Use of the False Claims Act to Enforce Federal Regulations: Necessary Limits on False Certification Cases Brought Under the Civil False Claims Act

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Introduction

The civil False Claims Act (“FCA”), originally known as the “Informer’s Act” or the “Lincoln Law,” was enacted in 1863 in response to unscrupulous private contractors who sold defective goods to the Union Army and price-gouged the government during the Civil War. The Supreme Court noted that the FCA, with its unique *qui tam* enforcement mechanism, was enacted following testimony before Congress that painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war. Congress wanted to stop this plundering of the public treasury. At the same time it is equally clear that the False Claims Act was not designed to reach every kind of fraud practiced on the Government.¹

Notably, the Court also recognized in this early FCA case, *United States v. McNinch*, that the scope of FCA liability was necessarily limited and it did not reach every fraud on the government, including an application for credit insurance in that case. The Court reemphasized this principle in *Allison Engine Co. v. United States ex rel. Sanders*, concluding that broad causes of action that “threaten to transform the FCA into an all-purpose antifraud statute” must be avoided.²

In 1986, significant FCA amendments were enacted in order to combat fraud in the defense and health care industries. These amendments dramatically expanded the incentives to filing *qui tam* suits by strengthening the rights of whistleblowers and increasing the bounties that may be awarded to successful *qui tam* relators. The amendments expanded the *qui tam* enforcement mechanism by: increasing the relators’ share to up to 30 percent of the government’s recovery; removing the government knowledge bar and replacing it with public disclosure and original source provisions; adding a retaliation provision; allowing *qui tam* participation after intervention by the United States; and encouraging *qui tam* enforcement if the United States declined to intervene. The 1986 amendments also lowered the intent needed for an FCA violation to the “recklessness” standard, and established preponderance of the evidence as the burden of proof.

The 1986 amendments brought one other major development: the attempt by FCA plaintiffs—relators and the government—to expand FCA liability for violations of ancillary laws and regulations, commonly known as “false certifications.” In these “false certification” cases, the contractor/grantee/provider delivers the goods or services paid for by the government but, in the process, violates some other law or regulation. The jurisprudence that has grown up around these “false certification” cases demonstrates how courts have implemented the Supreme Court’s teaching in *McNinch* and *Allison Engine* that the FCA is a statute of limited scope.

Subsequent FCA amendments enacted in 2009 and 2010 were intended to further the FCA’s application in the mortgage insurance, financial, and health care sectors of the economy and to make it easier to bring FCA claims in those areas as well as more generally.³ Rather than addressing the details of those amendments, however, this paper focuses on a largely unanticipated consequence of the Fraud Enforcement and Recovery Act’s (“FERA”) 2009 amendments: the effect of FERA’s amendments on a fundamental requirement for FCA liability—falsity—and in particular, on recent judicial decisions that

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³ *See* Appendices 2, 3, and 4 (attaching three FraudMail Alerts issued contemporaneously with the 2009 and 2010 amendments).
have strengthened that requirement in the false certification context. While FERA’s amendments—for the first time—adopted a materiality analysis in two of the statute’s liability provisions, the importance of that analysis in distinguishing failures to comply with technical or regulatory requirements from serious violations of conditions of payment has diminished greatly since these amendments became law.

Specifically, FERA applied the term “material” to Section 3729(a)(1)(B) and Section 3729(a)(1)(G), and it defined “material” using the more relaxed definition preferred by plaintiffs—“having a natural tendency to influence or be capable of influencing” payment. A recurring problem with the natural tendency test of materiality is that in determining whether the government could have refused to pay or approve a claim, it is rarely deemed necessary under that standard to consider the government officials’ actual responses to the alleged false claims. This approach leaves out the key interest of the agency officials who are responsible for the transaction and who have the public interest in mind when deciding whether or not to pay the claim. With FERA’s adoption of the “weaker” standard of materiality, the concept of materiality has become a less reliable basis for distinguishing between requirements that, if violated, render a claim false, and requirements that do not in cases based on the “false certification” theory of liability. For this reason, the author, in an article published shortly after the 2009 amendments were passed, postulated that courts would find a legal way to reinstate the “prerequisite to payment” requirement to establish falsity in false certification cases, which is the turn of events addressed below.5

As recent decisions show, the courts have spearheaded a jurisprudence that has strengthened the concept of falsity by requiring a “prerequisite to payment” violation for falsity to be established in these cases. This limitation on false certification liability accords with the FCA’s purpose of protecting the Treasury from fraud, while at the same time it follows the Supreme Court’s precept in Allison Engine that broad causes of action that “threaten to transform the FCA into an all-purpose antifraud statute” must be avoided.6 Nearly every circuit court has applied a “prerequisite to payment” analysis of falsity to limit FCA liability under the false certification theory.

The Falsity Requirement

The terms “false” or “fraudulent” are fundamental to liability under the statute’s primary liability provisions in Sections 3729(a)(1)(A) through (C), and Section 3729(a)(1)(G), but the FCA does not define them. As a result, courts have construed these terms with reference to other contexts, most notably, criminal cases brought under 18 U.S.C. §§ 287 and 1001. In both criminal and civil FCA cases, proof of actual falsity is required.7

FCA Cases Based on “Factual Falsity”

Prior to the 1986 amendments, FCA cases typically involved allegations that the defendant submitted a “factually false” claim for payment to the government. In many instances, there is no doubt that a claim is false in these cases. For example, if the government is billed for 1,000 man-hours of work under a federal contract, but that number is inflated based upon falsified time cards, any invoice based on those

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4 See, e.g., United States v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008) (applying the “capable of influencing” test of materiality and finding that testimony of a government official showing that it would not have paid was not a required component of materiality).


6 Allison Engine, 553 U.S. at 672.

7 See United States v. Diogo, 320 F.2d 898, 902 (2d Cir. 1963); United States v. Lange, 528 F.2d 1280, 1287 (5th Cir. 1976).
time cards is clearly “false.” Similarly, if a contract calls for the delivery of a certain grade of wire, but the contractor supplies a cheaper grade but bills for the higher grade of wire, the invoice for the substandard product is “false.” Or, if a doctor overcharges Medicare for surgery performed in the hospital at a higher rate when the patient’s surgery actually was performed in the doctor’s office at a lower rate, the voucher is unquestionably “false.” In these standard “factually false” cases, proving falsity is a relatively straightforward matter of showing that the request for reimbursement used “an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.”

FCA Cases Based on “Legal Falsity”

Liability for “legally false” claims—predicated on an express or implied false certification of compliance with a regulation, statute or contract term—is more complicated, and has resulted in one of the most controversial debates on the proper scope of FCA liability. In a “legally false” claim or a “false certification” case, the defendant has provided the goods or services to the government or government beneficiary for the agreed upon price. For example, the hospital has provided medically necessary services to a Medicare eligible beneficiary and billed the government the proper amount, or the contractor has provided a part that meets all specifications and billed the government for the contract price, but the hospital or contractor has not complied with some other regulation, statute, or contract term in the course of delivering that service or producing that article. The hospital may have violated one or more “conditions of participation” in the course of delivering the necessary services to the eligible beneficiary, or the contractor may have violated a discrimination law in hiring workers for its plant where the contract is performed. Under the false certification theory, FCA liability attaches to those violations if they are deemed important enough to render the claim legally false. Private relators and the government have attempted to use the false certification theory of FCA liability to enforce numerous other federal regulations and regulatory schemes under the FCA.

Limits on the False Certification Theory

The expansive false certification theory of FCA liability is controversial for a number of reasons. First, by expanding FCA liability to a violation of regulatory requirements that may be tangential to the product or service provided by the defendant, the theory extends the statute’s punitive treble damages and mandatory penalties to those requirements even though they are not mentioned in the government contract or in the contractor’s invoice. Second, under the implied certification theory, liability may be extended

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8 United States ex rel. Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001); see, e.g., United States v. Aerodex, 469 F.2d 1003, 1008 (5th Cir. 1972) (ruling that “the deliberate mislabeling in the case at bar, coupled with the fact that the parts delivered did not actually meet the specifications of the contract, compels a finding of liability under the Act”); United States ex rel. Green v. Northrop Corp., 59 F.3d 953, 956 (9th Cir. 1995) (qui tam suit alleging that “Northrop had ‘double charged’ the U.S. Air Force for equipment procured for the B-2 bomber program”). Cf. United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) (certification that school district would comply with applicable federal law was not a “prerequisite” to receipt of federal funds under the Individuals with Disabilities Education Act).

to the defendant’s invoice without any false statement by the defendant.\textsuperscript{10} Third, damages in such cases may be much higher than in cases based on factual falsity because, plaintiffs argue, each claim submitted under the contract could be deemed legally false.\textsuperscript{11} As one court put it, in a fraudulent inducement case, False Claims Act liability is asserted as to each claim submitted to the government under a contract, if that contract was originally obtained through false statements or fraudulent conduct. The claims for payment may be accurate, but the antecedent fraud in obtaining the contract makes each claim submitted a false or fraudulent claim.\textsuperscript{12}

A number of circuits have adopted the “legally false” claim analysis and have accepted the “false certification” theory of liability, but they also have recognized the expansiveness of this theory and its potential misapplication in FCA cases premised on regulatory violations. This concern was highlighted by the Second Circuit in \textit{United States ex rel. Mikes v. Straus}:

\textit{[C]aution should be exercised not to read this theory expansively and out of context \ldots \ T}he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment—and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act’s reach.\textsuperscript{13}

The Materiality Analysis

Because it is obvious that no regulated party could ever comply with the tens of thousands of applicable laws, regulations, and guidelines, courts needed to develop a legal mechanism for differentiating violations that went to the heart of the claim for federal money from violations that were inconsequential to the funding decision. At first, that legal mechanism became known as “materiality,” and the historical basis of the materiality requirement can be traced to \textit{United States v. McNinch}, in which the Supreme Court held that the civil False Claims Act is “not designed to reach every kind of fraud practiced on the Government.”\textsuperscript{14} More recently, in \textit{Allison Engine Co. v. United States ex rel. Sanders}, the Supreme Court clearly indicated in the context of its discussion of the elements of liability under Section 3729(a)(2) that a showing of “materiality” is required, and that a false statement must be a “condition of payment” in order to satisfy that materiality requirement.\textsuperscript{15}

After FERA, however, the statutory definition of “material” became “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” This standard is not new, and courts have interpreted it as strongly limiting FCA liability to false statements that directly affect the government’s payment decision. For example, several courts have held that violations of

\begin{itemize}
\item \textit{Mikes}, 274 F.3d at 699.
\item \textit{McNinch}, 356 U.S. at 599.
\item \textit{Allison Engine}, 553 U.S. at 671–72 (2008).
\end{itemize}
“conditions of participation” in a federal healthcare program did not result in FCA violations. In *United States ex rel. Conner v. Salina Regional Health Center*, the Tenth Circuit found that sweeping, general certifications of compliance with conditions of participation in annual Medicare cost reports were not actionable because they were not specific conditions of payment.\(^{16}\) Similarly, in *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, the district court found that there was no evidence showing that noncompliance with Medicare’s conditions of participation would make the defendants ineligible for Medicare payments or lead to nonpayment of the claims.\(^{17}\)

However, the materiality analysis used by other courts obscures the difference between violations of conditions of participation and conditions of payment. For example, in *United States ex rel. Hendow v. University of Phoenix*, the Ninth Circuit found it unimportant that the University’s certification was a promise to comply with a restriction on enrollment incentive compensation in the future, and ruled that the distinction between a condition of participation and payment was “a distinction without a difference” because the government “plainly care[d]” about the restriction.\(^{18}\) Ultimately, the court required “a causal . . . connection between fraud and payment,” but this condition to payment requirement was undercut by the court’s emphasis on materiality in its analysis of the allegations.

In *United States v. Science Applications International Corp.*, the D.C. Circuit adopted a similar approach in rejecting SAIC’s effort to limit the implied certification theory to exclude the violation of an organizational conflict of interest provision that was not an express condition of payment:

> Even though we have rejected SAIC’s effort to cabin the implied certification theory, we fully understand the risks created by an excessively broad interpretation of the FCA. As SAIC compellingly points out, without clear limits and careful application, the implied certification theory is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA’s generous remedial scheme, may attempt to turn the violation of minor contractual provisions into an FCA action. In our view, however, instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, this very real concern can be effectively addressed through strict enforcement of the Act’s materiality and scienter requirements.\(^{19}\)

The D.C. Circuit’s concern about potential abuse under the implied false certification theory of liability is unhelpful given the low “materiality” threshold put in place by FERA’s amendments.

In light of the potential for abuse under this theory, business groups have proposed reforms that include eliminating the implied false certification theory of liability in FCA cases.\(^{20}\) Meanwhile, the courts have found another way to limit this broad liability, and they are easing the impact of FERA’s low materiality threshold by refusing to conflate the elements of “materiality” and “falsity” in FCA cases premised on this theory.

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\(^{16}\) *United States ex rel. Conner v. Salina Reg’l Health Ctr.*, 543 F.3d 1211, 1220–23 (10th Cir. 2008).

\(^{17}\) *United States ex rel. Landers v. Baptist Mem’l Health Care Corp.*, 525 F. Supp. 2d 972, 978–79 (W.D. Tenn. 2007). The reader should note that the author was one of the attorneys representing the defendants in this case.

\(^{18}\) *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1176–77 (9th Cir. 2006).

\(^{19}\) *Sci. Applications*, 626 F.3d at 1270.

The “Prerequisite to Payment” Analysis of Falsity

Following FERA’s 2009 amendments, a majority of circuit courts have adopted the analysis of falsity that the Second Circuit introduced in *United States ex rel. Mikes v. Straus*: to establish “legal falsity,” the defendant must falsely certify “compliance with a statute or regulation as a condition to government payment.”21 As the Third Circuit recently explained, the FCA should not be used to “enforce compliance with all medical regulations” such as those that require resolving medical issues that are not requirements for reimbursement.22

In a remarkable decision in 2010, the Fifth Circuit adopted a stringent standard for false certification cases that prevents the FCA from becoming a catch-all vehicle for punishing minor violations of law that occur in the course of providing federally-funded medical services or performing under government contracts. In *United States ex rel. Steury v. Cardinal Health, Inc.* (“*Steury I*”),23 the Fifth Circuit ruled that a defendant can be liable under the FCA for a false certification of compliance with a regulatory requirement—even one that is “material” to the government’s decision to pay the claim—only if the payment by the government agency is conditioned on compliance with the statute, regulation, or contract provision. The relator in *Steury I* claimed that by submitting claims for payment to the Veterans Administration for allegedly defective intravenous fluid pumps, Cardinal Health falsely and implicitly certified compliance with an implied warranty of merchantability. Without deciding whether it would adopt the implied false certification theory, the Fifth Circuit found that Cardinal Health did not make an implied certification simply because the FAR includes warranty of merchantability provisions. This basis of liability did not suffice because the FAR also allows the government to choose to override implied warranties of merchantability with express warranties, or to accept and pay for noncompliant commercial items. The court held that the claim could not be “false” within the meaning of the FCA if compliance with this warranty was not required in order to receive payment, and that “a false certification, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.”24

The court further found that determining whether a false certification is “material” under the expansive “natural tendency” definition of that term does not eliminate the applicability of the “prerequisite to payment” test.25 The court concluded that there could be no liability in *Steury I* because payment by the government agency was not conditioned on compliance with the certification alleged. The language used by the court in *Steury I* permits the argument that the Fifth Circuit would apply this “falsity” requirement in both express and implied certification cases. The Fifth Circuit’s analysis of falsity introduces a welcome concept—fundamental fairness—and imposes it on False Claims Act enforcement.

In reaching its decision in *Steury I*, the Fifth Circuit cited with approval the Second Circuit’s decision in *Mikes*, which also required the false certification to be a “prerequisite for payment” in order to support an FCA violation. As the recent circuit court decisions summarized below demonstrate, most other circuit courts have adopted this prerequisite to payment requirement in the analysis of legal falsity, and they have applied it as a threshold determination for FCA liability based on a false certification—whether express or implied.

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21 *Mikes*, 274 F.3d at 697 (emphasis added).
24 *Id.* at 269.
25 *Id.*
This analysis is fully supported by the 2009 amendments. When Congress added the word “material” in 2009, the word was not added to 31 U.S.C. §3729(a)(1)(A)—the false claim element of the FCA. Thus, courts had to define “falsity” without considering materiality because the word “material” did not appear in subsection (a)(1)(A). “Materiality” is only a factor when there is a separate false statement (under the two relevant provisions of the FCA containing a materiality standard) and the false statement has to have a causal link to the separate false claim. Thus, though the legal analysis by the courts discussed below has been applied to both pre- and post-2009 FCA cases, the legislative revisions in 2009 fully support that analysis.

Key Case Law by Circuit

First Circuit. In *United States ex rel. Ge v. Takeda Pharmaceutical Co.*,26 the First Circuit affirmed the dismissal of Dr. Ge’s *qui tam* complaint allegations—that Takeda failed to disclose adequately the risks associated with four of its drugs and that this failure resulted in the submission of false claims to Medicare and Medicaid by patients and physicians—because the complaint did not establish that false claims were submitted as a result of the misconduct, even assuming that the misconduct alleged a fraud on the FDA. Not only did that deficiency mean that the complaint failed to satisfy Rule 9(b)’s pleading requirements, but the court also indicated that, beyond supplying the details of an alleged reporting violation or even the alleged fraud on the FDA, the plaintiff must show that the defendant’s misconduct caused claims for payment, and that the claims were rendered “false” by the misconduct or fraud.27 The appellate court’s decision in *Ge* reflects an emerging stringent falsity analysis by quoting with approval the district court’s conclusion that “although relator has alleged facts that would demonstrate a ‘fraud-on-the-FDA’ with respect to intentional under-reporting of adverse events, she has failed to allege the specific details of any claims that were allegedly rendered ‘false’ as a result.”28

Second Circuit. As noted above, in *United States ex rel. Mikes v. Straus*, the Second Circuit found that the regulatory quality of care requirements cited by the relator were conditions of participation in the Medicare program, rather than conditions of payment. To ensure that FCA suits would be limited to obligations that actually were prerequisites to payment, the court imposed a further limitation:

> Specifically, implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid….Liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing—as that term is defined by the Act—that payment expressly is precluded because of some noncompliance by the defendant.29

Some courts have followed *Mikes* in requiring the violation of an express statutory or regulatory prerequisite to payment as a limit on implied false certification liability, particularly in Medicare and Medicaid cases.

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27 *Id.* at 124–26 (rejecting Dr. Ge’s *per se* rule that the misconduct necessarily resulted in false claims as well as her assertion that “as a result of Takeda’s alleged misconduct, certain reimbursement claims were rendered false under the FCA because they impliedly—and incorrectly—certified that the subject drugs were “reasonable and necessary”).

28 *Id.* at 121.

29 *Mikes*, 274 F.3d at 700 (emphasis in original) (citations omitted).
Third Circuit. In *United States ex rel. Wilkins v. United Health Group, Inc.*, the Third Circuit joined other circuits in adopting the implied false certification theory liability.\(^{30}\) The court determined that this ruling was consistent with congressional intent that the FCA covered legally false claims:

> [A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation . . . . [Claims made to Medicare or Medicaid programs] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program.\(^{31}\)

The court held that compliance with Medicare marketing regulations was not a condition of government payment under federal health insurance programs, but that submitting claims to these programs while violating the Anti-Kickback Statute (“AKS”) was actionable under the FCA.

The court agreed with the Second Circuit in *Mikes* that the implied false certification theory should not be applied expansively, particularly in advancing FCA allegations under federal health care programs. Despite its acceptance of the theory, the Third Circuit affirmed the dismissal of the marketing claims because the government’s payment of the claims was not conditioned on compliance with the marketing regulations. The court based its ruling on the finding that the marketing regulations were conditions of participation because, under CMS regulations, CMS could take various actions ranging from allowing a plan sponsor to correct a violation to terminating the contract. Further, the court observed:

> [W]e think that anyone examining Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them. Moreover, it is ironical that if we allowed appellants, though they are ostensibly acting on behalf of the Government, to bring suit based on United Health’s non-compliance with marketing regulations, we would short-circuit the very remedial process the Government has established to address non-compliance with those regulations. “It would ... be curious to read the FCA, a statute intended to protect the government’s fiscal interests, to undermine the government’s own regulatory procedures.”\(^{32}\)

Fourth Circuit. The core allegation in *United States ex rel. Rostholder v. Omnicare, Inc.*,\(^{33}\) was that Omnicare, a pharmaceutical services provider to nursing homes, sought reimbursement from Medicare and Medicaid for drugs that were repackaged in violation of FDA safety regulations. The relator claimed that Omnicare improperly repackaged non-penicillin drugs in the same facility as penicillin drugs, leading to potential contamination in violation of FDA regulations and rendering the drugs “ineligible for coverage under government [healthcare] programs.”\(^{34}\) Notably, before the relator filed his *qui tam* complaint, the FDA investigated the claims, issued a warning letter to Omnicare, and cautioned that the drugs at issue were “adulterated.” In response, Omnicare destroyed drugs worth $19 million but did not recall any drugs previously distributed or reimburse the government for Medicare and Medicaid payments previously made for allegedly contaminated drugs. Despite the FDA’s conclusions, the Department of

\(^{30}\) *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011).


\(^{32}\) *Id.* at 310 (citing *Conner*, 543 F.3d at 1221).


\(^{34}\) *Id.* at 698.
Justice declined to intervene in the *qui tam* case but filed a Statement of Interest in support of the relator’s broad legal argument for FCA liability.

The Fourth Circuit affirmed the dismissal of the *qui tam* claims. Citing the Third Circuit’s *Wilkins* opinion, the court concluded that it was not enough to allege that compliance was “material” to the government’s payment, and held that both materiality and a false statement or fraudulent course of conduct must be alleged. The Fourth Circuit concluded that, if compliance with an FDA regulatory requirement is not a prerequisite to payment under Medicare and Medicaid, there is no FCA violation. In support of its primary holding, the Fourth Circuit noted that the FCA was not the appropriate enforcement mechanism for mere regulatory violations:

> Were we to accept relator’s theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct. When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could “short-circuit the very remedial process the Government has established to address non-compliance with those regulations.”

The Fourth Circuit’s ruling is significant in that it appears to hold that, unless it is clearly stated in a statute or otherwise that compliance with a regulation is a prerequisite to payment, a defendant cannot act with the requisite scienter and cannot submit a “false” claim. This holding, which is essentially the current standard in the Second Circuit, if adopted more widely, would greatly undermine “implied certification” cases brought under the FCA.

**Fifth Circuit.** In *United States ex rel. Steury v. Cardinal Health, Inc.* ("Steury II"), the Fifth Circuit bolstered its holding in *Steury I*, discussed above, by reemphasizing the necessity of establishing a statutory, contractual, or a similar foundation for the prerequisite to payment requirement, and concluding that the relator did not identify any contractual provisions regarding merchantability or show how the intravenous pumps deviated from the government’s specifications. Moreover, the relator did not state an FCA claim based on implied false certification of merchantability, the court held, because she failed to allege that “the contractual merchantability provision, whether express or implied, was a condition without which the government would not have paid Cardinal.”

More recently, in *United States ex rel. Spicer v. Westbrook*, the Fifth Circuit reiterated that a false certification does not give rise to a false claim unless payment is conditioned on compliance. Spicer

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35 Id. at 702 (internal citation omitted).
36 Id. ("Because the Medicare and Medicaid statutes do not prohibit reimbursement for drugs packaged in violation of the [FDA safety regulations], Omnicare could not have knowingly submitted a false claim for such drugs.").
37 A footnote within the Fourth Circuit’s decision alludes to this broader implication. Id. at 702 n.7 ("Because adulterated drugs are subject to reimbursement by Medicare and Medicaid and therefore any claim for payment cannot be ‘false,’ ‘we do not separately address relator’s arguments for FCA liability under ‘implied certification’ or ‘worthless services’ theories.’"); see also *Mikes*, 274 F.3d at 702.
39 Id. at 207.
alleged a breach of contract—a failure to inspect whether component parts of mine resistant vehicles conformed to specifications, and invoices indicating that component parts conformed to chemical agent resistant coating requirements—without establishing that these inspections or certifications were required to receive payment. In dismissing the allegations, the court noted that the prerequisite requirement—a false certification of compliance—derives from “materiality” but is not fully encompassed by the natural tendency definition of that term, and that a false certification does not give rise to a false claim for payment unless payment is conditioned on compliance. The court also observed that when the government rejected some of the vehicles for improper coating, the defective parts were replaced and payment made.

**Sixth Circuit.** In *United States ex rel. Chesbrough v. Visiting Physicians Association*, the Sixth Circuit dismissed the complaint because no regulation mentioned the purported radiology testing standards allegedly violated or required compliance with HIPAA’s patient confidentiality provisions as a condition of payment. The court cited with approval the Second Circuit’s conclusion in *Mikes* that the FCA should not be interpreted to “enforce compliance with all medical regulations” such as those that require resolving medical issues that are not requirements for reimbursement. In order to plead and prove “falsity” under the implied false certification theory, the Sixth Circuit held, relators must establish that a statute or regulation conditioned payment on compliance.

Subsequently, in *United States ex rel. Hobbs v. MedQuest Associates*, the Sixth Circuit reversed the district court’s entry of summary judgment and vacated the $11 million judgment that went along with it because the liability was based on regulatory non-compliance that was a “condition of participation” in Medicare, but not a “condition of payment” of MedQuest’s Medicare claims. As a result, while expressing no tolerance for the defendant’s Medicare program violations—characterizing them as “clearly . . . at odds with the goals and aims of the Medicare program in several respects”—the Sixth Circuit ruled that the government cannot use the FCA to enforce or punish that type of conduct and should utilize available administrative remedies instead. The Sixth Circuit made clear that regulatory noncompliance that violates “conditions of participation”—even if serious and intentional—is not enough to establish an FCA violation and does not “mandate the extraordinary remedies of the FCA.”

**Seventh Circuit.** In *United States ex rel. Hill v. City of Chicago*, the Seventh Circuit affirmed the dismissal of false certification allegations for lack of falsity. The City of Chicago applied for federal grants under the Omnibus Crime Control and Safe Streets Act and in accordance with regulations, the City certified that it had an Equal Employment Opportunity ("EEO") plan and would implement a program within the specified period. The relator claimed that this certification was false because the City’s program as implemented differed from the plan described in its grant application. There was no allegation that the City’s program fell short of federal requirements in any way or that the City intended to defraud the federal government. The Seventh Circuit rejected the relator’s formalistic claim and concluded that there was no false claim because the similarity between the City’s written plan and its program as implemented meant that “no federal agency has parted with money under false pretenses.” The court’s recognition that circumstances may require a departure from the plan was a reasonable explanation for the City’s actions and simply made good common sense:

41 *Chesbrough*, 655 F.3d at 467–69.
42 *Id.* at 468 (quoting *Mikes*, 274 F.3d at 699–700).
44 *Id.* at 713.
45 *Id.*
Departing from the formal documents in order to get things done more quickly or accurately is common, and some flexibility is essential when administrators encounter circumstances that plan-writers did not anticipate. Chicago has a huge bureaucracy; what works in one bureau may not work in another, and slavishly following a single plan could be counterproductive. . . . Practical accommodations are a relief. . . . As long as it has a plan, and does get the job done, the City is in compliance with the representations made to obtain the grants.47

**Eighth Circuit.** The Eighth Circuit joined other circuits in limiting FCA liability to regulatory violations that are conditions of payment in *United States ex rel. Ketroser v. Mayo Foundation.*48 Ketroser and three other relators claimed that the Mayo Clinic billed Medicare for surgical pathology services that were not provided. The government filed a complaint in partial intervention alleging that Mayo billed for surgical pathology slides it did not create or examine, and the parties settled that claim. Subsequently, the relators asserted additional claims that Mayo billed Medicare when it prepared and read a permanent tissue slide but had not prepared a separate written report for that service. The district court dismissed the additional claims because the billing codes for the services did not explicitly require written reports, and the regulations required reports for “clinical” pathology services but not “surgical” pathology services.

The Eighth Circuit affirmed, ruling that relators’ claim that a written report must underlie each claim for surgical pathology services was a claim of “regulatory noncompliance, not a plausible claim that Mayo submitted false or fraudulent claims for Medicare payment.” Like the Seventh Circuit in *Hill,* the Eighth Circuit applied common sense in ruling that the relators failed to state an FCA claim:

> nowhere in the Medicare regulations or in the American Medical Association Codebook have we found a requirement that physicians using the CPT codes for surgical pathology services must prepare the additional written reports that Relators claim Mayo fraudulently failed to provide. The FCA may not properly be used to impose an onerous and costly burden on the healthcare system without plausible evidence that Medicare would consider such redundant reports to be a material condition of payment.49

While the court explained that the dismissal was due to a failure to allege a violation of any regulation or code, it also found that a further failure was that the reporting requirement was not a “material condition of payment.” To the extent that the court used a “condition of payment” analysis to reject the relators’ theory, it employed the essential element of a “prerequisite to payment” analysis of falsity.

**Ninth Circuit.** As noted in the discussion of materiality above, in *Hendow,* the Ninth Circuit required “a causal . . . connection between fraud and payment,”50 but its underlying materiality analysis obscured the difference between conditions of eligibility and conditions of payment. In *United States ex rel. Ebeid v. Lungwitz,*51 however, the Ninth Circuit joined other circuits in ruling that the false certification theory is premised on a false certification of compliance that is “a prerequisite to obtaining a government benefit,” although this early formulation limiting false certification liability was grounded in a materiality analysis.

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47 Id. at *2; see also *United States ex rel. Gross v. AIDS Research Alliance-Chi.,” 415 F.3d 601, 604–05 (7th Cir. 2005) (complaint did not satisfy Rule 9(b) because it failed to allege a false certification of regulatory compliance that was a condition of or prerequisite to government payment).


49 Id. at 832.

50 *Hendow,” 461 F.3d at 1174.

51 *United States ex rel. Ebeid v. Lungwitz,” 616 F.3d 993, 998 (9th Cir.), cert. denied, 131 S. Ct. 801 (2010).
**Tenth Circuit.** As noted above, in *United States ex rel. Conner v. Salina Regional Health Center*, the Tenth Circuit found that the certifications in a hospital’s annual cost reports to Medicare—that the hospital was in compliance with all applicable Medicare statutes and regulations—were not express false certifications that violated the FCA because they were sweeping, general certifications that did not violate conditions stating that payment “was conditioned on perfect compliance with any particular law or regulation.” The court described the lengths to which Conner’s theory, if upheld, could stretch:

by arguing that the certification’s language is adequate to create an express false certification claim, Conner fundamentally contends that any failure by [the hospital] to comply with any underlying Medicare statute or regulation during the provision of any Medicare-reimbursable service renders this certification false, and the resulting payments fraudulent. Lest there be any doubt about the potential impact of this proposed theory, Conner estimates that the United States has been damaged by [the hospital] in an amount exceeding $100,000,000 per year in reliance on allegedly false certifications.

In dismissing the allegations, the Tenth Circuit adopted a “materiality” requirement that limited FCA liability to violations of conditions of payment, and concluded that, “although the government considers substantial compliance a condition of ongoing Medicare participation, it does not require perfect compliance as an absolute condition to receiving Medicare payments for services rendered.”

**Eleventh Circuit.** Although the Eleventh Circuit has not recently ruled on the prerequisite to payment requirement for falsity, in *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, the court found that “[t]he False Claims Act does not create liability merely for a health care provider’s disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.” In addition, in *McNutt ex rel. United States v. Haleyville Medical Supplies, Inc.*, the Eleventh Circuit affirmed the denial of a motion to dismiss based on the defendant’s concession that compliance with the AKS was a condition precedent to receipt of Medicare payments. These decisions reflect that the Eleventh Circuit adheres to the prerequisite to payment line of cases on false implied certification liability.

**D.C. Circuit.** As noted above, in *United States v. Science Applications International Corp.*, the D.C. Circuit adopted the implied false certification theory and limited the potentially dangerous theory’s scope by requiring strict enforcement of the FCA’s materiality and scienter requirements and by strengthening the scienter requirement in implied certification cases. In the course of discussing the scienter requirement in implied certification cases, the court made a critical ruling that strengthens scienter in these cases and emphasized the rational, but rarely stated, burden that an FCA plaintiff must prove not only that the defendant “knew” that the claim was false, but also that the defendant “knew” that compliance with that obligation was “material” to the government’s decision to pay:

FCA section 3729(a)(1) imposes liability only when a person “knowingly presents, or causes to be presented . . . a false or fraudulent claim.” Establishing knowledge under

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52 Conner, 543 F.3d at 1219.
53 Id. at 1219.
54 Id. at 1220 n.6 (emphasis in original).
55 Id.
56 United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002).
58 Sci. Applications, 626 F.3d at 1269–73.
this provision on the basis of implied certification requires the plaintiff to prove that the defendant knows (1) that it violated a contractual obligation, and (2) that its compliance with that obligation was material to the government’s decision to pay. If the plaintiff proves both, and does so based on the proper standard for knowledge—which as we explain below excludes “collective knowledge,” . . .—then it will have established that the defendant sought government payment through deceit, surely the very mischief that the FCA was designed to prevent.\footnote{Id. at 1271.}

This important holding means that, in implied certification cases, a defendant can argue (and the government or qui tam relator has the burden of proving otherwise) that the defendant was not aware that violating an “implied” provision or requirement was a basis to deny payment on the claim.
THE FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729-3733

As amended by:


§ 3729. False claims

(a) Liability for Certain Acts.—Any

(1) In general.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid or approved by the Government;

(C) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, knowingly delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to
defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or

(7G) knowingly makes, uses, or causes to be made or used, a false record or statement material to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person, except that if

(2) REDUCED DAMAGES.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person.

(3) COSTS OF CIVIL ACTIONS.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) KNOWING AND KNOWINGLY DEFINED.—For purposes of this section,
(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud is required.

(c) CLAIM DEFINED.—For purposes of this section, the term "claim" includes—

(A) means any request or demand, whether under a contract or otherwise, for money or property which and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property which is requested or demanded, or if the Government

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property;

(3) the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and
the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

EXEMPTION FROM DISCLOSURE.—Any information furnished pursuant to subparagraphs (A) through (C) of subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

EXCLUSION.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

§ 3730. Civil actions for false claims

(a) RESPONSIBILITIES OF THE ATTORNEY GENERAL.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) ACTIONS BY PRIVATE PERSONS.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or
(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) RIGHTS OF THE PARTIES TO QUI TAM ACTIONS.—

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2) (A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government’s prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person’s participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person’s cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the
defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government’s expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government’s investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) AWARD TO QUI TAM PLAINTIFF.—

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or
transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys’ fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys’ fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys’ fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) CERTAIN ACTIONS BARRED.—
(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person’s service in the armed forces.

(2) (A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, “senior executive branch official” means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) The court shall have jurisdiction over an action or claim under this section based upon the public disclosure of, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) in a Federal criminal, civil, or administrative hearing, in which the Government or its agent is a party;

(ii) in a congressional, administrative, or Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) 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.

(B) For purposes of this paragraph, “original source” means an individual who has direct and independent knowledge of either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which the allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section which is based on the information.
(f) **GOVERNMENT NOT LIABLE FOR CERTAIN EXPENSES.**—The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) **FEES AND EXPENSES TO PREVAILING DEFENDANT.**—In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) **Any employee who is subjected to retaliation.**—

1. **IN GENERAL.**—Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or associated others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief or other efforts to stop 1 or more violations of this subchapter.

2. **RELIEF.**—Relief under paragraph (1) shall include reinstatement with the same seniority status such that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees. An employee may bring an action under this subsection in the appropriate district court of the United States for the relief provided in this subsection.

3. **LIMITATION ON BRINGING CIVIL ACTION.**—A civil action under this subsection may not be brought more than 3 years after the date when the retaliation occurred.

§ 3731. **False claims procedure**

(a) A subpoena requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought—

1. more than 6 years after the date on which the violation of section 3729 is committed, or

2. more than 3 years after the date 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.

(c) If the Government elects to intervene and proceed with an action brought under 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

(d) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(e) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

§ 3732. False claims jurisdiction

(a) Actions under section 3730.—Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under state law.—The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

(c) Service on state or local authorities.—With respect to any State or local government that is named as a co-plaintiff with the United States in an action brought under subsection (b), a seal on the action ordered by the court under section 3730(b) shall not preclude the Government or the person bringing the action from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence and information possessed by the person bringing the action on the law enforcement authorities that are authorized under the law of that State or local government to investigate and prosecute such actions on behalf of such governments, except that such seal applies to the law enforcement authorities so served to the same extent as the seal applies to other parties in the action.

§ 3733. Civil investigative demands
(a) **IN GENERAL.**—

(1) **ISSUANCE AND SERVICE.**—Whenever the Attorney General, or a designee (for purposes of this section), has reason to believe that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation, the Attorney General, or a designee, may, before commencing a civil proceeding under section 3730(a) or other false claims law, or making an election under section 3730(b), issue in writing and cause to be served upon such person, a civil investigative demand requiring such person—

(A) to produce such documentary material for inspection and copying,

(B) to answer in writing written interrogatories with respect to such documentary material or information,

(C) to give oral testimony concerning such documentary material or information, or

(D) to furnish any combination of such material, answers, or testimony.

The Attorney General may not delegate the authority to issue civil investigative demands under this subsection. Whenever a civil investigative demand is an express demand for any product of discovery, the Attorney General, the Deputy Attorney General, or an Assistant Attorney General shall cause to be served, in any manner authorized by this section, a copy of such demand upon the person from whom the discovery was obtained and shall notify the person to whom such demand is issued of the date on which such copy was served. Any information obtained by the Attorney General or a designee of the Attorney General under this section may be shared with any qui tam relator if the Attorney General or designee determine it is necessary as part of any false claims act investigation.

(2) **CONTENTS AND DEADLINES.**—

(A) Each civil investigative demand issued under paragraph (1) shall state the nature of the conduct constituting the alleged violation of a false claims law which is under investigation, and the applicable provision of law alleged to be violated.

(B) If such demand is for the production of documentary material, the demand shall—

(i) describe each class of documentary material to be produced with such definiteness and certainty as to permit such material to be fairly identified;
(ii) prescribe a return date for each such class which will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying; and

(iii) identify the false claims law investigator to whom such material shall be made available.

(C) If such demand is for answers to written interrogatories, the demand shall—

(i) set forth with specificity the written interrogatories to be answered;

(ii) prescribe dates at which time answers to written interrogatories shall be submitted; and

(iii) identify the false claims law investigator to whom such answers shall be submitted.

(D) If such demand is for the giving of oral testimony, the demand shall—

(i) prescribe a date, time, and place at which oral testimony shall be commenced;

(ii) identify a false claims law investigator who shall conduct the examination and the custodian to whom the transcript of such examination shall be submitted;

(iii) specify that such attendance and testimony are necessary to the conduct of the investigation;

(iv) notify the person receiving the demand of the right to be accompanied by an attorney and any other representative; and

(v) describe the general purpose for which the demand is being issued and the general nature of the testimony, including the primary areas of inquiry, which will be taken pursuant to the demand.

(E) Any civil investigative demand issued under this section which is an express demand for any product of discovery shall not be returned or returnable until 20 days after a copy of such demand has been served upon the person from whom the discovery was obtained.
(F) The date prescribed for the commencement of oral testimony pursuant to a civil investigative demand issued under this section shall be a date which is not less than seven days after the date on which demand is received, unless the Attorney General or an Assistant Attorney General designated by the Attorney General determines that exceptional circumstances are present which warrant the commencement of such testimony within a lesser period of time.

(G) The Attorney General shall not authorize the issuance under this section of more than one civil investigative demand for oral testimony by the same person unless the person requests otherwise or unless the Attorney General, after investigation, notifies that person in writing that an additional demand for oral testimony is necessary. The Attorney General may not, notwithstanding section 510 of title 28, authorize the performance, by any other officer, employee, or agency, of any function vested in the Attorney General under this subparagraph.

(b) PROTECTED MATERIAL OR INFORMATION.—

(1) IN GENERAL.—A civil investigative demand issued under subsection (a) may not require the production of any documentary material, the submission of any answers to written interrogatories, or the giving of any oral testimony if such material, answers, or testimony would be protected from disclosure under—

(A) the standards applicable to subpoenas or subpoenas duces tecum issued by a court of the United States to aid in a grand jury investigation; or

(B) the standards applicable to discovery requests under the Federal Rules of Civil Procedure, to the extent that the application of such standards to any such demand is appropriate and consistent with the provisions and purposes of this section.

(2) EFFECT ON OTHER ORDERS, RULES, AND LAWS.—Any such demand which is an express demand for any product of discovery supersedes any inconsistent order, rule, or provision of law (other than this section) preventing or restraining disclosure of such product of discovery to any person.Disclosure of any product of discovery pursuant to any such express demand does not constitute a waiver of any right or privilege which the person making such disclosure may be entitled to invoke to resist discovery of trial preparation materials.

(c) SERVICE; JURISDICTION.—
(1) **BY WHOM SERVED.**—Any civil investigative demand issued under subsection (a) may be served by a false claims law investigator, or by a United States marshal or a deputy marshal, at any place within the territorial jurisdiction of any court of the United States.

(2) **SERVICE IN FOREIGN COUNTRIES.**—Any such demand or any petition filed under subsection (j) may be served upon any person who is not found within the territorial jurisdiction of any court of the United States in such manner as the Federal Rules of Civil Procedure prescribe for service in a foreign country. To the extent that the courts of the United States can assert jurisdiction over any such person consistent with due process, the United States District Court for the District of Columbia shall have the same jurisdiction to take any action respecting compliance with this section by any such person that such court would have if such person were personally within the jurisdiction of such court.

(d) **SERVICE UPON LEGAL ENTITIES AND NATURAL PERSONS.**—

(1) **LEGAL ENTITIES.**—Service of any civil investigative demand issued under subsection (a) or of any petition filed under subsection (j) may be made upon a partnership, corporation, association, or other legal entity by—

(A) delivering an executed copy of such demand or petition to any partner, executive officer, managing agent, or general agent of the partnership, corporation, association, or entity, or to any agent authorized by appointment or by law to receive service of process on behalf of such partnership, corporation, association, or entity;

(B) delivering an executed copy of such demand or petition to the principal office or place of business of the partnership, corporation, association, or entity; or

(C) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to such partnership, corporation, association, or entity at its principal office or place of business.

(2) **NATURAL PERSONS.**—Service of any such demand or petition may be made upon any natural person by—

(A) delivering an executed copy of such demand or petition to the person; or

(B) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to the person at the person’s residence or principal office or place of business.
(e) **Proof of Service.**—A verified return by the individual serving any civil investigative demand issued under subsection (a) or any petition filed under subsection (j) setting forth the manner of such service shall be proof of such service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such demand.

(f) **Documentary Material.**—

1. **Sworn Certificates.**—The production of documentary material in response to a civil investigative demand served under this section shall be made under a sworn certificate, in such form as the demand designates, by—

   A. in the case of a natural person, the person to whom the demand is directed, or
   
   B. in the case of a person other than a natural person, a person having knowledge of the facts and circumstances relating to such production and authorized to act on behalf of such person.

   The certificate shall state that all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the false claims law investigator identified in the demand.

2. **Production of Materials.**—Any person upon whom any civil investigative demand for the production of documentary material has been served under this section shall make such material available for inspection and copying to the false claims law investigator identified in such demand at the principal place of business of such person, or at such other place as the false claims law investigator and the person thereafter may agree and prescribe in writing, or as the court may direct under subsection (j)(1). Such material shall be made so available on the return date specified in such demand, or on such later date as the false claims law investigator may prescribe in writing. Such person may, upon written agreement between the person and the false claims law investigator, substitute copies for originals of all or any part of such material.

(g) **Interrogatories.**—Each interrogatory in a civil investigative demand served under this section shall be answered separately and fully in writing under oath and shall be submitted under a sworn certificate, in such form as the demand designates, by—

   1. in the case of a natural person, the person to whom the demand is directed, or
   
   2. in the case of a person other than a natural person, the person or persons responsible for answering each interrogatory.
If any interrogatory is objected to, the reasons for the objection shall be stated in the certificate instead of an answer. The certificate shall state that all information required by the demand and in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted. To the extent that any information is not furnished, the information shall be identified and reasons set forth with particularity regarding the reasons why the information was not furnished.

(h) **ORAL EXAMINATIONS.**—

(1) **PROCEDURES.**—The examination of any person pursuant to a civil investigative demand for oral testimony served under this section shall be taken before an officer authorized to administer oaths and affirmations by the laws of the United States or of the place where the examination is held. The officer before whom the testimony is to be taken shall put the witness on oath or affirmation and shall, personally or by someone acting under the direction of the officer and in the officer’s presence, record the testimony of the witness. The testimony shall be taken stenographically and shall be transcribed. When the testimony is fully transcribed, the officer before whom the testimony is taken shall promptly transmit a copy of the transcript of the testimony to the custodian. This subsection shall not preclude the taking of testimony by any means authorized by, and in a manner consistent with, the Federal Rules of Civil Procedure.

(2) **PERSONS PRESENT.**—The false claims law investigator conducting the examination shall exclude from the place where the examination is held all persons except the person giving the testimony, the attorney for and any other representative of the person giving the testimony, the attorney for the Government, any person who may be agreed upon by the attorney for the Government and the person giving the testimony, the officer before whom the testimony is to be taken, and any stenographer taking such testimony.

(3) **WHERE TESTIMONY TAKEN.**—The oral testimony of any person taken pursuant to a civil investigative demand served under this section shall be taken in the judicial district of the United States within which such person resides, is found, or transacts business, or in such other place as may be agreed upon by the false claims law investigator conducting the examination and such person.

(4) **TRANSCRIPT OF TESTIMONY.**—When the testimony is fully transcribed, the false claims law investigator or the officer before whom the testimony is taken shall afford the witness, who may be accompanied by counsel, a reasonable opportunity to examine and read the transcript, unless such examination and reading are waived by the witness. Any changes in form or substance which the witness desires to make shall be entered and identified upon the transcript by the officer or the false claims law investigator, with a statement of the reasons given by the witness for making such changes. The transcript shall then be signed by the witness,
unless the witness in writing waives the signing, is ill, cannot be found, or
refuses to sign. If the transcript is not signed by the witness within 30 days
after being afforded a reasonable opportunity to examine it, the officer or
the false claims law investigator shall sign it and state on the record the
fact of the waiver, illness, absence of the witness, or the refusal to sign,
Together with the reasons, if any, given therefor.

(5) Certification and delivery to custodian.—The officer before whom
the testimony is taken shall certify on the transcript that the witness was
sworn by the officer and that the transcript is a true record of the testimony
given by the witness, and the officer or false claims law investigator shall
promptly deliver the transcript, or send the transcript by registered or
certified mail, to the custodian.

(6) Furnishing or inspection of transcript by witness.—Upon payment
of reasonable charges therefor, the false claims law investigator shall
furnish a copy of the transcript to the witness only, except that the
Attorney General, the Deputy Attorney General, or an Assistant Attorney
General may, for good cause, limit such witness to inspection of the
official transcript of the witness’ testimony.

(7) Conduct of oral testimony.—

(A) Any person compelled to appear for oral testimony under a civil
investigative demand issued under subsection (a) may be
accompanied, represented, and advised by counsel. Counsel may
advise such person, in confidence, with respect to any question
asked of such person. Such person or counsel may object on the
record to any question, in whole or in part, and shall briefly state
for the record the reason for the objection. An objection may be
made, received, and entered upon the record when it is claimed
that such person is entitled to refuse to answer the question on the
grounds of any constitutional or other legal right or privilege,
including the privilege against self-incrimination. Such person may
not otherwise object to or refuse to answer any question, and may
not directly or through counsel otherwise interrupt the oral
examination. If such person refuses to answer any question, a
petition may be filed in the district court of the United States under
subsection (j)(1) for an order compelling such person to answer
such question.

(B) If such person refuses to answer any question on the grounds of the
privilege against self-incrimination, the testimony of such person
may be compelled in accordance with the provisions of part V of
title 18 [18 USCS §§ 6001 et seq.].
(8) **Witness Fees and Allowances.**—Any person appearing for oral testimony under a civil investigative demand issued under subsection (a) shall be entitled to the same fees and allowances which are paid to witnesses in the district courts of the United States.

(i) **Custodians of Documents, Answers, and Transcripts.**—

(1) **Designation.**—The Attorney General shall designate a false claims law investigator to serve as custodian of documentary material, answers to interrogatories, and transcripts of oral testimony received under this section, and shall designate such additional false claims law investigators as the Attorney General determines from time to time to be necessary to serve as deputies to the custodian.

(2) **Responsibility for Materials; Disclosure.**—

(A) A false claims law investigator who receives any documentary material, answers to interrogatories, or transcripts of oral testimony under this section shall transmit them to the custodian. The custodian shall take physical possession of such material, answers, or transcripts and shall be responsible for the use made of them and for the return of documentary material under paragraph (4).

(B) The custodian may cause the preparation of such copies of such documentary material, answers to interrogatories, or transcripts of oral testimony as may be required for official use by any false claims law investigator, or other officer or employee of the Department of Justice, who is authorized for such use under regulations which the Attorney General shall issue. Such material, answers, and transcripts may be used by any such authorized false claims law investigator or other officer or employee in connection with the taking of oral testimony under this section.

(C) Except as otherwise provided in this subsection, no documentary material, answers to interrogatories, or transcripts of oral testimony, or copies thereof, while in the possession of the custodian, shall be available for examination by any individual other than a false claims law investigator or other officer or employee of the Department of Justice authorized under subparagraph (B). The prohibition in the preceding sentence on the availability of material, answers, or transcripts shall not apply if consent is given by the person who produced such material, answers, or transcripts, or, in the case of any product of discovery produced pursuant to an express demand for such material, consent is given by the person from whom the discovery was obtained. Nothing in this subparagraph is intended to prevent disclosure to the Congress, including any committee or subcommittee of the
Congress, or to any other agency of the United States for use by such agency in furtherance of its statutory responsibilities. Disclosure of information to any such other agency shall be allowed only upon application, made by the Attorney General to a United States district court, showing substantial need for the use of the information by such agency in furtherance of its statutory responsibilities.

(D) While in the possession of the custodian and under such reasonable terms and conditions as the Attorney General shall prescribe—

(i) documentary material and answers to interrogatories shall be available for examination by the person who produced such material or answers, or by a representative of that person authorized by that person to examine such material and answers; and

(ii) transcripts of oral testimony shall be available for examination by the person who produced such testimony, or by a representative of that person authorized by that person to examine such transcripts.

(3) USE OF MATERIAL, ANSWERS, OR TRANSCRIPTS IN OTHER PROCEEDINGS.—Whenever any attorney of the Department of Justice has been designated to appear before any court, grand jury, or Federal agency in any case or proceeding, the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony received under this section may deliver to such attorney such material, answers, or transcripts for official use in connection with any such case or proceeding as such attorney determines to be required. Upon the completion of any such case or proceeding, such attorney shall return to the custodian any such material, answers, or transcripts so delivered which have not passed into the control of such court, grand jury, or agency through introduction into the record of such case or proceeding.

(4) CONDITIONS FOR RETURN OF MATERIAL.—If any documentary material has been produced by any person in the course of any false claims law investigation pursuant to a civil investigative demand under this section, and—

(A) any case or proceeding before the court or grand jury arising out of such investigation, or any proceeding before any Federal agency involving such material, has been completed, or

(B) no case or proceeding in which such material may be used has been commenced within a reasonable time after completion of the
examination and analysis of all documentary material and other information assembled in the course of such investigation,

the custodian shall, upon written request of the person who produced such material, return to such person any such material (other than copies furnished to the false claims law investigator under subsection (f)(2) or made for the Department of Justice under paragraph (2)(B)) which has not passed into the control of any court, grand jury, or agency through introduction into the record of such case or proceeding.

(5) APPOINTMENT OF SUCCESSOR CUSTODIANS.—In the event of the death, disability, or separation from service in the Department of Justice of the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony produced pursuant to a civil investigative demand under this section, or in the event of the official relief of such custodian from responsibility for the custody and control of such material, answers, or transcripts, the Attorney General shall promptly—

(A) designate another false claims law investigator to serve as custodian of such material, answers, or transcripts, and

(B) transmit in writing to the person who produced such material, answers, or testimony notice of the identity and address of the successor so designated.

Any person who is designated to be a successor under this paragraph shall have, with regard to such material, answers, or transcripts, the same duties and responsibilities as were imposed by this section upon that person’s predecessor in office, except that the successor shall not be held responsible for any default or dereliction which occurred before that designation.

(j) JUDICIAL PROCEEDINGS.—

(1) PETITION FOR ENFORCEMENT.—Whenever any person fails to comply with any civil investigative demand issued under subsection (a), or whenever satisfactory copying or reproduction of any material requested in such demand cannot be done and such person refuses to surrender such material, the Attorney General may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person a petition for an order of such court for the enforcement of the civil investigative demand.

(2) PETITION TO MODIFY OR SET ASIDE DEMAND.—

(A) Any person who has received a civil investigative demand issued under subsection (a) may file, in the district court of the United States for the judicial district within which such person resides, is
found, or transacts business, and serve upon the false claims law investigator identified in such demand a petition for an order of the court to modify or set aside such demand. In the case of a petition addressed to an express demand for any product of discovery, a petition to modify or set aside such demand may be brought only in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending. Any petition under this subparagraph must be filed—

(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the demand to comply with the provisions of this section or upon any constitutional or other legal right or privilege of such person. During the pendency of the petition in the court, the court may stay, as it deems proper, the running of the time allowed for compliance with the demand, in whole or in part, except that the person filing the petition shall comply with any portions of the demand not sought to be modified or set aside.

(3) PETITION TO MODIFY OR SET ASIDE DEMAND FOR PRODUCT OF DISCOVERY.—

(A) In the case of any civil investigative demand issued under subsection (a) which is an express demand for any product of discovery, the person from whom such discovery was obtained may file, in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending, and serve upon any false claims law investigator identified in the demand and upon the recipient of the demand, a petition for an order of such court to modify or set aside those portions of the demand requiring production of any such product of discovery. Any petition under this subparagraph must be filed—

(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or
(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the portions of the demand from which relief is sought to comply with the provisions of this section, or upon any constitutional or other legal right or privilege of the petitioner. During the pendency of the petition, the court may stay, as it deems proper, compliance with the demand and the running of the time allowed for compliance with the demand.

(4) PETITION TO REQUIRE PERFORMANCE BY CUSTODIAN OF DUTIES.—At any time during which any custodian is in custody or control of any documentary material or answers to interrogatories produced, or transcripts of oral testimony given, by any person in compliance with any civil investigative demand issued under subsection (a), such person, and in the case of an express demand for any product of discovery, the person from whom such discovery was obtained, may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian, a petition for an order of such court to require the performance by the custodian of any duty imposed upon the custodian by this section.

(5) JURISDICTION.—Whenever any petition is filed in any district court of the United States under this subsection, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry out the provisions of this section. Any final order so entered shall be subject to appeal under section 1291 of title 28. Any disobedience of any final order entered under this section by any court shall be punished as a contempt of the court.

(6) APPLICABILITY OF FEDERAL RULES OF CIVIL PROCEDURE.—The Federal Rules of Civil Procedure shall apply to any petition under this subsection, to the extent that such rules are not inconsistent with the provisions of this section.

(k) DISCLOSURE EXEMPTION.—Any documentary material, answers to written interrogatories, or oral testimony provided under any civil investigative demand issued under subsection (a) shall be exempt from disclosure under section 552 of title 5.

(l) DEFINITIONS.—For purposes of this section—

(1) the term “false claims law” means—

(A) this section and sections 3729 through 3732; and
(B) any Act of Congress enacted after the date of the enactment of this section [enacted Oct. 27, 1986] which prohibits, or makes available to the United States in any court of the United States any civil remedy with respect to, any false claim against, bribery of, or corruption of any officer or employee of the United States;

(2) the term “false claims law investigation” means any inquiry conducted by any false claims law investigator for the purpose of ascertaining whether any person is or has been engaged in any violation of a false claims law;

(3) the term “false claims law investigator” means any attorney or investigator employed by the Department of Justice who is charged with the duty of enforcing or carrying into effect any false claims law, or any officer or employee of the United States acting under the direction and supervision of such attorney or investigator in connection with a false claims law investigation;

(4) the term “person” means any natural person, partnership, corporation, association, or other legal entity, including any State or political subdivision of a State;

(5) the term “documentary material” includes the original or any copy of any book, record, report, memorandum, paper, communication, tabulation, chart, or other document, or data compilations stored in or accessible through computer or other information retrieval systems, together with instructions and all other materials necessary to use or interpret such data compilations, and any product of discovery;

(6) the term “custodian” means the custodian, or any deputy custodian, designated by the Attorney General under subsection (i)(1);

(7) the term “product of discovery” includes—

   (A) the original or duplicate of any deposition, interrogatory, document, thing, result of the inspection of land or other property, examination, or admission, which is obtained by any method of discovery in any judicial or administrative proceeding of an adversarial nature;

   (B) any digest, analysis, selection, compilation, or derivation of any item listed in subparagraph (A); and

   (C) any index or other manner of access to any item listed in subparagraph (A); and

(8) the term “official use” means any use that is consistent with the law, and the regulations and policies of the Department of Justice, including use in connection with internal Department of Justice memoranda and reports;
communications between the Department of Justice and a Federal, State, or local government agency, or a contractor of a Federal, State, or local government agency, undertaken in furtherance of a Department of Justice investigation or prosecution of a case; interviews of any qui tam relator or other witness; oral examinations; depositions; preparation for and response to civil discovery requests; introduction into the record of a case or proceeding; applications, motions, memoranda and briefs submitted to a court or other tribunal; and communications with Government investigators, auditors, consultants and experts, the counsel of other parties, arbitrators and mediators, concerning an investigation, case or proceeding.

* * *

S. 386 Section 4(f):

**EFFECTIVE DATE AND APPLICATION.**—The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that—

(1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date; and

(2) section 3731(b) of title 31, as amended by subsection (b); section 3733, of title 31, as amended by subsection (c); and section 3732 of title 31, as amended by subsection (e); shall apply to cases pending on the date of enactment.
CIVIL FALSE CLAIMS ACT: The False Claims Act is Amended for the First Time in More Than Twenty Years as the President Signs the Fraud Enforcement and Recovery Act of 2009

Last night, the Fraud Enforcement and Recovery Act of 2009 ("FERA") was signed into law by the President, marking only the second time in the history of the civil False Claims Act ("FCA") that all-embracing amendments have been made to this 1963 law. After its first large-scale revision in 1986, the FCA became the government's most successful weapon in its fight against suspected fraud on the United States, but it also became a weapon that competitors, disappointed bidders, disgruntled employees, and antagonistic agencies could use to punish and destroy those who opposed them. Congress's stated purpose in passing the FERA was to expand the FCA's liability provisions to reach frauds by financial institutions and other recipients of TARP and economic stimulus funds, but those funds were already covered by the FCA. The real purpose of these amendments is to overturn many decisions—like the unanimous Supreme Court decision last year in Allison Engine Co. v. United States ex rel. Sanders—which set logical and reasonable limits on the scope of the FCA, a punitive statute that has the power to destroy any individual, institution, municipal entity, or company subject to its provisions.

The new amendments will adversely affect everyone—all government contractors and subcontractors, all healthcare providers, every public and private grantee and sub-grantee, and every other person, company, and entity that pays money to the government or receives Federal funds—by making it far easier to conduct FCA investigations and to win FCA recoveries. Quite simply, many logical defenses have been eliminated, and those who deal in any way with the Federal government are entering a whole new world in which FCA liability is much broader and easier to prove.

Prior FraudMail Alerts have commented on the FCA amendments in the FERA throughout the legislative process. See FraudMail Alert Nos. 09-05-16; 09-05-15; 09-05-13; 09-05-08; 09-04-30. Here is a comprehensive look at these FCA amendments. A red-line version of the changes that have now become final is available here. Attached is the final version of the FCA that is effective as of May 20, 2009.
Major FCA Amendments Expanding Liability

Under the FERA, the key liability sections of the FCA remain the provisions addressing false claims, false statements supporting false claims, conspiracy, and the reverse false claims and obligation provisions. These provisions have been renumbered as well as expanded to cover additional conduct. The new sections 3729(a)(1)(A), (B), (C), and (G) extend liability to any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

[...]
or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Many of the key changes are in the definitions, found in section 3729(b).

Elimination of Allison Engine's Intent Requirement: Under the Supreme Court's unanimous decision in Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008), FCA liability was limited to fraudulent statements that were designed "to get" false claims paid or approved "by the Government." See FraudMail Alert No. 08-06-02. See also John T. Boese, Civil False Claims and Qui Tam Actions §2.06[G] (3d ed. 2006 & Supp. 2009-1). The Supreme Court's interpretation in Allison Engine no longer applies after the FERA because the new law removes both the "to get" language and the "by the Government" limitation in section 3729(a)(2)—as well as comparable language in sections 3729(a)(3) and (a)(7). Further, it attempts to make those changes in section 3729(a)(1)(B) effective as of June 7, 2008—the date Allison Engine was decided.

The Court in Allison Engine found that, without a clear link between a false claim and payment or approval by the government, the FCA would be "boundless" and become an "all-purpose antifraud statute." 128 S. Ct. at 2128, 2130. To replace this rational limitation, the FERA adds a new definition of "claim," and FCA liability will be limited only by requiring some sort of nexus to the government. The FCA now covers requests for funds to a contractor, grantee, or other recipient, if the money or property requested "is to be spent or used on the Government's behalf or to advance a Government program or interest." The legislation does not define the key terms "used on the Government's behalf" or "to advance a Government program or interest," and presumably courts will have to decide their meaning on a case by case basis. No one knows the scope. Are government funds invested in GM or AIG "advancing a Government program" so that a false
claim to those entities will violate the FCA and be enforced by qui tam relators? Recognizing that this new language is not very clear, Senator Kyle attempted to limit its scope:

[previous understanding, as well as common sense, dictate that a particular transaction does not “advance a Government program or interest” unless it is predominately federal in character—something that at least would require . . . that the claim ultimately results in a loss to the government . . . [rather than] any garden-variety dispute between a general contractor and a subcontractor simply because the general receives some federal money.


Materiality Requirement: In addition to the nexus to the government requirement, the FERA, at long last, specifically incorporates a materiality requirement in the False Claims Act (a position the government and relators fought, without success, for over 15 years), but it defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,” which is the “weaker” materiality standard that has been applied in some FCA cases. See John T. Boese, Civil False Claims and Qui Tam Actions §2.04 (Aspen Publishers) (3rd ed. & Supp. 2009-2). How much of a difference will this make? That depends entirely on how literally courts will read this provision. Almost every violation or mistake is arguably “capable of influencing a payment decision by the government, but many courts in the past have read this text as strongly limiting the application of the FCA. For example, despite applying this “weaker” materiality standard, at least two courts have held that violations of “conditions of participation” in a Federal healthcare program do not result in FCA violations. See United States ex rel. Conner v. Salina Reg’l Health Ctr., 543 F.3d 1211 (10th Cir. 2008); United States ex rel. Landers v. Baptist Mem’l Health Care Corp., 525 F. Supp. 2d 972 (W.D. Tenn. 2007).

Conspiracy: Under the prior FCA, the conspiracy section was drafted to cover only a conspiracy “to get a false claim paid or approved.” Courts had properly interpreted this language to limit the conspiracy section to apply only to violations of then-subsection 3729(a)(1), and not to violations of the reverse false claim provision. Moreover, the conspiracy section required that the government pay the false claim. The new conspiracy section, 31 U.S.C. §3729(a)(1)(C), expands the conspiracy section to include a conspiracy to commit a violation of any other substantive section of the FCA. The amendment also eliminates the need for the false claim to be paid or approved, and assesses liability for conspiring to commit the violation. Importantly, the word “knowingly” still does not appear in the language of the new conspiracy section, so the argument remains that a common law liability, including specific intent, is still required to prove a conspiracy under the FCA.

Liability for Overpayments: The amended reverse false claims liability provision in section 3729(a)(1)(G) quoted above extends new liability to “knowingly and improperly avoid[ing] or decrease[ing] an obligation to pay or transmit money or property to the Government.” Under this provision, there is no need for a person to have taken an affirmative act—a false statement or record—in order to conceal, avoid, or decrease the obligation to the government. This new
provision is even more dangerous because an “obligation” is specifically defined to include within the scope of FCA liability the retention of an overpayment from the government. The term “improperly” is intended to limit this liability, and would presumably exclude overpayments such as those under Medicaid that undergo a reconciliation process. Practitioners will be required, almost immediately after passage, to begin to advise clients whether they have received overpayments and the potential liability that could result from retention of such overpayments. Moreover, even though this provision is not retroactive, an overpayment is an overpayment, whether it occurred before or after May 20, 2009. The government and relators are almost certain to argue that this provision applies to overpayments made before the date of the legislation.

**Expanded Definition of “Obligation”**: The definition of “obligation” that triggers reverse false claims liability is expanded to encompass an “established duty, whether or not fixed” that arises from a contractual, grantee, licensee, or fee-based relationship, from a statute or regulation, or from the retention of any overpayment. According to government statements, this is intended to overturn, among other cases, the Sixth Circuit’s decision 10 years ago in *United States ex rel. American Textile Manufacturers Institute, Inc. v. The Limited, Inc.*, 190 F.3d 729 (6th Cir. 1999) (“ATMI”), which defined “obligation” to include only established obligations to pay money to the government. In addition to extending new liability to the retention of overpayments, this expanded definition seeks to extend liability to duties to pay fees that were not covered previously because they were not fixed in all particulars. Whether much of an expansion is actually achieved under this provision remains to be seen because even the DOJ concedes that the new language is not intended to extend FCA liability to penalties or fines. (The reader should note that the author represented many of the defendants in the ATMI case.)

**Effective Date**: Under the effective date provision in the FERA, the FCA liability amendments would apply prospectively, with one important exception. The amendment to section 3729(a)(2) takes effect on the date that *Allison Engine* was decided—June 7, 2008—making that amendment retroactive. The retroactivity of this amendment will raise a host of practical problems in pending cases, and is almost certain to be challenged as unconstitutional because conduct which the Supreme Court defined as outside the scope of FCA liability is, retroactively, now a violation. Were this a normal civil statute, such retroactivity would be allowable. But the Supreme Court has already defined the FCA as an “essentially punitive” statute. *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000). Whether a clearly punitive statute can be applied retroactively is a completely different question.

**Additional FCA Amendments**

In addition to amending the FCA’s liability provisions, the FERA includes four other amendments that make recoveries and investigations under the FCA easier. These amendments are as follows:

**Retaliation**: The prohibition against retaliation is expanded to include a “contractor, or agent,” in addition to an employee—without requiring prohibited retaliatory acts to be taken by an “employer.” Under this unusually broad definition, a retaliation action could be based on many different types of relationships that do not involve an employment contract, which could lead to unintended consequences.
Civil Investigative Demands: Under the FCA as passed in 1986, the Attorney General had to personally approve a CID, which can require deposition testimony under oath, clearly a power and a potentially abusive power. Under FERA, the Attorney General is now authorized to appoint a designee to approve a civil investigative demand, and the Attorney General or designee may share the information obtained with "any qui tam relator if the Attorney General or designee determine it is necessary as part of any false claims act investigation." In addition, "official use" is broadly defined, allowing the Justice Department to use the information in communications with government personnel, consultants, and counsel for other parties in matters concerning an investigation, case, or proceeding. The expanded use and sharing of CID responses with any qui tam relator, consultant, and counsel is potentially harmful to businesses and individuals, and in recognition of this, one hopes it will be narrowly and carefully circumscribed by the Justice Department to curb abuses.

Relation Back: The government's complaint in intervention or amendment to a relator's complaint relates back to the date of the original complaint. Under this amendment, the government could delay its intervention in ways that could dramatically undermine a defendant's ability to defend itself. See, e.g., United States v. Baylor Univ. Med. Ctr., 469 F.3d 263 (2d Cir. 2006), United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc., 409 F. Supp. 2d 43 (D. Mass. 2006).

Service on State or Local Authorities: The seal provision would not prevent the government or relator from serving the written disclosure, a qui tam complaint, or other pleading on state and local law enforcement authorities that investigate the case.

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CIVIL FALSE CLAIMS ACT: Here They Go Again – Newly Enacted Comprehensive Health Care Reform Law Contains More FCA Amendments

In May of last year, Congress enacted a dramatic revision to the substantive provisions of the civil False Claims Act, but left alone the key jurisdictional “public disclosure / original source” bar put in place by Congress in 1986 to avoid parasitic qui tam suits. See FraudMail Alert No. 09-05-21 (discussing FCA amendments in the Fraud Recovery and Enforcement Act of 2009 (“FERA”)) in the FCA amendments in FERA, Congress refused to weaken the public disclosure bar, but that restraint did not last a full year.

The Patient Protection and Affordable Care Act, signed into law by the President on March 23, 2010, directly amends the FCA’s public disclosure bar and original source exception to expand private enforcement of qui tam actions beyond these long-established boundaries. The FCA-related amendments are not limited to FCA actions against health care companies, but instead apply to all individuals and organizations covered by the FCA. The new law also contains confusing provisions that attempt to bootstrap FCA definitions such as “knowingly” and “obligation” to enforcement actions against participants in health care programs without amending the FCA. Similarly, it defines certain conditions of eligibility as “material” conditions of entitlement to receive payment, a designation that does not necessarily accord with FCA case law on conditions of eligibility. There is no substantive legislative history on these FCA-related provisions and amendments, which is unfortunate for those trying to understand and abide by them. As with past FCA amendments, these changes will trigger extensive litigation, and courts will be forced to grapple with how to apply them in the years to come.

A red-line version of the new public disclosure provision can be found here.

The FCA’s Public Disclosure Bar is Amended

The FCA’s public disclosure bar is amended in major ways. The new law provides:

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) 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.

(B) For purposes of this paragraph, “original source” means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.


The new public disclosure bar maintains the essential structure of the prior bar by requiring a court to dismiss a whistleblower’s qui tam suit if the allegations were “publicly disclosed,” unless the relator is an “original source” of the information underlying the allegations. However, the reach of the new public disclosure provision is limited by the following revisions:

- Dismissal is not required if the government opposes it;
- Only federal hearings in which the government or its agent is a party are considered public disclosures of qui tam allegations;
- Only a federal report, hearing, audit or investigation qualifies as a public disclosure.

While the word “jurisdiction” has been removed, the use of the words “shall dismiss” means that the provision is similar to jurisdiction in that this issue should be resolved before the substantive case goes forward. Because the public disclosure bar is limited to federal hearings, however, fewer proceedings will be considered “public” and trigger the bar; fewer reports, audits, or investigations will trigger it for the same reason. Thus, although the question of whether a state report qualifies as a public disclosure is currently pending before the Supreme Court in Graham County Soil & Water Conservation District v. United States ex rel. Wilson, No. 08-304, that issue would be moot in future cases to which the amendment applies. See FraudMail Alert No. 09-11-30. Importantly, the “news media” prong of the public disclosure bar is unchanged.

The new “original source” amendments also expand the exception to the public disclosure bar by eliminating the requirement that a person must have “direct” knowledge of the information underlying the allegations. This revision, however, does not eliminate the need for some firsthand knowledge, which is the very essence of a true whistleblower; otherwise, it would allow anyone who acquired information secondhand from public sources to bring a qui tam suit and share in any recovery. With the new changes, a person with such “independent” knowledge must “materially add” to the publicly disclosed allegations to qualify as an original source. It is not clear exactly what is intended by the language “materially add,” which is not defined in the law. There does not
appear to be any intent by Congress, however, to overturn the result in *Rockwell International Corp. v. United States ex rel. Stone*, 549 U.S. 457 (2007), where the Supreme Court required the relator’s knowledge to encompass the allegations of fraud that were actually tried in the case, rather than simply to predict the ineffectiveness of a planned method of waste disposal that was never used. See *FraudMail Alert Nos. 07-04-11* and *07-03-27*. More importantly, the dual purposes of the bar—encouraging whistleblowers to alert the government to fraud while preventing parasitic suits—which date back to the statute’s origins, appear to remain intact after this revision.

Nothing in the new amendments to the FCA appears to express congressional intent for any of these changes to apply retroactively. Under the teaching of *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997), that should mean that this new language would apply only to conduct occurring after March 23, 2010.

**Attempts to Apply FCA Liability and Definitions in New Health Care Contexts**

The other FCA “amendments” in the new health law are truly bizarre. The new law attempts to apply several of the FCA’s definitions to various health care transactions without amending the FCA’s liability provisions to cover these transactions. For example, a program integrity provision governing enforcement of retained overpayments states that an overpayment retained beyond the deadline for reporting and returning it is an “obligation” as defined in the FCA. See H.R. 3590, § 6402(k). The provision also states that “knowingly” is defined as it is defined for purposes of the FCA, but the term “knowingly” does not appear in the provision on overpayments. Rather, the new provision requires reporting or return of an overpayment within 60 days after it was “identified”—a term that the provision does not define.

Despite this attempt to attach FCA liability using the definitions (or lack thereof) provided in the new enforcement provisions, the FCA itself governs liability based on “knowingly” avoiding or decreasing an “obligation.” Under the FCA, “obligation” is defined to include retention of an overpayment, but the FCA’s reverse false claims liability is limited to “knowingly and improperly” avoiding or decreasing an obligation, which requires the element of bad faith rather than the “identification”—however that term is defined—of an overpayment. See John T. Boese, Civil False Claims and Qui Tam Actions § 2.01[J] (Aspen Law & Business) (3d ed. 2006 & Supp. 2010-1).

The amendments provide a sense of the Congress relating to false claims and “payments made by, through, or in connection with an Exchange.” For example, the law’s tax credit and cost-sharing reduction provisions, which apply to health insurance exchanges, contain the statement that any payment in connection with an exchange that includes federal funds is subject to the FCA. The amendments contain language that would raise the FCA damages for such false claims to exchanges to an amount “not less than 3 times and not more than 6 times the amount of damages which the Government sustains,” but in another amendment, that language is declared null and void. See H.R. 3590, § 10104(j)(1).

Finally, the amendments provide:

Compliance with the requirements of this Act concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an
issuer’s entitlement to receive payments, including payments of premium tax
credits and cost-sharing reductions, through the Exchange.

H.R. 3590, § 1313(a)(6). This provision equates requirements for eligibility—whether important,
umimportant, general, or specific—with a material condition of entitlement to payment. But, under
the FCA, conditions of eligibility are not necessarily conditions of payment without a strong
showing of materiality. See, e.g., United States ex rel. Conner v. Salina Reg’l Health Ctr., 543
F.3d 1211 (10th Cir. 2008); United States ex rel. Landers v. Baptist Mem’l Health Care Corp., 525
F. Supp. 2d 972 (W.D. Tenn. 2007). While these conditions of eligibility—many of which are yet to
be established—may indeed be material under the FCA, a general statement that includes all of
them does not necessarily suffice under the FCA. See John T. Boese, Civil False Claims and Qui
Tam Actions, § 2.04 & n. 837 (citing cases). Also, the new law does not explain whether or how
improper tax credit claims could be subject to FCA liability in light of the FCA’s tax exception. See

* * * * *

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CIVIL FALSE CLAIMS ACT: Here They Go Again, Round III: Financial Reform Bill Contains More FCA Amendments

It seems that Congress cannot let any opportunity to amend the False Claims Act go to waste, and this month’s legislative frenzy brings with it yet another amendment to the FCA, the third amendment in a little over a year. The House-Senate Conference Committee for the financial reform bill has approved two amendments to the so-called “whistleblower protection” provision of the FCA, 31 U.S.C. § 3730(h). See H.R. 4173, 111th Cong. (2010). After Congress completely bolged the amendment of this section in the FERA amendments in 2009, see FraudMail Alert No. 09-05-21, the Committee has approved amendments that will (1) once again revise the definition of “protected conduct,” and (2) provide, for the first time, a three-year statute of limitations for actions brought under Section 3730(h), resolving the issue the Supreme Court addressed in Graham County Soil & Water Conservation District v. United States ex rel. Wilson, 545 U.S. 409 (2005) (“Graham County”). See FraudMail Alert No. 05-06-20. A redline comparison of the Committee’s and FERA’s retaliation amendments is attached.

Because the Committee’s amendments redefining “protected conduct” would remove defenses to retaliation suits, if enacted, these amendments should only apply prospectively to conduct occurring after their date of enactment. Even applying the amendments prospectively introduces new terms and issues for interpretation that will add to the thicket of alternatives already facing litigants and judges in this fast-changing area of the law.

“Protected Conduct” Amendments

Prior to the FCA amendments in the Fraud Enforcement and Recovery Act of 2009 (“FERA”), a retaliation claim under Section 3730(h) required three basic elements: (1) the employee engaged in “protected conduct,” defined as lawful acts in furtherance of an FCA action, (2) the employer knew about the protected conduct, and (3) the employer retaliated against the employee because of the protected conduct. See John T. Boose, Civil False Claims and Qui Tam Actions §4.11[8] (Aspen Publishers, Wolters Kluwer Law & Business) (3d ed. 2008 & Supp. 2010-1). FERA expanded the group of protected persons to “any employee, contractor, or agent,” and it removed the reference to discrimination by an “employer.” The reason for these changes was to eliminate the requirement that an employee-employer relationship was necessary for a retaliation violation—a requirement that excluded independent contractors from bringing retaliation actions. See id. at §4.11[8][2][b].
FERA also changed the conduct required for protection—from lawful acts “in furtherance of an action under this section,” to “other efforts to stop 1 or more violations.” Thus, to prove retaliation under FERA, rather than investigating the fraud in order to file a qui tam suit, the person must actually try to stop the fraud itself. This narrowed, rather than enlarged, the retaliation cause of action. The Committee’s amendment restores the original scope of protected conduct so that lawful acts in furtherance of a qui tam suit as well as “other efforts to stop 1 or more violations” are both covered. However, the Committee amendment also broadens the definition of conduct beyond the new boundaries established under FERA by expanding the group of actors who may engage in the conduct to include “associated others.” This ambiguous terminology undoubtedly will be used to support whistleblower retaliation claims based on the conduct of persons and businesses that are not in any relationship with employers, and therefore would apply in circumstances well beyond FERA’s independent contractor rationale. The only other requirement for this protection is that the conduct of the associated others must be “lawful.”

In any event, the new relationships and requirements in FERA and the latest amendments are subject to conflicting interpretations. Defining protected conduct of an “employee,” “contractor,” “agent,” and “associated others,” as well as determining what qualifies as discrimination “in the terms and conditions of employment” by non-employers, will surely be subject to debate and litigation. Because these amendments are substantive—they seemingly would enlarge liability and remove defenses—any dispute over which version of Section 3730(h) applies should be resolved under the principles that govern retroactive application of amendments to conduct occurring before their enactment, rather than by simply applying the newest version of the law. See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1400 n.1 (2010); Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 948 (1997).

Statute of Limitations Amendment

For the first time, the Committee has added a statute of limitations for retaliation in Section 3730(h), which requires these claims to be brought no more than three years from the date when the retaliation occurred. The lack of any statute of limitations for retaliation had prompted the Supreme Court to determine what limitation should be applied in Graham County I. The relator and the United States took the position in Graham County I that applying the FCA’s six-year limitation on qui tam actions would serve the purposes of uniformity and certainty, but the Court rejected their interpretation as unsupported by the statute itself and because it would lead to absurd results. Indeed, the Court found that substantive FCA violations and retaliation were separate causes of action, that a substantive violation of the FCA was not required for a violation of Section 3730(h), and that the limit for retaliation should begin to run when the cause of action for that violation accrued rather than when a substantive FCA violation occurred. The Court established a default rule under which state statutes of limitations for analogous state causes of action are applied to FCA retaliation actions.

The Committee’s three-year statute of limitations amendment finally fills the void that the Supreme Court’s default rule addressed in Graham County I. While a three-year limitation is longer than many analogous state statutes of limitations, uniformity will eventually be achieved when this amendment takes effect.
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CIVIL FALSE CLAIMS ACT: Fourth Circuit Rejects Mere Regulatory Non-Compliance as Basis for False Claims Act Liability and Adopts “Prerequisite to Payment” Test as Essential Element of “Falsity”

In its decision in United States ex rel. Rostholder v. Omnicare, Inc.—a case where regulatory non-compliance was sufficiently alleged—the Fourth Circuit resisted attempts to “sanction use of the False Claims Act as a sweeping mechanism to promote regulatory compliance.” No. 12-2431, 2014 WL 661351, at *6 (4th Cir. Feb. 21, 2014). Instead, the court made clear that unless compliance with the regulation at issue is a prerequisite to payment by the government, there is no FCA violation. This decision represents another example of courts adhering to the Supreme Court’s admonition against transforming the FCA into “an all-purpose antifraud statute.” Allison Engine Co v. United States ex rel. Sanders, 553 U.S. 682, 672 (2008). See, e.g., United States ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001), United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295 (3d Cir. 2011); United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010); United States ex rel. Chestbrough v. Visiting Physicians Ass’n, 655 F.3d 461 (6th Cir. 2011); United States ex rel. Hobbs v. MedQuest Assocs., 711 F.3d 707 (6th Cir. 2013). See also FraudMail Alert No. 10-11-03, Fifth Circuit Holds “Prerequisite to Payment” is a Fundamental Requirement in Establishing “Falsity” in a False Certification Case (Nov. 3, 2010); FraudMail Alert No. 11-08-31, Sixth Circuit Joins Second and Fifth Circuits in Holding That FCA Claims Based on Implied False Certifications Must Allege and Prove That the Alleged Violation Was a Prerequisite to Payment (Aug. 31, 2011).

Background in Rostholder

The core allegation in Rostholder was that Omnicare, a pharmaceutical services provider to nursing homes, sought reimbursement from Medicare and Medicaid for drugs that were repackaged in violation of certain FDA safety regulations. In particular, the relator claimed that non-penicillin drugs improperly were repackaged in the same facility as penicillin drugs, leading to potential contamination in violation of FDA regulations and rendering the drugs “ineligible for coverage under government [healthcare] programs.” Rostholder, 2014 WL 661351, at *2. Notably, before the relator filed his qui tam complaint, the FDA investigated the claims, issued a warning letter to Omnicare, and cautioned that the drugs at issue were “adulterated.” In response, Omnicare destroyed $18 million worth of drugs but allegedly did not recall any drugs previously distributed or reimburse the government for Medicare and Medicaid payments previously made for allegedly contaminated drugs. Despite the FDA’s conclusions, the Department of Justice...
declined to intervene in the *qui tam* case but did file a Statement of Interest in the trial court supporting the relator’s broad legal argument for FCA liability.

At the trial court level, Omnicare moved to dismiss the complaint on multiple grounds, including that it failed to state an FCA violation. The district court granted the motion, holding that the complaint failed to allege a false statement or fraudulent conduct and also failed to detail any false claims. After first addressing the jurisdictional public disclosure bar argument raised by Omnicare, the Fourth Circuit affirmed the dismissal, joining other circuits in holding that, if compliance with an FDA regulatory requirement is not a prerequisite to payment under Medicare and Medicaid, there is no FCA violation.

Specifically, the Fourth Circuit ruled that Medicare and Medicaid (1) do not expressly prohibit reimbursement for drugs that were manufactured or packaged in violation of the FDA’s safety regulations, and (2) do not require compliance with FDA’s safety regulations as a “precondition to reimbursement.” Rather, the drug merely must have FDA approval in order to be covered by Medicare or Medicaid. Based on this statutory and regulatory framework, the Fourth Circuit ruled that the relator’s complaint failed to state a false claim or fraudulent course of conduct.

**Rejecting Relator’s Argument, Court Finds “Materiality” and “Falsity” Are Two Different Elements of FCA Liability**

On appeal, the relator argued that the complaint stated an FCA violation because compliance with the FDA safety regulations was “material” to the government’s decision to provide Medicare and Medicaid reimbursement. Faced with the same relator argument below and a supporting Statement of Interest filed by the Justice Department, the district court responded:

Relator...appears to argue that any claim for goods or services provided in violation of a statute or regulation represents “fraudulent conduct” within the meaning of *Harrison*—as long as the violation is material. In other words, the court need not analyze whether “fraudulent conduct” exists separately from the materiality prong of the test... [R]elator does not argue there was an affirmative false statement or false certification; relator does not argue this court should adopt the implied certification theory; and relator does not argue for the theory of fraud by omission, which *Harrison* appears to suggest may be appropriate under some circumstances. Relator’s argument instead appears to read the first prong—false statement or fraudulent conduct—out of the *Harrison* test for FCA liability. **Without clearer guidance from the Fourth Circuit,** I cannot agree that such an approach is appropriate...


On appeal, the Fourth Circuit delivered clear guidance by flatly rejecting relator’s argument (which had been supported by the Justice Department in the district court) and stating that “materiality” and “falsity” are two distinct elements of an FCA claim and relator did not and could not show a “false statement or fraudulent course of conduct” where compliance with the FDA safety regulations was not required for Medicare and Medicaid reimbursements. *Rostholder*, 2014 WL 661351, at *5.
The FCA Is Not a “Sweeping Mechanism” for Regulatory Compliance or a Substitute for Regulatory Enforcement

In support of its primary holding, the Fourth Circuit noted that the FCA was not the appropriate enforcement mechanism for mere regulatory violations:

Were we to accept relator’s theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct. When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could “short-circuit the very remedial process the Government has established to address non-compliance with those regulations.”

Rostholder, 2014 WL 661351, at *6 (internal citation omitted).

Even so, the Fourth Circuit did not sanction Omnicare’s actions and it hinted that the FDA was partially at fault for not fully exercising its enforcement powers to ensure that safety standards were followed. Id. at *7 (“[W]e do not condone Omnicare’s disregard of FDA safety regulations that apparently occurred in this case...[n]evertheless,...we are confident that the FDA’s use of its regulatory enforcement powers may be exercised fully to ensure further compliance with applicable safety standards.”). Notably, the Secretary of Health and Human Services had the authority to withdraw approval of improperly packaged drugs, id. at *6, an action which, if taken, would have changed the facts of this case and presumably made any Omnicare reimbursement requests to Medicare or Medicaid (after the withdrawal of approval) false and otherwise actionable under the FCA.

Potential Broader Implications of the Fourth Circuit’s Decision: Reducing the Significance of Both the Post-FERA Materiality Definition and the Implied Certification Theory

In deciding this case, the Fourth Circuit joined the growing chorus of courts that have refused to extend the reach of the FCA to all manner of regulatory violations. And, even though this case involved pre-FERA conduct, the Fourth Circuit also may have provided some much-needed perspective to the 2009 FERA amendments to the FCA and, in particular, the defining of “material” as “having a natural tendency to influence or be capable of influencing” payment by the government. 31 U.S.C. § 3729(b)(4). See Fraud Enforcement and Recovery Act, Pub. L. No. 111-21 (2009) (“FERA”). See also Fraud/Mail Alert No. 03-05-21, The Falsa Claims Act is Amended for the First Time in More Than Twenty Years as the President Signs the Fraud Enforcement and Recovery Act of 2009 (May 21, 2009). By refusing to conflate the “materiality” and “falsity” elements of the FCA, the Fourth Circuit eases the impact of the low “materiality” threshold that the FERA amendment put in place.

Moreover, the Fourth Circuit’s ruling is interesting because the court appears to hold that, unless it is clearly stated in a statute or otherwise that compliance with a regulation is a prerequisite to payment, a defendant cannot act with the requisite scienter and cannot submit a “false” claim. See Rostholder, 2014 WL 661351, at *6 (“Because the Medicare and Medicaid statutes do not prohibit reimbursement for drugs packaged in violation of the [FDA safety regulations], Omnicare could not have knowingly submitted a false claim for such drugs.”). Such a holding, which is essentially the current standard in the Second Circuit, if adopted more widely, would greatly undermine “implied certification” cases brought under the FCA. See, e.g., Mikas, 274 F.3d at 702. A footnote within the Fourth Circuit’s decision alludes to this
potential broader implication. *Roshko, 2014 WL 661351, at *5 n.7 (*Because adulterated drugs are subject to reimbursement by Medicare and Medicaid and therefore any claim for payment cannot be 'false,' we do not separately address relator's arguments for FCA liability under 'implied certification' or 'worthless services' theories.*).

* * *

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