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

The TAF Education Fund is a nonprofit charitable organization dedicated to combating fraud against the Federal Government through the promotion and use of the *qui tam* provisions of the False Claims Act (FCA). The TAF Education Fund serves to inform and educate the general public, the legal community, and other interested groups about the FCA and its *qui tam* provisions.

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

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FROM THE EDITOR

The federal False Claims Act has been a remarkable weapon in the fight against fraud, returning over twenty billion dollars to the U.S. Treasury and deterring untold billions from ever leaving the public ledger. However, as successful as the FCA has been in the securing the public fisc from procurement fraud, the FCA tax bar has largely prevented whistleblowers from protecting the federal government's revenue dollar.

In the waning hours of the last Congressional session, this imbalance changed with the passage of the IRS Whistleblower provisions and the foundation of the new IRS Whistleblower Office. The IRS Whistleblower legislation, 26 U.S.C. § 7623, does not have all of the bells and whistles of the False Claims Act, but it most certainly ushers in a new era of fraud enforcement—an era of accountability, responsibility, and transparency.

Sincerely,

Jeb White
jwhite@quitam.org

P.S. Here is the text of this historical law:

a) In general.—The Secretary, under regulations prescribed by the Secretary, is authorized to pay such sums as he deems necessary for—

(1) detecting underpayments of tax, or

(2) detecting and bringing to trial and punishment persons guilty of violating the internal revenue laws or conniving at the same,

in cases where such expenses are not otherwise provided for by law. Any amount payable under the preceding sentence shall be paid from the proceeds of amounts collected by reason of the information provided, and any amount so collected shall be available for such payments.

(b) Awards to whistleblowers.—

(1) In general.—If the Secretary proceeds with any administrative or judicial action described in subsection (a) based on information brought to the Secretary's attention by an individual, such individual shall, subject to paragraph (2), receive as an award at least 15 percent but not more than 30 percent of the collected proceeds (including penalties, interest, additions to tax, and additional amounts) resulting from the action (including any related actions) or from any settlement in response to such action. The determination of the amount of such award by the Whistleblower Office shall depend upon the extent to which the individual substantially contributed to such action.

(2) Award in case of less substantial contribution.—
(A) In general.—In the event the action described in paragraph (1) is one which the Whistleblower Office determines to be based principally on disclosures of specific allegations (other than information provided by the individual described in paragraph (1)) resulting from a judicial or administrative hearing, from a governmental report, hearing, audit, or investigation, or from the news media, the Whistleblower Office may award such sums as it considers appropriate, but in no case more than 10 percent of the collected proceeds (including penalties, interest, additions to tax, and additional amounts) resulting from the action (including any related actions) or from any settlement in response to such action, taking into account the significance of the individual's information and the role of such individual and any legal representative of such individual in contributing to such action.
(B) Nonapplication of paragraph where individual is original source of information.—Subparagraph (A) shall not apply if the information resulting in the initiation of the action described in paragraph (1) was originally provided by the individual described in paragraph (1).

(3) Reduction in or denial of award.—If the Whistleblower Office determines that the claim for an award under paragraph (1) or (2) is brought by an individual who planned and initiated the actions that led to the underpayment of tax or actions described in subsection (a)(2), then the Whistleblower Office may appropriately reduce such award. If such individual is convicted of criminal conduct arising from the role described in the preceding sentence, the Whistleblower Office shall deny any award.

(4) Appeal of award determination.—Any determination regarding an award under paragraph (1), (2), or (3) may, within 30 days of such determination, be appealed to the Tax Court (and the Tax Court shall have jurisdiction with respect to such matter).

(5) Application of this subsection.—This subsection shall apply with respect to any action—
(A) against any taxpayer, but in the case of any individual, only if such individual's gross income exceeds $200,000 for any taxable year subject to such action, and
(B) if the tax, penalties, interest, additions to tax, and additional amounts in dispute exceed $2,000,000.

(6) Additional rules.—
(A) No contract necessary.—No contract with the Internal Revenue Service is necessary for any individual to receive an award under this subsection.
(B) Representation.—Any individual described in paragraph (1) or (2) may be represented by counsel.
(C) Submission of information.—No award may be made under this subsection based on information submitted to the Secretary unless such information is submitted under penalty of perjury.

Recent False Claims Act & *Qui Tam* Decisions

OCTOBER 1–DECEMBER 31, 2006

STATUTORY INTERPRETATIONS

A. Section 3729(A)(2) Presentment Requirement

U.S. ex rel. Sanders v. Allison Engine, 471 F.3d 610 (6th Cir. Dec. 19, 2006)

The Sixth Circuit reversed in part and affirmed in part the dismissal of FCA *qui tam* action, in which a government subcontractor submitted false claims to a contractor in order to obtain government funds. The court of appeals, rejecting the lower court's adoption of a controversial D.C. Circuit holding, held that Section 3729(a)(2) and (a)(3) liability attaches even when a false claim is not presented to a federal government employee or official. The Sixth Circuit, however, affirmed the lower court's decision to dismiss an alleged FCA-TINA violation case, where, at the time of government contract negotiations, the private parties merely *planned* on decreasing their costs.

Roger Sanders and Roger Thacker, former employees of General Tool Company (GTC) who worked on the Gen-Set generator assembly teams, brought two separate FCA *qui tam* actions against Allison Engine, General Motors, GTC and SOFCO, alleging fraud in the negotiation and execution of subcontracts relating to the construction of generators for the United States Navy Arleigh Burke-class Guided Missile Destroyers. After the government declined to intervene in the suits, the suits were consolidated in Southern District of Ohio.

The first action, dubbed the "Quality Case," alleged that the defendants violated the FCA when they submitted claims for payment despite knowing that the generators did not conform to contract specifications or Navy regulations. At the close of the relators' case at trial, the lower court granted judgment as a matter of law to the defendants, based on a strained reading of the Act endorsed in *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004). Specifically, the *Totten* court had misconstrued the liability provisions of 31 U.S.C. 3729 to require a showing that a false claim had actually been presented to the federal government for FCA liability to attach. Here, because the relators supposedly failed to show this "presentation" during trial, the court dismissed the suit.

The second action, dubbed the "Pricing Case," alleged that the defendants violated the Truth in Negotiations Act (TINA), 10 U.S.C. § 2306a, and the FCA by withholding cost or pricing data during negotiations with the government's agent. The district court, once again, granted summary judgment to the defendants, finding that at the time of the negotiations, the defendants did not know for a fact that their costs would be reduced, and thus they had no obligation to disclose their "mere hope or expectation" that costs could be lowered. Both decisions were appealed to the Sixth Circuit.

Court Rejects *Totten* (a)(2) and (a)(3) "Presentment Requirement"

In the "Quality Case," even though the relators introduced evidence that all of the money used to pay the relevant prime contracts and subcontracts, including all the money paid to the defendants, came from the federal government, the district court faulted the relators for failing to present any evidence that the defendants ever presented any false or fraudulent claims directly to the government for payment. Relying on *Totten*, the lower court held that liability under the FCA required a showing that a false or fraudulent claim was *presented to the government*, either by the defendants or by the prime contractor.

The Sixth Circuit, in reversing the dismissal of the "Quality Case," refused to follow the D.C. Circuit's lead in reading a "presentment requirement" into 31 U.S.C. § 3729(a)(2) or (3). In short, the Sixth Circuit determined that the plain language of § 3729, the legislative history accompanying the 1986 FCA Amendments, and the policy rationales behind FCA do not support such a reading of the Act.

While conceding that the language of 31 U.S.C. 3729(a)(1) requires actual present of a claim to the government, the Sixth Circuit noted that (a)(2) and (a)(3), which are separate bases for liability, contain no such presentment language. Subsection (a)(2) requires only that a defendant "make[ ]" or "use[ ]" a "false record or statement" in order to induce the government to pay or approve a claim. Subsection (a)(3), on the other hand, requires a conspiracy to defraud the government to pay or allow a false claim.

Moreover, the definition of "claim" in part (c) further supports the reading that presentment is not required under all sections of the FCA. A "claim" is specifically defined as *"any* request or demand . . . for money or property which is made to a contractor . . . if the United States provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor . . . for any portion of the money or property which is requested or demanded." *Id.* § 3729(c) (emphasis added)

Furthermore, in the court's view, the legislative history further solidified this interpretation. In particular, the committee reports written when Congress restructured § 3729 in 1986, broke section (a) into subsections and added subsection (c), indicating that Congress intended to broaden the reach of the FCA to cover fraudulent claims submitted by subcontractors that result in loss to the government. Indeed, the legislative history explicitly endorsed this interpretation: "[A] false claim is actionable although the claims or false statements were made to a party other than the Government, if the payment thereon would ultimately result in a loss to the United States."

Therefore, after careful examination, the Sixth Circuit ruled that there was no indication that a claim must be presented to the government in order to be actionable, for the statute covers false claims made to parties other than the government so long as the claim will be paid with government funds.

Decision Includes *Dicta* That Reads "Actual Payment" Requirement into (a)(2) Liability

Then, in an attempt to address a question posed by the *Totten* majority, the Sixth Circuit potentially deviated from the language and intent of the Act. Specifically, the *Totten* majority asked why would any plaintiff bring a claim under subsection (a)(1) when she could just use the "more lenient subsection (a)(2)" for all claims. The Sixth Circuit answered that "subsection (a)(2) contains its own more burdensome requirement-the claim must have actually been paid."

According to the Sixth Circuit, while this "actual payment" requirement is an element of (a)(2) liability, it is not an element of subsection (a)(1), which merely covers the presentment of a false or fraudulent claim to the government or its agent *"for* payment or approval," regardless of whether the payment was actually made.

Recognizing the novelty of its interpretation, the Sixth Circuit noted that this was "an issue of first impression" and that "no authority exists either supporting the proposition that a claim must have been paid or approved to establish a violation of subsection (a)(2) or rejecting it." Then, reducing its diatribe to mere dicta, the Sixth Circuit stressed that "[t]he precise question before us is whether subsection (a)(2) requires presentment, not whether it requires payment."

In turn, because the lower court applied an incorrect interpretation of the law, the Sixth Circuit reversed and remanded the "Quality Case" to the district court.

Failure To Disclosure *Plans* To Lower Costs Does Not Violate TINA

Then, the Sixth Circuit turned its attention to the "Pricing Case," which stemmed from a redesign of the generators in the early 1990s. The key issue for the for the Sixth Circuit was whether Allison and GTC failed to disclose pertinent "cost and pricing data" relating to anticipated cost decreases with the Navy during the negotiation of the redesign. According to the court, any such omission would violate TINA and because Allison and GTC submitted claims for payment despite knowledge of their non-compliance with all contractual provisions and applicable statutes (including TINA), a cause of action would exist under the FCA.

The parties filed motions for summary judgment on the issue of whether the defendants' failure to disclose its plans to lower its costs for the Gen-Sets violated TINA.

In ruling for the defendants, the lower court found that while Allison might have realized a profit in the future, Allison did not make a false claim during the negotiation of the redesign when it said that "cost" remained unchanged under the proposed redesign. In particular, the district court found that TINA unambiguously defines "cost" as "cost to the government." In turn, because the *government*'s cost would remain unchanged, the lower court determined that Allison did not submit a false claim, even though *its* costs would potentially decrease in the future.

Secondly, the lower court held that Allison had no duty to disclose its *plans* to lower costs because "any such ideas were merely speculative" during the negotiations

of the redesign. Thus, Allison did not withhold any "facts" from the government. The relators also appealed the "Pricing Case" to the Sixth Circuit.

Defendants Did Not Violate TINA

The Sixth Circuit agreed with the district court. TINA requires subcontractors to make available "cost or pricing data" prior to "the pricing of a change or modification to the subcontract" if the "price adjustment is expected to exceed $100,000." 10 U.S.C. § 2306a(a)(1)(D)(i). "Cost or pricing data" under TINA includes "all facts that, as of the date of agreement on the price of a contract (or the price of a contract modification), ... a prudent buyer or seller would reasonably expect to affect price negotiations significantly." 10 U.S.C. § 2306a(h)(1).

According to the Sixth Circuit, Allison and GTC did not violate TINA, for they had only "preliminary plans" to negotiate a lower price for the generators and had not actually agreed to lower the price by the time they negotiated the agreement for the redesign. "The only thing that Allison knew as a fact prior to [negotiating the agreement] was that it *wanted* to negotiate a lower price."

In turn, because the Sixth Circuit could find no additional evidence of any "cost or pricing data" possessed by Allison that was not furnished to the government, it ruled that summary judgment was appropriate. Accordingly, the Sixth Circuit affirmed the decision of the district court in the "Pricing Case."

Dissent Buys *Totten* "Presentment Requirement"

Judge Batchelder concurred in part and dissent in part with the majority's decision. Specifically, he dissented from that portion of the majority opinion that revived the relators' "Quality Case."

In short, the dissent wholeheartedly bought the *Totten* majority's reading of the § 3929(a)(2) "presentment requirement": "I would read the term '[a] claim paid or approved by the Government' as creating a causal connection between the claim and the payment. Payment of a claim 'by the Government' presupposes that the claim has been presented to the government as a request for that payment." Therefore, under the dissent's reading of the Act, "[i]f payment of the fraudulent claim was made by the shipyards (i.e., prime contractors) rather than 'by the Government,' then Section (a)(2) imposes no liability."

Notably, the dissent took issue with the majority's *dicta* proposition that, under Section (a)(2), "the claim must have actually been paid." For support, the dissent highlighted that the plain language of Section (a)(2) applies to one who "knowingly makes, uses or causes to be made or used, a false record or statement," which, according to the dissent, "reasonably encompasses even an *attempt* to get a claim paid." The dissent, however, concurred with the remainder of the opinion.

B. Section 3729(A)(7) Obligation to Pay

U.S. ex rel. Bahrani v. Conagra, Inc., 465 F.3d 1189 (10th Cir. Oct. 12, 2006)

The Tenth Circuit reversed and remanded a district court's dismissal of an FCA *qui tam* action, in which a relator alleged that an importer violated the FCA reverse false claims provision, when it did not request and pay for replacement import certificates when corrections were made to original certificates. The court of appeals determined that it avoided an obligation under § 3729(a)(7), to the extent that the importer made "major" or "significant" changes without applying for replacement certificates.

Ali Bahrani filed an FCA *qui tam* action against importer Conagra, Inc., alleging that the company violated the FCA reverse false claims provision, 31 U.S.C. 3729(a)(7), when it failed to request and pay for replacement export certificates when the company made corrections to the original certificates. Congra filed a motion for summary judgment, which the district court granted on the grounds that Conagra's alleged "obligation" to obtain and pay for replacement certificates was not "quantifiable and existing before the allegedly fraudulent acts taken to avoid it." Bahrani appealed the decision to the Tenth Circuit.

"Obligation" Turned On Whether It Was A "Major" Change

In order to determine Conagra's "obligations," the Tenth Circuit noted that the Food Inspection Service's regulations expressly provide for such new certificates. *See* 9 C.F.R. § 322.2(c) (setting forth the requirements for "in lieu of" certificates). However, the regulations do not set forth a standard for determining when these "in lieu of" and replacement certificates are required. On the other hand, the record from the district court indicated that, as to a certain class of errors and omissions in export certificates—those deemed "major" or "significant"—the USDA required Conagra to obtain replacement certificates and pay the accompanying fee.

With a better understanding of the facts, the Tenth Circuit then attempted to define "obligation" as used in Section 3729(a)(7). Unfortunately, Congress did not provide a definition of an "obligation" under § 3729(a)(7), so the Tenth Circuit reviewed prior judicial decisions, which some have required the relator to allege that the defendant had "*an existing legal obligation* to pay or transmit money or property to the government." *Kennard v. Comstock Res. Inc.*, 363 F.3d 1039, 1048 (10th Cir.2004)(emphasis added by the court). Moreover, the fact that the making or using of a false statement or record might result in a fine or a penalty is insufficient to establish a § 3729(a)(7) obligation, under some decisions. *See, e.g., U.S. ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657 (5th Cir.2004)

However, the Tenth Circuit took note of a Sixth Circuit decision, *Am. Textile Mfrs. Inst., Inc. v. The Limited, Inc.*, 190 F.3d 729 (6th Cir. 1999), which suggested that a statute or a regulation might create a § 3729(a)(7) "obligation," "at least where the statute or regulation imposes an obligation essentially contractual in nature, such

as the imposition of the requirement that those using the Postal Service pay the appropriate rate." *Id*. at 737-38 (internal quotation marks omitted).

Against this judicial backdrop, the Tenth Circuit reduced these cases into a dichotomy between "existing debts," which are covered by the statute, and "contingent penalties," which are not. Therefore, the Tenth Circuit was faced with the task of deciding how to characterize an exporter's obtaining "in lieu of" and replacement certificates and paying the accompanying fee.

The court of appeals started its analysis by rejecting Bahrani's expansive reading of the USDA statutes and regulations. "None of the ... authorities cited in [Bahrani's] argument ... establishes that an exporter is required to obtain a replacement certificate *every time* a change to an existing certificate is made." However, the court stressed that the fact that new certificates were not required "every time a change to an existing certificate [wa]s made," does not foreclose the possibility that new certificates (and the accompanying fees) are required in some instances.

Then, the court of appeals weaved a "materiality" element into the equation, reworking the issue into whether Conagra's alleged failure to obtain new certificates in those instances (where there were "major" or "significant" changes) constituted the avoiding of a 3729(a)(7) "obligation."

Section 3729(a)(7) Speaks of "Obligations," Not "*Fixed* Obligations"

According to the an *amicus curiae* brief submitted by the federal government, two kinds of obligations may be the subject of a reverse false claims action under § 3729(a)(7):

> (1) "[t]here may be a fixed obligation, spelled out by a judgment, contract, statute, or regulation, that imposes a duty on the person to pay money or transmit property to the government. This fixed obligation may be liquidated as with a judgment, or it may be unliquidated but easily determinable [;]" Amicus Br. at 10; and
>
> (2) there are other obligations that are "not yet 'fixed' in all particulars"; these "obligations" may be present "by virtue of the relationship between the government and the person who owes the government money or property." *Id*. For example, such obligations may exist "[w]hen the person and the government have a contractual, grantor-grantee, licensor-licensee, fee-based, or similar relationship." *Id*.

The government maintained that, accepting Bahrani's contention that the USDA regulations require exporters to pay for new certificates when the original certificates contain errors or omissions, the fees for the new certificates fall within this second category of actionable § 3729(a)(7) obligations.

Amazingly, the Tenth Circuit not only embraced the government's reading, but it echoed the government's sentiment that § 3729(a)(7) refers to "an obligation" and not "a fixed obligation." In turn, the Tenth Circuit agreed that there are instances in which

a party is required to pay money to the government, but, at the time the obligation arises, the sum has not been precisely determined.

Under this enlightened reading of the Act, the Tenth Circuit pointed out that it was not Conagra employees' making of corrections on the original export certificates that created the obligation to pay the fee; instead, that obligation arose from an independent source—from the determination that the original certificate contains a major or significant error or omission and that an "in lieu of" or replacement certificate and payment of the accompanying fee were necessary. In short, it was the discovery that these changes were necessary that created the obligation.

For support of its reading of the Act, the Tenth Circuit highlighted the legislative history:

> The cost of fraud cannot always be measured in dollars and cents, however. GAO pointed out in its 1981 report that fraud erodes public confidence in government's ability to efficiently and effectively manage its programs. Even in cases where there is no dollar loss, for example where *a defense contractor certifies an untested part for quality* yet there are no apparent defects-the integrity of quality requirements in procurement programs is seriously undermined.

S.Rep. No. 99-345, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5268 (emphasis added).

Government Discretion Does Not Remove Section 3729(a)(7) Liability

The Tenth Circuit, going one step further, stressed that the discretion afforded USDA officials to determine whether to issue new certificates and charge the accompanying fees does not render the obligation outside the scope of Section 3729(a)(7) liability: "Some discretion inheres in a wide variety of government decisions.... The fact that USDA officials may have some subsequent discretion whether to actually charge the authorized fee does not mean that the 'obligation' is a contingent one outside the scope of § 3729(a)(7)." In short, the fact that a government official may subsequently waive an established fee does not negate the "potential effect" of a false record or statement.

Accordingly, the court of appeals ruled that to the extent that Conagra employees made "major" or "significant" changes without applying for "in lieu of" or replacement certificates, they avoided an obligation under § 3729(a)(7). Thus, the Tenth Circuit remanded the decision for further development of the record and to determine the extent to which Conagra employees made "major" or "significant" changes without obtaining "in lieu of" or replacement certificates and paying the accompanying fee.

C. Section 3730(d)(4) Fee-Shifting Provision

U.S. ex rel. Bain v. Georgia Gulf Corporation, 2006 WL 3093637 (5th Cir. Oct. 26, 2006)

In an unpublished decision, the Fifth Circuit affirmed a lower court's decision to assess attorney fees against a relator under FCA Section 3730(d)(4), where the relator had tacked on a new FCA claim in an unsealed, nonintervened amended complaint without first following the FCA procedural requirements, including filing the claim under seal and allowing the government a chance to review the claim before serving the defendant.

Ronald Bain filed an original complaint under seal on July 13, 2001 against his former employer, Georgia Gulf Corporation, alleging violations of the FCA's reverse false claims provision, 31 U.S.C. 3729(a)(7). After the government declined to intervene in the suit, the seal was lifted and Bain filed an amended complaint, added allegations related to the § 3729(a)(7) reverse false claim and adding a new direct false claim under Section 3729(a)(1) against Georgia Gulf.

Georgia Gulf filed a motion to dismiss. The court ruled that Bain had stated an actionable Section 3729(a)(7) claim, but the court did not address the new direct false claim raised in Bain's amended complaint. Georgia Gulf subsequently appealed the decision to the Fifth Circuit, which reversed the decision as it pertained to the Section 3729(a)(7) claims and remanded the decision as it pertained to the direct false claim allegations. In doing so, the court of appeals questioned whether in filing a new direct claim, Bain had complied with the procedural requirements of the FCA, which require that the government be served with the complaint and written disclosure of all material evidence and information so that it may choose whether to intervene.

On remand, the district court followed the Fifth Circuit's hint and dismissed the direct claim for failing to follow the FCA procedural requirements. Then, Georgia Gulf filed a post-judgment motion with the district court seeking attorneys' fees under the FCA fee-shifting provision, 31 U.S.C. § 3730(d)(4), which the court granted. Bain appealed the attorneys' fees decision to the Fifth Circuit.

Claim Violative of FCA Procedural Requirements Deemed "Frivolous"

In reviewing the district court's order for Section 3730(d)(4) attorneys' fees, the court of appeals applied an abuse of discretion standard of review. Mindful that the district court was in the best position to render an informed judgment on an award of attorneys' fees, the Fifth Circuit's review was highly deferential to the lower court.

Section 3730(d)(4) provides reasonable attorneys' fees to a prevailing defendant in a *qui tam* action if the court "finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4). A claim is frivolous if it has no arguable support in existing law or any reasonably based suggestion for its extension. *See Farguson v. MBank Hous-*

ton, N.A., 808 F.2d 358, 359 (5th Cir. 1986). A claim is vexatious when the plaintiff brings the action for an improper purpose, such as to annoy or harass the defendant. *Pfingston v. Ronan Eng'g Co.*, 284 F.3d 999, 1006 (9th Cir. 2002).

Against this legal backdrop, the Fifth Circuit concluded that the district court did not abuse its discretion, for when Bain filed his amended complaint, adding a new direct false claim, he failed to satisfy a number of jurisdictional and procedural prerequisites under the FCA. Accordingly, the Fifth Circuit affirmed the lower court's decision.

JURISDICTIONAL ISSUES

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

U.S. ex rel. Bly-Magee v. Premo, 2006 WL 3615042 (9th Cir. Dec. 13, 2006)

The Ninth Circuit affirmed a district court's dismissal of an FCA *qui tam* action, in which a state agency had previously released an audit report that detailed the same allegations raised in the relator's complaint. The court of appeals held that the report qualified as an "administrative ... report [or] audit" under the FCA public disclosure bar, particularly where the audited program is connected significantly to federal regulations and funds, for the federal government is sufficiently placed "on the trail of fraud."

Charlotte Bly-Magee, the former executive director of Southern California Rehabilitation Services, a non-profit organization that receives government funds to serve the disabled, filed an FCA qui tam action against the California Department of Rehabilitation (CDR), accusing it of defrauding the federal government by, *inter alia*, forcing the government to purchase unnecessary and duplicative services. The government declined to intervene in the action, and the defendant eventually filed a motion for summary judgment. The district court, in granting the motion, ruled that the FCA public disclosure bar precluded Bly-Magee from proceeding with the suit. Bly-Magee appealed the decision to the Ninth Circuit.

Statutory Language Raises Doubt Over Whether State Reports Are "Public Disclosures"

The FCA public disclosure bar, 31 U.S.C. 3730(e)(4)(A), only comes into play in limited, explicitly defined circumstances, namely where an action is "based upon the public disclosure of allegations or transactions" via (1) "a criminal, civil, or administrative hearing"; (2) "a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation"; or (3) "the news media." *Id.* In the case at bar, the court of appeals noted that the California State Auditor published a prior June 30, 1999 report raising similar allegations against CDR.

Thus, the court of appeals was faced with the controversial issue of whether a disclosure in a report issued by a state agency amounts to a "public disclosure" for purposes of the public disclosure bar.

State Reports Are "Public Disclosures" Under the FCA Public Disclosure Bar

The Ninth Circuit, first turning its attention to the language of the Act, quickly placed the report under category (2) as an "administrative ... report [or] audit." The court of appeals, however, admitted that some doubt existed, for other sources in category (2), such as congressional reports or reports of the Government Accounting Office, refer exclusively to *federal* agency materials.

Faced with this doubt, the Ninth Circuit peered into the other circuits for assistance. Two circuits that have addressed the question have reached opposite conclusions. In *U.S. ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 745 (3d Cir. 1997), the Third Circuit held that, because the word "administrative" is placed between "congressional" and "Government Accounting Office," when read with the word "report" it "refers only to those administrative reports that originate with the federal government." *Id*. In *Hays v. Hoffman*, 325 F.3d 982, 988 (8th Cir. 2003), however, the Eighth Circuit rejected *Dunleavy* and concluded that Medicaid audits prepared by a state agency are public disclosures within the meaning of the Act.

The Ninth Circuit agreed with the Eighth Circuit and held that the second category of sources includes non-federal reports, audits, and investigations. The Ninth Circuit also placed great emphasis on the fact that the words "congressional," "administrative," and "Government Accounting Office" are separated by commas and the conjunction "or." Accordingly, the Ninth Circuit opined that each word might be read as a separate modifier for the nouns that follow.

For further support, the Ninth Circuit pointed out that a similar interpretation was embraced by the circuit in *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238 (9th Cir. 2000), in which the Ninth Circuit held that state and local administrative hearings are sources of public disclosure. In defending this line of interpretation, the court maintained that the statute would seem to be inconsistent if it included state and local administrative hearings as sources of public disclosures and then, in the next breath, excluded state administrative reports as sources.

FCA Public Disclosure Bar Prevents Relator from Proceeding with Suit

Then, in perhaps grafting qualifying language to its ruling, the Ninth Circuit stated that its holding was necessary, particularly in cases like this where the audited program is connected significantly to federal regulations and funds. Here, because CDR's operation depends on federal funding and compliance with federal regulations, the court maintained that the state report placed the federal government "on the trail of fraud," so the relator's qui tam action merely echoed what the government already knew. In turn, the court ruled that the suit was blocked by the FCA public disclosure bar.

The court, then, without much discussion, quickly determined that Bly-Magee did not qualify for the original source exception.

FCA Public Disclosure Bar Does Not Bar Allegations Involving Claims Made After the Public Disclosure

Bly-Magee alleged in her complaint, however, that the false claims continued through the 1999-2000 fiscal year, which ended June 30, 2000. The Ninth Circuit concluded, therefore, that Bly-Magee could proceed with allegations involving false claims occurring after June 30, 1999, because these allegations were not publicly disclosed. In turn, the Ninth Circuit reversed the dismissal of those portions of the complaint alleging the making of false claims after June 30, 1999.

***U.S. ex rel. Battle v. Board of Regents for Georgia*, 468 F.3d 755 (11th Cir. Oct. 25, 2006)**

The Eleventh Circuit affirmed the dismissal of a former state employee's First Amendment action and FCA *qui tam* action against his former employer. The court determined that since the employee's job responsibilities included reporting fraud, the First Amendment did not protect her when she was fired for voicing concerns about fraud at a state university. The court of appeals also ruled that the FCA public disclosure bar precluded her *qui tam* suit, for the relator pointed to the results of a government audit as a basis of calculating damages in her case. Moreover, she did not qualify for the original source exception, for her complaint did not sufficiently plead that she had "direct and independent knowledge" of the information revealed in the government audit.

Between 1987 and 1998, Lillie Battle worked in the Office of Financial Aid and Veterans Affairs at Fort Valley State University (FVSU). In the spring of 1995, while working as a work study supervisor and veterans affairs counselor, Battle began to observe and document what she believed were fraudulent practices in the Federal Work Study Program. In late 1996, "overwhelmed" by the evidence of fraud, Battle met with the president of the university and told him that the university was falsifying information, awarding financial aid to ineligible recipients, making excessive awards, and forging documents.

Three years later, on May 25, 1998, Battle received a letter indicating her employment contract would not be renewed effective June 30, 1998. The letter indicated that Battle had been approved for transfer to a position in a different department, but she was later informed that no position was available.

Battle never spoke to anyone outside of the university about the fraudulent activity until after she received notice that her contract would not be renewed. A month after receiving her notice, in June 1998, Battle met with the Department of Education and provided sixty-one pages of documents showing potential fraud and a thirty-two page analysis of student files.

From June 1998 to February 1999, the Georgia Department of Audits conducted an independent annual audit of the university, which revealed serious noncompli-

ance with federal regulations and risk factors for fraud. In April 2002, the university reached a $2,167,941 settlement with the Department of Education to settle questionable costs identified by the state auditors in audits from 1997-2000 and in lieu of further file review.

Over two years later, in June 2004, Battle filed a suit alleging that she was discharged in violation of the First Amendment for reporting her concerns about fraud, and that the university knowingly submitted false claims in violation of the FCA.

The lower court, in granting the defendants' motion for summary judgment, concluded that the university and its employees were entitled to qualified immunity on Battle's First Amendment claim because the motivation for Battle's speech was unclear and preexisting case law did not give the defendants fair warning that her speech was "a matter of public concern" under the circumstances. The district court also concluded that Battle's FCA claims were barred by the FCA public disclosure bar. Battle appealed the decision to the Eleventh Circuit.

Speech Not Protected Because Part of Job Responsibilities

In determining whether a public employee's speech is entitled to constitutional protection, the Eleventh Circuit first asked "whether the employee spoke as a citizen on a matter of public concern. If the answer is no, the employee has no First Amendment cause of action based on his or her employer's reaction to the speech." *Garcetti v. Ceballos*, 126 S.Ct. 1951, 1958 (2006).

In this case, Battle admitted that she had a clear employment duty to ensure the accuracy and completeness of student files as well as to report any mismanagement or fraud she encountered in the student financial aid files. In addition, Department of Education Guidelines require all financial aid workers to report suspected fraud. Battle alleged that her contract was not renewed because of her "continuous efforts to expose the fraud within FVSU's Financial Aid Department." In fact, Battle even admitted that her speech to university officials about inaccuracies and signs of fraud in student files was made pursuant to her official employment responsibilities. In turn, the Eleventh Circuit, in the wake of *Garcetti*, concluded that because the First Amendment protects speech on matters of public concern made by a government employee speaking as a citizen, not as an employee fulfilling official responsibilities, Battle's retaliation claim must fail.

Damage Calculation "Based Upon" Public Audit Triggers Public Disclosure Bar

Borrowing from its earlier ruling, the Eleventh Circuit stated that the FCA public disclosure bar "is most naturally read to preclude suits based in *any part* on publicly disclosed information." *Cooper v. Blue Cross and Blue Shield of Florida, Inc.*, 19 F.3d 562, 567 (11th Cir. 1994). In the lower court, Battle "refer[red] Defendants to the audits performed by the State of Georgia Department of Audits and Accounts on June 30, 1998 and June 30, 1999" and indicated she would "seek all damages allowed under

the False Claims Act for these violations." The Eleventh Circuit then made the leap in saying that Battle's claims "rel[ied] chiefly on information that was publicly disclosed in the 1997-1998 and 1998-1999 state audits."

Relator Is Not an Original Source

The Fifth Circuit, then turning its attention to the original source exception, faulted Battle for not providing facts in her complaint that established herself as an original source of the information in the state audits: "Although Plaintiff need not trace the flow of information from herself to the DOE to the state audit reports, summary judgment was proper because Plaintiff failed to provide the district court with specific facts showing that she had direct and independent knowledge of the audit findings on which she bases her FCA claims."

Therefore, the Fifth Circuit agreed that the FCA public disclosure bar precluded Battle from proceeding with her FCA *qui tam* suit.

U.S. ex rel. McElmurray v. Consolidated Government of Augusta-Richmond County, **2006 WL 3469529 (N.D. Ga. Nov. 30, 2006)**

A Georgia district court dismissed an FCA *qui tam* action under the public disclosure bar, where a relator used information obtained from discovery material from the relator's prior civil suit against the same defendant. Applying another jurisdiction's holding, the court ruled that a qualifying Section 3730(e)(4)(A) "public disclosure" occurred because the discovery material was disclosed "to a party who [wa]s not under any court imposed limitation as to its use."

R.A. McElmurray brought an FCA *qui tam* action against Consolidated Government of Augusta-Richmond County, alleging that it knowingly misrepresented its compliance with state and local environmental laws in order to receive three loans, the funds for which originated with the federal Environmental Protection Agency (EPA). The county filed a motion to dismiss, arguing, *inter alia*, that the FCA public disclosure bar precluded the suit from going forward.

Discovery Material Triggered FCA Public Disclosure Bar

The Georgia district court reached far outside of the Eleventh Circuit and borrowed a distorted Second Circuit interpretation of the FCA public disclosure bar. Specifically, in *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149 (3d Cir. 1991), the Second Circuit interpreted § 3730(e)(4)(A)'s language regarding "the public disclosure of allegations or transactions in a ... civil ... hearing" to mean that discovery material disclosed "to a party who is not under any court imposed limitation as to its use" is a public disclosure. *Stinson*, 944 F.2d at 1158.

In this case, where the defendant had previously sued the defendant in another matter, the court ruled that the relator was barred, for she had utilized some discovery material that was obtained in her own prior suit. Thus, the court ruled that the public

disclosure bar applied, and McElmurray could only proceed with the suit if she was qualified for the original source exception.

Relator Was Not an Original Source

Then, the court summarily decided that she could not possibly have the requisite "direct and independent knowledge" to qualify for the original source exception, for she obtained knowledge from discovery in previous, separate lawsuits filed against the defendant. Thus, the court ruled that she did not qualify for the FCA public disclosure bar's original source exception, 31 U.S.C. 3730(e)(4)(B). Accordingly, the court granted the defendant's motion to dismiss.

***U.S. ex rel. Villafane v. Solinger*, 2006 WL 2927509 (W.D. Ky. Oct. 12, 2006)**

A Kentucky district court refused to dismiss a *qui tam* action under the FCA public disclosure bar, even though the relator obtained information through a FOIA request and previously disclosed "funding improprieties" in a publicly-disclosed state administrative hearing. The court ruled that the response to a FOIA request did not automatically trigger the FCA public disclosure bar unless the disclosure included one of the enumerated 3730(e)(4)(A) sources. The court also ruled that broad allegations about "funding improprieties" did not trigger the bar, for the disclosure could not place the government "on to the trail of fraud."

Dr. Villafane, a pediatric cardiologist and professor at the University of Louisville School of Medicine, brought an FCA qui tam action against a host of entities and individuals, including his supervisors, their practice group, a neonatologist employed at the medical school, a neonatologist's practice group, a children's hospital, the university's research fund, and a research foundation. In his complaint, he alleged, *inter alia*, violations of the Stark law and the Anti-kickback statute.

The defendants filed a motion for summary judgment, arguing that the court lacked jurisdiction because the FCA public disclosure bar precluded the suit. The defendants point to two separate "public disclosures": (1) when information was obtained through Kentucky Open Records Act (ORA) requests to the university, and (2) when Villafane made allegations in response to the National Practitioner Data Bank (NPDB) that were disclosed to the Commonwealth of Kentucky Board of Medical Licensure in connection with its proceedings to restrict his medical license.

FOIA Request Does Not Automatically Trigger FCA Public Disclosure Bar

As an initial matter, the court equated an ORA request with a federal Freedom of Information Act (FOIA) request. Unlike some circuits, in the Sixth Circuit, the disclosure of information in response to a FOIA request does not necessarily trigger the

public disclosure bar; rather, a court must examine each element of § 3730(e)(4)(A) before making such a determination. *See U.S. ex rel. Burns v. A.D. Roe Co.*, 186 F.3d 717, 722-725 (6th Cir. 1999). In other words, it must also be shown to be an "allegation or transaction" disclosed in one of the statutorily enumerated sources, i.e., "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." For further support, the court offered up a recent Ninth Circuit decision, which held that whether a FOIA request invokes the jurisdictional bar depends on the nature of the documents obtained. *U.S. ex rel. Haight v. Catholic Healthcare West*, 445 F.3d 1147, 1153 (9th Cir. 2006).

Here, without a fully developed record, the court ruled that there was not sufficient information to determine whether the information Villafane received in the Kentucky ORA requests qualified as a source enumerated in § 3730(e)(4)(A). In turn, the court stated that it would provide the defendants with an early opportunity to discover sufficient information about the nature of Villafane's Kentucky ORA request.

General Disclosure About "Funding Improprieties" Does Not Trigger 3730(e)(4)(A)

Defendants next argued that a public disclosure occurred when Villafane made allegations in response to the NPDP in the Kentucky Medical Board proceedings to restrict his medical license. The Board's orders state, in relevant part, that Dr. Villafane "complained about funding improprieties occurring at the hospital."

The court characterized the information disclosed in a Kentucky Board of Medical Licensure administrative proceeding as among the kind of statutorily enumerated public sources of disclosure. However, the issue for the court was whether these statements of "funding improprieties" constituted a public disclosure of "allegations or transactions" under § 3730(e)(4)(A).

The court concluded that Villafane's passing reference to "funding improprieties" fell short of a public disclosure of allegations of fraud. According to the court, "the disclosure must be 'sufficient to put the government on notice as to the possibility of fraud.'" *See Dingle v. Bioport Corp.*, 388 F.3d 209, 214-215 (6th Cir. 2004). Villafane's statement concerning "funding improprieties," which stated neither the type of impropriety nor how they could be found, did not sufficiently birddog the fraud to trigger the FCA public disclosure bar.

FALSE CLAIMS ACT RETALIATION CLAIMS

A. Section 3730(h) Retaliation Claims

U.S. ex rel. Whitten v. Triad Hospital, Inc., 2006 WL 3626992 (11th Cir. Dec. 13, 2006)

In an unpublished decision, the Eleventh Circuit reversed and remanded a district court's dismissal of an FCA *qui tam* action, in which a relator had signed a release agreement with his former employer that explicitly preserved claims against a third party that arise "out of [his] employment." The court of appeals found that the filing of an FCA *qui tam* action could easily "arise out of his employment," since he worked as a compliance officer and his knowledge of the fraud came to him by way of his employment.

Between 1980 and 2001, Ted Whitten was employed by the Glynn Brunswick Memorial Hospital Authority in a number of positions, including compliance officer. In 1989, Quorum Health Group, LLC began providing the Authority with management services. On September 29, 2000, the Authority terminated its relationship with Quorum. A few months later, on January 3, 2001, Whitten and the Authority entered into a severance agreement, which contained a release agreement. Subsequently, Whitten brought an FCA *qui tam* action against Quorum, alleging that through its officers, it was responsible for the presentation of false claims for payment under the Medicare, CHAMPUS, and Tricare programs.

The district court, in granting Quorum's motion for summary judgment, held that the suit was barred by the provisions of the release signed by Whitten and his former employer. Whitten appealed the decision to the Eleventh Circuit, maintaining that the release did not preclude him from bringing a suit against Quorum. In the alternative, Whitten argued that even if Quorum was protected by the release, such a release was void as against public policy.

Agreement Preserving Claims "Arising Out of Employment" Include *Qui Tam* Actions

The Eleventh Circuit, in reversing the lower court decision, found that the release did not apply to actions brought against Quorum. In reaching its conclusion, the Eleventh Circuit noted that the release clearly referred to Quorum as a separate entity from the releasees. Moreover, the release specifically included a paragraph that preserved claims against Quorum "arising out of [Whitten's] employment."

Quorum argued that this paragraph preserved only claims involving typical employment law issues, such as discrimination. The Eleventh Circuit, in rejecting such a narrow reading, determined that an FCA *qui tam* suit could easily fit within this definition, especially since Whitten worked as a compliance officer and his knowledge

of the alleged fraud came to him by way of his employment. Therefore, the Eleventh ruled that even if Quorum was intended to be included as a releasee, this paragraph preserved Whitten's *qui tam* claim against it.

Thus, because the Eleventh Circuit reversed the decision on basis of the contract, it never reached the thornier issue of whether employment releases in the FCA *qui tam* context are void as against public policy.

***Nguyen v. City of Cleveland*, 2006 WL 2970215 (N.D. Ohio Aug. 8, 2006)**

In a suit brought under the FCA anti-retaliation provision, an Ohio district court granted the plaintiff-employee summary judgment, where the current employer removed the employee from a project after the encouragement of the former employer. The court ruled that it was irrelevant that the plaintiff no longer worked for the former employer.

Nam Nguyen worked as an engineer for Cleveland's Bureau of Air Pollution Control. In July 1998, he resigned from that position and went to work for Parsons, which was employed by the City as a contractor, working on city-related projects, including projects at the airport. Shortly after starting at Parsons, Nguyen filed a *qui tam* action against the city in which he alleged misuse of federal money by the city in the operations of the Bureau.

In June 1999, the federal government intervened in the suit and the case was unsealed. Shortly thereafter, a newspaper article described the *qui tam* action against the city and identified Nguyen as the relator. The project manager at the airport for Parsons was then contacted by city officials, who, in separate conversations, stated that they did not want Nguyen to have access to any city files and did not want him to work on any project with the city because of the *qui tam* action that he had filed. Parsons succumbed to their pleas and took Nguyen off any city-related projects, including the project at the airport. Subsequently, Nguyen brought a claim under the FCA anti-retaliation provision, 31 U.S.C. 3730(h), against Parsons and the City of Cleveland. All parties filed motions for summary judgment

Parsons confirmed that their removal of Nguyen from all city-related projects was motivated at least in part, if not completely, by Nguyen's *qui tam* action. In turn, the court easily granted Nguyen's motion for summary judgment against Parsons. The court then turned its attention to the claims against the City of Cleveland.

Former Employers Can Be Held Liable Under FCA Section 3730(h)

First, the city argued that because Nguyen was not employed by the city at the time of retaliation, the city could not be held liable under the FCA. However, the court soundly rejected this argument and held that "[31 U.S.C.] § 3730(h) permits suits against an employer even if it did not employ the plaintiff at the time he took action protected by the FCA."

Second, the city raised the specious argument that it did not wish Parsons to terminate Nguyen. The court found the city's wishes to be "immaterial," given the fact that even if the city did not want Nguyen *terminated,* it certainly wanted to *retaliate* against him. Thus, the court also denied the city's motion for summary judgment. Accordingly, the court granted Nguyen's motion for summary judgment and denied Parsons and the city's motions for summary judgment.

COMMON DEFENSES TO FCA ALLEGATIONS

A. Time-Barred

U.S. ex rel. Cosens v. The Baylor University Medical Center, 2006 WL 3317695 (2d Cir. Nov. 16, 2006)

The Second Circuit dismissed an intervened FCA *qui tam* action, in which the government filed its complaints-in-intervention nearly twelve years after the last allegedly false claim was submitted to the government, even though the relator filed his *qui tam* complaints well within the FCA statute of limitations period. The court of appeals ruled that government's complaints-in-intervention could not relate back to the *qui tam* complaint under Rule 15(c)(2), for the FCA seal mechanism prevented the defendants from receiving the requisite "notice."

In March 1994, Kevin Cosens filed an FCA *qui tam* complaint in the Western District of Washington against 132 hospitals from thirty states, alleging, *inter alia*, that the hospitals had defrauded Medicare by seeking and obtaining reimbursement for hospital services provided to patients participating in clinical trials involving investigational cardiac devices that had not received Food and Drug Administration's premarket approval. According to the complaint, reimbursement for such services contravened a provision in the Medicare manuals issued to its fiscal intermediaries.

From 1994 to 2002, the government made sixteen requests, on *ex parte* motion, to extend the sixty-day seal period. The district court granted each motion. During this period, the government and Cosens sought and obtained a partial lifting of the seal, with the result that some of the hospitals received limited information about the FCA suits.

Beginning in June 1999, the government, asserting that it was the real party in interest without formal intervention, filed *ex parte* motions for severance and transfer of venue as to particular hospitals, in each instance seeking transfer to the district where the hospital was located. These motions were all granted by the district court. At the same time, the government negotiated settlements with a number of the hospitals and voluntarily dismissed others.

In late 2002 to early 2003, the government filed complaints-in-intervention against the remaining defendants, asserting claims under the FCA and common law. Upon motion by the government and Cosens, the United States Judicial Panel on Multi-district Litigation assigned these cases to the District of Connecticut for coordinated or consolidated pretrial proceedings.

The hospitals moved to dismiss the government's claims pursuant to Rule 12(b)(6), arguing that the complaints failed to state a claim, failed to satisfy Rule 9(b) and violated the FCA's statute of limitations provision.

The district court, in denying the defendants' motion, ruled that the claims not only satisfied Rules 9(b) and 12(b)(6), but they were also timely on the ground that

the controlling date for statute-of-limitations purposes was the date of the original *qui tam* complaint and all claims had accrued within the applicable limitations period of that original complaint. The defendants appealed the decision to the Second Circuit.

Government's Actions Commenced With Filing of Complaints-in-Intervention

The Second Circuit began its analysis by laying out the text of the FCA statute of limitations, which reads:

> (b) A civil action under section 3730 may not be brought—
>
> (1) more than 6 years after the date on which the violation of [the FCA] is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

In this case, the earliest violations dated from 1986, and the government had filed its complaints-in-intervention in 2002–2003. The Second Circuit concluded that the date the government's actions commenced (for statute of limitations purposes) was the date on which the complaints-in-intervention were filed, and that the government's claims were therefore time-barred.

The government's complaints-in-intervention alleged that the hospitals made their last false claims in 1995. So, under the Second Circuit's reading, the six-year statute of limitations in 31 U.S.C. § 3731(b)(1) had expired for all claims by 2002, when the complaints-in-intervention were filed. Moreover, the court of appeals ruled that the three-year tolling provision of § 3731(b)(2) could not save the claims: "If the allegations in Cosens's original complaint sufficiently pled 'facts material to the right[s] of action'—*i.e.*, so that the Government should reasonably have had knowledge of such facts (a premise unchallenged by the parties)—the three-year toll under § 3731(b)(2) (even if applicable) expired in 1997."

FCA Seal Provision Does Not Allow Complaints-in-Intervention to "Relate Back" to Original *Qui Tam* Complaints

The government argued that its claims were not time-barred because they relate back to the original *qui tam* complaint pursuant to Rule 15(c)(2), which provides that "[a]n amendment of a pleading relates back to the date of the original pleading when . . . the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading."

The district court, agreeing with the government's reading of the Rule, determined that the date on which the relator filed the *qui tam* complaint constitutes the relevant date for determining the timeliness of the government's subsequent complaint-in-intervention if the government's complaint-in-intervention satisfies the requirements governing relation back under Rule 15(c)(2).

The Second Circuit, however, disagreed and held that-in light of the scheme created by 31 U.S.C. § 3730(b)—Rule 15(c)(2) does not allow complaints-in-intervention filed by the government to relate back to a relator's *qui tam* complaint. The Second Circuit was particularly troubled by the Act's seal provision which, according to court, makes the FCA incompatible with Rule 15(c)(2), because "the touchstone for relation back pursuant to Rule 15(c)(2) is notice, *i.e.*, whether the original pleading gave a party 'adequate notice of the conduct, transaction, or occurrence that forms the basis of the claim or defense.'"

"The rationale of Rule 15(c) is that a party who has been notified of litigation concerning a particular occurrence has been given all the notice that statutes of limitations were intended to provide." *Baldwin County Welcome Ctr. v. Brown*, 466 U.S. 147, 159 n. 3 (1984). By design, the seal provision of § 3730(b) deprived the defendant in an FCA suit of the notice usually given by a complaint. Accordingly, the Eleventh Circuit ruled that the complaints-in-intervention do not relate back to the original *qui tam* complaint.

B. Statutory Immunity

U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 2006 WL 3491784 (10th Cir. Dec. 5, 2006)

The Tenth Circuit, in affirming in part and remanding in part the dismissal of an FCA *qui tam* action against a Medicare contractor and a health care facility, ruled that absolute immunity did not shield the Medicare contractor when claims are submitted with fraud or gross negligence. Moreover, the state university-owned health care facility could not qualify as an "arm-of-the-state," where the entity is privatized and structured to achieve financial independence from the state university. However, for those claims that fell outside of the FCA statute-of-limitations period, the tolling provision could not save these claims, for the provision does not apply to relators.

For five years, Edyth Sikkenga worked for Regence BlueCross BlueShield of Utah, the Medicare carrier for the State of Utah. Her job responsibilities included reviewing claims submitted by medical service providers, including laboratories such as Associated Regional and University Pathologists (ARUP), a laboratory entirely owned by and located at the University of Utah Medical Center. After complaining internally that ARUP was presenting false claims for Medicare reimbursement, and that Regence had failed to take appropriate action to stop the fraud, Sikkenga filed an FCA qui tam action against Regence and ARUP and an FCA Section 3730(h) suit against Regence.

The district court, in dismissing the suit, determined that Regence and its managers were immune from suit and that ARUP was not a "person" under the FCA. The lower court also determined that some of the claims were barred under the FCA's statute of limitations provision. Lastly, the district court tossed Sikkenga's anti-retaliation suit, for Regence was not put on notice about the possibility of a qui tam action. Sikkenga appealed the decision to the Tenth Circuit, arguing that the court erred in ruling that Medicare Part B's immunity provision provided Regence with absolute immunity, that she had not adequately alleged that Regence "caused" ARUP to present false claims, and that ARUP was an arm-of-the-state.

No Medicare Contractor Immunity for Cases Involving Fraud or Gross Negligence

Relying on *U.S. ex rel. Body v. Blue Cross and Blue Shield of Alabama, Inc.*, 156 F.3d 1098 (11th Cir. 1998), the district court interpreted the Medicare immunity provision, 42 U.S.C. § 1395u(e), to provide absolute immunity to Medicare contractors' payments of claims. On that basis, the lower court found that Regence and the individual defendants were immune from suit as to any claims based on Regence's payment of the allegedly false claims, interpreting that provision to provide absolute immunity.

The version of Medicare's statutory immunity provision in effect at the time of this case states:

> (1) No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.
>
> (2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.
>
> (3) No such carrier shall be liable to the United States for any payments referred to in paragraph (1) or (2).

In *Body*, the Eleventh Circuit held that Medicare's Part A immunity provision, 42 U.S.C. § 1395h(i)(3), unambiguously provided absolute immunity to Medicare fiscal intermediaries, in contrast to the express limitation present in § § 1395h(i)(1) and (2), which provided immunity for payments by certifying or disbursing officers only in the absence of gross negligence or intent to defraud. Sikkenga argued that *Body* was wrongly decided and that the district court misinterpreted § 1395u(e)(3). Specifically, Sikkenga argued that the immunity conferred on Medicare carriers by this provision does not extend to circumstances involving gross negligence or an intent to defraud the United States.

Body looked solely to the "unambiguous" text of § 1395h(i)(3) and held that the absence of the qualifying language present in the first two paragraphs was determinative. Although the Tenth Circuit agreed that the language was unambiguous, it ruled that there was no gross negligence and fraud exception. Instead, the Tenth Circuit read the payments referred to and incorporated by § 1395u(e)(3) as being payments made "in the absence of gross negligence or intent to defraud the United States."

While the plain language did not require it to rummage through the legislative history, the Tenth Circuit found additional support in the legislative history. Specifically, in the House Conference Report accompanying the passage of § 1395u(e)(3), the committee stated that this provision provided carriers with "the same immunity from liability for incorrect payments as would be provided their certifying and disbursing officers." H.R.Rep. No. 89-682, at 37 (1965), *reprinted in* 1965 U.S.C.C.A.N. 2228, 2231. Thus, the legislative history unequivocally resolved any residual ambiguity that might exist in the language. In turn, the Tenth Circuit ruled that the immunity available to Regence as a Medicare carrier under § 1395u(e)(3) was co-extensive with that of its certifying and disbursing officers—in other words, the immunity excluded cases involving fraud and gross negligence.

Defendant's Assurances to Co-Defendant "Caused" False Claims To Be Presented

The Tenth Circuit's interpretation did not, however, lead to an automatic reversal of the entire suit against Regence. In his complaint, Sikkenga had maintained that Re-

gence had violated the FCA by making fraudulent payments. The FCA, however, does not provide a remedy for claims for *payment* of a false or fraudulent claim. Thankfully for Sikkenga, she had also alleged that Regence *caused* fraudulent claims to be submitted to the federal government.

Nonetheless, the district court rejected Sikkenga's position that she sufficiently alleged that Regence "caused" ARUP to present false claims. In doing so, the lower court interpreted the FCA's "causing to be presented" language as requiring "some sort of affirmative action on the part of the defendant before imposing liability." Interpreting Sikkenga's complaint to allege only passive acceptance of ARUP's claims, the district court found that Sikkenga's allegations had failed to demonstrate an affirmative action, and thus dismissed the claim against Regence.

Sikkenga, in appealing the decision to the Tenth Circuit, stressed that "[b]y *assuring* ARUP that such claims would continue to be accepted, Regence encouraged, facilitated, and caused ARUP's presentation of false claims for payment." (emphasis added).

To see if this "assurance" rose to level of "causation," the Tenth Circuit first laid out what was required for an entity to have "caused" a claim to be presented under the FCA. One case, *U.S. ex rel. Long v. SCS Bus. & Technical Inst.*, 999 F. Supp. 78, 91 (D.D.C. 1998), supported Sikkenga's view that the failure to prevent a third party from filing false claims after having knowledge that the claims were false is sufficient to state a claim under the FCA. More recently, a Massachusetts district court applied this ruling in maintaining that "Where a defendant has an ongoing business relationship with a repeated false claimant, and the defendant knows of the false claims, yet does not cease doing business with the claimant or disclose the false claims to the United States, the defendant's ostrich-like behavior itself becomes 'a course of conduct that allowed fraudulent claims to be presented to the government.'" *United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 187 (D.Mass. 2004).

However, the Tenth Circuit warned that, generally, mere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA. Borrowing the principles of tort law to analyze causation for damages under the FCA, the court endorsed a familiar test-that of proximate causation—to determine whether there was a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim.

Applying this standard to Sikkenga's allegations, the Tenth Circuit disagreed with the lower court's assessment that Sikkenga had failed to sufficiently allege a "causing to be presented" claim under the FCA. Here, Sikkenga's allegations stated that Regence engaged in certain actions, specifically "agreeing to circumvent" contractual and statutory requirements and "assuring" ARUP that Regence would continue to accepting misappropriately coded claims. Sikkenga alleged that these actions assisted ARUP in continuing to submit the allegedly false claims.

Defendant Is Not an Arm-of-the-State

The Tenth Circuit also determined that the lower court had misapplied the arm-of-the-state test articulated in *Sturdevant v. Paulsen*, 218 F.3d 1160 (10th Cir. 2001), when it concluded that ARUP was "sufficiently tied to the University of Utah to be considered an arm of the state."

In her appeal of this decision, Sikkenga advanced two arguments. First, she argued that because ARUP is a corporation, it must be a person and therefore liable under the FCA. Second, Sikkenga maintained that the lower court improperly found that ARUP was an arm-of-the-state.

Even though the Tenth Circuit recognized the ordinary presumption of "personhood" that arises from ARUP's incorporation, this recognition was tempered by the Supreme Court's express instruction that under the FCA, the court must apply the "longstanding interpretive presumption" that the term "person" does not include a sovereign. *See Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*, 529 U.S. 765 (U.S. 2000).

In *Sturdevant*, the Tenth Circuit stated that there were three factors to be considered in the arm-of-the-state analysis: (1) the state's legal liability for a judgment; (2) the degree of autonomy from the state-both as a matter of law and the amount of guidance and control exercised by the state; and (3) the extent of financing the agency received independent of the state treasury and its ability to provide for its own financing. 218 F.3d at 1164.

In the case at bar, the Tenth Circuit was particularly swayed by the fact that while it was clear that ARUP was a wholly owned corporation, the stock of which was owned by the University of Utah and its day-to-day operations were independent. Moreover, ARUP engaged in nationwide activity as a commercial laboratory and was licensed in nine states and marketed its services in all fifty. In fact, for the fiscal year ending in June 1998, seventy-six percent of ARUP's revenues were derived from testing provided to other hospitals.

The Tenth Circuit reduced its arm-of-the-state analysis to a succinct rule: "When, as here, an entity is privatized and is structured to achieve financial independence from the state entity which owns it, we will not disregard its structure merely because the state retains proprietorial title to its asset." In turn, the Tenth Circuit concluded that ARUP, with its anticipated and actual financial independence, was not an arm-of-the-state. Accordingly, the Tenth Circuit reversed the lower court's dismissal of ARUP.

FCA Tolling Provision Does Not Apply to Relators

The lower court had also dismissed some of Sikkenga's claims for being violative of the Act's statute of limitations. Sikkenga had maintained that while these particular claims did not fall within the six-year time limitation, she should have been allowed the benefit of the Act's tolling provision, 31 U.S.C. 3731(b). The district court, however, interpreted this provision to only apply to those claims brought by the federal government, not *qui tam* relators.

In its analysis of the issue, the Tenth Circuit first turned to the statutory language, which reads:

> (b) A civil action under [31 U.S.C.] section 3730 may not be brought—
>
> (1) more than 6 years after the date on which the violation is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

The Tenth Circuit, finding ambiguity in the language, rummaged through the legislative history and discovered that Congress's intent was to provide the Department of Justice with "a little more flexibility in bringing some cases that otherwise would be barred." *False Claims Act Amendments: Hearings Before the H. Subcomm. on Admin. Law and Governmental Relations of the H. Comm. on the Judiciary*, 99th Cong. 159 (1986) (Statement of Mr. Richard K. Willard, Assistant Attorney General, Dep't of Justice). Consequently, the Tenth Circuit concluded that the district court correctly interpreted Section 3731(b) to bar Sikkenga's claims that fell outside of the six-year time window.

Plaintiff Did Not Place Defendant On Notice About Possible FCA Action

The Tenth Circuit then turned its attention to Sikkenga's Section 3730(h) anti-retaliation suit, which the lower court dismissed because she was unable to show by a preponderance of the evidence that the employer's retaliatory actions resulted "because of" the whistleblower's participation in a protected activity.

The Tenth Circuit's inquiry of the "because of" standard has evolved into a two-pronged approach: One, the whistleblower must show the employer had knowledge the employee was engaged in "protected activity" and, two, the retaliation was motivated, at least in part, by the employee engaging in protected activity.

However, under *U.S. ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514 (10th Cir. 1996), where an employee's regular duties include investigation of fraud, such person has the added burden of clearly pleading notice to her employer of her intentions of bringing or assisting in an FCA action in order to overcome the presumption that he is merely acting in accordance with his employment obligations. In this case, as in *Ramseyer*, Sikkenga's duties included monitoring compliance with Medicare requirements; and, as in *Ramseyer*, the court of appeals determined that the plaintiff did not clear the elevated notice hurdle for compliance officers. Accordingly, the Tenth Circuit affirmed the dismissal of Sikkenga's Section 3730(h) suit.

Dissent Read FCA Tolling Provision to Apply to Relators

Judge Hartz concurred with most of the majority opinion, but he dissented when it came to the FCA's tolling provision, 31 U.S.C. § 3731(b). The dissent joined the majority in rejecting the Ninth Circuit's view in *U.S. ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211 (9th Cir. 1996), that a relator can be "the official of the United States charged with responsibility to act" in paragraph (2). However, the dissent maintained that the tolling provision applied to the government and to relators. For support of this reading, the dissent noted that if Congress had wanted to limit relators to the six-year limitation period, it could have easily said so. In turn, the dissent would have allowed these particular claims to survive.

C. Government Knowledge Defense

U.S. ex rel. Englund v. Los Angeles County, 2006 WL 3097941 (E.D. Cal. Oct. 31, 2006)

A California district court dismissed an FCA *qui tam* action against a county-defendant, where the federal government knew and approved the county's actions and the county raised a reasonable interpretation of the law that made the claims not "knowingly false."

Beverly Englund brought an FCA *qui tam* action against Los Angeles County, alleging that the county was either causing and/or conspiring with the State of California to falsely claim Medicaid funds which the county was not entitled to receive. Namely, the county allegedly caused the state to submit a false claim for additional Medicaid funds under the federal SB 1255 program, even though the county supposedly could not meet the requirement of demonstrating a "purpose" for the additional funding. In support of her complaint, Englund maintained that the "purpose" language of the relevant regulation should be construed as a restriction on how the county could use the SB 1255 funds. Because the county did not use all SB 1255 funds for medical services, Englund contended that the county could not demonstrate a purpose for supplemental funding under SP 1255 and thus, did not qualify for the supplemental funding.

The county, in seeking to dismiss the suit, maintained that there was no restriction on how the county spent the SB 1255 funds.

Claims Are Not "False" When Defendant Raises Reasonable Interpretation of Law

Before diving into the nuances of the applicable regulations and laws, the court, embracing a rule that has divided the courts, ruled that claims are not "false" under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the government. *See U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (holding that "errors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA").

Under this microscope, the court was then faced with the relevant regulation, Cal. Welf. & Inst.Code § 14085.6(g), which the court found to impose criteria or requirements upon which reasonable minds could differ. Pointing to differing judicial and governmental interpretations of this regulation, the court decided that, in fact, "reasonable" minds had embraced differing interpretations.

Moreover, the court, borrowing from a neighboring court, maintained that "False Claims Act only attaches liability to false claims for payment, not to underlying activity that allegedly violates federal law." *U.S. ex rel. Swan v. Covenant Care, Inc.*, 279 F.Supp.2d 1212, 1221 (E.D. Cal. 2002). Here, because the regulation did not clearly require "perfect regulatory compliance" as a condition of payment, the court ruled that FCA liability could not attach.

"Government Knowledge Defense" Negates Defendant's Intent

In the case at bar, the court ruled that even if the county did not sufficiently comply with the applicable regulation, FCA liability could not attach, for there was no evidence that the county "knowingly" caused the State to make false claims.

Known as the "government knowledge defense," this defense holds that the "knowing" submission of a false claim is logically impossible when responsible government officials have been fully apprised of all relevant information. *U.S. ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 988 (E.D. Wis. 1998). In other words, since the crux of an FCA violation is intentionally deceiving the government, no violation exists where the government has not been deceived.

Here, the court noted that it was undisputed that the federal government knew what the county was doing and implicitly approved of the county's actions. In turn, given that the county's alleged "scheme" was "well known and public," the court determined that it could not also be true that the county had the requisite intent to purposefully defraud the government. Accordingly, the court granted the county's motion for summary judgment.

D. *Pro Se* Relator

U.S. ex rel. Szymczak v. Covenant Healthcare Systems, Inc., 2006 WL 3793376 (7th Cir. Dec. 27, 2006)

The Seventh Circuit, in affirming the dismissal of a *pro se* FCA *qui tam* action, held that a *pro se* relator cannot prosecute a *qui tam* action under the FCA.

James Szymczak brought a *pro se* FCA *qui tam* action against Covenant Healthcare Systems, Inc., the operator of the hospital and nursing home where his mother was treated in the summer of 2003. Szymczak alleged that Covenant had filed fraudulent Medicare claims and received payment for "unnecessary, unrendered, misrepresented, and unreimbursable services," in violation of the FCA. The district court, in granting Covenant's motion to dismiss, echoed the Seventh Circuit's holding in *U.S. ex rel. Lu v. Ou*, 368 F.3d 773, 775 (7th Cir. 2004) by holding that a *pro se* relator cannot prosecute a *qui tam* action under the FCA. Szymczak appealed the decision to the Seventh Circuit.

Over Szymczak's plea that he "respectfully disagrees with *Lu*," the Seventh Circuit reaffirmed its ruling in *Lu* and affirmed the lower court's decision to dismiss the suit.

FEDERAL RULES OF CIVIL PROCEDURE

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

U.S. ex rel. Atkins v. McInteer, 2006 WL 3461441 (11th Cir. Dec. 1, 2006)

The Eleventh Circuit affirmed, on alternative grounds, the dismissal of an FCA *qui tam* action, in which a relator alleged that a health care provider violated the FCA by submitting false claims to a state Medicaid agency. While the court of appeals ruled that the lower court had jurisdiction over such an action, it ruled that the complaint did not satisfy the Rule 9(b) particularity requirements, for he merely provided a "general outline" of the alleged scheme and did not show any "indicia of reliability" that the claims were actually submitted to the government.

Dr. Patrick Atkins is an Alabama physician who specializes in adult psychiatry. In March 2003, while Atkins was seeing residents at the Park Manor Nursing Home in Tuscaloosa, Alabama, he discovered that a particular physician was submitting false claims to the Medicaid program, including claims for medical services never performed. Subsequently, Atkins filed a *qui tam* action against the hospital and the individual doctor.

The defendants filed a motion to dismiss, which the court granted on the grounds that the complaint failed to state a claim for relief and, alternatively, under Rule 9(b) for failing to allege fraud with sufficient "particularity." More specifically, the court actually dismissed the suit for lack of subject matter jurisdiction under 28 U.S.C. § 1331. Relying on the D.C. Circuit's decision in *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), the court concluded that it lacked § 1331 jurisdiction to entertain the suit.

However, *Totten* held that the defendant's presentation of a fraudulent claim to Amtrak did not constitute the presentation of a fraudulent claim "to an officer or employee of the United States Government" so as to state a claim under the FCA. The court then took one more misstep and concluded that it could not invoke the court's § 1331 jurisdiction.

Atkins appealed the district court's judgment and raised two main arguments: (1) the district court had subject matter jurisdiction under 28 U.S.C. § 1331 because he asserted a claim under the FCA; and (2) the allegations of his complaint were sufficient to state a claim for relief.

Court Had Subject Matter Jurisdiction

The district court read *Totten* for the proposition that if a plaintiff failed to state a claim under the FCA, his action does not arise under the laws of the United States; therefore, his complaint must be dismissed for lack of subject matter jurisdiction. The

Eleventh Circuit disagreed with the lower court's ruling, particularly since *Totten* does not present a jurisdictional rule.

According to the Eleventh Circuit, the notion that *Totten* barred subject matter jurisdiction conflated the "failure to state a claim upon which relief can be granted" under Rule 12(b)(6) with federal question jurisdiction under 28 U.S.C. § 1331. As the Supreme Court explained in *Bell v. Hood,* 327 U.S. 678 (1946), "Jurisdiction . . . is not defeated . . . by the possibility that the averments might fail to state a cause of action on which [the plaintiffs] could actually recover. In sum, it was clear to the Eleventh Circuit that the lower court had subject matter jurisdiction in the case.

Complaint Failed to Satisfy Rule 9(b)

Echoing its reading from the controversial *Clausen* decision, the court of appeals then stressed that Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a relator to merely describe a private scheme in detail but then allege that false claims "must have been submitted" to the government. Rather, according to the court, "if Rule 9(b) is to be adhered to, some indicia of reliability must be given *in the complaint* to support the allegation of *an actual false claim* for payment being made to the Government." *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (emphasis added by the court).

Examining the alleged facts of the case under this text, the Eleventh Circuit ruled that the complaint failed Rule 9(b) for want of sufficient indicia of reliability to support the assertion that the defendants submitted false claims. Atkins had described in detail what he believed was an elaborate scheme for defrauding the government by submitting false claims, but he failed, according to the court, to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services.

Moreover, the Eleventh Circuit faulted Atkins for not including some "indicia of reliability" in the complaint—namely, that he had firsthand knowledge of the defendants' submission of false claims. Accordingly, the Eleventh Circuit ruled that his complaint did not meet the jurisdiction's Rule 9(b) threshold requirements. In turn, the court of appeals affirmed the lower court's decision.

***U.S. ex rel. Salmeron v. Enterprise Recovery Systems, Inc.*, 2006 WL 3445579 (N.D. Ill. Nov. 30, 2006)**

An Illinois district court refused to dismiss an FCA *qui tam* action under Rule 9(b), where, as the Rule requires, the relator provided a general outline of "the *circumstances* constituting fraud." The court noted that at the pleading stage, this sufficiently gives the defendant notice of the claims the relator is advancing, as well as informing it of what it would have to do to mount a defense.

United Student Aid Funds, Inc., an entity that guarantees student loans for both state and private lenders. As part of its guaranty services, United Student often contracts with other agencies that act as third-party servicers performing due diligence and col-

lecting on defaulted loans for United Student accounts. Enterprise Recovery Systems, Inc., one such third-party servicer, has contracts with various educational institutions and is required to submit annual compliance reports to the Secretary of Education.

From 1998 to July 2002, Rhonda Salmeron worked as a general manager for Enterprise. During the course of her employment, she discovered an elaborate scheme to defraud the federal government. Specifically, to maintain its contract with United Student, Enterprise was subjected to an annual audit performed by United Student, designed to monitor Enterprise's success at communicating with debtors and collecting on outstanding loans. According to Salmeron, to pass those annual audits, Enterprise created false records of the contacts it made with debtors. Furthermore, to facilitate that scheme, United Student would, in turn, let Enterprise know in advance which accounts it would be inspecting, a benefit that no other third-party servicer received. Salmeron subsequently file an FCA *qui tam* action against United Student and Enterprise. United Student filed a motion to dismiss, arguing that Salmeron's complaint failed to satisfy Rule 9(b).

General Outline of the Alleged Scheme Satisfied Rule 9(b)

The district court correctly pointed out that Rule 9(b) mandates particularity about "the *circumstances* constituting fraud." Hence such cases as *Midwest Grinding Co. v. Spitz*, 976 F.2d 1016, 1020 (7th Cir. 1992) have held that a plaintiff is required to provide only a "general outline" of the alleged scheme sufficient to put defendants on notice about their roles in the fraudulent or false activity. According to the court, "'To serve the well-known goals of Rule 9(b), plaintiff must provide fair notice by supplying just such a general outline of the 'circumstances constituting fraud.'"

Under this interpretation of Rule 9(b), the court determined that Salmeron had sufficiently adumbrated the scheme at issued, so as to place United Student on notice of the claims she was advancing, as well as informing it of what it would have to do to mount a defense: "'To require Salmeron to provide more detail at the pleading stage would be unrealistically demanding. Instead both she and Funds will be able to proceed to discovery to flesh out the chapter-and-verse details." In sum, Salmeron had satisfied the Rule 9(b) particularity requirement. In turn, the court denied the motion to dismiss.

The Role of the False Claims Act in Combatting Medicare & Medicaid Fraud by Drug Manufacturers: An Update

The Role of the False Claims Act in Combatting Medicare and Medicaid Fraud by Drug Manufacturers: An Update

prepared for Taxpayers Against Fraud Education Fund
by Andy Schneider, Principal
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This is the third in a series of reports issued by Taxpayers Against Fraud Education Fund (TAFEF) describing the role the False Claims Act (FCA) has played in protecting the Medicare and Medicaid programs against fraud by drug manufacturers. Viewed as "one of the most important tools" available to federal prosecutors and investigators, the FCA imposes treble damages and civil penalties on companies that knowingly present false claims for payment to the federal government programs.[2] Medicare is the federal program of health insurance coverage for 43 million elderly and disabled Americans. Medicaid is the federal-state program of health and long-term care for 55 million low-income Americans. This year, the federal government is expected to spend a total of $621 billion on both of these programs.[3]

The previous two TAFEF reports found that, as of September 2004, seven pharmaceutical manufacturers, including three of the top five U.S. drug companies by sales volume, had settled cases with the Department of Justice (DOJ) involving allegations by whistleblowers[4] of pricing or marketing fraud against Medicare and Medicaid. These settlements resulted in criminal fines of $652 million, over $2.4 billion in civil fines to the federal government, and payments of $413 million to state governments to compensate them for losses incurred by their Medicaid programs. The two reports speculated that additional settlements would follow, noting that there were under seal in the fall of 2004 in the neighborhood of 100 whistleblower cases involving allegations against over 200 drug manufacturers with respect to 500 different products.[5]

In the two years since that time, six more whistleblower cases against drug manufacturers were settled for a total of $1.4 billion. One of these cases was settled in FY 2005 for a total of $149 million; the others were settled in FY 2006 for a total of $1.3

1. The author gratefully acknowledges the contributions Vikki Wachino, Wachino Health Policy Consulting, for her analysis of all Medicaid FCA settlements between FY 2004 and FY 2006; Amy Wilken, J.D., for her analysis of the recent corporate integrity agreements that appear in Table 3; and Jeb White, Staff Attorney at TAFEF, for his careful editing and assistance with relevant case law. The author also thanks Daniel R. Anderson, Assistant Director, Commercial Litigation Branch, Civil Division, Department of Justice, and Patrick O'Connell, Assistant Attorney General, State of Texas, for their assistance in understanding the terms of certain settlements. However, the data and analysis presented in this report are solely the responsibility of the author.

2. Department of Health and Human Services and the Department of Justice, *Health Care Fraud and Abuse Control Program: Annual Report for FY 2005* (August 2006), p. 33, *available at* http://www.oig.hhs.gov/publications/hcfac.html#1 (last visited February 14, 2007).

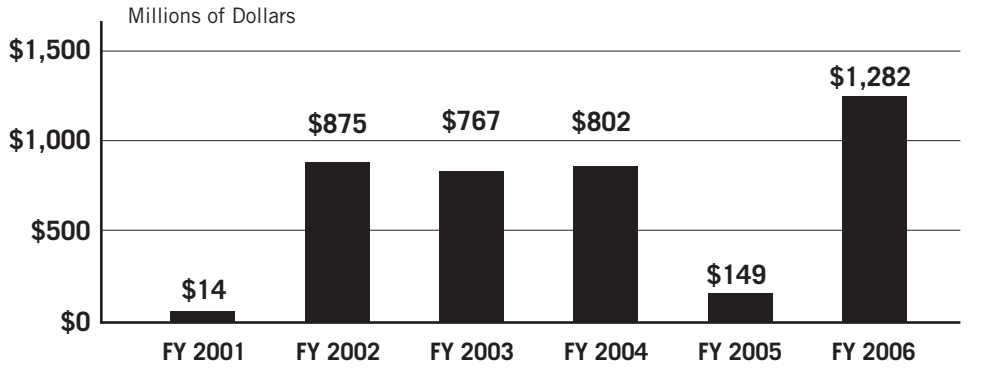
3. Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2008 to 2017* (January 2007), Table 3-3, p. 55, *available at* www.cbo.gov (last visited February 14, 2007).

4. Under the False Claims Act, whistleblowers are referred to as "relators." For a brief summary of the FCA, see http://www.taf.org/whyfca.htm (last visited February 14, 2007).

5. A. Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (November 2003); A. Schneider, *The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update* (November 2004), p.5, *available at* www.taf.org (last visited February 14, 2007).

billion. Over the FY 2001–2006 period, recoveries in such cases total nearly $3.9 billion. (See Figure 1.)

Figure 1. Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid. FY 2001–FY2006



Source: DOJ press releases and settlement agreements

These six settlements during FY 2005 and FY 2006 bring to sixteen the total number of settlements of whistleblower cases against drug manufacturers involving allegations of Medicaid or Medicare fraud. Twelve of these cases were brought under the FCA; the remaining four were brought under the Texas false claims act. In ten of these sixteen cases, the whistleblowers were employees of the manufacturer or the manufacturer's competitor (see Table 1 at the end of this report). In six cases the whistleblower was a specialty pharmacy doing business with the manufacturers and having access to pricing data not available to federal or state governments.[6] It is highly unlikely that, in absence of the information supplied by these employee-whistleblowers and the specialty pharmacy, federal or state officials administering the Medicaid or Medicare programs would have learned of the non-transparent marketing or pricing practices at issue in these cases.

As noted, nearly $3.9 billion has been recovered from drug manufacturers over the past six fiscal years as the result of cases brought by whistleblowers. During this period, two other FCA cases involving drug manufacturers were settled: Abbott Laboratories, settled on July 23, 2003 for $622 million;[7] and Eli Lilly and Company, settled on December 21, 2005 for $36 million.[8] Neither of these cases was initiated by whistleblowers. Thus, between FY 2001 and FY 2006, the FCA produced $4.5 billion in recoveries from drug manufacturers; of this amount, $3.9 billion, or 85 percent, is directly attributable to actions brought by whistleblowers.

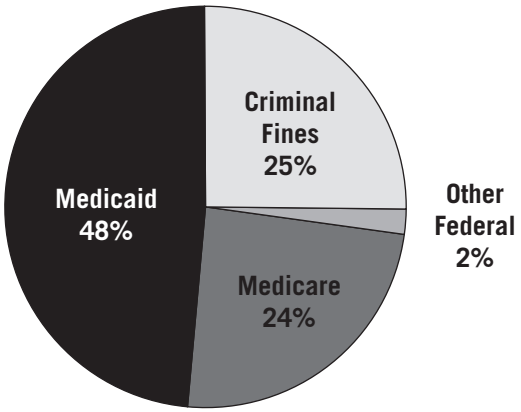
6. Ven-a-Care of the Florida Keys, *available at* http://66.98.181.12/venacare.htm (last visited February 14, 2007).

7. *U.S. v. Abbott Laboratories, Inc.* (S.D. Ill.), July 23, 2003, noted in *False Claims Act & Qui Tam Quarterly Review* (October 2003), p. 59.

8. *U.S. v. Eli Lilly and Co.*, No IP05-CR-0206-01-B/F (S.D.Ind., Dec. 21, 2005), *available at* http://www.usdoj.gov/civil/ocl/cases/Lilly/index.htm (last visited February 14, 2007).

As shown in Figure 2 below, of the nearly $3.9 billion recovered in sixteen whistleblower settlements with drug manufacturers over the past six years, about three quarters is civil recoveries and the remaining quarter is criminal fines.[9] The single largest source of the recoveries is Medicaid: nearly half of the total recoveries, and over two thirds of the total civil recoveries, are attributable to allegations of violations of Medicaid requirements. Of the $1.89 billion in Medicaid recoveries, just over $1 billion went to the federal government, and the remaining $830 million was distributed among the states.[10] A breakdown of the recoveries in each of the sixteen settlements is provided in Table 2 at the end of this report.

Figure 2. Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid (FY2001–FY2006), by Type



Note: Due to rounding, percentages do not add to 100

Source: DOJ press releases and settlement agreements

Cases involving drug manufacturers have been the single largest source of FCA recoveries in whistleblower cases involving Medicare, Medicaid, and other programs administered by the Department of Health and Human Services. According to DOJ, between FY 2001 and FY 2006, there were $5.7 billion in total FCA whistleblower recoveries. [11] Over this same period, over $2.9 billion, or about half of this amount, was attributable to civil settlements in cases initiated by whistleblowers against drug

9. Six of the sixteen whistleblower settlements included criminal fines totaling $968 million, or 25 percent of all recoveries. As shown in Table 2 at the end of this report, the largest of the criminal fines was paid in the *TAP Pharmaceutical*s case in 2001 ($290 million), followed by *Pfizer II* ($240 million), *Schering-Plough III* ($180 million), *Serono* ($136.9 million), *AstraZeneca* ($63.9 million), *Schering-Plough II* ($52.5 million), and *Bayer II* ($5.6 million).

10. State-by-state distributions of the $830 million (for states other than Texas) by settlement are in the possession of the National Association of Medicaid Fraud Control Units.

11. Civil Division, U.S. Department of Justice, *Fraud Statistics – Health & Human Services, October 1, 1986 – September 30, 2006, available at* http://www.taf.org/statistics.htm (last visited February 14, 2007).

manufacturers. The whistleblowers' shares account for about 13 percent of the civil recoveries.[12]

This update focuses on the six whistleblower cases against drug manufacturers settled during FY 2005 and FY 2006. It briefly reviews the main types of illegal conduct alleged and the remedies provided, which include Corporate Integrity Agreements (CIAs) summarized in Table 3 at the end of this report. (CIAs, which are part of each of the settlements other than those with the State of Texas, are negotiated by the Office of Inspector General (OIG) of the Department of Health and Human Services).[13] The update concludes with a short discussion of the impact of these drug manufacturer settlements on Medicare and Medicaid spending on prescription drugs.

THE FY 2005 AND FY 2006 SETTLEMENTS

Over the two-year period from October 1, 2004 through September 30, 2006, there were six settlements in cases initiated by a whistleblower against a drug manufacturer: *GlaxoSmithKline II*; *King Pharmaceuticals*; *Schering-Plough III*; *Serono*; *Roxane* and *Baxter*. All six of these settlements involved allegations of fraud against Medicaid; *GlaxoSmithKline II* also involved allegations of fraud against Medicare. The *Roxane* and *Baxter* settlements resulted from whistleblower cases brought under the Medicaid false claims act of the State of Texas and settle only FCA claims relating to the Texas Medicaid program. All six settlements are summarized in Table 1 at the end of this report. The amounts recovered by each settlement are summarized in Table 2. The corporate integrity agreements (CIAs) entered into by GlaxoSmithKline, King Pharmaceuticals, Serono, and Schering-Plough Corporation are summarized in Table 3.

The allegations of fraud against Medicaid and Medicare in these and previous whistleblower cases fall into three broad categories: "marketing the spread;" concealment of "best price;" and off-label marketing. Three of the cases involve marketing the spread (*Baxter*, *GlaxoSmithKline II* and *Roxane*). Two involve concealment of best price (*King Pharmaceuticals*, *Schering-Plough III*), and two involve off-label marketing (*Serono*, *Schering-Plough III*).

Marketing the Spread

This occurs when a manufacturer uses the "spread"—i.e., the difference between (1) the price paid for a drug by Medicaid to a pharmacist and (2) the actual cost of the

12. As show in Table 2 at the end of this report, whistleblowers received a share of the recoveries in all but two of the sixteen settlements. The whistleblower's share in *Schering-Plough III* is not resolved, so this case was excluded from the computation (the remaining fifteen cases were included). The whistleblower in *GlaxoSmithKline I* was also the whistleblower in *Bayer II*, settled on the same day. *See* A. Schneider (November 2003), *op. cit*., pp. 33–34.

13. Under section 1128(b)(7) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(7), the OIG has the authority to exclude from participation in Medicare, Medicaid, and other federal health care programs any provider or entity that submits a false claim in violation of the FCA. In exchange for OIG's agreement not to seek exclusion, the defendant in an FCA settlement enters into a CIA that is enforced by the OIG. All CIAs are posted on the OIG website at http://www.oig.hhs.gov/fraud/cias.html (last visited February 14, 2007).

drug to the pharmacist—as a tool for selling its product to the pharmacist. The illegality results from the manufacturer's decision to inflate the price of the drug that it provides to an independent price reporting service, knowing that the Medicare and Medicaid programs will use that reported price information in determining how much they will pay the pharmacist. For example, many state Medicaid programs have used the "average wholesale price" (AWP) as a basis for paying pharmacists for prescriptions they fill for Medicaid beneficiaries. The AWP, in turn, is based upon what the manufacturer reports. If the reported AWP for a particular drug is much higher than what the pharmacist actually pays to acquire the drug, and if the pharmacist can keep all or most of the difference between AWP and the actual cost, then the pharmacist has a strong incentive to fill prescriptions with a drug with the greatest "spread." (Marketing the spread has also occurred when Medicare or Medicaid pays physicians for drugs that they administer in their offices directly to patients).

In June of 2005, the Assistant Attorney General for the State of Texas testified before the Senate Finance Committee that:

> "…some manufacturers make conscious, deliberate business decisions to create enhanced spreads and market the sale of their products based on the spreads. For example, manufacturers engaged in the following activities:
>
> - purposefully reported false and inflated prices to Texas Medicaid—as well as to third party price reporting services— in order to create enhanced spreads;
>
> - deliberately failed to report prices to certain classes of trade in violation of Texas law;
>
> - instructed their sales personnel to market spreads to consumers;
>
> - created spread sheets showing pharmacies how much more profit they can make off Medicare and Medicaid when purchasing one product over another;
>
> - tied sales personnel compensation to success in marketing the spread.
>
> We also found that some manufacturers actually kept two sets of computer records with prices: one with inflated prices that are reported to the price reporting services like First Data Bank, or in Texas' case, directly to the Medicaid program; and another with real contract prices that are used in every day fussiness transactions with the manufacturer's customers."[14]

Three of the cases settled in FY 2005 and 2006 involved marketing the spread:

14. Testimony of Patrick J. O'Connell, Assistant Attorney General, State of Texas, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

GlaxoSmithKline II.[15] On September 20, 2005, GlaxoSmithKline, the second largest drug manufacturer as measured by U.S. sales,[16] settled FCA whistleblower allegations of marketing the spread for Zofran and Kytril, two anti-emitic drugs used to control nausea resulting from oncology and radiology treatments, from 1994 though 2002. The settlement totaled $150 million, of which $126 million was attributable to Medicare and TRICARE and $24 million was attributable to Medicaid (Table 2). This was the company's second settlement of an FCA whistleblower case; in 2003 the company settled allegations of concealing "best price" for $88 million (See Table 1). In addition to allegations of marketing the spread, the 2005 settlement involved allegations that the company encouraged customers to "double dip" by billing Medicare for an injection of Kytril, then pooling Kytril leftover from several vials to create a full dose, and then bill Medicare again for administering that dose. The whistleblower, Ven-A-Care of the Florida Keys, received $26 million. As part of the settlement, the corporate integrity agreement (CIA) into which the company had previously entered with the Office of Inspector General was amended to require the company to report accurate average sales prices (ASPs) and accurate average manufacturer prices (AMPs) for drugs covered by Medicare, Medicaid, and other federal health care programs (Table 3).

By definition, FCA whistleblower cases address false or fraudulent claims presented to federal government programs like Medicare and Medicaid. There are, however, other parties to these transactions—notably, program beneficiaries. In the case of Medicare Part B, which covers physician-administered drugs like Zofran and Kytril, the program at the time of the litigation paid 80 percent of the cost of the drug, with the beneficiary responsible for the remaining 20 percent coinsurance. Because the coinsurance amount is tied to the drug's AWP, beneficiaries paid more out of pocket than they would have paid if manufacturer had not inflated the AWP. On August 10, 2006, GlaxoSmithKline paid $70 million to settle a class action brought on behalf of Medicare beneficiaries who paid some or all of the cost of these two drugs. The plaintiffs also included private insurers and union benefit funds that pay for these drugs on behalf of their members, and state Medicaid programs who paid Part B cost-sharing amounts for low-income Medicare beneficiaries.[17]

Roxane.[18] On November 25, 2005, Roxane Laboratories settled allegations that it marketed the spread on albuterol drugs (asthma inhalants) by knowingly inflating the

15. *U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. GlaxoSmithKline PLC*, docket number sealed, settlement announced (D. Mass. Sept. 20, 2005).

16. GlaxoSmithKline had prescription pharmaceutical sales of $19.1 billion in the U.S. in 2005, giving it a market share of 7.9 percent, second only to that of Pfizer (10.8 percent). IMS Health, *Leading 20 corporations by U.S. Sales, 2005, available at* www.imshealth.com (last visited July 16, 2006).

17. *In re* Pharmaceutical Industry Average Wholesale Price Litigation, No. 01-CV-12257-PBS settlement announced (D.Mass. Aug. 10, 2006). The settlement also involved allegations of marketing the spread for Amoxil, an antibiotic. Under the terms of the settlement, GSK will establish a national restitution fund of about $40 million from which Medicaid beneficiaries may make claims for reimbursement for excess coinsurance payments for these drugs. *See* www.oag.state.ny.us/press/2006/aug/aug10a_06.html (last visited February 14, 2007).

18. Settlement Agreement and Release, November 25, 2005, *State of Texas ex rel. Ven-A-Care of the Florida Keys,Inc. v. Roxane Laboratories Inc.*, No. GV3-03079 (District Court Travis County, 201st Judicial District) and No. GV002327 (District Court Travis County, 53rd Judicial District).

prices it reported to the Texas Vendor Drug program. Roxane was one of three manufacturers competing in the Texas Medicaid market for generic inhalant medicines for asthma; the other two had previously settled allegations of marketing the spread with the Texas Attorney General in June 2003 (Dey Laboratories, $18.5 million) and May 2004 (*Schering-Plough I*/Warrick Pharmaceuticals, $27 million).[19] The whistleblower in the Roxane case was the same as in the other two settlements: Ven-A-Care of the Florida Keys. The United States was not a party to the settlement, and Roxane did not enter into a CIA.

Baxter.[20] On June 9, 2006, Baxter Healthcare Corporation settled allegations that it marketed the spread on various intravenous fluids and injectables by knowingly reporting inflated prices for these products to the Texas Medicaid program. Like *Roxane*, this case was brought under the Texas Medicaid Fraud Prevention Act by Ven-A-Care. The settlement amount was $10 million, of which about $3.8 million went to the federal government for its share of the alleged damages to Medicaid. As in *Roxane*, the United States was not a party to the settlement and Baxter did not enter into a CIA.

Concealment of Best Price

This fraud is specific to Medicaid. In order for a manufacturer to sell drugs to Medicaid, it must enter into an agreement to provide rebates for drugs purchased by the program. The federal and state governments share in the rebates in the same proportion as they share in the cost of the Medicaid program (on average, 57 percent of the cost is born by the federal government). In the case of brand-name drugs, the rebate amount is the greater of two amounts: (1) 15.1 percent of the Average Manufacturer Price (AMP) of the drug (i.e., the average price paid to the manufacturer by wholesalers for drugs distributed through retail pharmacies), and (2) the difference between the AMP and the best price—i.e., the lowest price at which the manufacturer sells the drug to wholesalers, pharmacists, HMOs, hospital buying groups, or most other private sector customers. When the best price is below 84.9 percent of the AMP, the manufacturer must make higher rebate payments to Medicaid than 15.1 percent of the AMP. Under the terms of its rebate agreement, the manufacturer must provide both the AMP and the best price during each reporting period. If the manufacturer does not report the actual best price at which it sells a drug, and if the best price is lower than 84.9 percent of AMP, then Medicaid overpays for the drug, because the rebate amount paid by the manufacturer is lower than it should be. A Congressional Budget Office analysis of a sample of top-selling brand-name drugs in 2003 found that, on average, if the AWP for a drug was 100, the AMP was 79, and the best price was 63.[21] (The amount of the Medicaid rebate on a drug also determines the discount

19. Testimony of Patrick J. O'Connell, Assistant Attorney General, State of Texas, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

20. Settlement Agreement and Release, June 9, 2006, *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc. et. al.*, No. GV401286 (District Court Travis County, 201st Judicial District), *available at* www.oag.state.tx.us/oagnews/index (last visited February 14, 2007).

21. Congressional Budget Office, *Prices for Brand-name Drugs Under Selected Federal Programs* (June 2005), Table 1, p. 4, *available at* http://www.cbo.gov/showdoc.cfm?index=6481&sequence=0 (last visited February 14, 2007).

that manufacturers are required to give to community health centers, AIDS drug purchasing assistance programs, and other "PHS entities" specified in section 340B of the Public Health Service Act that purchase the drug for their non-Medicaid patients).[22]

Two of the settlements in FY 2005 and FY 2006 involved concealment of "best price."

King Pharmaceuticals.[23] On October 31, 2005, King Pharmaceuticals settled allegations that, over the period 1994 through 2002, it knowingly submitted inaccurate best price and AMP data to the federal government, resulting in Medicaid rebate amounts on its drug products that were lower than they should have been. The products at issue involved King's entire products line, including Altace, an ACE inhibitor that reduces the likelihood of heart attack and stroke. The total settlement amount was $124.1 million, of which $73.4 million was paid to the federal government and $50.6 million to the states. (The government asserted a claim of $186.1 million).[24] Of the federal government's share, a portion (not specified in the settlement agreement) was allocated to community health centers, AIDS drug purchasing assistance programs, and other entities entitled under the Public Health Service (PHS) Act to discounts based on the Medicaid rebates, as well as the Department of Veterans Affairs (VA) drug pricing program. As part of the settlement, King entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) that, among other things, requires the company to engage an Independent Review Organization (IRO) to test periodically the accuracy of (1) the best price and AMP data for any of its products that it submits to the federal government in connection with the Medicaid rebate program as well as (2) the Average Sales Price (ASP) data it submits to CMS in connection with Medicare Part B. The IRO is required to report the results of its reviews to the OIG.[25]

Schering-Plough III.[26] On August 29, 2006 the Schering-Plough Corporation entered into a global settlement totaling $435 million in criminal and civil liability in connection with the marketing of several different drug products.[27] This was the second settlement between DOJ and Schering-Plough disposing of allegations of concealment of best price.[28] A portion of the August 2006 settlement addresses allegations

22. The 340B program, 42 U.S.C. § 256b, is described at http://www.hrsa.gov/opa/introduction.htm (last visited February 14, 2007).

23. *U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, CA No 03-1538 (E.D. Pa Dec. 14, 2005).

24. Stipulation and Order of Agreement, *U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, CA No 03-1538 (E.D. Pa Oct. 31, 2005), p. 18, *available at* www.usdoj.gov/usao/pae/News/Pr/2005/oct/oct05.html (last visited February 14, 2007).

25. *Appendix B to the CIA for King Pharmaceuticals, Inc. Government Pricing and Medicaid Drug Rebate Engagement*, (October 28, 2005), *available at* http://www.oig.hhs.gov/fraud/cia/index.html (last visited February 14, 2007).

26. The settlement agreement and criminal information in this case are posted at http://www.justice.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

27. Michael J. Sullivan, U.S. Attorney, District of Massachusetts, "Schering to Pay $435 Million for the Improper Marketing of Drugs and Medicaid Fraud," August 29, 2006, *available at* http://www.justice.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

28. The prior settlement with DOJ, *Schering-Plough II*, is discussed in the November 2004 Update, *op. cit.*, at pp. 11–12. The whistleblower in that case testified about the conduct at issue before the Senate Finance Committee on August 29, 2005, *available at* http://www.finance.senate.gov/sitepages/hearing062905.htm (last visited February 14, 2007).

that Schering-Plough knowingly and willfully misreported its best price for Claritin Redi-Tabs (an antihistamine) and K-Dur 20 (a potassium chloride supplement) to the federal government in 1998 and 1999.[29] Allegedly, Schering-Plough failed to report deeply discounted prices for these drugs that it gave to a health maintenance organization (Kaiser Permanente Medical Care Program) in order to enable it to retain the HMO as a customer without giving the Medicaid program the same deep discounts. For example, in the case of Claritin Redi-Tabs, the HMO was willing to include the drug on its formulary only if the price was reduced to $1.10 per RediTab, which would represent a new best price. According to the criminal information in the case, the Schering-Plough Sales Corporation, a subsidiary of the Schering-Plough Corporation, shipped sufficient free "samples" of Claritin Redi-Tabs to the HMO so that cost of the drug purchased by the HMO and the zero cost of the "samples" resulted in a blended price of $1.10 per RediTab. Schering-Plough did not report the $1.10 price as best price, resulting in a loss to the Medicaid program of $4.4 million in rebate payments.

Off-Label Marketing

This conduct is prohibited not by the Medicare or Medicaid statutes but by the Food, Drug and Cosmetic Act (FDCA).[30] Under the FDCA, manufacturers may not sell a drug to U.S. consumers unless it is approved as safe and effective by the Food and Drug Administration (FDA). When a manufacturer applies for FDA approval of a new drug, it must specify the use(s) for which the drug is safe and effective. Generally, once the FDA has approved a drug as safe and effective for a specified use, physicians may prescribe it for the approved use as well as for unapproved—"off-label"—uses. Manufacturers may market or promote their products among physicians for approved uses. However, the FDCA prohibits a manufacturer from marketing or promoting its drug products among physicians for any off-label uses. Medicaid purchases drugs on behalf of its low-income beneficiaries if they are prescribed by licensed physicians as medically necessary, regardless of whether the use is specifically approved by the FDA or off-label. When a manufacturer promotes an off-label use of a drug and physicians respond by prescribing the product for such unapproved uses, the Medicaid program spends more for the drug than it would if its purchases were limited to approved uses. In FCA terms, the manufacturer's violation of the FDCA has "caused" the presentation of false or fraudulent claims to the Medicaid program because the manufacturer's illegal promotion of off-label uses lead physicians to write prescriptions for these uses that they otherwise would not have written.[31]

29. The marketing of K Dur 20 is also the subject of an FTC complaint and a consumer class action summarized at http://www.prescriptionaccess.org/index.php?doc_id=586 (last visited February 14, 2007).

30. 21 U.S.C. § 331(d), 355.

31. Because physicians are permitted to prescribe drugs for off-label purposes, some have argued that off-label marketing does not cause a "false" claim to be submitted to the government. However, the two courts that have addressed this argument rejected it and held that FCA liability attaches for off-label marketing. *See U.S. ex rel. Fraklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D.Mass. 2001) and *U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127 (E.D. Mo. April 21, 2006).

Two of the settlements in FY 2005 and 2006 involved off-label marketing. The civil recoveries in these two settlements totaled $818 million, making them the largest and third largest Medicaid FCA recoveries to date.

Serono.[32] On October 17, 2005, DOJ announced that Serono S.A., a Swiss firm, had agreed to pay $567 million in civil liabilities and $136.9 million in criminal fines as a consequence of off-label marketing of the drug Serostim from 1996 through 2004. Serostim is an injectable recombinant human growth hormone used to treat AIDS wasting, or large involuntary weight loss, especially of lean body mass, in patients with AIDS. At the time the FDA approved Serostim for this use, in August 1996, AIDS wasting was the leading cause of death among AIDS patients. A twelve-week course of therapy cost over $21,000. The majority of AIDS patients with health care coverage were insured through Medicaid. Approximately 80 percent of all Serostim prescriptions written during the 1997–2004 period were covered by Medicaid, which spent over $600 million in federal and state funds on these claims.

Around the same time as Serostim came to market a new class of drugs, protease inhibitors (Highly Active Anti-Retroviral Therapy, or HAART), also became available. These drugs proved highly effective in reducing the viral loads in HIV-positive patients, so the incidence of AIDS wasting syndrome declined markedly. As a result, the demand for Serostim began to drop. The whistleblowers, former Serono employees, alleged that Serono undertook a marketing campaign to redefine AIDS wasting in order to induce physicians to prescribe, and Medicaid to pay for, the administration of Serostim to patients for whom the drug was not medically necessary. The company allegedly sought to persuade physicians and patients that loss of "body cell mass" was an indicator of AIDS wasting. Integral to this marketing effort was a medical device that used bioelectrical impedance analysis (BIA) and certain software packages to estimate body cell mass by measuring the rate at which low levels of electrical current pass through the body. In some instances, Serono Labs employees directly administered BIA tests to patients in order to induce physicians to prescribe Serostim. The BIA device and software packages had not been approved for this use by the FDA, which regulates medical devices as well as drugs.

Under the civil settlement, Serono Inc. agreed to pay a total of $567.1 million to the federal and state governments to settle allegations that it promoted Serostim for an unapproved use (the treatment of "body cell mass" wasting) and that it knowingly caused false or fraudulent claims to be submitted to the Medicaid program for medically unnecessary prescriptions.[33] Of this amount, the federal share was $305.1 million, while the States received $262 million. Four whistleblowers received a total of $51.9 million, paid by the federal government from its share.

The civil settlement, in turn, was contingent on guilty pleas by Serono Laboratories, an affiliate of Serono's U.S. subsidiary. Serono Laboratories pleaded guilty to

32. *U.S. ex rel. Driscoll v. Serono Laboratories,, Inc.*, C.A. No. 00-11680 (D. Mass. August 17, 2000). Department of Justice, "Serono to Pay $704 Million for the Illegal Marketing of AIDS Drug," October 17, 2005, *available at* www.usdoj.gov/opa/pr/2005/October/05_civ_545.html (last visited February 14, 2007).

33. The federal government also alleged that Serono caused false or fraudulent claims for Serostim to be submitted to FEHBP, TRICARE, and the Department of Veterans Affairs as well as Medicaid.

conspiring with the manufacturer of the unapproved BIA device to increase the market for the device in order to increase the market for Serostim. Serono Laboratories also pleaded guilty to conspiring to offer "thought leader" physicians an all-expense paid trip to an international conference on nutrition and HIV infection in Cannes, France, in return for the physicians writing up to 30 additional prescriptions of Serostim (which, at $21,000 per course of treatment, would generate $630,000 in sales). As a result of its two criminal conspiracy pleas, Serono Laboratories is excluded from participation in Medicaid, Medicare, or any other federal health care program for at least five years. Serono, through its U.S. subsidiary Serono, Inc., will be able to continue to participate, subject to the five-year CIA into which it entered with the HHS Office of Inspector General (Table 3).

In February, 2006, a class action was filed against Serono by consumers and third party payors alleging that Serono's illegal promotion of Serostim caused them to purchase prescriptions that were not medically necessary. The case is currently pending in the U.S. District Court for the District of Massachusetts.[34]

Schering-Plough III. As discussed above, on August 29, 2006, the Schering-Plough Corporation entered into a global settlement of criminal and civil allegations, including allegations relating to concealment of best price. The settlement also resolved allegations relating to off-label marketing of certain oncology drugs, including Temodar and Intron A. The FDA had approved Intron A for various conditions including chronic hepatitis B, chronic hepatitis C, and malignant melanoma. The allegations were the Schering-Plough Sales Corporation, a subsidiary of Schering-Plough, promoted Intron A for treatment of superficial bladder cancer. Similarly, the FDA had approved Temodar for the treatment of three specific types of brain cancers. The Sales Corporation was alleged to have promoted the use of Temodar for other types of brain tumors and metastases. In addition, the government alleged that the Sales Corporation induced physicians to prescribe Temodar and Intron A for these unapproved uses through illegal remuneration in the form of improper preceptorships, advisory boards, entertainment, and placement of clinical studies. These actions, the government alleged, caused the submission of false or fraudulent claims to Medicaid and other federal health care programs.

Schering-Plough settled its civil liabilities for a total of $255 million. Of this amount, $159.5 million was allocated to the federal government for losses to Medicare, Medicaid, and other federal programs; $91.6 million was distributed among the states and the District of Columbia for their share of the losses to Medicaid; and the remaining $3.9 million was paid to community health centers and other PHS entities. (The whistleblowers' share of the settlement has not yet been resolved.) Schering Plough Sales Corporation pleaded guilty to conspiracy for making false statements to HCFA (the federal Medicaid agency) by concealing the best price of Claritin RediTabs and for making false statements to the FDA to avoid scrutiny of its off-label promotion of

34. *Government Employees Hospital Association v. Serono International, S.A.*, MDL No. 1456, C.A. No. 05-cv-11935 (PBS) (D.Mass. Feb. 13, 2006), *available at* http://www.prescriptionaccess.org/index.php?doc_id=997 (last visited February 14, 2007).

Temodar. According to the criminal information, pre-tax profits to Schering-Plough as a result of the off-label marketing of Temodar and Intron A amounted to $124.2 million. The Sales Corporation agreed to pay a criminal fine of $180 million and is permanently excluded from participation in Medicaid, Medicare, and other federal health care programs.

As part of the global settlement, Schering-Plough also agreed to an addendum to the CIA it entered into in July 2004 in *Schering-Plough II*. Under the expanded CIA, Schering-Plough is required to implement three different measures designed to identify potential off-label marketing of any of its products over the five year period covered by the addendum. These measures include monitoring of marketing activities by the company's field sales force; monitoring of responses to requests from physicians for information about off-label uses; and periodic studies of physician recall of marketing messages delivered by the company's sales forces with respect to particular drugs. The CIA also requires Schering-Plough to retain an Independent Review Organization (IRO) to monitor its policies and procedures to determine whether these measures are being implemented and whether off-label marketing is occurring. The findings must be reported annually to the OIG.[35]

TRENDS IN DRUG MANUFACTURER FCA SETTLEMENTS

Two important trends emerge from a review of the drug manufacturer FCA settlements to date. The first has to do with the increasing attention to off-label marketing. The second concerns an increased focus on fraud against Medicaid.

Off-Label Marketing

The 2001 *TAP Pharmaceuticals* case is still the largest of the FCA settlements by a drug manufacturer as measured by total civil and criminal recoveries ($875 million). And, as discussed above, the conduct at issue in that case—marketing the spread and concealment of best price—continues to be the basis of whistleblower settlements with drug manufacturers. But it seems clear that the off-label marketing of drugs has also become increasingly significant as a basis for FCA liability. The 2004 settlement with Pfizer and its Warner-Lambert subsidiary concerning allegations of off-label marketing of Neurontin *(Pfizer II)*, the 2005 *Serono* settlement, and the *2006 Schering-Plough III* settlement, are, after *TAP Pharmaceuticals*, the three largest settlements in whistleblower FCA cases, as measured by total civil and criminal recoveries ($430 million, $704 million, and $435 million, respectively). To underscore DOJ's interest in this area, the Deputy Attorney General Paul J. McNulty, in announcing the *Schering-Plough III* settlement last August, stressed the importance of curbing off-label marketing beyond reducing unnecessary spending by Medicaid and other federal health programs: "It is vital to public health and safety that pharmaceutical companies are

35. *Addendum to Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation*, August 25, 2006, pp. 5–7, *available at* http://www.oig.hhs.gov/fraud/cia/index.html (last visited February 14, 2007).

deterred from improperly marketing their drugs to doctors and patients to treat illnesses that these drugs are not approved to treat."[36]

Medicaid Fraud

A previous report for TAFEF concluded that, between 1997 and 2001, most FCA activity involving health care focused on fraud against Medicare rather than Medicaid.[37] Medicare FCA recoveries continue to outpace federal Medicaid FCA recoveries; between FY 2001 and FY 2005, $6.2 billion was returned to the Medicare Trust Fund, while $416 million in federal Medicaid recoveries were transferred to the Centers for Medicare & Medicaid Services.[38] Nonetheless, since 2001 Medicaid FCA recoveries to both the federal and state governments have grown substantially, largely as the result of the drug manufacturer settlements. The top ten largest FCA settlements of allegations of fraud against Medicaid to date are listed below. Every one involves a drug manufacturer. All but one of these cases *(Abbott Laboratories)*, accounting for over 97 percent of the recoveries, were brought by whistleblowers. In each case in which the whistleblower is known, the whistleblower was an employee of the settling company or a subsidiary, or an employee of a competitor.

Largest Medicaid Settlements Under the False Claims Act

Rank	Case (Settlement Date)*	Settlement Amount**
1	Serono (10/17/05)	$567.1 million
2	Schering-Plough II (7/29/04)	$282.4 million
3	Schering-Plough III (8/29/06)	$251.1 million
4	Bayer II (4/16/03)	$242.1 million
5	Pfizer II (Warner-Lambert) (5/13/04)	$152 million
6	King Pharmaceuticals (10/30/05)	$124.1 million
7	GlaxoSmithKline I (4/16/03)	$85.1 million
8	TAP Pharmaceuticals (10/3/01)	$56.7 million
9	Abbott Laboratories (7/23/03)	$50.2 million
10	Pfizer I (10/28/02)	$49.0 million
	Total Medicaid Recoveries	**$1.86 billion**
	*Includes cases brought by government (9) and cases brought by whistleblowers (1–8, 10)	** Federal and state recoveries to Medicaid. Amounts do not include Medicare recoveries or criminal fines

36. Press Release of Michael J. Sullivan, U.S. Attorney, District of Massachusetts," Schering to Pay $435 Million for the Improper Marketing of Drugs and Medicaid Fraud," August 29, 2006, *available at* http://www.usdoj.gov/usao/ma/schering-plough.html (last visited February 14, 2007).

37. Schneider, *Reducing Medicaid Fraud: The Potential of the False Claims Act* (June 2003), *available at* www.taf.org (last visited February 14, 2007).

38. Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Account Annual Reports*, FY 2001 through FY 2005, *available at* http://www.oig.hhs.gov/reading/hcfac.html (last visited February 14, 2007).

IMPACT ON MEDICARE AND MEDICAID PRESCRIPTION DRUG POLICIES

The FCA whistleblower cases against drug manufacturers have had a demonstrable impact on Medicare and Medicaid prescription drug policy. The contribution is sometimes visible to the public, as when the whistleblower in *Schering-Plough II* testified before the Senate Finance Committee as it considered ways to reduce waste, fraud and abuse in Medicare and Medicaid.[39] The contribution of these cases is often less obvious, however, in part because they often remain out of public view while agency staff identify program vulnerabilities exposed by the whistleblowers and develop policy solutions.

Medicare

As seen in Table 2, four of the sixteen settlements *(TAP Pharmaceuticals, AstraZeneca, GlaxoSmithKline II,* and *Schering-Plough III)* include recoveries for allegations of fraud against Medicare. The Medicare recoveries in these settlements total $950 million, or about one third of the total civil recoveries to date. Congressional concern about the marketing the spread conduct underlying these settlements helped to bring about policy changes in Medicare Part B reimbursement for physician-administered drugs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) eliminated the use of Average Wholesale Price (AWP) as a basis for establishing reimbursement for physician-administered drugs under Medicare Part B and substituted the Average Sales Price (ASP) plus six percent, effective January 1, 2005. [40] ASP was first used in the corporate integrity agreements in connection with the 2001 *TAP Pharmaceuticals* and 2003 *AstraZeneca* settlements.

Medicaid

The drug manufacturer settlements have also prompted a Congressional reexamination of Medicaid policies vis-à-vis drug rebates and drug price disclosure. Under the Deficit Reduction Act of 2005 (DRA), the Secretary of HHS is required to promulgate a regulation by July 1, 2007, clarifying how average manufacturer prices (AMP) are determined for purposes of calculating the Medicaid rebate.[41] In developing this

39. Testimony of Beatrice Manning before the Committee on Finance, U. S. Senate, August 29, 2005, *available at* http://www.finance.senate.gov/sitepages/hearing062905.htm (last visited February 14, 2007).

40. Section 303 of P.L. 108-173, adding a new section 1847A, Use of Average Sales Price Methodology, to the Social Security Act. A June 2005 Office of Inspector General study of over 2000 drug codes found that, on average, ASPs were 26 percent below AWP for sole source brand-name drugs and 68 percent below AWP for generic drugs. OIG, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*, OEI-003-05-00200, June 2005, p. 8, *available at* www.oig.hhs.gov/oei/reports (last visited February 14, 2007).

41. Section 6001(c)(3) of P.L. 109-171. The Centers for Medicare & Medicaid Services (CMS) published a proposed rule on December 22, 2006 (71 *Fed. Reg.* 77174). Unlike average wholesale price (AWP) or wholesale acquisition cost (WAC), both of which are "catalogue" or "sticker" prices published by manufacturers, AMP, to a large extent, reflects actual transactions: it is the average price paid by wholesalers and retail pharmacies to manufacturers for drugs dispensed through retail pharmacies. AMP does not reflect rebates paid by manufacturers to Medicaid or pharmacy benefit managers (PBMs).

regulation, the Secretary is required to consider recommendations from the OIG.[42] And in order to increase transparency, the Secretary of HHS is required to provide on a monthly basis to States the AMPs reported by manufacturers for brand-name and generic drugs and to post this price data on a website accessible to the public.[43]

Under prior law, disclosure of AMP data was prohibited; the DRA extinguished this constraint effective January 1, 2007.[44] State Medicaid programs are now able to use this data to more closely align the prices they pay to pharmacists for drugs with the pharmacists' actual acquisition costs. As the Congressional Budget Office recently noted, and as the *Baxter*, *Dey*, *Roxane*, and *Schering-Plough I* cases confirm, list prices of drugs such as AWP "are not good predictors of actual transaction prices for generic drugs as they are for single-source brand-name drugs."[45] Thus, the availability of AMP data should be especially helpful to States in determining what to pay pharmacists for generic drugs.

The DRA also tightens the "nominal price" exclusion from the Medicaid best price calculation in order to address abuse of this exclusion for marketing purposes, as highlighted by whistleblower allegations in FCA cases.[46] In contrast to its termination of AWP as a reference price for drugs covered by Part B, Congress has not prohibited state Medicaid programs from continuing at their option to use AWP as a reference point for payments to pharmacists for covered drugs. However, class action litigation in federal court in Massachusetts raises questions about the long-term viability of AWP.[47]

The DRA also establishes financial incentives for states to enact their own false claims acts with whistleblower provisions addressing false or fraudulent claims against Medicaid.[48] While this DRA provision is not specific to drug manufacturers, it was advocated before the originating Congressional committee in testimony that discussed the use of the Texas false claims act to recover losses to the state's Medicaid program from marketing of the spread by certain generic drug manufacturers.[49]

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42. OIG, *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005* (A-06-06-00063), May 2006, discussed at 71 *Fed. Reg.* 77177–77189 (December 22, 2006).

43. Section 6001(b) of P.L. 109-171. The requirement, originally effective July 1, 2006, has been postponed.

44. 71 *Fed. Reg.* at 77175 (December 22, 2006).

45. Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (January 2007), p. 52, *available at* www.cbo.gov (last visited February 14, 2007).

46. Section 6001(d) of P.L. 109-171. In *State of Nevada ex rel. Steinke v. Merck & Company, Inc.*, 2006 WL 1506901 (D. Nev. May 31, 2006), the whistleblower alleges the Merck violated the FCA by failing to report as "best prices" for Medicaid rebate purposes discounts of 92 percent off of catalogue price of Vioxx and Zocor given to hospitals in exchange for the hospital's commitment to maintain a specified market share for each drug. The case is discussed at 42 *False Claims Act & Qui Tam Quarterly Review* 33 (July 2006).

47. One of the leading drug price reporting firms, First DataBank, recently settled a class action complaint alleging manipulation of AWP prices based on the ratio of AWP to Wholesale Acquisition Cost (WAC), the price reported by drug manufacturers as the average amounts paid by pharmacies to wholesalers. Settlement Agreement and Press Release (October 6, 2006), *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, C.A. No. 1:05-CV-11148-PBS (D. Mass.), *available at* www.prescriptionaccess.org (last visited February 14, 2007). As part of the settlement, First DataBank agreed to stop publishing AWP data within two years.

48. Section 1909 of the Social Security Act, 42 U.S.C. § 1396h, as added by section 6031 of P.L. 109-171. Office of Inspector General guidance was published at 71 *Fed. Reg.* 48552 (August 21, 2006). OIG reviews of individual state FCAs are posted at http://oig.hhs.gov/fraud/falseclaimsact.html (last visited February 14, 2007).

49. *See* Testimony of Patrick J. O'Connell, *op. cit.*; Testimony of James Moorman, President and Chief Executive Of-

CONCLUDING OBSERVATIONS

This report has focused on recoveries to the federal and state governments resulting from FCA whistleblower cases against drug manufacturers. Although these amounts are large, they almost certainly understate the savings that the FCA and its whistleblower provisions are producing for the federal and state governments with respect to Medicaid spending on prescription drugs. Health economist Jack Meyer has noted that FCA settlements of allegations of fraud against the Medicare program have indirect, non-quantifiable benefits in the form of increased compliance and deterrence of fraudulent conduct.[50] This observation has equal force in the Medicaid context. In all likelihood, the sixteen settlements to date, along with the ten corporate integrity agreements (CIAs) in place, will promote compliance with Medicaid program requirements (and with FDA off-label marketing prohibitions) by all drug manufacturers, not just those directly affected.

It is clear that there will be more settlements, and that some of them will be large. In August 2006, the Assistant Attorney General told the Congress that there are "over 180 matters involving fraud allegations against pharmaceutical manufacturers and other entities" on the DOJ docket.[51] In December 2006, Bristol-Myers Squibb Company announced that it had agreed to pay $499 million to settle allegations relating to fraudulent pricing and marketing of drugs for the treatment of schizophrenia and bipolar disorder.[52] In addition, DOJ intervened in two FCA whistleblower cases in 2006. In May of that year, DOJ announced its intervention in a whistleblower case alleging that Abbott Laboratories' Hospital Products Division violated the FCA by marketing the spread on certain drugs purchased by Medicare and Medicaid since 1991.[53] In September 2006, DOJ intervened in another marketing the spread case involving Dey, Inc.[54] Presumably, DOJ would not join these actions unless it believed

ficer, Taxpayers Against Fraud, before the Committee on Finance, U.S. Senate, June 29, 2005, pp. 4–5, *available at* www.finance.senate.gov (last visited February 14, 2007).

50. Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck* (July 2006), p. 4, *available at* www.taf.org (last visited February 14, 2007).

51. Written Responses of Peter D. Keisler , Assistant Attorney Geenral, Civil Division, Department of Justice, before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, Hosue of Representatives, August 11, 2006, p. 6.

52. Kaiser Daily Health Policy Report, "Bristol-Myers Squibb Agrees To Settle Federal Investigation of Pricing, Sales, Marketing Practices for $499M," December 22, 2006, *available at* www.kaiserhealthnetwork.org (last visited February 14, 2007).

53. DOJ Press Release, "United States Intervenes in Suit Against Abbott Laboratories, Inc.," May 23, 2006, *available at* http://www.usdoj.gov/opa/pr/2006/May/06_civ_309.html (last visited February 14, 2007). According to the Press Release, "The government's complaint alleges that from at least on or before January 1, 1991 Abbott's Hospital Products Division (HPD) reported prices that were more than 10 times (1000 percent) the actual sales prices on many of the drugs it manufactures. The United States alleges that federal healthcare programs, both Medicare and Medicaid, have reimbursed Abbott's customers in excess of $175 million for the drugs which are the subject of the complaint."

54. DOJ Press Release, "United States Joins Suit Against Dey," September 11, 2006, *available at* http://www.usdoj.gov/opa/pr/2006/September/06_civ_605.html (last visited February 14, 2007). According to the Press Release, "The government's complaint alleges that the pharmaceutical manufacturer from at least on or before January 1, 1993 reported prices that were more than five times (500 percent) the actual sales prices on many of the drugs it manufactures. The United States alleges that Medicare and Medicaid have reimbursed Dey's customers in excess of $500 million for the drugs which are the subject of the complaint. Dey sells generic drugs that are reimbursed by the two federal health care programs."

the claims to be meritorious. Of course, the final outcomes remain to be determined. It is highly likely, however, that the named manufacturers, as well as their competitors, will be focused on the disposition of these cases and the alleged conduct from which they arose.

TABLE 1. Whistleblower Cases Under Federal and State False Claims Acts Settled with Prescription Drug Manufacturers as of September 30, 2006

Company	Settlement Date	Product	Total Recovery	Type of Fraud Alleged	Whistleblower
AstraZeneca	6/20/03	Zoladex (prostate cancer)	$355 million	Marketing the spread Concealment of Best Price	Sales executive of competitor TAP Pharmaceuticals
Baxter*	6/13/06	Intravenous fluids, injectables	$8.5 million	Marketing the spread	Specialty pharmacy
Bayer I	1/23/01	Kogenate, Koate-HP (hemophilia) Gamimmune (immune deficiency)	$14 million	Marketing the spread Concealment of Best Price	Specialty pharmacy
Bayer II	4/16/03	Adalat CC (blood pressure) Cipro (antibiotic)	$257 million	Concealment of Best Price	Bayer marketing executive
Dey*	6/11/03	Albuterol Sulfate and Ipratropium Bromide (asthma inhalants)	$18.5 million	Marketing the spread	Specialty pharmacy
GlaxoSmith-Kline I	4/16/03	Paxil (antidepressant) Flonase (nasal allegy spray)	$88 million	Concealment of Best Price	(derived from Bayer marketing executive allegations)
GlaxoSmith-Kline II	9/20/05	Zofran, Kytril (antiemetics)	$149 million	Marketing the spread	Specialty pharmacy
King Pharmaceuticals	10/30/05	Entire produce line, including Altace (heart attack and stroke risk reduction)	$124 million	Concealment of Best Price	Director of National Accounts at a King subsidiary
Pfizer I	10/28/02	Lipitor (cholesterol)	$49 million	Concealment of Best Price	National account manager for Pfizer subsidiary
Pfizer II (Warner-Lambert)	5/13/04	Neurontin (anti-seizure for epilepsy)	$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
Roxane Laboratories*	11/25/05	Albuterol drugs (asthma inhalants)	$10 million	Marketing the spread	Specialty pharmacy
Schering-Plough I* (Warrick)	5/3/04	Albuterol drugs (asthma inhalants)	$27 million	Marketing the spread	Specialty pharmacy

Company	Settlement Date	Product	Total Recovery	Type of Fraud Alleged	Whistleblower
Schering-Plough II	7/29/04	Claritin family of products (non-sedating antihistamines)	$345 million	Concealment of Best Price	Three employees at Schering-Plough subsidiary
Schering-Plough III	8/29/06	Claritin RediTabs; K-Dur 20 (potassium supplement); Temodar, Intron A (oncology drugs)	$435 million	Concealment of Best Price	Three Schering-Plough sales representatives
Serono	10/17/05	Serostim (AIDS wasting)	$704 million	Off-label marketing, kickbacks	Five Serono employees in two states
TAP Pharmaceuticals	10/3/01	Lupron (prostate cancer)	$875 million	Marketing the spread Concealment of Best Price	HMO physician and TAP sales executive

* Settled under Texas Medicaid Fraud Prevention Act

TABLE 2. Recoveries in Whistleblower Cases Against Pharmaceutical Man ufacturers(Settlements as of September 30, 2006)

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Whistleblower's Share
AstraZeneca (6/20/03)	$355 million	$63.9 million	$266.1 million[55]	$24.9 million	$13.7 million	$11.2 million	$47.6 million
Baxter (6/12/06)	$8.5 million[56]	None	None	$8 million	$4.8 million	$3.2 million	$1.7 million
Bayer I (1/23/01)	$14 million	None	None	$14 million	$7.8 million	$6.2 million	$1.6 million
Bayer II (4/16/03)	$257 million[57]	$5.6 million	None	$242.1 million	$133.2 million	$108.9 million	$34.2 million
Dey (6/11/03)	$18.5 million[58]	None	None	$16.2 million	$9.2 million	$7.0 million	$3.2 million
GlaxoSmith-Kline I (4/16/03)	$88 million[59]	None	None	$85.1 million	$46.8 million	$38.3 million	None
GlaxoSmith-Kline II (9/20/05)	$149 million	None	$125.9 million	$24 million	$13.72 million	$10.35 million	$26 million
King Pharm. (10/30/05)	$124.1 million[60]	None	None	$124.1 million	$73.4 million	$50.6 million	$7.5 million
Pfizer I (10/28/02)	$49 million	None	None	$49 million	$27.9 million	$21.1 million	$5.9 million
Pfizer II (5/13/04)	$430 million[61]	$240 million	None	$152 million	$83.6 million	$68.4 million	$24.6 million
Roxane (11/25/05)	$10.1 million[62]	None	None	$7.1 million	$4.2 million	$2.9 million	$1.6 million
Schering-Plough I (Warrick) (5/3/04)	$27 million[63]	None	None	$20 million	$12 million	$8 million	$4.6 million

55. This amount includes payments to settle claims by TRICARE and Department of Defense.

56. This amount includes payment of $500,000 in costs and fees to relator and state of Texas.

57. This amount includes Bayer payments of $9.5 million to PHS entities.

58. This amount includes payment of $2.3 million in costs and fees to relator and to state of Texas.

59. This amount includes GSK payments of $2.6 million to PHS entities.

60. This amount includes an unspecified amount of King Pharmaceuticals payments to PHS entities.

61. This amount includes Pfizer payments of $38 million to states for harm to consumers and to fund remediation program.

62. The amount includes $3.0 million payment for costs and fees to relator and state of Texas.

63. This amount includes $7.0 million payment for costs and fees to relator and state of Texas.

Manufacturer (settlement date)	Total Recovery	Criminal Fine	Medicare Recovery	Total Medicaid Recovery	Federal Medicaid Recovery	State Medicaid Recovery	Whistleblower's Share
Schering-Plough II (7/29/04)	$345.5 million[64]	$52.5 million	None	$282.4 million	$165.3 million	$117.1 million	$31.7 million
Schering-Plough III (8/29/06)	$435 million[65]	$180 million	$30.2 million[66]	$203.6 million	$112 million	$91.6 million	Not resolved
Serono (10/17/05)	$704 million	$136.9 million	None	$567.1 million	$305.1 million	$262.0 million	$51.9 million
TAP Pharmaceuticals (10/3/01)	$875 million	$290 million	$528.3 million	$56.7 million	$31.2 million	$25.5 million	$95.1 million
Totals	$3.89 billion	$968 million	$950 million	$1.88 billion	$1.04 billion	$833 million	$337 million

Source: Settlement agreements on file at TAF Education Fund library; Joyce Branda, Deputy Director, Commercial Litigation Branch, Civil Division, DOJ (9/6/06); Patrick O'Connell, Assistant Attorney General, State of Texas (9/4/06).

Note: Columns do not add across. Medicare Recovery, and Federal and State Medicaid Recovery columns present gross recoveries, not amounts net of whistleblower's share.

64. This amount includes Schering-Plough payments of $10.6 million to PHS entities.

65. This amount includes Schering-Plough payments of $3.9 million to PHS entities and $17.3 million in disgorgement payments to the federal government.

66. This amount includes payments to settle claims by TRICARE and FEHBP.

TABLE 3. Obligations Under Corporate Integrity Agreements (CIAs) Whistleblower Cases Against Pharmaceutical Manufacturers (Settlements as of September 30, 2006)

Manufacturer (CIA effective date)	Term (Expiration Date)	Compliance Program[67]	Average Sales Price (ASP) Reporting	Independent Review Organization Review: Rebates	Independent Review Organization Review: Other	Annual Compliance Report
AstraZeneca (6/4/03)	5 years (2008)	Yes	Yes (8 products only)	Yes	Yes (sales and marketing; ASP reporting)	Yes
Bayer I (1/23/01)	5 years (incorporated into Bayer II)	Yes	Yes	Yes	Yes (compliance with CIA)	Yes
Bayer II (1/23/03)	6 years (2009)	Yes	Yes	Yes	Yes (managed care transactions)	Yes
GlaxoSmithKline I (4/15/03)	5 years (2008)	Yes	No	Yes	Yes (contract pricing)	Yes
GlaxoSmithKline II (9/20/05)	5 years (2010)	Yes	Yes	Yes	No	Yes
King (10/30/05)	5 years (2010)	Yes	No	Yes	No	Yes
Pfizer I (10/24/02)	5 years (2007)	Yes	No	Yes	Yes (managed care transactions)	Yes
Pfizer II (Warner-Lambert) (5/11/04)	5 years (2009)	Yes	No	Yes	Yes (managed care contracting; promotional services)	Yes
Schering-Plough II, III (7/29/04)	5 years (2009); Addendum III 5 years (2011)	Yes	Yes (9 products)	Yes	Yes (managed care expenditures; off-label marketing)	Yes

67. Compliance Program includes written standards of conduct; compliance officer and compliance committee; education and training programs for relevant employees; disclosure mechanism (e.g., employee hotline); and required reporting to OIG of probable violations of criminal or civil laws applicable to Federal health care programs.

Manufacturer (CIA effective date)	Term (Expiration Date)	Compliance Program[67]	Average Sales Price (ASP) Reporting	Independent Review Organization Review: Rebates	Independent Review Organization Review: Other	Annual Compliance Report
Serono (10/17/05)	5 years (2010)	Yes	No	No	Yes (off-label uses; educational grants)	Yes
TAP (9/28/01)	7 years (2008)	Yes	Yes	Yes	Yes (sales and marketing; ASP reporting; compliance with CIA	Yes

Source: Text of CIAs as posted on www.oig.hhs.gov (last visited February 14, 2007).

Legal Analysis

Who's On First: 31 U.S.C. § 3730(b)(5)

Who's On First: 31 U.S.C. § 3730(b)(5)

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Abbott: Let's see, we have on the bags … Who's on first, What's on second, I Don't Know is on third.

Costello: That's what I want to find out.[1]

Title 31 U.S.C. § 3730(b)(5) in the federal False Claims Act provides that a qui tam whistleblower cannot "intervene or bring a related action based on the facts underlying" a pending action. This generally means that when two or more qui tam cases are filed based on similar facts, only the first-filed case will survive. Accordingly, § 3730(b)(5) has come to be known as the "first-to-file rule" and is regarded by the courts as a jurisdictional bar.[2]

The first-to-file rule has been described as a "race to the courthouse."[3] A "race," however, implies that the contestants know of one another's existence. Typically, multiple qui tam plaintiffs, or relators, do not know there are other relators until well after they have paid their respective visits to the courthouse, complaints in hand. Frequently, they do not receive that unwelcome news until late in the evolution of the case. When that happens, one option is to agree amongst themselves on how to divide up the relator share and, in appropriate cases, how to work together to make their cases better and stronger.

For those unable or unwilling to craft such an agreement, the future is uncertain. This is not just because a consistent approach to "based on the facts underlying the pending action" has yet to emerge from the caselaw. It also is because there rarely will be two identical cases. Each will possess, to a greater or lesser degree, its own unique circumstances and perspectives on the alleged wrongdoing, as well as its own particular legal context. Nevertheless, we have done our best to extract from the cases as much guidance for the practitioner as we can in an inherently uncertain and evolving area. Part I of this paper explores the efforts of courts to parse out the meaning of "based on the facts underlying," and the attached chart provides a circuit-by-circuit summary of the caselaw. Part II discusses the meaning of "pending action" and two recent Circuit Court decisions that have allowed a second-filed case to survive where the first was subsequently dismissed. Part III discusses policy reasons articulated by the courts in first-to-file cases and Part IV contains some concluding observations.

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1. Abbott & Costello, Who's on First, available at www.abbottandcostello.net (last visited August 30, 2006).

2. "While § 3730(b)(5) is not one of the express 'jurisdictional bars' set forth at §§ 3730(e)(1)-(4), the practical effect of § 3730(b)(5)'s 'bar' is that a court lacks jurisdiction to hear, and must dismiss, an action that is a 'related action based on the facts underlying the pending action.'" United States *ex rel.* Merena v. Smithkline Beecham Clinical Labs, Inc., 1997 U.S. Dist. LEXIS 19896, 48, n. 21 (D. Pa. 1997) (citing Hyatt v. Northrop Corp., 1989 U.S. Dist. LEXIS 18941 (C.D. Cal. Dec. 27, 1989)).

3. Campbell, *ex rel.* United States v. Redding Med. Ctr., 421 F.3d 817, 821 (9th Cir. 2005).

I. "BASED ON THE FACTS UNDERLYING"

The first-to-file rule frequently is described by courts as an absolute, unambiguous "exception-free" rule.[4] This view is based on a plain language reading of § 3730(b)(5), which itself does not provide for any exceptions. Thus, for example, there is no exception for a second-filing relator who reported the allegations to the government before the filing of the first action.[5] Note however that two recent Circuit Court decisions have made inroads into the "absolute bar" rule. These are discussed in Part II.

A plain language reading of the statute also has led to universal agreement that the first-to-file rule does not mean that relators are only barred from pursuing subsequent suits if they are *identical* to earlier filed actions—because the statute refers to a "related action," not an identical one.[6]

Beyond that, the courts have articulated a variety of tests for deciding whether a second filed case is sufficiently similar to the first to be caught by the § 3730(b)(5) bar. Collectively, these tests fall into two groups: those that rely on a "same material elements/essential facts/core facts" analysis, and those that take a hybrid approach, adding to this analysis a "separate and distinct recovery" element. Either way, the courts agree that differences in detail, such as different times or places, or additional factual support, will not save a second-filed case.[7]

A. Rejecting the Identical Facts Theory

The identical facts test has been rejected by the courts despite this statement in the FCA's legislative history:

> Subsection (b)(5) of section 3730 further clarifies that only the Government may intervene in a qui tam action. While there are few known instances of multiple parties intervening in past qui tam cases, United States v. Baker-Lockwood Manufacturing Co., 138 F.2d 48 (8th Cir. 1943), the Committee wishes to clarify in the statute that private enforcement under the civil False Claims Act is not meant

4. United States *ex rel.* Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1183 (9th Cir. 2001), cert. denied, 534 U.S. 1040, 151 L. Ed. 2d 538, 122 S. Ct. 615 (2001); United States *ex rel.* LaCorte v. Wagner, 185 F.3d 188, 191 (4th Cir. 1999); United States *ex rel.* Fry v. Guidant Corp., 2006 U.S. Dist. LEXIS 29862, 18-20 (D. Tenn. 2006); Smith, 411 F. Supp. 2d at 75; United States *ex rel.* Tillson v. Lockheed Martin Energy Sys., 2004 U.S. Dist. LEXIS 22246, 17 (D. Ky. 2004); United States *ex rel.* Ortega v. Columbia Healthcare, 240 F. Supp. 2d 8, 12 (D.D.C. 2003); United States *ex rel.* Goodnight v. Texaco Exploration & Prod., Inc. (In re Natural Gas Royalties Quitam Litig.), 2002 U.S. Dist. LEXIS 27844, 9 (D. Wyo. 2002).

5. Lujan, for example, argued that "§ 3730(b)(5) should not bar her case because (1) her action could benefit the U.S. Treasury, (2) she was an original source, (3) she had personal knowledge of specific mischarging, and (4) she informed the government of her allegations and facts before the [first] action. We reject each contention, holding that § 3730(b)(5) does not provide for such exceptions." Lujan, 243 F. 3d 1181, 1187.

6. See infra, footnotes 12-19 and accompanying text.

7. See infra, footnotes 20-26 and accompanying text. Similarly, a recent district court decision held that relator cannot "bypass the first-to-file requirements of § 3730(b)(5)" by amending his or her complaint to include allegations which mirror those in a second relator's filed complaint. United States *ex rel.* Harris v. Alan Ritchey, Inc. et al., 2006 U.S. Dist. LEXIS 91921, 15 (W.D. Wash. 2006) ("Amending the Complaint to include factually distinct new allegations first raised in another case is indistinguishable from filing a new action based on already-filed allegations, which is prohibited by § 3730(b)(5)").

> to produce class actions or multiple separate suits based on identical facts and circumstances.[8]

Other than one subsequently overruled District Court decision in 1997, no reported decisions have adopted an identical facts test.[9] Courts have taken the position that since the plain language of § 3730(b)(5) refers unambiguously to a "related" and not an "identical" action, there is no need to consult the legislative history.[10] "Giving each word its ordinary meaning, the phrase 'related action based on the facts underlying the pending action,' clearly bars claims arising from events that are already the subject of existing suits. A later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar."[11]

B. Same Material Elements/Essential Facts/Core Facts

The Third,[12] Ninth,[13] and DC[14] Circuit Courts of Appeal have adopted a "same material elements" test which would bar any qui tam complaint which is based upon the "'same material elements of fraud' as an earlier suit, even if the allegations 'incorporate somewhat different details.'"[15] The same material elements test had been earlier articulated in United States *ex rel*. Merena v. Smithkline Beecham Corp., 1997 U.S. Dist. LEXIS 19896 (D. Pa. 1997), which found that "[t]he 'facts underlying' a qui tam action (or any action for that matter) are not merely the details regarding the time and place of the alleged fraud…; they are, as the plain meaning of 'facts underlying' more broadly suggests, the allegations regarding the material elements of a fraudulent transaction which will support a claim for relief under the FCA[.]"[16]

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8. S. Rep. No. 99-345, at 25 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5290; see also, Lujan, 243 F.3d at 1188.

9. United States *ex rel*. Dorsey v. Dr. Warren E. Smith Community Mental Health/Mental Retardation and Substance Abuse Ctrs., 1997 U.S. Dist. LEXIS 9424 (E.D. Pa. June 25, 1997) (an unpublished decision which employed the identical facts test); implicitly overruled by United States *ex rel.* St. John LaCorte v. Smith-Kline Beecham Clinical Labs., Inc. 149 F.3d 227, 232-34 (3d Cir. 1998).

10. Lujan, 243 F.3d at 1189; see also, Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279-1280 (10th Cir. 2004) ("An identical facts test would be contrary to the plain meaning of the statute, which speaks of 'related' qui tam actions, not identical ones"); see also, United States *ex rel*. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 218 (D.C. Cir. 2003) ("It might be argued that a single sentence from the legislative history, which states that 'private enforcement under the civil False Claims Act is not meant to produce class actions or multiple separate suits based on identical facts and circumstances,' S. REP. NO. 99-345, at 25 (1986), supports such a test. But § 3730(b)(5) does not say that the later action must rest on identical facts, and the purposes of the qui tam provisions are against such a reading").

11. LaCorte, 149 F.3d at 232-233 (quoting Hyatt, 883 F. Supp. at 485 n.3 (C.D. Cal. 1995) ("§ 3730(b)(5) 'bars qui tam actions based on matters subject to earlier filed actions'"). "Moreover an identical facts test might decrease incentives for relators to report fraud promptly, while encouraging duplicative lawsuits which are unlikely to increase total recovery." United States *ex rel*. Capella v. United Techs. Corp., 1999 U.S. Dist. LEXIS 10520, 23-24 (D. Conn. 1999) (citing LaCorte, 149 F.3d at 232 (3d Cir. 1998)).

12. LaCorte, 149 F.3d at 232-34.

13. Lujan, 243 F.3d at 1189.

14. Hampton, 318 F.3d at 217-218.

15. Hampton, 318 F.3d at 217 (D.C. Cir.) (quoting Lujan, 243 F.3d at 1189; citing LaCorte, 149 F.3d at 232-34 (3d Cir. 1998)).

16. Merena, 1997 U.S. Dist. LEXIS 19896, 54 (citing Wilkins *ex rel*. United States v. State of Ohio, 885 F. Supp. 1055, 1059-60 (S.D. Ohio 1995)).

Similarly, in Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279-1280 (10th Cir. 2004), the Tenth Circuit held that "so long as a subsequent complaint raises the same or a related claim based in significant measure on the core facts or general conduct relied upon in the first qui tam action, the § 3730(b)(5)'s first-to-file bar applies."[17] The Grynberg court used the "same material elements" language it its decision:

> The pendency of the initial qui tam action consequently blocks other private relators from filing copycat suits that do no more than assert the *same material elements* of fraud, *regardless of whether those later complaints are able to marshal additional factual support* for the claim.[18]

The Sixth Circuit, in Walburn v. Lockheed Martin Corp., 431 F.3d 966 (6th Cir. 2005), cited the above decisions of the Third, Ninth, D.C. and Tenth Circuits in holding that a complaint which alleges "all the essential facts of the underlying fraud" will be barred even if it incorporates slightly different details.[19]

C. The Hybrid Test: Different Material Facts and Separate and Distinct Recovery by the Government

In Erickson *ex rel.* United States v. American Inst. of Biological Sciences, 716 F. Supp. 908 (E.D. Va. 1989), the court held that "[a] subsequently filed qui tam suit may continue only to the extent that it (a) is based on facts different from those alleged in the prior suit and (b) gives rise to separate and distinct recovery by the government."[20] This "hybrid" test has been followed twice in the District of Connecticut but specifically rejected in the Eastern District of Pennsylvania.

In United States *ex rel.* Capella v. United Techs. Corp., 1999 U.S. Dist. LEXIS 10520 (D. Conn. 1999), the District of Connecticut concluded "that section 3730(b)(5) bars a later claim unless: (1) it alleges a different type of wrongdoing, based on different material facts than those alleged in the earlier suit; and (2) it gives rise to a separate recovery of actual damages by the government. In applying this standard, the court asked whether the earlier and later actions possess the typical qualities of a parasitic relationship, such that the subsequent suit receives support or advantage without offering any useful or proper return."[21]

17. Grynberg, 390 F.3d at 1279.

18. Id. (emphasis added).

19. Walburn v. Lockheed Martin Corp., 431 F.3d 966, 971 (6th Cir. 2005), rehearing, en banc, denied by Walburn v. Lockheed Martin Corp., 2006 U.S. App. LEXIS 9228 (6th Cir. 2006).

20. Erickson *ex rel.* United States v. American Inst. of Biological Sciences, 716 F. Supp. 908, 918 (E.D. Va. 1989).

21. Capella, 1999 U.S. Dist. LEXIS 10520, 27. "[A] court should look first to whether the two cases can properly be viewed as having the qualities of a host/parasite relationship. In answering this question, we think it would be useful for the court to be guided by the definition of the word 'parasite,' and ask whether the qui tam case is receiving 'support, advantage, or the like' from the 'host' case (in which the government is a party) 'without giving any useful or proper return' to the government (or at least having the potential to do so)." United States *ex rel.* S. Prawer & Co. v. Fleet Bank, 24 F.3d 320, 328 (1st Cir. 1994) (citing Random House Dictionary of the English Language 1409 (2d ed. unabridged 1987). In Ortega, 240 F. Supp. 2d 8, the District of Columbia adopted the hybrid test (but see supra, footnote 22) but disagreed that "actual damages" were the appropriate measure of a separate recovery: The "use of the phrase 'actual damages' clouds rather than clarifies the issue." According to the Ortega court, "actual damages are only one element of the government's recovery, and an

The Cappella approach—minus the "parasitic relationship" part of the analysis—was followed in that District in 2003, in United States *ex rel.* Smith v. Yale-New Haven Hosp., Inc., 411 F. Supp. 2d 64 (D. Conn. 2005): "This Court agrees that the hybrid approach is helpful looking to whether the complaints allege the same material facts, i.e. whether they involve the same core conduct, and would give rise to separate recovery."[22]

The hybrid analysis, however, has its critics. The Eastern District of Pennsylvania rejected it "because it seems to further complicate the already difficult task of applying § 3730(b)(5)."[23] In the court's view, "Erickson impermissibly reads into § 3730(b)(5) the requirement that a qui tam claim 'give rise to a separate and distinct recovery' when there is no such language or requirement in § 3730(b)(5); that section only requires that a court determine whether an action is barred because it is a 'related action based on the facts underlying the pending action.' Moreover, it is unclear what meaning should be given to 'gives rise to a separate and distinct recovery for the government.'"[24]

II. "PENDING ACTION" AND SUBSEQUENT DISMISSAL OF THE FIRST-FILED CASE

An action is "pending" when it is filed.[25] Accordingly, in Lujan, the Ninth Circuit held that an action that is dismissed after the filing of a later case is still a "pending action" for the purpose of § 3730(b)(5). "'To hold that a later dismissed action was not a then-pending action would be contrary to the plain language of the statute and the legislative intent."[26]

In Lujan, the first-filed case was dismissed on the merits. Recently, courts have allowed second-filed cases to survive where the original case was dismissed for other reasons. The Ninth Circuit, distinguishing Lujan, held in 2005 that a complaint that is jurisdictionally barred by reason of public disclosure does not bar a later filed case.[27] The Sixth Circuit, also in 2005, held that, if the first complaint is legally infirm under Fed. R. Civ. P. 9(b), the second complaint will survive. The Sixth Circuit, also in 2005, held that if the first complaint is legally infirm under Fed. R. Civ. P. 9(b), the second complaint will survive, not because it is not a "pending action," but because according

examination of whether the government will have a separate recovery under a later-filed suit should take all possible forms of recovery into account." Id. at 13.

22. United States *ex rel.* Smith v. Yale-New Haven Hosp., Inc., 411 F. Supp. 2d 64, 76 (D. Conn. 2005), vacated in part by, United States ex rel. Smith v. Yale Univ., 2006 U.S. Dist. LEXIS 24847 (D. Conn. 2006). In Ortega, 240 F. Supp. 2d 8, the District of Columbia also adopted the hybrid standard. The Ortega decision came down on January 15, 2003 (decided and filed). The appeal in Hampton, 318 F.3d at 214 (D.C. Cir. 2003) was argued on November 1, 2002, and decided on February 7, 2003. The Court of Appeals in Hampton adopted a simple "same material elements" test without any reference to Ortega. Therefore, it is doubtful whether the hybrid test in Ortega would be followed in the District of Columbia.

23. Merena, 1997 U.S. Dist. LEXIS 19896, note 22.

24. Id.

25. "Section 3730(b)(5) prohibition attaches when a party 'brings an action.' A party brings or commences an action by filing a complaint (or counterclaim)." United States v. Kinder Morgan Co2 Co., L.P., 2005 U.S. Dist. LEXIS 31103, 6 (D. Colo. 2005) (citing Fed. R. Civ. P. 3).

26. Lujan, 243 F.3d 1181, 1187.

27. Campbell, 421 F.3d at 822-825.

preemptive effect to an overly-broad complaint would discourage whistleblowers from notifying the government of potential frauds.[28]

To that extent, these two recent decisions represent a challenge to the "absolute, exception-free" rule so often articulated by the courts.

A. First Complaint Barred by Public Disclosure

In Campbell *ex rel.* United States v. Redding Medical Center, et al., 421 F.3d 817 (9th Cir. 2005), the Ninth Circuit held that a second-filed case is not barred by a first-filed case that is itself barred by public disclosure. In that case, the first case was filed five days after the publication of a search warrant authorizing the FBI to investigate the defendant. Campbell's case was filed three days later. The District Court granted the government's motion to dismiss Campbell's suit on the basis that it was barred by § 3730(b)(5). Campbell appealed, arguing that since the relators in the first case were not "original sources" under § 3730(e)(4)(b), their case was barred by public disclosure and it was not a "pending action" under §3730(b)(5). The appellate court agreed that § 3730(b)(5) does not create an absolute bar when the first complaint is jurisdictionally defective:

> Construing § 3730(b)(5) to create an absolute bar would permit opportunistic plaintiffs with no inside information to displace actual insiders with knowledge of the fraud. The government conceded at oral argument that under its interpretation of § 3730(b)(5), a purely frivolous sham complaint filed in an instance where the allegations had been publicly disclosed would bar a subsequently filed action by an original source. This cannot be what Congress intended.[29]

Distinguishing Lujan on the basis that the first-filed case was dismissed on the merits, the court summed up its decision by holding that, "in a public disclosure case, the first-to-file rule of § 3730(b)(5) bars only subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of § 3730(e)(4)."[30]

B. First Complaint Overly Broad and Legally Infirm Under 9(b)

In Walburn v. Lockheed Martin Corp., 431 F.3d 966 (6th Cir. 2005), the Sixth Circuit held that a second-filed case was not barred by a prior complaint containing "broad and conclusory allegations" that were "legally insufficient under Rule 9(b) because they fail to provide 'the time, place, and content' of any allegedly fraudulent claim submitted to the government."[31]

28. Walburn, 431 F.3d at 973.

29. Campbell, 421 F.3d at 823.

30. Campbell, 421 F.3d at 822-825 (Distinguishing itself from Lujan where the first-filed case was dismissed on the merits, the court said "we do not believe the reasoning behind Lujan extends to a situation not presented in that case, where the first complaint filed does not fulfill the jurisdictional prerequisites established by 31 U.S.C. § 3730(e)").

31. Walburn, 431 F.3d at 972. The first relator's "allegations merely set forth that 'documents' and 'records' relating to the management and operation of the plant were falsified, without specifying the nature of the alleged falsifications." Id. In

The court held that "[o]nly a complaint that complies with Rule 9(b) can have preemptive effect under § 3730(b)(5)."[32]

> Lockheed argues that, notwithstanding the breadth of the *Brooks* allegations, a holding that only a complaint that complies with Rule 9(b) can have preemptive effect under § 3730(b)(5) carves out an exception from the "exception-free" first-to-file bar that undermines its policy of discouraging parasitic suits. *See Lujan*, 243 F.3d at 1187. However, we fail to see how according preemptive effect to a fatally-broad complaint furthers the policy of encouraging whistleblowers to notify the government of potential frauds. *See id*. A complaint that is insufficient under Rule 9(b) is dismissed precisely because it fails to provide adequate notice to the defendant of the fraud it alleges.[33]

Accordingly, "[i]f the first complaint filed is legally infirm under 9(b), the there will be no bar."[34] This position is supported by dicta in two prior cases. In Ortega, the District of Columbia, in finding that a complaint broadly alleging the time and location of a fraud would preempt a later-filed complaint containing more detailed allegations, observed that "[t]he strictures of Rule 9(b) limit the preclusive effect of the first-filed complaint to claims that can be pleaded with particularity, thus obviating the danger of opportunistic relators filing unsupported placeholder complaints for the sole purpose of preemption." [35] The court in that case cited United States *ex rel.* St. John LaCorte v. Smith-Kline Beecham Clinical Labs., Inc. 149 F.3d 227 (3d Cir. 1998), in which the Third Circuit rejected the argument that failing to adopt an "identical facts" test would allow a relator to file a broadly pled complaint in order to preempt later claims. The court noted that: "*Federal Rule of Civil Procedure 9(b)* requires plaintiffs to plead fraud with particularity, specifying the time, place and substance of the defendant's alleged conduct."[36]

III. POLICIES SERVED BY THE FIRST-TO-FILE RULE

"Both the history of the FCA and the legislative history of the 1986 Amendments demonstrate the effort to achieve 'the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own.'"[37] The first-to-file provision under § 3730(b)(5) aims to address both of these

contrast, Walburn had given specific details about the falsification of dosage readings obtained from thermoluminescent dosimeters in order to maintain Department of Energy accreditation and to receive payments from the government under its contract to operate a uranium enrichment plant. Id.

32. Id. at 971.

33. Id. at 973.

34. Walburn, at 971 (6th Cir. 2005).

35. Ortega, 240 F. Supp. 2d at 13.

36. LaCorte, 149 F.3d at 234.

37. Campbell, 421 F.3d at 823 (quoting United States *ex rel.* Devlin v. California, 84 F.3d 358, 362 (9th Cir. 1996)); see also, LaCorte, 149 F.3d at 233-34 (discussing legislative history).

concerns.[38] First, § 3730(b)(5) aims to encourage whistle-blowing by motivating potential relators to alert the government to fraud as soon as possible.[39]

> A strict first-to-file interpretation… serves Congress' goal of encouraging relators to file qui tam actions as soon as they learn of a fraud on the government. If relators feel compelled to file suit promptly, the government will be able to investigate promptly and bring about a speedy recovery of the money that has been stolen from the federal fisc. The basic objective of the qui tam provisions is, after all, to enable the government, through private enforcement, to restore stolen money to the federal fisc.[40]

Moreover, an "original qui tam relator would be less likely to act on the government's behalf if they had to share in their recovery with third parties who do no more than tack on additional factual allegations to the same essential claim."[41] Or, as the District of Columbia put it: "[P]ermitting infinitely fine distinctions among complaints has the practical effect of dividing the bounty among more and more relators, thereby reducing the incentive to come forward with information on wrongdoing. This is inconsistent with the FCA's purpose of encouraging whistleblowers to approach the government and file suit as early as possible."[42]

Title 31 U.S.C. § 3730(b)(5) also seeks to prevent opportunistic plaintiffs from draining public funds by preventing double recovery.[43] "Duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds."[44] Therefore, § 3730(b)(5) is a key tool in balancing the False Claims Act's twin aims of incentivizing legitimate whistle-blowers and discouraging opportunistic plaintiffs.

38. The objectives of § 3730(b)(5) are to encourage whistle-blowing and to discourage opportunistic behavior. Hampton, 318 F.3d at 217; see also, Lujan, 243 F.3d at 1187 ("The first-filed claim provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims").

39. Campbell, 421 F.3d at 821 (stating that "the first-to-file bar… encourages prompt disclosure of fraud by creating a race to the courthouse among those with knowledge of fraud").

40. Merena, 1997 U.S. Dist. LEXIS 19896 (citing S. Rep. No. 99-345, at 1 (1986), reprinted in 1986 U.S.C.C.A.N. 5266); see also, Grynberg, 390 F.3d at 1279 ("Once the government is put on notice of its potential fraud claim, the purpose behind allowing qui tam litigation is satisfied. Further, original qui tam relators would be less likely to act on the government's behalf if they had to share in their recovery with third parties who do no more than tack on additional factual allegations to the same essential claim").

41. Grynberg, 390 F.3d at 1279-1280; see also, Ortega, 240 F. Supp. 2d at 12 (citing LaCorte, 149 F.3d at 234) ("Further, permitting infinitely fine distinctions among complaints has the practical effect of dividing the bounty among more and more relators, thereby reducing the incentive to come forward with information on wrongdoing. This is inconsistent with the FCA's purpose of encouraging whistleblowers to approach the government and file suit as early as possible.").

42. Ortega, 240 F.Supp. at 12.

43. Erickson, 716 F. Supp. at 918 ("The qui tam complaint filed first blocks subsequent qui tam suits based on the same underlying facts. In so doing, the statute prevents a double recovery"); see also, Kinder Morgan, 2005 U.S. Dist. LEXIS 31103 ("Certainly avoiding duplicative consumption of scarce judicial resources in resolving essentially the same issue is sound policy").

44. LaCorte, 149 F.3d at 234.

IV. CONCLUSION

For the most part, courts have taken a hard line approach to § 3730(b)(5). With the early rejection of the "identical facts" theory, the courts have proceeded to eliminate second-filed cases based on a plain language reading of the statute and a conviction that the Congressional intent to encourage the prompt reporting of fraud and discourage opportunistic and duplicative suits is thereby served. Taking a broad view, the courts have not allowed later filed cases to survive just because they describe a different time period or geographic location[45] or involve different corporate subsidiaries.[46] The courts generally have construed § 3730(b)(5) as an "absolute, unambiguous, exception-free" rule.[47]

The Sixth and Ninth Circuit recently signaled a possible departure from this hard line approach in circumstances in which it would not promote the policy objectives of the qui tam law. Specifically, the courts refused to allow overly-broad or jurisdictionally barred cases to preempt later filed cases. It remains to be seen whether this approach will continue to gain support and strength as more first-to-file cases emerge.

As arbitrary as the first-to-file rule often seems, it is instructive to speculate on the possible alternatives. Allowing multiple relators to slug it out for their share of the recovery in a free-for-all certainly does not encourage the filing of qui tam cases. And if the courts are to be left to decide who should share in the bounty, what criteria should they use? And what would the government's role in this contest be? It may well be that the first-to-file rule, like democracy, is the worst possible system, except for all the others.[48]

45. Ortega, 240 F. Supp. 2d at 13 (quoting United States *ex rel.* Palladino v. VNA of S. New Jersey, Inc, 68 F. Supp.2d 455, 478-79 (D.N.J. 1999) (finding a broad allegation in a complaint describing misconduct in Philadelphia sufficient to preempt a later complaint focusing on Runnemede, New Jersey)); see also, Hampton, 318 F.3d at 219; see also, Capella, 1999 U.S. Dist. LEXIS 10520 ("Although these related standards are worded differently, they contain one common principle—section 3730(b)(5) precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action, even if the allegations cover a different time period or location within a company"). Ortega, 240 F. Supp. 2d at 17 (finding that "a variation in geographic location is not the type of "material fact" that will protect a complaint from § 3730(b)(5)'s first-to-file bar")(quoting Palladino, 68 F. Supp.2d at 478-79); see also, LaCorte, 149 F.3d 227 (barring subsequent qui tam actions alleging FCA violations in different corporate offices and in different regions of the country).

46. Hampton, 318 F.3d 214 (the first relator's complaint did not explicitly specify a Georgia-based subsidiary, but allegations against the subsidiary were considered to be encompassed by the first relator's allegations against the company"); see also, LaCorte, 149 F.3d 227 (barring subsequent qui tam actions alleging FCA violations in different corporate offices and in different regions of the country).

47. See supra, footnote 4.

48. "It has been said that democracy is the worst form of government except all the others that have been tried from time to time." Winston S. Churchill, Speech Before the House of Commons (Nov. 11, 1947), in 7 Winston S. Churchill: His Complete Speeches, 1897-1963 at 7566 (Robert Rhodes ed., 1974).

FIRST-TO-FILE CIRCUIT-BY-CIRCUIT SUMMARY January 2007				
Court	**Date**	**Case**	**3730(b)(5) Test**	**Exceptions**
First Circuit				
NO CASES OF SIGNIFICANCE				
Second Circuit				
Second Circuit	1999	United States *ex rel.* Pentagen Techs. Int'l, Ltd. v. CACI Int'l, et al., 172 F.3d 39 (2d Cir. 1999)(affirmed without opinion); 1999 U.S. App. LEXIS 1728 (2d Cir. 1999)(reported in full)	Same facts	None
District of Connecticut	2005	United States *ex rel.* Smith v. Yale-New Haven Hosp., Inc., 411 F. Supp. 2d 64 (D. Conn. 2005),vacated in part by, United States ex rel. Smith v. Yale Univ., 2006 U.S. Dist. LEXIS 24847 (D. Conn. 2006).	Different type of wrongdoing based on different material facts alleged in prior suit and gives rise to a separate recovery of actual damages by the government	None
District of Connecticut	1999	United States *ex rel.* Capella v. United Techs. Corp., 1999 U.S. Dist. LEXIS 10520 (D. Conn. 1999)	Different type of wrongdoing based on different material facts alleged in prior suit and gives rise to a separate recovery of actual damages by the government (whether the allegations involve different time periods or locations within company is irrelevant)	None
Third Circuit				
Third Circuit	1998	United States *ex rel.* LaCorte v. Smith-Kline Beecham Clinical Labs., Inc., 149 F.3d 227 (3d Cir. 1998)	Same material elements; Implictly overruled identical facts test (whether allegations include different corporate offices or geographic locations is irrelevant)	None
Eastern District of Pennsylvania	2001	United States *ex rel.* Friedman v. Eckerd Corp., 183 F. Supp. 2d 724 (E.D. Pa. 2001)	No test articulated	None
District of New Jersey	1999	Palladino *ex rel.* United States v. VNA of S. N.J., Inc., 68 F. Supp. 2d 455 (D.N.J. 1999)	Same material elements (whether allegations involve different geographic areas is irrelevant)	None
Eastern District of Pennsylvania	1997	United States *ex rel.* Merena v. Smithkline Beecham Corp., 1997 U.S. Dist. LEXIS 19896 (E.D. Pa. 1997)	Same material elements	None

FIRST-TO-FILE
CIRCUIT-BY-CIRCUIT SUMMARY
January 2007

Court	Date	Case	3730(b)(5) Test	Exceptions
Eastern District of Pennsylvania	1997	United States *ex rel.* Dorsey v. Dr. Warren E. Smith Community Mental Health/Mental Retardation and Substance Abuse Ctrs., 1997 U.S. Dist. LEXIS 9424 (E.D. Pa. June 25, 1997) (an unpublished decision).	Identical facts test; Implictly overruled by United States ex rel. LaCorte v. Smith-Kline Beecham Clinical Labs., Inc. 149 F.3d 227, 232-34 (3d Cir. 1998)	None
Fourth Circuit				
Fourth Circuit	2000	Webster v. United States, 2000 U.S. App. LEXIS 16006 (4th Cir. 2000)	No test articulated	None; 3730(b)(5) will apply to relators who initially brought an action which was dismissed (voluntarily) and subsequently seek to join a separate action brought by the government.
Eastern District of Virginia	1989	Erickson *ex rel.* United States v. American Inst. of Biological Sciences, 716 F. Supp. 908 (E.D. Va. 1989)	Facts different from those alleged in a prior suit and separate and distinct recovery by the government	None
Fifth Circuit				
NO CASES OF SIGNIFICANCE				
Sixth Circuit				
Sixth Circuit	2005	Walburn v. Lockheed Martin Corp., 431 F.3d 966 (6th Cir. 2005)	Same essential facts	Yes; A complaint that is legally insufficient under Rule 9(b) will not bar a subsequent case under 3730(b)(5).
Middle District of Tennessee	2006	United States *ex rel.* Fry v. Guidant Corp., 2006 U.S. Dist. LEXIS 29862 (M.D. Tenn. 2006)	No test articulated	None
Western District of Kentucky	2004	United States *ex rel.* Tillson v. Lockheed Martin Energy Sys., 2004 U.S. Dist. LEXIS 22246 (W.D. Ky. 2004)	Same material elements	None
Seventh Circuit				
Northern District of Illinois	2003	United States *ex rel.* Wilson v. Emergency Med. Assocs. of Ind., Inc., 2003 U.S. Dist. LEXIS 16734 (N.D. Ill. 2003)	Same material elements; Same essential facts (whether the allegations name additional parties is irrelevant)	None
Eighth Circuit				
NO CASES OF SIGNIFICANCE				

FIRST-TO-FILE
CIRCUIT-BY-CIRCUIT SUMMARY
January 2007

Court	Date	Case	3730(b)(5) Test	Exceptions
Ninth Circuit				
Ninth Circuit	2005	Campbell v. Redding Med. Ctr., 421 F.3d 817 (9th Cir. 2005)	No test articulated	Yes; A complaint which does not satisfy the jurisdictional requirements of § 3730(e)(4) § will not bar subsequent complaints under § 3730(b)(5)
Ninth Circuit	2001	United States *ex rel.* Lujan v. Hughes Aircraft Co., 243 F.3d 1181 (9th Cir. 2001)	Same material elements	None; Established "exception-free rule" language.
Western District of Washington	2006	United States *ex rel.* Harris v. Alan Ritchey, Inc. et al., 2006 U.S. Dist. LEXIS 91921, 15 (W.D. Wash. 2006).	No test articulated	No; Amending complaint in first-filed case to include allegations in second-filed case is indistinguishable from filing a new action.
District of Nevada	1990	United States *ex rel.* Lawyers Title Ins. Corp. v. Mortgages, Inc., 1990 U.S. Dist. LEXIS 20939 (D. Nev. 1990)	Facts different from those alleged in a prior suit and separate and distinct recovery by the government	None
Central District of California	1989	Hyatt v. Northrop Corp., 1989 U.S. Dist. LEXIS 18941 (C.D. Cal. 1989)	Issues which are the subject of a pre-existing suit	None
Tenth Circuit				
Tenth Circuit	2004	Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276 (10th Cir. 2004)	Same or related claim based in significant measure on the core facts or general conduct	None
Tenth Circuit	2005	United States v. Kinder Morgan Co2 Co., L.P., 2005 U.S. Dist. LEXIS 31103 (D. Colo. 2005)	Resolving essentially the same issue (whether the allegtions include different time periods is irrelevant)	None
Tenth Circuit	1994	United States *ex rel.* Precision Co. v. Koch, 31 F.3d 1015 (10th Cir. 1994):	No test articulated	Yes; Parties that are sufficiently related to the original filer that they would not be considered "intervenors" are allowed to join pre-existing qui tam suits.
District Wyoming	2002	United States *ex rel.* Goodnight v. Texaco Exploration & Prod., Inc. (In re Natural Gas Royalties Quitam Litig.), 2002 U.S. Dist. LEXIS 27844 (D. Wyo. 2002)	Same essential facts; Same type of wrongdoing (whether the allegations involve different geographic areas is irrelevant)	None

FIRST-TO-FILE CIRCUIT-BY-CIRCUIT SUMMARY January 2007				
Court	**Date**	**Case**	**3730(b)(5) Test**	**Exceptions**
District of Wyoming	2002	In re Natural Gas Royalties Quitam Litig., 2002 U.S. Dist. LEXIS 27843 (D. Wyo. 2002)	Same essential facts; Same type of wrongdoing	None
Eleventh Circuit				
Eleventh Circuit	1994	Cooper v. Blue Cross & Blue Shield, 19 F.3d 562 (11th Cir. 1994)	Against same defendant based on same kind of conduct	None
Middle District of Alabama	1996	United States *ex rel.* Sanders v. East Ala. Healthcare Auth., 953 F. Supp. 1404 (M.D. Ala. 1996)	No test articulated	Yes; Allowed parties related to, or sharing a common question of law or fact with, the original plaintiff to join suit under a Precision analysis.
D.C. Circuit				
D.C. Circuit	2003	United States *ex rel.* Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214 (D.C. Cir. 2003)	Same material elements (whether allegations involve different corporate subsidiaries is irrelevant)	None
D.C. Circuit	2003	United States *ex rel.* Ortega v. Columbia Healthcare, 240 F. Supp. 2d 8 (D.D.C. 2003).	Different type of wrongdoing based on different material facts alleged in prior suit and gives rise to a separate recovery by the government (whether allegations involve different geographic areas is irrelevant)	None

Spotlight

Rockwell International v. U.S. ex rel. Stone **(U.S. 2006),**
Amicus Curiae **Brief of Senator Charles E. Grassley**

No. 05-1272

In the
Supreme Court of the United States

Rockwell International Corp.
and Boeing North American, Inc.,
Petitioners,

v.

United States of America

and

United States *Ex Rel.* James S. Stone
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Tenth Circuit

BRIEF OF SENATOR CHARLES E. GRASSLEY AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE*

Amicus Curiae Senator Charles Grassley was the principal sponsor in the Senate of the False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153, *codified as amended* at 31 U.S.C. §§ 3729-3733. That Act substantially revised the original False Claims Act, which was first enacted in 1863 to draw on the information and resources of private citizens in combating fraud against the Government. Since the enactment of the 1986 amendments, *qui tam* relators have assisted in returning well over $15 billion to the United States Treasury.[1] As a principal sponsor of this important legislation, Senator Grassley has a strong interest in presenting his purpose in crafting the 1986 amendments to the Act generally and specifically the public disclosure bar and its original source exception at issue in this case.

SUMMARY OF ARGUMENT

The *qui tam* provisions of the False Claims Act have always had as their central purpose enlisting the information and resources of private citizens to assist the Government in its efforts to combat fraud. That purpose is as essential to the Government today to confront fraud in Government programs from reconstruction in Iraq to aid for victims of Hurricane Katrina, as it was when the Act was first adopted in 1863 to redress profiteering during the Civil War. As a result of the 1986 Amendments, the Government has recovered billions of dollars taken from it by fraud, which the Government might never have learned about or pursued without the assistance of private citizens.

As originally enacted, the False Claims Act authorized a private person, or *qui tam* relator, to pursue a fraud claim on behalf of the United States Government, without regard to the source of the person's information. The Act did not authorize the Government to intervene in the relator's case, and a successful relator was entitled to fifty percent of the total recovery.

In 1943, at the request of the Attorney General, Congress amended the *qui tam* provisions of the False Claims Act to bar *qui tam* suits that were based upon information about fraud already in the Government's possession. The Attorney General had expressed concern that relators were abusing the Act by copying criminal indictments and filing them as complaints to claim a reward, without contributing any information of their own. Although some members of Congress questioned the extent of the problem, Congress was persuaded to bar such parasitic suits. The 1943 amendment required a relator to provide all information in the relator's possession to the Govern-

* In accordance with Rule 37.6, *amicus curiae* certifies that counsel for a party did not author this brief in whole or in part and that the only monetary payment for preparation or submission of this brief was by the law offices of John Clark for its printing. Counsel for *amicus* represents that counsel for all parties have consented to the filing of this brief.

Petitioners have filed a letter with the Clerk granting blanket consent to any party filing an *amicus* brief in support of either petitioners or respondents, and letters reflecting respondents' consent to the filing of this brief have been filed with the Clerk.

1. *See* www.usdoj.gov/opa/pr/2005/November/05_civ_595.html (reporting recoveries though fiscal year 2005); http://www.taf.org/statistics.htm (reporting additional recoveries).

ment before filing suit and allowed a relator to pursue a case only if the Government elected not to do so. If the Government declined to pursue the case, the *qui tam* suit could not be pursued if the Government possessed information about the fraud at the time the case was filed.

Courts applied the literal language of the 1943 amendment to bar any *qui tam* suit where the Government was already aware of the fraud, even if the only source of the Government's knowledge was the information the relator provided before filing suit, as the law required. As a result, *qui tam* relators whose lawsuits were not in any sense parasitic were barred from pursuing a civil action on the Government's behalf, and the *qui tam* provisions of the statute largely fell into disuse.

In 1986, Congress sought to revitalize the False Claims Act and make it a more effective means of combating fraud. The 1986 Congress agreed with the policy choice of the 1943 Congress that parasitic actions should be barred. To ensure that only parasitic suits were barred, however, Congress discarded the Government knowledge bar and replaced it with the public disclosure bar. The public disclosure bar was intended to exclude only suits actually based upon revelations about specific instances of fraud that were publicly disclosed in certain Government proceedings or the news media. In order to limit such exclusion only to truly parasitic *qui tam* actions, Congress added the "original source" exception to the bar. The exception allows a relator to proceed with a case based upon publicly disclosed allegations of fraud, if the relator brought his own information underlying his allegations, independent of the public disclosure, to the Government before filing his suit.

Courts have since interpreted the public disclosure bar and its original source exception to bar a wide range of suits that are not parasitic in any sense, in conflict with both the language of the law and congressional intent. In the process, courts have created an increasingly complex and burdensome set of requirements that unnecessarily deter private citizens from assisting the Government. Unless a suit is truly parasitic of disclosures made public in certain Government proceedings or the news media, the suit serves Congress's purposes in authorizing *qui tam* actions. The Act seeks to encourage persons with information about fraud to provide that information to the Government and to bring their resources to bear on the problem. The Act provides other ways to address concerns about the level of the relator's contribution to the ultimate resolution of the case. The public disclosure bar and its original source exception were never intended to be used to deprive the Government of the assistance of relators whose actions are not parasitic.

ARGUMENT

I. THE PARAMOUNT PURPOSE OF THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT IS TO ENLIST PRIVATE CITIZENS TO CONTRIBUTE THEIR INFORMATION AND RESOURCES TO ASSIST THE GOVERNMENT IN ITS ANTI-FRAUD LAW ENFORCEMENT EFFORTS.

Since the inception of the False Claims Act, the central purpose of the *qui tam* provisions has been to enlist private citizens in combating fraud against the Government in several important ways. First, the provisions hold out the promise of a reward to the private citizens who file suits on the Government's behalf to encourage them to disclose their information about fraud to the Government, notwithstanding the considerable personal risks that can entail. Second, and equally important, by providing the relator an ongoing role in the case, the Act enhances the ability of the Government to pursue cases it might otherwise need to abandon for lack of resources. Finally, authorizing private citizens to pursue cases on the Government's behalf provides a measure of public oversight when the Government fails to act.

Within this framework, the public disclosure bar serves the limited purpose of preventing parasitic suits based on fraud that has already been publicly exposed in a manner that is likely to alert the Government to the misconduct alleged and to spur it to appropriate action. The sole purpose of the original source exception to the public disclosure bar is to further limit the reach of the public disclosure bar. The exception preserves cases involving publicized fraud allegations that were brought by persons who gave their own information underlying their complaint's allegations to the Government before filing suit. As courts have noted, in enacting the 1986 Amendments to the False Claims Act, Congress sought to balance the Government's interests in enlisting the information and resources of private citizens with the need to discourage opportunistic suits by persons who did not contribute their own information. However, Congress did not afford those interests equal weight. The Act Congress adopted weighs heavily in favor of pursuing fraud against the Government, while providing narrow filters to exclude only truly parasitic actions.

A. As Originally Enacted in 1863, the False Claims Act Authorized Private Persons To Pursue Fraud Claims on Behalf of the Government Regardless of the Source of the Person's Knowledge.

Congress first adopted the False Claims Act in 1863 during the Civil War.[2] The measure had been introduced in Congress at the "urgent solicitation of the officers who [were] connected with the administration of the War Department and Treasury Department" in response to complaints about "the frauds and corruptions practiced in obtaining pay from the Government during the [Civil] War."[3] Congress sought to en-

2. Act of March 2, 1863, ch. 67, 12 Stat. 696.

3. Cong. Globe, 37th Cong., 3d Sess. 952 (1863).

act "a more speedy and vigorous remedy" that would seek the assistance of private citizens in prosecuting fraud. As the sponsor explained, "The bill offers, in short, a reward to the informer who comes into court and betrays his coconspirator, if he be such; but it is not confined to that class."[4] The 1863 Act authorized private individuals, or "*qui tam* relators," to bring a suit on behalf of the United States to redress fraud against the Government. The Act provided for double damages and a $2,000 civil penalty per false claim. A private individual who successfully pursued a claim was entitled to half of the Government's recovery. The Act did not authorize the Government to intervene in the private individual's case, nor did the Act preclude *qui tam* actions based upon the source of the relator's information.[5] The Government thus sought both to encourage private citizens to report their information about fraud and to use their own resources in pursuing claims on the Government's behalf.

B. Congress Amended the False Claims Act in 1943 To Address a Perceived Problem with Parasitic Suits by Prohibiting *Qui Tam* Actions When the Complaint Was Based Upon Information Already in the Government's Possession.

Nearly 80 years later, in the midst of another war, Attorney General Francis Biddle wrote to Congress to seek a change to the False Claims Act based on his concern that lawyers were filing *qui tam* complaints that were copied straight from criminal indictments.[6] These types of suits, the Attorney General urged, did not serve the original purposes of the *qui tam* provisions. Relators who copied the Government's own work contributed little or no information to the Government and interfered with the Government's criminal cases.[7] The example the Department cited was a case from the Third Circuit, *United States ex rel. Marcus v. Hess*, 127 F.2d 233, where the appellate court had reversed a trial court award in favor of a relator.[8] The Attorney General pressed Congress to repeal the authorization for *qui tam* actions.

Although the Senate quickly responded to the Attorney General's entreaty by adopting a measure to repeal the *qui tam* provisions in their entirety, the House did not act before the close of the 77th Congress.[9] At the commencement of the 78th Congress, the House took up H.R. No. 1203, which was identical to the earlier Senate bill proposing repeal of the *qui tam* provisions.[10] The House Committee on the Judi-

4. Cong. Globe, 37th Cong., 3d Sess. 955 (1863).

5. Act of March 2, 1863, 12 Stat. 696.

6. S. Rep. No. 1708, 77th Cong., 2d Sess. (1942) (reprinting letter).

7. *Id.*

8. *United States ex rel. Marcus v. Hess*, 127 F.2d 233, 235 (3d Cir. 1942) (observing that because informer statutes have been regarded with disfavor, they must be construed with utmost strictness, and concluding that the relator had not established that a claim had been submitted to the United States).

9. S. 2754, 77th Cong., 2d Sess. (1942), passed, Nov. 27, 1942, 88 Cong. Rec. 9138 (1942). The Senate Report recommending passage consisted solely of the Attorney General's letter. *See* S. Rep. No. 1708, *supra* note 6.

10. H.R. 1203, 78th Cong., 1st Sess. (1943).

ciary reported the measure without substantive amendment,[11] and the House passed H.R. 1203 on April 1, 1943.[12]

When the Senate took up the proposed repeal this time, acquiescence in the Attorney General's request was not immediately forthcoming. The Committee on the Judiciary did not recommend approval of the repeal, but instead reported the measure with amendments. The proposed amendments would have maintained the *qui tam* provisions, but would have provided a bar to parasitic suits. The proposed bar would have provided that no court "shall have power or jurisdiction" over a *qui tam* action unless:

- the case was "based upon information, evidence, and sources original with such person and not in the possession of or obtained by the United States in the course of any investigation or proceeding instituted or conducted by it;"
- prior to commencement of the action the person "made full disclosure in writing to the Attorney General of the grounds thereof, and has requested the Attorney General to cause such suit to be brought;" and
- the Attorney General has "declined in writing to comply with such request, or has allowed six months to elapse after receipt of such disclosure and request without causing a suit to be brought."[13]

The report explained that the Committee had amended the House proposal "to protect and compensate genuine informers who comply with the provisions respecting notice to the Attorney General."[14] At the same time, the proposal sought to address the concerns of the Department of Justice that:

> many persons who have filed suits and may file suits under this section, have no information or facts of their own, but prepare and file complaints which obviously are based on information and alleged facts obtained bodily from indictments returned in United States courts, from newspaper stories, and congressional investigations. In some of the cases filed the indictment was copied in the complaint filed, the only difference being the caption and the prayer of the complaint.[15]

The report included the minority views of Senator William Langer of North Dakota, who took issue with the Department of Justice's claim that there was a crisis caused by parasitic *qui tam* suits. Senator Langer observed that it appeared from the records of the cited lawsuits that the Government had been letting defendants plead to small

11. H.R. Rep. No. 263, 78th Cong., 1st Sess. 2 (1943). Like the earlier Senate Report, the House Report consisted solely of a letter from the Attorney General requesting the repeal, this time citing the Supreme Court's then very recent decision in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), which reversed the Third Circuit and allowed the relator to recover.

12. 89 Cong. Rec. 2801 (1943).

13. S. Rep. No. 291, 78th Cong., 1st Sess. 1–2 (1943).

14. *Id.* at 1.

15. *Id.* at 2–3.

criminal fines and leaving the civil damages and penalties untouched.[16] Noting that the opportunities for contractor fraud were greater than ever before, Senator Langer championed the *qui tam* actions as a way for citizens to act as a check on the Government, so that Government officials could not let favored individuals off lightly.[17]

When the measure proceeded to the Senate floor, this debate continued. On the one hand, Senator Van Nuys urged that the measure as amended by the committee would "stop racketeers, who are springing up like mushrooms all over the United States, from taking advantage of this antiquated statute."[18] On the other hand, Senator Langer questioned whether a problem with parasitic suits even existed. Pointing out that the committee had not contacted any of the parties or lawyers in these cases, he read into the record telegrams explaining the nature and extent of the fraud alleged in the cases, and efforts of relators to pursue fraud.[19] In his view, the current effort was an attempt "not merely to amend the act but to emasculate it to such an extent as to amount to its practical repeal."[20] Senator Langer was not alone in protesting the amendment. Other Senators pointed out that the proposed amendment created a catch-22 for potential relators because the person would have to give the information to the Attorney General before filing suit, but once the Government had the information, the person would be barred from bringing a suit.[21] Although efforts to recommit the measure were rejected,[22] the Senate did agree to delete the requirement that the relator's information be "original with such person." As one Senator explained, "taken literally," this language could be understood to prohibit a person from bringing or conducting a suit "unless all the information originated with himself."[23] There were no objections to the change, which would not have altered the expressed purpose of the amendment's sponsors, which was to preclude parasitic suits based on information about fraud that was already in the Government's possession.

The measure was sent to conference to reconcile the Senate and House proposals.[24] The amendment that emerged provided that if the United States proceeded with a case, the case would be prosecuted solely by the United States and the relator would have no role. If the United States failed to join the case after 60 days, the person could continue on his or her own. The Government had no ability to join the case at a later date. Critically, however, if the Government did not join the case, no court would have "jurisdiction" to proceed with a relator's case "whenever it shall be made to appear that such suit was based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought."[25]

16. S. Rep. No. 291, Pt. 2, 78th Cong., 1st Sess. 1 (1943).

17. *Id.* at 4.

18. 89 Cong. Rec. 7439 (1943) (statement of Sen. Van Nuys).

19. 89 Cong. Rec. 7578–79, 7601–02 (1943) (remarks of Sen. Langer).

20. 89 Cong. Rec. 7438 (1943) (statement of Sen. Langer).

21. 89 Cong. Rec. 7614 (1943) (statements of Sens. Clark and Wheeler).

22. 89 Cong. Rec. 7608, 7614–15 (1943).

23. 89 Cong. Rec. 7614 (1943) (statement of Sen. Wheeler).

24. 89 Cong. Rec. 7806 (1943).

25. H.R. Rep. No. 933, 78th Cong., 1st Sess. (1943), *reprinted in* 89 Cong. Rec. 10844 (1943); Act of December 23, 1943, ch. 377, 57 Stat. 608.

As one congressman pointed out, this proposal placed "limitations upon the prosecution of true informer actions which defeat the very purpose and in practical effect nullify true informer suits."[26] He explained that, if a person with information about fraud was about to file an informer suit but was subpoenaed to testify before Congress, that person could not bring a suit because the Government would already have the information before the suit was brought.[27] "This is the vice of this [conference] report, or of this bill. Instead of encouraging the disclosure of frauds perpetrated against the Government, it places a premium upon secrecy, because what potential informer would dare disclose the information he had when he had not filed a suit if by disclosing it he is forever precluded from the prosecution of the action?"[28]

C. In 1986 Congress Sought To Correct the 1943 Version of the Law By Carefully Crafting a Limited Bar to Certain Parasitic Suits.

While it was never clear how significant a problem parasitic suits were, predictions that the 1943 amendments would put an end to informer actions proved prescient. Following the 1943 amendment, courts construed the literal terms of the Act to preclude a *qui tam* action if the Government had information about the fraud in its possession, even if the relator had provided that information. *See United States ex rel. Lapin v. Int'l Bus. Machines Corp.*, 490 F. Supp. 244 (D. Haw. 1980); *United States v. Aster*, 275 F.2d 281 (3d Cir.), *cert. denied*, 364 U.S. 894 (1960); *United States v. Rippetoe*, 178 F.2d 735, 738 (4th Cir. 1949). Thus the provision was interpreted to effectively bar all suits the Government did not take over, including suits that were in no sense parasitic.

In a case that epitomized the way in which the exception undermined the Act itself, in 1984 the Seventh Circuit held in *United States ex rel. Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984), that the Government knowledge bar precluded the relator from bringing a *qui tam* action. In *Wisconsin v. Dean*, the only reason the Government was already aware of the fraud allegations contained in the relator's complaint was because the relator, the state of Wisconsin, had provided the information to the federal Government as required under another federal law. Precluding Wisconsin from pursuing the case did not protect the Government from a parasitic suit, but rather deprived the Government of a significant partner in pursuing a well-documented case of fraud. The United States had in fact wanted Wisconsin to proceed as the relator because Wisconsin was in the best position to prosecute the case.[29] Following the decision, the National Association of Attorneys General adopted a resolution to urge Congress to "rectify the unfortunate result of the *Wisconsin v. Dean* decision."[30]

At about the same time, members of Congress had begun to study the problem of fraud against the Government. The General Accounting Office had reported in 1981

26. 89 Cong. Rec. 10847 (1943) (statement of Rep. Miller).

27. *Id.*

28. *Id.*

29. *United States ex rel. Wisconsin v. Dean*, 123 F.2d at 1103, n.2.

30. False Claims Amendments Act of 1986, S. Rep. No. 345, 99th Cong., 2d Sess. 13, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5278.

that the known cases of fraud against the Government totaled between $100 million and $200 million, but that that number was likely very low because most fraud goes undetected.[31] The Department of Justice informed Congress that fraud was draining between one and ten percent of the federal budget.[32] In an effort to stem this tide, Congress decided to revisit the Government's "primary weapon against fraud."[33] Examining the existing law, and finding a number of flaws, Congress set out to breathe new life into the law to "establish a solid partnership between public law enforcers and private taxpayers."[34] Senate bill 1562, introduced on August 1, 1985,[35] would have amended the False Claims Act to, among other things, replace the 1943 "Government knowledge bar" which had undermined the *qui tam* provisions.[36] The proposed amendment would have replaced the Government knowledge bar with a more limited "public disclosure" bar. Under S. 1562 as introduced, a *qui tam* action could not proceed if it was based on specific evidence or information that the Government had disclosed as a basis of allegations in a prior administrative, civil, or criminal proceeding, or specific information disclosed during the course of a congressional investigation or disseminated in the news media, unless the Government failed to act within a certain time.[37] If the Government intervened in the *qui tam* action, the bar would not have applied.[38] Unlike the 1943 bar, this proposal would not have prohibited the filing of a *qui tam* action simply because it was based on information somewhere in the vast Government bureaucracy.

The Senate Judiciary Committee reported a substitute measure, which the Senate adopted, along with some modifications.[39] Among other changes, the Senate proposal addressed the Department of Justice's concern that the *qui tam* provisions would give rise to a greater number of actions filed against public officials for political purposes. Accordingly, the Senate proposal provided that *qui tam* actions could not be brought against public officials if the Government already had the information about the fraud in its possession. This provision essentially retained the Government knowledge bar for suits against public officials.[40] In addition, the Senate proposal limited the reward

31. *See* S. Rep. No. 345, *supra* note 30, at 2, *reprinted in* 1986 U.S.C.C.A.N. at 5267 (citing GAO Report to Congress, Fraud in Government Programs: How Extensive is it? How Can it be Controlled? (1981)).

32. S. Rep. No. 345, *supra* note 30, at 3, *reprinted in* 1986 U.S.C.C.A.N. at 5268.

33. 132 Cong. Rec. 20535 (1986) (statement of Sen. Grassley).

34. 132 Cong. Rec. 28580 (1986) ("Primary in the original 'Lincoln Law' as well as this legislation is the concept of private citizen assistance in guarding taxpayer dollars. The expanded *qui tam* provisions of this bill will serve to establish a solid partnership between public law enforcers and private taxpayers in the fight against fraud.") (statement of Sen. Grassley).

35. 131 Cong. Rec. 22322 (1985).

36. *Id.* (observing that change was necessary in part because "the teeth of President Lincoln's law were removed during World War II, and the provision has been little used since") (statement of Sen. Grassley).

37. S. 1562, *reprinted in* False Claims Reform Act: Hearing Bef. the Subcomm. on Admin. Prac. and Proc. of the Sen. Comm. on the Judiciary, 99th Cong., 1st Sess. (Sept. 17, 1986).

38. *Id.*

39. 132 Cong. Rec. 20530–42 (1986).

40. S. Rep. No. 345, *supra* note 30, at 29, *reprinted in* 1986 U.S.C.C.A.N. at 5294 ("This provision actually reflects current law in that any *qui tam* suit based on information already known to the Government is currently without jurisdiction. While S. 1562 repeals that jurisdictional bar for most suits, the Committee, at the request of the Justice Department, retained the bar for those suits which might be politically motivated.").

for persons who brought an action based on information of fraud of which they did not have independent knowledge.[41]

The Senate proposal also altered the public disclosure bar to provide that no court would have jurisdiction over a *qui tam* action that was "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information."[42] The proposal defined "original source" as an individual who has "direct and independent knowledge of the information on which the allegations are based and has voluntarily informed the Government or the news media prior to an action filed by the Government."[43] The exception would have allowed a *qui tam* action based on publicly disclosed allegations or transactions to be maintained by relators who, like the relator in the *Dean* case, brought information, independent of the public disclosure, to the Government.

The Senate subsequently adopted a revision to the definition of original source to require that the person "voluntarily provided the information to the Government before filing an action under this section which is based on the information," rather than before the Government filed an action.[44] This final version, which Congress adopted, barred a *qui tam* action based upon allegations or transactions publicly disclosed in certain Government proceedings or the news media, unless the person bringing the suit was an original source of the information on which the allegations in his own complaint were based, as Congress had defined that term.[45]

II. THE PUBLIC DISCLOSURE BAR PROVIDES A LIMITED FILTER TO PRECLUDE *QUI TAM* ACTIONS THAT ARE BASED UPON SPECIFIC FRAUD ALLEGATIONS ALREADY AVAILABLE TO THE GOVERNMENT IN ITS OWN PROCEEDINGS AND INVESTIGATIONS OR THROUGH THE NEWS MEDIA.

As the history of the public disclosure bar demonstrates, Congress intended this provision to serve a narrow purpose, and the original source exception was intended to make the bar more narrow still. If a *qui tam* suit is not parasitic, nothing in the Act, its legislative history, or the policies underlying it suggest that Congress had any interest in precluding it. The complex requirements that have been grafted onto this simple concept create a landscape of hidden pitfalls that can disqualify relators whose suits are clearly not parasitic, based on so-called "public disclosures" of which neither the relators nor the Government were, or could even reasonably be expected to be, aware. Such harsh and unjust results serve only to discourage relators with meritorious cases from taking the risk of coming forward, which is precisely the opposite of the statute's purpose.

41. 132 Cong. Rec. 20536 (1986) (statement of Sen. Grassley).

42. S. 1562, as amended, *reprinted in* 132 Cong. Rec. 20531 (1986).

43. *Id.*

44. 132 Cong. Rec. 28533 (1986).

45. Pub. L. No. 99-562, 100 Stat. 3153 (1986).

A. The Public Disclosure Bar Has no Application When the Government Joins the Case.

Because the public disclosure bar is intended to protect the Government's interest, the bar has never had any application to a *qui tam* action that the Government joins and decides to pursue on its merits. From its inception, the 1986 public disclosure bar was intended to arise only when the Government did not proceed with the case.[46] The final version of the public disclosure bar enacted into law expressly provides that the bar does not apply if the Attorney General brings the case, as occurs when the Attorney General elects to join and proceed with a *qui tam* action.[47]

Nothing in the text of the False Claims Act or its legislative history suggests that the public disclosure bar was ever intended to aid defendants in dismissing a *qui tam* relator from a case that the Government had joined and was pursuing on its merits. Under those circumstances, dismissing a relator at the defendant's request would serve only to deprive the Government of resources to assist it in pursuing the case, contrary to the purposes of the Act. To the extent the Government has concerns about the relator's participation or contribution to the case, the statute provides other ways for the Government to address those concerns.[48]

B. The Public Disclosure Bar Precludes Only Parasitic Suits.

The public disclosure bar was intended only to bar certain parasitic suits that did not contribute to the Government's knowledge about, and ability to pursue, claims against a particular defendant.[49] For this reason, Congress limited the bar to situations in which a relator's complaint is based upon allegations or transactions that have been disclosed in a limited set of Government proceedings or the news media, where public disclosure of fraud allegations or transactions would mean that the federal Government and the general public were aware of the allegations.[50] There is no reason to assume that disclosures of fraud allegations in local government proceedings,[51] private lawsuits,[52] or other types of proceedings not listed in the statute make the federal Government aware of the fraud allegations and put it in a position to pursue them.

46. *See supra* at 13–14, discussing S. 1562, 99th Cong., 2d Sess. (1986).

47. *See* 31 U.S.C. § 3730(e)(4); *see also* 31 U.S.C. § 3730(b)(4)(A) (providing that when the Government elects to proceed "the action shall be conducted by the Government"). Similarly, the 1943 Government knowledge bar came into play only if the Government declined the case. *See* Act of December 23, 1943, ch. 377, 57 Stat. 608. *See also United States v. Pittman*, 151 F.2d 851 (5th Cir. 1945) (holding that the 1943 bar did not apply when the Government pursued the case), *cert. denied*, 328 U.S. 843 (1946).

48. *See, e.g.*, 31 U.S.C. § 3730(d) (providing courts discretion in making awards based upon the contribution of the relator); 31 U.S.C. § 3730(c)(2)(A) (authorizing the Government to dismiss action); 31 U.S.C. § 3730(d) (authorizing reduced relator's reward where *qui tam* complaint is based primarily on publicly disclosed information).

49. 145 Cong. Rec. 16025, 16031 (1999) (reprinting letter from Rep. Berman and Sen. Grassley to Attorney General Reno).

50. *See* 31 U.S.C. § 3730(e)(4)(A).

51. *See, e.g., A-1 Ambulance Service, Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir.), *cert. denied*, 529 U.S. 1099 (2000).

52. *See, e.g., United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326 (6th Cir. 1998).

Congress did not list those types of proceedings in the public disclosure bar because they were not relevant to the purpose of the section. Applying the public disclosure bar to these types of disclosures would expand the public disclosure bar even beyond the broad "Government knowledge bar" that Congress sought to replace.

Similarly, the primary fraud-fighting objective of the Act must be considered when determining whether a relevant "public disclosure" of "allegations or transactions" involving False Claims Act violations exists. To remain consistent with that purpose, the benchmark for determining whether one or more public "disclosure(s)" warrant invocation of the statutory bar must be whether such disclosures provide sufficient indication of fraud so that the Government and the general public reasonably can be expected to have been alerted to the need for the Government to investigate specific conduct or transactions. Barring *qui tam* suits based on any public disclosure that fails to meet this minimum standard of disclosure defeats rather than serves the overriding interest of the United States in effectively combating fraud.

Thus, for example, mere awareness on the part of the Government that a particular type of fraud occurs, without information that a specific defendant engaged in that conduct, does not put the Government in a position to pursue a case. The Government is well aware that practices such as overbilling, or failure to test, do occur in certain industries. It is unrealistic to conclude, however, that awareness that a general practice occurs means the Government is aware of fraud by a particular defendant and is in a position to pursue it.[53]

When a public disclosure occurs in one of the fora enumerated in the Act, specific allegations of fraud committed by identifiable wrongdoers obviously provide the level of notice necessary to alert the Government and spur it to action. Determining whether exposure of bits and pieces of information about "transactions" suffices to trigger the Act's public disclosure bar must begin with consideration of the extent to which the "disclosure(s)" at issue actually can be expected to have provided the kind of alert needed to effectively combat fraud. As the D.C. Circuit correctly noted, pieces of information about a defendant and some of its actions, even when publicly disclosed, rarely add up to an allegation of fraud. There must be "enough information . . . in the public domain to expose the fraudulent transaction."[54] This analysis, however, cannot always be reduced to a simple, formulaic inquiry. Even if all the critical elements of the fraud or the fraudulent transaction appear somewhere in the public domain, if the information needed to piece together a discernible picture of actionable fraud must be gathered from several places, it may be unrealistic to assume that the Government is aware or likely to become aware of the apparent fraud. The issue remains whether clear enough indications or allegations of fraud were disclosed in one of the ways Congress specified in the Act so that the Government can proceed with the case if it wants,

53. False Claims Act Implementation: Hearing Bef. the Subcomm. on Admin. Law and Government Relations of the House Comm. on the Judiciary, 101st Cong., 2d Sess. 6 (1990) ("The publication of general, non-specific information does not necessarily lead to the discovery of specific, individual fraud which is the target of the *qui tam* action.") (statement of Sen. Grassley).

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

or be held accountable if it does not. A relator who collects and analyzes dispersed public information and brings an otherwise unrecognized fraudulent transaction to light is not a parasite. Congress intended to encourage such persons to bring the fruits of their labor to the Government's attention.[55]

C. The Original Source Exception Prevents the Public Disclosure Bar from Excluding Persons Who Brought to the Government Their Own Information That Was Independent of the Public Disclosure.

The original source exception to the public disclosure bar serves a very limited function under the False Claims Act. Like the relator in *Wisconsin v. Dean*, some relators whose complaints are based on allegations or transactions of fraud that have been publicly disclosed are not parasites. A person's disclosure of information to the Government could itself result in a public disclosure, as, for example, when a criminal indictment was the result of the relator's information. A leak to the press about a Government investigation based on information provided by a relator could also result in a public disclosure. Under these circumstances, Congress did not \want the relator to be barred from bringing a *qui tam* case.[56] Such relators are precisely the types of individuals the Government should reward.

Congress expressly decided not to limit the original source exception to persons whose information led to the particular public disclosure.[57] Congress adopted a specific definition of "original source" that requires only that the information upon which the relator bases the allegations in his or her complaint be provided to the Government before the relator files suit.[58] The reason Congress required no more is clear. If before filing suit, the relator provides to the Government direct information about the allegations in his complaint that is independent of the publicly disclosed allegations, that suffices to demonstrate that the person's *qui tam* action is not parasitic. Such a case does not implicate the concerns underlying the public disclosure bar, even though the complaint involves publicly disclosed allegations or transactions of fraud. Congress also recognized that in some cases this could potentially result in a relator proceeding in a case that was based only in small part on his or her own information. The statute addresses this concern as well, by permitting a lesser reward when the action is primarily based on publicly disclosed allegations or transactions of fraud.[59]

Because the original source requirement serves the narrow function of ensuring

55. *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (observing that "to a certain degree, Congress wanted to encourage busybodies who, through independent efforts, assist the government in ferreting out fraud").

56. 145 Cong. Rec. 16025, 16031 (1999) (reprinting letter of Rep. Berman and Sen. Grassley to Attorney General Reno).

57. *See, e.g., United States ex rel. Longstaffe v. Litton Industries, Inc.*, 296 F. Supp. 2d 1187 (C.D. Cal. 2003) (requiring relator to be the source of the disclosure).

58. 31 U.S.C. § 3730(e)(4)(B) (requiring that information be provided to the Government "before filing an action" based on the information).

59. 31 U.S.C. § 3730(d).

that persons who bring their own information to the Government before filing suit are not improperly filtered out by the public disclosure bar, as they were under the 1943 version of the law, no stringent requirements are necessary to qualify as an original source. There is no need for a person to have seen the fraud with his or her own eyes or to have received no information from other people or sources. Someone who sees a fraudulent transaction take place has direct and independent knowledge of the fraud, but that is not the only way such knowledge may be obtained. For example, a relator who learns of false claims by gathering and comparing data could have direct and independent knowledge of the fraud, regardless of his or her status as a percipient witness to the fraud and regardless of whether some of the information was filtered through other people. The purpose of the original source inquiry is simply to confirm that the person's complaint, which was based on publicly disclosed allegations or transactions of fraud, was not in fact parasitic because the person had his or her own information about the fraud that was not dependent upon the public disclosure. Congress had no interest in preventing persons with their own information about fraud from assisting the Government in its efforts to pursue that fraud.

CONCLUSION

The False Claims Act balances the need for information with concerns about opportunistic behavior, but the 1986 amendments did not assign equal weight to those interests. The overriding purpose of the Act is to enlist the information and resources of the public to assist the Government in pursuing fraud. The 1986 Amendments have been highly effective in achieving those goals.

As Congress recognized in 1986, "[t]he Federal Government has a big job on its hands as it attempts to ensure the integrity of the nearly $1 trillion we spend each year on various programs and procurement. That job is simply too bigif Government officials are working alone."[60] Reading the public disclosure bar too broadly, and the original source exception too narrowly, undermines the central purpose of the *qui tam* provisions of the Act.

Where the Government joins a *qui tam* case, no jurisdictional bar based on potential public disclosure can apply. The Act provides other tools to protect the Government's interests in cases in which it intervenes despite potential public disclosures. In a non-intervened case, once a court has found that the complaint is based upon allegations or transactions of fraud disclosed in one of the ways enumerated in the statute (and is therefore potentially parasitic), the only issue is whether the person brought supporting information, about which he or she had direct knowledge independent of the public disclosure, to the Government before filing the case. A person who merely copied an indictment or a government report would not have such direct and independent knowledge. If the person did have direct information about fraud independent of the public disclosure, then the goal underlying the public disclosure bar, precluding parasitic suits, is not implicated and Congress had no interest in barring the suit.

60. 132 Cong. Rec. 20535 (Aug. 11, 1986) (statement of Sen. Grassley).

Respectfully submitted,

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Upcoming Legal Battles

Testimony on the False Claims Act and Fraud Against Medicaid by Drug Manufacturers

Testimony of James W. Moorman,
President and CEO, Taxpayers Against Fraud

The False Claims Act and Fraud Against Medicaid by Drug Manufacturers

Before the Committee on Oversight and Government Reform
United States House of Representatives

2/09/2007

SUMMARY OF TESTIMONY

The federal government is spending hundreds of billions of dollars to fund Medicare, Medicaid and other health care programs. It is essential that as much as possible be done to ensure that these funds are not lost to fraud, but are spent on purchasing health care services for the more than 90 million Americans these programs serve.

One particular area, fraud by pharmaceutical companies against Medicaid, is ripe for effective anti-fraud action. Whistleblower cases under the False Claims Act have brought three types of fraud into view that are costing Medicaid many billions of dollars:

- Medicaid Best Price fraud,
- Average Wholesale Price fraud, and
- Off-label marketing fraud.

So far there have been 16 settlements that have recouped nearly $4 billion in civil damages and criminal penalties from drug manufacturers. There are more than 180 additional unresolved cases. The potential liability involved has not been reported, but based on the cases settled to date, it's likely to be in the $60 billion range.

There is a serious danger that the Justice Department will be unable to resolve most of these cases in a timely and satisfactory manner. The reason is a lack of resources and top-level leadership. Cases are being resolved at the rate of less than three a year. Many cases are over a decade old. A seriously inadequate number of lawyers are assigned to the cases. Only a few U.S. Attorneys offices (principally Boston and Philadelphia) are seriously involved. Money allocated from the Health Care Fraud and Abuse Control ("HCFAC") Account for health care fraud cases has been withheld. Support from investigative agencies is skimpy. The active support of the Attorney General and his Deputy are not in evidence. The drug manufacturer defendants are aware of these deficiencies and many of them appear to be trying to run out the clock on the Justice Department's attorneys.

These problems are particularly frustrating because the entire set of cases provides the government with an opportunity to close a multi-billion dollar fraud gap—-the difference between fraudulent conduct that has occurred and fraudulent conduct held to account. In order to grasp this opportunity, however, the Department of Justice must alter the *status quo*. The top officers of the Department must take an active inter-

est in these cases; adequate resources must be deployed quickly; HHS must provide more support; full support by investigative agencies is mandatory; the Civil Division's fraud section must be augmented; more US Attorney offices must participate in these cases in a significant way; and action must be taken to prevent these cases from languishing or allowing the clock to run out on them.

INTRODUCTION

My name is James W. Moorman and I am the President of Taxpayers Against Fraud, also known as "TAF" and as "The False Claims Act Legal Center," a position I have held for the past seven years. I am an attorney by training and served as an Assistant Attorney General of the Department of Justice under Attorneys General Griffin Bell and Benjamin Civiletti. Between my service at Justice and TAF, I was a partner in the law firm of Cadwalader, Wickersham & Taft.

Taxpayers Against Fraud and its sister organization, Taxpayers Against Fraud Education Fund, are non-profit charitable organizations dedicated to combating fraud against the Federal Government and state governments through the promotion of the use of the *qui tam* provisions of false claims acts, especially the federal False Claims Act, 31 U.S.C. §§ 3729- 33 ("FCA"). *Qui tam* is the mechanism in the FCA that allows persons with evidence of fraud involving government programs or contracts to bring suit on behalf of the federal government. The cases are filed in federal court under seal, giving the Justice Department an opportunity to review the allegations and decide if it wants to intervene. Under the FCA, those that commit fraud are subject to triple damages and civil penalties.

Thanks to the efforts of whistleblowers that use false claims acts, their lawyers, lawyers on the fraud team in the Civil Division of the Department of Justice, Assistant United States Attorneys in several very active US Attorneys offices, and certain members of Congress, the public, over the past few years, has become aware of fraud against government health care programs and the potential of the FCA and its whistleblower provisions to curb such fraud. Since the enactment of the 1986 amendments to the FCA, settlements and judgments related to health care fraud have totaled more than $12 billion. This money has, further more, been recouped very efficiently. As health economist Jack Meyer concluded in a report, updating earlier reports and released by TAF Education Fund, the federal government has realized $15 in direct recoveries for every $1 it has invested in investigating and prosecuting health care fraud through the FCA.[1]

TYPES OF FRAUD AGAINST MEDICAID

My testimony focuses on fraud by some drug manufacturers against Medicaid, which, until the enactment of Medicare Part D, was the largest government purchaser of drugs and remains the second largest. TAF Education Fund has been monitoring cas-

1. Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck*, July 2006. See www.taf.org

es in this area, the first of which was settled in 2001. We have published two reports on the subject that are posted on our website, and we are about to release a third. [2] This testimony draws upon the information in these reports.

Over the past six years, there have been 16 settlements of FCA cases involving allegations of fraud by drug manufacturers against federal health care programs, 14 of which have involved Medicaid. These settlements total nearly $4 billion, including $3 billion in civil damages recouped by the federal government and the states, as well as nearly $1 billion in criminal penalties.[3]

The settlements involve three general categories of fraud: concealment of best price; inflation of average wholesale prices (AWP); and off-label marketing:

- **Concealment of Best Price.** In order for a drug manufacturer to sell its prescription drug products to Medicaid, the manufacturer must enter into an agreement with the Secretary of HHS to provide rebates to the federal and state governments for the drugs that Medicaid buys on behalf of its beneficiaries. In the case of generic drugs, the rebate is 11 percent of average manufacturer price, or AMP (the average price paid by wholesalers to manufacturers for drugs distributed to retailer pharmacies.) In the case of brand-name drugs, the rebate amount is the greater of (1) 15.1 percent of AMP or (2) the difference between AMP and the "Best Price" (the lowest price a manufacturer sells its product to most customers.) Manufacturers must report AMP and Best Price information to HHS, which calculates the rebates due based on the data. More than half of the FCA settlements involve manufacturers concealing Best Prices that they gave to customers on brand-name drugs in order to avoid paying higher Medicaid rebates. As a result, the cost of these drugs to federal and state governments was higher than it should have been. Nine of the settlements to date, totaling over $2.5 billion, have involved concealment of Best Price.

- **Average Wholesale Price (AWP).** When State Medicaid programs pay for prescriptions, they pay the pharmacist a dispensing fee plus the estimated cost to the pharmacist of acquiring the drug from the wholesaler or directly from the manufacturer. Many states base their estimated acquisition cost on a drug's "Average Wholesale Price," or "AWP," which is reported by the manufacturer to price reporting services or, in some cases, directly to the state. AWP fraud occurs when a manufacturer reports inflated prices that bear no relation to the actual price that the pharmacist pays for the drug. The pharmacist keeps the difference between what the Medicaid program pays for the drug and the price the pharmacist actually pays the wholesaler or the manufacturer. Manufacturers use this differential in order to incent pharmacies to purchase

2. Andy Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers*, November 2003; Andy Schneider, *The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update*, November 2004; see www.taf.org

3. Attachment B contains tables and figures summarizing these settlements. Attachment C is a list of citations of the cases.

their drug instead of that of a competitor. This is often referred to as "marketing-the-spread." The result is that Medicaid pays inflated prices for the ingredient cost of the drug.

- **Off-label Marketing.** Medicaid covers all prescription drugs approved by the Food and Drug Administration when they are prescribed by a physician and are medically necessary. The FCA approves drugs only for specific purposes, which appear on the drug's labeling materials. Doctors are legally permitted to prescribe drugs for unapproved, or "off-label" uses as well, and many physicians do so. Manufacturers, however, may not lawfully promote or market their products for unapproved, off-label uses to physicians or others. However, such marketing does occur, often accompanied by the use of illegal kickbacks. When off-label marketing induces physicians to prescribe drugs for unapproved uses and Medicaid pays for those prescriptions, Medicaid spending goes up.

BEST PRICE FRAUD

As noted, FCA settlements involving concealment of Best Price account for the largest share of recoveries to date. While this may change as future settlements are announced, I want to explain this type of fraud in more detail because of the importance of drug coverage to Medicaid beneficiaries and the importance of the Medicaid rebate program to lowering Medicaid spending on prescription drugs. The more the federal government can reduce fraud against the Medicaid rebate program, the farther that federal and state tax dollars will go in purchasing needed medicines for low-income Americans.

Assume that a manufacturer reports to HHS that the average manufacturer price, or AMP, of a specific unit of one of its brand-name drugs is $79. If the manufacturer charges all of its customers $68 or more for that unit of that drug, then the rebate the manufacturer is required to pay on each prescription sold to Medicaid is 15.1 percent of the AMP, or $11.93. Thus, if Medicaid buys 100 prescriptions, the rebate owed is $1193.

Now assume that the manufacturer charges a customer $64 for that unit of the drug in question. In that case, $64 becomes the Best Price and the rebate that the manufacturer has to pay on each prescription sold to Medicaid is AMP ($79) minus Best Price ($64), or $15 dollars. If Medicaid pays for 100 prescriptions of the drug, the rebate owed becomes $1500.

Best Price fraud involves concealing the $64 Best Price from HHS, so that HHS calculates the rebate amount to be 15.1 percent, or $11.93. The gain to the manufacturer is the difference between $11.93 and $15, or $3.07, multiplied by the number of prescriptions Medicaid buys. Thus if Medicaid buys 100 prescriptions, that amount is $307 ($1,500 minus $1,193 equals $307). In other words, $307 is the loss to Medicaid and federal and state taxpayers, who are paying $307 more for the 100 prescriptions than federal law allows.

There are several ways Best Price has been concealed from HHS. The most straightforward is to simply not report the cash discounts given to a customer. That is what happened in the $49 million settlement with Pfizer in 2002. Pfizer marketed Lipitor to the Ochsner Health Plan by giving it cash discounts to list the drug in its formulary. The cash discount reduced the price of Lipitor to Ochsner. However, when Pfizer reported its Lipitor prices to HHS, it did not report the discount to HHS. Because the discounts were not reported, the rebate amount on the drug was less than it should have been, and Medicaid ended up paying over $20 million more for Lipitor than it should have during the time period covered by the case.

A variation on this theme is the $345 million settlement with Schering-Plough in 2004. In order to place its most profitable product, the anti-histamine Claritin, on the formularies of certain national HMOs, Schering-Plough paid the HMOs kickbacks disguised as "data fees" or "risk share" payments. These kickbacks had the effect of lowering the price of Claritin to the HMO, but when Schering-Plough reported to HHS the price charged to the HMO, it did not report the price net of the "data fees" or "risk share" payments. As a result, Schering-Plough paid a significantly smaller rebate to Medicaid than it was required to pay.

An even more creative approach to concealing Best Price is known as "lick and stick." This is what happened in the $257 million settlement with Bayer Corporation in 2003, which involved, among other drugs, the antibiotic Cipro. An HMO insisted on a deep discount, but Bayer did not want to give Medicaid a rebate based on that discounted price. In order to evade reporting that price as its Best Price, Bayer placed the HMO's National Drug Code number instead of its own on the label of the drugs it sold to the HMO at the deeply discounted price. Bayer did not include the price of the mislabeled drugs in its reports to HHS.

It is worth stressing that in each of these settlements (and others), the reason the federal government found out about the fraud was not because of a government audit or HHS oversight. Rather, it was because a private whistleblower, using the FCA, brought the information to the federal government's attention.

THE EXTENT OF THE FRAUD

The scale of the fraud problem with the pharmaceutical manufacturers is only hinted at by the sixteen settlements (nine of which included Best Price fraud) and the $4 billion in civil damages and criminal penalties they have produced. In addition to those sixteen cases, there are a very large number of cases on file involving extensive fraud liability that have not been resolved. Because of a peculiarity of the False Claims Act, cases brought by whistleblowers under the Act are filed under seal and remain under seal while government investigations are undertaken. For that reason, it is difficult to obtain precise information about this litigation. However, Mr. Peter Keisler, the Assistant Attorney General for the Civil Division of the Justice Department informed the House Judiciary Committee on August 11, 2006 that the Department had "over 180" such cases on its docket.[4] Added to these cases would be cases filed in state courts

4. *Written Responses of Peter D. Keisler, Assistant Attorney General, Civil Division, before the Subcommittee on Commercial*

under state false claims acts and cases filed by state attorneys general under other statutes.

In addition to the cases under seal, there are some cases out from under seal that have not been resolved, most prominently a series of cases against Abbott Laboratories in California, Florida, Massachusetts, and Texas. In addition to Abbott, cases now out from under seal in Massachusetts involve at least 48 drug companies.[5] Also, a preliminary settlement for half a billion dollars with Bristol Myers Squibb has been announced, though details have not been released. As recently as January 29, 2007, the Justice Department announced that it had unsealed and joined a case against Boehringer Ingelheim Roxane, Inc alleging damages of $500 million.

It is also difficult to get a precise handle on the amount of the potential liability involved in the unresolved cases, but it appears to be very large. The announced half-billion dollar settlement with Bristol alone equals 12 percent of the $4 billion recovered in the sixteen previous settlements. The alleged half-billion dollars of damages owed by Boehringer is another 12 percent. The potential liability in the cases against Abbott and others out from under seal are in the same magnitude or larger. There are indications that many of the other cases under seal also involve quite large liabilities. Thus it would not be unreasonable to assume that the total potential liability of the 180 outstanding cases could be somewhere in the $60 billion range, or above.

THE DANGERS AND OPPORTUNITIES PRESENTED

This astounding situation presents us with a danger and with an opportunity. The danger is that these cases will not be satisfactorily resolved; that one way or another the drug manufacturers will find a way to dodge their liability; and that they would be able to continue to develop and implement business plans and practices designed to plunder Medicaid and other government health programs, damaging those programs, taxpayers, and the beneficiaries of these programs.

The opportunity to be found in these cases is that the leaders of the departments responsible for pursuing the drug company fraud cases, the Attorney General and the Secretary of Health and Human Services, could, if they chose, use these cases to force the drug manufacturers to disgorge their fraudulently obtained funds. At the same time they could impose corporate integrity agreements with the settling companies that would put an end to the fraudulent practices and establish honest dealing with Medicaid and other health care programs. Such agreements could become the keystone of the companies' future good citizenship.

As things stand now, failure is far more likely than that the opportunity will be grasped. A drift toward failure is the current *status quo*, while grasping the opportunity would require a change of course.

and Administrative Law, Committee on the Judiciary, United States House of Representatives, Concerning Budget and Resource Needs of the Justice Department Civil Division for Fiscal Year 2007, submitted August 11, 2006

5. See Attachment A.

MAJOR PROGRAM INSUFFICIENCIES

The Committee will no doubt be interested in why the current course of conduct will lead to failure, especially in the light of the successes so far. The answer is complex, involving insufficiencies in manpower and the leadership necessary to bring the cases to a satisfactory resolution.

To begin with, the Department of Justice attorneys handling the cases against the drug manufacturers are simply overwhelmed and unable to prosecute a large portion of the cases in a timely manner. This is not because they are not good lawyers or because they are not trying. To the contrary, the Justice Department's attorneys involved in cases against drug manufacturers are very capable, hard working and dedicated. They are simply stretched to the breaking point.

The Justice Department in recent years has been able, on an annual basis, to resolve only between 90 and 100 FCA cases of all kinds. Of those cases, in the last six years, they have averaged less than three drug fraud cases resolved per year. At that rate, it will take many decades to resolve the 180 cases against drug manufacturers currently on the Departments docket. Actually, the backlog is not declining and cannot decline under the *status quo*, because more cases against drug manufacturers are filed each year than are resolved.

A further indication of the Justice Department's resource problem is the length of time the cases in question remain under seal. Many have remained under seal for ten years or more. When the Justice Department recently unsealed and joined a case against Abbott Laboratories that it could not settle, the case had been under seal for eleven years. The reason for this situation relates directly to the shortage of resources. The FCA provides that cases brought by whistleblowers be filed under seal in order to give the government a chance to investigate the cases in order to determine whether they wish to join the cases or leave them to the whistleblowers to pursue. A complicated fraud case, such as those against the drug manufacturers, could easily require two or three years of intensive investigation. However, the extensive time periods that drug fraud cases remain under seal indicates that the Department does not want to decline the cases, but does not have the resources to make timely investigations or to litigate the cases it cannot settle. Furthermore, the manufacturers are aware of this and are attempting to use Justice's lack of resources as leverage to reduce the amount they are required to repay or to delay settlement indefinitely with the hope of running out the clock on Justice.

A review of the Department's resources dedicated to FCA cases indicates that funds available for such a major set of cases are woefully inadequate. The monetary resources available for FCA cases at the Civil Division, which houses the central FCA fraud section, has been in the $20 million to $23 million range in the years FY2004 through FY2006. This pays for a fraud section that includes about 70 or so attorneys and is responsible for all civil matters involving fraud against the United States. How many of these have been deployed on drug manufacturer fraud cases in recent tears is not clear to me, but I estimate, very uncertainly, that it adds up to a dozen or so full time attorneys.

The money available for all FCA cases in the U.S. Attorneys offices has dropped from $58.5 million to $57.3 million in the years from FY2004 to FY2006. It is unclear, however, how much of the money and how many attorneys in the U.S. Attorneys offices are actually working on FCA cases, much less working on drug fraud cases. It appears that the money referred to is widely distributed to the various U.S. Attorneys offices, but that only a small percentage of those offices evidence concerted efforts to pursue FCA cases. Thus, an unusually large percentage of cases seem to be lodged in only a few U.S. Attorneys offices—for example, in Boston and Philadelphia, which appear to be completely swamped by the cases. A few other offices may also have begun to pursue a significant number of cases, but most U.S. Attorneys offices are simply missing in action. Though a guess, probably about 25 Assistant U.S. Attorneys are pursuing the 180 cases against the drug manufacturers on a full time basis. Whatever the precise number, though, there are simply far too few attorneys deployed to seriously pursue all of these huge cases.

The lack of resources available to pursue drug FCA cases cannot be a matter of economy. To the contrary, the resources deployed by the Justice Department in health care fraud cases have been repaid many fold. As noted above, health economist Jack Meyer calculates that the government, principally the Justice Department, gets back $15 for every dollar it spends on health care FCA cases. Despite this outstanding return-on-investment, it appears that the Department is actually withholding funds intended for health care fraud cases from the offices pursuing such cases. The Attorney General and the Secretary of Health and Human Services have routinely reported that they are providing $14.5 million to the Civil Division and $30 million to the U.S. Attorneys offices for health care fraud. Money appropriated to the Health Care Fraud and Abuse Control (HCFAC) Account is allocated annually by the Attorney General and the Secretary of HHS.[6] In FY 2005, for example, the HCFAC Report[7] reveals that $30,400,000 was allocated to U.S. Attorneys and $14,459,000 to the Civil Division for "anti-fraud activities." These numbers are typical of such allocations in recent years. However, as reported by Assistant Attorney General Peter Keisler to the House Judiciary Committee on August 11, 2006, it seems that only $10 million was actually provided to the U.S. attorneys in each of the years 2004–2006 and a varying amount as low as $6.5 million to the Civil Division in those years.

It also appears that the key investigative agencies have not stepped up to the plate to support these cases. Jack Meyer, in making the report mentioned above, determined that the Office of Inspector General at HHS is only supporting the Justice Department's health care FCA cases to the amount of $10 million or less.[8] The FBI, which has been provided $114 million from the HCFAC Account on an annual basis to combat health care fraud, simply spends nowhere near that amount to support health care FCA cases. While this cannot be quantified without the FBI's cooperation, the FBI appears to be spending far, far less, but has not been candid about what it has spent.

6. See Sections 112C(a) and 1817(k)(5) of the social security Act.

7. oig.hhs.gov/publications

8. Jack A. Meyer, *Fighting Medicaid Fraud, More Bang for the Federal Buck*, July 2006 (Table 4, p.10); see www.taf.org

It is not just resources that are lacking, it is also leadership that is lacking. The Department of Justices fraud section is lodged within the Commercial Litigation Branch of the Civil Division. Its attorneys do not have the standing within the government to command additional resources from within or without their own Department or to cause other elements of the government to give priority to any particular set of their cases. Only the Attorney General and the Deputy Attorney General have such standing. Thus, the actual attorneys struggling with the fraud cases are not going to receive the additional assistance they need without leadership initiative from above.

The consequences of allowing the FCA drug cases to drift along on their current course, with only two or three cases resolved each year, no matter how much effort the current set of attorneys put into them, is predictably negative. A few more cases will be settled with apparent good results, but eventually this set of cases will falter. One cannot predict with certainty how they will falter, but falter they will. One way they could falter would be as the result of an unexpected judicial development. Recently the Court of Appeals for the Second Circuit ruled that the government, when it unsealed an FCA case and filed its own complaint, could not, for purposes of the statute of limitations, take advantage of the date when the whistleblower filed the original complaint.[9] Because the government has been forced to keep the drug cases under seal for so long, were that ruling to be followed and applied to the drug cases, many could falter on that ground alone. That is but an example of how an unexpected development could undermine the drug cases. Certainly, as time drags on, legal, political and other developments can and, over time, are likely to occur that will erode the government's ability to prevail. If not timely pressed to resolve these matters, eventually the companies could find a way to beat the rap.

PROGRAM OPPORTUNITIES

One can hope that the faltering of the cases against drug manufacturers through delay and want of prosecution does not occur, for surely they present us with golden opportunities, including

- An opportunity to bring many billions of dollars defrauded from the government back to the taxpayers;
- An opportunity, going forward, to greatly reduce fraud against Medicaid and other government health care programs;
- An opportunity to redirect important companies that have become addicted to bilking Medicaid and Medicare;
- An opportunity for the pharmaceutical companies to put a shameful era of questionable billing practices behind them; and
- An opportunity to set rules of conduct in corporate integrity agreements that

9. *U.S. ex rel. Cosens v. The Baylor University Medical Center,* 468 F.3d 263 (2d Cir. Nov.16 2006).

would prevent any one company from gaining an economic advantage over its competitors by cheating Medicaid and Medicare.

RECOMMENDATIONS

In order to grasp these opportunities, the following things must occur:

1. First and foremost, the highest officials of the Department of Justice, the Attorney General and the Deputy Attorney General, should act now to provide leadership, in word and deed, to force a resolution of the FCA cases against the pharmaceutical manufacturers on a basis favorable to the government.

2. The resource shortage dragging down the Justice Department's fraud fighters must be addressed quickly and affirmatively. The fraud team requires significant augmentation. Its status should be raised to the branch level. The missing HCFAC Account money should be immediately provided to both the Civil Division's fraud team and to the U.S. Attorneys Offices that are actually engaged. More U.S. Attorneys offices should be recruited into the action. The missing FBI's HCFAC Account funds should be located and put to their appointed use.

3. The full support of the Department of Health and Human Services is necessary from the Secretary on down. The full support, with significantly augmented resources, by the HHS—OIG and by CMS should be insisted on to provide support of the FCA cases against drug manufacturers.

4. The Departments of Justice and of Health and Human Services should use their full authority and leverage to bring the pharmaceutical companies to the table and impose agreements that will end the fraudulent practices that characterize the FCA cases. Only the direct efforts of these officials can end the manipulations on a basis that prevents any one company from victimizing its competitors and the taxpayers by cheating.

5. The Attorney General should take all possible action to keep the clock from running out on these cases and to prevent these cases from languishing.

CONCLUSION

If the recommended actions are taken, we could see an end to the business plan frauds by the pharmaceutical manufacturers against Medicaid and other government programs. If the *status quo* continues, we can expect the FCA cases against drug manufacturers to limp along with some more settlements, but at some point the effort will fail and there will be no reform of the massive fraud drug practices weighing down Medicaid and other health care programs.

- Attachment A -

PHARMACEUTICAL COMPANIES IN UNSEALED MEDICAID FRAUD FALSE CLAIMS ACT CASES

- Abbott Laboratories
- Amgen
- Armour Pharmaceutical
- Aventis Pharmaceuticals
- Baxter Healthcare
- Bedford Laboratories
- Ben Venue Laboratories
- Boehringer Ingelheim Pharmaceuticals
- Braun of America
- C.H. Boehringer Sohn
- Centocorps Inc.
- Dey Pharmaceuticals
- Forest Pharmaceuticals
- Grundstucksverwaltung GMBH & Co.
- EMD
- Geneva Pharmaceuticals
- GlaxoSmithKline
- Glaxo Wellcome
- Burroughs Wellcome
- Hoechst Marion Roussell
- Hoffman-LaRoche
- Hospria Inc.
- Immunex
- Ivax Pharmaceuticals
- Janssen Pharmaceutical Products
- Johnson & Johnson
- Lipha
- McGaw
- Merck
- Mylan Laboratories

- Mylan Pharmaceuticals
- Novartis
- Ortho Biotech Products
- Pfizer
- Pharmacia
- Pharma Investment
- PurePac Pharmaceutical
- Roche Laboratories
- Roxane Laboratories
- Sandoz
- Sicor
- Gensia Pharmaceuticals
- Schering-Plough Corp.
- SmithKline Beecham Corp.
- GlaxoSmithKline
- Teva Pharmaceuticals
- Warrick Pharmaceuticals
- Z.L.B. Behring

- Attachment B -

SETTLED FALSE CLAIMS ACT CASES AGAINST PHARMACEUTICAL COMPANIES

Company	Settlement Date	Product	Total Recovery	Fraud Type	Whistleblower
AstraZeneca	6/20/03	Zoladex	$355 million	Marketing the spread and concealment of best price	Sales exec from competitor at TAP Pharmaceuticals
Baxter International	6/13/06	Generic drugs made by Baxter	$8.5 million	Marketing the spread	Independent pharmacy
Bayer I	1/23/01	Kogenate, Koate-HP, Gamimmune	$14 million	Marketing the spread and concealment of best price	Independent pharmacy
Bayer II	1/23/01	Adelat CC, Cipro	$257 million	Concealment of best price	Bayer marketing executive
Dey I	6/11/03	Albuterol	$18.5 million	Marketing the spread	Independent pharmacy
Dey 2 (Connecticut FCA)	8/7/04	Albuterol	$2.5 million	Marketing the spread	Independent pharmacy
GlaxoSmithKline I	4/16/03	Paxil, Flonase	$88 million	Concealment of best price	Derived from Bayer marketing executive allegations.
GlaxoSmithKline II	9/17/05	Zofran, Kytril	$150 million	Marketing the spread	Independent pharmacy
King Pharmaceutical	10/30/05	Altace, Aplisol, Lorabid, and Fluogen	$124 million	Concealment of best price	Executive of King Pharmaceuticals
Pfizer I	10/28/02	Lipitor	$49 million	Concealment of best price	National account manager for Pfizer subsidiary
Pfizer II	5/13/04	Neurontin	$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
Roxane Labs, Boehringer Ingelheim Pharmaceuticals, and Ben Venue Laboratories (Texas FCA)	11/25/05	Albuterol	$10 million	Marketing the spread	Independent pharmacy
Schering-Plough I	5/3/04	Albuterol	$27 million	Marketing the spread	Independent pharmacy
Schering-Plough II	7/29/04	Claritin	$345 million	Concealment of best price	Three employees of Schering-Plough subsidiary
Schering-Plough III	8/26/06	Temodar, Intron-A, K-Dur, Claritin RediTabs	$435 million	Concealment of best price and marketing the spread	Three employees of Schering-Plough

Company	Settlement Date	Product	Total Recovery	Fraud Type	Whistleblower
Serono	10/17/05	Serostim	$704 million	Off-label marketing and kickbacks	Five Serono employees in two states.
TAP Pharmaceuticals	10/3/01	Lupron	$875 million	Marketing the spread and concealment of best price	HMO Physician and TAP sales executive
TOTAL			**$3.894 billion**		

- Attachment C -

CITATIONS FOR SETTLED FALSE CLAIMS ACT CASES AGAINST PHARMACEUTICAL COMPANIES

Defendant	Case Citation
AstraZeneca	*U.S. ex rel. Durand v. AstraZeneca Pharmaceuticals LP*, No. 03-122-JJF (D. Del. 2003)
Baxter International	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc. et. al.*, No. GV401286 (District Court Travis County, 201st Judicial District 2006)
Bayer I	*U.S. ex rel. Ven-A-Care v. Bayer Corporation*, No. 95-1354-Civ. (S.D. Fla. 2001)
Bayer II	*U.S. ex rel. Estate of Couto v. Bayer Corporation*, No. 00-10339 (D. Mass. 2001)
Dey I	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. Dey Pharmaceuticals*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
GlaxoSmithKline I	*U.S. ex rel. Estate of Couto v. Bayer Corporation. et al*, No. 00-10339 (D. Mass. 2003)
GlaxoSmithKline II	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. GlaxoSmithKline PLC*, docket number sealed, settlement announced (D. Mass. 2005)
King Pharmaceuticals	*U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, No 03-1538 (E.D. Pa 2005)
Pfizer I	*U.S. ex rel. Foster v. Pfizer*, No.1:00-cv-00246 (E.D. Tex. 2002)
Pfizer II	*U.S. ex rel. Franklin v. Warner-Lambert*, No. 96-11651-PBS (D. Mass. 2004)
Roxane Labs et al.	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Roxane Laboratories Inc.*, No. GV3-03079 (District Court Travis County, 201st Judicial District) and No. GV002327 (District Court Travis County, 53rd Judicial District 2005)
Schering-Plough I	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering-Plough*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
Schering-Plough II	*U.S. ex rel. Alcorn v. Schering-Plough Corporation*, No. 98-5868 (E.D. Pa. 2004)
Schering-Plough III	*In re Pharmaceutical Industry Average Wholesale Price Litigation*, No. 01-CV-12257-PBS settlement announced (D.Mass. Aug. 10, 2006).
Serono	*U.S. ex rel. Driscoll v. Serono Laboratories, Inc.*, C.A. No. 00-11680 (D. Mass. 2000)
TAP Pharmaceuticals	*U.S. ex rel. Gerstein v. TAP Holdings, Inc.*, No. 00-10547 (D. Mass. 2001)

The Big Picture

Department of Justice Statistics,
October 1985–September 2006

FRAUD STATISTICS—OVERVIEW

October 1, 1986–September 30, 2006

Civil Division, U.S. Department of Justice

FY	New Matters[1]		Settlements & Judgments[2]					Relator Share Awards[3]		
			Non Qui Tam[2]	Qui Tam						
	Non Qui Tam	Qui Tam	Total	Where U.S. Intervened or Otherwise Pursued	Where U.S. Declined	Total	Total Qui Tam and Non Qui Tam	Where U.S. Intervened or Otherwise Pursued	Where U.S. Declined	Total
1987	361	66	86,479,949	0	0	0	86,479,949	0	0	0
1988	246	60	172,843,696	355,000	35,431	390,431	173,234,127	88,750	8,638	97,388
1989	236	95	197,202,180	15,111,719	0	15,111,719	212,313,899	1,446,770	0	1,446,770
1990	256	82	193,239,367	40,483,367	75,000	40,558,367	233,797,734	6,590,936	20,670	6,611,606
1991	243	90	270,945,467	69,705,771	69,500	69,775,271	340,720,738	10,667,537	18,750	10,686,287
1992	357	119	136,862,236	134,099,447	994,456	135,093,903	271,956,139	24,196,648	259,784	24,456,432
1993	329	132	187,234,076	171,438,383	5,978,000	177,416,383	364,650,459	25,636,134	1,756,902	27,393,036
1994	291	222	706,187,897	379,646,074	1,822,323	381,468,397	1,087,656,294	70,112,579	538,897	70,651,476
1995	236	277	279,522,866	245,463,627	1,813,200	247,276,827	526,799,693	46,475,379	517,238	46,992,617
1996	187	363	247,357,271	124,565,203	14,033,433	138,598,636	385,955,907	22,193,539	3,896,058	26,089,597
1997	185	533	468,549,359	622,666,381	7,136,144	629,802,525	1,098,351,884	65,938,921	1,981,346	67,920,267
1998	119	470	151,585,794	432,813,410	29,225,385	462,038,795	613,624,589	69,660,944	8,527,750	78,188,694
1999	141	481	196,613,009	454,268,984	62,509,047	516,778,031	713,391,040	49,414,054	17,593,462	67,007,516
2000	96	367	367,887,197	1,202,552,907	1,814,847	1,204,367,754	1,572,254,951	183,600,387	391,733	183,992,120
2001	88	309	494,496,974	1,175,104,715	125,726,963	1,300,831,678	1,795,328,652	187,475,850	30,294,843	217,770,693
2002	63	320	113,692,470	1,070,943,672	29,866,186	1,100,809,858	1,214,502,328	159,395,905	5,593,086	164,988,991
2003	93	334	703,003,368	1,430,379,125	87,140,070	1,517,519,195	2,220,522,563	307,961,126	19,322,900	327,284,026
2004	113	415	115,656,023	557,573,854	9,474,879	567,048,733	682,704,756	110,136,352	2,433,638	112,569,990
2005	107	394	276,914,983	1,133,354,057	24,896,229	1,158,250,286	1,435,165,269	162,832,340	6,900,933	169,733,273
2006	65	382	1,754,393,122	1,401,254,330	16,596,926	1,417,851,256	3,172,244,378	193,552,112	4,423,810	197,975,922
Total	3,812	5,514	5,366,154,182	10,665,243,139	397,608,163	11,062,851,302	18,183,518,606	1,700,406,864	99,037,984	1,799,444,848

1. "New Matters" refers to newly received referrals and investigations, and newly filed *qui tam* actions.

2. Non *qui tam* settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.

3. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims which may not be the entire settlement or judgment amount. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U.S.C. § 3730(h).

Fraud Statistics—Health & Human Services[1]

October 1, 1986–September 30, 2006
Civil Division, U.S. Department of Justice

FY	New Matters[2]		Settlements & Judgements[3]			
	Non Qui Tam	Qui Tam	Non Qui Tam[3]	Qui Tam		Total Qui Tam and Non Qui Tam
			Total	Total	Relator Share[4]	
1987	14	4	11,361,826	0	0	11,361,826
1988	9	9	1,382,675	355,000	88,750	1,737,675
1989	20	15	350,460	5,099,661	50,000	5,450,121
1990	28	12	12,202,500	903,158	119,474	13,105,658
1991	23	13	8,670,735	4,741,340	861,401	13,412,075
1992	30	17	9,821,640	2,192,478	446,648	12,014,118
1993	22	39	12,523,165	142,800,000	21,576,000	155,323,165
1994	43	80	381,635,015	16,564,684	2,752,827	398,199,699
1995	27	94	96,290,779	86,498,324	15,237,303	182,789,103
1996	20	204	63,059,873	52,876,698	9,624,568	115,936,571
1997	49	298	354,371,325	565,978,803	56,744,071	920,350,128
1998	36	287	40,107,920	257,320,610	47,807,528	297,428,530
1999	29	310	38,000,792	404,488,079	42,554,782	442,488,871
2000	37	223	208,899,015	708,090,743	113,594,529	916,989,758
2001	36	180	435,849,179	758,362,679	131,789,429	1,194,211,858
2002	24	197	74,117,427	935,922,512	149,173,648	1,010,039,939
2003	26	217	536,834,879	1,296,419,238	279,707,112	1,833,254,117
2004	28	276	34,816,447	474,575,690	97,346,065	509,392,137
2005	34	268	204,821,548	915,787,965	123,452,837	1,120,609,513
2006	16	110	1,087,314,755	1,208,428,854	149,215,240	2,295,743,609
Total	551	2,853	2,526,317,200	6,618,897,502	1,257,906,389	11,553,971,634

1. The information reported in this table covers matters in which the Department of Health and Human Services is the primary agency.

2. "New Matters" refers to newly received referrals and investigations, and newly filed *qui tam* actions.

3. Non *qui tam* settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.

4. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims which may not be the entire settlement or judgment amount. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U.S.C. § 3730(h).

Fraud Statistics—Department of Defense[1]

October 1, 1986–September 30, 2006
Civil Division, U.S. Department of Justice

FY	New Matters[2]		Settlements & Judgements[3]			
	Non Qui Tam	Qui Tam	Non Qui Tam[3]	Qui Tam		Total Qui Tam and Non Qui Tam
			Total	Total	Relator Share[4]	
1987	245	18	27,897,128	0	0	27,897,128
1988	138	36	149,136,213	33,750	8,437	149,169,963
1989	128	40	154,588,297	10,002,058	1,394,770	164,590,355
1990	77	45	118,915,978	21,699,713	3,795,720	140,615,691
1991	79	50	227,813,245	57,242,000	8,636,300	285,055,245
1992	78	64	62,603,695	129,294,456	23,874,784	191,898,151
1993	94	55	83,968,840	31,812,641	5,291,923	115,781,481
1994	62	96	222,799,421	361,385,206	67,285,578	584,184,627
1995	54	103	110,498,386	149,504,237	29,617,461	260,002,623
1996	44	135	78,085,099	63,347,938	12,991,758	141,433,037
1997	45	146	30,734,273	52,370,622	9,172,921	83,104,895
1998	29	78	71,063,139	145,277,685	20,041,579	216,340,824
1999	33	109	27,211,319	18,577,833	3,394,779	45,789,152
2000	10	77	53,007,693	124,696,475	20,893,416	177,704,168
2001	11	74	17,472,751	165,641,285	28,279,241	183,114,036
2002	16	72	9,561,543	42,665,096	8,235,954	52,226,639
2003	11	78	107,337,000	193,018,638	42,686,070	300,355,638
2004	16	99	10,098,491	17,941,119	3,104,889	28,039,610
2005	16	97	19,049,935	93,711,552	19,904,255	112,761,487
2006	11	52	586,430,385	35,063,952	6,693,210	621,494,337
Total	1,197	1,524	2,168,272,831	1,716,584,369	315,437,256	3,884,857,200

1. The information reported in this table covers matters in which the Department of Defense is the primary agency.

2. "New Matters" refers to newly received referrals and investigations, and newly filed *qui tam* actions.

3. Non *qui tam* settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.

4. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims which may not be the entire settlement or judgment amount. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U.S.C. § 3730(h).

Fraud Statistics—Other (Non-HHS, Non-DOD)[1]

October 1, 1986–September 30, 2006
Civil Division, U.S. Department of Justice

FY	New Matters[2]		Settlements & Judgments[3]			
	Non Qui Tam	Qui Tam	Non Qui Tam[3]	Qui Tam		Total Qui Tam and Non Qui Tam
			Total	Total	Relator Share[4]	
1987	102	12	47,220,995	0	0	47,220,995
1988	99	20	22,324,808	1,681	200	22,326,489
1989	88	46	42,263,423	10,000	2,000	42,273,423
1990	151	33	62,120,889	17,955,496	2,696,412	80,076,385
1991	141	38	34,461,487	7,791,931	1,188,586	42,253,418
1992	249	57	64,436,901	3,606,969	135,000	68,043,870
1993	213	66	90,742,071	2,803,742	525,113	93,545,813
1994	186	105	101,753,461	3,518,507	613,071	105,271,968
1995	155	134	72,733,701	11,274,266	2,137,853	84,007,967
1996	123	163	106,212,299	22,374,000	3,473,272	128,586,299
1997	91	366	83,443,761	11,453,100	2,003,275	94,896,861
1998	54	168	40,414,735	59,440,500	10,339,588	99,855,235
1999	79	153	131,400,898	93,712,119	21,057,955	225,113,017
2000	49	165	105,980,489	371,580,535	49,504,175	477,561,024
2001	41	134	41,175,045	376,827,714	57,702,023	418,002,759
2002	23	122	30,013,500	117,885,326	7,382,373	147,898,826
2003	56	136	58,831,489	26,788,697	5,210,103	85,620,186
2004	69	180	70,741,084	73,030,755	11,950,182	143,771,839
2005	57	185	53,043,500	148,750,769	26,376,181	201,794,269
2006	38	74	80,647,982	174,358,450	42,067,470	255,006,432
Total	2,064	2,357	1,339,962,518	1,404,627,254	226,101,202	2,744,589,772

1. The information reported in this table covers matters in which an agency other than the Department of Health and Human Services or the Department of Defense is the primary agency.

2. "New Matters" refers to newly received referrals and investigations, and newly filed *qui tam* actions.

3. Non *qui tam* settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.

4. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims which may not be the entire settlement or judgment amount. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U.S.C. § 3730(h).

Fraud Statistics
Qui Tam Intervention Decisions & Case Status
As of September 30, 2006
Civil Division, U.S. Department of Justice

	Active	Settlement or Judgment	Dismissed	Inactive	Unclear	Total
U.S. Intervened	63	905	50	3	7	1,028
U.S. Declined	355	191	3,018	2	5	3,571
Under Investigation						915
						5,514