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**Recent Developments
Under the Federal False Claims Act**

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INTRODUCTION

The False Claims Act (“FCA”) was enacted in 1863 in response to allegations of fraud that arose in the context of Civil War procurements, but the FCA became a significant enforcement tool only after Congress enacted watershed amendments in 1986, including stiffer damages and penalties, and the expansion of the rights of private citizens, known as *qui tam* relators, to bring suits on behalf of the government. The Department of Justice recovered more than \$3.7 billion under the FCA in fiscal year 2017, bringing total FCA recoveries to more than \$56 billion since 1986.¹ More than \$3.4 billion recovered in 2017 was in *qui tam* cases initiated or brought by relators, whose “relator’s share” totaled \$393 million that year. The number of *qui tam* suits filed in fiscal year 2017 was 674, roughly five times the number of non-*qui tam* suits that the government filed that year. There are no signs that *qui tam* actions are going to decline.

The Affordable Care Act strengthened the government’s focus on health care fraud, allocating an additional \$350 million to that effort over the next ten years, but the single most effective weapon in the government’s arsenal continues to be the civil False Claims Act. Of the \$3.7 billion in FCA recoveries in 2017, nearly \$2.5 billion was from the health care industry (broadly defined to include pharmaceutical and medical device companies).² As the Justice Department has noted, the government’s focus on healthcare-related actions has consistently produced large FCA recoveries. Increasingly, the Justice Department is demanding “nonmonetary remedial measures,” such as expensive corporate integrity agreements, in FCA settlements. Also, the Justice Department announced its intent to follow the new policy memorandum known as the “Yates Memo” that takes a more aggressive approach toward pursuing individuals as FCA defendants in addition to corporations.³ Although the Yates memo has been criticized and is under review by the Trump Administration,⁴ the Department of Justice has continued these enforcement policies.⁵

¹ See Press Release, Dep’t of Justice, Justice Department Recovers Over \$3.7 Billion from False Claims Cases in Fiscal Year 2017 (Dec. 21, 2017) (“DOJ’s 2017 Press Release”).

² See DOJ’s 2017 Press Release.

³ See Memorandum from Deputy Att’y Gen. Sally Quillian Yates, Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015) (“Yates Memo”), available at <https://www.justice.gov/dag/file/769036/download>; Press Release, Dep’t of Justice, Principal Deputy Assistant Att’y Gen. Benjamin C. Mizer Delivers Remarks at the 16th Pharma Compliance Cong. and Best Practices Forum (Oct. 22, 2015), available at <https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-16th>.

⁴ See ABA News, Former Deputy AG James Cole says DOJ’s new white-collar crime policy is “impractical” (Nov. 24, 2015) (pointing out that as a practical matter, individual prosecutions in complex regulated fields like financial transactions and healthcare are rare due to the difficulty of finding evidence that a single individual had the requisite intent; other significant ramifications from the Yates Memo’s requirement that “all” information about individual wrongdoers be disclosed in order to get “any” credit for cooperation are that employees are less willing to cooperate with internal investigations or may want their own counsel before cooperating, and that internal investigations take more time and are more expensive to complete), available at https://www.americanbar.org/news/abanews/aba-news-archives/2015/11/former_deputy_agjam.html; NYU Sch. of Law, Program on Corporate Compliance & Enforcement, Deputy Att’y Gen. Rod Rosenstein Keynote Address on Corporate Enforcement Policy (Oct. 6, 2017) (stating that “[t]he individual accountability policy issued by former Deputy Attorney General Yates is one of the policy memos under review”) (“Rosenstein 2017 Keynote Address”), available at https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/.

⁵ See Rosenstein 2017 Keynote Address (“Our Civil Fraud Section has recovered over \$60 million to date in actions in fiscal year 2017 against individual defendants under the False Claims Act, not including recoveries where corporate owners were held jointly and severally liable with the corporate entity.”); Press Release, Dept. of Justice, Medicare Advantage Organization and Former Chief Operating Officer to Pay \$32.5 Million to Settle

Substantive areas of particular concern to health care providers and the health care industry include upcoding, off-label promotion, Medicaid rebates, failure to document patient care, deficient compliance, worthless services, and the expanded use of the Antikickback statute as bases for FCA liability.⁶ In addition, the knowing nonpayment of an “obligation”—defined to include “knowingly and improperly” retaining an “overpayment” from a government health care program—is a basis for the FCA’s treble damages and penalties under the “reverse false claim” theory of liability. The Supreme Court’s recent decision in *Universal Health Services v. United States ex rel. Escobar*, which validated application of the implied false certification theory in FCA cases, and provisions linking the FCA to government health care program requirements, ensure that the FCA’s role in health care fraud enforcement will only increase.

Substantive and procedural FCA amendments enacted in 2009 and 2010—in the Fraud Enforcement and Recovery Act of 2009 (“FERA”), the Affordable Care Act (“ACA”), and the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank”)—make it easier for the government and *qui tam* relators to conduct investigations and obtain recoveries under the FCA.⁷ The full impact of FERA’s and the ACA’s amendments is now being felt, and it is clear that these amendments will be the basis for attempts to recover more funds, cover more potential defendants, and narrow defenses to FCA suits in the years to come. Now that twenty-nine states plus the District of Columbia, New York City, Chicago, and Philadelphia have false claims laws, false claims litigation often takes place at the federal, state, multi-state, and municipal levels. The considerable resources of the government—federal and state—coupled with the seemingly limitless supply of whistleblowers willing to litigate FCA claims on behalf of the government, assure that the civil False Claims Act will remain one of the government’s most powerful weapons against fraud.

Major changes relating to FCA liability, damages, and penalties occurred as a result of legislation, judicial decisions, and government agency rules in the past year. The Supreme Court’s decision in June 2016 validating the implied false certification theory of liability in *Universal Health Services v. United States ex rel. Escobar* established a new paradigm for analyzing false certification cases. The Court established limits for this potentially expansive theory, including a demanding materiality standard, and held that rigorous enforcement of both materiality and scienter was required to keep the FCA from becoming an “all-purpose antifraud statute.” The *Escobar* decision affects the application of both the federal FCA and state false claims acts, and it has changed the focus in every phase—pre-trial motions and discovery through trial—of the litigation of a false certification case. On the penalties side, the Justice Department has implemented a congressional mandate that has resulted in the doubling of FCA penalties for violations occurring after November 1, 2015. This enormous increase in FCA penalties is certain to raise constitutional challenges under the Excessive Fines Clause of the Eighth Amendment. Another important recent development is that new provisions in the tax law passed in December 2017 will alter the approach to tax deductibility—placing the burden on the taxpayer to demonstrate the amount that constitutes restitution for damages, requiring the

False Claims Act Allegations (May 30, 2017), available at <https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle>.

⁶ See, e.g., Law 360, What the DOJ’s Elite Health Fraud Squads Are Watching (Sept. 21, 2017), available at https://www.law360.com/governmentcontracts/articles/960133/what-the-doj-s-elite-health-fraud-squads-are-watching?nl_pk=68d0f0c3-b32d-42ae-8ec6-f7aaded1d632&utm_source=newsletter&utm_medium=email&utm_campaign=governmentcontracts&read_more=1.

⁷ See FERA, Pub. L. No. 111-21 (2009); ACA, Pub. L. No. 111-148, 124 Stat. 119 (2010); Dodd-Frank Act, Pub. L. No. 111-203, §3301, 124 Stat. 1376, 2079 (2010).

restitution amount to be identified in FCA judgments and settlements, and limiting the taxpayer's deduction to that amount (although mere identification alone is not sufficient to carry the taxpayer's burden).⁸

Important recent developments discussed in this paper include:

- Materiality and false certification liability after the Supreme Court's *Escobar* decision
- Falsity
- Causation
- The FCA's knowledge and intent standards—including *Escobar's* scienter requirement
- Reverse false claims
- Damages and penalties
- Public disclosure and first-to-file
- Retaliation

For a full discussion of the FCA and decisional law under it, please refer to JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (Wolters Kluwer Law & Business) (4th ed. & Supp. 2018-1) ("BOESE"). A redline showing the current FCA, as amended, is attached as Appendix 1. Appendix 2 is a FraudMail Alert issued the day following the *Escobar* decision on the impact of that decision on false certification cases; Appendix 3 is a recent FraudMail Alert discussing how tax reform affects settlements under the FCA; and Appendix 4 is a FraudMail Alert on the government's first Medicare Advantage test cases.

A. FCA Fundamentals

Some important features that are present in both versions of the FCA—before and after FERA—should be noted at the outset:

- Violations of the FCA give rise to potentially enormous economic liability. The law provides that all damages are trebled. Each false claim submitted has been subject to a mandatory penalty of \$5,500 and \$11,000 per violation. However, effective August 1, 2016, these penalties nearly doubled for violations occurring after November 1, 2015. In 2018, FCA penalties are from \$11,181 to \$22,363.
- The FCA can be enforced not only by the powerful resources of the federal government, but also through the use of private plaintiffs, referred to as *qui tam* relators. The term "*qui tam*" is derived from a Latin phrase, "*qui tam pro domino rege quam pro se ipso*," or "who pursues this action on our Lord the King's behalf as well as his own." As this phrase indicates, the *qui tam* action arose in early English common law as a device for permitting private individuals to litigate claims on the sovereign's behalf. Like relators in modern FCA actions, early *qui tam* litigants not only gained standing they otherwise would lack, but also a share of any recovery obtained on the sovereign's behalf as a result of the *qui tam* action. Significant amendments to the False Claims Act in 1986 strengthened the rights of relators, and

⁸ See H.R. 1, 115th Cong. § 13306(a) (2017) (enacted). See also FraudMail Alert No. 18-01-08 (attached as Appendix 3).

increased the bounties that may be awarded to successful relators, thus dramatically increasing the incentives to filing suit. There are unique procedural steps involved when a *qui tam* relator initiates FCA litigation, including the requirement that the complaint must be filed under seal, and the United States may intervene and take over the action.

- Whether an FCA suit is initiated by the government or by a *qui tam* relator, the liability, damages and penalties provisions remain the same. Defendants are also liable for the attorneys' fees and costs of relators.
- A number of state and local governments have adopted their own versions of false claims acts, with *qui tam* enforcement. Although in the past these laws have varied considerably from the federal FCA, most of them no longer do because they must follow the federal model in order to receive an economic incentive under the Deficit Reduction Act of 2005.⁹

It is also important to note what the False Claims Act does not cover. Although false tax returns are almost certainly the most common false claim filed with the federal government, the False Claims Act expressly excludes such claims from the scope of its coverage.¹⁰ This FCA “tax bar” has been held to apply broadly whenever a false claim is made or a benefit is procured under the Internal Revenue Code, and is not limited to false income tax claims.¹¹ However, New York amended its state FCA to allow *qui tam* enforcement of tax law violations.¹²

B. The 1986 Law

Prior to the 2009 and 2010 amendments, liability under the civil False Claims Act has arisen primarily under the provisions of 31 U.S.C. §§ 3729(a)(1) - (7). The government (or the *qui tam* relator) bears the burden of proving each element of a False Claims Act violation, including damages, by the preponderance of the evidence.¹³ The four most commonly-invoked liability provisions of the 1986 FCA are:

- Section 3729(a)(1) establishes liability for so-called “direct” false claims to the government;
- Section 3729(a)(2) imposes liability for making false records or false statements to support a false claim;

⁹ Pub. L. No. 109-171, §§ 6031-6033, 120 Stat. 4, 72-74 (2006) (to be codified at 42 U.S.C. §§ 1396a(a), 1396b(i), 1396h(a)).

¹⁰ 31 U.S.C. § 3729(e) provides that “This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1954.”

¹¹ *United States ex rel. Lissack v. Sakura Global Capital Mkts., Inc.*, 377 F.3d 145 (2d Cir. 2004). Congress has enacted a “tax *qui tam*” statute which provides a bounty to anyone who brings tax underpayments by certain corporations and high-income individuals to the attention of the IRS. See Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, §406, 120 Stat. 2922, 2958 (Dec. 20, 2006). See also BOESE, §1.07[A][1].

¹² See N.Y. State Fin. Law §189.4(a). See also FraudMail Alert No. 10-08-26, New York State FCA: New York’s False Claims Act Now Equals or Exceeds Federal Fraud Law—False State Tax Returns Are Now Privately Enforceable under State FCA,

<http://friedlive.icvmgroup.net/siteFiles/Publications/Fried%20Frank%20FraudMail%20Alert.pdf>.

¹³ 31 U.S.C. § 3731(c).

- Section 3729(a)(3) involves conspiracy to get a false claim paid; and
- Section 3729(a)(7), the so-called “reverse false claims provision,” imposes liability for false records or statements made to reduce or avoid an obligation to the government.

The remaining three subsections of Section 3729(a), subsections (a)(4), (a)(5) and (a)(6), tend to be either redundant or to apply to situations that occur infrequently under modern government contracting procedures. These sections of the FCA are seldom invoked, and therefore have not been the subject of significant case law analysis.¹⁴

The 1986 amendments lowered the intent needed for an FCA violation to the “recklessness” standard, established the burden of proof at a preponderance of the evidence, and expanded the *qui tam* enforcement mechanism by:

- increasing the relators’ share to up to 30 % of the government’s recovery;
- removing the government knowledge bar and replacing it with public disclosure/original source provisions;
- adding a retaliation provision;
- allowing *qui tam* participation after U.S. intervention; and
- encouraging *qui tam* intervention if the U.S. declined to intervene.

C. The 2009 Amendments—FERA

Although Congress stated that its purpose in enacting FERA was to expand the FCA’s liability provisions in order to reach frauds by financial institutions and other recipients of TARP and economic stimulus funds, the 2009 amendments were not needed for that purpose because financial institutions and stimulus funds were already covered by the existing FCA. FERA was simply the vehicle for FCA amendments that had been languishing in Congress since well before the financial crisis in 2008. The broader purpose of a general expansion of the FCA is reflected in the amendments: they are not limited to mortgage and financial fraud, they have nothing to do with financial markets, and they apply across the board to all recipients and payers of government money or property, including health care providers and the health care industry.

The amendments expand FCA liability beyond previous limits by revising all seven of the statute’s liability provisions and redefining key terms such as “claim,” “material,” and “obligation.” While the key liability provisions of the FCA remain those addressing false claims, false statements supporting false claims, conspiracy, and reverse false claims, FERA renumbered and expanded these provisions to cover additional conduct.

FERA’s Liability Amendments. The new Sections 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(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;

¹⁴ For a review of the limited case law arising under subsections (a)(4), (a)(5), and (a)(6), see BOESE, §§ 2.01[G] - [J].

- (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.

A red-line version of the False Claims act is attached as Appendix 1, and use of this red-line is critical to understanding the revisions. Many of the important details of the 2009 amendments are discussed in a contemporaneously issued FraudMail Alert (attached as Appendix 2). A few key illustrations of the expansion in FCA liability under FERA include the following:

- Section 3729(a)(1)(B) amended Section 3729(a)(2) to remove the phrase “to get,” on which the unanimous Supreme Court relied in *Allison Engine Co. v. United States ex rel. Sanders*¹⁵ to limit FCA liability to false statements or claims made by defendants for the purpose of getting the government to pay the claim. FERA expressly applied this amendment retroactively to “claims” pending on or after June 7, 2008 (which was two days before the Supreme Court’s decision in *Allison Engine*). This attempt to apply the amendment retroactively to prior conduct has been challenged, and courts are divided on its retroactive application in pending cases.¹⁶
- The language in Section 3729(a)(3) had been properly interpreted to limit liability for conspiracy to violations of then-Section 3729(a)(1). Section 3729(a)(1)(C) amended this provision to extend liability for conspiracy to commit a violation of any other substantive section of the FCA.
- Section 3729(a)(1)(G) expanded the scope of reverse false claims liability in the prior law under Section 3729(a)(7) to include retention of an overpayment. In 1986, Congress amended the FCA to add the so-called “reverse false claim” provision in Section 3729(a)(7). This provision was intended to address situations where money flows not from the federal government to a recipient, but rather

¹⁵ 553 U.S. 662 (2008).

¹⁶ Compare *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009) (defining “claim” as a demand for payment as under Section 3729(b)(2)(A) and finding that no such claims were pending as of June 7, 2008), and *Allison Engine Co. v. United States ex rel. Sanders*, No. 1:95CV970, 2009 WL 3626773 (S.D. Ohio Oct. 27, 2009) (defining “claim” as a demand for payment, and finding that applying the amendment retroactively would violate the Ex Post Facto Clause), and *United States v. Science Applications Int’l Corp.*, No. 04-1543, 2009 WL 2929250 (D.D.C. Sept., 14, 2009), with *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010) (applying amendment retroactively because relator’s claim was pending as of June 7, 2008), and *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (same). See also *New York v. Sprint Nextel Corp.*, No. 103917/2011 (N.Y. Sup. Ct. July 1, 2013) (slip op.) (ruling that the New York FCA’s tax liability amendment was not sufficiently punitive in nature or effect to preclude its retroactive application under the *Ex Post Facto* Clause); *United States ex rel. Romano v. New York-Presbyterian Hosp.*, No. 00 Civ. 8792(LLS), 2008 WL 612691 (S.D.N.Y. Mar. 5, 2008) (ruling that the relator could not add state FCA claims to federal claims that were based on Medicaid claims submitted more than six years prior to the New York FCA’s effective date).

from a person who has an obligation to pay the federal government. Reverse false claims may arise in many contexts. In the health care industry, for example, federal funds are distributed to some health care providers on a regular basis throughout the fiscal year. At the end of that period, a final reconciliation of the accounts is made using a cost reporting process. If the government has paid more to the provider than it should, the provider may be required to refund the difference to the government. If the provider instead submits false documents to the government indicating that it owes no money to the government, these documents may arguably give rise to a “reverse false claim” if all other elements of liability are proven.

More key changes to FCA liability are included in FERA’s statutory definitions of “claim,” “obligation,” and “material” in Section 3729(b), which are discussed below.

Civil Investigative Demand Amendment. The Department of Justice has authority to conduct broad pre-intervention discovery through civil investigative demands (“CIDs”) that allow it to demand production of documents, oral testimony, and answers to interrogatories. This CID discovery power augments DOJ’s pre-existing power to obtain documentary evidence through subpoenas and authorized investigative demands, and it is stronger than standard civil discovery because the Federal Rules of Civil Procedure do not apply to it. FERA expanded DOJ’s power to issue CIDs and to use the information received in response to CIDs for an “official use.”¹⁷ Under this expanded authority, the Attorney General’s authority to issue CIDs was delegated to the Assistant Attorney General for the Civil Division,¹⁸ who then re delegated this authority to certain senior enforcement officials in the Civil Division as well as to U.S. Attorneys in certain cases.¹⁹ After this expansion, use of CIDs by both DOJ and U.S. Attorneys’ Offices has increased dramatically.²⁰

Relation Back Amendment. FERA also amended the FCA to permit the government’s complaint-in-intervention and amendments to the complaint to relate back to the original *qui tam* complaint for statute of limitations purposes.²¹ FERA revised the FCA’s retaliation provision so that it protects contractors and agents in addition to employees, although the conduct and remedies under this provision are still employment-based.²²

Unchanged Provisions. Key FCA provisions unchanged by FERA include (1) the FCA’s standard of scienter, which is “knowing” or “knowingly,” (2) the FCA’s definition of damages, and (3) the public disclosure/original source jurisdictional bar provisions, which are discussed in the recent developments section of this paper. FERA made no change in the law on the question of whether government employees can be *qui tam* relators, and on the application of

¹⁷ See Appendix 2 at 5 (discussing CID amendment).

¹⁸ See Order No. 3134-2010 (Jan. 15, 2010).

¹⁹ See Dep’t of Justice, Directive No. 1-10, Redlegation of Authority of Assistant Attorney General, Civil Division, to Branch Directors, Heads of Offices and United States Attorneys in Civil Division Cases (Mar. 8, 2010) (to be codified at 28 C.F.R. Part 0).

²⁰ In fiscal year 2011, DOJ authorized the issuance of 888 CIDs—more than ten times the number issued during the two years before re-delegation combined. See Press Release, Dep’t. of Justice, Acting Assistant Attorney General Stuart F. Delery Speaks at the American Bar Association’s Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 7, 2012), <http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html>.

²¹ See Appendix 2 at 5 (discussing relation-back amendment).

²² See *id.* at 4 (explaining FERA’s retaliation amendments).

Rule 9(b)'s pleading requirements to FCA complaints. As discussed below, the Affordable Care Act amended the FCA's public disclosure bar in 2010, and a further revision of the FCA's retaliation provision was made by the Dodd-Frank Act.

D. Recent Developments in FCA Liability, *Qui Tam* Enforcement, and Retaliation

The dominant developments this year are the result of the Supreme Court's unanimous, watershed decision in *United States ex rel. Escobar v. Universal Health Services, Inc.*, which held that the false certification theory of liability may be applied in FCA cases, and established critical limits on the scope of this theory for all false certification cases (express and implied).²³ A key limit on liability established in *Escobar* is its demanding materiality standard that focuses on the government's knowledge of the allegations and its payment decisions, making it essential to take discovery from the government on these matters. The doubling of FCA penalties (for violations after November 2, 2015) is another major change that occurred in 2018.

Given the number of important developments this year, only a few of the most significant can be briefly touched upon in these pages. For a more exhaustive analysis of recent FCA developments, see JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (Wolters Kluwer Law & Business) (4th ed. & Supp. 2018-1).

1. Claims and Presentment

Prior to FERA, Section 3729(a)(2) liability was limited to false statements supporting false claims for money or property that the government "provides" or "will reimburse." Some courts read this language to require the false claim to be subjected to a government payment or approval process, but the circuits were split on the underlying question of whether "presentment" of the false claim to the government was required under Section 3729(a)(2). In a unanimous decision, in *Allison Engine Co. v. United States ex rel. Sanders*,²⁴ the Supreme Court resolved this split by holding that presentment was not required under Section 3729(a)(2), but that was limited to false statements that were designed "to get" a false claim paid or approved "by the Government." The Court found that this limitation was necessary because, without a clear link to payment or approval by the government, the FCA would be "boundless" and become an "all-purpose antifraud statute."²⁵

FERA, however, eliminated 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). Now Section 3729(a)(1)(B) liability is limited by a nexus to the government requirement in the definition of "claim" in Section 3729(b)(2)(ii), which 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." FERA does not define the key terms "used on the Government's behalf" or "to advance a Government program or interest," and therefore their meaning is left to the courts to determine on a case-by-case basis.

The presentment requirement remains in Section 3729(a)(1)(A), however, and the definition of "claim" in Section 3729(b)(2)(A)(i) makes clear that presentment must be directly to the government. The Fourth Circuit's decision in *United States ex rel. Nathan v. Takeda Pharm. N.A., Inc.* emphasizes that this requirement is still of primary importance under Section

²³ 136 S. Ct. 1986 (2016).

²⁴ 553 U.S. 662 (2008).

²⁵ 553 U.S. at 669, 672.

3729(a)(1)(A) and must be pled with particularity under Rule 9(b) even when a fraudulent scheme is alleged:

[T]he critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.”²⁶

The Fourth Circuit compared the *Nathan* relator’s allegations with those in *United States ex rel. Grubbs v. Kanneganti*,²⁷ and *United States ex rel. Duxbury v. Ortho Biotech Products*,²⁸ and drew clear distinctions between allegations of fraudulent conduct that necessarily lead to an inference that false claims were presented to the government and the allegations made by the *Nathan* relator, which did not lead to the same inference. The relator in *Nathan* asked the Supreme Court to review the Fourth Circuit’s decision, and the Court invited the Solicitor General to submit a brief expressing the views of the United States on the question of whether Rule 9(b) requires an FCA complaint to allege with particularity that specific false claims actually were presented to the government. After the Solicitor General submitted a brief opposing a per se rule but noting that this *qui tam* suit would be dismissed under either standard, the Court denied *certiorari* in *Nathan*.

2. Requirements under Rule 9(b)

Rule 9(b) provides:

In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind may be averred generally.

Courts have explained that the purposes of this “heightened” requirement to plead the circumstances of the fraud with particularity are to deter meritless claims of fraud, to protect defendants’ reputations, to give particularized notice to defendants of plaintiffs’ claims, and to prevent fraud suits in which the dispositive facts are learned through discovery.²⁹ To satisfy this requirement, the complaint must set forth specifics as to the who, what, when, where, and how of the fraud alleged.³⁰ Courts universally apply this heightened pleading requirement to FCA complaints because the allegations sound in fraud, and there is no conflict between the FCA’s lower intent requirements and Rule 9(b), which provides that intent may be averred generally. Courts use a case-by-case approach in applying Rule 9(b) to substantive claims that have various

²⁶ 707 F.3d 451, 456 (4th Cir. 2013) (internal citations omitted)).

²⁷ 565 F.3d 180 (5th Cir. 2009).

²⁸ 579 F.3d 13 (1st Cir. 2009). It should be noted that the scope of the claims in *Duxbury* were strictly limited when the First Circuit affirmed the district court’s order limiting discovery to the claims that survived dismissal and precluding the relator from discovery on “nationwide” fraud that was outside the time frame and geographic location of the original relator’s employment. See *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 719 F.3d 31 (1st Cir. 2013).

²⁹ See, e.g., *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir.), *cert. denied*, 125 S. Ct. 59 (2004); *United States ex rel. Clausen v. Lab. Corp. of Am.* 290 F.3d 1301, 1313, 1316-17 (11th Cir. 2002); *United States v. Rogan*, No. 02-C-3310, 2002 WL 31433390, at *3 (N.D. Ill. 2002).

³⁰ See, e.g., *United States ex rel. Cafasso v. General Dynamics C4 Sys.*, 637 F.3d 1047, 1057 (9th Cir. 2011); *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App’x 421 (10th Cir. 2009); *Corsello v. Lincare, Inc.* 428 F.3d 1008, 1014 (5th Cir. 2005).

proof requirements, and this approach helps to define the contours of FCA liability. However, some erosion in the heightened standard is occurring in certain *qui tam* cases where the details of a fraudulent scheme have been alleged with particularity but no actual false claim was pled.

As the *Nathan* case discussed above reflects, the False Claims Act was not designed to punish every type of fraud committed upon the government. Instead, because liability under the FCA attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme, “the critical question is whether the defendant caused a false claim to be presented to the government.”³¹ Despite this key requirement for FCA liability, a clear circuit split has developed over whether Rule 9(b) requires FCA complaints to allege the details of a false claim that actually was submitted. Some recent decisions from the First, Second, Third, Fifth, Sixth, Seventh, Eighth, Ninth, and Eleventh Circuits have found that detailed allegations of a particular fraudulent scheme that produce a strong inference that false claims were submitted may meet Rule 9(b)’s requirement for specificity,³² although even within those circuits there is some confusion over the proper standard. The Fourth Circuit has applied a stricter standard under which not just the existence of the fraudulent scheme, but false claims that actually were submitted as a result, must be pled with particularity.³³ The fact that the lower standard is still in flux within individual circuits that have applied it,³⁴ and the subsequent dismissals in cases where the inference that false claims were submitted was not borne out following discovery,³⁵ indicate that the limits to its application are still being delineated.

Sampling and Extrapolation. Where a complaint alleges a complex or far-reaching scheme and survives a motion to dismiss under Rule 9(b), the finding that the complaint was sufficient for pleading purposes does not remove the plaintiff’s ultimate burden to establish liability and damages based on specific false claims.³⁶ This proof requirement has been directly challenged in some FCA cases by plaintiffs who have argued that FCA liability and damages could be based on a sampling of specific false claims and extrapolated to other claims in the

³¹ 707 F.3d 451, 456 (4th Cir. 2013).

³² See, e.g., *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009); *United States ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71 (2d Cir. 2017); *United States ex rel. Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153 (3d Cir. 2014); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750 (6th Cir. 2016); *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770 (7th Cir. 2016); *United States ex rel. Thayer v. Planned Parenthood*, No. 13-1654, 2014 WL 4251603 (8th Cir. Aug. 29, 2014); *Ebeid v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010); *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App’x 693, 708 (11th Cir. 2014). Cf. *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242 (3d Cir. 2016) (ruling that scheme allegations that used a flawed and untested statistical analysis based on eBay sampling met Rule 9(b) pleading standard).

³³ See, e.g., *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 81 U.S.L.W. 3650 (U.S. Mar. 31, 2014) (No. 12-1349).

³⁴ See, e.g., *United States ex rel. Grenadyor v. Ukrainian Village Pharmacy, Inc.*, 772 F.3d 1102 (7th Cir. 2014); *United States ex rel. Dunn v. North Mem’l Health Care*, 739 F.3d 417 (8th Cir. 2014); *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116 (1st Cir. 2013); *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890, 892-95 (5th Cir. 2013) (unpublished decision).

³⁵ See, e.g., *United States ex rel. Lusby v. Rolls-Royce Corp.*, No. 1:03CV680-SEB-WGH, 2012 WL 4357438 (S.D. Ind. Sept. 24, 2012) (granting summary judgment to defendant because relator had no proof that Rolls-Royce made a false claim for payment to the government); *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 719 F.3d 31 (1st Cir. 2013) (“*Duxbury II*”) (granting summary judgment to defendant).

³⁶ Cf. *United States ex rel. Zverev v. USA Vein Clinics of Chicago, LLC*, No. 12CV8004, 2017 WL 1148468 (N.D. Ill. Mar. 27, 2017) (relator’s claim that diagnoses indicated surgery was necessary “at a significantly higher rate than would be expected,” without identifying which procedures were fraudulent, fell short of alleging false claims due to medically unnecessary procedures).

scheme.³⁷ These challenges are at odds with the FCA’s pleading and proof requirements, which are based on the language and purpose of the statute requiring each claim for which recovery is sought to be proven false and submitted knowingly on a claim-by-claim basis.

3. Falsity and False Certification

The terms “false” and “fraudulent” are not specifically defined in the FCA. They have been construed and interpreted by the courts with reference to their construction and interpretation in other contexts, most notably in criminal cases brought under 18 U.S.C. §§ 287 and 1001. Establishing falsity under both the FCA and the criminal False Claims or False Statements Act requires proof of “actual falsity.”³⁸ Matters that are the subject of legitimate scientific dispute are not a basis for a “false” claim within the meaning of the FCA.³⁹ In the FCA context, resolving disputed questions of falsity often involves the interpretation of a law, regulation, contract, or agreement.

False certification liability. Two types of false claims have been recognized as actionable under the FCA—“factually false” claims and “legally false” claims. Proving falsity in a run-of-the-mill “factually false” claim case is a relatively straight forward matter of showing that the defendant submitted “an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.”⁴⁰ For example, a hospital that bills Medicare for a “phantom” patient it has never treated may be liable under the FCA—without the need to determine “materiality” or false certification issues. Those issues are similarly irrelevant in a case where a doctor treats a Medicare patient and then codes the treatment at a higher reimbursement level. In such cases, where the defendant has billed the government for a service that it has not provided, which is the essence of a false claim, the falsity of the claim is obvious and materiality is assumed. Of course, plaintiffs may not simply allege factual falsity to avoid proving that the basic requirements for liability have been met. Courts have rejected such attempts where the proper predicate for liability has been lacking.

³⁷ See, e.g., *United States v. AseraCare Inc.*, No. 2:12-cv-00245, 2015 WL 8486874 (N.D. Ala. Nov. 3, 2015); *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-KFA, 2015 WL 3903575 (D.S.C. June 25, 2015), *appeal dismissed as improvidently granted*, 848 F.3d 330 (4th Cir. 2017) (declining to rule on statistical sampling issue on interlocutory appeal because controlling issues were questions of fact); *United States v. Ageis Therapies, Inc.*, No. 2:10-cv-00072, 2015 WL 1541491 (S.D. Ga. Mar. 31, 2015. See also *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338 (2011); *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016).

³⁸ See *United States v. Diogo*, 320 F.2d 898 (2d Cir. 1963); *United States v. Lange*, 528 F.2d 1280 (5th Cir. 1976).

³⁹ See, e.g., *United States ex rel. Hill v. University of Medicine & Dentistry of N.J.*, No. 10-4364, 2011 WL 5008427 (3d Cir. Oct. 20 2011) (finding that scientific judgments or conclusions on which reasonable minds may differ cannot be “false”); *United States ex rel. Morton v. A Plus Benefits, Inc.*, No. 04-4148, 139 F. App’x 980 (10th Cir. July 19, 2005) (unpublished decision); *United States ex rel. Polukoff v. St. Mark’s Hosp.*, No. 2:16CV00304-JNP-EJF, 2017 WL 237615 (D. Utah Jan. 19, 2017) (physician’s medically reasonable and necessary representation could not be proven false because it was a medical judgment about which reasonable minds may differ); *United States ex rel. Milam v. Regents of the Univ. of California*, 912 F. Supp. 868, 886 (D. Md. 1995).

⁴⁰ See *United States ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153 (3d Cir. 2014) (finding that relator’s allegation that Renal’s overfill claim misrepresented goods provided and overcharged the government was a “factually false claim”); *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) (distinguishing factually false from legally false claims); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (same); *United States ex rel. Sanchez-Smith v. AHS Tulsa Reg’l Med. Ctr.*, 754 F. Supp. 2d 1270, 1288 (N.D. Okla. 2010) (finding no evidence that services were so deficient that claims were factually false and rejecting relators’ allegations that “would stretch FCA ‘factual’ falsity liability too far beyond its intended purpose of preventing misrepresentations of fact on claim forms”).

Many FCA cases are based not on facially or factually false claims, but on an alleged false certification of compliance with a law, regulation or contract provision. Some of the most significant FCA developments each year arise in “false certification” or “legally false” claim cases that involve something quite different from direct overbilling or factually false claims. FCA plaintiffs use the statute to litigate alleged regulatory and statutory violations, most of which lack a private right of action, on the theory that the defendant falsely certified compliance with the regulatory scheme and the government would not have paid the claim had it known about the noncompliance. In a “false certification” claim, the defendant has provided the goods or services to the government or government beneficiary for the agreed upon price. For example, a hospital has provided medically necessary services to a Medicare eligible beneficiary and billed the government the proper amount, but the hospital has not complied with some other regulation, statute, or contract term in the course of delivering those services. The hospital may have violated one or more “conditions of participation” in the course of delivering the necessary services to the eligible beneficiary. The hospital may have expressly certified compliance with the conditions, or its certification may be implied.

Prerequisite to payment analysis. With FERA’s adoption of the more lenient test for materiality, under which a false statement only has to “be capable of influencing” the government’s decision to pay the claim, courts began to rely more heavily on a “prerequisite to payment” analysis of falsity as a limit on liability under the false certification theory. Under that analysis, technical or minor violations of federal laws and regulations that are “conditions of participation” but not prerequisites to payment do not render a claim “false” for purposes of the FCA. Some courts further limited liability to situations in which the government explicitly conditioned its payment on compliance with the regulations or laws violated,⁴¹ but this “express condition of payment” is not dispositive following the Supreme Court’s decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*,⁴² as explained in the materiality section below. Prior to *Escobar*, most circuit courts held that FCA liability turned on falsity, and that the determining factor in that analysis was the prerequisite to payment requirement.⁴³

⁴¹ See, e.g., *United States ex rel. Bishop v. Wells Fargo & Co.*, No. 15-2449, 2016 WL 2587426 (2d Cir. May 5, 2016) (stating that the *Mikes* express test holding is not limited to the healthcare industry, and concluding that some of the same concerns raised in the Medicare fraud context in *Mikes* are also relevant to the banking industry); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (“a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment.”); *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (relator’s implied certification theory was “doomed by the rule, adopted by all courts of appeals to have addressed the matter, that a false certification of compliance with a statute or regulation cannot serve as the basis for a qui tam action under the FCA unless payment is conditioned on that certification.”); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999).

⁴² 136 S. Ct. 1989 (2016).

⁴³ See, e.g., *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir.), *cert. denied*, 135 S. Ct. 85 (2014) (holding that claims for drugs re-packaged in violation of FDA processing regulations were not “false”); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (ruling that an “underlying claim for payment is not ‘false’ within the meaning of the FCA if the contractor was not required to certify compliance in order to receive payment”); *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707 (6th Cir. 2013) (holding that “approved physician” and updating enrollment information requirements were not conditions of Medicare payment); *United States ex rel. Hill v. City of Chicago*, 772 F.3d 455 (7th Cir. 2014) (affirming dismissal of relator’s false certification allegation that program as implemented differed from the City’s grant application for lack of falsity); *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825 (8th Cir. 2013) (“[t]he absence of a clear requirement that a written report must underlie or support each claim for surgical pathology services means that Relators pleaded a claim of regulatory noncompliance, not a plausible claim that Mayo submitted false or fraudulent claims for Medicare payment.”). 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),

For example, in *United States ex rel. Steury v. Cardinal Health, Inc.*,⁴⁴ the relator 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 false certification simply because the FAR included warranty of merchantability provisions. The court concluded 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 held that “a false certification, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.”⁴⁵ As the Third Circuit explained in *United States ex rel. Chesbrough v. Visiting Physicians Ass’n*,⁴⁶ 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 reaching its decision in *Steury*, the Fifth Circuit cited with approval the Second Circuit’s decision in *United States ex rel. Mikes v. Straus*,⁴⁷ which also required the false certification to be a “prerequisite for payment” in order to support an FCA violation. Most other circuit courts adopted this prerequisite to payment requirement in the analysis of legal falsity, and they applied it as a threshold requirement for FCA liability based on a false certification—whether express or implied.⁴⁸

<http://www.friedfrank.com/siteFiles%2FPublications%2FFried%20Frank%20FraudMail%20Alert%20No.%2010-11-03.pdf>; 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), <http://www.friedfrank.com/siteFiles%2FPublications%2FFried%20Frank%20FraudMail%20Alert%20C2%AE%20No.%2011-08-31.pdf>.

⁴⁴ 625 F.3d 262 (5th Cir. 2010).

⁴⁵ 625 F.3d at 269.

⁴⁶ 655 F.3d 461 (6th Cir. 2011).

⁴⁷ 274 F.3d 687, 700.

⁴⁸ See, e.g., *United States ex rel. Ge v. Takeda Pharm.Co.*, 737 F.3d 116, 121 (1st Cir. 2013) (ruling that the relator “alleged facts that would demonstrate a ‘fraud-on-the-FDA’ with respect to intentional under-reporting of adverse events,” but she failed to allege that any claims submitted to Medicare or Medicaid by patients and physicians were rendered “false” as a result), *cert. denied*, 83 U.S.L.W. 3184 (U.S. 2014); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011) (holding 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 AKS was actionable under the FCA); *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir.) (“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”) (emphasis in original), *cert. denied*, 83 U.S.L.W. 3185 (U.S. 2014); *United States ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 713 (6th Cir. 2013) (holding that regulatory noncompliance that violates “conditions of participation”—even if serious and intentional—is not enough to establish an FCA violation and that “approved physician” and updating enrollment information requirements were not conditions of Medicare payment); *United States ex rel. Hill v. City of Chicago*, No. 14-1317, 2014 WL 6065418 (7th Cir. Nov. 14, 2014) (affirming dismissal of relator’s false certification allegations that the City’s implemented program differed from its grant application for lack of falsity); *United States ex rel. Ketrosor v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (rejecting relator’s reporting violation claim because it did not allege a violation of any regulation or code and the reporting requirement was not a “material condition of payment”); *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir.) (joining 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”), *cert. denied*, 131 S. Ct. 801 (2010); *United States ex rel. Conner Salina Reg’l Health Ctr.*, 543 F.3d 1211, 1220 n.6 (10th Cir. 2008) (adopting a “materiality” requirement that limited FCA liability to violations of conditions of payment and concluding that, “although the government considers

In *Escobar*, however, the Supreme Court declined to adopt “a circumscribed view of what it means for a claim to be false or fraudulent” using an express condition of payment requirement. Instead, the Court shifted the analysis from falsity to materiality, opting to apply a “demanding” materiality standard that is derived from its common law antecedents in fraudulent misrepresentation, and abrogating the express prerequisite to payment requirement in *Mikes*. The Court concluded that stringent limitations were necessary, however, to keep the false certification theory from improperly expanding the FCA’s punitive sanctions and using the FCA as an “all-purpose antifraud statute.”⁴⁹ These limitations are discussed immediately below.

4. Materiality

In *Escobar*, the Supreme Court unanimously validated applying the implied false certification theory in appropriate cases and, for the first time, drew the contours of the materiality analysis required in order for that theory to apply.⁵⁰ The relators—the parents of a teenage girl who suffered a fatal reaction to medication after receiving treatment at the defendant’s mental health facility in Massachusetts—alleged that the facility’s noncompliance with state staffing and licensing requirements rendered false the defendant’s claims for payment to Medicaid under this theory. Observing that the statutory terms “false or fraudulent” referred to the common law meaning of “fraud”—and that common law fraud has long been understood to encompass misrepresentation by certain misleading omissions—the Court accepted the implied false certification theory to the extent that it is supported by this long established basis for fraud. Instead of narrowly circumscribing the meaning of a “false or fraudulent claim” in implied false certification cases, the Court opted to apply a “demanding” materiality standard, defined as under its “common-law antecedents” in fraudulent misrepresentation.⁵¹ The *Escobar* decision became a game changer in the analysis of false certification claims—both express and implied, and its impact pervades every phase of the litigation in a false certification case.

Specific Representations. As the Supreme Court explained in *Escobar*, when a defendant makes specific representations in submitting a claim but omits violations of material statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided. The Court found that the claims for payment in *Escobar* did more than request payment, and that by submitting claims using payment codes that corresponded to specific services, the mental health facility represented that it had provided certain therapy and treatment, but the provider identification numbers corresponding to those job titles were misleading in the context of the defendant’s noncompliance with Massachusetts Medicaid staffing and licensing requirements. Thus, the Court found that the implied false certification theory could apply at least where two conditions are met: (1) the defendant made specific representations about its goods or services, and (2) the defendant failed to disclose noncompliance with a statutory,

substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition to receiving Medicare *payments* for services rendered”) (emphasis in original); *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039 (11th Cir. 2015) (expressly adopting the false certification theory and finding that a certification that is a prerequisite to obtaining a government benefit is required).

⁴⁹ *Id.* at 2003 (quoting *Allison Engine*).

⁵⁰ 136 S. Ct. 1989 (2016). See FraudMail Alert No. 16-06-17, Supreme Court Rejects DOJ’s Expansive Theory for FCA Falsity and Requires Rigorous Materiality, Scienter Standards in All False Certification Cases (June 17, 2016) (attached as Appendix 2).

⁵¹ 136 S. Ct. at 2002.

regulatory, or contractual condition that was “material” to the government’s payment decision.⁵² Many courts interpret this two-part test as a threshold requirement for a valid false certification theory,⁵³ while some courts have applied this test less restrictively on the theory that it was not intended to define the “outer reaches of FCA liability.”⁵⁴

Government Knowledge and Payment. As under its common law antecedents, *Escobar* materiality looks to “the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”⁵⁵ This focus means that both government awareness of the allegations and the government’s payment practices play key roles in determining materiality. Indeed, once the government is aware of the allegations, its decisions—to renew (or not renew) a contract, to continue approval of a drug or device, to continue payment of claims, and even the decision not to intervene in the *qui tam* case—have been considered relevant to determining materiality.⁵⁶ For example, in *D’Agostino v. ev3, Inc.*, the First Circuit affirmed dismissal of a complaint alleging that misrepresentations about safety and training relating to a medical device “could have” influenced the FDA to approve the device, leading to later false claims to CMS.⁵⁷ The First Circuit examined the evidence of the government’s conduct and concluded that because the FDA did not withdraw its approval and CMS continued to pay for the device after these agencies were made aware of the allegations, *Escobar*’s demanding materiality standard was not satisfied. Under some circumstances, however, continued payment alone has been insufficient to preclude summary judgment in the government’s favor if there was no prolonged period of government acquiescence.⁵⁸ This focus on the government’s knowledge, payment

⁵² *Id.* at 2001.

⁵³ See, e.g., *United States ex rel. Whatley v. Eastwick Coll.*, 657 F. App’x 89 (3d Cir. 2016); *United States ex rel. Schimelpfenig v. Dr. Reddy’s Labs. Ltd.*, No. 11-4607, 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017); *United States ex rel. Tessler v. City of New York*, No. 14CV6455 (JMF), 2016 WL 7335654 (S.D.N.Y. Dec. 16, 2016).

⁵⁴ *United States ex rel. Brown v. Celgene Corp.*, No. 10-03165-GHK (SSx), 2016 WL 7626222, at *8 (C.D. Cal. Dec. 28, 2016). See *United States ex rel. Wood v. Allergan, Inc.*, No. 10CV5645 (JMF), 2017 WL 1233991 (S.D.N.Y. Mar. 31, 2017); *United States ex rel. Landis v. Tailwind Sports Corp.*, No. 1:10CV0976 (CRC), 2017 WL 573470 (D.D.C. Feb. 13, 2017); *United States ex rel. Rose v. Stephens Inst.*, No. 09CV5966-PJH, 2016 WL 5076214, at *5 (N.D. Cal. Sept. 20, 2016).

⁵⁵ 136 S. Ct. 1989, 2003 (quoting Williston on Contracts).

⁵⁶ See, e.g., *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746 (3d Cir. 2017) (finding defendants’ minor, insubstantial misstatements that allowed patients to get their medications immaterial where government employees knew dummy identifiers were being used and the reason for them, and the government nevertheless paid the prescription claims); *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 2017 WL 3167622 (1st Cir. July 26, 2017) (affirming dismissal of fraud on the FDA claim because, after relators informed the FDA of alleged substandard design, the FDA allowed device to remain on the market until DePuy discontinued it); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (affirming dismissal because relator disclosed the allegations to the FDA, the FDA continued approval and even added indications, CMS consistently reimbursed, and DOJ declined to intervene in the suit); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017) (affirming dismissal because government accepted noncompliance with reporting guideline and continued to pay for work performed); *United States ex rel. Ruckh v. Salus Rehab., LLC*, No. 8:11-cv-1202-T-23TBM, 2018 WL 375720 (M.D. Fla. Jan. 11, 2018) (finding the record’s silence on whether the government “would refuse to pay [major statewide] provider because of a dispute about the method or accuracy of payment after the government has permitted a practice to remain in place for years without complaint or inquiry” insufficient proof of materiality under *Escobar*). Cf. *United States ex rel. Williams v. Renal Care Group Inc.*, 696 F.3d 518 (6th Cir. 2012) (upholding government’s assertion of deliberative process privilege and allowing it to withhold evidence as to CMS’s interpretation of relevant Medicare provisions and knowledge of industry practice).

⁵⁷ 845 F.3d 1 (1st Cir. 2016).

⁵⁸ See *United States v. Luce*, 873 F.3d 999 (7th Cir. 2017) (noting that “the Government . . . began debarment proceedings, culminating in actual debarment” of Luce’s mortgage company, and “[t]here was no prolonged period of acquiescence”).

decisions, and payment practices is making it essential to take discovery from the government on these matters.

Heightened Materiality Standard. The Supreme Court defined the *Escobar* materiality standard as “demanding,” and cautioned that it does not encompass “minor or insubstantial” noncompliance. Citing specific examples of fraudulent misrepresentation by omission—including a seller’s misleading statements representing that two new roads may be near the land he was offering for sale, without disclosing that a third road might bisect the property—the Court emphasized that the type of fraudulent omission of critical facts required by this demanding materiality standard is one that goes “to the very essence of the bargain.”⁵⁹ The Court clearly signaled that to keep the FCA from becoming an “all-purpose antifraud statute,”⁶⁰ facts supporting allegations of materiality must be pled, and false certification allegations must be closely scrutinized under its rigorous materiality standard.⁶¹ Given the fact-specific nature of the materiality inquiry, it is not surprising that the *Escobar* materiality inquiry has resulted in decisions that find noncompliance material⁶² as well as that dismiss complaints for not satisfying this materiality standard.⁶³

Defendant’s Knowledge. In addition, the Court required that an FCA plaintiff also has the burden to prove that the defendant actually knew that compliance with the regulation was material to the government,⁶⁴ adopting the views of the DC Circuit in the *SAIC* case cited above. This requirement adds a significant hurdle to pleading and proving a false certification claim. Finally, the Court made clear that simply saying that a regulation is material is not enough. The plaintiff must plead and prove that compliance truly was material.

5. Causation

Section 3729(a)(1) of the FCA imposes liability on any person who “knowingly presents, or *causes to be presented*, to an officer or employee of the United States Government or a

⁵⁹ 136 S. Ct. 1989, 2003 & n.5.

⁶⁰ *Id.* at 2003 (quoting *Allison Engine*, 553 U.S. 662, 672).

⁶¹ *Id.* at 2004 n.6.

⁶² *See, e.g.*, *United States v. Luce*, 873 F.3d 999 (7th Cir. 2017) (finding false criminal history certification in annual verification forms material); *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017) (finding guards’ inability to “shoot straight” material to government’s payment); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 102 (1st Cir. Nov. 22, 2016) (“*Escobar II*”); *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, No. 14-2804, 2016 WL 4555648 (7th Cir. Sept. 1, 2016) (finding unqualified employees’ use of inapplicable billing code material).

⁶³ *See, e.g.*, *D’Agostino*, 835 F.3d 1 (1st Cir. 2016); *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645 (5th Cir. 2017) (overturning \$663 million judgment against Trinity for lack of materiality where government continues to use guardrails, to pay reimbursements, and to keep approval of guardrails in place); *United States ex rel. Kelly v. Serco, Inc.*, No. 14-56769, 2017 WL 117154 (9th Cir. Jan. 12, 2017) (cost formatting standard); *Carlson v. DynCorp Int’l, LLC*, 657 F. App’x 168 (4th Cir. 2016) (violations of accounting regulations or best practices); *United States ex rel. Sheet Metal Workers Int’l Ass’n v. Horning Invs., LLC*, 828 F.3d 587 (7th Cir. 2016) (fringe benefit contribution). *But see* *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017) (reversing dismissal of fraud on the FDA allegations and finding that not too much should be read into FDA’s continued approval) (petition for cert. filed, No. 17-936). *Cf.* *United States ex rel. Salters v. Am. Family Care, Inc.*, No. 5:10CV2843-LSC, 2017 WL 1384381 (N.D. Ala. Apr. 18, 2017) (ruling in favor of relator on improper coding claim, but against relator on improper ear popper billing claim where government had never questioned, investigated, or requested a refund); *United States ex rel. Quartararo v. Catholic Health Sys. of Long Island Inc.*, No. 12CV4425 (MKB), 2017 WL 1239589 (E.D.N.Y. Mar. 31, 2017) (finding alleged use of old nursing home operator’s reimbursement rate not material, but alleged misuse of mitigation payment material).

⁶⁴ 136 S. Ct. 1989, 1996 (“What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision”).

member of the Armed Forces of the United States a false or fraudulent claim for payment or approval.” (Emphasis added). Liability under this provision specifically requires a causal link between the defendant’s actions and the submission of a false claim to the government, but the Act does not include a definition of causation.

Principles of causation from tort law have been applied by some courts, but their application to FCA allegations could stretch these principles beyond their legal foundation. In view of the FCA’s punitive nature, and because the provisions of the civil FCA and the criminal false claims statute were historically the same until relatively recently, a strong argument can be made for strictly construing undefined or ambiguous provisions such as causation under the FCA as under criminal statutes. As the Third Circuit recently made clear in *United States ex rel. Petratos v. Genentech Inc.*, the causation requirement is distinct from materiality, it cannot be met merely by showing “but for” causation, and its focus is on the government as the recipient of the false misrepresentation or claim in both direct and indirect causation cases.⁶⁵ In *Allison Engine*, the Supreme Court applied a common law principle underlying proximate cause in interpreting Section 3729(a)(2) liability to ensure that “a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct.”⁶⁶ And while FERA’s amendments in Section 3729(a)(1)(B) eliminated the purpose-based “to get” limitation which was the focus of the Court’s analysis in *Allison Engine*, there is no indication of congressional intent to extend liability beyond these natural, ordinary, and reasonable consequences.

Courts are developing the causal standard to apply in determining whether different types of conduct caused the government’s loss in FCA cases. For example, in *United States ex rel. Franklin v. Parke-Davis*, the court held that common law tort causation principles required two questions to be considered in determining whether the defendant’s allegedly improper promotion of off-label uses caused the submission of false claims: (1) whether the defendant’s conduct was a “substantial factor” in producing the harm; and (2) whether the outcome was foreseeable.⁶⁷ The court concluded that the relator provided sufficient evidence to show that the defendant “played a key role in setting in motion a chain of events that led to false claims,” and that it was foreseeable that the defendant’s actions would “ineluctably result in false Medicaid claims.”⁶⁸ In *United States ex rel. Drescher v. Highmark, Inc.*, however, the court cautioned the government that basing causation on medical insurers’ incorrect denial or incorrect payment of claims and subsequent submission of false claims by a secondary insurer was a “novel” theory that required evidence of direction and control on the medical insurers’ part and few options on the part of

⁶⁵ 855 F.3d 481, 491 (3d Cir. 2017) (citing cases).

⁶⁶ 553 U.S. 662, 672 (2008).

⁶⁷ No. Civ. A. 96-11651PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003). See also *United States ex rel. Freedman v. Suarez-Hoyos, MD*, No. 8:04CV933-T-24 EAJ, 2012 WL 4344199 (M.D. Fla. Sept. 21, 2012) (citing *Parke-Davis* and ruling that liability could attach to a kickback arrangement that was a substantial factor in causing presentation of a false claim); *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395 (D. Mass. 2010) (finding allegations that defendant’s literature compared its drug favorably with other drugs approved for off-label outpatient use and failed to reflect unfavorable information about the drug were sufficient to pass the “substantial factor” test for causation of claims to Medicare for off-label use); *United States ex rel. DeCesare v. Americare In Home Nursing*, No. 1:05CV696, 2010 WL 5313315, at *13 (E.D. Va. Dec. 16, 2010) (finding that it was a “necessary, foreseeable, and obvious consequence of VNSN’s referrals that Medicare and Medicaid claims would be filed,” and therefore that the complaint alleged that VNSN caused false claims to be submitted under the “substantial factor” test); *United States ex rel. Strom v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (finding that the causation requirement of Rule 9(b) had been met by the allegation that “Defendants’ marketing activities created the market for the outpatient use of [the drug], and . . . encouraged such a use even though they had no credible evidence that [the drug] was effective in that context”).

⁶⁸ 2003 WL 22048255, at *6.

secondary insurers.⁶⁹ And, under the Affordable Care Act, the Antikickback Statute was amended to provide that Medicare or Medicaid claims that include “items or services resulting from” a kickback violation are false claims under the FCA. Defendants have argued that the phrase “resulting from” requires the government to plead that the kickback scheme actually caused false claims to be submitted on a claim-by-claim basis. One court has rejected that argument as calling for “a strict ‘but for’ causation requirement” that would narrow the scope of the word “false.”⁷⁰

In one of a series of recent off-label marketing cases discussing causation, *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, the Sixth Circuit ruled that a representative claim describing each step of the improper off-label promotion scheme was required to show that a prescription reimbursement was submitted to the government for a tainted prescription of the drug.⁷¹ The court explained:

[t]o cover the ground from one end of this scheme—defendants’ improper promotion—to the other—claims for reimbursement—the complaint must allege specific intervening conduct. First, a physician to whom BMS and Otsuka improperly promoted Abilify must have prescribed the medication for an off-label use or because of an improper inducement. Next, that patient must fill the prescription. Finally, the filling pharmacy must submit a claim to the government for reimbursement on the prescription. While this chain reveals just what an awkward vehicle the FCA is for punishing off-label promotion schemes, a single adequately pled claim of this nature would allow relators to satisfy Rule 9(b)’s pleading requirement and proceed to discovery on the entire scheme.

While the relators in *Ibanez* alleged knowledge of a complex scheme, their failure to provide any representative claim that actually was submitted to the government failed to satisfy Rule 9(b).

Following *Escobar*, courts have adopted the proximate cause standard for FCA cases based on the reasoning that the statutory language “because of” clearly requires causation, and the term “fraudulent” incorporates the common law meaning of fraud.⁷² The proximate cause standard incorporates the common law requirement that a fraudulent misrepresentation is a legal cause of a pecuniary loss only if: (1) the loss might reasonably be expected to result from the

⁶⁹ 305 F. Supp. 2d 451 (E.D. Pa. 2004).

⁷⁰ See *United States ex rel. Kester v. Novartis Pharma Corp.*, No. 11CV8196(CM), 2014 WL 4230386 (S.D.N.Y. Aug. 7, 2014) (ruling that the government sufficiently pled an AKS violation against Novartis under the express false certification theory without requiring the government to allege that the kickback scheme actually caused the pharmacy’s sale to a particular patient).

⁷¹ 874 F.3d 905 (6th Cir. 2017). See *United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318 (5th Cir. 2017) (per curiam) (affirming summary judgment in Solvay’s favor based on finding that relators’ nationwide off-label marketing scheme evidence failed to establish that this scheme had an impact on Medicaid prescriptions); *United States ex rel. Kelly v. Novartis Pharma. Corp.*, 827 F.3d 5 (1st Cir. 2016) (affirming dismissal for failure to tie allegations that doctors received incentives and prescribed drug to particular charges for specific false claims); *United States ex rel. Lawton v. Takeda Pharma. Co.*, 842 F.3d 145. (1st Cir. 2016) (same). Cf. *United States ex rel. Dhillon v. Endo Pharma.*, 617 F. App’x 3d 208 (3d Cir. 2015) (allowing off-label promotion allegations to proceed where false records were created and kickback allegations also were present).

⁷² See *United States v. Luce*, 873 F.3d 999 (7th Cir. 2017); *United States v. Americus Mortgage Corp.*, No. 4:12-CV-2676, 2017 WL 4117347 (S.D. Tex. Sept. 14, 2017). See also *United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977); *United States v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006).

reliance, and (2) the loss is within the foreseeable risk of harm that the fraudulent misrepresentation creates.

6. Knowledge and Intent

Under Section 3729(b) of the FCA, "knowing" and "knowingly" are defined as:

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

FERA made no substantive change in this definition.

a. The "Reckless Disregard" Standard

The FCA's actual knowledge and deliberate ignorance standards are rarely used by the government to prove intent because the defendant's specific state of mind is the determining factor under them. Reckless disregard, on the other hand, has been described as aggravated gross negligence, gross negligence-plus, or conduct that runs an unjustifiable risk of harm.⁷³ The government has also argued that the FCA's knowledge standard can be met with "collective knowledge," but that argument was soundly rejected by the D.C. Circuit in *SAIC*, as discussed below.

In *Safeco Insurance Co. of America v. Burr*, the Supreme Court held that the reckless disregard standard was an objective one in a case interpreting a similar standard in the Fair Credit Reporting Act ("FCRA").⁷⁴ Under this objective standard, the Court found that a defendant's incorrect interpretation of an ambiguous statutory provision, if reasonable, does not provide a basis for liability unless there was an unjustifiably high risk of violating the statute. In *United States ex rel. K & R Ltd. Partnership v. Massachusetts Housing Finance Agency*, the D.C. Circuit applied the definition of reckless disregard from the Supreme Court's *Safeco* decision to an FCA case.⁷⁵ *Safeco* and *K & R Ltd.* make examinations of subjective intent unnecessary in FCA cases involving reasonable interpretations of ambiguous requirements where the government has not provided formal guidance.⁷⁶ The Eleventh Circuit modified this rule

⁷³ See *United States v. Krizek*, 859 F. Supp. 5 (D.D.C. 1994), *aff'd*, 111 F.3d 934 (D.C. Cir. 1997).

⁷⁴ 551 U.S. 47 (2007).

⁷⁵ 530 F.3d 980 (D.C. Cir. 2008).

⁷⁶ See, e.g., *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874 (8th Cir. 2016); *United States ex rel. Ketrosor v. Mayo Found.*, 729 F.3d 825 (8th Cir. 2013) ("Mayo's reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA"); *United States ex rel. Farmer v. City of Houston*, 523 F.3d 332 (5th Cir. 2008) (finding that relator could not show that the defendants "knew" of the falsity of the claims because the regulations governing the program were unclear). See also *Chapman Law Firm v. United States*, No. 09-891C, 2012 WL 256090 (Fed. Cl. Jan. 18, 2012) (applying the doctrine of *contra proferentem* to the ambiguous contract provision that was drafted by the government, accepting the contractor's reasonable interpretation, and denying the government's motion for partial summary judgment on the FCA claim). Cf. *United States ex rel. Chilcott v. KBR, Inc.*, No. 09CV4018, 2013 WL 5781660 (C.D. Ill. Oct. 25, 2013) (finding both interpretations facially reasonable, but drawing from the

slightly in *United States ex rel. Phalp v. Lincare Holdings, Inc.*, holding that an ambiguity, while relevant to the analysis of scienter, does not foreclose a finding of scienter.⁷⁷ The Eleventh Circuit pointed out that scienter can exist even if the defendant's interpretation is reasonable, and in that case the court must determine whether the defendant "actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation."⁷⁸

Recently, the D.C. Circuit reinforced the important principles that the FCA does not reach "an innocent, good-faith mistake about the meaning of an applicable rule or regulation" or extend to claims made based on "reasonable but erroneous interpretations of a defendant's legal obligations," and that informal guidance on the interpretive issue is insufficient to warn a regulated defendant away from its otherwise reasonable interpretation.⁷⁹ In *United States ex rel. Purcell v. MWI Corp.*, the D.C. Circuit ruled that no jury could properly find that MWI acted "knowingly" in certifying that it paid "regular commissions"—an ambiguous term—to its sales agents in connection with a transaction funded by an Ex-Im Bank loan.⁸⁰ The D.C. Circuit also recognized that the outcome avoided the potential due process problems posed by "penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule."⁸¹

In a memo issued on January 25, Associate Attorney General Rachel Brand limited the use of agency guidance in affirmative civil enforcement actions brought by the Justice Department.⁸² The Brand Memo reinforces the court's holding in *Purcell* that informal agency guidance cannot be the basis for FCA liability.

b. Collective Knowledge

The government has argued that corporate "collective knowledge" is appropriate under the False Claims Act because the Act is remedial rather than penal in nature. This fundamentally misconstrues the nature of the statute, particularly in light of rulings characterizing FCA damages and penalties as punitive. In *United States v. Science Applications International Corp.* ("SAIC"), the D.C. Circuit forcefully and definitively rejected the government's argument that collective knowledge can be used to prove intent under the False Claims Act.⁸³ Exhibiting a clear grasp of the high stakes involved in FCA liability, the panel unanimously held that collective knowledge was "an inappropriate basis for [FCA] scienter" because

it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act's language, structure, and purpose.⁸⁴

As a result, the court found that the FCA's scienter standard must be strictly enforced, and it

allegations the "reasonable inference that [Relator's] interpretation is the correct one" and inferring that "Defendants did not simply choose, in good faith, a reasonable interpretation among equal alternatives").

⁷⁷ No. 16-10532, 2017 WL 2296878 (11th Cir. May 26, 2017).

⁷⁸ *Id.* at *4.

⁷⁹ 807 F.3d at 287-90.

⁸⁰ 807 F.3d 281 (D.C. Cir. 2016). See FraudMail Alert No. 17-01-10, Supreme Court Denial of Certiorari in *U.S. ex rel. Purcell v. MWI* Lets Stand DC Circuit Decision Limiting FCA Liability Based on Ambiguous Agency Regulation (Jan. 10, 2017) (attached as Appendix 3).

⁸¹ *Id.* at 287.

⁸² Memorandum for Heads of Civil Litigating Components, United States Attorneys, From Assoc. Att'y Gen. Rachel Brand, Re: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), available at <https://www.justice.gov/file/1028756/download>.

⁸³ 626 F.3d 1257 (D.C. Cir. 2010).

⁸⁴ *Id.* at 1274.

interpreted this standard to allow liability based on constructive knowledge only when defendants act with “reckless disregard” or “deliberate ignorance,” noting that innocent mistakes or negligence remain defenses to liability. Collective knowledge conflicts with this statutory standard, the court concluded, because it lacks balance and precision, noting that it would allow

“a plaintiff to prove scienter by piecing together scraps of ‘innocent’ knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.” *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 452 F.2d 908, 918 n.9 (4th Cir. 2003). In other words, even absent proof that corporate officials acted with deliberate ignorance or reckless disregard for the truth by submitting a false claim as the result of, for instance, a communication failure, the fact-finder could determine that the corporation knowingly submitted a false claim.⁸⁵

The court held that the proper standard for knowledge under the FCA excludes collective knowledge. Because the district court’s instruction to the jury allowed it to find that SAIC submitted false claims “knowingly” where no individual at SAIC had all of the knowledge necessary for FCA liability, the court found that the district court’s instruction was erroneous and prejudicial, and ordered a new trial.

The *SAIC* case included one more knowledge element that limits false certification liability:

Establishing knowledge . . . 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.⁸⁶

This knowledge requirement is a critical limit on the use of the false certification theory of liability because it means that the government or the relator will have to prove the defendant knew that the government’s paying agent considered the violation to be material. As noted in the discussion of materiality above, the Supreme Court explicitly adopted this additional knowledge requirement in *Escobar*.⁸⁷

7. Reverse False Claims

The FCA’s “reverse false claim” provision, 31 U.S.C. § 3729(a)(1)(G), formerly Section 3729(a)(7), is intended to provide a potential remedy to the government when the flow of money or property is from a person with an obligation to the government, rather than the more common situation, in which money flows from the government to a recipient. Under the reverse false claim provision, liability extends to any person who knowingly and improperly avoids or decreases an “obligation” to pay the government.

What constitutes an “obligation” to pay or transmit money or property to the government was once hotly disputed, but it became relatively settled prior to FERA. This was largely due to the Sixth Circuit’s decision declining to adopt the DOJ’s position in *American Textile*

⁸⁵ *Id.* at 1275.

⁸⁶ *Id.* at 1271.

⁸⁷ *Escobar*, 136 S. Ct. 1989, 1996.

Manufacturers Institute, Inc., v. The Limited, Inc. (“ATMI”), holding instead that liability could arise under Section 3729(a)(7) only if the defendant “made a false record or statement at a time that the defendant owed to the government an obligation sufficiently certain to give rise to an action of debt at common law.”⁸⁸ The Sixth Circuit emphasized that the obligation must exist before the false claim or statement was made in order for liability to arise under Section 3729(a)(7).⁸⁹

Post-FERA, reverse false claim theory has undergone further development, with renewed attempts to extend this liability to potential obligations to repay the government. Under FERA, “obligation” is defined in Section 3729(b)(3) as:

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.

Using this definition, reverse false claims liability under Section 3729(a)(1)(G) may be based on an “established duty” to pay the government—one that arises from a contractual, grant, license, or other fee-based relationship—although the amount owed may be unfixed. The legal obligations arising under these relationships are relatively clear and easy to define. The word “contingent” was specifically stricken from the duties listed in the legislation prior to passage, and the general understanding has been that this definition is not intended to encompass contingent duties such as penalties and fines.⁹⁰ A considerable body of case law supports the view that the government’s ability to pursue reimbursement does not transform the potential reimbursement into an “obligation” under the FCA.⁹¹ But relators have seized on the 2009 amendment as an opportunity to revisit these limitations, arguing that the amendment opened the door to FCA liability based on the failure to pay contingent fines and penalties, and that the duty arising from a “statute or regulation” covers a potential penalty, a view that, if followed, could create extensive and unforeseen reverse false claim liability.⁹²

⁸⁸ 190 F.3d 729, 736 (6th Cir. 1999). The reader should note that the author represented the defendants in the *ATMI* case.

⁸⁹ *Id.* at 742. Other courts reaching similar conclusions include the Eighth Circuit, in *United States v. Q International Courier, Inc.*, 131 F.3d 770 (8th Cir. 1997), the District of Colorado, in *United States ex rel. Bahrani v. Conagra, Inc.*, 338 F. Supp. 2d 1202 (D. Colo. 2004), and the District of Maine, in *United States ex rel. S. Praver & Co. v. Verrill & Dana*, 962 F. Supp. 206 (D. Me. 1997). Court decisions that have found an existing “obligation” in cases alleging reverse false claims violations include *United States v. Pemco Aeroplex, Inc.*, 195 F.3d 1234 (11th Cir. 1999) (en banc), *United States ex rel. Ervin & Associates v. Hamilton Securities Group*, 370 F. Supp. 2d 18 (D.D.C. 2005), and *United States v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436 (S.D.N.Y. 1999).

⁹⁰ See 155 Cong. Rec. S4539 (daily ed. Apr. 22, 2009) (statement of Sen. Kyl). At one point in the legislative process, there was an intent to overturn the Sixth Circuit’s decision in *ATMI*, but whether the law as enacted actually did so is questionable because the court found the penalties and duties in *ATMI* “contingent,” and the definition of “obligation” in Section 3729(b)(3) excludes “contingent” duties.

⁹¹ See, e.g., *United States ex rel. Guth v. Roedel Parsons Koch Blache Balhoff & McCollister*, No. 15-30043, 2015 WL 5693302 (5th Cir. Sept. 29, 2015) (approving district court’s reasoning in dismissing claim that was predicated on potential or contingent obligation to pay amounts not levied or assessed) (per curiam) (unpublished op.); *United States ex rel. Mason v. State Farm Aut. Ins. Co.*, 398 F. App’x 233, 235 (9th Cir. 2010); *United States ex rel. Landis v. Tailwind Sports Corp.*, No. 1:10-cv-00976 (CRC), 2016 WL 141615 (D.D.C. Jan. 12, 2016); *United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 811-12 (E.D. La. 2009).

⁹² See *Simoneaux v. E.I. DuPont DeNemours & Co.*, No. 12-219-SDD-SCR, 2014 WL 4352185 (M.D. La. Sept. 2, 2014), *rev’d*, No. 16-30141, 2016 WL 7228813 (5th Cir. Dec. 13, 2016).

For example, in *United States ex rel. Simoneaux v. E.I. DuPont De Nemours & Co.*,⁹³ the relator alleged that DuPont violated Section 3729(a)(1)(G) by failing to report to EPA certain Toxic Substances Control Act (“TSCA”) violations and, in so doing, concealed or avoided the obligation to pay penalties that could be assessed for such violations. The Fifth Circuit rejected the relator’s assertion that FERA’s definition of “obligation” covers contingent penalties, and that by imposing liability “at the statutory level,” the TSCA makes assessment of a penalty mandatory. The court agreed with defense and government (as amicus) arguments that “established” is the key word and that (a) the FERA amendments did not change the overarching requirement that the obligation must be one “to pay or transmit money or property to the Government,” and (b) “[a] statute enforceable through an unassessed monetary penalty . . . creates an obligation to obey the law, not an obligation to pay money.”⁹⁴ That is, “established” refers to whether there is a duty to pay, while “fixed” refers to the amount owing. The Fifth Circuit specifically rejected the relator’s broad construction of the term “obligation,” noting the harsh consequences that would result:

For example, 45 C.F.R. § 3.42(e) prohibits roller-skating at the National Institutes of Health, and a person violating that regulation “shall be fined under title 18, United States Code, imprisoned for not more than 30 days, or both.” 40 U.S.C. 1315(c). Under [the relator’s] reasoning, roller-skating at the NIH results in a penalty “of not less than \$5,000” and three times the fine assessed under Title 18. And any private person who saw the roller-skater could bring a *qui tam* action against him. The statutory definition of “obligation” cannot bear the weight of that interpretation.⁹⁵

The Fifth Circuit also analyzed the applicable regulations and held that the TSCA penalties at issue are discretionary, not mandatory. As a result, since EPA had not assessed any penalty against DuPont for the supposed violations, and had not even commenced any penalty proceedings, there was no “established” duty to pay within the meaning of the reverse false claim provision.

While the Justice Department’s clear statement against the excesses urged by the *Simoneaux* relator should discourage most relators from continuing to pursue reverse false claim liability based on contingent obligations of this type, the application of the *Simoneaux* decision to reverse false claim cases arising in the customs arena remains uncertain. For instance, the Fifth Circuit distinguished allegations of failure to pay duties on mismarked goods (such as found in *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*⁹⁶), on the basis that “the customs law imposes a duty to *pay*,” whereas most regulatory statutes, such as the TSCA, “impose only a duty to obey the law, and the duty to *pay* regulatory penalties is not ‘established’ until the penalties are assessed.”⁹⁷ Extension of Section 3729(a)(1)(G) liability to breaches of contract also is in flux.⁹⁸

⁹³ No. 16-30141, 2016 WL 7228813 (5th Cir. Dec. 13, 2016).

⁹⁴ *Id.* at *3.

⁹⁵ *Id.* at *6.

⁹⁶ 839 F.3d 242 (3d. Cir. 2016).

⁹⁷ 2016 WL 7228813, at *6.

⁹⁸ See, e.g., *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2014 WL 43388726 (S.D. Tex. Sept. 5, 2014) (ruling that a fine under a corporate integrity agreement could be an “obligation” under the FCA); *Ruscher*, 2015 WL 517807 (S.D. Tex. Sept. 3, 2015) (on summary judgment, finding no evidence of a reportable event under Omnicare’s corporate integrity agreement and dismissing reverse false claim); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 4461793 (E.D. Pa. July 21, 2015) (agreeing with relators that

A final note—it is not clear precisely how a duty arises from the retention of an overpayment and when that duty becomes “established.” The Senate Report accompanying FERA explained that the statutory language was not intended “to create liability for a simple retention of an overpayment that is permitted by a statutory or regulatory process for reconciliation.”⁹⁹ However, under the Affordable Care Act of 2010 (“ACA”), an overpayment retained beyond the deadline for reporting and returning it is an “obligation” as defined in the FCA,¹⁰⁰ which links reverse false claim liability for an overpayment to the ACA’s 60-day rule for reporting and returning “identified” overpayments. This link between FCA liability and the ACA’s overpayment deadline raised a plethora of questions from health care providers.¹⁰¹ CMS addressed the ACA’s overpayment requirements for Medicare Parts C and D in a 2014 final rule, and more recently, in 2016, CMS issued a final rule on the overpayment requirements for Medicare Parts A and B.¹⁰² In an intervened case, the defendant challenged one of the first *qui tam* cases brought using the FCA to enforce the ACA’s overpayment requirements under Medicaid.¹⁰³

The government’s and relators’ pursuit of alleged fraud in the Medicare Advantage program has been challenged through an Administrative Procedure Act suit asserting that CMS’s 2014 “Overpayment Rules” undermine the entire theory behind risk adjustment payments, violate statutory requirements, and should be set aside.¹⁰⁴ The impact of any decision there on FCA cases remains to be seen. Courts have been weighing in on the viability of FCA claims against Medicare Advantage providers for allegedly submitting false diagnosis information in order to increase their risk adjustment reimbursements.¹⁰⁵ The Ninth Circuit has found that alleging deliberate avoidance of identifying certain erroneous coding was a “cognizable legal theory” under the FCA because Medicare Advantage Plans are obligated by Medicare regulations to undertake “due diligence” to ensure accuracy of diagnostic codes.¹⁰⁶

Cephalon’s contractual obligation to pay the government upon breach of its corporate integrity agreement was an “established duty”).

⁹⁹ S. Rep. No. 111-10, at 15 (2009).

¹⁰⁰ See ACA, Pub. L. No. 111-148, 124 Stat. 119, § 6402 (2010) (amending 42 U.S.C. § 1128J)).

¹⁰¹ The ACA established the deadline for reporting and returning an overpayment as the later of either 60 days after an overpayment has been “identified” or the date of a corresponding cost report, without defining the term “identified,” for example.

¹⁰² See Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014); Medicare Program: Reporting and Returning of Overpayments, 81 Fed. Reg. 7654-7684 (Feb. 12, 2016) (to be codified at 421 C.F.R. pts. 401, 405).

¹⁰³ See *United States ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015) (defining “identified” as when a provider is put on notice of a potential overpayment). See also *United States ex rel. Ortiz v. Mount Sinai Hosp.*, No. 13 Civ. 47335 (RMB), slip op. (S.D.N.Y. Nov. 9, 2015) (finding that relators sufficiently pled wrongful overpayment retention with illustrative examples).

¹⁰⁴ See *UnitedHealthCare Ins. Co. v. Price*, 255 F. Supp. 3d 208 (D.D.C. 2017) (denying defendants’ motion for stay).

¹⁰⁵ See, e.g., *United States ex rel. Swoben v. Scan Health Plan*, No. 09-5013-JFW (JEMx), 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017) (dismissing the government’s affirmative Medicare Advantage claims for insufficiently pleading scienter and materiality) (*Swoben II*); *United States ex rel. Poehling v. Unitedhealth Group, Inc.*, No. 16-08697-MWF (SSx), slip op. (C.D. Cal. Feb. 12, 2018) (finding affirmative Medicare Advantage claims insufficiently pled and dismissing them, but allowing reverse false claims to proceed).

¹⁰⁶ See *United States ex rel. Swoben v. United Healthcare Insurance Co.*, 848 F.3d 1161 (9th Cir. 2016) (“*Swoben I*”).

8. Damages and Penalties

FCA violations result in liability for:

a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains *because of* the [person's] act.”¹⁰⁷

The measure of damages in a False Claims Act case is dependent on the nature of the alleged fraud, but the test is always the same: the difference between what the government actually paid and what it should have paid absent the FCA violation.

a. Damages

In false certification cases, courts of appeals appear to be divided regarding whether a broad “but for” test of causation or an actual loss test is the proper measure of damages in FCA cases. In *United States v. Science Applications International Corp.*,¹⁰⁸ the D.C. Circuit vacated the damages portion of the decision below because of a flawed jury instruction that required the jury to assume that SAIC’s services had no value. That assumption was particularly egregious in this case because the jury had already decided that actual damages to the government, as measured for purposes of the alternative breach of contract claim, were \$78, yet the district court imposed FCA damages of \$6.49 million. Reversing that portion of the lower court’s decision, the circuit court held that there is no irrebuttable presumption that expert services and advice are worthless if an organizational conflict of interest provision has been violated, and ruled that the damages must take into account the value of the goods and services. The panel pointed out that, under the benefit of the bargain framework that applied in this case, damages should be calculated by determining the amount the government paid minus the value of the goods or services provided, which is the standard measure under the FCA. Indeed, the evidence showed that the government agency, NRC, continued to use SAIC’s work product after its contract with SAIC was terminated in 1999, and an NRC project manager testified that SAIC’s “actual work product ‘constituted the opposite of a conflict,’ . . . due to its transparency and fairly conservative results.” The jury instruction erroneously removed this calculation from the case, and established an irrebuttable presumption that the services of an expert are worthless where a violation of a conflict of interest requirement has occurred. Because the district court’s instruction to the jury required them to assume that SAIC’s services had no value, the court vacated and remanded the damages for a new trial. This case ultimately settled for \$1.5 million.

In *United States v. Rogan*,¹⁰⁹ on the other hand, the district court did not apply a benefit of the bargain analysis in evaluating damages in the context of Stark Act and AKS violations. The court noted that the violations were “myriad” and “overwhelming,” and found that the government would not have paid anything for the claims of patients referred by physicians that had prohibited financial relationships with the hospital, citing the Stark Act. Rather than engaging in a benefit analysis, the court measured the damages as the entire federal share of these claims to Medicare and Medicaid.¹¹⁰ After they were trebled, the damages were more than \$50 million. In addition, the court found that there were 18,000 penalties, bringing the total damages and penalties to over \$64 million. The Seventh Circuit affirmed the damages award in

¹⁰⁷ 31 U.S.C. § 3729(a)(1) (emphasis supplied).

¹⁰⁸ 626 F.3d 1257 (D.C. Cir. 2010).

¹⁰⁹ 459 F. Supp. 2d 692 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

¹¹⁰ *Id.* at 726-27.

Rogan, adopting the lower court’s decision that placed no value on the medical services provided during the period of the unlawful payments for referrals and agreeing that “when the conditions [of the government’s payment] are not satisfied, nothing is due.”

More recently, in *United States ex rel. Wall v. Circle C Construction, LLC*,¹¹¹ the Sixth Circuit rejected the government’s claim that its entire payment for electrical work on dozens of warehouses was “tainted” by a subcontractor’s underpayment of some of the electricians who worked on the project (a Davis-Bacon Act violation). The court applied the benefit of the bargain analysis and emphasized that FCA damages are focused on actual damages, not the “hypothetical scenario” advanced by the government.¹¹² Exposing the incongruity between the government’s theory and its actual losses, the court observed that, in all of those warehouses, “the government turns on the lights every day.”¹¹³ Applying the concrete question of whether the government “in fact got less value than it bargained for,” the court readily determined that the government received all of the value of the electrical work on all of the warehouses minus the wage shortfall.

As the decisions above reflect, a key feature of FCA liability is its treble damages provision. An important development on the application of this multiplier is the Seventh Circuit’s revisitation of the question of whether net or gross damages are trebled when deducting the value of goods or services received by the government. Historically, the Justice Department advocated and employed the “gross trebling” method—which trebles the claim amount first and afterward deducts the value of goods and services provided—but that method distorts the government’s actual damages by severely diminishing the value of any benefit received. In *United States v. Anchor Mortgage Corp.*,¹¹⁴ the Seventh Circuit held that the proper approach was “net trebling”—which subtracts the value of goods or services provided before multiplying the damages and thus accounts for the actual benefit that the government received. The Seventh Circuit based its holding on the finding that no FCA language or policy supported departure from the norm in civil litigation, where damages are based on net loss, and it rejected the Justice Department’s misreading of the Supreme Court’s decision in *United States v. Bornstein*.¹¹⁵ Given the Ninth Circuit’s decision that applied gross trebling in *United States v. Eghbal*,¹¹⁶ a circuit split has emerged on this issue.

b. Penalties

Without question, one of the most feared remedies under the False Claims Act is the per claim penalty. The Justice Department recently implemented a major increase in the FCA’s penalty range, with additional adjustments to be made annually—pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, part of the Bipartisan Budget Act

¹¹¹ No. 14-6150, 2016 WL 423750 (6th Cir. Feb. 4, 2016). *See also* FraudMail Alert No. 16-02-10, Sixth Circuit Rejects Government’s “Fairyland” FCA Damages Theory (Feb. 10, 2016), <http://www.friedfrank.com/siteFiles%2FPublications%2F021016-FINALVERSION-FRAUDMAIL-Civil%20False%20Claims%20Act%20Sixth%20Circuit.pdf>.

¹¹² 2016 WL 423750, at *2.

¹¹³ *Id.* at *1.

¹¹⁴ 711 F.3d 745 (7th Cir. 2013).

¹¹⁵ *Id.* at 750. In *Bornstein*, the Court supported using the traditional market value approach to measure actual damages—and thus net trebling—but found that this approach did not apply to a *third party*’s settlement payments to the government, which were deducted after damages were multiplied. 423 U.S. 303, 317 n.13 (1976).

¹¹⁶ 548 F.3d 1281 (9th Cir. 2008).

of 2015.¹¹⁷ As of February 2018, FCA penalties now range between \$11,181 and \$22,363. Drafted in the innocent-sounding verbiage of inflation adjustments tied to the Consumer Price Index, Congress required the first “catch up adjustment,” implemented through rulemaking, to take effect by August 1, 2016, and authorized further, automatic annual adjustments without any agency assessment of the need for an increase. This automatic annual adjustment provision raises the potential for an Administrative Procedure Act challenge. The impact of this legislation on civil fraud defendants is substantial because it may unfairly enhance the enormous settlement leverage the Justice Department already has against many defendants in the civil fraud enforcement arena. Increases in FCA penalties will exacerbate constitutional concerns in penalties-heavy FCA cases, particularly where there are large numbers of relatively small monetary claims.

FCA penalties are assessed on a per-claim basis regardless of the amount of the damages, except when the court finds that the result is an excessive civil penalty. A recent decision by the Fourth Circuit in *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, unwittingly may have opened the door to a new and unsettling era in *qui tam* litigation.¹¹⁸ Dispensing with decades of Supreme Court jurisprudence—including one case argued by Chief Justice Roberts before he took the federal bench—the Fourth Circuit ordered the trial court to impose \$24 million in FCA penalties against the defendants following a trial at which the relator pointedly sought no FCA damages and no proof of economic harm to the United States was ever established. This result is squarely at odds with a number of constitutional protections, particularly the Eighth Amendment’s Excessive Fines Clause, as well as decisions applying that constitutional provision to FCA penalty awards.¹¹⁹ The Fourth Circuit’s sole reliance on intangible and non-economic factors such as “deterrent effects” and public policy considerations to override the traditional excessive fines analysis lacks precedent. The Supreme Court declined to review this decision, however, and on remand, the trial court imposed the \$24 million *qui tam* award that it previously found excessive.

9. Public Disclosure, Original Source, and First-to-File

In 2010, Congress amended the FCA’s public disclosure bar as part of the comprehensive health care reform initiative in the Affordable Care Act,¹²⁰ adding new limitations to the public disclosure provision in Section 3730(e)(4)(A) and expanding the original source exception in Section 3730(e)(4)(B). Section 3730(e)(4) now provides:

¹¹⁷ See Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599-600 (2015) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note).

¹¹⁸ 741 F.3d 390, 408 (4th Cir. 2013), *cert. denied*, 83 U.S.L.W. 3184 (2014). The reader should note that the author represented one of the other defendants in the *Bunk* case, but was not involved in the trial or appeal.

¹¹⁹ See FraudMail Alert No. 13-12-20, Fourth Circuit Holds That a \$24 Million FCA Penalty is Not an “Excessive Fine” Even Where the Relator Fails to Prove That the United States Suffered Any Economic Harm (Dec. 12, 2013), <http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%20FraudMail%20Alert%20-%2012-20-13%20-%20Fourth%20Circuit%20Holds%20That%20a%20%2424%20M%20FCA%20Penalty%20is%20Not%20an%20%E2%80%9CExcessive%20Fine%E2%80%9D.pdf>.

¹²⁰ ACA, Pub. L. No. 111-148, 124 Stat. 119, 901-02 (2010) (amending 31 U.S.C. § 3730(e)(4)). See FraudMail Alert No. 10-03-24, Here They Go Again—Newly Enacted Comprehensive Health Care Reform Law Contains More FCA Amendments, <http://www.friedfrank.com/siteFiles/Publications/774D87395C8E15E59B979BCB2E52F5C0.pdf>.

(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 has 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

(ii) 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.

Under the 2010 bar, if “substantially the same” allegations or transactions were publicly disclosed, then the *qui tam* relator must be an “original source,” unless the government opposes dismissal. While the 1986 public disclosure bar was considered a threshold *jurisdictional* determination,¹²¹ the 2010 amendments eliminated the word “jurisdiction,” and replaced it with the requirement that “the court shall dismiss an action or claim . . . unless opposed by the Government.” The government has exercised this veto in only a few cases as yet.¹²²

In addition, the amendments narrowed the definition of public disclosures to disclosures in *federal* sources—that is, disclosures in federal criminal, civil, or administrative hearings under Section 3730(e)(4)(A)(i), and in federal hearings, reports, audits, or investigations under Section 3730(e)(4)(A)(ii). These revisions effectively overruled the Supreme Court’s ruling in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, (“*Graham County II*”)¹²³ that *qui tam* allegations could be publicly disclosed by state and local sources, and eliminate defenses based on disclosures from state and local government sources unless the information is also disclosed in the news media or otherwise publicly disclosed. The defense to public disclosures in federal hearings is further narrowed to hearings in which the government or its agent is a party, thus excluding disclosures made in purely private litigation such as retaliation or negligence actions.

The amendments also revised the original source exception. Rather than requiring the original source to have both “direct” and “independent” knowledge of the alleged fraud, the original source exception is met by knowledge that is “independent” of and “materially adds” to the publicly disclosed allegations, which must be voluntarily disclosed to the government before

¹²¹ See *Rockwell Int’l Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397, 1406 (U.S. 2007).

¹²² See, e.g., *United States ex rel. Baker v. Community Health Sys., Inc.*, No. 05-279 WJ/ACT, slip op. (D.N.M. May 14, 2014); *United States ex rel. Szymoniak v. Am. Home Mortgage Serv. Inc.*, No. 0:10-cv-01465-JFA, 2014 WL 1910845 (D.S.C. May 12, 2014).

¹²³ 130 S. Ct. 1396 (U.S. 2010). The reader should note that the author filed an amicus brief on behalf of the Washington Legal Foundation and the Allied Educational Foundation in support of Petitioners in *Graham County II*.

filing suit. In applying this new statutory language in *United States ex rel. Paulos v. Stryker Corp.*, the Eighth Circuit rejected the relator’s claim that he had knowledge that materially added to the publicly disclosed allegations despite his claim that he was among the first to link the defendant’s medical device to the resulting disease, because, even if he discovered the link to chondrolysis *first*, Section 3730(e)(4)(B) does not provide an exception for “early discoveries or suspicions.”¹²⁴ And, in *United States ex rel. Bogina v. Medline Industries, Inc.*, the Seventh Circuit ruled that the differences between Bogina’s claims and a settled *qui tam* suit against the same defendant failed to satisfy the “materially adds” requirement because the settled suit’s focus on bribes and kickbacks to hospitals put the government on notice of the possibility that Medline may have engaged in a broader kickback scheme that included nursing homes, as Bogina alleged.¹²⁵

¹²⁴ 762 F.3d 688, 694 (8th Cir. 2014).

¹²⁵ 809 F.3d 365 (7th Cir. 2016).

Because of the ACA's silence on the issue of an effective date for these *qui tam* amendments, the Supreme Court applied the presumption against retroactivity in *Graham County II*, limiting the impact of the ACA's public disclosure amendments in cases pending at the time of enactment and leaving open the question of whether the amendments apply retroactively to prior conduct where no *qui tam* case was pending.

Under a separate bar in Section 3730(b)(5) known as the “first-to-file” bar, when a relator brings a *qui tam* action, “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” The primary purpose of this bar—the text of which has remained unchanged since its inclusion in the 1986 amendments—is to prevent multiple *qui tam* suits based on the same underlying conduct. A circuit court split developed over whether the phrase “pending action” is a timing requirement, as the Fourth Circuit interpreted it, or whether it is a shorthand reference to the first-filed action that distinguishes the first action from subsequent actions, as the D.C. Circuit decided.¹²⁶ In May 2015, the Supreme Court resolved that issue in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*.¹²⁷ The Court saw no reason to interpret the term “pending” other than by reference to its ordinary meaning, which Black’s and Webster’s defined as “remaining undecided.” Courts are divided on other interpretive questions not answered by the Court in *Carter*, however, such as what happens *after* dismissal of the original complaint that was pending when a subsequent related action was filed.¹²⁸

10. Whistleblower Retaliation

In 1986, a whistleblower’s cause of action for retaliation was enacted in Section 3730(h) of the FCA, which provided that an employee who was discharged or otherwise discriminated against in the terms or conditions of employment by an “employer” because of lawful acts done by the “employee” in furtherance of an action under Section 3730 “shall be entitled to all relief necessary to make the employee whole.” FERA revised the definition of both protected persons and protected conduct in Section 3730(h) by (1) removing the specific reference to the “employer” (and thus the requirement of an employee-employer relationship) so that independent contractors could bring retaliation actions,¹²⁹ and (2) replacing lawful acts “in furtherance of an action under this section” with the phrase “in furtherance of other efforts to stop 1 or more violations.” The new definition of protected conduct seemed to require the

¹²⁶ See *United States ex rel. Carter v. Halliburton Co.*, 701 F.3d 171 (4th Cir. 2013), *cert. granted sub nom. Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 134 S. Ct. 2899 (U.S. 2014); *United States ex rel. Shea v. Cellco P’ship*, 748 F.3d 338 (D.C. Cir. 2014).

¹²⁷ No. 12-1497, 2015 WL 2456621 (U.S. May 26, 2015). See FraudMail Alert No. 15-05-26, Supreme Court Squarely Rejects Justice Department’s Use of Wartime Suspension of Limitations Act in Civil FCA Actions, but Offers Hope to Relators with Its First-to-File Ruling (May 26, 2015), [http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%205-26-15%20-%20Fraudmail%20Alert%20-%20Supreme Court Squarely Rejects Justice Dept.pdf](http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%205-26-15%20-%20Fraudmail%20Alert%20-%20Supreme%20Court%20Squarely%20Rejects%20Justice%20Dept.pdf).

¹²⁸ Compare *United States ex rel. Shea v. Cellco P’ship*, 863 F.3d 923 (D.C. Cir. 2017) (ruling that subsequent related action must be dismissed rather than “left on ice” if it was brought when related first-filed action was pending), and *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199 (4th Cir. 2017) (same), with *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015) (ruling that Rule 15(d) allows second relator to amend complaint brought during pendency of a related first-filed action, which was subsequently dismissed, rather than “expose the relator to the vagaries of filing a new action”).

¹²⁹ See BOESE, § 4.11[B][2][b] (discussing the term “employer” and the independent contractor issue).

person to actually try to stop the fraud itself rather than simply take steps toward filing a *qui tam* action.

The following year, Congress provided a new definition of protected conduct under Section 3730(h) in the Dodd-Frank Wall Street Reform and Consumer Protection Act.¹³⁰ This revision restored the original protection of lawful acts in furtherance of a *qui tam* action in addition to FERA's "other efforts to stop 1 or more violations." As amended, Section 3730(h) now provides:

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 because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor or agent, or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

The Dodd Frank amendments also provided, for the first time, a statute of limitations for retaliation that requires the action to be brought within three years of the date when the retaliation occurred.¹³¹

Courts are applying the new definitions in Section 3730(h) to a variety of employment relationships and conduct. In most cases, the term "employee" has been limited to persons in an employment-like relationship with the defendant, which does not include applicants or non-employer corporations.¹³² Protected conduct has been interpreted to include reporting the fraud within the organization, such as informing a board member or the company's corporate compliance arm in some cases.¹³³ However, if the plaintiff was not reporting fraud to a supervisor in furtherance of an FCA claim and never said that the defendant committed fraud on

¹³⁰ Pub. L. No. 111-203, § 3301, 124 Stat. 1376 (2010). See FraudMail Alert No. 10-06-29, Here They Go Again, Round III: Financial Reform Bill Contains More FCA Amendments, <http://www.friedfrank.com/siteFiles/Publications/E81F1748D2D2912B1C54CB77388F98CA.pdf>.

¹³¹ 31 U.S.C. §3730(h)(3). See *Weslowski v. Zugibe*, 14 F. Supp.3d 295 (S.D.N.Y. Mar. 31, 2014) (rejecting plaintiff's attempt to bring an action against his employer more than three years after his resignation and ruling that this "continuing violation" theory of liability could not be used because the FCA's retaliation provision only applies to retaliatory conduct that occurred during the plaintiff's employment).

¹³² See, e.g., *Boegh v. Energysolutions, Inc.*, 772 F.3d 1056, 1064 (6th Cir. 2014) (finding that the "FCA's legislative history and case law from other courts reinforce that "employee" is limited to employment-like relationships); *United States ex rel. Abou-Hussein v. Science Applications Int'l Corp.*, No. 2:09-1858-RMG, 2012 WL 6892716, at *3-4 (D.S.C. May 3, 2012) (reasoning that Congress intended to extend protection to "individuals who [a]re not technically employees within the typical employer[-]employee relationship, but nonetheless have a contractual or agent relationship with an employer"), *aff'd*, 475 Fed. App'x. 851 (4th Cir. 2012) (per curiam). Cf. *O'Hara v. NIKA Techs., Inc.*, 878 F.3d 470 (4th Cir. 2017) (finding that a whistleblower's action against his own employer could be premised on the employer's knowledge that the whistleblower contemplated a lawsuit against another company); *Tibor v. Michigan Orthopedic Inst.*, No. 14-10920, 2014 WL 6871320 (E.D. Mich. Dec. 5, 2014) (noting that the amended provision prohibits retaliation against independent contractors or "doctors without traditional employment relationships with hospitals" who are not technically "employees").

¹³³ See, e.g., *United States ex rel. Si v. Laogai Research Found.*, No. 09CV2388 (KBJ), 2014 WL 5446487 (D.D.C. Oct. 14, 2014); *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34 (D. Mass. 2014). 9 F. Supp. 3d 34 (D. Mass. 2014).

the government, the retaliation claim has been dismissed.¹³⁴ Thus, refusing to participate in the fraud alone has not been deemed protected activity if the decisionmaker was unaware of the protected activity.¹³⁵

III. State False Claims Acts

As a result of the Medicaid fraud provisions in the Deficit Reduction Act of 2005 ("DRA") and an economic incentive in the DRA that encourages every state without a state false claims act with *qui tam* provisions to adopt one, state legislatures have enacted state false claims laws with provisions that mirror, or exceed, the federal FCA.¹³⁶ There are now 29 of these state laws, and they are increasing false claims visibility, enforcement actions, and recoveries.¹³⁷ The states that have *qui tam* false claims statutes are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington. The District of Columbia, New York City, Philadelphia, and Chicago also have false claims laws with *qui tam* enforcement. Many states have amended their state false claims laws to include the far more onerous provisions in the FERA, ACA, and Dodd-Frank amendments in order to qualify for the DRA incentive.

¹³⁴ See *Fakorede v. Mid-South Heart Ctr., P.C.*, 709 F. App'x 787 (6th Cir. 2017) (ruling that plaintiff's efforts related to costs reimbursed by county hospital district did not lead to a reasonable inference that fraud was being committed against the federal government); *Lee v. Computer Scis. Corp.*, No. 1:14cv581 (JCC/TCB), 2015 U.S. Dist. LEXIS 21998 (E.D. Va. Feb 24, 2015).

¹³⁵ See *Halasa v. ITT Educ. Servs., Inc.*, 690 F.3d 844, 848 (7th Cir. 2012) (7th Cir. 2012) (finding no evidence that any of the decisionmakers knew of plaintiff's protected conduct); *United States ex rel. Tran v. Computer Scis. Corp.*, No. 11-cv-0852 (KBJ), 2014 WL 2989948 (D.D.C. July 3, 2014).

¹³⁶ See Deficit Reduction Act of 2005, Pub. L. 109-171, § 6031 (2006). Updated guidelines for evaluating whether state FCAs conform to the current federal FCA were issued by HHS OIG in 2013. See Dep't of Health & Human Servs., Office of Inspector Gen., *OIG Guidelines for Evaluating State False Claims Acts* (Mar. 15, 2013), available at <http://oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf>.

¹³⁷ See BOESE, Chapter 6 (discussing individual state and municipal false claims laws).

Appendix 1

THE FEDERAL FALSE CLAIMS ACT

31 U.S.C. §§ 3729-3733

As amended by:

The Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009) (signed by the President on May 20, 2009)

The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1303, 124 Stat. 119, 168 (2010) (signed by the President on Mar. 23, 2010)

The Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A, 124 Stat. 1376, 2077 (2010) (signed by the President on July 21, 2010).

§ 3729. False claims

(a) LIABILITY FOR CERTAIN ACTS.—~~Any~~

(1) IN GENERAL.—Subject to paragraph (2), any person who—

- (1A) 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;
- (2B) 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~~;
- (3C) 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);
- (4D) 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;
- (5E) 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~~that 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~~DEFINITIONS.—For purposes of this section;

==

(1) the ~~terms~~terms “knowing” and “knowingly” —

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

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) 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,~~ (2) 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

(4) the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

~~(d)~~ 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.

~~(e)~~ 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) ~~No~~The court shall ~~have jurisdiction over~~dismiss 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 are based~~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~~ (h) Relief From Retaliatory Actions. —

(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, contractor, agent, 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 may be brought 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 [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.

~~(e)~~(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.

~~(d)~~ 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 OF 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); ~~and~~
- (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.

Appendix 2

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CIVIL FALSE CLAIMS ACT: Supreme Court Rejects DOJ's Expansive Theory for FCA Falsity and Requires Rigorous Materiality, Scienter Standards in All False Certification Cases

The Supreme Court yesterday issued a watershed False Claims Act ("FCA") decision, *Universal Health Services, Inc. v. United States ex rel. Escobar*, No. 15-7, 2016 WL 3317565 (U.S. June 16, 2016). In a unanimous decision authored by Justice Thomas, the Court wasted little time on its ruling that the implied false certification theory of liability may be applied to FCA cases, a result that was neither surprising nor groundbreaking. The most important aspect of the Court's opinion is its focus on devising critical limits on the scope of this theory in all false certification cases (express or implied) and its unequivocal rejection of the DOJ's and relators' arguments that the "falsity" element of the FCA is easily proven.

- First, the Court made clear that the FCA imposes a "rigorous" materiality standard that derives from the common law understanding that fraud cannot exist "without proof of materiality." *Id.* at *11. Materiality requires a misrepresentation that "went to the very essence of the bargain," not a "minor" or "insubstantial" violation. *Id.* at *11 n.5, 12.
- Second, the Court emphasized that materiality requires much more than mere designation by the government that compliance is a "condition of payment," or *post hoc* assertions that the government would not have paid had it known of the misrepresentation. The Court completely rejected the government and relator arguments that merely labeling a statute or regulation as a "condition of payment" made it so. *Id.* at *4, *9.
- Third, the Court recognized what the DOJ and relators have always denied: that the government's payment of a claim can be compelling evidence that violations of statutory or regulatory requirements were not "material." *Id.* at *12.
- Fourth, proof that the defendant knew that the violation was material to the government's payment decision—at the time of claim submission—is required. *Id.* at *4, *10.
- Finally, the Court made clear that the materiality question can be addressed at the outset of litigation, through a motion to dismiss, or on summary judgment. The Court emphasized this point in particular, noting that "False Claims Act plaintiffs must also plead their claims with

plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Id.* at *12 n.6.

The Court justified imposing "rigorous" materiality and scienter standards as a check on the false certification theory by pointing to its prior rulings that the FCA is "essentially punitive," and that it "is not 'an all-purpose antifraud statute.'" *Id.* at *5, *12 (quoting *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000); *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

Background of the *Escobar* Case

The relators in *Escobar* are parents of a teenage girl who suffered a fatal reaction to medication after receiving treatment at the Arbor Counseling Services, a mental health facility owned by Universal Health Services in Lawrence, Massachusetts. Prior to bringing their *qui tam* suit, the relators initiated a state administrative action against the facility and its caregivers, which resulted in one individual's agreement to pay a \$1,000 fine and the clinical director's agreement to a two-year supervised probationary period. In their *qui tam* suit, the relators alleged that the facility submitted false claims for payment to Medicaid. There was no claim that the Medicaid claims were factually false, that the claims described services other than those provided, or that the facility billed incorrectly for the services. Neither Massachusetts nor the federal government intervened in the relators' suit.

The district court dismissed the *qui tam* suit for failing to allege that a condition of payment was violated. The First Circuit reversed, concluding that the claims were "legally false" under the implied false certification theory because of the defendants' misrepresentation of compliance with regulatory staffing and supervision requirements that the court deemed to be conditions of payment. Both the federal government and Massachusetts supported the relators in amicus briefs to the Supreme Court.

Overview of the Implied False Certification Theory

The Supreme Court agreed to review both the validity and scope of the implied false certification theory—issues that have divided the circuit courts for more than twenty years. See John T. Boese, Civil False Claims and *Qui Tam* Actions, §§ 2.03[G], 2.04 (Wolters Kluwer Law & Business) (4th ed. & Supp. 2016-2). See also FraudMail Alert [No. 15-12-09](#); FraudMail Alert [No. 15-06-15](#); FraudMail Alert [No. 13-04-04](#); FraudMail Alert [No. 11-08-31](#); FraudMail Alert [No. 10-11-03](#). Under this theory, relators and the government have argued that FCA liability, with its extraordinary consequences of treble damages and per claim penalties, attaches to the slightest statutory, regulatory, or contractual noncompliance, without the need for any false statement in the claim for payment, or even any awareness of a regulatory violation by the claimant. One need only look at recent court of appeals decisions to demonstrate how abusive such a theory can be. See, e.g., *United States ex rel. Bishop v. Wells Fargo & Co.*, No. 15-2449, 2016 WL 2587426 (2d Cir. May 5, 2016); *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, No. 15-3155, 2016 WL 1612857 (10th Cir. Apr. 22, 2016); *United States ex rel. Wall v. Circle C Constr., LLC*, 813 F.3d 616 (6th Cir. 2016). See also FraudMail Alert [No. 16-02-10](#). (The reader should note that the authors of this Alert advised the defendant in the *Thomas* case and represent the defendant in the *Bishop* case on other matters).

The Petitioner (a defendant below) argued against the theory's validity by looking to the common law meaning of the key statutory terms "false" and "fraudulent," which are not defined in the FCA, and contending that, under common law "fraud" and the FCA, absent active concealment, there is no duty to disclose noncompliance with regulatory requirements that are not referenced in the claim for payment.

Thus, Petitioner argued that, absent a legal obligation to disclose them, the regulatory staffing and supervision violations are not a basis for FCA liability. Alternatively, Petitioner contended that a defendant should face FCA liability only if it fails to disclose a violation of a statutory, regulatory, or contract provision that the government expressly designated a condition of payment. The Court rejected both of these positions.

The Supreme Court's Materiality and Scienter Standards

As already noted, the Court validated the implied false certification theory, holding that a claim may be fraudulent by omission under the common law fraud rule that half-truths can be actionable as misrepresentations. The Court also rejected Petitioner's second argument—that liability should turn on whether the requirements allegedly violated expressly were designated as conditions of payment. *Escobar*, 2016 WL 3317565, at *4, *9. While that type of evidence may be relevant, the Court specified that it is not dispositive. The Court reasoned that an express designation requirement would create arbitrariness, and ruled that neither the government nor defendants could rely solely on such designations or lack thereof. In rejecting the express designation rule, the Court rejected the Second Circuit's test in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) in favor of the D.C. Circuit's formulation of the implied false certification theory in *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010) ("SAIC"). However, the Court added significant rigor and specifics to the materiality and scienter standards that went beyond the more limited definitions of those standards in SAIC. Indeed, the Court addressed FCA defendants' concerns about fair notice and open-ended liability by requiring strict—the government and relators will probably contend "overly strict"—enforcement of the FCA's materiality and scienter requirements. *Escobar* at *10 (citing SAIC).

While the Court's materiality standard is not new, *id.* at *8, the Court's inclusion of two examples of omissions that went to the heart of the transaction firmly establishes that the regulatory violation must substantially undermine the claim for payment for the specific goods or services provided. These examples reflect the high level of materiality required—i.e., the case of a seller of property who mentions two new roads may be near the property, but fails to disclose that a third road might bisect the property, and the case of an applicant for a teaching position at a college who uses a resume disclosing a "retirement" from a previous job, without revealing that the "retirement" was occasioned by a prison sentence for bank fraud. Based on these examples, and on the use of payment codes and provider identification numbers corresponding to specific job titles without disclosing the "many violations of basic staff and licensing requirements" by the mental health facility in *Escobar*, the Court arrived at the following threshold for FCA liability under the implied certification theory:

at least . . . two conditions [must be] satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Id. at *9. In other words, proof of a defendant's nondisclosure of noncompliance with specific, material representations is a necessary element of an FCA violation under the implied certification theory.

Moreover, the Court described the enforcement of the FCA's materiality and scienter requirements as "rigorous." *Id.* at *10. In clarifying how materiality should be enforced, the Court added teeth to that requirement by pointing to the common law fraud requirement of "proof" of materiality. *Id.* at *11. The

Court also emphasized that the material misrepresentation must go “to the very essence of the bargain,” *id.* at *11 n.5, and that materiality is not found where noncompliance is “minor or insubstantial,” *id.* at *12. Evidence that the defendant knows that the government “consistently” refuses to pay in cases of noncompliance can be proof of materiality. *Id.* Thus, where no record or pattern of payment has been established with respect to a particular requirement, or where the government’s payment has been inconsistent, it would be extremely difficult to prove materiality. Not surprisingly, misrepresenting compliance with a non-collusive bidding requirement for federal program contracts, such as in *Marcus v. Hess*, 317 U.S. 537 (1943), is clearly material. *Escobar* at *12. It is also noteworthy that the Court emphasized that the facts of materiality must be properly pled under Rules 8 and 9(b). *Id.* at 12 n.6.

Finally, and perhaps most importantly, the Court included a final example drawn from the oral argument in *Escobar*—the hypothetical in which the contractor provided health services but used non-American-made staplers in violation of an additional requirement that staplers must be purchased in the U.S. At oral argument, the Justices expressed overt skepticism at the Deputy Solicitor General’s insistence that violation of such an ancillary regulation could be “material” and result in a false claim. That skepticism proved prophetic, with the Court’s opinion yesterday firmly rejecting liability under that very scenario. *Id.* at *12. The mere possibility that a violation “could” lead the government not to pay a claim can no longer be argued as a basis for proving materiality.

Thus, while the Court declined to fashion a bright line rule for separating material from nonmaterial violations in false certification cases, the Court’s decision means that the government and relators will have a much tougher time proving that a violation is “material.” The Court’s characterization of the materiality and scienter standards as “rigorous” and “demanding,” its setting of parameters for these standards by way of clear examples, and its emphasis on the common law’s proof requirements give FCA defendants, the government, relators, and the courts more guidance than they had before. Most importantly, the application of rigorous standards and additional fact-dependent proof requirements should prevent the most egregious overreaching under the implied certification theory.

Conclusion

Application of the *Escobar* standards in the lower courts will not be easy, almost assuring the future need for the Supreme Court to revisit and clarify the tests it sets forth in *Escobar*. Because FCA liability can implicate millions of dollars (and referrals for exclusion or debarment), and—in false certification cases—is based on what the contractor did not say, clear boundaries would be very useful. While contractors may have hoped that the Court would provide clearer direction, enabling them to determine the difference between a breach of contract and an FCA violation, the Court’s emphasis on the limited nature of the FCA and its reaffirmation that the FCA is “essentially punitive in nature,” “not ‘an all-purpose antifraud statute,’” and not “a vehicle for punishing garden-variety breaches of contract or regulatory violations,” provides some comfort. *Id.* at *5, *12. Moreover, while the Court’s decision today validates the theory of implied false certification in certain cases, the Court rejected the government’s and the First Circuit’s expansive view of materiality:

that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation The False Claims Act does not adopt such an extraordinarily expansive view of liability.

Id. at *12. The *Escobar* decision requires courts to rigorously enforce this theory using demanding materiality and scienter standards, and requiring a close, factual inquiry into each element. Thus, false certification cases will continue to be resolved case-by-case, but under more demanding materiality and scienter standards.

* * *

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. If you have any questions about the contents of this memorandum, please call your regular Fried Frank contact or the attorney listed below:

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Appendix 3

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CIVIL FALSE CLAIMS ACT: How “Tax Reform” Affects Settlements under the False Claims Act and Certain Other Statutes

While most of America has focused on more prominent features of the new tax law—such as changed corporate tax rates, increased standard deductions, and limitations on the deductibility of state and local taxes—very little attention has been paid to a less prominent provision that is sure to impact False Claims Act (“FCA”) and other settlements involving the government going forward. That provision amends the Internal Revenue Code (“IRC”) by, among other things, mandating that federal agencies specify, at the time of settlement of government claims, the portion of the settlement that may be deductible as a business expense.

Corporate defendants settling FCA and other cases that result in payments to the U.S. Treasury routinely factor in the tax impact of their settlements, but the Justice Department, citing a long-lost interagency agreement with the IRS, heretofore has declined to set forth or agree to any tax position at the time of settlement. This new provision will require both sides to add this item to the list of material settlement terms that will need to be negotiated. In addition, with the increased Justice Department focus on individual liability following the September 2015 Yates Memo, non-corporate defendants also will have to keep this provision in mind when negotiating FCA settlements. However, even with the additional federal agency reporting requirement, companies and individuals alike will have to ensure that the deductible “restitution” amount is included in the settlement agreement and, even with that, taxpayers remain exposed to later IRS challenges.

Prior Law

Since 1969, the IRC has prohibited taxpayers from deducting as a business expense “any fine or similar penalty paid to a government for the violation of any law.” 26 U.S.C. § 162(f). Shortly thereafter, the IRS issued a technical memorandum stating its “liberalized” position that single damages paid under the FCA would be deductible, while amounts attributable to the statute’s damages multiplier and penalties provisions would not be deductible. 1972 TM LEXIS 15 (July 25, 1972). However, the Supreme Court recognized in *Cook County v. United States ex rel. Chandler*, 538 U.S. 119 (2003), that the FCA’s damages multiplier (*i.e.*, treble damages) serves remedial as well as punitive purposes. This led to the general proposition—in tax cases concerning FCA payments—that the portion of the payment to the government that can be considered compensatory is deductible, while the portion of the payment that is punitive is not deductible.

Nonetheless, FCA settlement payments that lacked clarity or an adequate record as to the compensatory versus punitive allocation of the settlement amount presented some tax risk and uncertainty for the

businesses making the payments. While a company may have expected to be able to deduct the full amount of a settlement based on its view that the entire payment was compensatory, the IRS—sometimes years later—would challenge the deduction and claim that a significant portion of the payment must have been attributable to punitive purposes either through a damages multiplier or statutory penalties. For those not familiar with FCA settlements, many not only did not distinguish between the punitive and compensatory aspects of any payment, they did not even identify the single damages amount. In 1999, the Tax Court emphasized the risk and uncertainty that companies faced through its holding that the absence of any characterization of the payment in the settlement agreement itself, and the fact that the taxpayer and the government disagreed over the tax treatment, meant that the taxpayer could not establish a right to the disputed deduction. See *Talley Indus., Inc. v. Comm’r*, No. 27826-92, 1999 Tax Ct. Memo LEXIS 237, at *23 (June 18, 1999), *aff’d*, 18 F. App’x 661 (9th Cir. 2001).

In 2004, an IRS Technical Advice Memorandum (“TAM”) stated that, because the FCA’s damages multiplier encompassed both remedial and punitive objectives, and Section 162(f) only precludes deductions for punitive payments, the deductibility determination may require an examination of the facts and circumstances surrounding the agreement to determine the parties’ intent. The TAM also placed the burden on the taxpayer to prove the compensatory purpose of the portion of the settlement amount for which a deduction is sought. This IRS position disadvantaged businesses because of the Justice Department’s refusal—at least in FCA settlements—to specify or allocate the compensatory versus punitive portion of the settlement payment. The absence of any expressed government intent, coupled with the taxpayer’s burden of demonstrating intent, created unnecessary uncertainty and risk for the taxpayer, making it difficult to determine and account for—at the time of settlement—the true net cost of the settlement.

More recently, a federal court issued an important decision that turned the tide back toward the taxpayer. Recognizing the unfairness of the government’s position of both refusing to characterize the payment for tax purposes in the settlement agreement, while at the same time using the lack of any tax treatment agreement as grounds for denying the deduction, the First Circuit rejected the Justice Department’s arguments and the reasoning expressed by the Tax Court and affirmed by the Ninth Circuit in *Talley*:

We cannot accept the government’s rationale. A rule that requires a tax characterization agreement as a precondition to deductibility focuses too single-mindedly on the parties’ manifested intent in determining the tax treatment of a particular payment. Such an exclusive focus would give the government a whip hand of unprecedented ferocity: it could always defeat deductibility by the simple expedient of refusing to agree—no matter how arbitrarily—to the tax characterization of a payment.

Fresenius Med. Care Holdings, Inc. v. United States, 763 F.3d 64, 70 (1st Cir. 2014). The seeming conflict between the First and Ninth Circuits on this topic remains unresolved. In the meantime, even following *Fresenius*, the Justice Department has continued to refuse to agree to any characterization of FCA settlement payments for tax purposes.

As a result, the debate and uncertainty continued. Prior to the recent tax law changes, it was generally accepted that compensatory payments—i.e., payments for actual damages—and non-punitive payments (including payment of relators’ legal fees and the portion of the payment that is allocated to the relator’s share) were deductible. See Treas. Reg. 1.162-21(b)(2); *Chandler*, 538 U.S. at 131 (“The most obvious indication that the treble damages ceiling has a remedial place under this statute is its *qui tam* feature with its possibility of diverting as much as 30 percent of the Government’s recovery to a private relator”). However, there often was ample room for disagreement as to how much of the payment should be

deemed compensatory and how much was properly deemed punitive. For example, if the Justice Department initially demanded \$20 million to settle an FCA action (based on actual damages of \$10 million and a double multiplier), but the case ultimately settled for \$10 million, the taxpayer justifiably could have asserted that the entire settlement payment was compensatory (and deductible)—since it was equal to the government's claimed actual damages—while the Justice Department and IRS might have argued that, consistent with the Justice Department's initial demand for a double multiplier, only 50% or \$5 million was deductible.

The New Tax Law

So what has changed? The new tax law adds important limitations and conditions on the deductibility of payments to the government. See H.R. 1, 115th Cong. § 13306(a) (2017) (enacted). As discussed below, (1) taxpayers will no longer be able to deduct settlement payments (or portions thereof) unless those payments are identified—in the settlement agreement—as restitution, and the taxpayer otherwise establishes that the payment constitutes restitution, (2) taxpayers will no longer be able to deduct payments to reimburse the government's investigation and litigation costs, and (3) federal agencies are now required to characterize and report the settlement payment—for tax purposes—at the time of settlement.

As amended by the new law, Section 162(f) begins with the general proposition that—absent specified exceptions—payments made to the government “in relation to the violation of any law or the investigation or inquiry by [the government] into the potential violation of any law” are not deductible. Although not mentioned expressly, the IRS is certain to contend that FCA settlement payments are “qualifying payments” to the government under this Section.

The key then, for FCA defendants, is the exceptions. Relevant here is Section 162(f)'s specification that the payment *will* be deductible if

1. the taxpayer demonstrates that the amount “constitutes restitution ... for damage or harm which was or may be caused by the violation of any law or the potential violation of any law,” *and*
2. the amount sought to be deducted “is identified as restitution ... in the court order or settlement agreement” (although the provision specifies that this mere identification “alone” is not sufficient to carry the taxpayer's burden).

Section 162(f)(2)(A). Moreover, the amendment makes clear that this exception will not apply “to any amount paid or incurred as reimbursement to the government or entity for the costs of any investigation or litigation.” Section 162(f)(2)(B).

These new provisions are critical to understand, as they represent significant changes to existing law and apply to any payments made pursuant to settlements entered into after the effective date of the law (*i.e.*, on or after December 22, 2017). Thus, going forward, taxpayers may be precluded from taking deductions for settlement payments to the government (arising out of alleged violations of law) unless the settlement agreement itself specifies that the amount sought to be deducted is for restitution. And no amounts can be deducted for reimbursement of the government's investigation and litigation costs.

The next very important change that will affect FCA settlements is the addition of a new federal agency reporting requirement. See H.R. 1, 115th Cong. § 13306(b) (2017) (enacting new 26 U.S.C. § 6050X). On a going forward basis for all new settlements (including FCA settlements) resulting in a payment to the government, the affected government agency will be required to “make a return”—as directed—

specifying: (1) the amount paid to the government; (2) the portion of the amount that constitutes restitution to the government; and (3) any amount that was required to be paid as a result of the agreement for the purpose of coming into compliance with the law at issue in the investigation or suit. This return also must be prepared if the payments are made due to a court order (*i.e.*, following trial or judgment).

The new law specifies that the return must be completed by the "appropriate official of any government...which is involved in the suit or agreement." Section 6050X(a)(1). The provision does not clearly state whether the reporting may be completed by the Justice Department—which represents the federal agencies in FCA cases—or just the affected agencies themselves, or both. See Section 6050X(c) (defining "appropriate official" as the "officer or employee having control of the suit, investigation, or inquiry or the person appropriately designated for purposes of this section"). Either way, however, since the Justice Department has, by statute, control of all FCA litigation and negotiates FCA (and many other government) settlements, the Justice Department will need to be involved in both the establishment of the restitution amount and the new reporting.

Finally, the new law mandates that (1) the return must be "filed" at the time the agreement is entered into and (2) at the same time as it is filed, the government must provide each party to the agreement a "written statement" containing the same information that is included in the return. In the past, companies had been forced to use a Freedom of Information Act request to obtain this type of information, but that should no longer be necessary under the new bill. The provision may, however, open the Justice Department and relevant agencies to discovery in any later tax proceeding where the IRS has challenged the deductibility of the taxpayer's payment even in the face of clear settlement agreement language and the government's separate reporting to the IRS.

Key Takeaways

The new tax law changes the landscape for FCA settlements (and settlements of other potential violations of law).

With respect to FCA settlements, there are open questions about the application and workability of the statute in non-intervened *qui tam* cases. And, whereas FCA defendants previously could deduct amounts ultimately paid to relators, the revised law does not address that issue directly.

In most high value cases, the tax law changes will force all parties to negotiate over the amount of the settlement payment that will constitute "restitution." For settling companies or individuals factoring a deduction into their settlement position, they must insist on any settlement agreement including a characterization of the "restitution" aspect of the payment that is considered deductible as that is a precondition for later attempting to claim a deduction. Thus, the Justice Department will now have to abandon its stance of being "tax neutral" in the settlement (and such a stance would be contrived in light of the separate IRS reporting requirement that the government now must comply with at the same time as the settlement). How the Justice Department and defendants adapt to this new reality will become evident in the coming months.

Finally, FCA defendants and other settling parties, even in the face of agreed-upon tax treatment language in the settlement and the government's separate reporting to the IRS, will have to be prepared for an IRS challenge of the deductibility and the burden of establishing that the payments indeed are deductible "restitution." Defendants settling FCA cases should consult with tax counsel experienced in resolving FCA claims.

* * *

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Appendix 4

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CIVIL FALSE CLAIMS ACT: Mixed Signals from the Government's First Medicare Advantage Test Cases

The Medicare Advantage program has been in the False Claims Act ("FCA") spotlight recently, with courts beginning to weigh in on the viability of claims against providers for allegedly submitting false diagnosis information in order to increase their risk adjustment reimbursements. The first significant case ended quietly in October 2017 when the Government filed a notice of dismissal after its complaint-in-intervention was rejected for pleading deficiencies in *United States ex rel. Swoben v. Scan Health Plan*, No. 09-5013-JFW (JEMx), 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017). But, just a few months later, in *United States ex rel. Poehling v. Unitedhealth Group, Inc.*, No. 16-08697-MWF (SSx), slip op. (C.D. Cal. Feb. 12, 2018), the Government fared better when a district court allowed the Government to move forward on a reverse false claims theory, even as it dismissed other FCA claims. These early decisions suggest that (1) the Supreme Court's rigorous materiality and scienter standards from *Escobar* will limit the scope of some Medicare Advantage liability, but (2) the door may be open for relators and the Government to circumvent those limits by pursuing reverse – rather than affirmative – false claims theories.

Background of *Swoben* & *Poehling*

The *Swoben* case, filed in the U.S. District Court for the Central District of California, began in July 2009 as a *qui tam* complaint and ultimately named multiple defendants, including various Senior Care Action Network (SCAN) defendants and United Healthcare defendants. In 2012, the SCAN defendants settled for \$322 million. In January 2013, the Government declined to intervene as to the remaining defendants. The *Poehling qui tam* case was filed against United Healthcare and various other defendants in the U.S. District Court for the Western District of New York in March 2011, but later was transferred to the Central District of California in anticipation of consolidation with *Swoben*.

The allegations in *Swoben* and *Poehling* arise from Medicare's "risk adjustment" process under Medicare Part C – the Medicare Advantage program. That risk adjustment process enables privately run Medicare Advantage ("MA") Plans to be reimbursed by Medicare, on a per-member-per-month basis, in accordance with the health status and demographics of their beneficiaries. MA Plans submit diagnosis codes received from providers to the Centers for Medicare & Medicaid Services ("CMS") in order to make these risk adjustments. In addition, MA Plans routinely retain coding companies to conduct retrospective reviews of patient medical records and identify additional diagnosis codes that may have been missed during the original transmittal. Generally speaking, to the extent that additional diagnosis codes demonstrate that a member has increased medical needs, the reimbursement adjustment typically is increased. The *Swoben* and *Poehling* complaints alleged that audit error rates put the United Healthcare

defendants on notice that they also needed to “look the other way” in their reviews to identify inaccurate codes submitted to CMS and that this awareness rendered false the United Healthcare defendants’ attestations that the data submitted from providers was accurate to the best of their “knowledge, information, and belief,” as required by Medicare regulations.

Following dismissal by the district court for failure to plead with particularity and a determination that any amendment would be futile, the *Swoben* relator appealed. In August 2016, the Ninth Circuit vacated the dismissal after finding that the relator’s proposed fourth amended complaint could state an FCA claim by alleging that the United Healthcare defendants used “one-sided” medical record reviews. Consistent with the reasoning advanced by the Government in an amicus brief, the Ninth Circuit held that the deliberate avoidance of identifying certain erroneous coding is a “cognizable legal theory” under the FCA because MA Plans are obligated by Medicare regulations to undertake “due diligence” to ensure the accuracy of diagnostic codes, and FCA liability can be established by a defendant’s deliberate ignorance. *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1172-79 (9th Cir. 2016).

In March 2017, the Government filed a complaint-in-partial-intervention in *Swoben* against the United Healthcare defendants only. Around the same time – in February 2017 – the Government filed notice of its partial intervention in the *Poebling* case against the United Healthcare defendants.

The *Swoben* Dismissal and the Government’s Decision to Drop the Case

In *Swoben*, the United Healthcare defendants sought dismissal of the revived action on a number of separate grounds, including that the Government failed to (1) allege that the individuals who signed the United Healthcare defendants’ risk adjustment attestations knew them to be false; (2) allege that the attestations were material to the Government’s payment decision; and (3) identify the acts of each of the seven distinct corporate entities who made up the United Healthcare defendants. On October 5, 2017, the court granted United Healthcare’s motion to dismiss, with leave to amend.

First, acknowledging *Escobar*’s admonition that the FCA’s scienter requirement is “rigorous” and “strict[ly] enforce[d]” and reaffirming that the Ninth Circuit does not recognize collective scienter for corporations, the court found that the complaint failed to identify the particular corporate officers who signed the attestations or to allege that those individuals knew or should have known that the attestations were false. While the Government argued that the defendants could be liable for actions that shielded the signatories from knowing about the fraud, the court – without addressing the merits of this theory – found no allegations that anyone at United Healthcare undertook such actions and that the Government failed to identify anyone at United Healthcare other than the signatories who had the requisite knowledge. 2017 WL 4564722, at *7.

With respect to materiality, the court found that the Government’s allegations were merely conclusory. In particular, the bare allegation that CMS would have refused to make risk adjustment payments if it had known the facts about the “one-sided” records review process did not meet the heightened materiality standard mandated by the Supreme Court in *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). 2017 WL 4564722, at *5-6.

Finally, the court found the Government’s failure to distinguish the individual roles of the multiple defendants to be “a classic ‘shotgun pleading’ that wholly fails to state ‘clearly how each and every defendant is alleged to have violated’” the FCA. As such, the complaint failed to satisfy the heightened pleading requirements of Rule 9(b). *Id.* at *7.

The court allowed the Government to file an amended complaint by October 13, 2017, *i.e.*, in only eight days. Rather than do so, the Government filed a notice of voluntary dismissal, ending the Government's first intervention in a Medicare Advantage FCA suit with a whimper.

The *Poehling* Partial Dismissal and the Government's Surviving Reverse False Claims Allegations

Following the *Swoben* dismissal, the United Healthcare defendants moved to dismiss the very similar *Poehling* allegations on the same grounds. The Government, however, was first given the opportunity to file an amended complaint to address *Swoben*. Most significantly, the Government added a claim for reverse false claims liability – which was not alleged in *Swoben* – and argued that it was evidence of materiality for these reverse false claims that CMS would have automatically accepted repayments had the United Healthcare defendants affirmatively deleted invalid inaccurate diagnosis codes after conducting reviews. The Government also tried to address the materiality deficiencies of its affirmative false claims allegations.

The *Poehling* court, like the *Swoben* court, dismissed the affirmative FCA allegations for failure to plead materiality under *Escobar*. In particular, the court found that despite alleging that payments would be different if the United Healthcare defendants had submitted only valid diagnosis codes and deleted invalid diagnoses, the Government did not sufficiently allege that payments would be any different had CMS known that the United Healthcare defendants' risk adjustment *attestations* about data accuracy and due diligence were false. Slip op. at 16. The court left open the possibility of the Government curing this materiality pleading deficiency by amending to make clear – if there is a factual basis to do so – that the attestations themselves are material, not merely that they are linked to the material diagnosis codes.

Despite this reaffirmation of the rigor of *Escobar* materiality and the outcome of *Swoben*, the *Poehling* decision represents something of a win for the Government because the case will proceed at least on the reverse false claims allegations. Whereas the affirmative false claims allegations were based on the submission of false attestations, the Government's reverse false claims allegations are based on the United Healthcare defendants' failure to delete invalid diagnosis codes. While it is well established that there cannot be affirmative and reverse false claims liability for the same act, *see, e.g., United States ex rel. Scharber v. Golden Gate Nat'l Senior Care LLC*, 135 F. Supp. 3d 944 (D. Minn. 2015); *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73 (D.D.C. 2014), the Government nevertheless was permitted, for now, to transform what may be the same underlying conduct into reverse false claims allegations. Moreover, while the *Poehling* court found that the retention of payments for invalid diagnosis codes would be enough to satisfy *Escobar* materiality, it also observed that *Escobar* materiality may not even apply to reverse false claims, picking up the argument in the Government's briefing that reverse false claims were not at issue in *Escobar* and materiality under the reverse false claims provision logically would focus on the impact to a defendant's obligation. *Cf. United States ex rel. Bishop v. Wells Fargo & Co.*, 870 F.3d 104 (2d Cir. 2017) (per curiam) (finding that the rationale for *Escobar*'s common-law materiality requirement extends beyond *Escobar*'s implied false certification context to an express false certification claim); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746 (3d Cir. 2017) (ruling that the FCA always included the common law understanding of materiality and that *Escobar*'s definition of materiality applies to more than just post-2009 § 3729(a)(1)(A) conduct).

It is unclear whether the Government will re-plead its affirmative false claims allegations and whether the reverse false claims allegations will stand up to further scrutiny and challenge as the case advances. In addition, United Healthcare continues to challenge the Government's and relators' pursuit of alleged fraud in the Medicare Advantage program on another front – through an Administrative Procedure Act suit asserting that CMS's 2014 "Overpayment Rules" undermine the entire theory behind risk adjustment

payments, violate statutory requirements, and should be set aside. See *UnitedHealthCare Ins. Co. v. Price*, 255 F. Supp. 3d 208 (D.D.C. 2017) (denying defendants' motion for stay). Cross-motions for summary judgment in that action now are fully briefed, but the impact of any decision there on FCA cases remains to be seen.

Takeaways

The *Swoben* and *Poebling* outcomes represent the still-shifting nature of the protections *Escobar* provides to FCA defendants. While the Government repeatedly has argued that *Escobar* is limited and toothless, those arguments have been knocked down by numerous courts, including the *Swoben* court and partially by the *Poebling* court. Indeed, it is significant that *Swoben* and *Poebling* dismissed government complaints-in-intervention, given district courts' traditional reluctance to do so because courts often presume that the Government has had the necessary time and investigative tools at its disposal to ensure that any claims pleaded are not only plausible, but well supported by actual evidence. But the mixed *Poebling* outcome demonstrates that the Government's press to carve out spaces free from the reach of *Escobar* may be gaining some traction. And this outcome is particularly troubling due to the relative ease with which the Government and relators can rebrand failed affirmative FCA allegations into reverse false claims allegations.

* * *

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