

**Health Care Compliance Association  
Healthcare Enforcement Compliance Institute**

**Litigating a False Claims Act Case:  
Fundamentals of the 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 the 1986 amendments.<sup>1</sup> 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.

The Affordable Care Act strengthened the government’s focus on health care fraud, allocating an additional \$350 million to that effort over 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).<sup>2</sup> 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 policy memorandum known as the “Yates Memo” that takes a more aggressive approach toward pursuing individuals as FCA defendants in addition to corporations, and the government has implemented that policy in health care fraud cases.<sup>3</sup> Although the Yates Memo is under review by the Trump administration, the Justice Department has continued these enforcement policies.<sup>4</sup>

Areas of particular concern to the health care industry include upcoding, off-label promotion, Medicaid rebates, failure to document patient care, deficient compliance, medical necessity, worthless services, and the expanded use of the AntiKickback statute as bases for FCA liability.<sup>5</sup> In addition, the knowing nonpayment of an “obligation”—defined to include

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<sup>1</sup> See Press Release, Dep’t of Justice, Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>.

<sup>2</sup> See *id.*

<sup>3</sup> See Memorandum from Deputy Att’y Gen. Sally Quillian Yates, Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015) (“Yates Memo”), <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 Pharm Compliance Cong. and Best Practices Forum (Oct. 22, 2015), <https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-16th>. See also DOJ’s 2016 Press Release.

<sup>4</sup> See, e.g., Press Release, Dept. of Justice, Medicare Advantage Organization and Former Chief Operating Officer to Pay \$32.5 Million to Settle 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>; Law 360, Fla. Medical Group’s Ex-CFO Settles FCA Charges For \$100K (Sept. 14, 2017), [https://www.law360.com/governmentcontracts/articles/964178/fla-medical-group-s-ex-cfo-settles-fca-charges-for-100k?nl\\_pk=68d0f0c3-b32d-42ae-8ec6-](https://www.law360.com/governmentcontracts/articles/964178/fla-medical-group-s-ex-cfo-settles-fca-charges-for-100k?nl_pk=68d0f0c3-b32d-42ae-8ec6-)

<sup>5</sup> See, e.g., Law 360, What the DOJ’s Elite Health Fraud Squads Are Watching (Sept. 21, 2017), <https://www.law360.com/governmentcontracts/articles/960133/what-the-doj-s-elite-health-fraud-squads-are->

“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 decision in *Universal Health Services v. United States ex rel. Escobar*, which validated application of the implied false certification theory of liability in FCA cases, and statutory provisions specifically linking the FCA to government health care program requirements, ensure that the FCA’s role in health care fraud enforcement will only increase. The *Escobar* decision also has changed the landscape for discovery in false certification cases by focusing on government knowledge, making discovery into the government’s payment decisions essential.

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.<sup>6</sup> Key FCA amendments and changes affecting the health care industry are discussed in the sections below. Most of these amendments took effect upon their enactment and therefore apply to conduct on or after that date, although FERA’s liability amendments in Section 3729(a)(1)(B) apply to “claims” pending as of June 7, 2008, and several procedural amendments specifically apply to “cases” pending when the amendments were enacted. As a result, two different FCAs may be involved in pending cases—the statute as it existed prior to the amendments in 2009 and 2010, and the statute after those amendments. Now that twenty-nine states plus the District of Columbia have state false claims laws, false claims litigation often takes place at the federal, state, and multi-state levels.

Major changes relating to FCA liability and damages have occurred as a result of judicial decisions and actions by government agencies. As already mentioned, the Supreme Court’s decision in *Universal Health Services v. United States ex rel. Escobar* validating the implied false certification theory of liability and establishing limits for this potentially expansive theory, including a demanding materiality standard, has altered the landscape of the litigation of these cases at both the federal and state level, from pre-trial motions and discovery through trial. On the damages side, the Justice Department has implemented a congressional mandate that vastly increased FCA penalties for violations occurring after November 1, 2015, subject to annual adjustment. This enormous increase in FCA penalties is certain to raise constitutional challenges under the Excessive Fines Clause of the Eighth Amendment.

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. 2018-2) (“BOESE”). Please note that a redline showing the current FCA, as amended, is attached as Appendix 1. Appendix 2 is a FraudMail Alert issued the same day as the *Escobar* decision on the impact of that decision on false certification cases. Appendix 3 includes topics for motions in limine related to FCA litigation.

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[watching?nl\\_pk=68d0f0c3-b32d-42ae-8ec6-f7aaded1d632&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=governmentcontracts&read\\_more=1](https://www.fraudmail.com/watching?nl_pk=68d0f0c3-b32d-42ae-8ec6-f7aaded1d632&utm_source=newsletter&utm_medium=email&utm_campaign=governmentcontracts&read_more=1).

<sup>6</sup> 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).

## 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. Notably, the range for FCA penalties nearly doubled in 2016 due to a budget law inflation “catch-up” provision, and this provision makes FCA penalties subject to adjustment upward annually.<sup>7</sup> In February 2018, the FCA penalty range was \$11,181 - \$22,363.<sup>8</sup>
- 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 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 varied considerably from the federal FCA, most of them no longer do because they must

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<sup>7</sup> See FraudMail Alert No. 16-06-30, DOJ’s New Civil Penalty Amounts Are Cause for Concern (June 30, 2016), available at <http://www.friedfrank.com/siteFiles/Publications/FINALv2-06-30-2016-Fraud%20Mail-CIVIL%20FALSE%20CLAIMS%20ACT%20&%20FIRREA%20DOJ's%20New%20Civil%20Penalties%20Increase.pdf>.

<sup>8</sup> See Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018) (FCA penalties to be codified at 28 C.F.R. § 85.3(a)(9)).

follow the federal model in order to receive an economic incentive under the Deficit Reduction Act of 2005.<sup>9</sup>

It also is 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.<sup>10</sup> 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.<sup>11</sup> However, New York amended its state FCA to allow *qui tam* enforcement of tax law violations.<sup>12</sup>

## **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.<sup>13</sup> 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;
- 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

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<sup>9</sup> 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)).

<sup>10</sup> 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.”

<sup>11</sup> 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].

<sup>12</sup> 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, available at <http://friedlive.icvmgroup.net/siteFiles/Publications/Fried%20Frank%20FraudMail%20Alert.pdf>.

<sup>13</sup> 31 U.S.C. § 3731(c).

contracting procedures. These sections of the FCA are seldom invoked, and therefore have not been the subject of significant case law analysis.<sup>14</sup>

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

**Overview.** 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. 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;
  - (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

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

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.

**Section 3729(a)(1)(B).** 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*,<sup>15</sup> 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.”<sup>16</sup>

FERA 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. 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.<sup>17</sup>

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.

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<sup>15</sup> 553 U.S. 662 (2008).

<sup>16</sup> 553 U.S. at 669, 672.

<sup>17</sup> 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), 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), *rev’d on other grounds*, 131 S. Ct. 1885 (2011), and *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (same). See also *People ex rel. Empire State Ventures, LLC v. Sprint Nextel Corp.*, 970 N.Y.S.2d (N.Y. Sup. Ct. July 1, 2013) (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), *aff’d*, 980 N.Y.S.2d 769 (N.Y. App. Div. 2014); *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).

**Section 3729(a)(1)(C).** 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 2739(a)(1)(G).** 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 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, and at the end of that period, a final reconciliation of the accounts is made using an annual 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.<sup>18</sup> Reverse false claim allegations also have been raised in cases involving the alleged underpayment of royalties for natural resources (like timber, oil, and gas) removed from federal land.

Under Section 3729(a)(7), liability for a “reverse false claim” is triggered only when a person:

knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

This requires the person to take an affirmative step to avoid an obligation to pay the government. However, FERA, eliminated the key words denoting purpose in Section 3729(a)(7)—“to conceal, avoid, or decrease”—and instead, bases liability under Section 3729(a)(1)(G) on making, using, or causing a false record or statement that is “material” to an “obligation” to pay money to the government. In addition, FERA provides an alternative basis for liability which requires simply knowingly concealing, or knowingly and “improperly” avoiding or decreasing an “obligation” to pay the government—without the necessity of making any false statement. FERA also provided a definition for an “obligation.”

**“Obligation.”** FERA defines “obligation” as an established duty, whether or not fixed, arising from a contract, grant, license, fee-based, or similar relationship, or from retention of an overpayment. The phrase “whether or not fixed” in this definition of “obligation” has been

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<sup>18</sup> See, e.g., *United States ex rel. Bahrani v. ConAgra, Inc.*, 624 F.3d 1275 (10th Cir. 2010) (agreeing with defendants that *Allison Engine*’s intent requirement applied to claims under Section 3729(a)(7)); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 414-16 (6th Cir. 2002), *petition for reh’g en banc denied*, No. 01-5019, 2002 U.S. App. LEXIS 16358 (6th Cir. July 26, 2002) (affirming the imposition of liability where defendants failed to file amended cost reports reflecting fact that defendants did not comply with Medicare regulations relating to certain Employee Stock Ownership Plan payments, and where defendants allegedly were not entitled to retain Medicare funds paid by the government for the ESOP plan). The reader should note that the author was an expert witness for the defense on the issue of attorneys’ fees in *Bahrani*.



interpreted to cover cases where an established duty to pay the government is owed but the amount owed is unfixed.<sup>19</sup> A considerable body of case law supports the view that the government's ability to pursue reimbursement for overpayments does not constitute an "obligation."<sup>20</sup> Extension of Section 3729(a)(1)(G) liability to breaches of contract, including corporate integrity agreements, is still in flux.<sup>21</sup>

**“Retention of any overpayment.”** Precisely how a duty arises from retention of an overpayment and when it becomes “established” is not clear under this statutory language. 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.”<sup>22</sup> Then, under the Affordable Care Act of 2010 (“ACA”), an overpayment retained beyond the deadline for reporting and returning it became an “obligation” as defined in the FCA,<sup>23</sup> linking overpayments, the ACA’s deadline, and FCA liability. The ACA’s 60-day rule for reporting and returning “identified” overpayments and the link to FCA liability raised a plethora of questions from health care providers.<sup>24</sup> 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.<sup>25</sup>

Recently, a federal district court in the District of Columbia vacated CMS’s Medicare Part C final rule, agreeing with the rule’s challengers that CMS’s standard for identifying and

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<sup>19</sup> See, e.g., *United States ex rel. Simoneaux v. E.I. DuPont de Nemours & Co.*, 843 F.3d 1033, 1036 (5th Cir. 2016).

<sup>20</sup> 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).

<sup>21</sup> See, e.g., *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1223 (11th Cir. 2012) (finding pharmaceutical company was contractually obligated to return government overpayments); *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 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), *aff’d*, No. 15-20626, 2016 WL 6407128 (5th Cir. Oct. 28, 2016) (per curiam) (finding no evidence of a 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 Cephalon’s contractual obligation to pay the government upon breach of its corporate integrity agreement was an “established duty”).

<sup>22</sup> S. Rep. No. 111-10, at 15 (2009).

<sup>23</sup> See ACA, Pub. L. No. 111-148, 124 Stat. 119, § 6402 (2010) (amending 42 U.S.C. § 1128J).

<sup>24</sup> 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.

<sup>25</sup> 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).

reporting overpayments was more stringent than the FCA’s scienter standards, and finding no authority for CMS’s application of FCA consequences based on that more stringent standard.<sup>26</sup> While the court’s findings were in the context of its review of CMS’s rulemaking, attempts to apply a more stringent standard than the FCA’s scienter standards in FCA cases should be rejected for the same reasons as the court rejected this rule.<sup>27</sup>

**Civil Investigative Demand Amendment.** FERA also expanded the Department of Justice’s (“DOJ”) authority to conduct pre-intervention discovery. DOJ 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.” Under this expanded authority, the Attorney General’s authority to issue CIDs was delegated to the Assistant Attorney General for the Civil Division,<sup>28</sup> 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.<sup>29</sup> After this expansion, use of CIDs by both DOJ and U.S. Attorneys’ Offices has increased dramatically.<sup>30</sup>

**Relation Back Amendment.** In addition, FERA 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. 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.

**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. These

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<sup>26</sup> *UnitedHealthCare Ins. Co. v. Azar*, No. 16-157 (RMC), 2018 WL 4275991 (D.D.C. Sept. 7, 2018). The court also ruled that CMS’s final rule violated the APA because its definition of “identified” significantly departed from the definition in the proposed rule and imposed a more burdensome definition than originally proposed without adequate notice to the regulated entities.

<sup>27</sup> *See, e.g., 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); *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).

<sup>28</sup> *See* Order No. 3134-2010 (Jan. 15, 2010).

<sup>29</sup> *See* Dep’t of Justice, Directive No. 1-10, *Redelegation 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).

<sup>30</sup> 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>.

provisions are discussed in the recent developments section below. FERA made no change in the law on the question of whether government employees can be *qui tam* relators, and on the application of 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**

As noted at the outset, the Supreme Court's watershed decision in *Universal Health Services v. United States ex rel. Escobar* affects all cases that are premised on the false certification theory of liability. In *Escobar*, the Court validated this theory but adopted a demanding materiality standard that focuses on the government's knowledge of the allegations and its payment decision. This focus makes taking discovery from the government on these matters essential. The *Escobar* decision and its significance are addressed following the historical background of pre-*Escobar* materiality, falsity, and false certification discussed immediately below. A second major change is the vast increases in FCA penalties commencing August 1, 2016, which is discussed in the penalties section.

Only a few of the most significant recent developments are 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. 2018-2).

##### **1. Pre-*Escobar* Materiality**

Because it is obvious that no regulated party could ever comply with the tens of thousands of applicable laws, regulations, and guidelines, courts needed to develop a legal mechanism for differentiating violations that went to the heart of the claim for federal money from violations that were inconsequential to the funding decision. At first, that legal mechanism became known as "materiality," and the historical basis of the materiality requirement can be traced to *United States v. McNinch*, in which the Supreme Court held that the civil False Claims Act is "not designed to reach every kind of fraud practiced on the Government."<sup>31</sup> More recently, in *Allison Engine Co. v. United States ex rel. Sanders*, the Supreme Court clearly indicated in the context of its discussion of the elements of liability under Section 3729(a)(2) that a showing of "materiality" is required, and that a false statement must be a "condition of payment" in order to satisfy that materiality requirement.<sup>32</sup>

After FERA, however, the statutory definition of "material" became "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." This standard was not new, and courts interpreted it as strongly limiting FCA liability to false statements that directly affect the government's payment decision. For example, several courts held that violations of "conditions of participation" in a federal healthcare program did not result in FCA violations. In *United States ex rel. Conner v. Salina Regional Health Center*, the Tenth Circuit found that sweeping, general certifications of compliance with conditions of participation in annual Medicare cost reports were not actionable because they were not specific

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<sup>31</sup> 356 U.S. 595, 599 (1958).

<sup>32</sup> 553 U.S. 662, 672 (2008) (FCA defendants must "intend the Government to rely on [their] false statement as a condition of payment").

conditions of payment.<sup>33</sup> Similarly, in *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, the district court found that there was no evidence showing that noncompliance with Medicare's conditions of participation would make the defendants ineligible for Medicare payments or lead to nonpayment of the claims.<sup>34</sup>

However, the materiality analysis used by other courts obscured the difference between violations of conditions of payment and lesser regulatory violations. For example, in *United States ex rel. Hendow v. University of Phoenix*, the Ninth Circuit found it unimportant that the University's certification was a promise to comply with a restriction on enrollment incentive compensation in the future, and ruled that the distinction between a condition of participation and payment was "a distinction without a difference" because the government "plainly care[d]" about the restriction.<sup>35</sup> Ultimately, the court required "a causal . . . connection between fraud and payment," but this condition of payment requirement was undercut by the court's emphasis on a broad interpretation of materiality in its analysis of the allegations.

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

Even though we have rejected SAIC's effort to cabin the implied certification theory, we fully understand the risks created by an excessively broad interpretation of the FCA. As SAIC compellingly points out, without clear limits and careful application, the implied certification theory is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA's generous remedial scheme, may attempt to turn the violation of minor contractual provisions into an FCA action. In our view, however, instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, this very real concern can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.<sup>36</sup>

But the D.C. Circuit's concern about potential abuse under the implied false certification theory of liability was unhelpful given the low "materiality" threshold put in place by FERA's amendments.

In light of the potential for abuse under the "implied false certification theory," the author proposed that courts would find a way to reinstate the "prerequisite to payment requirement,"<sup>37</sup> and business groups proposed reforms that included eliminating the implied false certification

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<sup>33</sup> 543 F.3d 1211 (10th Cir. 2008).

<sup>34</sup> 525 F. Supp. 2d 972 (W.D. Tenn. 2007). The reader should note that the author was one of the attorneys representing the defendants in this case.

<sup>35</sup> 461 F.3d 1166, 1176-77 (9th Cir. 2006).

<sup>36</sup> 626 F.3d 1257, 1270 (D.C. Cir. 2010).

<sup>37</sup> See John T. Boese, The Past, Present, and Future of "Materiality" Under the False Claims Act, 3 ST. LOUIS U.J. OF HEALTH L. & POL'Y 291 (2010).

theory of liability in FCA cases.<sup>38</sup> After FERA, the courts developed a way to limit this broad liability, easing the impact of FERA’s low materiality threshold by refusing to conflate the elements of “materiality” and “falsity” in FCA cases premised on this theory, as discussed in the section on falsity and false certification below. Materiality has a much more significant role now that the Supreme Court has explained its importance in establishing the validity of the implied false certification theory in FCA cases in *Escobar*.

## 2. Pre-*Escobar* False Certification Analysis

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.”<sup>39</sup> In the FCA context, resolving disputed questions of falsity often involves the interpretation of a law, regulation, contract, or agreement.

Many FCA cases are based not on facially or factually false claims, but on allegedly false certifications of compliance with a law, regulation or contract provision. Some of the most significant FCA developments each year arise in “false certification” (known as “legally false” claim) cases that involve something quite different from direct overbilling or factually false claims. FCA plaintiffs are using 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. For example, the hospital may have violated one or more “conditions of participation” in the course of delivering the necessary services to the eligible beneficiary.

FCA liability based on implied false certifications has been rightly criticized because it imposes potentially enormous liability under the statute’s reckless disregard standard without the defendant’s making an express false claim or a false statement in support of a false claim. Many courts limited the application of this theory to situations in which the government had explicitly conditioned its payment upon compliance with the statute or regulation violated, and refused to infer a false claim if the claimant was not expressly required to certify compliance in order to receive payment.<sup>40</sup> With the statutory adoption in 2009 of the more lenient test for materiality

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<sup>38</sup> See U.S. Chamber, Institute for Legal Reform, Fixing the False Claims Act; The Case for Compliance-Focused Reforms (Oct. 2013), [http://www.instituteforlegalreform.com/uploads/sites/1/Fixing\\_The\\_FCA\\_Pages\\_Web.pdf](http://www.instituteforlegalreform.com/uploads/sites/1/Fixing_The_FCA_Pages_Web.pdf).

<sup>39</sup> See *United States v. Diogo*, 320 F.2d 898 (2d Cir. 1963); *United States v. Lange*, 528 F.2d 1280 (5th Cir. 1976).

<sup>40</sup> See, e.g., *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 435 (S.D.N.Y. 1999) (The “implied false certification” theory applies “only in those exceptional circumstances where the claimant’s adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the Government, or . . . where the Government would have refused to pay had it been aware of the claimant’s non-compliance”); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010). See also BOESE, § 2.03 (citing cases by circuit).

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 the “prerequisite to payment” analysis of *falsity* as a limit on liability under the false implied certification theory. To establish “legal falsity” in these cases, the certification of “compliance with a statute or regulation as a condition to government payment” was required.<sup>41</sup>

**The Prerequisite to Payment Analysis.** For example, in a remarkable decision in 2010, the Fifth Circuit adopted a stringent standard for false certification cases that prevented the FCA from becoming a catch-all vehicle for punishing minor violations of law that occur in the course of providing federally-funded medical services or performing under government contracts. In *United States ex rel. Steury v. Cardinal Health, Inc.*,<sup>42</sup> the Fifth Circuit ruled that a defendant could be liable under the FCA for a false certification of compliance with a regulatory requirement—even one that was “material” to the government’s decision to pay the claim—only if the payment by the government agency was conditioned on compliance with the statute, regulation, or contract provision. The relator in *Steury* claimed that by submitting claims for payment to the Veterans Administration for allegedly defective intravenous fluid pumps, Cardinal Health falsely and implicitly certified compliance with an implied warranty of merchantability. Without deciding whether it would adopt the implied false certification theory, the Fifth Circuit found that Cardinal Health did not make an implied certification simply because the FAR includes warranty of merchantability provisions. This basis for liability did not suffice because the FAR also allows the government to choose to override implied warranties of merchantability with express warranties, or to accept and pay for noncompliant commercial items. The court held that the claim could not be “false” within the meaning of the FCA if compliance with this warranty was not required in order to receive payment, and that “a false certification, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.”<sup>43</sup>

Moreover, the court found that determining whether a false certification is “material” under the expansive “natural tendency” definition of that term did not eliminate the applicability of the “prerequisite to payment” test.<sup>44</sup> The court concluded that there could be no liability in *Steury* because payment by the government agency was not conditioned on compliance with the certification alleged. The language used by the court in *Steury* permitted the argument that the Fifth Circuit would apply this “falsity” requirement in both express and implied certification cases. The Fifth Circuit’s analysis of falsity introduced a welcome concept—fundamental fairness—and imposed it on False Claims Act enforcement.

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*,<sup>45</sup> 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—

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<sup>41</sup> *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001).

<sup>42</sup> 625 F.3d 262 (5th Cir. 2010).

<sup>43</sup> *Id.* at 269.

<sup>44</sup> *Id.*

<sup>45</sup> 274 F.3d 687, 700 (2d Cir. 2001).

whether express or implied.<sup>46</sup> In validating the false certification theory of liability in *Escobar*, the Supreme Court declined to adopt “a circumscribed view of what it means for a claim to be false or fraudulent,” and shifted the analysis to focus on materiality, abrogating the express prerequisite to payment requirement in *Mikes*.

### 3. The Supreme Court’s Decision in *Escobar*

In *Universal Health Services v. United States ex rel. 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 analysis required to apply that theory.<sup>47</sup> 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”

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<sup>46</sup> 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. Ketroser 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 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).

<sup>47</sup> 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).

materiality standard, defined as under its “common-law antecedents” in fraudulent misrepresentation.<sup>48</sup> The *Escobar* decision is a game changer in the analysis of false certification claims—both express and implied, and its impact pervades every phase in the litigation of a false certification case.

**Two-Part Threshold Test.** The decision makes clear that the analysis of implied false certification claims is no longer limited to whether the violation of a prerequisite to payment rendered the claim “false,” although many courts may continue to find that analysis useful in applying the new standard. In any event, the focus is now squarely on a new “materiality” standard, defined as under the common law of fraudulent misrepresentation by omission. In *Escobar*, the Court found that the claims for payment 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, regulatory, or contractual condition that was “material” to the government’s payment decision.<sup>49</sup> Many courts interpret this two-part test as a threshold requirement for a valid false certification theory,<sup>50</sup> 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.”<sup>51</sup>

**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.”<sup>52</sup> This focus means that both government knowledge 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, continued approval of a drug or device, continued payment of claims, and even the decision not to intervene in the *qui tam* case—have been considered relevant to determining materiality.<sup>53</sup> For example, in *D’Agostino v. ev3, Inc.*, the First Circuit affirmed dismissal of a

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<sup>48</sup> 136 S. Ct. at 2002.

<sup>49</sup> *Id.* at 2001.

<sup>50</sup> *See, e.g.*, *United States ex rel. Rose v. Stephens Inst.*, No. 17-1511, 2018 WL 4038194 (9th Cir. Aug. 24, 2018); *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).

<sup>51</sup> *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).

<sup>52</sup> 136 S. Ct. 1989, 2003 (quoting Williston on Contracts).

<sup>53</sup> *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



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.<sup>54</sup> 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. This focus on the government’s knowledge, payment decisions, and payment practices is making it essential to take discovery from the government on these matters.<sup>55</sup>

**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.”<sup>56</sup> The Court clearly signaled that to keep the FCA from becoming an “all-purpose antifraud statute,”<sup>57</sup> facts supporting allegations of materiality must be pled, and false certification allegations must be closely scrutinized under its rigorous materiality standard.<sup>58</sup> Given the fact-specific nature of the materiality inquiry, it is not surprising that the *Escobar* materiality inquiry has resulted in

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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-1303-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*); *United States ex rel. Worthy v. E. Maine Healthcare Sys.*, No. 2:14CV00184-JAW, 2017 WL 211609 (D. Me. Jan. 18, 2017) (citing CMS’s previous actions as evidence that government would not have paid claims involving unbundling and double-billing). *Cf. United States ex rel. Prather v. Brookdale Senior Living Communities*, 892 F.3d 822 (8th Cir. 2018) (concluding that the government’s response to defendants’ claims had no bearing on the materiality analysis in this case); *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”).

<sup>54</sup> 845 F.3d 1 (1st Cir. 2016).

<sup>55</sup> *See United States ex rel. Dean v. Paramedics Plus LLC*, No. 4:14-CV-00203, 2018 WL 620776 (E.D. Tex. Jan. 30, 2018) (holding that *Escobar* affords FCA defendants the ability to broadly discover how the government actually has handled the disputed issue both in this case and others). *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).

<sup>56</sup> 136 S. Ct. 1989, 2003 & n.5.

<sup>57</sup> *Id.* at 2003 (quoting *Allison Engine*, 553 U.S. 662, 672).

<sup>58</sup> *Id.* at 2004 n.6.

decisions that find noncompliance material<sup>59</sup> as well as that dismiss complaints for not satisfying this materiality standard.<sup>60</sup>

**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,<sup>61</sup> 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.

#### 4. 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 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, and considers evidence of how the claim gets 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 el. Petratos v. Genentech Inc.*, the causation requirement is distinct from

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<sup>59</sup> See, e.g., *United States ex rel. Prather v. Brookdale Senior Living Communities*, 892 F.3d 822 (8th Cir. 2018) (finding materiality of timing requirement for physician’s certification sufficiently alleged); *United States ex rel. Rose v. Stephens Inst.*, No. 17-1511, 2018 WL 4038194 (9th Cir. Aug. 24, 2018) (finding compliance with incentive compensation ban material); *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).

<sup>60</sup> See, e.g., *D’Agostino*, 835 F.3d 1 (1st Cir. 2016); *United States ex rel. Winter v. Gardens Reg’l Hosp. & Med. Ctr.*, No. CV 14-08850-JFW (Ex), 2017 U.S. Dist. LEXIS 221356 (C.D. Cal. Dec. 29, 2017) (industry standards for inpatient admission not material under Medicare); *United States ex rel. Swoben v. Scan Health Plan*, No. 09-5013-JFW (JEMx), 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017) (dismissing government’s affirmative Medicare Advantage claims for insufficiently pleading materiality and scienter). 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).

<sup>61</sup> 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”). Cf. *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746 (3d Cir. 2017) (recognizing government knowledge defense to scienter and finding ample evidence that CMS knew about the industry practice of submitting dummy prescriber identifiers to avoid rejection of valid claims, but finding insufficient evidence that Caremark knew that CMS knew this).

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.<sup>62</sup>

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.<sup>63</sup> 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.”<sup>64</sup> 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 secondary insurers.<sup>65</sup> More recently, in *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 must show that a prescription reimbursement was submitted to the government for a tainted prescription of the drug.<sup>66</sup> As 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

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<sup>62</sup> 855 F.3d 481, 491 (3d Cir. 2017) (citing cases).

<sup>63</sup> 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”).

<sup>64</sup> 2003 WL 22048255, at \*6.

<sup>65</sup> 305 F. Supp. 2d 451 (E.D. Pa. 2004).

<sup>66</sup> 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 impacted Medicaid prescriptions).

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 off-label scheme, their failure to provide any representative false claim actually submitted to the government meant that the complaint did not satisfy Rule 9(b).

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.”<sup>67</sup> 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. A continuing concern is that too broad an interpretation of causation would impose liability on parties merely for failing to prevent the fraudulent acts of others. Therefore, courts have required some level of direct involvement through affirmative acts that cause the submission of false claims.<sup>68</sup>

For example, the Affordable Care Act amended the Antikickback Statute 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.”<sup>69</sup>

Following *Escobar*, however, most courts have adopted the proximate cause standard for FCA cases based on the reasoning that the statutory language “because of” clearly requires causation, the term “fraudulent” incorporates the common law meaning of fraud, and proximate cause 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

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<sup>67</sup> 553 U.S. 662, 672 (2008).

<sup>68</sup> See, e.g., *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 715 (10th Cir. 2006) (requiring an “affirmative act” that caused or assisted the submission of a fraudulent claim); *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 196 F. Supp. 3d 477 (E.D. Pa. July 26, 2016) (requiring a sufficient level of direct involvement in the scheme).

<sup>69</sup> 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). Cf. *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. 2018) (finding no evidence tying kickback to a federally insured patient’s claim); *United States ex rel. Fla. Soc’y of Anesthesiologists v. Choudhry*, 262 F. Sup. 3d 1299 (M.D. Fla. 2017) (finding that relator failed to allege a claim tied to a kickback). The *Kester* case has been settled and dismissed. See *Kester*, No. 11CV8196(CM), 2015 WL 13716148 (S.D.N.Y. Nov. 20, 2015).

reliance, and (2) the loss is within the foreseeable risk of harm that the fraudulent misrepresentation creates.<sup>70</sup>

## 5. 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.

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.<sup>71</sup> The government also has 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").<sup>72</sup> 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.<sup>73</sup> *Safeco* and *K & R Ltd.* made examinations of subjective intent unnecessary in FCA cases involving reasonable interpretations of ambiguous requirements where the government had not provided guidance.<sup>74</sup> The Eleventh Circuit modified this rule slightly in

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<sup>70</sup> 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 *Sikkenga*, 472 F.3d 702, 714 (10th Cir. 2006); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *United States v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981); *United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977).

<sup>71</sup> See *United States v. Krizek*, 859 F. Supp. 5 (D.D.C. 1994), *aff'd*, 111 F.3d 934 (D.C. Cir. 1997).

<sup>72</sup> 551 U.S. 47 (2007).

<sup>73</sup> 530 F.3d 980 (D.C. Cir. 2008).

<sup>74</sup> See, e.g., *United States ex rel. Streck v. Allergan, Inc.*, No. 17-1014, 2018 WL 3949031 (3d Cir. Aug. 16, 2018) (applying the "objectively reasonable interpretation" test and finding no FCA scienter); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015) (same); *United States ex rel. Ketroser 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

*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.<sup>75</sup> 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.”<sup>76</sup>

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.<sup>77</sup> 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.<sup>78</sup>

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

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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 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”).

<sup>75</sup> No. 16-10532, 2017 WL 2296878 (11th Cir. May 26, 2017).

<sup>76</sup> *Id.* at \*4.

<sup>77</sup> 626 F.3d 1257 (D.C. Cir. 2010).

<sup>78</sup> *Id.* at 1274.

result of, for instance, a communication failure, the fact-finder could determine that the corporation knowingly submitted a false claim.<sup>79</sup>

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 includes one more element that is critical to the "knowledge" requirement in FCA cases based on implied false certifications. While the D.C. Circuit accepted this basis for FCA liability, the court placed an important limit on its use:

Establishing knowledge under this provision on the basis of implied certification requires the plaintiff to *prove that the defendant knows* (1) that it violated a contractual obligation, and (2) *that its compliance with that obligation was material* to the government's decision to pay.<sup>80</sup>

This knowledge requirement is a critical limit on the use of the implied 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.

The Supreme Court adopted this additional knowledge requirement in *Escobar*:

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*.<sup>81</sup>

Requiring the FCA plaintiff to prove this additional knowledge element—that the defendant actually knew that compliance was material to the government—will be a significant impediment to false certification cases.

## 6. 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."<sup>82</sup>

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<sup>79</sup> *Id.* at 1275.

<sup>80</sup> *Id.* at 1271. (Emphasis added).

<sup>81</sup> S. Ct. 1989, 1996. (Emphasis added).

<sup>82</sup> 31 U.S.C. §3729(a)(1). (Emphasis added). As discussed below, the Justice Department recently has implemented major increases in the FCA's penalty range.

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.

**Damages.** In false certification cases, courts of appeals appear to be divided regarding whether a broad “but for” test or an actual loss test of causation is the proper measure of damages. In *United States v. Science Applications International Corp.*,<sup>83</sup> 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*,<sup>84</sup> 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. It measured the damages as the entire federal share of these claims to Medicare and Medicaid.<sup>85</sup> 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 *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*, 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

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<sup>83</sup> 626 F. 3d 1257 (D.C. Cir. 2010).

<sup>84</sup> 459 F. Supp. 2d 692 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

<sup>85</sup> *Id.* at 726-27.



worked on the project (a Davis-Bacon Act violation).<sup>86</sup> 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.<sup>87</sup> 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.”<sup>88</sup> 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 revisit 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.*,<sup>89</sup> 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*.<sup>90</sup> Given the Ninth Circuit’s decision that applied gross trebling in *United States v. Eghbal*,<sup>91</sup> a circuit split has emerged on this issue.

**Penalties.** One of the most feared remedies under the False Claims Act is its per claim penalty. The Justice Department recently implemented a major increase in the FCA’s penalty range, subject to upward adjustment annually—pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which is part of the Bipartisan Budget Act of 2015.<sup>92</sup> The initial adjustment in 2016 nearly doubled the prior penalty range—from \$5,500 -

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<sup>86</sup> 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>.

<sup>87</sup> *Id.* at \*2.

<sup>88</sup> *Id.* at \*1.

<sup>89</sup> 711 F.3d 745 (7th Cir. 2013).

<sup>90</sup> 423 U.S. 303 (1976). 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. at 317 n.13.

<sup>91</sup> 548 F.3d 1281 (9th Cir. 2008) (noting defendants’ concession that damages were subject to gross trebling, and stating that, in computing treble damages in *Bornstein*, “the Court specifically directed that ‘the Government’s actual damages are to be [multiplied] before any subtractions are made for compensatory payments previously received by the Government from any source’”).

<sup>92</sup> *See* Pub. L. No. 114-74, § 701, 129 Stat. 584, 599 (2015).

\$11,000 to \$10,781 - \$21,563.<sup>93</sup> The current range for FCA penalties is \$11,181 - \$22,363 for violations occurring after November 2, 2015 that are assessed on or after January 29, 2018.<sup>94</sup> While the enabling legislation for these increases was drafted in the innocent-sounding verbiage of inflation adjustments tied to the Consumer Price Index, their impact on civil fraud defendants is substantial—considering that the FCA penalty range has more than doubled within two years of the 2015 Budget Act’s enactment. The legislation’s authorization of further, automatic annual adjustments without any agency assessment of the need for an increase raises the potential for an Administrative Procedure Act challenge. These 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.<sup>95</sup> In *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, the Fourth Circuit adopted an unprecedented and unsettling approach to FCA damages in a *qui tam* case.<sup>96</sup> 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.<sup>97</sup> 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.

## **7. 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,<sup>98</sup> 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:

(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—

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<sup>93</sup> See Civil Monetary Penalties Inflation Adjustment, 81 Fed. Reg. 42,491, 42,494 (June 30, 2016).

<sup>94</sup> See Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018) (FCA penalties to be codified at 28 C.F.R. § 85.3(a)(9)).

<sup>95</sup> See, e.g., *United States v. Cabrera-Diaz*, 106 F. Supp.2d 234 (D.P.R. 2000) (refusing to impose any penalties at all, because they would be excessive). See also *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001) (holding that FCA damages and penalties are subject to Eighth Amendment limitations).

<sup>96</sup> No. 12-1369 (4th Cir. Dec. 19, 2013).

<sup>97</sup> 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/index.cfm?pageID=25&itemID=6834>.

<sup>98</sup> ACA, Pub. L. No. 111- 148, 124 Stat. 119, 901-02 (2010) (amending 31 U.S.C. § 3730(e)(4)).

- (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,<sup>99</sup> the 2010 amendments eliminate the word “jurisdiction,” and replace 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 so far.<sup>100</sup>

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 overrule the Supreme Court’s holding in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, (“*Graham County II*”)<sup>101</sup> 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.<sup>102</sup>

The 2010 amendments also revised the original source exception to provide two alternatives. Under the first alternative, the individual must “voluntarily disclose” to the

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<sup>99</sup> See *Rockwell Int’l Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397, 1406 (U.S. 2007).

<sup>100</sup> 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).

<sup>101</sup> 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*.

<sup>102</sup> Cf. *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2018 WL 2688424, at \*9 (E.D. Pa. June 4, 2018) (ruling that the government becomes a party to the entire case when it intervenes in part).

government the information on which “the allegations or transactions” are based “prior to a public disclosure.” Under the second alternative, rather than requiring the original source to have both “direct” and “independent” knowledge of the alleged fraud, the individual’s knowledge must be “independent” of and “materially add” to the publicly disclosed allegations, and the information must be “voluntarily provided” to the government before filing suit. The courts are developing standards for the “materially adds” requirement case by case. For example, 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.”<sup>103</sup> 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 focus of the settled suit 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.<sup>104</sup>

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.<sup>105</sup>

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. In *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, the Supreme Court resolved a circuit split on whether the phrase “pending action” was a timing requirement or a shorthand reference to the first-filed action that distinguishes the first action from subsequent actions. The Supreme Court determined that the word “pending” should be interpreted according to its ordinary meaning and definition in Black’s and Webster’s dictionaries as “remaining undecided.”<sup>106</sup> Subsequently,

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<sup>103</sup> 762 F.3d 688, 694 (8th Cir. 2014).

<sup>104</sup> 809 F.3d 365 (7th Cir. 2016). *See United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201 (1st Cir. 2016) (finding that relator’s personal knowledge of overbilling was unnecessary because public disclosures made it clear that CVS was not providing its health savings program prices to Medicaid, and by extension, to Medicare Part D); *United States ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, No. 11Civ. 00181 (BMC), 2018 WL 1320658, at \*13 (E.D.N.Y. Mar. 14, 2018) (finding results from relator’s parallel studies were not materially different from those arrived at earlier by others).

<sup>105</sup> *See Graham County II*, 130 S. Ct. 1396, 1400 n.1 (2010). To the extent that it is not effectively foreclosed under *Schumer*, this will be a disputed issue, with defendants arguing, as they did in *Schumer*, that the *qui tam* amendments should not be given retroactive effect because they would enlarge liability and eliminate defenses in *qui tam* suits, and relators arguing in favor of retroactivity. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 948 (1997).

<sup>106</sup> 135 S. Ct. 1970 (U.S. 2015).

courts have become divided on other interpretive questions not answered in *Carter*, such as what happens *after* dismissal of the “pending action,” with the majority holding that a first-to-file violation cannot be cured by amending a complaint brought when the first-filed action was pending.<sup>107</sup>

## 8. 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.<sup>108</sup> To satisfy this requirement, the complaint must set forth specifics as to who, what, when, where, and how regarding the fraud alleged.<sup>109</sup> 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 proof requirements, and this approach helps to define the contours of FCA liability. However, some relaxing of the heightened standard has occurred in certain *qui tam* cases, in particular, in third-party inducement claims, where the details of a fraudulent scheme have been alleged with specificity but no actual false claim was pled.

As the *Escobar* decision reflects, the False Claims Act was not designed to punish every type of fraud committed upon the government. 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.”<sup>110</sup> Despite this key requirement for FCA liability, a clear circuit split has

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<sup>107</sup> Compare *United States ex rel. Carter v. Halliburton Co.*, No. 1:11cv602, 2015 WL 7012542 (E.D. Va. Nov. 12, 2015) (ruling that subsequent relator’s action must be dismissed and refiled because no amendment could cure the first-to-file violation), and *United States ex rel. Shea v. Verizon Commc’ns, Inc.*, No. 09-1050 (GK), 2015 WL 7769624 (D.D.C. Oct. 6, 2016) (same), with *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015) (ruling that Rule 15(d) allowed second relator to amend complaint once related first-filed action was dismissed).

<sup>108</sup> See, e.g., *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1<sup>st</sup> Cir. ); *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).

<sup>109</sup> 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).

<sup>110</sup> *United States ex rel. Nathan v. Takeda Pharms., N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013).

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,<sup>111</sup> although 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.<sup>112</sup> The fact that the lower standard is not applied consistently even within individual circuits that have applied it,<sup>113</sup> and the subsequent dismissals in cases where the inference that false claims were submitted was not borne out following discovery,<sup>114</sup> 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.<sup>115</sup> 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 scheme.<sup>116</sup> These challenges are at odds with the FCA's pleading and proof requirements, which

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<sup>111</sup> 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. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849 (7th Cir. 2009); *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).

<sup>112</sup> See, e.g., *Nathan*, 707 F.3d 451 (4th Cir. 2013).

<sup>113</sup> 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).

<sup>114</sup> 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).

<sup>115</sup> See *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).

<sup>116</sup> 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).

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.

## 9. 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,<sup>117</sup> 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 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.<sup>118</sup> This revision restores 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.<sup>119</sup>

Courts are delineating the application of 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

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<sup>117</sup> See BOESE, § 4.11[B][2][b] (discussing the term "employer" and the independent contractor issue).

<sup>118</sup> Pub. L. No. 111-203, § 3301, 124 Stat. 1376 (2010).

<sup>119</sup> 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).

applicants or non-employer corporations.<sup>120</sup> 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.<sup>121</sup> 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 the government, the retaliation claim has been dismissed.<sup>122</sup> Refusing to participate in the fraud alone has not been deemed protected activity.<sup>123</sup>

### 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.<sup>124</sup> There are now 29 of these state laws, and they are increasing false claims visibility, enforcement actions, and recoveries.<sup>125</sup> 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 addition to increased FCA penalties, in order to qualify for the DRA incentive.

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<sup>120</sup> 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. *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").

<sup>121</sup> See, e.g., *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, No. 1:11-cv-029 (WOB), 2015 WL 1439054 (S.D. Ohio Mar. 27, 2015) (complaint plausibly pled protected activity in alleging that relators reported misconduct "up the chain of command"); *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).

<sup>122</sup> See *Lee v. Computer Scis. Corp.*, No. 1:14cv581 (JCC/TCB), 2015 U.S. Dist. LEXIS 21998 (E.D. Va. Feb 24, 2015).

<sup>123</sup> See *United States ex rel. Tran v. Computer Scis. Corp.*, No. 11-cv-0852 (KBJ), 2014 WL 2989948 (D.D.C. July 3, 2014). Cf. *Rodriguez v. Reston Hosp. Ctr., LLC*, No. 1:16CV623 (JCC/JFA), 2017 WL 772348 (E.D. Va. Feb. 28, 2017) (finding plaintiff's opposition to backdating assessments an attempt to stop a possible violation).

<sup>124</sup> 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>.

<sup>125</sup> See BOESE, Chapter 6 (discussing individual state and municipal false claims laws).



**Appendix 1**  
**Redline False Claims Act**

# 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;

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

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

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

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

~~(e) 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 Arbour 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 Scierter 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 scierter 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 scierter 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 scierter 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**  
**Motions in Limine**

## **Topics for Motions in Limine in FCA Cases**

Exclusion of relator testimony about “fraud” as a legal conclusion

Evidence of assertion of Fifth Amendment privileges in prior cases

Exclusion of references to grand jury or government investigations

Evidence of out-of-state conduct

Evidence about claims other than those at issue

Expert qualifications under *Daubert*. See, e.g., *United States ex rel. Plaintiffs v. AseraCare Inc.*, No. 2:12CV245-KOB, 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014) (granting and denying motions); *Veridyne Corp. v. United States*, No. 06-150C, 2011 WL 6017920 (Fed. Cl. Dec. 5, 2011) (finding government expert witness’s testimony inadmissible).

Expert testimony on statistical sampling and extrapolation. See, e.g., *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, No. 8:11-cv-1303-T-23TBM, 2015 WL 1926417 (N.D. Fla. Apr. 28, 2015) (allowing testimony); *United States ex rel. Plaintiffs v. AseraCare Inc.*, No. 2:12CV245-KOB, 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014) (allowing jury to decide questions of credibility, fact, and relative weight to give statistical sampling evidence); *United States ex rel. Loughren v. Unumprovident Corp.*, 604 F. Supp. 2d 259 (D. Mass. 2009) (granting motion in limine and excluding testimony of expert who used statistical techniques to extrapolate from the number of false claims within a sample of claims to estimate the total number of false claims filed).

Expert testimony on defendant’s conduct. *Simoneaux v. E.I. Du Pont De Nemours & Co.*, No. 12-219-SDD-SCR, 2014 WL 5453587 (M.D. La. Oct. 27, 2014) (ruling that expert could not give an opinion on the “reasonableness” of the defendant’s conduct because it was the ultimate issue for the jury).

Evidence of government’s continuing contracts with defendant. *United States ex rel. Ubl v. IIF Data Solutions*, No. 009-2280, 2011 WL 1474783 (4th Cir. Apr. 19, 2011) (ruling that this evidence was properly admitted).

Evidence of damages. See, e.g., *Veridyne Corp. v. United States*, No. 06-150C, 2011 WL 6017920 (Fed. Cl. Dec. 5, 2011) (ruling lay witness testimony offered to show intangible harm to SBA program inadmissible); *United States ex rel. Purcell v. MWI Corp.*, No. 98-2088 (GK), slip op. (D.D.C. Nov. 6, 2013) (allowing defendant’s evidence of loan repayment).

Retaliation claims. See, e.g., *Murphy vs. Baptist Medicare, Inc.*, No. 4:02-cv-440, U.S. Dist. LEXIS 104991 (E.D. Ark. Dec. 22, 2008) (excluding evidence of similar employee dismissed by same individual at another company); *Takeh v. United Planning Organization, Inc.*, DDC No 05-1271 (GK), 587 F. Supp. 2d 125 (Nov. 19, 2008) (rulings on various motions in limine).

Failure to disclose witness in a timely fashion. *Williams v. C. Martin Co.*, No. 07-6592, 2014 WL 3385129 (E.D. La. July 10, 2014).