label. In addition, the federal government is inclined to use the False Claims Act in several other situations, including those in which the manufacturer: i) has lied to physicians or government payers about the off-label use of the drug; ii) has applied to the FDA for approval of the use and been rejected; or, iii) has corrupted the independent, decision-making of doctors through kickbacks and other means. Regardless of whether one or more of these factors is present, a critical litmus test for the govern-

28. *See, e.g., U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172-73 (9th Cir. 2006), *cert. denied* 127 S.Ct. 2099, 167 L.Ed. 2d 813 (2007); *U.S. ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 441 (3d Cir. 2004); *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 697-700 (2d Cir. 2001); *Harrison v. Westinghouse Savannah River Co.*, *supra*, 176 F.3d at 786-87.

29. 31 U.S.C. § 3729 imposes liability for damages "caused" by violations of the FCA.

30. http: //www.taf.org/publications/PDF/TAF_v44.pdf

ment, of course, will be whether the off-label marketing led to significant, government financial expenditures.[31]

The federal government's focus on these factors is evidenced by the cases they have elected to pursue. Thus, the first major off-label case that the Department of Justice pursued under the federal False Claims Act involved **Warner-Lambert's** promotion of the anti-seizure medication, Neurontin, for use by children and in other unapproved circumstances.[32] Medicaid unwittingly had paid pharmacies around the country millions of dollars for such off-label uses of the drug. To promote the drug, Warner-Lambert, among other things, made false statements to health care professionals about the efficacy of the off-label uses, falsely represented that the uses were approved by the FDA, and overpaid physicians to serve as "consultants" to induce off-label usage. To settle these claims, Warner-Lambert paid $430 million in 2004.

The Warner-Lambert settlement was followed by a $704 million settlement with **Serono** for off-label promotion of the AIDS-wasting drug Serostin.[33] This case also involved financial inducements to doctors in exchange for their prescribing the drug off-label (such as all-expense paid trip to a medical conference in Cannes), and false representations to patients and health professionals regarding the medical necessity of the drug.

In 2007, **Cell Therapeutics, Inc**. of Seattle, Washington, paid the United States $10.5 million to resolve claims based on its off-label promotion of Trisenox, an oncology drug paid for by Medicare.[34] This case also involved sham consulting agreements to corrupt independent medical decision-making and false statements to physicians regarding the efficacy and regulatory approval of the off-label use.

Medicis Pharmaceutical of Scottsdale, Arizona, also recently resolved its liability for off-label marketing of drugs paid for by federal health programs, paying $9.8 million to resolve claims based on its off-label promotion of the topical skin cream Loprox for use by children.[35] Significantly, as was the case with the use of Neurontin by children, the off-label use in this case would have been apparent to anyone knowledgable about the product label who reviewed the claims forms submitted to Medicaid. The Department of Justice pursued the case nonetheless on the apparent theory that government health care programs should not have to shoulder the onerous responsibility of reviewing each and every claim for compliance with the detailed and complicated product label.

Most recently, in July 13, 2007, **Jazz Pharmaceuticals, Inc**. agreed to pay $20 million to resolve criminal and civil liability arising from the off-label marketing of the "date rape drug" Xyrem by its subsidiary, Orphan Medical, Inc.[36] Although the FDA had approved Xyrem only for the treatment of excessive daytime sleepiness and certain other symptoms of narcolepsy, Orphan Medical allegedly marketed the drug for many

31. *See* Remarks of Lew Morris, Chief Counsel to the Office of Inspector General of the U.S. Department of Health & Human Services, as reported in the article "Off-Label Drug Promotion Remains Key Concern for Federal Law Enforcers," Health Care Report, Vol. 10, No. 23, Nov. 22, 2006.

32. *See* http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.

33. *See* http://www.usdoj.gov/op/pr/2005/October/05_civ_545.html.

34. *See* http://www.usdoj.gov/opa/pr/2007/April/07_civ_258.html.

35. *See* "Medicis Pharmaceutical to Pay $9.8 million to Settle False Claims Act Charge," 21 Corporate Crime Reporter 20, May 8, 2007.

36. *See* http://www.usdoj.gov/usao/nye/pr/2007jul13a.html.

other uses, such as the treatment of insomnia, chronic pain, depression and bipolar and movement disorders. Many of these uses were billed to Medicaid and Medicare.

The settlement with Jazz Pharmaceuticals is of particular interest because the government's press release highlighted the role played by a physician in the off-label scheme. Thus, the U.S. Attorney for the Eastern District of New York informed the public that:

> Orphan also admitted that it relied on a psychiatrist to give talks around the country . . . promoting Xyren to physicians for "off-label" uses and paid him tens of thousands of dollars for such promotional speaking engagements. With the approval of Orphan sales personnel, the psychiatrist allegedly made misleading statements about Xyrem in the course of promoting the drug for "off-label" use . . . [and] also advised physicians how to conceal "off-label" Xyrem prescriptions in order to ensure reimbursement from insurers for unapproved uses that, the government alleges, were not medically accepted and generally not reimbursed.[37]

III. ASSESSING A POSSIBLE OFF-LABEL, FALSE CLAIMS ACT ACTION

A. Filing a Lawsuit Quickly

To be well positioned to claim a reward for blowing the whistle on off-label marketing, it is critical to be the first one in the door. To encourage informants to come forward early, two aspects of the false claims laws bar lawsuits with second-in-time allegations.

The first provision is the so-called "public disclosure" bar. This bar prohibits an individual from filing a false claims act case based on information already in the public domain unless the individual is an "original source" who provided the government with the information before filing suit and had direct and independent knowledge of that information. The intent of this bar is to preclude "parasitic lawsuits" such as those based on a criminal indictment, government audit report or newspaper coverage.

The second provision is the so-called "first-to-file" bar. This prohibition is aimed at law suits that follow on the heels of other false claims act lawsuits with the same allegations, whether those lawsuits are on the public record or pending under seal. There is no "original source" exception to this provision. Even those with true insider information may be barred if someone else has filed a *qui tam* case first.

B. Ten Question Checklist:

WHAT FACTS GIVE RISE TO A STRONG FALSE CLAIMS ACT CASE?

If you believe you may have knowledge of off-label promotional activity, you should consider the following questions in deciding whether to pursue an action under fed-

37. Id.

eral or state false claims laws; generally, it will make sense to file a false claims act case only if the answer to all of these inquiries is "yes."

1. **Clearly Off-Label.** Is the use in question without a doubt outside the scope of the FDA-approved label?

2. **Evidence of Off-Label Promotion.** Do you have documents or other evidence, such as business plans, recordings of training sessions or sales pitches, sales materials or e-mails, demonstrating the off-label promotional activity?

3. **Evidence of Management Knowledge.** Do you have documents or other evidence indicating that management directed, approved or condoned the off-label promotional activity; in other words, is the problem more than an overly aggressive marketing campaign by a single, rogue sales representative?

4. **Government Payment.** Is there good reason to believe that government health plans paid for the off-label uses?

5. **Significant Government Payment.** Is there good reason to believe that the off-label sales to government health plans are so significant in dollar amount that the potential pay-out from a government investigation and litigation would be well worth the time, expense and other non-financial costs to the government and the whistle blower?

6. **Lack of Government Coverage.** Is there good reason to believe that the government payers never approved payment of the off-label use, or, if they did so, approved payment based on materially inaccurate or misleading information submitted by the manufacturer?

7. **Corrupting or Misleading Physicians.** Can you identify specific actions by the pharmaceutical company that compromised the objectivity and/or the quality of the physician's prescribing habits, such as the provision of financial benefits in exchange for prescriptions, or the making of false representations concerning drug studies, performance or approval?

8. **Patient Harm.** Does the off-label use pose a significant threat of patient harm through adverse side effects or ineffective treatment?

9. **Inside Information.** Is your information based on direct and independent knowledge of the misconduct rather than on a public document?

10. **First in Time.** Do you have a reasonable basis to believe that the off-label activity is not yet the subject of a government investigation or a lawsuit on the public docket?

On the Horizon

A Patient-Centered Approach to Health Care Fraud Recovery

A PATIENT-CENTERED APPROACH TO HEALTH CARE FRAUD RECOVERY[1*]

Joan H. Krause[2+]

This Article begins with a simple premise: Health care fraud hurts patients. From that premise flows a simple corollary: efforts to combat health care fraud should, if possible, remedy this patient harm. Despite its intuitive appeal, this syllogism does not represent current practice. Funds recovered through health care fraud enforcement are distributed to the Medicare Trust Fund, to the federal agencies that investigate and prosecute health care fraud, and to private parties who initiate suits on the government's behalf under the civil False Claims Act[3]—but rarely to patients who may have been harmed by the conduct. While focusing enforcement efforts on returning funds to the Federal Treasury clearly helps to assure that the federal health care programs[4] remain solvent and continue to provide care to beneficiaries in the aggregate, it offers little solace to injured individuals.

This approach stands in marked contrast to efforts to make the United States health care system more "patient-centered." In 2001, the Institute of Medicine's Committee on Quality of Health Care in America identified "patient-centeredness" as one of the six health care aims for the next century, "focus [ing] on the patient's experience of illness and health care and on the systems that work or fail to work to meet individual patients' needs."[5] While advocates initially focused their efforts on clinical practice—emphasizing respect for patients, the provision of honest and complete information, physical comfort, and emotional support for patients and their families[6]—these concepts have grown to encompass systemic structural concerns as well. A patient-centered approach to access to health care makes "serving the practical health care needs of patients (1) the focal point of the health care system, (2) the paramount responsibility of health professionals, and (3) the primary role of private and public

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3. *See* 31 U.S.C. §§ 3729-33 (2000).

4. As used in the fraud statutes, "Federal health care program" includes "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government" with the exception of the Federal Employees Health Benefit Program, as well as state-funded health care programs. *See* 42 U.S.C. § 1320a-7b(f)(1) (2000).

5. Comm. on Quality of Health Care in Am., Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century 48 (2001); *see also* Through the Patient's Eyes: Understanding and Promoting Patient-Centered Care 5 (Margaret Gerteis *et al.* eds., 1993) (focusing "on the patient's experience of illness and health care and the systems that work, and fail to work, to meet patients' needs, as they define them").

6. *See* Through the Patient's Eyes: Understanding and Promoting Patient-Centered Care, *supra* note 3, at 5-11 (defining dimensions of patient-centered care).

financing [of] health care."[7] A health care fraud enforcement system that assures large monetary recoveries for the Federal fisc but makes no attempt to compensate injured beneficiaries does not achieve these goals. In short, current health care fraud recoveries are not patient-centered.

The reasons for this failure are complex, and derive both from the factual context in which health care fraud occurs and from the traditional white collar crime enforcement framework. In large part, health care fraud recovery is not patient-centered because patients are not viewed as the victims of the fraud; that distinction instead belongs to the federal government, the ultimate payer under the federal health care programs. Consistent with that view, the federal statutes most commonly invoked in fraud cases channel recoveries to the federal coffers rather than directing compensation to injured individuals. Indeed, to the extent the government's primary interest in prosecuting health care fraud derives from its role as a defrauded payer, rather than as the more general protector of its citizenry, individualized compensation would appear to be unnecessary.[8] This focus on financial harm to the government is reinforced by situating health care fraud within the context of white collar crime, an area of law that focuses almost exclusively on economic harm.[9] In short, the recognition that health care fraud harms individual patients in ways that merit compensation—particularly if such harm is non-financial in nature—does not fit into the dominant conceptual model of health care fraud.

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7. Laura D. Hermer & William J. Winslade, Access to Health Care in Texas: A Patient-Centered Perspective, 35 Tex. Tech. L. Rev. 33, 34 (2004) (emphasis added). Even Congress has jumped on the patient-centered care bandwagon. *See* Bill Frist, Speeches: Frist Outlines Plan for "Putting the Patient at the Heart of Health Care," July 23, 2005, *available at* http://frist.senate.gov/index.cfm?FuseAction=Speeches.Detail&Speech_ id =254&Month=7&Year=2005 (text of speech by Sen. Bill Frist to Commonwealth Club of California).

Patient-centered care is in many ways the clinical counterpart to therapeutic jurisprudence, "the study of the use of the law to achieve therapeutic objectives." David B. Wexler, An Introduction to Therapeutic Jurisprudence, in Therapeutic Jurisprudence: The Law as Therapeutic Agent 4 (David B. Wexler ed., 1990). The core insight of therapeutic jurisprudence is that the legal system—both in terms of substantive legal rules and systemic structure—may have effects that are more or less "healing" in nature. *Id*. at 14 (arguing that "the legal system itself . . . should be examined, and perhaps restructured, to maximize its therapeutic aspects and to minimize its anti-therapeutic aspects"). Although its genesis was in the area of mental health law, the theory has been applied to a variety of legal issues including tort suits and appellate advocacy. *See, e.g., id*. at 4 (discussing application of theory to mental health law); Harold S. Kaplan, Benefiting from the "Gift of Failure": Essentials for an Event Reporting System, 24 J. Legal Med. 29, 42 (2003) (discussing therapeutic failures of malpractice litigation); Daniel W. Shuman, Making the World a Better Place Through Tort Law?: Through the Therapeutic Looking Glass, 10 N.Y.L. Sch. J. Hum. Rts. 739 (1993) (discussing application of theory to tort law); Christopher Slobogin, Therapeutic Jurisprudence: Five Dilemmas to Ponder, 1 Psychol. Pub. Pol'y & L. 193 (1995) (identifying issues that may arise in applying theory to practice); David B. Wexler, Introduction: Therapeutic Jurisprudence in the Appellate Arena, 24 Seattle U. L. Rev. 217, 217 (2000) (discussing "the use of therapeutic jurisprudence in the appellate courts"). In the health law literature, recent scholarship by academics such as Mark Hall has used therapeutic jurisprudence as the basis for thought-provoking discussions of the role of trust in the health care system. *See generally* M. Gregg Bloche, Trust and Betrayal in the Medical Marketplace, 55 Stan. L. Rev. 919 (2002); Robert Gatter, Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law, 39 Wake Forest L. Rev. 395 (2004); Mark A. Hall, Law, Medicine, and Trust, 55 Stan. L. Rev. 463 (2002). Despite anecdotal evidence, this approach does not appear to have been applied in detail to the topic of health care fraud—perhaps indicating a fruitful area for future study.

8. Note, however, that powerful statutes also permit federal prosecution of private health care fraud in the absence of federal harm as long as jurisdictional requirements are met, thus invoking the federal government's more traditional role as protector. *See, e.g.*, 18 U.S.C. § 1341 (2000) (mail fraud); *id*. § 1343 (wire fraud); *id*. § 1347 (health care fraud).

9. *See, e.g.*, J. Kelly Strader, The Judicial Politics Of White Collar Crime, 50 Hastings L.J. 1199, 1204-14 (1999) (discussing definitions of white collar crime).

Part I of this Article explores the varied ways in which patients are harmed by fraudulent health care activities. Part II analyzes barriers to patient compensation under current law, addressing not only limitations on the disposition of recovered funds but also the conceptual difficulties posed by the white collar crime framework. Part III discusses recent developments at the state and federal levels, and explores compensation mechanisms common in consumer protection cases to determine whether they could be imported into the health care fraud context. The Article concludes that while there may be good reasons not to convert the entire health care fraud enforcement scheme to a patient-centered model, it nevertheless should be possible to reduce existing barriers to compensating patient harm.

I. HEALTH CARE FRAUD AND PATIENT HARM

Health care fraud encompasses activities by a wide range of actors. It includes fraud by and upon health care professionals, health care institutions, health insurers and managed care companies, manufacturers of prescription drugs and other health care supplies, and even patients.[10] When such activities occur in the federal health care programs, such as Medicare and Medicaid, they are subject to a broad array of civil, criminal, and administrative statutes.[11] Yet, virtually all of these provisions consider the ultimate victim of the fraud to be the federal government, rather than the individual patient. As a result, health care fraud is largely considered a "bloodless" form of wrongdoing, an image reinforced by characterizations of such fraud as a stereotypical white collar crime.[12] White collar crimes are thus the opposite of "street crimes" in which money and property are taken by violence or the threat thereof.[13] In health care, these principles evoke images of highly trained physicians and executives misusing their positions and professional skills for personal financial gain, accomplished through deceptive yet nonviolent tactics such as falsifying bills for services. The victim—if the term even applies—is a hapless federal bureaucracy that serves as easy prey for unscrupulous individuals.

10. *See, e.g.*, Sharon L. Davies & Timothy Stolzfus Jost, Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?, 31 Ga. L. Rev. 373, 383-84 (1997) (describing potential for fraud in relationships between health care "consumers, purchasers, providers, and intermediaries"); Joan H. Krause, A Conceptual Model of Health Care Fraud Enforcement, 12 J.L. & Pol'y 55, 64-81 (2003) [hereinafter Krause, A Conceptual Model] (describing industries affected by recent health care fraud initiatives). In the federal health care programs, the term "provider" technically refers to institutional entities, such as hospitals, home health agencies, and nursing homes. 42 U.S.C. § 1395x(u) (2000) (defining "provider of services"). Because they face similar fraud liability, this Article will use the term "health care provider" to refer more broadly to both individual health care professionals and institutional health care entities. *See* Dep't. of Health & Human Servs., Special Advisory Bulletin: Practices of Business Consultants 1 n.1 (2001), *available at* http:// oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf (using the term to include "providers, suppliers, and practitioners that provide items or services payable in whole or in part by a Federal health care program").

11. *See, e.g.*, 42 U.S.C. § 1320a-7 (2000) (exclusion from federal health care programs); *id.* § 1320a-7a (civil monetary penalties applicable to federal health care programs); *id.* § 1320a-7b(b) (Medicare & Medicaid Anti-Kickback Statute); *id.* § 1395nn (limitations on self-referrals).

12. *See* Pamela H. Bucy, Fraud by Fright: White Collar Crime by Health Care Providers, 67 N.C. L. Rev. 857, 870-71 (1989) [hereinafter Bucy, Fraud by Fright] (noting that health care fraud shares essential features of white collar crime).

13. *See, e.g.*, Darryl K. Brown, Cost-Benefit Analysis in Criminal Law, 92 Cal. L. Rev. 325, 342 (2004) ("In criminal law, street crime (theft and violent crime) is especially vivid and frightful for most people. In contrast, white collar crimes, such as financial frauds in which many victims lose small amounts, seem much less threatening. Compared to corporate crime risks, street crime risks are more vivid.").

Not surprisingly, public statements by prosecutors suggest a zero-tolerance approach to those who take advantage of the federal health care programs. In commenting on a recent pharmaceutical settlement, for example, the United States Attorney for the Eastern District of Pennsylvania stated,

> This wasn't a mistake. It was a marketing strategy. The result was that programs created to provide healthcare to the poorest among us were actually paying more for drugs than those who have private health insurance. There is a point at which pursuit of market share crosses the line that separates competition and illegal conduct. This case serves as an example that the consequences of stepping over that line can be costly.[14] Where the federal health care programs are viewed as suffering the greatest losses, it is logical to concentrate enforcement efforts on reimbursing those programs. But the federal government is not the only victim of fraudulent activities. Health care fraud also causes significant harm to patients—harm that may be financial, physical, or less tangible in nature. Although initially slow to recognize these effects, prosecutors and policymakers have now embraced the goal of "patient protection" as a key justification for fraud enforcement. Yet despite this rhetoric, the financial model of health care fraud recovery has not changed accordingly. And while returning funds to the federal Treasury helps to assure that the federal health care programs remain able to provide care to beneficiaries in the aggregate, this approach fails to remedy harm to individual patients.

A. Harm to the Federal Government

Health care fraud became a key priority for federal law enforcement officials in the 1990's.[15] The motivation for these efforts is clear: As the authors of one treatise note, health care fraud is "where the money is."[16] For a sense of just how much money is at stake, note that the first comprehensive audit of Medicare fee-for-service payments found that more than $23 billion had been paid out improperly in fiscal year 1996 alone.[17] Although the numbers have improved each year, auditors estimate that the Medicare program still paid $12.1 billion in improper claims in fiscal year 2005, an

14. Press Release, U.S. Attorney's Office, Schering-Plough to Pay $345 Million to Resolve Criminal & Civil Cases: Schering to Admit Paying Kickback in Exchange For Preferred Treatment—Will Also Settle False Claims Liability (July 30, 2004), *available at* http://www.usdoj.gov/opa/pr/2004/July/04_civ_ 523.htm.

15. In fact, former Attorney General Janet Reno identified health care fraud as her "number two priority," second only to violent crime. Annual Report of the Attorney General of the United States (1994), *available at* http://www.usdoj.gov/ag/annualreports/ar94/finalag.txt.

16. Robert Fabrikant *et al.*, Health Care Fraud: Enforcement and Compliance 1-3 (2004) (paraphrasing statements made by infamous bank robber Willie Sutton).

17. *See* Dep't of Health & Human Servs., Office of the Inspector Gen., Improper Fiscal Year 2001 Medicare Fee-for-Service Payments, No. A-17-01-02002, at 1 (2002), *available at* http://oig.hhs.gov/oas/reports/cms/a0102002.pdf (acknowledging that 2002 error rate represented a significant reduction from the $23.2 billion in improper payments identified in 1996, the first year such audits were conducted).

error rate of 5.2 percent.[18] Given ongoing concerns over the solvency of the Medicare program, particularly once the so-called "Baby Boomers" become eligible, policymakers may view health care fraud recoveries as a means to offset escalating program costs without raising taxes, reducing the scope of benefits, or otherwise incurring the wrath of the powerful aging lobby.[19]

Health care fraud is actionable under a wide range of federal criminal, civil, and administrative statutes. Some of these laws, such as the Medicare and Medicaid Anti-Kickback Statute, the "Stark Law" prohibition on physician self-referral, and the provisions governing exclusion from the federal health care programs, specifically target improper health care activities.[20] Others, such as the civil and criminal false claims prohibitions,[21] apply more broadly to all entities that transact business with the federal government. Health care fraud also may be prosecuted under broad federal criminal statutes, such as mail and wire fraud, conspiracy, and the Racketeer Influenced and Corrupt Organizations Act ("RICO"),[22] which prohibit improper conduct regardless of the industry in which it occurs.

The current centerpiece of the government's anti-fraud efforts is the Civil False Claims Act ("FCA"), a Civil War-era statute that prohibits the knowing submission of false or fraudulent claims to the federal government.[23] Because violators are subject to a civil penalty of $5,500 to $11,000 per claim, plus three times the amount of damages sustained by the government,[24] repeated submission of bills containing small

18. Centers for Medicare & Medicaid Services, Improper Medicare FFS Payment Short Report (Web Version) for November 2005, https://www.cms.hhs.gov/ apps/er_report/preview_er_report.asp?from=public&which=short&reportID=3&tab=2 (last visited Dec. 12, 2005). Of course, it is not clear that all such payments constitute fraud rather than errors or good faith disagreements. *See* David A. Hyman, HIPAA and Health Care Fraud: An Empirical Perspective, 22 Cato J. 151, 162 (2002) (arguing that these audits are not designed to measure fraud).

19. *See, e.g.*, Office of Management and Budget, Mid-Session Review: Medicare Trust Funds (2003), *available at* http://www.whitehouse.gov/omb/budget/fy2002/msr03.html (projecting Medicare shortfalls through 2011); Jonathan W. Emord, Murder by Medicare: The Demise of Solo and Small Group Medical Practices, 21-3 Regulation 31, 32-33 (1998) (arguing that the "Medicare enforcement scheme . . . seeks to expand definitions of improper billing, fraud, and abuse as a means to help Medicare recoup funds from physicians," with the result that "Congress has been able to take credit for a broad array of seemingly ever-expanding federally funded benefits and for holding down costs, while not being held politically accountable for the program's adverse effects on medical practices and health care markets").

20. *See* 42 U.S.C. § 1320a-7 (2000) (exclusion from federal health care programs); *id.* § 1320a-7a (civil monetary penalties applicable to federal health care programs); *id.* § 1320a-7b(b) (Medicare & Medicaid Anti-Kickback Statute); *id.* § 1395nn (limitations on self-referrals). For a detailed discussion of these statutes, *see* Krause, A Conceptual Model, *supra* note 8, at 64-81.

21. *See* 18 U.S.C. §§ 286-87 (2000) (criminal false claims provisions); 31 U.S.C. §§ 3729-33 (2000) (Civil False Claims Act).

22. *See* 18 U.S.C. § 371 (conspiracy); *id.* §§ 1341, 1343, 1346 (mail and wire fraud); *id.* §§ 1961-62 (RICO). RICO provides for both criminal and civil causes of action. *See id.* § 1964 (setting forth civil remedies).

23. 31 U.S.C. §§ 3729-33 (2000). The law was enacted in 1863 in response to reports of "rampant fraud" perpetrated on the United States military during the Civil War. *See* S. Rep. No. 99-345, at 8 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 (noting history of False Claims Act). The most commonly invoked FCA cause of action applies where: (1) a defendant presents (or causes to be presented) a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the defendant's acts are undertaken "knowingly." 31 U.S.C. § 3729(a)(1). "Knowingly" includes not only actual knowledge, but also deliberate ignorance and reckless disregard of truth or falsity. *See id.* § 3729(b). An actionable "claim" includes "any request or demand . . . for money or property" if any portion thereof comes from the federal government. *Id.* § 3729(c).

24. *See* 31 U.S.C. § 3729(a)(7) (listing statutory penalties and treble damages); 28 C.F.R. § 85.3(a)(9) (2005) (increasing statutory penalties by 10% for inflation).

increments of fraud quickly leads to astronomical aggregate liability.[25] Moreover, the FCA's unique *qui tam* provisions permit private whistleblowers (known as "relators") who sue on the government's behalf to retain fifteen to thirty percent of the proceeds of the suit—creating a powerful incentive for private parties to police their neighbors in the health care market.[26] The number of health care FCA suits has grown exponentially since amendments in 1986 made it more lucrative to pursue *qui tam* actions, and health care *qui tam* suits now eclipse those in other areas of government contracting.[27]

In response to growing concerns about the magnitude of health care fraud, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[28] made significant changes to federal law enforcement authority. In addition to creating new criminal causes of action,[29] HIPAA required that more funds be appropriated to the federal agencies with jurisdiction over health care fraud, particularly the Department of Justice ("DOJ") and the Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG"). A key aspect of this effort was the creation of a "Fraud and Abuse Control Program," designed to coordinate federal, state, and local health care fraud enforcement efforts.[30] The centerpiece of the Program is the "Fraud and Abuse Control Account," which funds health care fraud inspections, investigations, and prosecutions undertaken by the DOJ and OIG.[31] HIPAA set fiscal year 1997 Control Account appropriations at $104 million, with an increase of up to 15 percent per year through fiscal year 2003.[32]

To a certain extent, these investments have paid off. The DOJ recovered more than $1.4 billion in civil fraud suits in fiscal year 2005, with $1.1 billion of that amount attributed to health care fraud cases.[33] While this certainly counts as progress, it represents merely the proverbial drop in the bucket in the face of almost $20 billion in improper payments each year. Viewed as a return on investment, however, the picture is decidedly more cheerful: Taxpayers Against Fraud, a nonprofit organization that pro-

25. In *United States v. Krizek*, for example, a psychiatrist was alleged to have submitted 8002 false claims, each inflated by approximately $30; assessing penalties of $10,000 per claim, the government sued for $81 million dollars. 111 F.3d 934 (D.C. Cir. 1997); *see also* Timothy Stoltzfus Jost & Sharon L. Davies, The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement, 51 Ala. L. Rev. 239, 260 (1999) (noting that "[e]ven if individually quite small, astronomical sums are quickly reached").

26. *See, e.g.*, 31 U.S.C. §§ 3730(b), (d) (noting that a private person who brings a civil action may potentially receive fifteen to thirty percent of the proceeds of the suit).

27. By 1998, 61% of the filed *qui tam* cases involved the federal health care programs, compared to only twelve percent in 1987. *See* Fried, Frank, Harris, Shriver & Jacobsen LLP, *Qui Tam* FCA Statistics, *available at* http:// www.ffhsj.com/quitam/fcastats.htm (last visited Feb. 23, 2006).

28. Pub. L. No. 104-191, 110 Stat. 1937 (1996).

29. *Id.* at 241-49 (revising criminal law provisions relating to health care fraud) (codified as amended in scattered sections of 18 U.S.C., including, e.g., 18 U.S.C. § 247 (2000) (injunctive relief relating to health care offenses), *id.* § 669 (theft or embezzlement in connection with health care), *id.* § 1035 (false statements relating to health care matters), *id.* § 1347 (health care fraud), *id.* § 1518 (obstruction of criminal investigations of health care offenses)).

30. *See* 42 U.S.C. § 1320a-7c (2000) (establishing program).

31. *Id.* § 1395i(k)(3) (describing appropriations to the account).

32. *Id.* § 1395i(k)(3)(A)-(B) (setting out the maximum amounts available for appropriation).

33. Press Release, U.S. Dep't of Justice, Justice Department Recoveries total $1.4 Billion in Fraud & False Claims in Fiscal Year 2005; more than $15 Billion since 1986 (Nov. 7, 2005), *available at* http:// www.usdoj.gov/opa/pr/2005/November/05_civ_595.html.

motes the use of the FCA to combat fraud, has estimated that "for every dollar spent to investigate and prosecute health care fraud in civil cases, the federal government receives nearly thirteen dollars back in return."[34] With a positive return on investment, and billions of dollars in improper payments yet to be recouped, federal interest in health care fraud is unlikely to wane any time soon.

B. Harm to Patients

Given the magnitude of the problem, it is logical that recovery efforts have focused on the government's role as a defrauded payer. While health care fraud clearly causes significant financial harm to the federal Treasury, however, the federal government is not the only—or in some cases even the primary—victim. Health care fraud also causes significant harm to patients, be it financial, physical, or less tangible in nature.

1. Financial Injury

Financial injury to patients is perhaps the easiest type of harm to recognize, in part because it mirrors the government's own economic injury. Due to the cost-sharing structure of the health care reimbursement system, fraud often has financial repercussions for patients. Under Medicare Part B, for example, beneficiaries are responsible for paying 20% of the Medicare approved charge for covered outpatient services, which include physician services and drugs administered in a physician's office.[35] Under such a cost-sharing mechanism, a fraudulently inflated charge will result in additional expense to both insurer and patient[36]—expense that may have disproportionately detrimental effects on patients who subsist on limited incomes, such as many federal program beneficiaries.[37]

These concepts are illustrated by the ongoing controversy over the prices charged by prescription drug manufacturers. The issue received widespread public attention in October 2001, when TAP Pharmaceutical Products agreed to pay $875 million dollars to settle a variety of civil and criminal fraud allegations stemming from the sale of its cancer drug, Lupron.[38] TAP was alleged to have inflated the prices it reported to the publications on which Medicare contractors based their "average wholesale price" ("AWP") calculations for reimbursement purposes, thus assuring that Medicare pay-

34. Jack A. Meyer, Fighting Medicare Fraud: More Bang for the Federal Buck 2 (2004), *available at* www.taf.org/meyer-report.htm.

35. *See* 42 U.S.C. § 1395i(a) (setting forth 80/20 split for Medicare Part B). This structure also is common in private insurance. *See, e.g.*, Anne M. Stoline & Jonathan P. Weiner, The New Medical Marketplace: A Physician's Guide to the Health Care System in the 1990s, at 62-63 (rev. ed. 1993) (describing co-insurance as a cost-sharing mechanism).

36. Although the pricing mechanisms may be slightly different, similar fraud also occurs in private insurance. *See, e.g.*, Smith v. United Healthcare Servs., Inc., No. CIV 00-1163 ADM/AJB, 2002 WL 192565 (D. Minn. Feb. 5, 2002) (certifying class in ERISA suit alleging that insurer overcharged beneficiaries for prescription drug copayments).

37. As Congress recognized while debating the 2003 Medicare reform legislation, "low-income beneficiaries must often make unacceptable choices between life-saving medicines and other essentials." H.R. Rep. No. 108-391, at 427 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1810.

38. *See* Press Release, U.S. Dep't of Justice, TAP Pharmaceutical Products, Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges (Oct. 3, 2001), *available at* http:// www.usdoj.gov/opa/pr/2001/October/ 513civ.htm.

ment for Lupron would remain artificially high. By actively marketing this "spread" between the discounted price paid by physician customers and the artificially high rate at which Medicare reimbursed the product, TAP was accused of offering its customers a financial inducement to prescribe Lupron in violation of the Medicare & Medicaid Anti-Kickback Statute (and thereby causing customers to submit false claims under the FCA).[39] The allegations involved a substantial amount of money: A subsequent private suit against the company alleged that while the actual cost of the drug dropped from $340 to $207 over several years, the published AWP in fact increased from $418.75 to $623.79.[40]

Due to the 20% copayment structure, the Medicare beneficiaries who took Lupron—patients suffering from cancer, no less—were the direct victims of this alleged fraud scheme.[41] Because of the widespread use of AWP as a reimbursement benchmark, the scheme was equally applicable to patients who purchased the drug through many private insurers. Following settlement of the federal fraud allegations, a consortium of patients, health plans, and state attorneys general filed a series of civil actions against the company for injunctive relief and damages.[42] Subsequent investigations have made clear that the problem is not limited to one pharmaceutical company, and virtually all of the major drug manufacturers have been sued for similar activities.[43] At this point, the effect on patients appears incontestable: The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs, reported that the spread for some drugs was so large that the patient's 20% Medicare copayment was greater than the total price paid by the physician.[44] In the aggregate, OIG has estimated "that if Medicare had paid reimbursements equal to widely available wholesale prices, beneficiaries would have paid $175 million less in coinsurance" annually.[45] When the effect on privately insured patients is taken into account, it is clear that the scheme's overall financial impact on patients was substantial.

2. Physical Injury

Although financial harm may be the easiest form of injury to recognize, fraudulent activities may also cause physical harm to patients. As one commentator has noted:

39. *See id.*

40. *See In re* Lupron(R) Mktg. & Sales Practices Litig., 295 F. Supp. 2d 148 (D. Mass. 2003). As the court noted, "[d]efendants repeatedly assert that . . . AWP was a ' sticker price' and never intended to reflect the drug's true average wholesale price. . .. There is a difference between a sticker price and a sucker price." *Id.* at 168 n.19 (emphasis added).

41. As Congress has noted, "[i]n addition to the financial toll on the U.S. Treasury, these large spreads also affect Medicare beneficiaries, who are often required to pay dramatically inflated co-payments for the drugs they receive." H.R. Rep. No. 108-391, at 583.

42. *See In re* Lupron(R) Mktg. & Sales Practices Litig., 228 F.R.D. 75 (D. Mass. 2005) (certifying class and approving final settlement).

43. *See, e.g., In re* Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005) (resolving class certification issues in suit brought by consumers and third-party payers against pharmaceutical companies); *In re* Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D. Mass. 2004) (addressing RICO, antitrust, and consumer protection allegations brought by employee health plans against pharmaceutical companies).

44. *See* Medicare Program; Payment Reform for Part B Drugs, 68 Fed. Reg. 50428, 50430 (Aug. 20, 2003) (proposing to revise Medicare drug reimbursement methodology).

45. *Id.* (emphasis added).

> Health care fraud is unique among white collar crimes in its ability to cause physical harm. This is true for several reasons: (1) often the fraudulent provider is also an incompetent provider; (2) some types of fraud are also malpractice, such as performing unnecessary medical procedures to increase billing; and (3) some types of fraud lead legitimate providers to render poor health care.[46] Unlike financial harm, which in fact is the goal of the scheme, physical injuries tend to be mere byproducts of the fraud. Rather than being motivated by any malice toward patients, such injury results from the medical activities (or lack thereof) through which the fraudulent scheme was carried out. One way patients may suffer physical injury is when unnecessary medical procedures are performed solely for the purpose of obtaining payment from the federal health care programs. A substantial medical literature has documented the health effects of overtreatment. Even if not physically harmful in itself, for example, unnecessary diagnostic testing may lead to "a false positive result [that] may trigger a cascade of progressively more invasive and expensive tests," with adverse physical and psychological consequences.[47] Similarly, the growing literature on iatrogenic complications in hospital settings—adverse events caused in some way by the medical intervention itself, including what have come to be known as "medical errors"—makes clear that such overtreatment is not a benign phenomenon.[48] As one researcher has noted, "More is not better, and it often is very, very much worse."[49]

If health care is reimbursed on a fee-for-service basis, in which separate payment is made for each item or service billed, there is a strong incentive to order unnecessary care.[50] These incentives most clearly exist with regard to minimally invasive tests and other procedures where overuse is difficult to detect. In one such case, a laboratory provider drew blood for unnecessary tests despite being aware that the procedures "would provide no medical or economic benefit (other than to the Lab's bottom line)

46. Pamela H. Bucy, Crimes By Health Care Providers, 1996 U. Ill. L. Rev. 589, 660-61 [hereinafter Bucy, Crimes By Health Care Providers].

47. Peter Franks *et al.*, Gatekeeping Revisited—Protecting Patients from Overtreatment, 327 New Eng. J. Med. 424-25 (1992); *see also* Elliott S. Fisher & H. Gilbert Welch, Avoiding the Unintended Consequences of Growth in Medical Care: How Might More Be Worse?, 281 J. Am. Med. Ass'n 446, 449-50 (1999) (noting that harms caused by over-diagnosis include "labeling" someone who feels well as sick and identification of "pseudodisease," i.e., "disease that would never become apparent to patients during their lifetime without the diagnostic test").

48. *See, e.g.*, Comm. on Quality of Health Care in Am., Inst. of Med., To Err is Human: Building a Safer Health System (Linda T. Krohn *et al.* eds., 2000) (analyzing magnitude and causes of medical errors); Franks *et al.*, *supra* note 45, at 425 (noting studies of hospital-based complications); Chunliu Zhan & Marlene R. Miller, Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization, 290 J. Am. Med. Ass'n 1868, 1873 (2003) (concluding that "medical injuries in hospitals pose a significant threat to patients and incur substantial costs to society").

49. Gina Kolata, More May Not Mean Better in Health Care, Studies Find, N.Y. Times, July 21, 2002, § 1, at 1 (quoting Dr. Donald M. Berwick, President of the Institute for Healthcare Development).

50. *See* Davies & Jost, *supra* note 8, at 384 (describing incentives for fraud in fee-for-service systems).

and would subject sick patients to needless and intrusive withdrawal of additional blood, with the attendant (albeit incremental) medical risks."[51]

Yet there also are documented instances of providers performing extremely invasive (and far more lucrative) surgeries on patients who did not need them. Federal prosecutors recently settled allegations that cardiac surgeons at Redding Medical Center performed unnecessary heart surgeries on as many as 700 patients. This included unnecessary open heart and coronary bypass surgeries, often performed on patients who had already undergone procedures such as cardiac catheterization or heart valve replacement.[52] Similarly, in what is "believed to be the first major scam in which clinics and surgeons allegedly paid healthy patients to actually undergo invasive and risky procedures," several Blue Cross and Blue Shield plans filed suit in March 2005 against a number of Southern California outpatient surgery clinics, alleging a massive "Rent-a-Patient" scheme in which healthy individuals were recruited to travel to the surgery centers for procedures such as colonoscopies and endoscopies.[53]

Harm may also occur when medically necessary care is performed in an improper manner in order to maximize reimbursement. In *United States v. Laughlin*, for example, an obstetrician-gynecologist was convicted of multiple counts of Medicaid fraud and mail fraud.[54] In one case the physician performed a tubal ligation four weeks after delivering a patient's baby by caesarian—a tactic that permitted him to bill for two surgeries rather than one, which would have been the case had he performed the tubal ligation at the same time as the original procedure.[55] Unfortunately, undergoing a second surgery in the same anatomical area so soon after the first also posed a risk of serious harm to the patient.[56]

Even if the unnecessary or ill-timed services do not in themselves pose any risk to patients, courts have recognized that harm may occur if patients rely on these useless treatments to delay seeking legitimate care. In *United States v. Vivit*, a physician was convicted of mail fraud based on the provision of unnecessary services, including physical therapy ultrasound and electrical muscle stimulation performed by unlicensed office personnel.[57] Acknowledging that patients had relied on the physician to treat their medical conditions, the court noted, "[b]y failing to examine such patients properly, Vivit created a risk that, had these patients suffered serious injuries, their in-

51. United States ex rel. Kneepkins v. Gambro Healthcare Inc., 115 F. Supp. 2d 35, 42 (D. Mass. 2000).

52. *See* Press Release, U.S. Attorney, E. Dist. of Cal., Doctors Accused of Performing Unnecessary Heart Surgeries at Redding Medical Center Agree to Pay Millions to Settle Fraud Allegations and Accept Restrictions on Their Medical Practice (Nov. 15, 2005), *available at* www.usdoj.gov/usao/cae/PRESS/pdf_2005/11-15-05RMC.pdf; Prosecutors Reach Overall Settlement of Allegations of Unneeded Cardiac Surgery, 14 Health L. Rptr. (BNA) 1487 (2005).

53. Blue Cross and Blue Shield Plans File $30 Million Lawsuit Alleging Rent-A-Patient Fraud in Southern California, BCBSHealthIssues.com, Mar. 11, 2004, http://bcbshealthissues.com/proactive/newsroom/release.vtml?id=152284; Jonathan D. Glater, In a Surgery Capital, a Swirl of Fraud Charges, N.Y. Times, July 10, 2005, § 3, at 1 (describing the allegations and some of the "patients").

54. 26 F.3d 1523 (10th Cir. 1994).

55. *Id*. at 1530.

56. *Id*. at 1530-31.

57. 214 F.3d 908 (7th Cir. 2000). The case also involved more straightforward allegations of billing fraud, including bills submitted for ultrasound therapy a year before the equipment was delivered to the physician's office. *Id*. at 912.

juries would remain untreated."[58] In some cases, the false reliance also endangers third parties. A scheme involving the sale of fraudulent HIV kits, for example, was found to "pose[] a substantial threat to public health because [the defendant] purported to provide reliable HIV screening when in fact there was no scientific basis for the test' results' he sent to customers," leading to at least one customer "who unwittingly put a new partner at risk."[59]

Moreover, while overtreatment is the hallmark of fraud in a fee-for-service reimbursement system, the incentives are quite different when payment is made on a lump-sum basis—as under the Medicare inpatient prospective payment system, or in capitated forms of managed care. Where reimbursement is limited to a predetermined amount, the temptation may be to "inappropriately deny necessary care or provide substandard care, thus defrauding and abusing consumers, purchasers, and intermediaries."[60] One area of particular interest has been the quality of care provided to beneficiaries in health care institutions, such as nursing homes and hospitals. Since the mid-1990's, the federal government has investigated allegations that understaffed nursing facilities pose serious threats to patient health, thus resulting in fraudulent bills for care.[61] Although the nursing facilities have not admitted any liability in these proceedings, common elements of the settlements include the payment of civil penalties, the development of specific training and oversight procedures for problem areas, quality monitoring by outside entities, and the adoption of a corporate compliance program.[62] More recently, the Washington Post ran a series of stories on continuing quality problems in Medicare hospitals, profiling not only Redding Medical Center but also Palm Beach Gardens Medical Center, whose heart surgery unit was long-perceived as "a breeding ground for germs."[63] In other cases, the fraud scheme results in a combination of over-, under-, and improper treatment. *United States v. Talbott*, for example, involved allegations "that root canal procedures were performed on teeth that should have been extracted as well as on healthy teeth; that some procedures billed as root canals were at best pulpotomies, and that in certain instances teeth were filled for no apparent reason

58. *Id.* at 922; *see also* United States v. Bachynsky, 949 F.2d 722, 735 (5th Cir. 1991) ("[W]hile relying on Dr. Bachynsky's ineffective course of treatment, his patients may have been foregoing more effective, safer, and legitimate treatments elsewhere.").

59. United States v. Greene, 17 F. App'x 722, 724 (9th Cir. 2001).

60. Davies & Jost, *supra* note 8, at 385-86 (describing potential fraud in managed care).

61. *See, e.g.*, United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051, 1056 (W.D. Mo. 2001) ("At some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient's quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States."); David R. Hoffman, The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities, 6 Annals Health L. 147 (1997) (describing patient injuries that gave rise to nursing home settlement).

62. *See* Hoffman, *supra* note 59, at 154-55 (explaining terms of settlement); Consent Order and Judgment, United States v. Chester Care Ctr., No. 98-CV-139 (E.D. Pa. Jan. 1998), *available at* http:// www.usdoj.gov/usao/pae/nursing/chester3.pdf (describing terms of settlement).

63. Gilbert M. Gaul, Inefficient Spending Plagues Medicare: Quality Often Loses Out as 40-Year-Old Program Struggles to Monitor Hospitals, Oversee Patients, Wash. Post, July 24, 2005, at A1 ("[Long-standing problems at Palm Beach Gardens included:] Dust and dirt covered some surgical equipment. Trash cans and soiled linens were stored in hallways. IV pumps were spattered with dried blood. One patient's wife said she saw a medical assistant tear surgical tape with his teeth."); Gilbert M. Gaul, At California Hospital, Red Flags and an FBI Raid: State Regulators Cited Concerns But Say They Couldn't Force Change, Wash. Post, July 25, 2005, at A9 (describing problems at Redding Medical Center).

while obvious cavities went undetected."[64] From these examples, it is clear that fraudulent activities may cause physical injuries to patients in a variety of ways.

3. Intangible Harm

In addition to financial and physical harm, patients can be injured by health care fraud in less tangible ways. One of the key commodities of the health care system is information, specifically patient information. At core, information constitutes the sum total of the record of our individual health histories—information that will be used not only as the basis for future treatment decisions, but also for purposes as varied as insurance underwriting and job applications. Professor Peter Jacobson explains: "Health care is a flashpoint for the debate over privacy because of the inherent sensitivity of our medical records. Used properly, medical records can be disclosed for life-saving purposes. Used improperly, the results can be very damaging to one's reputation or ability to seek employment."[65] From the perspective of those tempted to commit health care fraud, however, information performs a more crass function: it is also the basis on which health care is reimbursed. In short, bills are paid only if they list specific services performed for identifiable patients. This creates incentives for the fraudulent use of health care information, and explains why Congress considered the protection of such information to be a federal priority.[66]

Intangible harm may arise when a health care provider misuses patient information to obtain reimbursement for services that were not performed—a traditional form of health care false claim.[67] In *United States v. Sidhu*, for example, a physician billed the federal health care programs for biofeedback services, despite the fact that patients "never saw [the] biofeedback machine, and [the provider] generally just talked to the patient, performing more of a counseling role."[68] In some cases the provider renders legitimate services to the patient, but also submits bills for additional services the patient did not receive. That was the case in *Del Mazo v. Sanchez*, where a physician who treated a mother also billed Medicaid for the treatment of her five children, whom he had never seen.[69] In other cases, the goal of the scheme is to permit the provider to generate bills without any patient interaction at all—such as where patient information is stolen or where bills are generated in the names of deceased patients.[70]

64. 590 F.2d 192, 194 (6th Cir. 1978) (affirming convictions of dentists).

65. Peter D. Jacobson, Medical Records and HIPAA: Is It Too Late To Protect Privacy?, 86 Minn. L. Rev. 1497, 1497 (2002).

66. *See* HIPAA, Pub. L. No. 104-191, 110 Stat. 1935, 2021-34 (1996) (enacting privacy and security protections); 45 C.F.R. §§ 160.101-164.534 (2005) (setting forth privacy regulations).

67. *See, e.g.*, Peterson v. Weinberger, 508 F.2d 45, 47-48 (5th Cir. 1975) (imposing liability on a physician who submitted bills to Medicare for physical therapy services that were not performed).

68. 130 F.3d 644, 648 (5th Cir. 1997).

69. 366 S.E.2d 333, 335 (Ga. Ct. App. 1988).

70. *See* U.S. Gen. Accounting Office, Health Care Fraud: Schemes Committed by Career Criminals and Organized Criminal Groups and Impact on Consumers and Legitimate Health Care Providers 8-9 (1999) [hereinafter GAO, Health Care Fraud] (noting fraudulent use of beneficiary information that was stolen, illegally purchased, or otherwise obtained); *see also Sidhu*, 130 F.3d at 647 (accusing physician of billing for psychotherapy on dates when he was out of town and, in one case, for "a patient who was no longer living"). Note that an enterprising criminal could also obtain payment by fraudulently

When Medicare is billed for services allegedly rendered to nonexistent or deceased patients, the primary harm is to the federal Treasury. Where fraudulent bills are generated in the name of a living patient, on the other hand, they may interfere with the patient's ability to obtain medical services in the future. As Professor Pamela Bucy notes, part of that concern is clinical: "If a fraudulent provider falsifies a patient's diagnosis or misrepresents medical services that were provided so as to increase billings, the patient's file may contain false information. Subsequent providers relying on such information may unknowingly render inadequate or inappropriate medical care."[71] And even where fraudulent bills do not affect future treatment, they may implicate future coverage. Because most insurance benefits have annual or lifetime limits, the submission of fraudulent bills in a patient's name may mean that little or no coverage will be available when the patient legitimately requires care.[72] In one reported case, a psychiatrist was accused of submitting false bills for daily therapy for hospitalized patients.[73] The court noted:

> [Patients] were often admitted to the hospital needlessly or their stays in the hospital were extended beyond what was necessary and their insurance companies were billed for treatment not given. Further, the patients' treatment benefits were often exhausted by the time of their discharge. In some cases, patient benefits were exhausted for a life-time; therefore, any future treatment needs would not be covered under their current policy.[74] Thus, even if it has no immediate physical or financial effect, the use of fraudulent information has the potential to cause significant harm to patients in the future. In addition, some fraudulent schemes interfere with patient autonomy by coercing patients into making certain care choices. In one particularly egregious Anti-Kickback case, the head of a chemical dependency program for pregnant women paid illegal remuneration to obtain referrals of patients from a federally-funded drug abuse treatment research program.[75] More disturbing than the obvious payment for referrals was the fact that the illegal arrangement directly interfered with the counseling the women received: at trial, several women testified that they had been threatened with the loss of their children if they did not opt to receive treatment from this specific chemical de-

submitting bills in the name of a provider. *See, e.g.*, Oregon Medical Association, Medicare Fraud Alert, Oma Online, Jan. 7, 2005 (on file with author) (warning physicians of individuals who are obtaining provider information by misrepresenting themselves as Medicare employees).

71. Bucy, Crimes By Health Care Providers, *supra* note 44, at 661; *see also* GAO, Health Care Fraud, *supra* note 68, at 4 (noting that "false medical histories for some beneficiaries could affect the care prescribed, as the care could be based on false data").

72. *See, e.g.*, 42 U.S.C. § 1395d(a) (2000) (limiting Medicare Part A coverage of inpatient hospital services is limited to 90 days per spell of illness plus 60 lifetime reserve days, and skilled nursing care to 100 days per spell of illness).

73. United States v. Burgos, 137 F.3d 841 (5th Cir. 1998).

74. *Id.* at 844; *see also* GAO, Health Care Fraud, *supra* note 68, at 4 (concluding that beneficiaries "unknowingly risk exhaustion of their insurance benefits, due to false information included in the claims that use their names").

75. United States v. Starks, 157 F.3d 833 (11th Cir. 1998).

pendency program.[76] Although such "dignitary" affronts to autonomy are notoriously difficult to compensate under the tort system, they nonetheless constitute a relevant form of harm for the purposes of this inquiry.[77]

II. BARRIERS TO RECOGNITION OF PATIENT HARM IN FRAUD RECOVERY

Despite evidence that health care fraud harms patients, patient compensation has not been a priority of enforcement efforts to date. There are many reasons for this oversight. The failure to make patient compensation an integral component of fraud recovery is due, in large part, to limitations on the uses that can be made of recovered funds under current federal law. Other reasons are more practical in nature: the emphasis on governmental recovery is consonant with the government's goals in pursuing fraud cases, and such recoveries do in fact benefit the patient population (albeit indirectly). Finally, the assumptions underlying the white collar crime framework may well be a contributing factor.

A. Where Do Health Care Fraud Recoveries Go?

Despite the influx of dollars from successful fraud enforcement, current law provides few avenues for these funds to be allocated directly to injured beneficiaries. The disposition of federal health care fraud recoveries is governed by HIPAA.[78] In a civil false claims case, for example, a portion of the proceeds (usually 15-30%) will be awarded to any *qui tam* relator(s) who initiated the suit.[79] Most of the remaining funds—as well as those recovered from civil monetary penalties, other civil assessments, and criminal fines and forfeitures[80]—are deposited into the perennially near-insolvent Medicare Part A Trust Fund.[81] Under the HIPAA Fraud and Abuse Control Program provisions, however, this money is available for appropriation back to the Health Care Fraud and Abuse Control Account, a special expenditure account created to fund DOJ and OIG health care anti-fraud efforts.[82] Appropriations are controlled by the Secretary of HHS and the Attorney General, who jointly certify the amounts necessary to

76. *Id*. at 837.

77. *See, e.g.*, Alan Meisel, A "Dignitary" Tort as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent, 16 J.L. Med. & Healthcare 210 (1988) (discussing how dignitary injuries have not adequately been addressed by informed consent law); Richard S. Saver, Medical Research and Intangible Harm, 74 Cinn. L. Rev. (forthcoming 2006) (discussing intangible harm in medical research context).

78. Pub. L. No. 104-191, 110 Stat. 1936 (1996).

79. *See* 31 U.S.C. § 3730(d) (2000) (discussing the range of awards for *qui tam* plaintiffs); 42 U.S.C. § 1395i(k)(2)(C)(iv) (2000) (exempting funds awarded to relator from amounts allocated to Trust Fund under HIPAA).

80. *See* 42 U.S.C. § 1395i(k)(2)(C) (setting forth rules for deposits).

81. *See id*. § 1395i(k)(2)(C)(iv) (authorizing the transfer of penalties and damages obtained in health care FCA cases to the Trust Fund, with the exception of funds awarded to a relator, funds designated for restitution, or as otherwise authorized by law).

82. *See id*. § 1395i(k)(3) (describing appropriations to the Health Care Fraud and Abuse Control Account).

fund anti-fraud programs each year within broad ranges established by Congress.[83] In loose terms, a portion of the money recovered through federal fraud prosecutions and settlements is available—at the discretion of the agencies themselves—for appropriation back to DOJ and HHS.

This funding structure suggests that HIPAA may have created a "bounty system," albeit an attenuated one.[84] To be sure, the very nature of law enforcement provides incentives for prosecutors to be successful, just as an annual appropriations process puts a premium on agencies demonstrating that Congress gets what it pays for. Indeed, DOJ has long had a "3% fund," under which money from civil recoveries is deposited in a special fund that supports other civil enforcement actions.[85] Nonetheless, there is a fear that HIPAA may have tied future funding too closely to past success. Just as critics have warned that the FCA *qui tam* provisions create incentives for relators to file meritless suits in the hopes of reaping financial windfalls,[86] critics fear that the motivations of OIG and DOJ personnel will be tainted by a structure that permits them to receive a financial boost with each successful prosecution.[87] In light of longstanding concerns about overzealous health care fraud enforcement, these new developments are decidedly unwelcome.[88] Nor are these concerns simply academic. Within the health care provider community, the Control Account mechanism is derided as

> a self-perpetuating enforcement scheme. . . . Rewarding those who enforce Medicare fraud and abuse regulations with more program funds creates strong institutional incentives for those enforcers to pursue as many investigations and fraud and abuse prosecutions as possible, thus increasing the risk that the innocent as well as the

83. *See id*. § 1395i(k)(3)(A)(i) (setting out the maximum amounts available to HHS and DOJ). In FY 2004, the Secretary and the Attorney General certified $240 million as necessary for health care anti-fraud efforts; HHS received approximately $191 million, and DOJ received approximately $49 million. *Id*.; *see* Dep't of Health & Human Servs. & Dep't of Justice, Health Care Fraud and Abuse Control Program Annual Report for FY 2004, at 4 (2005), *available at* http://www.oig.hhs.gov/publications/docs/hcfac/ hcfacreport2004.htm.

84. *See, e.g.*, Roger Feldman, An Economic Explanation for Fraud and Abuse in Public Medical Care Programs, 30 J. Leg. Stud. 569, 574 (2001) ("Although this is not a pure bounty system, it is much closer than had previously been the case."). The effect is further attenuated by the fact that appropriations are capped. *See* 42 U.S.C. § 1395i(k)(3)(A)(i)(III) (capping appropriations at FY 2003 levels).

85. *See, e.g.*, Civil Division, http://www.usdoj.gov/usao/okn/civil.html (last visited Mar. 7, 2006) (describing the Affirmative Civil Enforcement ("ACE") program in the U.S. Attorneys Office for the Northern District of Oklahoma).

86. As the Supreme Court cynically has concluded, "*qui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good." Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 948 (1997).

87. Professor Dayna Matthew argues that while "[p]ublic prosecutors do not have a direct personal interest in funds deposited into the Control Account from their prosecutorial efforts . . . they do have an interest in the size of the Control Account as a measure of their professional success and as a source of financing for future professional endeavors." Dayna Bowen Matthew, Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act, 76 Ind. L.J. 525, 580 n.319 (2001); *see also id.* at 580 (noting that "[i]ronically, these financial incentives arguably pose the same threat to prosecutorial discretion, as prosecutors claim self-referral fees pose to providers' medical judgment").

88. *See, e.g.*, Joan H. Krause, "Promises to Keep": Health Care Providers and the Civil False Claims Act, 23 Cardozo L. Rev. 1363, 1412-13 (2002) [hereinafter Krause, "Promises to Keep"] (discussing complaints of prosecutorial overreaching in health care fraud cases).

guilty will suffer punishment.[89] The criticism has been vocal enough to put the government on the defensive: vehemently denying the existence of a bounty system, Medicare publications tout the fact that "[a]ll recovered monies are returned to the Medicare Trust Funds" and seek to assure the public that HIPAA-mandated enforcement activities have "a stable source of funding under" the law.[90] The Control Account is by no means the first productivity-based funding structure that has been alleged to taint the discretion of prosecutors and law enforcement personnel. Virtually identical allegations have been levied against the forfeiture provisions that, since the 1970's, have supported the nation's so-called "War on Drugs."[91] Similar to the Control Account, federal law has permitted forfeited assets to be placed into a special DOJ Assets Forfeiture Fund, rather than deposited into the general federal Treasury.[92] This money, in turn, is available to the Attorney General to fund a variety of law enforcement activities, including reimbursement of forfeiture-related expenses by federal, state, and local agencies.[93] According to Professors Eric Blumenson and Eva Nilsen, who have made a detailed study of expenditures and enforcement priorities under this program, these provisions "have not simply enhanced the ability of law enforcement to do its job, but rather have changed the nature of the job itself."[94] Blumenson and Nilsen describe two primary objections to the self-funding nature of the law: (1) the conflict of interest between "legitimate law enforcement goals" and initiatives that "maximize funding for their operations,"[95] and (2) the loss of accountability that occurs when agencies are able to self-fund rather than going through the normal legislative appropriations process.[96] The result, in their view, is a Drug War that has become self-perpetuating not so much due to

89. Emord, *supra* note 17, at 32; *see also* Hyman, *supra* note 16, at 158 ("To be sure, CMS does not get to ' eat what it kills.' . . . Although this structure prevents the government's fraud control system from operating on a pure bounty system, there is still considerable suspicion in the provider community on this point.").

90. Health Care Fin. Admin., U.S. Dep't of Health & Human Servs., The Medicare Integrity Program: Pay It Right! 1, 11 (2001); *see also* Hyman, *supra* note 16, at 158 (noting that CMS publications "go out of their way to label [the bounty allegation] a ' common misperception'").

91. *See* Eric Blumenson & Eva Nilsen, Policing for Profit: The Drug War's Hidden Economic Agenda, 65 U. Chi. L. Rev. 35 (1998).

92. 28 U.S.C. § 524(c)(1) (2000); Blumenson & Nilsen, *supra* note 89, at 50-51 (describing funding mechanism).

93. 28 U.S.C. § 524(c)(1)(A) (describing allowable use of funds). Even if the case is a federal one, state and local law enforcement agencies are permitted to receive funding "that bears a reasonable relationship to the degree of direct participation . . . and will serve to encourage further cooperation between" the agencies. 21 U.S.C. § 881(e)(3)(A)-(B) (2000); *see also* Blumenson & Nilsen, *supra* note 89, at 50-51 (describing effect of the "equitable sharing program," which directs a significant portion of seized assets to state and local law enforcement).

94. Blumenson & Nilsen, *supra* note 89, at 56.

95. *Id.*

96. *Id.* at 84-100 (noting both separation of powers and policy objections).

> the political urgency of its objective, but rather because of the hidden bureaucratic financial incentives.[97]

While there is little empirical research on the topic, the first of these concerns—that the promise of self-funding can skew law enforcement priorities—is a distinct possibility in the health care fraud context. As the Author has argued elsewhere, the vague contours of the fraud laws leave prosecutors with enormous discretion over which activities to target.[98] The process is complicated by the specter of enormous FCA penalties and the threat of exclusion from federal health care programs, which give health care providers strong incentives to settle fraud allegations rather than pursuing the litigation through trial.[99] In fact, the potential for skewing priorities may be greater in health care fraud cases than in the drug context, where the prohibitions appear relatively clear (albeit draconian). Because of significant ambiguity in the regulations governing participation in the federal health care programs, however—what Professor James Blumstein has described as regulatory "gray area[s]" rather than "raw fraud"[100]—prosecutors have a great deal of discretion over whether to pursue questionable activities as fraud or to permit them to be resolved through HHS administrative channels. This discretion, in turn, raises the possibility that prosecutors may use the litigation process as a means to resolve such regulatory ambiguities.[101] Indeed, to the extent federal prosecutors benefit financially from fraud settlements involving gray areas, but do not similarly benefit if HHS personnel address the same behavior by clarifying federal health care program rules, the Control Account mechanism provides yet another motive for pursuing much maligned forms of "regulation by litigation."[102]

In the health care fraud context, Blumenson and Nilsen's non-accountability concerns may be mitigated by the fact that Congress established upper limits on the amount that may be appropriated to the Control Account, and required the Attorney General and Secretary of HHS to submit a joint annual report accounting for their

97. *Id*. at 39-40. Blumenson and Nilsen note that the self-perpetuating nature of these law enforcement activities is particularly ironic in light of the failure to achieve any meaningful improvement in drug usage. *Id*. at 37-39.

98. For a discussion of prosecutorial discretion in the context of health care fraud, *see* Krause, "Promises to Keep," *supra* note 86, at 1410-15.

99. *Id*.

100. James F. Blumstein, What Precisely is "Fraud" in the Health Care Industry?, Wall St. J., Dec. 8, 1997, at A25.

101. *See* Krause, A Conceptual Model, *supra* note 8, at 110-32 (describing examples of the use of litigation to fill regulatory gaps, and the problems inherent in such an approach).

102. *See* Joan H. Krause, Regulating, Guiding, and Enforcing Health Care Fraud, 60 N.Y.U. Ann. Surv. Am. L. 241, 272-74 (2004) [hereinafter Krause, Regulating, Guiding, and Enforcing] (describing dangers of "regulation by litigation" in the health care fraud context). Whether these incentives rise to the level of illegality is unclear. In 1980, the Supreme Court held that a provision of the Fair Labor Standards Act that returned civil penalties from child labor violations to the Department of Labor, rather than the federal Treasury, did not violate the Due Process Clause because the possibility of prosecutorial bias was remote. Marshall v. Jerrico, Inc., 446 U.S. 238 (1980). In particular, the Court noted that no individual stood to benefit from overzealous collection efforts, the civil penalties accounted for a small percentage of the agency's budget, and the distribution mechanism functioned in a non-biased way. *Id*. at 250-51. Application of these factors to the Control Account requires an analysis of data that is beyond the scope of this Article. Cf. Blumenson & Nilsen, *supra* note 89, at 62-66 (arguing that an analysis of these factors in the drug forfeiture context suggests the funding scheme is unconstitutional).

expenditures.[103] While subject to some degree of oversight, however, the Control Account mechanism still permits HHS and DOJ to favor fraud enforcement over other health care funding needs. Because the funds certified for inclusion in the Control Account are transferred from the Medicare Part A Trust Fund, they are not available to be spent on patient care or other efficiency-enhancing administrative program activities.[104] This is analogous to problems noted by Blumenson and Nilsen, who note that forfeited assets that are siphoned off for law enforcement purposes are no longer available for public funding of proactive drug treatment and education programs.[105] Yet this logic is also somewhat circular: without the Control Account mechanism, Congress would be required to fund all fraud enforcement activities directly in addition to funding the Medicare program, all from the same finite pool of resources.[106] Moreover, such criticism is belied by the fact that the amount collected in fraud prosecutions—and hence returned to the Trust Fund—far exceeds the amount transferred back to the Control Account.[107] While it is possible to argue that any removal of Trust Fund monies is ill-advised, the net effect of this investment strategy appears to be a positive one.

Although the precise nature of prosecutors' stake in health care fraud settlements may not be critical to the debate over patient-centered recovery, it nonetheless raises concerns. For our purposes, what is clear is that the funds recovered from health care fraud enforcement go to the Medicare Trust Fund, to the Control Account, to any relators who initiated the litigation, and to the federal agencies that investigate and prosecute health care fraud—but not directly to remedy the harm suffered by the patients in whose names these investigations are mounted. Combined with the practical considerations underlying the government's approach to these cases and the traditional posture of white collar crime enforcement, these funding rules help to explain why patient compensation has been disfavored, or at the very least overlooked.

B. Recognition of Patient Harm Under Current Law

The laws governing health care fraud and abuse recognize the potential for patient harm as relevant both to the imposition and to the amount of sanctions. A prime example is the "health care fraud" crime enacted by HIPAA, which imposes progressively longer terms of imprisonment on those who defraud a health care benefit program depending on the level of physical harm caused—ranging from a base term of no more than 10 years in prison, to no more than twenty years if the activity "results

103. *See* 42 U.S.C. § 1395i(k)(3) (2000) (setting caps); *id.* § 1395i(k)(5) (requiring annual report). *But see* 28 U.S.C. § 524(c)(6) (2000) (requiring Attorney General similarly to transmit reports to Congress regarding the Asset Forfeiture Fund).

104. 42 U.S.C. § 1395i(k) (explaining funding transfer mechanism). As one critic notes, "[b]ecause funds extorted from physicians will not be used to cover Medicare program costs but to extort more funds, Congress will not be able to disguise cost increases in Medicare." Emord, *supra* note 18, at 32.

105. *See* Blumenson & Nilsen, *supra* note 89, at 82.

106. As one House Report on the HIPAA legislation noted, "[c]urrently, Medicare's program integrity functions are subsumed under Medicare's general administrative budget." H.R. Rep. No. 104-496 pt. 1, at 79 (1996).

107. *See* Meyer, *supra* note 32, at 5 (noting that an estimated $1.4 billion was returned to the Trust Fund in FY 2002, while only $209 million was transferred to the Control Account).

in serious bodily injury," to "any term of years or for life" if death results.[108] Similarly, in determining the length of a provider's mandatory exclusion from federal health care programs, the fact that the prohibited acts "had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals" is an aggravating factor weighing in favor of more lengthy exclusion.[109] When calculating the amount of civil monetary penalties to be imposed, the fact that "false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission" similarly is an aggravating circumstance warranting higher penalties.[110] In addition, physicians who knowingly and willfully bill Medicare patients for excessive charges are subject to civil monetary penalties,[111] as are managed care organizations that impose excessive premiums on their enrollees.[112] It is clear, then, that the federal laws and regulations governing health care fraud acknowledge physical and financial harm to patients as factors relevant to both the necessity and severity of sanctions. The fact that such harm is relevant, however, does not mean that it will be remedied separate from the government's own injury.

As a practical matter, part of the reason patient compensation is not a more significant aspect of health care fraud recovery is that the government's motivations for pursuing fraud enforcement are dual in nature and dependent on the factual context in which the fraud occurs. In schemes involving the misappropriation of patient information for the purposes of generating false bills, for example, the harm to the patient is largely incidental to the fraud on the government payer: the fraud occurs when the bill is submitted, regardless of whether the patient has suffered any injury. Other schemes, however, operate in the reverse: the fraud can only occur after the patient is harmed. If a nursing home mistreats a resident, for example, the harm to that patient is complete; in contrast, fraud will not occur until the institution submits a bill for the services (and only then, most likely, if the allegations are extensive and systemic).[113]

In essence, then, the federal government's interest in the former category of cases emanates from its role as a defrauded payer, and in the latter category from its authority to protect vulnerable individuals.[114] Demanding that the federal government be more creative in disbursing the money recovered from health care fraud investigations

108. 18 U.S.C. § 1347 (2000).

109. 42 C.F.R. § 1001.102(b)(3) (2005); *see also id.* § 1001.801(c)(2)(iii) (noting that where managed care organization fails to furnish medically necessary items and services, fact that such denial "had or could have had a serious adverse effect" is relevant to length of exclusion). Similarly, in determining the appropriate length of permissive exclusions, aggravating factors include the fact that the actions "had a significant financial impact on program beneficiaries or other individuals." *Id.* § 1001.201(b)(2)(i).

110. *Id.* § 1003.106(b)(1)(iv).

111. *See* 42 U.S.C. § 1395u(j)(1)(A) (2000) (stating prohibition); *id.* § 1395u(j)(2) (setting forth exclusion and CMP authorities).

112. *See id.* § 1395mm(i)(6) (stating prohibition and listing penalties).

113. *See, e.g.*, United States v. NHC Healthcare Corp., 163 F. Supp. 2d 1051, 1055 (W.D. Mo. 2001) (noting that "Defendants are not being sued simply for violating the standard of care . . .. [r]ather, Defendants are being sued because they allegedly failed to provide the services that they billed for"); *id.* at 1055 n.3 (distinguishing malpractice from FCA liability).

114. Unlike the states, the federal government does not have an explicit "police power" to protect the health of citizens; instead, the federal government's authority to regulate public health is derived from specific powers enumerated in the Constitution, such as the powers to tax, spend, and regulate interstate commerce. *See* Lawrence O. Gostin, Public Health Law: Power, Duty, Restraint 34-55 (2000) (analyzing state and federal public health authorities).

may conflate these roles. As Professor William Sage has noted, "[a] central, unresolved question is whether the principal purpose of fraud and abuse law is to protect financial integrity or patient welfare."[115] In both situations, the tendency to overlook patient compensation is based on a concern for diverting recovered funds from their respective primary purposes. Where the federal health care programs are defrauded, the primary goal is to remedy the government's own harm. Recovered funds are directed to the Medicare Trust Fund because it is the Trust Fund that improperly paid for these services; sharing the recovery with individual patients, while a laudable goal, would have the effect of siphoning scarce program resources away from the program.[116] Thus, the focus on health care fraud in these cases is largely one of program integrity and solvency, rather than an attempt to invoke a general police power to assure the quality of the country's medical care. By contrast, where the government is primarily acting in its role as protector, its goals are more in line with the traditional deterrent purposes of criminal law: "to prevent harm to society . . . accomplishe[d] by punishing those who have done harm and by threatening with punishment those who would do harm, to others."[117] But channeling recovered money to patients, at least in significant amounts, would drain the resources needed to fund such public welfare enforcement and might be perceived as weakening the deterrent force of the law.[118]

Lest this Article overstate the case, however, it is important to note that patients do, in fact, benefit from general fraud recoveries—both in terms of the quality and the security of their health care benefits.[119] When nursing homes or hospitals settle quality-related fraud allegations, for example, the settlement agreement is likely to include provisions directly related to improving the quality of the care rendered—such as specialized training, monitoring and quality assessment, and mandated reporting

115. William M. Sage, Fraud and Abuse Law, 282 J. Am. Med. Ass'n 1179, 1180 (1999).

116. *See supra* Part II.A (describing disposition of federal health care fraud recoveries).

117. Wayne R. LaFave, Criminal Law § 1.2(e) (4th ed. 2003).

118. One could argue, by analogy, to the analysis done in cases in which a portion of the recovery is diverted to a *qui tam* relator or private attorney general. *See, e.g.*, John C. Coffee, Jr., Rescuing the Private Attorney General: Why the Model of the Lawyer as Bounty Hunter is Not Working, 42 Md. L. Rev. 215, 246 (1983) (arguing that nonpecuniary settlements, which have become common in such cases, threaten deterrence more than victim compensation); Marsha J. Ferziger & Daniel G. Currell, Snitching for Dollars: The Economics and Public Policy of Federal Civil Bounty Programs, 1999 U. Ill. L. Rev. 1141, 1152 (noting that " higher bounties would decrease revenues in each individual case because of the higher bounty cost"); Jill E. Fisch, Class Action Reform, *Qui Tam*, and the Role of the Plaintiff, 60 Law & Contemp. Probs. 167, 201 (1997) (arguing in favor of a hybrid *qui tam*/class action remedy in which "the government would sacrifice its current monetary recovery in enforcement actions in favor of compensation for injured victims"); *cf.* Geoffrey P. Miller & Lori S. Singer, Nonpecuniary Class Action Settlements, 60 Law & Contemp. Probs. 97, 113 (1997) (arguing that non-monetary class action settlements serve the goal of deterrence to the extent they force "the defendant [to] internalize the costs of harm"); David Rosenberg, Decoupling Deterrence and Compensation Functions in Mass Tort Class Actions for Future Loss, 88 Va. L. Rev. 1871, 1892 (2002) (noting that "[h]ow damages are distributed among plaintiffs . . . is generally . . . irrelevant to achieving deterrence").

119. Nor are patients without options if the federal government declines to engage in more creative efforts to disburse fraud recoveries; a variety of mechanisms exist at the state level to redress direct patient harm, most notably the tort system. *See, e.g.*, W. Page Keeton *et al.*, Prosser and Keeton on the Law of Torts § 1, at 5-6 (5th ed. 1984) (describing tort law as "a body of law which is directed toward the compensation of individuals, rather than the public, for losses which they have suffered within the scope of their legally recognized interests").

to the U.S. Attorney's Office.[120] While such provisions may not compensate patients who have suffered harm in the past, they should improve the quality of care provided to facility residents in the future. Moreover, health care fraud recoveries play a role in extending the solvency of the Medicare Trust Fund, which in turn permits the program to provide services to present and future beneficiaries.[121] By reclaiming diverted program funds, health care fraud enforcement increases the likelihood that the Medicare program will be able to provide care for the ever-growing beneficiary population (a benefit as well to the future generations of taxpayers who may be called upon to shoulder an increasing portion of the program's finances). Once again, however, the protection of beneficiary entitlement in the aggregate is not the same thing as compensating individuals who personally have been harmed by fraudulent activities.

A few anti-fraud provisions do provide for a return of money directly to injured patients. For example, under current law physicians who do not participate in the Medicare program cannot charge Medicare patients more than 115% of the Medicare-approved charge.[122] A physician who violates this provision is subject to exclusion and/or civil monetary penalties, and the Secretary of HHS is authorized to use a portion of the funds collected in the proceeding to "make a payment to a beneficiary . . . in the nature of restitution for amounts paid by such beneficiary" that were found to be excessive.[123]

In criminal prosecutions under the health care fraud, mail fraud, and wire fraud statutes, even broader authority supports compensation.[124] Under Title 18 of the United States Code, restitution is a mandatory component of sentencing for "offense against property" and in cases "in which an identifiable victim or victims has suffered a physical injury or pecuniary loss."[125] In prosecutions under the Anti-Kickback Statute[126] and other health care fraud offenses found in Title 42 of the United States Code, restitution may be ordered as a part of a plea bargain or as a condition of probation

120. *See* Hoffman, *supra* note 60, at 154-55 (describing settlement in United States v. GMS Management-Tucker, Inc., No. 96-1271 (E.D. Pa. Feb. 21, 1996)); Press Release, U.S. Attorney's Office, U.S. Attorney's Office Reaches Agreement with Hospital to Resolve Failure of Care Allegations Stemming From Improper Use of Patient Restraints (July 25, 2005) *available at* www.usdoj.gov/usao/pae/News/Pr/2005/jul/CMMC.html (describing hospital's agreement to hire a consultant to review the facility's use of restraints).

121. *See* Medicare Payment Advisory Comm'n, A Data Book: Healthcare Spending and the Medicare Program 59 (2003), *available at* http:// www.medpac.gov/publications/congressional_reports/Jun03DataBook_Entire_report_links.pdf (projecting that Part A Trust Fund will become insolvent in 2026, and costs may exceed tax revenues as soon as 2013).

122. 42 U.S.C. § 1395w-4(g)(2)(C) (2000) (defining the "limiting charge").

123. *Id.* § 1395u(j)(4). The portion of FCA recoveries awarded for restitution is exempt from allocation to the Trust Fund, thus preventing a direct conflict between the needs of victims and the financial goals of federal prosecutors. *See id.* § 1395i(k)(2)(C)(iv) (exempting restitution amounts from transfer to the Control Account).

124. *See* 18 U.S.C. §§ 1341, 1343, 1346-47 (2000) (defining mail, wire, and health care fraud).

125. *Id.* § 3663A(c)(1)(A)(ii), (B) (listing crimes for which restitution must be ordered); U.S.S.G. § 5E1.1 (2005) (providing for restitution under the federal Sentencing Guidelines); *see also id.* § 8B1.1 (restitution for corporate defendants). Mandatory restitution does not apply to offenses against property, however, if

> the number of victims is so large as to make restitution impracticable; or determining complex issues of fact related to the cause or amount of the victim's losses would complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

18 U.S.C. § 3663A(c)(3); *see also* U.S.S.G. § 5E1.1(B)(2).

126. 42 U.S.C. § 1320a-7b(b).

or supervised release.[127] The expenses subject to restitution are defined broadly to include not only financial losses but also the costs of necessary medical care, including psychiatric, psychological, and certain "nonmedical care and treatment."[128] To the extent they remain applicable, the federal Sentencing Guidelines also permit an increase in offense level (and hence a more severe sentence) if the crime involves a vulnerable victim, the abuse of a position of trust, or the use of a special skill, as well as upward departures in sentences for crimes resulting in death, physical injury, or extreme psychological injury.[129] Thus, in criminal health care fraud cases, restitution likely will be an available remedy. Unfortunately, many health care fraud cases involve civil and administrative causes of action that do not independently provide for restitution. As a result, most health care fraud recoveries are destined for the Trust Fund and Control Account, rather than for the individual patient victims.

C. White Collar Crime and Recognition of Patient Harm

The lack of emphasis on patient harm, especially non-financial harm, is also related to the white collar crime context in which health care fraud is prosecuted. The DOJ has defined white collar crime as

> [n]onviolent crime for financial gain committed by means of deception by persons whose occupational status is entrepreneurial, professional or semi-professional and utilizing their special occupational skills and opportunities; also, nonviolent crime for financial gain utilizing deception and committed by anyone having special technical and professional knowledge of business and government, irrespective of the person's occupation.[130] This definition limits both the universe of individuals who will be subject to prosecution and the actionable forms of harm. Health care fraud fits this definition because the goal of the fraud is to obtain unlawful financial gain by means of deception, and because such fraud is accomplished by persons who utilize their specialized status, training, and knowledge of health care and the relevant reimbursement rules.[131] The fit is an imperfect one, however, as the definition does not encompass the full range of consequences from fraudulent activities, particularly to patients. The emphasis on

127. *See* 18 U.S.C. § 3556 (order of restitution); *id.* § 3563 (conditions of probation); *id.* § 3583 (conditions of supervised release after imprisonment); *id.* § 3663 (discretionary restitution authority).

128. *Id.* § 3663(b)(2)(A). For certain drug offenses in which there is no identifiable victim, restitution "based on the amount of public harm caused by the offense" is paid to the state agencies that administer crime victim assistance and federal substance abuse block grants. *Id.* § 3663(c); U.S.S.G. § 5E1.1(d).

129. *See* U.S.S.G. §§ 3A1.1, 3B1.3, 5K2.1-2.3; United States v. Booker, 543 U.S. 220 (2005) (overturning mandatory nature of Federal Sentencing Guidelines).

130. Strader, *supra* note 7, at 1207-08 (quoting U.S. Dep't of Justice, Bureau of Justice Statistics: Dictionary of Criminal Justice Data Terminology 215 (2d ed. 1981)).

131. *See also* Bucy, Fraud by Fright, *supra* note 10, at 870-71 (noting," Fraud by health care providers shares three essential features of all white collar offenses: first, it has a hybrid criminal/civil nature; second, it is difficult to investigate and prove; and third, successful prosecution necessitates a careful development of a theory of the case that accomplishes certain goals").

> the financial goals of the scheme, in particular, suggests not only that other forms of injury (physical and intangible) are irrelevant[132] but also that the focus is on the primary victim—in this case the federal health care programs. Under such a calculus, there is little incentive to characterize cases in a patient-focused way, and little urgency to seek compensation for individual patients with small-dollar (let alone intangible) injuries. In the words of one former prosecutor, "[b]ecause the legal theories historically used to prosecute health care providers have failed to identify the patients as fraud victims, the powerful evidence that a provider delivered poor medical care has seldom been used to its maximum advantage."[133]

Despite the emphasis on financial gain, it has been recognized "that white-collar crimes, particularly corporate crime, may have violent consequences."[134] This is perhaps acknowledged most clearly for environmental crimes, which have the potential to cause harm to large numbers of people.[135] While recognition that financially motivated crimes may have physical consequences is a welcome step, it still does not capture the essence of the problem in the health care context. Due to the underlying medical nature of the activities, the potential for physical harm is in many ways a defining characteristic of health care fraud.[136] The fact that the misuse of individual patient information is not merely a foreseeable consequence of the scheme but is in many ways a precondition to its success makes health care fraud very different from other crimes in which unknown individuals may, at some future point, suffer harm from causes such as environmental toxins, workplace hazards, or substandard products. Where the success of the fraud is linked so closely to the perpetrator's ability to affect an individual patient's medical care, or at the very least to utilize individual patient information, it is troubling that this harm remains undervalued. For that reason, alternate recovery mechanisms may need to be drawn from sources outside the white collar crime enforcement framework.

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132. *See* Jennifer S. Recine, Note, Examination of the White Collar Crime Penalty Enhancements in the Sarbanes-Oxley Act, 39 Am. Crim. L. Rev. 1535, 1559-60 (2002) (noting that "optimal penalty theorists," such as Richard Posner, suggest that "white-collar criminals do not pose a threat of physical harm to the public") (citing Richard A. Posner, Optimal Sentences for White-Collar Criminals, 17 Am. Crim. L. Rev. 409, 409-10 (1980)).

133. Bucy, Fraud by Fright, *supra* note 10, at 928. As a practical matter, however, a patient-centered focus might offer distinct prosecutorial advantages. *See id.* (noting that "[a] prosecutor able to identify a patient as a victim of the fraud will present a more complete picture of the scope of the provider's fraud and thus will have a stronger case").

134. Elizabeth Szockyj, Imprisoning White-Collar Criminals?, 23 S. Ill. U. L.J. 485, 487 (1999) (noting that physical costs of white collar crimes include "[p]ersonal injuries, diseases, and death due to occupational workplace hazards, environmental pollution, and the marketing of dangerous products"). Some theorists clarify that white collar crime is crime committed by non-violent means, although it may have violent effects. *See, e.g.*, Gilbert Geis, White-Collar Crime—What Is It?, in White-Collar Crime Reconsidered 31, 39 (Kip Schlegel & David Weisburd eds., 1992) (describing American Bar Association definition of "economic" crime).

135. *See, e.g.*, 42 U.S.C. § 6928(e) (2000) (specifying penalties for persons who knowingly endanger others by their handling of hazardous waste); Neal Shover & Aaron S. Routhe, Environmental Crime, 32 Crime & Just. 321, 322, 329-30 (2005) (noting "the financial and human costs of environmental crime," as well as the difficulty of ascertaining a dollar value for harm to non-human victims); Szockyi, *supra* note 132, at 487 (providing examples of environmental harms).

136. *See* Bucy, Crimes by Health Care Providers, *supra* note 44, at 660 ("Health care fraud is unique among white collar crimes in its ability to cause physical harm.").

III. DEVELOPING A PATIENT-CENTERED APPROACH TO FRAUD RECOVERY

The fact that compensation of patient injuries has not been a key component of fraud recoveries to date does not mean that such an approach is infeasible. Even within the limits imposed by HIPAA, alternative settlements may be possible. When these tactics are combined with approaches taken in other contexts, such as consumer class actions—particularly given the flexibility traditionally accorded to state governments in crafting compensation for injured individuals—there appears to be ample leeway to structure settlements that more directly benefit patients without significantly reducing the federal share of recovery.

A. Recent Federal Settlements

On occasion, federal prosecutors have undertaken direct efforts to return money to individual victims of health care fraud. Among the most prominent examples was the "72-Hour Window Project," a national investigation of hospitals that submitted separate Medicare bills for outpatient services (usually laboratory tests) provided within 72 hours of a related inpatient admission—services that, by law, are included in the lump-sum hospital inpatient payment.[137] As a result, patients were charged copayments for the additional outpatient services, rather than only their share of the inpatient costs. The settlements required the hospitals to reimburse patients for the improperly collected amounts.[138] Restitution appears to have been feasible due to the limited universe of claims for which each hospital was audited, making it possible to identify both the patient victims and the amounts by which they were overcharged.

Even where the victim population is significantly larger, federal prosecutors may have some ability to craft patient-centered settlements. For example, the Civil Injunction Statute, which permits the Attorney General to commence a civil action to enjoin a defendant from committing a health care offense, authorizes the court to "take such . . . action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought."[139] Federal prosecutors have suggested that this statute provides the basis for broad remedies in health care fraud cases, which could include some form of restitution.[140] Perhaps the most prominent public use of this tactic to date has been in *United States v. Merck-Medco Managed Care*, in which the government sought an injunction

137. *See* 42 C.F.R. § 412.2(c)(5) (2005) (defining certain preadmission services as included in inpatient prospective payment); U.S. Gen. Accounting Office, Medicare: Application of the False Claims Act to Hospital Billing Practices 3 (1998) [hereinafter GAO, Medicare] (describing project).

138. *See, e.g.*, GAO, Medicare, *supra* note 135, at 9 (describing settlements); Settlement Agreement P 10, United States v. Miss. Baptist Med. Ctr. (Oct. 10, 1999), cited in Compliance Rep. (CCH) P 130,318 (requiring hospital to refund copayments and deductibles to patients).

139. 18 U.S.C. § 1345 (2000).

140. Conversation with James G. Sheehan, Associate U.S. Attorney, E. Dist. of Pa., in Wilmington, Del. (June 6, 2003); *see, e.g.*, Entry of Consent Decree at *1, United States v. Corson, No. 93-CV-3637, 1993 WL 332268 (E.D. Pa. July 12, 1993) (requiring physician, under 18 U.S.C. § 1345, to reimburse Medicare beneficiaries who were overcharged for his services).

against fraudulent activities by a mail order pharmacy company that included "shorting" prescriptions by delivering too few pills and "switching" patients to alternate drugs for which the company received financial benefits (including alternate drugs manufactured by its parent company, Merck).[141] As part of the federal Consent Order, Medco was required to reimburse patients for all out-of-pocket costs for health care services incurred in connection with the unauthorized switches.[142]

Similar flexibility may be afforded by 18 U.S.C. § 3573, which permits the government to petition for a remission of a criminal fine under certain circumstances.[143] In October 2003, for example, United Memorial Healthcare Association ("UMH") pleaded guilty to one count of mail fraud in connection with an investigation of a physician who was convicted of performing medically unnecessary procedures at a UMH pain clinic.[144] In an interesting procedural turn, the plea was deferred by the presiding judge, which enabled the government to petition for remission of the fine. Using the flexibility afforded by the remissions statute, the U.S. Attorney's Office agreed to match up to $500,000 of the criminal fine, with the money designated for a specific patient-directed purpose: funding a program sponsored by UMH's new owner to provide health care and health education services to disadvantaged individuals in the hospital's service area.[145] The agreement essentially allowed UMH to pay only half the fine, but directed those funds (plus an equal amount of government funds) specifically to improve the health of indigent people in the population. While this strategy did not attempt to compensate any of the individual patients who were harmed by the unnecessary procedures, it did accomplish an important health-related goal by extending health care services to a disadvantaged local community. However, it is clear that devising such an alternative path for the funds required extreme procedural steps, as well as the cooperation of both prosecutors and the presiding judge. While intriguing, these examples may not provide an adequate model for large-scale alternative settlements.

B. Lessons From Consumer Protection

The limited options available to federal prosecutors stand in stark contrast to the broad consumer protection remedies available to state attorneys general, who have been able to craft innovative health care fraud settlements that target—at times with near poetic elegance—the disadvantaged patient populations. For example, in settlements with drug and medical device manufacturers accused of illegally excluding Medicare and Medicaid patients from their marketing promotions (usually in an attempt to avoid liability under the Anti-Kickback Statute), the Massachusetts Attorney General has

141. *See* Amended Complaint, United States v. Merck-Medco Managed Care, No. 00-737 (E.D. Pa. Dec. 9, 2003); Consent Order for Permanent Injunction, United States v. Merck-Medco Managed Care, No. 00-737, 2004 WL 977210 (E.D. Pa. 2004).

142. Consent Order, Merck-Medco Managed Care, 2004 WL 977210, at *7.

143. 18 U.S.C. § 3573 (permitting judge to modify or remit an unpaid fine or assessment); Telephone Interview with Glenn Martin, Assistant U.S. Attorney, Western District of Michigan (Nov. 6, 2003).

144. Press Release, W. Dist. of Mich. Dep't of Justice, Matching Fund Program to Provide Indigent Medical Care (Oct. 6, 2003) (attaching Matching Fund Agreement).

145. *Id.* (citing the Matching Fund Agreement P 6).

required the defendant companies to donate free products to indigent patients in the state.[146] In Utah, a pediatrician accused of charging private insurers for vaccines that were supposed to have been given away to indigent children paid $64,000 to settle the claims, with the money earmarked for a vaccination program administered by the state.[147] In Connecticut, drug manufacturer Dey Inc. settled pricing fraud allegations, in part, by donating $800,000 of its respiratory drugs to community health centers and other free clinics in the state.[148] Such settlements clearly confer a financial benefit on the state and local governments, which otherwise would be required to purchase similar items for publicly funded hospitals and health care programs. But more importantly, these settlements impose sanctions that are tailored to the underlying harm, making the previously denied products available to a disadvantaged population within the state. This more holistic approach to remedying the effects of fraud confers an advantage on those who were disadvantaged—if not the exact victims, then at least patients who are similarly situated.

While some of these settlements may hinge on specific state anti-fraud laws, conceptually they are drawn from a rich history of consumer protection lawsuits, especially class actions. Indeed, many of the factors that have driven the development of these doctrines pose equally vexing problems in health care fraud cases. In the antitrust and consumer protection arenas, for example, it has been possible to devise workable remedies in cases involving large numbers of potential victims, even where it is difficult to identify all injuries and where individual recoveries are likely to be small.[149] In such cases, commentators have argued in favor of more "fluid" forms of recovery that can meet the twin goals of benefiting injured consumers and forcing the wrongdoer to disgorge its ill-gotten gains[150]—goals that resonate with equal urgency in the health care fraud context.

146. *See, e.g.*, Press Release, Commonwealth of Mass. Office of the Attorney Gen., N.J. Pharmaceutical Corporation Settles with Attorney General: 21,000 Nitroglycerin Patches to be Distributed Free to Public (May 21, 1995) (on file with author) (describing settlement with Schering Corporation, which agreed to distribute free Nitro-Dur patches to state public hospitals); Press Release, Novo Nordisk, Novo Nordisk and Massachusetts Extend NovoPen 1.5 Delivery System Promotion to Medicaid Patients (Mar. 19, 1997) (on file with author) (announcing company's agreement to provide hundreds of free insulin delivery systems to indigent and Medicaid patients at certain hospitals in the state); *see also* Press Release, Attorney Gen. Bob Butterworth, Humana Medical Plan to Refund $800,000 to Settle Allegations (Feb. 16, 2000) (requiring Medicare HMO to refund money to beneficiaries who were overcharged for hearing aids), *available at* http:// myfloridalegal.com/newsrel.nsf/ newsreleases/AAECA64080033E5085256887004AC291?OpenDocument (last visited Apr. 3, 2006).

147. Press Release, Utah Attorney Gen. Mark Shurtleff, Doctor Pays Up for Selling Free Vaccine (Oct. 21, 2005), *available at* http:// attorneygeneral.utah.gov/PrRel/ proctober212005.htm.

148. Dey Inc. Settles Overcharge Case Filed by Connecticut AG, Will Pay $1.7M, 9 Health Care Fraud Rep. (BNA) 614 (2005).

149. *See* Gail Hillebrand & Daniel Torrence, Claims Procedures in Large Consumer Class Actions and Equitable Distribution of Benefits, 28 Santa Clara L. Rev. 747, 750 (1988) (noting that "[a] hallmark of the consumer class action is large class size and relatively small damages per class member"). Note that the feasibility of such actions in the future will be affected by the Class Action Fairness Act of 2005, which addresses not only the jurisdictions in which such suits may be brought but also the structure of non-monetary remedies, particularly coupons. Pub. L. No. 109-2, 119 Stat. 4 (2005).

150. *See, e.g.*, Hillebrand & Torrence, *supra* note 147, at 762-63 (noting that fluid recovery assures the disgorgement of illegal profits and "ensure[s] that the class will in fact receive benefits, whether direct or indirect, of some minimum amount"); Michael Malina, Fluid Class Recovery as a Consumer Remedy in Antitrust Cases, 47 N.Y.U. L. Rev. 477 (1972) (describing fluid distribution of remainder after compensation of direct claims of harm in antitrust suit); James R. McCall *et al.*, Greater Representation for California Consumers—Fluid Recovery, Consumer Trust Funds, and Representative Actions, 46 Hastings L.J. 797, 807-12 (1995) (describing fluid forms of recovery in consumer class actions); Miller & Singer,

Although fluid recovery may include mechanisms such as coupons, price rollbacks, or medical monitoring, the more relevant approaches for our purposes require deposit of all or part of the recovered money into a designated fund—accomplished, for example, by escheat to a general or specific state account, or by the establishment of a new consumer fund.[151] This is most often accomplished through application of the equitable doctrine of cy pres, in which settlement funds that cannot be delivered directly to injured individuals are instead used for their "next best use" by distributing them more generally, as through a consumer trust fund, to subsidize related consumer protection efforts.[152] Such funds "can be structured to serve the purposes of the underlying litigation . . . . The benefit takes the form of increased services to, or protection of rights of the entire class, which is preferable to limiting benefits only to those who successfully complete a claim."[153] The doctrine is most attractive in cases where:

> (1) the class of consumers represented is large and practically unidentifiable; (2) the individual damage suffered by each consumer is relatively small; (3) there are no creative alternatives to provide value directly to consumers; and (4) the recipients who will most likely benefit, albeit indirectly, are the consumers in whose name the original action is brought.[154] While the cy pres approach initially contemplated disbursement for a purpose closely related to the origin of the funds, courts have recognized that the modern doctrine "permit[s] use of funds for other public interest purposes by educational, charitable, and other public service organizations" more tangentially related to the original harm.[155] One of the key questions is whether this mechanism can be used to distribute an entire award, or whether it is limited to disposing of the remainder once the claims of identified class members have been satisfied. The latter use appears to be more common, as it prevents the non-compensatory (and potentially

supra note 116, at 102-07 (dividing "nonpecuniary settlements" into coupon settlements, monitoring settlements, securities settlements, reverter fund settlements that return excess funds to the defendant, and fluid recovery settlements); Anna A. Durand, Note, An Economic Analysis of Fluid Class Recovery Mechanisms, 34 Stan. L. Rev. 173 (1982) (arguing in favor of nonprice fluid recovery mechanisms). One impediment to the application of these principles in the health care fraud context may be the necessity that each class member suffer similar harm. *See* Malina, *supra*, at 488 (requiring that damage be "identical, if not in dollar amount, then in common percentage or like measure").

151. *See, e.g.*, McCall *et al.*, *supra* note 148, at 808-10 (describing fluid recovery mechanisms of price rollback, general escheat, earmarked escheat, and the establishment of a trust fund). Under this framework, note that the current HIPAA Control Account mechanism resembles a federal form of earmarked escheat.

152. Historically, the doctrine of cy pres permitted a court to avoid invalidation of a charitable trust when the testator's conditions could not be satisfied. As the California Supreme Court explained, "[w]here compliance with the literal terms of a charitable trust became impossible, the funds would be put to ' the next best use,' in accord with the dominant charitable purposes of the donor." California v. Levi Strauss & Co., 715 P.2d 564, 570 (Cal. 1986). For a discussion of the cy pres doctrine in the antitrust and consumer protection contexts, see, for example, Susan Beth Farmer, More Lessons from the Laboratories: Cy Pres Distributions in Parens Patriae Antitrust Actions Brought By State Attorneys General, 68 Ford. L. Rev. 361 (1999).

153. Hillebrand & Torrence, *supra* note 147, at 766.

154. Farmer, *supra* note 150, at 365 (setting forth factors relevant to cy pres remedies in parens patriae antitrust actions).

155. Superior Beverage Co. Inc. v. Owens-Illinois, Inc., 827 F. Supp. 477, 479 (N.D. Ill. 1993).

> anti-deterrent) effects of returning the remaining funds to the defendant or having them escheat to a general state fund.[156] In a class action suit against Toshiba for the sale of allegedly defective computers, for example, the court ordered that funds remaining after all individual claims were exhausted be distributed to a charity, which in turn would use the funds to purchase computers for distribution to "schools, churches, non-profit organizations, libraries, hospitals, and the poor."[157] Thus, even if full compensation is not available, cy pres makes it possible to achieve some measure of rough justice. Disbursing an entire settlement via a cy pres mechanism, however, has proven to be more controversial. As one commentator notes, "unless the costs of distribution are overly burdensome, it is preferable to distribute settlement funds directly to consumers rather than to put the entire fund to a related use that will only indirectly benefit those who were injured by the violation alleged."[158] As such, this option has been reserved for cases in which the compensation of individual class members appears to be unrealistic due to the size of the class and the small amount of each award.[159]

Despite these uncertainties, it is intriguing to consider whether this approach might be applied to health care fraud recoveries. The mechanism would appear particularly well-suited to situations in which the harm suffered by patients is diffuse and intangible, rather than discrete and of a serious nature. Of course, there are significant differences between consumer protection and antitrust suits and health care fraud enforcement actions (not the least of which is the lack of an enabling statute permitting the use of

156. *See* Hillebrand & Torrence, *supra* note 147, at 762 (noting that "[f]luid recovery is generally used to distribute the residue of a fund created by settlement or judgment when the claims rate is less than 100%"); McCall *et al.*, *supra* note 148, at 850-51 (calling on plaintiffs' counsel to recommend fluid recovery for the undistributed portion of an award to "ensure that the funds will be used either to promote the purposes of the statutory prohibitions to be enforced or to protect the interests of the persons injured by the illegal conduct").

157. Shaw v. Toshiba Amer. Info. Sys., Inc., 91 F. Supp. 2d 942, 981 (E.D. Tex. 2000); *see also* Patricia Studevant, Using the Cy Pres Doctrine to Fund Consumer Advocacy, Trial, Nov. 1997, at 80 (advocating use of cy pres distribution to fund advocacy efforts). A similar approach may be used for punitive damages in states with split-recovery statutes directing a portion of such damages to victim compensation funds. *See* DeMendoza v. Huffman, 51 P.3d 1232 (Or. 2002) (upholding Oregon Revised Statute § 18.540, which allocates 60% of punitive damage awards to the Criminal Injuries Compensation Account). The success of these statutes has spurred proposals for broader use of the mechanism for "a societal compensation goal: the redress of harm caused by defendants who injure persons beyond the individual plaintiffs in a particular case." Catherine M. Sharkey, Punitive Damages as Societal Damages, 113 Yale L.J. 347, 351-52 (2003) (suggesting that the Supreme Court's recent decision overturning a massive punitive damages award in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), may have unwittingly authorized this alternative). Such goals would be achieved, for example, by the statutory allocation of a portion of the punitive damage award to state funds created to address the type of harm caused by the defendant's activities, or to nonprofit organizations pursuing similar goals. *Id.* at 420-21; Dede W. Welles, Charitable Punishment: A Proposal to Award Punitive Damages to Nonprofit Organizations, 9 Stan. L. & Pol'y Rev. 203, 205, 210 (1998) (arguing in favor of funding targeted activities that are likely to benefit victims, rather than society more generally).

158. Farmer, *supra* note 150, at 394.

159. See, e.g., New York v. Reebok Int'l Ltd., 96 F.3d 44, 49 (2d Cir. 1996) (approving broader distribution "[b]ecause of the unlikelihood of there being any significant ' net monetary relief ' for individual claimants if an attempt were made to distribute the settlement proceeds among them," due to the large number of claimants and the minimal injury suffered per shoe purchase).

such remedies).[160] Nonetheless, to the extent these disbursement options represent the "next best use" of settlement funds by advancing both consumer protection and deterrence goals, they address many of the same issues seen in health care fraud cases and might provide a fruitful avenue for future patient compensation efforts.

C. Patient-Centered Strategies for Health Care Fraud Recovery

The state and federal governments already have begun to work together to apply these strategies in health care fraud cases. In the Merck-Medco litigation described above, for example, Medco negotiated a separate consent order with the Attorneys General of twenty states pursuant to which the company additionally agreed to pay: (1) $6.6 million, to be used for "attorney's fees and investigative costs, consumer education, litigation, public protection purposes or local consumer aid funds;"[161] (2) $2.5 million, to reimburse consumers up to $25 each for expenses incurred in connection with a particular cholesterol drug switch scheme;[162] and (3) $20 million, for the affected states to distribute via a cy pres mechanism to state agencies or programs, nonprofit corporations, or charitable organizations "to benefit low income, disabled, or elderly consumers of prescription medications, to promote lower drug costs for residents of that State, to educate consumers concerning the cost differences among medications, or to fund other programs reasonably targeted to benefit a substantial number of persons affected by the" conduct at issue.[163]

A similar approach was taken against pharmaceutical manufacturer Warner-Lambert, which was accused of extensive civil and criminal conduct in connection with the marketing of its drug Neurontin.[164] The company pled guilty to two counts of violating the federal Food, Drug & Cosmetic Act by "misbranding" the drug and agreed to a $240 million criminal fine, as well as a civil FCA fine of $83.6 million for the federal portion of relevant Medicaid losses.[165] In a separate settlement with the states, the company also agreed to pay $68.4 million plus interest for losses caused to the state Medicaid programs, as well as $38 million to fund a consumer protection program to

160. Another key difference is the government's role. In consumer protection or *parens patriae* antitrust actions, for example, the states sue on behalf of their injured citizens. *See* 15 U.S.C. § 15c (2000) (permitting *parens patriae* suits under the federal antitrust statutes); Richard P. Ieyoub & Theodore Eisenberg, State Attorney General Actions, The Tobacco Litigation, and the Doctrine of Parens Patriae, 74 Tul. L. Rev. 1859, 1863 (2000) (noting that in "parens patriae actions . . . a state may recover costs or damages incurred because of behavior that threatens the health, safety, and welfare of the state's citizenry"). In contrast, many health care fraud cases are brought on the government's own behalf as a defrauded payer. *See supra* notes 112-16 and accompanying text.

161. Consent Order at 24, State v. Medco Health Solutions, Inc., No. CV-04 (Me. Super. Ct. Apr. 26, 2004) (on file with author).

162. *Id.* at 18-19.

163. *Id.* at 21. As an alternative to a monetary payment, states were permitted to receive pharmaceuticals (of equivalent value plus 25%) from Medco in bulk and/or via the provision of prepaid generic drug cards. *Id.* at 22-23.

164. *See* Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), *available at* www.usdoj.gov/usao/ma/presspage/May2004/Warner-Lambert-globalsettlemnt.htm.

165. *Id.* (noting that the violation was a felony due to the company's prior, unrelated FDCA convictions); Food, Drug & Cosmetic Act, 21 U.S.C. § 301 (2000).

remedy the harm caused by the improper marketing efforts.[166] Under the terms of the state settlement, $6 million of the consumer fund was earmarked for the development of a National Advertising Program to provide information to prescribers regarding the appropriate use of Neurontin and similar drugs, and $21 million was designated for grants to "national programs, regional programs, or programs in individual states or in a group of states, relating to prescriber and consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed."[167] The government's sentencing memorandum noted the unique nature of this remedy, stating "the proposed resolution does include a significant state consumer protection component, which has not routinely been part of prior health care fraud settlements arising out of federal Department of Justice investigations."[168]

Several things are notable about these recent efforts. First, the fact that they arose in the pharmaceutical context was not a coincidence. Not only is the pharmaceutical industry under intense scrutiny regarding drug pricing and promotional activities,[169] but the fraud alleged in these cases contributed to the types of patient harm most easily addressed via a cy pres mechanism: widespread, often intangible harm to a diffuse population of patients whose care may have been affected (coupled, in the Merck-Medco litigation, with discrete financial harm to a large but identifiable subpopulation). Given the huge nationwide market for prescription drugs, the direct financial impact of pricing fraud on patients, and the potential for significant consumer confusion from improper marketing campaigns, this is a particularly attractive context in which to test a cy pres remedy. Second, it is notable that neither the federal nor state governments were able to achieve these settlements alone; only by banding together were prosecutors able to combine the flexibility of state consumer protection efforts with the threat of severe federal sanctions for fraud. In accordance with HIPAA, no portion of the federal recovery was diverted to compensate patients—Medco agreed to an injunction against the disputed conduct, and Warner-Lambert paid a hefty fine in direct settlement of the federal civil and criminal fraud allegations. Without the participation of the states, therefore, significantly less money would have been directed toward patients. While the results were extremely favorable for consumers, they appear to be feasible only in fraud investigations that similarly merit extensive joint enforcement efforts.

Whether these strategies can be applied more broadly remains to be seen. Current class action and consumer protection mechanisms may well be sufficient for situations

166. *In re* Warner-Lambert Company LLC, Assurance of Voluntary Compliance, *available at* http://209.190.248.167/upload/1084551748_Assurance_of_ Voluntary_Compliance.pdf (last visited Dec. 23, 2005).

167. *Id.*

168. Sentencing Memorandum of the United States at 43 n.10, United States v. Warner-Lambert Company LLC, No. 04-10150 RGS (D. Mass. May 13, 2004) (on file with author).

169. See, e.g., *In re* Pharma. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005) (resolving class certification issues in suit brought by consumers and third-party payers against pharmaceutical companies). Moreover, with the advent of the new Medicare Prescription Drug Benefit in January 2006, the federal government has an even stronger interest in prescription drug fraud. See 42 U.S.C. § 1395w-101 (2000 & Supp. 2005); Enforcement Officials Detail New Weapons, Concerns Posed by New Medicare Rx Benefit, 14 Health L. Rptr. (BNA) 947 (2005) (describing heightened opportunities for fraud in new program, as well as new enforcement plans).

in which discrete harm is suffered by an identifiable population of patients, such as harm arising from prescription drug price manipulation.[170] In such cases it may well be more efficient to leave the existing procedures in place, rather than create an additional level of federal bureaucracy. In other situations, however, the harm to patients may be so diffuse or intangible that broader fluid recovery will be superior to traditional class action mechanisms. For example, one of the allegations in the Warner-Lambert litigation was that the company marketed Neurontin "off-label," for conditions for which the drug had not been approved by the Food and Drug Administration (and, in fact, for one condition for which approval explicitly had been denied).[171] Because the off-label restrictions limit only the manufacturer's promotion of the drug, rather than a physician's use of the drug, physicians generally may prescribe an approved drug for any condition, even an unapproved one.[172] Compared to pricing fraud, where it safely can be assumed that any consumer who paid above a certain price for the drug was harmed, identifying the victims of an off-label promotional scheme is much more difficult. In the Warner-Lambert case, this would not simply have required the identification of all patients who received Neurontin, but rather the identification of those patients who were prescribed the drug for an off-label purpose (which likely would require review of individual medical records)—as well as consideration of the perhaps unanswerable question of whether the prescribing physician was influenced by Warner-Lambert's marketing efforts or would have prescribed the drug off-label anyway in his/her independent medical judgment. Given this daunting prospect, it is no wonder that a broader consumer fund approach was considered to be appropriate.

Moreover, it is possible that federal health care program beneficiaries are harmed in unique ways by health care fraud. Because many beneficiaries live on fixed incomes, fraud schemes that overcharge for health care items and services may have particularly detrimental effects.[173] Similarly, medically frail beneficiaries may be at greater risk of harm from fraudulent schemes with physical effects, such as those involving unnecessary diagnostic tests.[174] Indeed, there may even be a unique, intangible injury that arises from being targeted solely due to one's status as a federal health care program beneficiary. While a discussion of these subjects is beyond the scope of this Article, it is worth noting that beneficiaries may not fully be compensated even by traditional consumer remedies.

170. See, e.g., *In re* Cardizem CD Antitrust Litig., 218 F.R.D. 508, 516 (E.D. Mich. 2003) (describing plan for compensating consumers who overpaid for a drug due to illegal anti-competitive agreements by manufacturers to keep cheaper generic versions of the drug off the market).

171. See Sentencing Memorandum, *supra* note 166, at 10, 13-26 (documenting centralized decisions to engage in off-label marketing, as well as failed attempt to gain approval for the use of Neurontin as solo therapy for epilepsy).

172. *Id.* at 10.

173. Anecdotes abound about the difficulties of paying for medical care in addition to other necessities. See, e.g., Roger Alford, More Seniors Jailed for Prescription Drug Sales, Houston Chron., Dec. 12, 1995, at A39 (describing increases in arrests of Appalachian senior citizens for selling their prescription drugs). As one law enforcement official noted, "When a person is on Social Security, drawing $500 a month, and they can sell their pain pills for $10 apiece, they'll take half of them for themselves and sell the other half to pay their electric bills or buy groceries." *Id.* (quoting Floyd County jailer Roger Webb).

174. See, e.g., United States ex rel. Kneepkins v. Gambro Healthcare Inc., 115 F. Supp. 2d 35, 42 (D. Mass. 2000) (alleging performance of unnecessary blood tests).

How might beneficiary harm be addressed? At a minimum, direct compensation should be available for patients who have suffered identifiable harm. While Congress would need to enact a federal mechanism for this purpose, a similar result may be achieved currently through global resolutions that incorporate state-based consumer compensation mechanisms, as in the Merck-Medco case. But what of less tangible, or at least less demonstrable, forms of harm? Certainly, devoting money to the education of vulnerable beneficiaries is a good investment, but it may not be enough. An alternative might be to create a modified form of consumer fund tailored to the unique types of injuries experienced by federal health care program beneficiaries. Although beneficiaries who suffer physical harm due to fraud schemes are fortunate in that they have access to health care through the relevant federal health care programs, they are likely to face new financial burdens in the form of additional copayments and deductibles—not to mention the possibility of exceeding their coverage limits, either due to actual medical needs or as an effect of the fraudulent bills submitted in their names.[175] A Beneficiary Copayment Fund, for example, might be set aside for the payment of such expenses for patients who can meet defined eligibility criteria.[176] Because it would be unclear initially how many beneficiaries would incur such future liability, this mechanism would perhaps most closely resemble the use of medical monitoring funds in mass tort actions in which exposure to a toxic substance may have increased the risk of future harm to an identifiable population.[177] Although the details of such a "fraud monitoring" fund are beyond the scope of this Article, the mechanisms likely would be drawn from an amalgam of existing consumer protection and mass tort litigation strategies.

Clearly, congressional action would be necessary if the money for such a fund came from the federal government's share of fraud recovery, since the disposition of that money is tightly controlled by HIPAA. If federal prosecutors were so inclined, however, they might be able to test this strategy in individual cases through some of the mechanisms identified above, such as the § 1345 civil injunction statute or the § 3573 remissions provisions. In the alternative, creation of such a fund might be demanded—or at least strongly encouraged—as an additional state or private mechanism outside the official federal settlement process. However accomplished, the use of a Beneficiary Copayment Fund mechanism on an experimental basis is an option that should be considered.

175. See *supra* notes 69-72 and accompanying text.

176. Although beyond the scope of this Article, such a process could be modeled on that used to disburse awards in mass products liability claims involving bankrupt corporations. See, e.g., Settlement Facility and Fund Distribution Agreement Between Dow Corning Corporation and the Claimants' Advisory Committee 1 (2004), *available at* http:// www.tortcomm.org/downloads/SETTLEMENT_FACILITY_AGMT.pdf (last visited Feb. 26, 2006) (setting forth breast implant claims settlement criteria and procedures). In the health care fraud context, the criteria could be tailored so as to restrict the universe of claimants to deserving beneficiaries, but far less onerous than those required to prove causation in a tort suit, for example.

177. See Miller & Singer, *supra* note 116, at 103-04 (describing monitoring settlements as a category of nonpecuniary fluid recovery).

IV. CONCLUSION

How can we make health care fraud recovery more patient-centered? Amendments to current federal law, to permit either direct compensation of injured patients or a broader co-payment fund, would most efficiently achieve this goal. In the absence of such legislative changes, expanded use of global federal-state negotiations, in which consumer protection remedies are incorporated into the state settlements, remains the best option. To the extent federal health care fraud cases provide an opportunity for creative use of existing law to craft patient-centered remedies, as in the Medco suit, such creativity should be encouraged—within DOJ and HHS, by Congress, and in public debate. Without a congressional mandate to incorporate patient-centered values into health care fraud settlements, however, the success of such efforts will turn on prosecutorial priorities: on whether prosecutors truly believe that "the bigger issues are what is happening to the patients."[178]

178. James Sheehan, Biotech Fraud: Reality or Fantasy?, 2 Hous. J. Health L. & Pol'y 11, 26 (2002).