Chapter 11

Government Investigations Under the False Claims Act and Its Qui Tam Provisions

§ 11:1 Introduction

Over the past several years, government investigations of corporations have become increasingly focused on potential liability under the federal False Claims Act (FCA), a potent civil statute whose ancestry traces to the Civil War.[1] The FCA imposes treble damages, plus monetary penalties, for submitting false or fraudulent claims for payment of government funds. FCA charges are often an outgrowth of, or concomitant with, criminal investigations of fraud regarding government programs. FCA actions also can be initiated by private persons, called relators, on behalf of the government under the FCA's qui tam provisions, which allow relators to share in the monetary recovery of the government. Beyond the federal FCA, nearly every state, and even some municipalities, have enacted their own false claims act analogues with similar qui tam and multiple-damages provisions.[2]

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1. 31 U.S.C. § 3729 *et seq.*
2. *See, e.g.*, N.Y. STATE FIN. LAW §§ 187–94 (2010); CAL. GOV'T CODE §§ 12650–12656 (2010); 740 ILL. COMP. STAT. 175/1-8 (2010); N.Y.C. Admin. Code § 7-801 *et seq.* (2005) (New York City false claims act). Under the Deficit Reduction Act of 2005 § 6031, 42 U.S.C. § 1396(h), a state qualifies for enhanced Medicaid recovery if it has a false claims act as effective as the federal False Claims Act. Some states have enacted provisions in their false claims acts that permit wider application than the federal FCA. *See, e.g.*, N.Y. STATE FIN. LAW § 189(4) (extending liability to claims, records, or statements made under the tax law, which are explicitly excluded from liability under the federal FCA, 31 U.S.C. § 3729(e)); MASS. GEN. LAWS ANN. ch. 12, § 5B (providing for recovery of consequential damages, which are not recoverable under the federal

As a result, companies can find themselves targeted by the government under the FCA or state analogues, as well as by private persons—including current or former employees—who claim to have inside knowledge of alleged fraud.

In May 2009, President Obama signed the Fraud Enforcement and Recovery Act of 2009,[3] amending the FCA to expand its scope and upending various court rulings that, in the words of the House report, "created a complex patchwork of procedural and jurisdictional hurdles that have often derailed meritorious actions and discouraged private citizens from filing qui tam actions."[4] In 2010, the FCA was further amended as part of the new healthcare reform law, the Patient Protection and Affordable Care Act,[5] to make explicit that claims submitted as a result of illegal kickbacks constitute false claims under the FCA, and to limit the ability of defendants to dismiss relator suits where information about the alleged fraud has been publicly disclosed.[6]

Exposure to FCA liability extends to situations in which a corporation is not directly contracting with the government, particularly as the 2009 amendment now defines "claim" to include invoices and bills that are paid with federal government funds that are funneled through a private party to advance a "Government program or interest."[7] Even prior to this amendment, the substantial damages and bounty-hunting features of the FCA provisions encouraged attempts by law enforcement agencies and relators to extend the reach of the FCA to conduct that would not appear, on the face of the act, to fall

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FCA); TEX. HUM. RES. CODE § 36.052(a)(3) (providing enhanced penalties of up to $15,000 per unlawful act that results in injuries to elderly, disabled or minor persons).

3. Pub. L. No. 111-21 (FERA), 123 Stat. 1617 (2009).
4. H.R. REP. NO. 111-97, at 2 (2009).
5. Pub. L. No. 111-148 (PPACA), 124 Stat. 755 (2010).
6. *See* 31 U.S.C. § 3730. In 2021, a bipartisan bill was introduced in the Senate that would amend the FCA to: (1) set forth the proof needed to establish or rebut materiality (*see infra* section 11:4.3); (2) impose costs on defendants seeking burdensome discovery from the government in declined cases; (3) set parameters for court hearings when the government seeks dismissal of declined cases; and (4) extend retaliation protection to former employees. False Claims Amendments Act of 2021, S. 2428, 107th Cong. (2021). In July 2023, after no final legislative action was taken on that bill, Senator Charles Grassley and others reintroduced legislation amending the FCA that focused only on the proof needed regarding materiality and anti-retaliation protections for former employees. As of September 2024, there has been no further action on the reintroduced legislation.
7. 31 U.S.C. § 3729(b)(2).

within its purview—a trend that the 2009 amendments have accelerated. For example, pharmaceutical companies are routinely investigated under the FCA based on claims submitted to government agencies by doctors, pharmacies, and other healthcare providers—claims that result from the treatment of patients in which those companies are not directly involved.

The prospect of large damage recoveries also prompts FCA investigations and qui tam suits. The Department of Justice (DOJ) regularly announces multi-million-dollar settlements—and some multi-billion-dollar settlements—with targets of FCA actions.[8] Indeed, the potential damages exposure can be immense—damages can be based on the entire amount of an alleged false claim even if only a portion was inflated, or if the government received full value. That amount is then trebled, *and* penalties are then tacked on to the trebled damage amount. Exclusion of a defendant, or its employees, from participation in federal programs is also a possible consequence of an FCA violation. Given the hefty financial penalties of the FCA and its increasing use in government investigations of corporations, counsel should be familiar with the FCA's statutory regime as well as the body of law interpreting its provisions.

§ 11:2 The FCA Statute

§ 11:2.1 Liability and Damages Provisions

The FCA imposes liability for seven categories of conduct. The most frequently invoked provision imposes liability against a person who "knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval."[9] A person not in privity with

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8. In the fiscal year ending September 30, 2023, DOJ secured over $2.68 billion in settlements and judgments in civil cases involving fraud against the government. Since 1986, total recoveries under the False Claims Act have reached more than $52 billion. Press Release No. 24-203 False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023 (Feb. 22, 2024). Of that 2023 total, more than $1.8 billion related to claims involving federal healthcare programs such as Medicare and Medicaid. Of the total recovery, over $2.3 billion related to lawsuits brought by relators under the FCA's qui tam provisions.

9. 31 U.S.C. § 3729(a)(1)(A). Prior to the 2009 amendments, this provision required that a claim be "presented, to an officer or employee of the United States government" or member of the military. Because this change is not retroactive to conduct occurring prior to the amendment, determining whether a claim submitted to a third party, such as a government contractor, was presented to the federal government may still be important when defending an FCA case based on dated conduct.

the government regarding a claim can nevertheless be liable under section 3729(a)(1)(A) as someone who causes the submission of a false claim. Liability also attaches to making a false record or statement "material to a false or fraudulent claim," conspiracy, and improperly avoiding an obligation to pay money to the government. The latter is commonly termed a "reverse false claim."[10] False-record liability under 31 U.S.C. § 3729(a)(1)(B) has often been described as a "safety net" for government FCA charges because liability will most often attach under section 3729(a)(1)(A) as well. Prior to the 2009 amendments, liability under 31 U.S.C. § 3729(a)(1)(B) could arise only where a false record or statement was used or made "to get" a false or fraudulent claim paid. The 2009 amendment imposes liability where the false record or statement is "material" to a false or fraudulent claim, a change that reduces the required level of intent[11] and eliminates any requirement that the false claim actually have been paid.[12] Congress declared that this change is retroactive to "claims" pending as of June 7, 2008—the date of the Supreme Court decision the amendment seeks to reverse.[13] The circuit courts have split over the question of whether retroactivity applies only to claims pending on June 7, 2008—that is, unpaid claims for payment to the government—or to pending cases, as the government has argued.[14]

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10. 31 U.S.C. § 3729(a)(1)(B), (C), (G). In addition, the FCA contains three other liability provisions addressing conduct that less frequently arises: liability where someone in possession of government property delivers back to the government less property than that for which the defendant had been given a receipt; liability for making a false certification of receipt of property to the government; and purchasing property from the government knowing that the person selling the property is not authorized to sell it. 31 U.S.C. § 3729(a)(1)(D)–(F).
11. *See infra* section 11:4.2.
12. *See* United States v. Aguillon, 628 F. Supp. 2d 542, 550 n.11 (D. Del. 2009) ("the amended FCA arguably would allow civil penalties without proof of actual payment or approval of the false claims").
13. FERA § 4(f)(1).
14. *Compare* U.S. *ex rel.* Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co., 5 F.4th 315, 331 (3d Cir. 2021) ("Congress used 'claims' generically in FERA's retroactivity provision to mean cases or lawsuits"), U.S. *ex rel.* Cafasso v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1051 n.1 (9th Cir. 2011) (stating that "[t]hese amendments do not apply retroactively to this case"), *and* Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1327 n.3 (11th Cir. 2009) (finding that FERA does not apply retroactively because no reimbursement claims, as defined by FCA, were pending as of June 7, 2008), *with* U.S. *ex rel.* Garbe v. Kmart Corp., 824 F.3d 632, 641 (7th Cir. 2016) ("we have no trouble concluding that the word 'claims' . . . means 'cases'"), Sanders v. Allison Engine Co., 703 F.3d 930, 941–42 (6th Cir. 2012) (holding that "claim" in § 4(f)(1) refers to a civil action

A "reverse false claim" focuses on whether a defendant "avoids or decreases an obligation to pay or transmit money or property to the Government."[15] A defendant must be aware of both the obligation and his or her violation of that obligation.[16] No obligation exists if some discretionary government action is necessary to enforce it.[17] Nor is

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or case and applying FERA retroactively to the very case in which the Supreme Court's decision led Congress to amend the FCA), *and* U.S. *ex rel.* Kirk v. Schindler Elevator Corp., 601 F.3d 94, 113 (2d Cir. 2010) (ruling, without significant discussion, that "claims" under FERA § 4(f)(1) referred to "cases"), *rev'd on other grounds*, 563 U.S. 401 (2011). The Fifth Circuit has taken both positions. *Compare* Gonzalez v. Fresenius Med. Care N. Am., 689 F.3d 470, 475 & n.4 (5th Cir. 2012) (accepting the district court conclusion that FERA's retroactivity provision did not apply because no "claims" as defined by the FCA were pending on June 7, 2008), *with* U.S. *ex rel.* Steury v. Cardinal Health, Inc., 625 F.3d 262, 267 n.1 (5th Cir. 2010) (concluding that the current § 3729(a)(1)(B) applies retroactively to a complaint pending on June 7, 2008).

15. 31 U.S.C. § 3729(a)(1)(G). A provision of the 2010 healthcare reform law provides that a Medicare or Medicaid overpayment to a service provider, supplier, or managed care organization (but not a beneficiary) that is not returned within certain deadlines constitutes an "obligation" to the government that is actionable under the FCA. *See* PPACA § 6402. *See also* UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021) (upholding the Medicare overpayment rule as to Medicare Advantage plans).

16. U.S. *ex rel.* Harper v. Muskingum Watershed Conservancy Dist., 842 F.3d 430 (6th Cir. 2016). The obligation must exist at the time of the alleged improper conduct even if the amount of the obligation is not fixed. U.S. *ex rel.* Petras v. Simparel, Inc., 857 F.3d 497, 506–07 (3d Cir. 2017). *See also* U.S. *ex rel*. Angelo v. Allstate Ins. Co., 106 F.4th 441 (6th Cir. 2024) (plaintiff must show an "established duty," meaning "an affirmative obligation to pay money or property" to state a reverse FCA claim).

17. U.S. *ex rel*. Kasowitz Benson Torres LLC v. BASF Corp., 2019 WL 2896005 (D.C. Cir. July 5, 2019) (an unassessed potential regulatory penalty is not an obligation under the FCA); U.S. *ex rel.* Niazi v. CVS Pharmacy, Inc., 2018 WL 654289, at *6 (C.D. Cal. Jan. 31, 2018) (same); U.S. *ex rel.* Barrick v. Parker-Migliorini Int'l, LLC, 878 F.3d 1224, 1231 (10th Cir. 2017) (no obligation where "government officials were afforded discretion to determine whether to charge fees . . . ." (citation omitted)); U.S. *ex rel.* Simoneaux v. E.I. duPont de Nemours & Co., 843 F.3d 1033 (5th Cir. 2016) (no obligation if the government did not initiate a proceeding to assess an environmental penalty); U.S. *ex rel.* Landis v. Tailwind Sports Corp., 160 F. Supp. 3d 253 (D.D.C.), *reconsideration denied*, 167 F. Supp. 3d 80 (D.D.C. 2016) (requiring "a self-executing obligation to tender money or property"). *But see* Ruscher v. Omnicare, Inc., 2014 WL 4388726, at *5 (S.D. Tex. Sept. 5, 2014) ("The fact that some discretion is involved . . . does not preclude False Claims Act liability.").

there reverse FCA liability if the existence of the obligation depends on multiple assumptions or is potential or contingent.[18]

An FCA violation results in damages of "three times the amount of damages which the government sustains because of the act of that person," plus civil penalties.[19] As a result of legislation that took effect on August 1, 2016, the civil penalties that could be recovered under 31 U.S.C. § 3729(a)(1) nearly doubled from the range previously in effect.[20] As of June 19, 2020, the penalties range from $11,665 to $22,331 as to "violations" that occurred after November 2, 2015.[21]

The Supreme Court has held that the purpose of the FCA's treble damages provision is to ensure that the government has been "made completely whole."[22] Courts have diverged on whether to measure damages by the actual financial harm to the government or by the entire amounts paid to the defendant by the government. A recent Ninth Circuit case held that "the proper measure of damages" when a defendant provided a good or service to the government is the difference in value of the good or service had it been provided as promised.[23] But the Ninth Circuit pointed out that damages could be the entire amount paid by the government for the good or service where a defendant "lied about a fact that would have prevented the government for paying for a product or service had it known the truth."[24] In another case, the U.S. District Court for the District of Columbia held that the government had no damages where, despite defendant's fraud in securing loans from the Export-Import Bank, the loans had been paid back in full with interest.[25] The D.C. and Sixth Circuits

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18. U.S. *ex rel.* Sibley v. Univ. of Chi. Med. Ctr., 44 F.4th 646 (7th Cir. 2022); *see also* Miller v. U.S. *ex rel.* Miller, 2024 WL 3658830 (2d Cir. Aug. 6, 2024) (ruling that "potential or contingent exposure to penalties does not create an 'established' duty to pay").
19. 31 U.S.C. § 3729(a)(1). The statute allows for double instead of treble damages under very narrow circumstances in which a defendant fully cooperated with the government *prior to* the commencement of an investigation. 31 U.S.C. § 3729(a)(2).
20. *See* 28 C.F.R. § 85.5; Civil Monetary Penalties Inflation Adjustment, 81 Fed. Reg. 42,491, 42,501 (June 20, 2016).
21. 28 C.F.R. § 85.5. For violations that occurred on or after September 29, 1999, and on or before November 2, 2015, the civil penalties range from $5,500 to $11,000. *See id*. § 85.3(a)(9).
22. United States v. Bornstein, 423 U.S. 303, 314–15 (1976).
23. U.S. *ex rel*. Hendrix v. J-M Mfg. Co., 76 F.4th 1164, 1174 (9th Cir. 2023).
24. *Id*. at 1175 (stating that in such cases the government is entitled for damages of the entire amount paid because it was "legally barred from paying anything" for the service).
25. U.S. *ex rel.* Purcell v. MWI Corp., 15 F. Supp. 3d 18, 29–30 (D.D.C. Feb. 10, 2014). The D.C. Circuit reversed this case on the ground that

have focused on the value the government received from the underlying transaction when determining damages.[26] In a case alleging that a defendant's claims to Medicaid lacked adequate supporting documentation but reflected services that were provided, the D.C. Circuit stated that no damages were due "because the Government has gotten what it paid for."[27] The First Circuit affirmed that FCA case damages are typically measured under a breach of contract theory—the "difference between the value that the government received and the amount that it paid."[28] In other cases, however, courts have held that where a defendant makes false statements to gain entitlement to federal programs or claims resulting from alleged kickbacks, damages are the full amount of the government's payments to that defendant.[29] A lower court noted the "substantial variance" of case law on

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defendants did not knowingly submit a false claim, rendering the damages point moot. U.S. *ex rel.* Purcell v. MWI Corp., 807 F.3d 281, 283 (D.C. Cir. 2015); *see also* U.S. *ex rel.* Landis v. Tailwind Sports Corp., 308 F.R.D. 1, 6 (D.D.C. 2015) (stating that a "showing of damage" is necessary to obtain treble damages). The court in the *Landis* case, which involved allegations related to doping by Lance Armstrong, later ruled no damages would be allowed unless the relator could establish that the negative consequences of the USPS's sponsorship agreement of Armstrong outweighed the benefits the USPS received from that agreement. U.S. *ex rel.* Landis v. Tailwind Sports Corp., 324 F. Supp. 3d 67 (D.D.C. 2018).

26. United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1278 (D.C. Cir. 2010) (government was not entitled to the full value of payments to contractor because the court needed to consider the value of delivered services); U.S. *ex rel.* Wall v. Circle C Constr., LLC, 813 F.3d 616, 618 (6th Cir. 2016) (determining if government got "less value than it bargained for" when calculating damages).

27. U.S. *ex rel.* Davis v. District of Columbia, 679 F.3d 832, 840 (D.C. Cir. 2012); *see also* U.S. *ex rel.* Harman v. Trinity Indus., Inc., 872 F.3d 645, 653 (5th Cir. 2017) (damages should be zero if the government received products of equivalent value to those it expected); Baklid-Kunz v. Halifax Hosp. Med. Ctr., 2014 WL 2968251, at *4 (M.D. Fla. July 1, 2014) (holding that the measure of damages in a case in which relator claimed the hospital billed the government outpatient services as inpatient services was the "difference between what the government paid and the value of what it received"); United States v. Everglades Coll., Inc., 2014 WL 5139301, at *11–12 (S.D. Fla. Aug. 14, 2014) (finding no damage from false certifications by college regarding incentive compensation to its recruiters because no showing at trial that the government would have withdrawn all funding if it had known the truth and the government still would have paid expenses for students had they attended other schools).

28. U.S. *ex rel*. CSILO v. J.C. Remodeling, Inc., 962 F.3d 34 (1st Cir. 2020) (holding that district court did not abuse discretion in denying relator's attempt to add damage claim).

29. *See, e.g.*, United States v. Saavedra, 661 F. App'x 37 (2d Cir. 2016) (damages are the full value of fraudulently obtained grants); U.S. *ex rel.*

the measure of damages, which it noted depended on the facts of each case and whether it was possible to put a value on any nonconforming items purchased by the government.[30]

The statute is silent on whether penalties apply to each false claim or to each instance of defendant's fraudulent conduct. The answer may vary depending on whether defendant submits claims directly or causes someone else to submit claims. In *United States v. Bornstein*, the Supreme Court, interpreting a forfeiture provision in a previous version of the FCA, found that a subcontractor defendant committed only three acts that resulted in false claims, even though the prime contractor had submitted thirty-five claims.[31] Other courts have imposed penalties based on the number of claims or invoices to the government, usually in cases involving defendants who directly submitted such claims.[32]

The amount of penalties is within the discretion of the district court. To determine where in the range of penalties the defendant's conduct falls, courts generally consider the "totality of circumstances," which could include defendant's scienter, actual knowledge

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Drakeford v. Tuomey, 792 F.3d 364, 386–87 (4th Cir. 2015) (in Stark Law case prohibiting unlawful referrals, government damage is full amount of payments to offending hospital for medical services); United States v. Anghaie, 633 F. App'x 514, 519 (11th Cir. 2015) (damage to the government was the full amount of contract payments to a defendant that lied about being a small business); U.S. *ex rel.* Fesenmaier v. Cameron-Ehlen Grp., 2023 WL 36174, at *3 (D. Minn. Jan. 4, 2023) ("courts addressing damages calculations in FCA cases premised on AKS violations have routinely held that the proper measure of damages is the full amount paid for any false claims"); U.S. *ex rel.* Emanuele v. Medicor Assocs., 2017 WL 4867614, at *5, *9 (W.D. Pa. Oct. 26, 2017) (damages are the full amount of payments resulting from illegal referrals or kickbacks); U.S. *ex rel.* Savage v. Wash. Closure Hanford LLC, 2017 WL 3667709, at *3–4 (E.D. Wash. Aug. 24, 2017) (damages are the full amount of government payments to a business falsely qualifying as a small business); United States v. R.J. Zavoral & Sons, Inc., 2014 WL 5361991, at *15 (D. Minn. Oct. 21, 2014) (same).

30. *See* United States v. J-M Mfg. Co., 2018 WL 1801258 (C.D. Cal. Apr. 12, 2018).

31. United States v. Bornstein, 423 U.S. 303, 313 (1976); *see also* United States v. Thompson, 2017 WL 3738500, at *6 (D.S.D. Aug. 30, 2017) (assessing penalties based on the specific conduct of the defendant); *see also Hendrix*, 76 F.4th at 1173 ("courts applying the federal FCA have awarded penalties based on the number of contracts or invoices but not on each good.").

32. *See, e.g.*, U.S. *ex rel.* Maxwell v. Kerr-McGee Oil & Gas Corp., 2010 WL 3730894, at *4 (D. Colo. Sept. 16, 2010); United States v. Incorporated Village of Island Park, 2008 WL 4790724 (E.D.N.Y. Nov. 3, 2008).

of deliberate misconduct, the amount of damages suffered by the government, and the amount of resources expended to pursue the case.[33] Some courts have applied the Excessive Fines Clause of the Eighth Amendment to penalty claims.[34]

A violation of the FCA can also lead to debarment of a defendant from participation in federal programs under various statutes and regulations. For example, an FCA defendant could be excluded from "participation in any Federal health care program" if it has committed fraud, which is defined in terms that closely parallel the FCA.[35] Debarment may also extend to culpable individuals. Debarment for civil violations like the FCA is usually in the discretion of the relevant agency, while debarment for felony criminal convictions is usually mandatory.[36]

§ 11:2.2 Qui Tam Provisions

Section 3730 of the FCA contains detailed provisions setting forth the manner in which relators are to commence actions, including procedural and jurisdictional requirements. Familiarity with these procedures will help inform a company's response to a government investigation that may have been prompted by an underlying qui tam action. In an important development, Justice Thomas contended in a 2023 dissent that the qui tam provisions of the FCA could be unconstitutional because they delegate Article II executive power to private

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33. *See Purcell*, 15 F. Supp. 3d at 31; United States v. Dynamic Visions, Inc., 2017 WL 4773104, at *5 (D.D.C. Oct. 20, 2017) (consider "the totality of the circumstances," including the seriousness of the misconduct, scienter and the amount of damages); U.S. *ex rel.* Miller v. Bill Harbert Int'l Constr., Inc., 501 F. Supp. 2d 51, 56 (D.D.C. 2007); Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429, 434–35 (Fed. Cl. 1994) (noting that penalties are intended to "compensate the government for the costs of corruption").

34. *See* Grant v. Zorn, 107 F.4th 782 (8th Cir. 2024) (holding that Eighth Amendment's Excessive Fines Clause applies to FCA, including to a non-intervened case litigated by relator); U.S. *ex rel*. Fesenmaier v. Cameron-Ehlen Grp. 2024 WL 489708 (D. Minn. Feb. 8, 2024) (reducing penalties due to Eighth Amendment concerns); *see also* Stop Ill. Health Care Fraud, LLC v. Sayeed, 100 F.4th 899 (7th Cir. 2024) (noting skepticism about whether the Eighth Amendment applies to civil penalties under the FCA, but not resolving issue as it found the fines not unconstitutionally excessive).

35. 42 U.S.C. §§ 1320a-7, 1320a-7a. The statute does not define the term "participation" in a federal healthcare program, but it could conceivably encompass Medicare and Medicaid reimbursement with respect to products made by a corporate defendant.

36. *Id*.

entities.[37] That view, in which Justices Kavanaugh and Barrett joined, has fueled arguments by defendants challenging the constitutionality of the entire qui tam process that courts will grapple with going forward. Recently, a Florida district court judge found the FCA's qui tam provisions unconstitutional under the Appointments Clause, dismissing an action with prejudice that a relator had been litigating on her own for five years.[38] This issue will undoubtedly continue to come up in declined qui tam cases.

[A] Complaint Filed Under Seal

After filing an FCA qui tam action under seal, a relator must serve on the government a copy of the complaint accompanied by "written disclosure of substantially all material evidence and information the person possesses."[39] The complaint must be filed in camera and remains under seal for at least sixty days while the government determines whether to intervene and take over the action, or to decline, in which case the relator may proceed as plaintiff in the case on behalf of the government.[40] Once a qui tam is unsealed, the relator must serve the complaint within the ninety-day period of Federal Rule of Civil Procedure 4(m).[41] The government may move on good cause for extensions to the sealing period while it conducts its investigation—a common practice that often results in long investigatory periods.[42]

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37. U.S. *ex rel.* Polansky v. Exec. Health Res., Inc., 599 U.S. 419, 450 (2023).
38. U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024).
39. 31 U.S.C. § 3730(b)(2).
40. *Id*. § 3730(b)(2)–(4). A Georgia court ruled that an amended complaint asserting claims that were not substantially similar to the original complaint should be filed under seal. *See* U.S. *ex rel*. Williams v. Landmark Hosp. of Athens, LLC, 2023 WL 8720661 (M.D. Ga. Dec. 18, 2023).
41. *See* U.S. *ex rel.* Sy v. Oakland Physicians Med. Ctr., LLC, 44 F.4th 565, 2022 WL 3335658 (6th Cir. Aug. 12, 2022). The Second Circuit held that the "service-of-process clock" does not begin to run "until a district court expressly authorizes service." U.S. *ex rel*. Weiner v. Siemens AG, 87 F.4th 157 (2d Cir. 2023). In *Weiner*, the court reversed the granting of a motion to dismiss for failure to serve, ruling that a district court order directing service was necessary under the FCA to commence the Rule 4(m) clock even though the district court had ordered the complaint unsealed years before.
42. Some courts have criticized the government for seeking excessive extensions of the sealing period. For example, in U.S. *ex rel*. Aldridge v. Corp. Mgmt., Inc., 78 F.4th 727, 732, 745 (5th Cir. 2023), the court found the government's eighteen seal extension requests over an eight-year period to be "inexcusable" exercises in "gamesmanship" during which it conducted "one-sided discovery" against defendants. Nevertheless, the court

The sealing requirement prevents defendants from learning about the existence of a qui tam suit, unless the government moves to lift the seal partially to inform the defendant of the suit. This limited unsealing strategy is often employed by the government to create an inducement for defendant to settle before the government publicly joins the investigation.[43]

In 2016, the Supreme Court tackled the issue of the consequences that result from a violation of the seal. In *State Farm Fire & Casualty Co. v. U.S. ex rel. Rigsby*, the Court held that mandatory dismissal of a complaint was not required where relator's counsel violated the seal by discussing the sealed complaint with reporters. Finding that Congress did not intend to mandate dismissal for any seal violation, the Court held that the lower courts had properly exercised their discretion when deciding not to dismiss the case. The Court stated that standards to guide that discretion "could" be developed in later cases, noting that a 1995 Ninth Circuit decision appeared to articulate appropriate standards.[44]

The written disclosure statement that the relator must serve on the government is meant "to provide the United States with enough information on alleged fraud to be able to make a well-reasoned decision on whether it should participate in the filed lawsuit or allow the relator to proceed alone."[45] Defendants litigating FCA cases have had

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declined to dismiss the case, which had proceeded to trial after the government intervened, finding no precedent "where such an extraordinary sanction as dismissal has been awarded because of the Government's inexcusable delays in intervening in a relator's case." *Id*. at 747. Of course, courts that grow impatient with the government's repeated extension requests can deny an extension forcing the government to have to decide whether or not to intervene. *See, e.g.*, U.S. *ex rel*. Brasher v. Pentec Health, Inc., 338 F. Supp. 3d 396, 403–04 (E.D. Pa. 2018) (denying the government's eleventh request for an extension made over a five-year period).

43. The government will usually move to unseal the qui tam complaint when a case is settled.

44. State Farm Fire & Cas. Co. v. U.S. *ex rel.* Rigsby, 137 S. Ct. 436 (2016). The Ninth Circuit, in the case the Court mentioned, stated that considerations regarding the consequences of a seal violation included "extraordinary circumstances," "the presence of willfulness, bad faith, or fault," "the efficacy of lesser sanctions," the "nexus between the misconduct . . . and the matters in controversy," and, where appropriate, "the prejudice to the party victim . . . [and] the government interests at stake." U.S. *ex rel.* Lujan v. Hughes Aircraft Co., 67 F.3d 242, 245 (9th Cir. 1995).

45. U.S. *ex rel.* Woodard v. Country View Care Ctr., Inc., 797 F.2d 888, 892 (10th Cir. 1986); *see also* U.S. *ex rel.* Bagley v. TRW, Inc., 212 F.R.D. 554, 555 (C.D. Cal. 2003).

mixed success in obtaining the disclosure statements through discovery, an issue on which the FCA is silent. Some courts have protected some or all of the disclosure statements from discovery under the attorney work-product privilege based on a common interest between relator and the government, while other courts have allowed discovery of the entire statements.[46] Other courts have found attorney opinion within the statements protected by the work-product privilege, but have ordered production of factual material in the statements where defendants established they had a "substantial need" for the materials and could not obtain equivalent information without "undue hardship."[47] Notwithstanding the lack of clear authority, it makes good sense for a defendant to seek any discovery of any disclosure statements when facing an FCA suit once litigation gets under way.

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46. *Compare* U.S. *ex rel.* Burns v. A.D. Roe Co., 904 F. Supp. 592, 594–95 (W.D. Ky. 1995) (ordering production of relator's statement of material evidence; rejecting protection under the attorney-client and work-product privileges), *with TRW*, 212 F.R.D. at 562 (holding that disclosure statement protected by work-product privilege); U.S. *ex rel.* Spletzer v. Allied Wire & Cable, Inc., 2015 WL 7014620, at *3 (E.D. Pa. Nov. 12, 2015) (same); U.S. *ex rel.* Fisher v. Ocwen Loan Servicing, LLC., 2015 WL 4609742, at *3 (E.D. Tex. July 31, 2015) (same); U.S. *ex rel*. Fisher v. JP Morgan Chase Bank N.A., 2020 WL 3265060 (E.D. Tex. June 17, 2020) (finding work-product privilege applicable to disclosure statement and that defendant had not demonstrated substantial need for it); U.S. *ex rel*. Jacobs v. Advanced Dermatology & Skin Care Specialists, P.C., 2023 WL 9005630 (C.D. Cal. Dec. 18, 2023) (ordering relator to produce privilege log including disclosure statement and pre-suit communications with the government); U.S. *ex rel*. Eichner v. Ocwen Loan Servicing, LLC, 2024 WL 843900 (E.D. Tex. Feb. 28, 2024) (denying motion to compel disclosure statement because defendant did not show substantial need for the information to overcome work product protection).

47. *See, e.g.*, U.S. *ex rel.* Minge v. TECT Aerospace, Inc., 2011 WL 1885934, at *6 (D. Kan. May 18, 2011) (ordering production of disclosure statement but protecting attorney impressions, conclusions, opinions, and theories); U.S. *ex rel.* Yannacopoulos v. Gen. Dynamics, 231 F.R.D. 378, 386 (N.D. Ill. 2005) (holding that disclosure statement protected by attorney work-product privileges but ordering production of non-opinion factual material in disclosure statement after in camera review); U.S. *ex rel.* Cericola v. Ben Franklin Bank, 2003 WL 22071484 (N.D. Ill. Sept. 4, 2003) (holding defendants were entitled to the factual portions of the disclosure statement that did not reveal attorney mental impressions or opinions). *But see* United States v. Mount Sinai Hosp., 185 F. Supp. 3d 383 (S.D.N.Y. 2016) (disclosure statements protected by work product and defendant did not establish need or hardship); U.S. *ex rel.* Hunt v. Merck-Medco Managed Care, LLC, 2004 WL 868271, at *3 (E.D. Pa. Apr. 21, 2004) (holding that disclosure statements would not be discoverable because defendants could not establish substantial need for plaintiff's factual work product and undue hardship).

Some defendants have sued or counterclaimed against relators asserting breach of contract claims when relators take or disclose confidential company documents. Public policy considerations counsel against such claims, with the prevailing view being that such a claim can proceed if the defendant can demonstrate some harm from the taking or disclosures independent of FCA liability.[48]

[B] Provisions Allowing Relators to Share in Monetary Recovery

The FCA encourages qui tam actions by allowing relators to share in the government's recovery of money obtained as a result of the suit. If the government proceeds with a qui tam action, the FCA provides that the relator "shall" receive between 15% and 25% of the government's recovery, "depending upon the extent to which the person substantially contributed to the prosecution of the action."[49] The relator may receive a lower share (from 0% to 10%) if the action in which the government joins is based on disclosures from a prior government investigation or the news media. If the relator successfully brings the case on the government's behalf after the government declines, the relator's share of any recovery increases to between 25% and 30% of the recovery.[50] A relator's recovery is taxable and must be included in relator's calculation of his gross income.[51] Relators are also entitled

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48. *See, e.g.*, U.S. *ex rel.* Ruscher v. Omnicare, Inc., 2015 WL 4389589, at *5 (S.D. Tex. July 15, 2015) (allowing counterclaim against relator regarding documents relator took "beyond those reasonably calculated to support her FCA allegations"); Shmushkovich v. Home Bound Healthcare, Inc., 2015 WL 3896947, at *3 (N.D. Ill. June 23, 2015) (ordering relator to destroy documents that are irrelevant to his suit, but allowing relator to retain relevant documents); U.S. *ex rel.* Notorfransesco v. Surgical Monitoring Assocs., Inc., 2014 WL 7008561 (E.D. Pa. Dec. 12, 2014); United States v. Bos. Sci. Neuromodulation Corp., 2014 WL 4402118, at *5 (D.N.J. Sept. 4, 2014) (allowing breach of contract counterclaim to proceed); *cf.* U.S. *ex rel.* Cieszynski Lifewatch Servs., Inc., 2016 WL 2771798 (N.D. Ill. May 13, 2016) (dismissing claim that relator breached confidentiality agreement because relator did not take documents beyond those relevant to FCA claim); United States v. Mount Sinai Hosp., 2015 WL 7076092, at *6 (S.D.N.Y. Nov. 9, 2015) (noting "strong public policy in favor of protecting those who report fraud"). *See also* U.S. *ex rel.* Cooley v. Ermi, LLC, 2024 WL 815514 (N.D. Ga. Feb. 27, 2024) (allowing counterclaims to proceed against relator, who had served as defendant's chief compliance officer).

49. 31 U.S.C. § 3730(d)(1).

50. *Id.* § 3730(d)(2).

51. Campbell v. Comm'r, 658 F.3d 1255, 1258–59 (11th Cir. 2011); Brooks v. United States, 383 F.3d 521, 525 (6th Cir. 2004).

to recover attorney fees and reasonable expenses from the defendant, including upon settlement of a case, which may be substantial, especially if the relator has continued the case on his own after a declination by the government. Relators who have been criminally convicted regarding the fraud must be dismissed as relators even if they only had a minor role.[52]

These provisions motivate relators not only to file qui tam suits, but also to remain actively involved in the litigation even after the government intervenes. While some relators and their counsel will be content to sit back and let the government run the case once it has decided to intervene, others, seeking to obtain a share at the higher end of the range, will try to actively participate, sometimes leading to clashes with the government on strategy. The FCA contemplates the potential disruption from these differences and allows the government to seek a court order limiting the relator's participation in the litigation.[53] A defendant may also seek to curtail the relator's participation on a showing that relator's unrestricted participation would result in harassment, undue burden, or unnecessary expenses to the defendant, although experience under this provision has shown that it is difficult to remove or restrict the involvement of a relator on this basis.[54]

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52. Schroeder v. United States, 793 F.3d 1080, 1084 (9th Cir. 2015).

53. 31 U.S.C. § 3730(c)(2)(C). This provision allows the court to limit the "number of witnesses" a relator may call, limit the length of examination of relator's witnesses, limit the relator's cross-examination, and "otherwise limit[ ] the participation" by the relator in the action.

54. 31 U.S.C. § 3730(c)(2)(D). Courts have denied motions to dismiss relators under this provision. *See* U.S. *ex rel.* Schmuckley v. Rite Aid Corp., 2018 WL 4214887 (E.D. Cal. Sept. 5, 2018) (denying motion to restrict relator's participation, noting that court can manage the case to avoid duplicative motion practice); U.S. *ex rel.* Wilkins v. N. Am. Constr. Corp., 173 F. Supp. 2d 601, 644–45 (S.D. Tex. 2001) (denying defendant's motion to dismiss the relator and holding that the relator's participation in the litigation did not harass or cause an undue burden or expense to the defendant); U.S. *ex rel.* Roby v. Boeing Co., 995 F. Supp. 790, 796 (S.D. Ohio 1998) (denying defendant's motion to dismiss the relator and holding that the relator's pleadings and discovery independent of the government did not harass or cause delay or burden to defendant); *see also* U.S. *ex rel.* Bunk v. Birkhart Globistics GmbH & Co. Logistik Und Serv. KG, 2010 WL 1138434, at *1 (E.D. Va. Mar. 18, 2010) (denying defendant's objection to relator's motion to compel because although defendant alleged relator's discovery requests were duplicative of the government's requests, it did not make a showing of harassment, undue burden or unnecessary expense).

[C] Authority over Dismissal and Settlement

Beyond disagreements over the manner in which the case is conducted, disagreements between the government and relator can arise over dismissal or settlement of an FCA case. The FCA allows the government to dismiss cases even if relator continues to litigate after DOJ declination. In January 2018, the Administration announced that when declining cases, DOJ attorneys should also consider whether to seek dismissal—guidance that is embodied in what is referred to as the Granston Memorandum. In that memorandum, DOJ noted that government action to dismiss could be appropriate in a number of instances, such as to curb meritless suits, to prevent interference with government programs, or to control litigation.[55] Since then, DOJ has followed through, seeking dismissal of a number of relator cases on the ground that the case lacks merit or that it could distract agencies from their mission because of potential discovery.[56]

Under the FCA, a relator may object to the government's attempt to dismiss an FCA case initiated by him.[57] Courts had been split over the nature of review if relator objects. The District of Columbia Circuit held that the government's right to dismiss is "unfettered,"[58] while the Ninth Circuit, for example, held that there must be: (1) a valid government purpose, and (2) a rational relationship between the dismissal and the government purpose;[59] other circuits had different

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55. Memorandum from Michael Granston, www.insidethefalseclaimsact.com/wp-content/uploads/sites/860/2018/12/Granston-Memo.pdf (Jan. 10, 2018).
56. *See* Brief for United States as Amicus Curiae, Gilead Scis., Inc. v. U.S. *ex rel.* Campie, No. 17-936 (9th Cir. Nov. 30, 2018); U.S. *ex rel.* Panzey Belgium Harris v. EMD Serono, Inc., 2019 WL 1468934 (E.D. Pa. Apr. 3, 2019).
57. 31 U.S.C. § 3730(c)(2)(A); *see* U.S. *ex rel.* Kelly v. Boeing Co., 9 F.3d 743, 753 (9th Cir. 1993) (holding that the government did not have to intervene in a case in order to seek dismissal); *see also* U.S. *ex rel.* Killingsworth v. Northrop Corp., 25 F.3d 715, 720 (9th Cir. 1994).
58. Swift v. United States, 318 F.3d 250, 252 (D.D.C. 2003).
59. U.S. *ex rel.* Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139, 1145 (9th Cir. 1998); *see also* United States v. Academy Mortg., 968 F.3d 996 (9th Cir. 2020) (reaffirming *Sequoia* standard but also denying appellate review of the denial of government's motion to dismiss under the collateral order doctrine); U.S. *ex rel.* Shepard v. Grand Junction Reg'l Airport Auth., 2017 WL 749070 (D. Colo. Feb. 27, 2017). One court denied the government's motion to dismiss under this standard finding that there was no evidence that the government investigated the relator's allegations. United States v. Academy Mortg. Corp., 2018 WL 3208157 (N.D. Cal. June 29, 2018).

standards.[60] In 2023, the U.S. Supreme Court in *U.S. ex rel. Polansky v. Executive Health Resources, Inc*. resolved the split holding that the government's motion to dismiss a qui tam suit should be evaluated under Federal Rule of Civil Procedure 41, and requires only that the government "offer[ ] a reasonable argument for why the burdens of continued litigation outweigh its benefits."[61] Recently, the Fourth Circuit held in a post-*Polansky* decision that the "hearing" requirement of the relevant FCA provision does not require an evidentiary hearing and can be satisfied by a review of written submissions.[62]

The FCA also entitles a relator to object to a proposed settlement reached by the government.[63] The court may approve the settlement over a relator's objections if it finds, after a hearing, that the settlement is "fair, adequate, and reasonable under all the circumstances."[64] The Ninth Circuit has observed that the relator's ability to object to the settlement of an FCA case in practice is limited, noting legislative history that the right of a relator to a hearing on a settlement may not be absolute. As a result, "[i]t is not clear whether in practice this notice and hearing requirement has amounted to much of a hurdle for the government."[65]

Thus, as a practical matter, the relator's ability to derail a settlement advanced by the defendant and government is limited. Yet, because a share of the government's recovery usually is due to the relator, the government will prefer to have the relator bless a settlement and reach agreement with it on the amount of its bounty as part of an overall resolution of a case.

Conversely, the government can object to a settlement reached between a defendant and a relator who prosecutes an action following government declination. The FCA provides that an FCA action can only be dismissed "if the court and the Attorney General give

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60. U.S. *ex rel*. CIMZNHCA, LLC v. UCB, Inc., 2020 WL 4743033 (7th Cir. Aug. 17, 2020) (holding that the government's attempt to dismiss could only be invalidated on substantive due process grounds as executive action that is so irrational as to shock the conscience) *see also* Polansky v. Exec. Health Res. Inc., 17 F.4th 376 (3d Cir. 2021) (adopting 7th Circuit approach); U.S. *ex rel.* Health Choice All., L.L.C. v. Eli Lilly & Co., 4 F.4th 255 (5th Cir. 2021) (holding that the FCA requires a hearing when the government seeks to dismiss that "includes judicial involvement and action," but leaving the precise contours of such a hearing unstated).
61. U.S. *ex rel*. Polansky v. Exec. Health Res., Inc., 599 U.S. 419, 438 (2023).
62. U.S. *ex rel*. Doe v. Credit Suisse AG, 2024 WL 3974986 (4th Cir. Aug. 29, 2024).
63. 31 U.S.C. § 3730(c)(2)(B).
64. *Id*.
65. *Boeing Co.*, 9 F.3d at 754 n.11.

written consent to the dismissal and their reasons for consenting."[66] In February 2017, the Fourth Circuit held that the government has "absolute veto power" over a settlement that relator, who was pursuing the case on his own, sought with defendant.[67] Other courts have held that the government has a broad right to reject settlements—amounting to veto power—while others have conditioned the government's rights to reject a settlement in a relator-driven case upon a showing of good cause.[68]

§ 11:3 Steps of a Government Investigation

A government investigation of a qui tam complaint, or its own FCA investigation, may take a variety of forms, because there is no standard protocol. Investigatory mechanisms include the use of agency subpoenas, civil investigative demands, and informal witness interviews.

§ 11:3.1 Agency Subpoenas

A company often may first hear from the government through a subpoena issued through the inspector general's office of an administrative agency. For example, in the healthcare arena, a subpoena seeking information on a particular pharmaceutical often issues from an agent of the Office of Inspector General of the Department of Health and Human Services. A recipient of such a subpoena is directed to an attorney at DOJ, or to an assistant U.S. attorney, who will handle negotiations on behalf of the government regarding the recipient's response to the subpoena. DOJ itself may issue a subpoena under its various investigatory statutes.[69] Because qui tam complaints are filed

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66. 31 U.S.C. § 3730(b)(1).
67. U.S. *ex rel.* Michaels v. Agape Senior Cmty., Inc., 848 F.3d 330 (4th Cir. 2017).
68. *Compare* Searcy v. Philips Elecs. N. Am. Corp., 117 F.3d 154, 159–60 (5th Cir. 1997) ("The government asks us to sanction an absolute veto power over voluntary settlements in qui tam False Claims Act suits. The statutory language appears to grant just that . . . ."), United States v. Health Possibilities, P.S.C., 207 F.3d 335, 339 (6th Cir. 2000), *and In re* Pharm. Indus. Average Wholesale Price Litig., 2012 WL 366599, at *2 (D. Mass. Jan. 26, 2012), *with Killingsworth*, 25 F.3d at 725 (holding that the government does not have an absolute right to reject settlement, only a right upon a showing of good cause), *and* U.S. *ex rel.* Fender v. Tenet Healthcare Corp., 105 F. Supp. 2d 1228, 1231 (N.D. Ala. 2000).
69. *See, e.g.*, 18 U.S.C. § 3486 (authorizing the attorney general to issue investigative demands to obtain records regarding federal criminal healthcare fraud offenses).

under seal, the government usually will not reveal whether or not such a complaint has been filed. Rather, the government typically will inform the recipient of the subject matter or the nature of its investigation in general terms.

§ 11:3.2 Civil Investigative Demands

The FCA contains detailed provisions for the issuance of Civil Investigative Demands (CIDs), by which DOJ can obtain evidence in an FCA investigation. These provisions, found at 31 U.S.C. § 3733, were often viewed by prosecutors as cumbersome because of the approvals required from the upper echelons of the DOJ. The 2009 amendments removed these procedural barriers by allowing CIDs to be issued by the attorney general or a designee.[70] Therefore, CIDs—which allow for document discovery, written interrogatories, and oral testimony under oath—are being issued by U.S. attorneys' offices with far greater frequency. The amendments also expressly provide that the information obtained pursuant to a CID "may be shared with any qui tam relator" if necessary to the government's investigation.[71]

§ 11:3.3 The Government's Decision to Intervene

From a putative FCA defendant's perspective, the key objective during the investigation phase of an FCA case is to convince the government not to intervene in the case, assuming that there is some reason to believe that a qui tam complaint has been filed. The putative defendant can marshal facts to show that no false claim was knowingly submitted, present legal arguments as to the inapplicability of the FCA to the conduct, or assert other defenses, such as the statute of limitations. Statistics show less success by relators in prosecuting an FCA action on their own after the government declines to intervene.[72]

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70. 31 U.S.C. § 3733(a)(1). The FCA permits the government to issue CIDs "before commencing a civil proceeding under section 3730(a) or other false claims law" or before intervening in a qui tam action filed by a relator. *Id*. In United States v. Kernan Hosp., 2012 U.S. Dist. LEXIS 165688 (D. Md. Nov. 20, 2012), the district court interpreted this provision to prohibit the government from issuing a CID after the court had dismissed the government's FCA action against the recipient of the CID on Rule 9(b) grounds.
71. 31 U.S.C. § 3733(a)(1).
72. *See* U.S. Dep't of Just., Civ. Div., Fraud Statistics—Overview: October 1, 1987–September 30, 2016, at 1–2 (Dec. 13, 2016), www.justice.gov/civil/page/file/918371/download (reporting that of the $53 billion recovered by the government under the FCA between 1987 and 2016, only $2.3 billion, or 4.3%, is attributable to qui tam suits prosecuted solely

Procedurally, if the government decides to join the qui tam, it will notify the court while the complaint is under seal that it "elect[s] to intervene and proceed with the action,"[73] in which case it has the "primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action."[74] The complaint cannot be served on the defendant "until the court so orders,"[75] which will happen as a matter of course following the intervention notice. With its intervention notice, the government can also file a complaint amending the one crafted by the relator, a practice that the government appears to follow in nearly every case.[76] When the government declines, the relator has 120 days after the complaint is unsealed to serve the defendant.[77] Even if it declines, the government will likely monitor the litigation and has the statutory right to intervene later upon a showing of good cause.[78]

§ 11:4 Elements of FCA Liability

§ 11:4.1 False Claim

One of the key elements of most FCA liability provisions is a false claim. The FCA, under the 2009 amendments, broadly defines "claim" as any request for money or property that is "presented to an officer, employee, or agent of the United States," or "is made to" third parties, such as contractors, grantees or other recipients of federal money.[79] In the case of claims made to third parties, FCA liability could attach if the money sought "is to be spent or used on the government's behalf or to advance a government program or interest"

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by the relator). In recent years, however, relators have had more success in prosecuting cases and defeating motions to dismiss and for summary judgment.

73. 31 U.S.C. § 3730(b)(2).
74. *Id*. § 3730(c)(1).
75. *Id*. § 3730(b)(2).
76. *See In re* Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 397 (D. Mass. 2007) ("[O]nce the government is in the driver's seat, it has the statutory right to amend the complaint, and usually does so.").
77. FED. R. CIV. P. 4(m); U.S. *ex rel.* Pervez v. Maimonides Med. Ctr., 2010 WL 890236, at *13 (S.D.N.Y. Mar. 9, 2010). *But see* U.S. *ex rel.* Weiner v. Siemens AG, 2021 WL 3544718 (S.D.N.Y. Aug. 10, 2021) (Rule 4(m) does not apply if the court did not direct service of the complaint in its unsealing order).
78. 31 U.S.C. § 3730(c)(3). After declining a case, the government can demand that it be served with the pleadings and deposition transcripts. *Id*.
79. *Id*. § 3729(b)(2)(A).

where the government provides or has provided or will reimburse the third party for "any portion" of the money requested.[80]

The 2009 amendment of the definition of "claim," which is not retroactive, represents a potentially far-reaching change to the FCA. Prior to the 2009 amendments, the FCA required that an allegedly false claim be presented to a U.S. government official—either directly or indirectly by a contractor. As a result, courts had held that the FCA did not cover claims made to certain entities that received government money, such as Amtrak, where individual claims were not ultimately forwarded to a government entity.[81] Congress amended

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80. *Id*.

81. U.S. *ex rel.* Totten v. Bombardier Corp., 380 F.3d 488, 490 (D.C. Cir. 2004) (Roberts, J.). In *Totten*, then-Judge Roberts ruled that the FCA did not cover allegedly false claims made to the National Railroad Passenger Corporation (Amtrak), because Amtrak was not a government entity, and because the presentment requirement was not met as the particular claim was never forwarded to a government entity by Amtrak even though payment came out of funds received from the federal government.

The presentment requirement, as this was known, still applies to conduct prior to the 2009 amendments. Some defendants have sought dismissal of FCA claims based on the submission of claims to state Medicaid agencies or Medicare plan sponsors on the grounds that, like Amtrak, those entities are not agencies of the federal government and they do not forward individual claims to the federal government for payment. A clear majority of courts have rejected this argument as to state Medicare agencies, finding that the "comprehensive funding and reimbursement structure between the states and federal government under the Medicaid scheme" makes claims submitted to Medicaid the same as claims made to the federal government. U.S. *ex rel.* Nichols v. Omni H.C., Inc., 2008 WL 906425 (M.D. Ga. Mar. 31, 2008); *see also* United States v. Shelburne, 2010 WL 2542054, at *2 (W.D. Va. June 24, 2010) ("[I]t has been held that presenting a false claim to a 'state's Medicaid program is sufficient' for the FCA's presentment requirement because 'funds used to pay the claims are predominantly federal.'") (quoting U.S. *ex rel.* Putnam v. E. Idaho Reg'l Med. Ctr., 696 F. Supp. 2d 1190, 1200 (D. Idaho 2010)); U.S. *ex rel.* Ven-A-Care of the Fla. Keys, Inc. v. Actavis Mid Atl. LLC, 659 F. Supp. 2d 262, 269 (D. Mass. 2009); U.S. *ex rel.* Tyson v. Amerigroup Ill., Inc., 2005 WL 2667207 (N.D. Ill. Oct. 17, 2005) (same); United States v. Cathedral Rock Corp., 2007 WL 4270784 (E.D. Mo. Nov. 30, 2007) (same); Kane *ex rel.* U.S. v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015) (same). *But see* U.S. *ex rel.* Atkins v. McInteer, 345 F. Supp. 2d 1302, 1304 (N.D. Ala. 2004) (applying *Totten*, holding that the FCA does not apply to claims made to the Alabama Medicaid Agency). The *Atkins* case has been questioned even by courts within the same circuit. *See* U.S. *ex rel.* Graves v. Plaza Med. Ctrs. Corp., Case No. 10-CV-23382-FAM (S.D. Fla. Feb. 27, 2017). One court has held that Medicare plan sponsors are not government officials for presentment under the pre-2009 FCA. U.S. *ex rel.* Garbe v. Kmart Corp., 824 F.3d 632, 638 (7th Cir. 2016).

the FCA to address this situation, specifically criticizing court decisions that had "allow[ed] subcontractors paid with government money to escape responsibility for proven frauds."[82] In so doing, Congress sought to bring the FCA back into line with what it characterized as the intent of the 1986 amendments that the statute reach all fraudulent acts against the government.[83] The Supreme Court has likewise stated that the FCA, even prior to the 1986 amendments, "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money."[84]

The amended definition of "claim," however, may go too far, as it could expand FCA liability to situations where the relationship between the defendant and the government is remote. As the Seventh Circuit observed, the amended definition applies to claims "to intermediaries or other private entities that either implement government programs or use government funds."[85] There is no requirement in the statute that the person submitting a claim know that government funds will be used to pay its claim. Therefore, FCA liability and exposure to trebled damages and penalties can arise from the submission of invoices to a private party where, unknown to the person submitting the claim, the government has provided, or will provide, a portion of the funds used to pay the invoices. One court held that Rule 9(b)'s particularity requirements apply to the evaluation of allegations linking claims to government spending.[86] As more FCA cases are filed in the post-amendment period, issues regarding the scope of actionable claims under the FCA will continue to arise.[87]

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82. S. REP. NO. 111-10, at 3 (2009).
83. S. REP. NO. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.
84. United States v. Neifert-White Co., 390 U.S. 228, 233 (1968).
85. *Garbe*, 824 F.3d at 639; *see also* U.S. *ex rel.* Kraus v. Wells Fargo & Co., 943 F.3d 588 (2d Cir. 2019) (claims by defendant to Federal Reserve Banks for emergency lending are claims to the U.S. because the U.S. provides the funding and is the source of the Reserve Banks' purchasing power).
86. U.S. *ex rel.* Brooks v Wells Fargo Bank N.A., 2019 WL 1125834 (N.D. Ill. Mar. 12, 2019) (claims to Fannie Mae and Freddie Mac must be tied to government spending). *But see* U.S. *ex rel.* Grubea v. Rosicki, Rosicki & Assocs., 318 F. Supp. 3d 680 (S.D.N.Y. 2018) (claims to Fannie Mae and Freddie Mac while in government conservatorship were claims to the United States, finding that given size of the federal funding of those entities, claims were "virtually guaranteed to be paid with federal funds").
87. While some courts have noted that the new definition could expand liability for "a party submitting a false statement not directly to the government, but to a private third party (as in the case of a subcontractor and prime contractor)," U.S. *ex rel.* Loughren v. Unum Grp., 613 F.3d

In addition, as the statute requires, there must be a false statement or misrepresentation to trigger liability under the FCA. Many courts have held that the FCA "requires proof of an objective falsehood. Thus, liability must be predicated on an objectively verifiable fact."[88] Questions have arisen about whether scientific or clinical medical judgments can trigger FCA liability. While some courts had stated that subjective clinical judgments cannot be false,[89] more recent

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300, 307 (1st Cir. 2010); Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 16 (D.N.J. 2011) (quoting *Loughren*, 613 F.3d at 307), the Third Circuit has cautioned against reading the FCA too broadly, noting that the "FCA requires more than fraud against anyone who happens to receive money from the federal government" because "the plain language of the FCA requires that there be some greater nexus between the alleged fraud and the government funds." *See* U.S. *ex rel.* Garg v. Covanta Holding Corp., 478 F. App'x 736, 741 (3d Cir. 2012) (holding that the federal government's direct financial subsidy to a state entity permitting it to issue tax-exempt bonds is insufficient to establish the state entity as a federal contractor, grantee, or other recipient; therefore, alleging false certifications of compliance to the state entity does not state a claim under the FCA); *see also* Startley Gen. Contractors, Inc. v. Water Works Bd. of the City of Birmingham, 2021 WL 2065147 (11th Cir. May 24, 2021) (no claims where federal dollars were only used as a guarantee for a locally issued bond); United States v. McMahon, 2015 WL 115763 (N.D. Ill. Jan. 5, 2015) (dismissing FCA action on Rule 9(b) grounds based on relator's failure to demonstrate a link between federal funds and grants given by the City of Chicago); U.S. *ex rel.* Todd v. Fid. Nat'l Fin., Inc., 2014 WL 4636394, at *11 (D. Colo. Sept. 16, 2014) (dismissing relator's claims because "Plaintiff alleges only that Freddie Mac has received a sizable amount of government funding; he has not alleged that government money is the sole source of funds available to Freddie Mac, nor has he specified how Freddie Mac allocated its revenue such that Defendants' invoices were paid with at least a portion of government money"). *But see* Griffith v. Conn, 2016 WL 1029331 (E.D. Ky. Mar. 14, 2016) (attorney's application to the Social Security Administration for fees payable from plaintiff's disability award is a claim under the FCA); U.S. *ex rel.* Blaum v. Triad Isotopes, Inc., 104 F. Supp. 3d 901, 918 (N.D. Ill. 2015) (claims to Cook County Health System viable under FCA because of inference that "at least some of [Cook County's] expenditures were reimbursed by federal funding"); U.S. *ex rel.* Heath v. Wis. Bell, Inc., 111 F. Supp. 3d 923 (E.D. Wis. July 1, 2015) (claims made to Universal Service Fund administered by FCC, but funded by mandated payments from telecommunications carriers, are actionable under FCA despite no "direct loss" to the U.S. Treasury); U.S. *ex rel.* Futrell v. E-Rate Program, LLC, 2017 WL 3621368, at *2–3 (E.D. Mo. Aug. 23, 2017) (following *Heath*).

88. U.S. *ex rel.* Polukoff v. St. Mark's Hosp., 2017 WL 237615, at *8 (D. Utah Jan. 19, 2017) (quotation and citation omitted).

89. U.S. *ex rel.* Wall v. Vista Hospice Care, Inc., 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016) (citation omitted) ("[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which

decisions by appellate courts have held that such opinions are not insulated from scrutiny.[90]

§ 11:4.2 Intent

The FCA imposes liability only where false claims or records are "knowingly" submitted or made. The statute defines knowing as having "actual knowledge of the information," acting in "deliberate ignorance of the truth or falsity of the information," or acting in "reckless disregard of the truth or falsity of the information."[91] Importantly, the statute requires "no proof of specific intent to defraud."[92] Mere negligence, however, is not sufficient to state an FCA claim.[93] As the Fifth Circuit has stated, the evidence must show that defendant "possessed guilty knowledge or guilty intent to cheat the government."[94]

The intent requirement presents unique issues for corporate defendants. As the U.S. Court of Appeals for the District of Columbia Circuit has held, a plaintiff cannot establish scienter under the FCA by aggregating the "collective knowledge" of company employees; rather, plaintiff must show that particular employees acted with the

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reasonable minds may differ cannot be false."); U.S. *ex rel.* Dooley v. Metic Transplantation Lab, Inc., 2017 WL 4323142, at *10 (C.D. Cal. June 27, 2017); United States v. DaVita Inc., 2021 WL 1087769 (C.D. Cal. Feb. 1, 2021) (dismissing where "the available medical research is inconclusive on the issue of dialysis timing and thus cannot support a claim of falsity under the FCA"); *see also* Bell v. Cross, 2021 WL 5544685 (11th Cir. Nov. 26, 2021) (difference of opinion does not establish falsity of medical treatments).

90. Winter *ex rel*. U.S. v. Gardens Reg'l Hosp., 953 F.3d 1108 (9th Cir. 2020) (reversing dismissal of FCA claim holding that a clinical opinion can be false if not honestly held or implies the existence of facts that do not exist); U.S. *ex rel*. Druding v. Care Alternatives, 952 F.3d 89 (3d Cir. 2020) (holding that clinical judgments can be false, and reversing summary judgment stating that "expert testimony challenging a hospice certification creates a triable issue of fact"); U.S. *ex rel.* Polukoff v. St. Mark's Hosp., 895 F.3d 730 (10th Cir. 2018) (holding that medical judgments can be false or fraudulent because the FCA has a broad mandate, opinions can be fraudulent, and medically unnecessary treatments are actionable under the FCA); *see also* United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019) (holding that there can be no FCA falsity as to hospice care judgments based only on disagreement of experts, but remanding to district court to consider full record on that issue).

91. 31 U.S.C. § 3729(b).

92. *Id*.

93. *See, e.g.*, U.S. *ex rel.* Burlbaw v. Orenduff, 548 F.3d 931, 949 (10th Cir. 2008) ("simple negligence does not violate the FCA"); U.S. *ex rel.* Aflatooni v. Kitsap Physician Servs., 163 F.3d 516, 526 (9th Cir. 1999).

94. United States v. Thomas, 709 F.2d 968, 972 (5th Cir. 1983).

requisite intent.[95] Nor, as the Seventh Circuit stated, can "vague allegations" of reckless disregard against a corporation "simply by virtue of its size, sophistication, or reach" be considered sufficient to satisfy the FCA's intent requirement.[96]

Before 2023, many courts held that a defendant may be able to show that the claim was not knowingly false by demonstrating that the claim was based on a reasonable interpretation of an ambiguous requirement or regulation.[97] For example, the D.C. Circuit reversed

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95. United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1274 (D.C. Cir. 2010) ("'collective knowledge' provides an inappropriate basis for proof of 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"); *see also* U.S. *ex rel.* Berkowitz v. Automation Aids, 2017 WL 4570827, at *6 (N.D. Ill. July 7, 2017) (dismissing case where plaintiff failed to show that "at least one person" at defendant knew about both the noncompliance and the claims being submitted to the government); United States v. Regeneron Pharm., Inc., 2023 WL 6296393 at *25 n.19 (D. Mass. Sept. 27, 2023) ("[f]or purposes of establishing scienter under the FCA, however, the 'collective knowledge' doctrine does not apply").

96. Thulin v. Shopko Stores Operating Co., 771 F.3d 994, 1000 (7th Cir. 2014).

97. *See* U.S. *ex rel.* Gugenheim v. Meridian Senior Living, LLC, 36 F.4th 173 (4th Cir. 2022) (finding Medicaid policy and guidance "sufficiently ambiguous to foreclose the possibility of proving scienter"); Olson v. Fairview Health Servs. of Minn., 831 F.3d 1063, 1072 (8th Cir. 2016) (holding that a "reasonable interpretation of ambiguous statutory language does not give rise to a[n] FCA claim" and affirming the district court's grant of motion to dismiss); U.S. *ex rel.* Thomas v. Siemens AG, 593 F. App'x 139 (3d Cir. 2014) (because Veterans Administration forms were ambiguous, no reasonable jury could find that defendants knowingly made false statements to the government); U.S. *ex rel.* Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186, 1190 (8th Cir. 2010) ("a statement that a defendant makes based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute"); *Sci. Applications Int'l Corp.*, 653 F. Supp. 2d at 97 ("A defendant's reasonable interpretation of an ambiguous regulation may well be a successful defense to an alleged FCA violation in appropriate cases"); U.S. *ex rel.* Oliver v. Parsons Co., 195 F.3d 457, 464 (9th Cir. 1999) (contractor's reasonable interpretation of ambiguous accounting regulation could be exempted from FCA liability "not because his or her interpretation was correct or 'reasonable' but because the good faith nature of . . . action forecloses . . . the scienter requirement"); Sheldon v. Forest Labs, LLC, 2021 WL 409748 (D. Md. Feb. 5, 2021) (dismissing because language of statute was "not so precise that it is not susceptible to other interpretations," finding that defendant's reading was not "objectively unreasonable"); U.S. *ex rel.* Danielides v. Northrop

a jury finding of an FCA violation, ruling that defendant could not have the requisite intent where the term "regular commission" was ambiguous and where it was undisputed that "actual notice" from the government of the meaning of that term—that is, authoritative guidance that "warned the defendant away" from an objectively reasonable interpretation—"did not come until long after the conduct."[98] In contrast, the Eleventh Circuit stated that while relevant to scienter, ambiguity "does not foreclose a finding of scienter," and that a court needs to determine whether a defendant actually knew "that its conduct actually violated a regulation in light of any ambiguity at the time of the alleged violation."[99] The government acknowledged this defense, but has taken the position that a defendant must prove it actually believed in the reasonable interpretation at the time it submitted the claim at issue.[100]

Grumman Sys. Corp., 2015 WL 5916871, at *6 (N.D. Ill. Oct. 8, 2015) (differences in interpretation of a contract term not an "objective falsehood."); U.S. *ex rel.* Saldivar v. Fresenius Med. Care Holdings, Inc., 2015 WL 7293156, at *32 (N.D. Ga. Oct. 30, 2015) (whether a defendant's interpretation was reasonable depends on whether legal advice was sought, industry practice, and good-faith belief).

98. U.S. *ex rel.* Purcell v. MWI Corp., 807 F.3d 281, 287, 290 (D.C. Cir. 2015); *see also* U.S. *ex rel.* Streck v. Allergan, Inc., 746 F. App'x 101 (3d Cir. 2018) (setting out three-part test: 1) whether statute was ambiguous; 2) whether defendant's interpretation was objectively reasonable; and 3) whether defendant was "warned away" from that interpretation by administrative or judicial guidance); U.S. *ex rel.* Schutte v. Supervalu, Inc., 9 F.4th 455 (7th Cir. 2021) (no reckless disregard if regulatory interpretation is objectively reasonable and no authoritative government guidance "warning away"); *see also* U.S. *ex rel.* Proctor v. Safeway, Inc., 30 F.4th 649 (7th Cir. 2022) (footnote in CMS guidance not sufficiently authoritative to warn away defendant); U.S. *ex rel.* Sheldon v. Allergan Sales, LLC, 24 F.4th 340 (4th Cir. 2022) (no knowledge where defendant made reasonable assumptions about ambiguous statute, and agency resists clarifying its view); United States v. McKesson Corp., 2020 WL 4805034 (N.D. Cal. Aug. 18, 2020) (dismissing complaint on finding that regulations allegedly violated were subject to "broad discretion" by government to interpret).

99. U.S. *ex rel.* Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154–55 (11th Cir. 2017); *see also* U.S. *ex rel.* Bahnsen v. Bos. Sci. Neuromodulation Corp., 2017 WL 6403864, at *9 (D.N.J. Dec. 15, 2017) ("[A] claimant cannot avoid liability by manufacturing an after-the-fact reasonable interpretation of an ambiguous provision.").

100. *See* United States' Amicus Curiae Brief in Response to Defendants' Motion for Judgment on the Pleadings at 7, Gonzales v. Planned Parenthood, No. CV 05-8818 AHM (C.D. Cal. Jan. 24, 2011) ("[t]he mere fact that a defendant can show that its conduct was consistent with a reasonable interpretation of the pertinent rules is insufficient, absent proof that it actually believed in that interpretation at the time it

In 2023, the Supreme Court emphasized the importance of an FCA defendant's subjective intent in cases involving ambiguous requirements in reversing a grant of summary judgment where there was evidence that the defendant believed it was not complying with those requirements.[101] In *Schutte*, lower courts held that the defendants could not have acted knowingly where their conduct in reporting prices to the government was consistent with an objectively reasonable interpretation of relevant law that had not been ruled out by definitive legal authority. The Court reversed, holding that the lower courts erred by not considering evidence that the defendants thought at the time that their price reporting was false or fraudulent.[102] Since *Schutte*, other courts have reversed grants of summary judgment concerning ambiguous requirements letting questions of intent go to the jury.[103] While the Court made it harder to escape a jury trial on scienter grounds where regulations are ambiguous, a defendant should still examine whether it can argue a lack of falsity in such situations.

The 2009 amendments to the FCA reversed a Supreme Court decision in *Allison Engine Co. v. U.S. ex rel. Sanders* that had imposed a heightened intent requirement where a false record or statement is made "to get" a false claim paid. Relying on the plain language of the old FCA, the Court held that "'[t]o get' denotes purpose, and thus a person must have the purpose of getting a false or fraudulent claim" paid or approved by the government.[104] As the Court stated, a defendant that "does not intend the government to rely on that false statement as a condition of payment" is not liable under the FCA.[105]

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submitted its claims, and that its belief was neither reckless nor deliberately ignorant"). In contrast, the Seventh Circuit in *Schutte*, 9 F.4th 455, held that a defendant's "subjective intent" regarding an ambiguous regulation or statute "does not matter" in a scienter analysis because FCA liability is limited to violations of unambiguous standards.

101. U.S. *ex rel.* Schutte v. Supervalu Inc. 143 S. Ct. 1391 (2023).

102. *Id*.

103. *See* U.S. *ex rel.* Heath v. Wisc. Bell, Inc., 75 F.4th 778 (7th Cir. 2023); U.S. *ex rel*. Ocean State Transit, LLC, 2023 WL 6199183 (D.R.I. Sept. 22, 2023) (where the district court reversed its own grant of a motion to dismiss based on *Schutte*).

104. Allison Engine Co. v. U.S. *ex rel.* Sanders, 553 U.S. 662, 668–69 (2008).

105. *Id*. at 672. Applying *Allison Engine*, courts had dismissed actions where plaintiffs failed to show that an FCA defendant made a false statement to a government contractor intending that the government rely on that statement as a condition of payment to the contractor. *See* U.S. *ex rel.* Sterling v. Health Ins. Plan of Greater N.Y., Inc., 2008 WL 4449448 (S.D.N.Y. Sept. 30, 2008); *cf.* United States v. Hawley, 619 F.3d 886,

With the 2009 amendments, Congress deleted the requirement that a false record be made "to get" a false claim paid, changing the statute to require only that the false record be material to a false claim—whether paid or not.[106]

§ 11:4.3 Materiality

Courts have held that false statements or misrepresentations must be material to make an FCA case.[107] Congress defined the term "material"—which it had added to section 3729(a)(1)(B) liability—in the 2009 amendments to the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[108] Prior to this statutory change, most courts had defined materiality in a similar way to focus on the potential effect of a false statement when it is made.[109] Actual reliance by the government on an allegedly false representation is not required.[110]

FCA liability can attach not only in cases of a material false representation that causes the government to pay more than it otherwise would, but also to material representations of compliance with contractual or regulatory provisions. For example, a hospital may be liable for submitting a false claim to the government by falsely certifying that it has complied with Medicare regulations prohibiting

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895 (8th Cir. 2010) (holding that the government made the requisite showing that defendant intended for the government to rely on its false statement).

106. *See supra* section 11:2.1.

107. *See, e.g.*, U.S. *ex rel.* Berge v. Bd. of Trs. of the Univ. of Ala., 104 F.3d 1453, 1459 (4th Cir. 1997) ("If previously unclear, we now make explicit that the current civil False Claims Act imposes a materiality requirement.").

108. 31 U.S.C. § 3729(b)(4).

109. *See* United States v. Bourseau, 531 F.3d 1159, 1171 (9th Cir. 2008) (collecting cases). A minority of courts had applied a more restrictive "outcome materiality test" examining whether a statement had the purpose and effect of causing a payment of government funds or deprived the government of funds it was due—a test that focuses on the false statement's actual effect. *See* U.S. *ex rel.* A+ Homeshares, Inc. v. Medshares Mgmt. Grp., Inc., 400 F.3d 428, 445 (6th Cir.), *cert. denied*, 546 U.S. 1063 (2005). The Fifth Circuit has stated that Congress's adoption of the natural tendency test in the 2009 FCA amendments showed the outcome materiality test did not reflect Congress's intent when it originally enacted the FCA. U.S. *ex rel.* Longhi v. United States, 575 F.3d 458, 470 (5th Cir. 2009).

110. *See* United States v. United Techs. Corp., 626 F.3d 313, 321 (6th Cir. 2010) (FCA "liability does not depend on whether the government relied in fact on the false statement to pay out the claim").

referral fees.[111] Similarly, a defendant can be liable under the FCA for falsely certifying its status as a minority-owned business, even if it otherwise fully and efficiently performed the government contract.[112] This false certification theory of FCA liability was at issue in the qui tam suit against cyclist Lance Armstrong, in which the government intervened. The suit seeks recovery of sponsorship money the U.S. Postal Service paid to Armstrong's cycling team based on alleged violation of the sponsorship agreement provision requiring the team to follow the rules of cycling's governing bodies, which they failed to do when they used performance enhancing substances.[113]

Liability even may attach when there is no express certification by a defendant of compliance with government regulations, but rather where a certification is implied by the defendant's actions. As one court stated in a case alleging that non-disclosed referral fees to doctors by a hospital violated the FCA, "the theory of implied certification . . . is that where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent."[114]

In *Escobar*, a seminal Supreme Court decision issued in June 2016 involving allegations that defendant hospital failed to comply with staffing and supervision requirements, the Court resolved a circuit split and upheld the implied certification theory of FCA liability.[115] The Court held that FCA liability can be premised on implied certification "at least" where two conditions are met: (1) a claim makes specific representations about a good or service and (2) a defendant's failure to disclose noncompliance "with material statutory, regulatory, or contractual requirement makes those representations misleading half-truths."[116]

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111. *See, e.g.*, U.S. *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997).
112. *See, e.g.*, Ab-tech Constr., Inc. v. United States, 31 Fed. Cl. 429 (Fed. Cl. 1994); *see also Longhi*, 575 F.3d at 473 (FCA liability for false statements that a government contractor was an "eligible deserving" small business).
113. *See* Press Release No. 13-224, U.S. Dep't of Just., United States Joins Lawsuit Alleging Lance Armstrong and Others Caused the Submission of False Claims to the U.S. Postal Service (Feb. 22, 2013), www.justice.gov/opa/pr/2013/February/13-civ-224.html.
114. U.S. *ex rel.* Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 238 F. Supp. 2d 258, 264 (D.D.C. 2002); *see also* U.S. *ex rel.* Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 33 (D.D.C. 2003).
115. Universal Health Servs., Inc. v. U.S. *ex rel.* Escobar, 579 U.S. 176, 181 (2016).
116. *Id*. at 190.

While not spelling out precisely how a statutory, regulatory, or contractual requirement would be material, the Court stated that the materiality standard is "demanding" and "rigorous" and would not be met simply because the government designates a requirement as a payment condition. Materiality could include, but is not limited to, "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."[117] On the other hand, "very strong" evidence of nonmateriality would exist if "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated" or when "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position."[118] Noncompliance is not material "merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment" or where "noncompliance is minor or insubstantial."[119] Nor is it sufficient for a finding of materiality "that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."

Courts applying *Escobar* have diverged on the issue of whether the two-part test of *Escobar* is to be applied rigidly to implied certification claims. Some courts have held that the test is not always applicable, seizing on the Court's use of the words "at least" just before articulating the test, while others, including appellate courts, have applied the two-part test as a necessary first step in their analysis.[120] As to fraudulent inducement claims, the Second Circuit held that the materiality analysis applies both to the government's initial decision to award a contract and to ultimate decisions to pay under the contract.[121]

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117. *Id*. at 192, 194.
118. *Id*. at 195.
119. *Id*. at 194.
120. For a case holding that the two-part test is not rigid, see U.S. *ex rel.* Panarello v. Kaplan Early Learning Co., 11-CV-00353-WMS-JJM (W.D.N.Y. Nov. 14, 2016). Cases applying the two-part test include: United States v. Stephens Inst., 901 F.3d 1124 (9th Cir. 2018); United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016); U.S. *ex rel.* Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. 2017) (affirming dismissal because defendant made no specific representations about its project management performance in its payment vouchers); U.S. *ex rel.* Schimelpfenig v. Dr. Reddy's Lab'ys Ltd., 2017 WL 1133956, at *6 (E.D. Pa. Mar. 27, 2017) (stating that the "Third Circuit appears to interpret *Escobar* as requiring specific representations").
121. United States v. Strock, 982 F.3d 51 (2d Cir. 2020); *see also* U.S. *ex rel.* Druding v. Care Alts., 2023 WL 5494333 (3d Cir. Aug. 25, 2023) (same and collecting cases).

As would be expected, courts applying *Escobar* have decided questions of materiality and implied certification based largely on the specific facts of the case. The First Circuit, upon remand of the *Escobar* case from the Supreme Court, adopted a "holistic" approach to determine materiality, finding that the state licensing and supervision requirements went to the essence of the mental health service claims at issue.[122] Similarly, the Ninth Circuit held that compliance with regulatory provisions that defendant allegedly violated must be the "*sine qua non* of receipt of [federal] funding."[123] In another decision, the Tenth Circuit outlined key materiality factors as: (1) the government's payment history—that is, whether it refuses to pay based on noncompliance, or continues to pay despite knowledge of noncompliance; (2) whether the noncompliance "goes to the essence of the bargain" or is minor; and (3) whether the government expressly identified compliance as a condition of payment.[124]

Other post-*Escobar* decisions have similarly focused on whether or not the government continues to pay claims after being alerted to the alleged fraud.[125] But some circuit courts have emphasized that

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122. U.S. *ex rel.* Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 109 (1st Cir. 2016); *see also* U.S. *ex rel.* Prather v. Brookdale Senior Living Cmtys., Inc., 892 F.3d 822 (6th Cir. 2018) (applying "holistic" approach and finding that timing of physician certifications for home health care went to the essence of the bargain); U.S. *ex rel*. Dan Abrams Co. v. Medtronic Inc., 2024 WL 1699558 (C.D. Cal. Feb. 16, 2024) (holding that the defendant's alleged misrepresentations to the FDA "went to the very essence of the bargain" and were thus material under the FCA).

123. Barnes v. Clark County, 2020 WL 1818605 (9th Cir. Apr. 10, 2020) (finding no materiality where the government was aware of the fraud allegations and continued to pay claims).

124. U.S. *ex rel*. Janssen v. Lawrence Mem'l Hosp., 949 F.3d 533 (10th Cir. 2020); *see also* U.S. *ex rel*. Lemon v. Nurses To Go, Inc., 924 F.3d 155 (5th Cir. 2019) (listing three similar factors regarding materiality).

125. *See, e.g.*, U.S. *ex rel.* Kolchinsky v. Moody's Corp., 2017 WL 825478 (S.D.N.Y. Mar. 2, 2017) (finding no materiality because government continued to pay for allegedly false credit ratings). The court in *Kolchinsky* reaffirmed its ruling finding a lack of materiality; it stated that the government need not have "clear irrefutable proof of wrongdoing," when paying claims for there to be a lack of materiality. U.S. *ex rel.* Kolchinsky v. Moody's Corp., 2018 WL 1322183, at *3 (S.D.N.Y. Mar. 13, 2018). *See also* United States v. Krahling, 2024 WL 3664648 (3d Cir. Aug. 6, 2024) (no materiality where the government had actual knowledge of the facts concerning the defendant's MMR vaccine and continued to purchase it); U.S. *ex rel*. Foreman v. AECOM, 2020 WL 1849749 (S.D.N.Y. Apr. 13, 2020) (no materiality where government extended contract multiple times despite knowledge of alleged violations concerning timesheets and other matters); U.S. *ex rel.* Mei Ling v. City of Los Angeles, 2018 WL

factor requires actual government knowledge of fraud, not merely notice of fraud allegations.[126] Some post-*Escobar* decisions have found broad regulatory obligations, such as directives to keep accurate records, sufficiently material,[127] while other courts have been more

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3814498 (C.D. Cal. July 25, 2018) (dismissing intervened case because government had not pled materiality adequately given its continued payments to defendant after its knowledge of noncompliance); Chicago v. Purdue Pharma L.P., 2016 WL 5477522 (N.D. Ill. Sept. 29, 2016) (finding no materiality because city government continues to pay for opioids). Other courts, to the contrary, have found materiality even if there were continued government payments where the government may have only had "general suspicions" about violations. U.S. *ex rel.* Poehling v. UnitedHealth Grp., Inc., 2018 WL 1363487, at *12 (C.D. Cal. Feb. 12, 2018). The Sixth Circuit has held that continued payment is not "dispositive." U.S. *ex rel.* USN4U, LLC. v. Wolf Creek Fed. Servs., 34 F.4th 507 (6th Cir. 2022) (noting factors "that could cause the Government to continue contracting with a party" after becoming aware of fraud, such as lack of other feasible procurement options); Chowns Grp., LLC v. John C. Grimberg Co., 2024 WL 375824, at *6–7 (E.D. Pa. Jan. 30, 2024) ("Considering the totality of the circumstances," the defendant's failure to disclose defects was not material where the government was aware of the obvious noncompliance and had a representative regularly on site yet continued to make payments.).

The Seventh Circuit suggested that the issue of whether continued payment defeats an FCA claim is "better saved for a later stage, once both sides have conducted discovery" in reversing a dismissal for lack of materiality. U.S. *ex rel.* Prose v. Molina Healthcare of Ill., Inc., 2021 WL 3671433 (7th Cir. Aug. 19, 2021). *See also* U.S. *ex rel.* Bibby v. Mortg. Invs. Corp., 985 F.3d 825, 834 (11th Cir. Jan. 15, 2021) ("the significance of continued payment may vary depending on the circumstances").

126. *See* U.S. *ex rel.* Druding v. Care Alts., 2023 WL 5494333 (3d Cir. Aug. 25, 2023) ("[l]ike our sister circuits, we will not equate the government's awareness of allegations of fraud with 'actual knowledge' that fraud has occurred"); *Heath*, 75 F.4th 778, 789 (7th Cir. 2023) ("[t]he government's knowledge of a pending lawsuit making allegations simply does not indicate actual knowledge of actual violations"). The Fifth Circuit recently found materiality despite the government's continued payments to a rural hospital, reasoning that continued government payments were needed to prevent the hospital from shutting down, which would undermine the government's goal of providing healthcare access to underserved rural patients. U.S. *ex rel*. Aldridge v. Corp. Mgmt., Inc., 78 F.4th 727, 738 (5th Cir. 2023).

127. U.S. *ex rel.* Miller v. Weston Educ., Inc., 840 F.3d 494 (8th Cir. 2016) (keeping accurate grade and attendance records were material to college's claims for federal student loan funds); Rose v. Stephens Inst., 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016), *motion to certify appeal granted sub nom.* Scott Rose v. Inst., 2016 WL 6393513 (N.D. Cal. Oct. 28, 2016) (finding incentive compensation payments to recruiters material

demanding.[128] Post-*Escobar* law regarding implied certification and materiality will continue to develop, especially as factual records with the *Escobar* test in mind become more robust.[129] Meanwhile, the Senate is considering a bill to amend the FCA to allow the government or relator to prove materiality by a preponderance of the evidence which defendants can only rebut by clear and convincing contrary evidence.[130]

Some courts have imposed a temporal requirement for implied certification, holding that promises of compliance are false only if made with intent not to perform the promise.[131] Thus, defendants in such cases should analyze the purported certifications to see whether the statements are linked to evidence showing that the certifier intended not to perform when making the statement.

The *Escobar* Court defined materiality both in terms of the government's knowledge *and* the defendant's knowledge.[132] Very few cases, however, have analyzed how the defendant's knowledge of the government's conduct affects the materiality inquiry. One recent case held that despite the Supreme Court's language, the defendant's knowledge

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to college's claims for student loan funds); *see also* U.S. *ex rel.* Porter v. Magnolia Health Plan, Inc. 2020 WL 1887791 (5th Cir. Apr. 15, 2020) (noting *Escobar* rejects argument that all regulatory violations are material; also finding no materiality where state Medicaid continued to pay claims after being informed of putative regulatory violations by relator).

128. *See Schimelpfenig*, 2017 WL 1133956, at *7 (holding violation of child-proof packaging regulations not material where no statute, regulation or contract term tied payment to packaging and there were no allegations that the government refused payment or initiated recovery action for such violations); N.Y. *ex rel.* Khurana v. Spherion Corp., 2016 WL 6652735 (S.D.N.Y. Nov. 10, 2016) (finding nondisclosure of lack of progress on a quality assurance project was not material); U.S. *ex rel.* Scharff v. Camelot Counseling, 2016 WL 5416494 (S.D.N.Y. Sept. 28, 2016) (finding inadequate notes of treatment were merely "inattention to detail," and not material); *see also* U.S. *ex rel.* Taylor v. Boyko, 39 F.4th 177 (4th Cir. 2022) (whether defendant had valid certificate of corporate authorization not material to claims for medical services).

129. *See, e.g.*, U.S. *ex rel*. Khaira v. Blue Cross of Cal., Inc., 2024 WL 1020481, at *5 (E.D. Cal. Mar. 7, 2024) (finding relator's allegations insufficient to plead materiality because the reimbursement process was set up so that payments were made without regard to and before any certification from the defendant).

130. False Claims Amendments Act of 2021, S. 2428, 107th Cong. (2021); *see supra* note 6.

131. U.S. *ex rel.* Ziebell v. Fox Valley Workforce Dev. Bd., Inc., 806 F.3d 946, 951 (7th Cir. 2015).

132. *Escobar*, 579 U.S. at 195.

does not play a role in the materiality analysis.[133] A corollary of the materiality defense is the government knowledge defense; that is, that government officials were aware of the potential falsity of a statement, which can bar FCA claims by a relator or the government.

In a seminal case on this doctrine, *U.S. ex rel. Butler v. Hughes Helicopters, Inc.*,[134] the Ninth Circuit affirmed a directed verdict where the government knew that a defendant's statement about the distances used to test an Apache helicopter radio was not "strictly accurate . . . and that this discrepancy was the subject of dialog" between the defendant and the government. In addition to rebutting a claim of falsity, "open dialog" also can defeat the intent requirement.[135] In another case, the court found a relator's claim barred by the government knowledge defense where the relator himself had informed the government of the alleged falsity, following which the government continued to pay under the contract.[136] The Third Circuit recognized a two-prong test for the government knowledge defense, stating it can apply when: "(1) the government knew about the alleged false statement(s); and (2) the defendant knew that the government knew."[137] Some appellate decisions, however, have limited the use of a "government knowledge defense" at the dismissal stage, noting that "[g]overnment officials' knowledge of a claim's falsity is not a defense

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133. U.S. *ex rel*. Montcrieff v. Peripheral Vascular Assocs., P.A., 2024 WL 390091, at *4–5 (W.D. Tex. Jan. 30, 2024) (declining to add a "knowledge" element to the *Escobar* materiality analysis that would require an FCA claimant to show a defendant knew its submissions were material to the government, but recognizing that a defendant's actual knowledge of materiality may be relevant when the government attaches unreasonable importance to a misrepresentation).

134. U.S. *ex rel.* Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 326 (9th Cir. 1995); *see also* U.S. *ex rel.* Marshall v. Woodward, Inc., 85 F. Supp. 3d 973, 983 (N.D. Ill. 2015) (no materiality where government knew of concerns with parts and continued to purchase them).

135. *See* U.S. *ex rel.* Lamers v. City of Green Bay, 998 F. Supp. 971, 988 (E.D. Wis. 1998) ("the presence of an open dialogue with government officials about relevant factual circumstances does mitigate a defendant's specific intent to defraud"); *Burlbaw*, 548 F.3d at 951 (government knowledge can give rise to an "inference" that a defendant did not knowingly present a false claim).

136. U.S. *ex rel.* Marquis v. Northrop Grumman Corp., 2013 WL 951095, at *2 (N.D. Ill. Mar. 12, 2013); *see also* U.S. *ex rel.* Berg v. Honeywell Int'l, Inc., 2016 WL 7478959 (D. Alaska Dec. 29, 2016) (granting summary judgment on fraudulent inducement claim based on government knowledge).

137. U.S. *ex rel.* Spay v. CVS Caremark Corp., 875 F.3d 746, 756 (3d Cir. 2017).

to liability, but it may be 'highly relevant'" to intent.[138] Even so, courts have held that "the government's conduct is relevant to assessing materiality."[139] In one case, the Seventh Circuit found that the government's continued payment for a helicopter part despite being aware of the alleged misrepresentation rendered the misrepresentation immaterial in granting summary judgment.[140] Despite its limitations, given the potential viability of this defense at a later stage in the litigation, one of the key steps in defending against an FCA case is amassing information about what the relevant government officials knew about the allegedly false statements at issue.

§ 11:4.4 Causation

Although the FCA explicitly includes a causation requirement,[141] the FCA does not define causation. In the absence of a statutory definition or guidance from the Supreme Court, courts have grappled with a working definition for the FCA's causation requirement, with most district and appellate courts borrowing basic principles of causation from tort law.

In one decision, the District of Columbia Circuit held that the FCA requires a plaintiff to demonstrate both actual, or but-for, causation and proximate cause. In *United States ex rel. Cimino v. International Business Machines Corp.*,[142] the court held that a plaintiff claiming that a defendant fraudulently induced the government to enter a contract needs to establish but-for causation even if asserting that the alleged falsity was a "substantial factor" in causing the government to enter the contract. The court stated that plaintiff "cannot simply skip over a showing of actual cause and rely only on proximate cause."[143]

Other courts have taken a different view on causation. For example, the Tenth Circuit defined the FCA's causation language to include

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138. Berg v. Honeywell Int'l, Inc., 580 F. App'x 559 (9th Cir. 2014); *see also* United States v. Bollinger Shipyards, Inc., 775 F.3d 255 (5th Cir. 2014) ("[t]he government knowledge defense is not appropriate at the motion to dismiss stage").
139. U.S. *ex rel.* Marshall v. Woodward, Inc., 812 F.3d 556, 563 (7th Cir. 2015).
140. *Id*.
141. 31 U.S.C. § 3729(a) entitles the government to damages "which the Government sustains *because of the act of that person*" (emphasis added).
142. U.S. *ex rel.* Cimino v. Int'l Bus. Machs. Corp., 3 F.4th 412 (D.C. Cir. 2021).
143. *Id*. at 421.

proximate causation.[144] The court concluded that a but-for standard of causation was inappropriate and that the proximate causation standard strikes "the proper analytical balance and comports with the rule requiring strict construction of punitive civil statutes."[145] Furthermore, the court concluded that the proximate cause standard "separates the wheat from the chaff, allowing FCA claims to proceed against parties who can fairly be said to have caused a claim to be presented to the government, while winnowing out those claims with only attenuated links between the defendants' specific actions and the presentation of the false claim."[146]

In tort law, proximate causation requires that courts examine whether a defendant's conduct was a substantial factor in the outcome and whether the outcome was reasonably foreseeable. In general, courts using this standard in an FCA case will find for a plaintiff on the issue of causation if the defendant could have foreseen that a false or fraudulent claim would be filed with the government, despite the presence of "intervening links in the causal chain."[147]

§ 11:5 FCA Issues in the Healthcare Area

The FCA has been often applied in the area of healthcare, including as to both pharmaceutical and device manufacturers and healthcare providers. The FCA is a potent tool for the government in the healthcare arena, often leading to resolutions in which a healthcare company must pay billions or hundreds of millions of dollars and accept stringent future monitoring by the government.[148] We examine below issues pertinent to that area.

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144. *See* U.S. *ex rel.* Sikkenga v. Regence Bluecross Blueshield, 472 F.3d 702, 714–15 (10th Cir. 2006).

145. *Id*. at 715 n.17; *see also* United States v. Luce, 873 F.3d 999, 1013 (7th Cir. 2017) ("the clear weight of authority" supports the view that "'but-for' does not fulfill adequately the causation requirement of the statute") (collecting cases); U.S. *ex rel*. Fesenmaier v. Cameron-Ehlen Grp., 2021 WL 101193 (D. Minn. Jan. 12. 2021) ("multiple courts have applied a proximate cause standard"); U.S. *ex rel.* Tran v. Comput. Scis. Corp., 2014 WL 2989948, at *14 (D.D.C. July 3, 2014) (plaintiff must allege that "the defendant's conduct was 'at least a substantial factor in causing, if not the but-for cause of, submission of false claims").

146. *Sikkenga*, 472 F.3d at 714.

147. *See, e.g.*, U.S. *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754, at *13–14 (D. Mass. Aug. 22, 2003).

148. See *supra* chapter 10 for a detailed listing of recent healthcare fraud resolutions.

§ 11:5.1 Off-Label Marketing

[A] Generally

A significant focus of FCA qui tam plaintiffs and the government has been alleged off-label marketing by pharmaceutical companies. Relators and the government have accused pharmaceutical and device companies of violating criminal statutes and the FCA by promoting the use of medicines and devices for indications that have not received FDA approval. The government contends that such practices violate the FCA by inducing providers to submit claims for off-label uses not covered by Medicare and Medicaid. In those cases, the government typically contends that such claims allegedly were caused by statements made by the pharmaceutical or device company to the providers.[149] Apart from civil liability, the government may also assert criminal charges that off-label promotion unlawfully introduces a misbranded drug, or an unapproved new drug, into interstate commerce. Felony charges for such conduct ranging up to ten years in prison are available if the government has evidence that the defendant "intentionally violated [21 U.S.C.] § 331 with the specific intent to defraud or mislead an identifiable government agency."[150] For example, in September 2009, pharmaceutical executive W. Scott Harkonen was convicted in California federal court of wire fraud based on the issuance of a press release about the clinical trial results of a drug for an off-label use that the government contended presented false and misleading results.[151]

Criminal exposure could also arise under the criminal false claims provisions of 18 U.S.C. § 287, which provides for imprisonment of up to five years for those who knowingly present false, fictitious, or fraudulent claims to the government. A conviction also can result in criminal fines for individuals and corporations of up to $250,000 and $500,000, respectively, or twice the gross gain or gross loss from the offense.[152]

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149. The government contends that statutes limit reimbursement of pharmaceuticals only for approved indications. The statutes cited in support of this proposition, *see* U.S. *ex rel.* Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007), provide that drugs are reimbursable if they are used for a medical indication approved by the FDA, or if the use "is supported by" certain designated medical compendia. *See* 42 U.S.C. § 1396r-8(k)(3), (6); § 1396r-8(g)(1)(B).

150. United States v. Arlen, 947 F.2d 139, 143 (5th Cir. 1991), *cert. denied*, 503 U.S. 939 (1992).

151. *See* Press Release, U.S. Dep't of Just., W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud (Sept. 29, 2009), https://archives.fbi.gov/archives/sanfrancisco/press-releases/2009/sf092909.htm.

152. 18 U.S.C. § 3571(b)–(d).

[B] False Statements and First Amendment Issues

Despite these large settlements, FCA civil liability for off-label promotion is not clear-cut, and plaintiffs face significant challenges. In addition to pleading, causation, and proof-of-damage issues, issues arise as to whether off-label claims contain any statement that is false. Off-label payment claims submitted to Medicare/Medicaid may be truthful if they reveal the underlying diagnosis—that is, if they clearly disclose that the underlying prescription was off-label. Likewise, statements about off-label indications made by pharmaceutical companies to providers may also be completely truthful and protected by the First Amendment.[153]

In *U.S. ex rel. Franklin v. Parke-Davis*, the U.S. District Court for the District of Massachusetts held that the plain text of the FCA did not contain a "double falsehood requirement," that is, that liability under section (a)(1) does not require proof that the drug company made a materially false statement to a provider that in turn led to the filing of a false claim.[154] Therefore, the relator in *Parke-Davis* did not have to prove that the pharmaceutical company sales representatives made misrepresentations or omissions about off-label efficacy to a provider that in turn induced off-label prescriptions. Rather, the required falsehood is found in the claim for reimbursement of an off-label use, which the pharmaceutical defendant was alleged to have caused.[155]

DOJ has taken a similar position in briefs filed in off-label cases, contending that "[i]t is not necessary also to show (or allege) an express falsehood from the defendant to the provider to satisfy the 'falsity' element of section (a)(1)" of the FCA.[156] DOJ claims that

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153. The Second Circuit has held that the government "cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." United States v. Caronia, 703 F.3d 149, 169 (2d Cir. 2012). The holding in *Caronia* may have implications in other types of cases, such as civil FCA cases premised on allegations that off-label promotion led to the submission of false claims.

154. U.S. *ex rel.* Franklin v. Parke-Davis, No. 2003 WL 22048255, at *1 (D. Mass. Aug. 22, 2003). The court noted that section (a)(2)—which imposes FCA liability for making a false statement or record in order to get a false claim paid—does contain a double falsehood requirement by its terms.

155. *Id*. at *2. As the court explained, "§ 3729 does not require that the 'cause' be fraudulent or otherwise independently unlawful."

156. United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, at *8, U.S. *ex rel.* Rost v. Pfizer, Inc., No. 03-cv-11084-PBS (D. Mass. May 12, 2008).

"proof of falsity" for liability under section 3729(a)(1)—new section 3729(a)(1)(A)—of the FCA could simply be found in the fact that a provider sought payment for an uncovered off-label use.[157] As the government reiterated in an amicus brief, "the core question of 'falsity' under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable."[158] Yet courts have held that "off-label marketing of an approved drug is itself not inherently fraudulent."[159] In the seminal *Caronia* decision, the Second Circuit added to this jurisprudence by vacating on free speech grounds the conviction of a sales representative for conspiring to introduce a misbranded drug into commerce based solely on his off-label promotion of the drug.[160] The court vacated the conviction after recognizing that off-label use of a drug is lawful and "the promotion of off-label drug use is not in and of itself false or misleading."[161]

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157. Under that standard, however, a doctor who prescribes a drug off label—a practice that the government recognizes is vital to the practice of medicine—to a patient she knows is covered by Medicare or Medicaid could conceivably be charged with an FCA violation. An attempt by a relator to sue doctors under the FCA for off-label prescribing of psychiatric drugs to minors was rebuffed because of the public disclosure bar (*see infra* section 11:8.1) based on prior public disclosures regarding that type of off-label marketing. U.S. *ex rel.* Law Project for Psychiatric Rights v. Matsutani, No. 3:09-CV-0080-TMB (D. Alaska Sept. 24, 2010). A similar claim brought against a doctor who prescribed a drug off label reached the Seventh Circuit, which reversed the district court's grant of summary judgment in the prescribing doctor's favor, but it did so without reaching the underlying merits of the suit as to whether the doctor can be held liable under the FCA for prescribing a drug off label. U.S. *ex rel.* Watson v. King-Vassel, 728 F.3d 707 (7th Cir. 2013).

158. United States' Statement of Interest in Response to Defendant's Motion to Dismiss, at *5, U.S. *ex rel.* Polansky v. Pfizer, Inc., 2010 WL 3936992 (E.D.N.Y. Sept. 24, 2010) [hereinafter Polansky Statement of Interest]. However, as courts have recognized, a truthful claim to the government does not become false simply because the government may ultimately decide not to pay it. *See* U.S. *ex rel.* Burlbaw v. Orenduff, 400 F. Supp. 2d 1276, 1289 (D.N.M. 2005) ("It cannot be an actionable violation of the FCA for an individual to provide truthful information to the government, in order to allow the government to determine whether or not that information establishes eligibility for a certain program."), *aff'd*, 548 F.3d 931 (10th Cir. 2008); *cf.* United States v. Caremark, Inc., 634 F.3d 808, 818–19 (5th Cir. 2011) (holding truthful yet legally impermissible claims are not false claims under the FCA).

159. *See, e.g.*, Cent. Reg'l Emps. Benefit Fund v. Cephalon, Inc., 2009 WL 3245485, at *10 (D.N.J. Oct. 7, 2009); *In re* Actimmune Mktg. Litig., 614 F. Supp. 2d 1037, 1051 n.6 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011).

160. United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).

161. *Id*. at 165.

The Second Circuit noted, however, that "off-label promotion that is false or misleading is not entitled to First Amendment protection."[162] In light of the Second Circuit's decision, relators are likely to frame their FCA allegations to emphasize how the statements made by the pharmaceutical company to doctors were false and misleading, beyond the fact that they were off-label, and therefore led to the submission of false claims.

Under subsection (a)(1)(B), which imposes liability when a false record is created or maintained material to a false claim, DOJ admits the need to show a false statement by a pharmaceutical defendant, but argues that such falsity can be demonstrated by "material omission[s]" such as statements promoting off-label use that "fail[ ] to mention that the evidence does not support the drug's efficacy for the use he or she is promoting or that the FDA has specifically concluded that the drug is not safe or effective for that use."[163]

Nevertheless, issues arise about whether FCA liability attaches where a provider's claim for off-label use is not false irrespective of what prompted it. In one case in the U.S. District Court for the District of Maine, defendants claimed that there was no false claim because they had accurately identified the drug and the medical condition for which it was prescribed.[164] The court, having dismissed the case under Rule 9(b), did not address these issues. A prior authorization by a state Medicaid program allowing the use of a drug may also defeat an FCA claim. In *U.S. ex rel. Rost v. Pfizer, Inc.*, the court noted that, "if a state knowingly chose to reimburse for a drug, even for an off-label use, after a prior authorization review, liability would not attach because extensive government knowledge would negate the intent requirement under the FCA as a matter of law."[165] Moreover,

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162. *Id*. at 165 n.10. The Ninth Circuit affirmed the conviction of Scott Harkonen, former CEO of Intermune, for wire fraud based on the issuance of a press release about the clinical trial results of a drug for an off-label use because "[t]he First Amendment does not protect fraudulent speech." United States v. Harkonen, 2013 WL 782354, at *1 (9th Cir. 2013). As part of its analysis, the court considered whether the jury heard sufficient evidence to conclude that the press release was "fraudulent even if not 'literally false.'" *Id*. The court pointed to the fact that Harkonen prevented Intermune's clinical personnel from viewing the press release prior to its publication and his attempts to shield the post hoc analyses contained in the press release from the FDA as evidence supporting the finding that Harkonen knew the press release was misleading.

163. Polansky Statement of Interest, *supra* note 158, at 9.

164. U.S. *ex rel.* McDermott v. Genentech, Inc., 2006 WL 3741920, at *13 (D. Me. Dec. 14, 2006).

165. U.S. *ex rel.* Rost v. Pfizer, Inc., 253 F.R.D. 11, 16 (D. Mass. 2008); *see also* U.S. *ex rel.* Brown v. Celgene Corp., 2016 WL 7626222 (C.D. Cal.

courts have observed the lack of inherent falsity in an off label use of a medical device, noting that Medicare reimburses for such use if the procedure is reasonable and necessary.[166] Ultimately, the absence of any misrepresentation may have force in many factual settings.

Cases addressing the falsity requirement have reached different conclusions regarding off-label promotion allegations. In dicta in the *Polansky* case, Judge Korman of the U.S. District Court for the Eastern District of New York questioned the viability of the implied certification theory of falsity in an off-label case, noting that the pharmaceutical company "did not file any claims for reimbursement and made no implied certifications to obtain payment."[167] Observing that the FDA has expressly advised physicians that off-label prescribing is appropriate, the court stated that "the entities to which reimbursement claims are made can hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing" the drug "consistent" with the label.[168] Another court reached a similar conclusion, albeit in dicta, stating that relator had not demonstrated "how the mere act of promoting the subject drugs [off-label] resulted in the submission of a claim containing a *false* representation."[169] The U.S. District Court for the Northern District of California court looked at the issue of falsity differently in an off-label case, finding that the requirement of a "false statement" in the FCA was met where the government alleged that the drug company promoted the drug for a use for which

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Dec. 28, 2016) (summary judgment granted as to three states that covered off-label uses of the subject drugs).

166. U.S. *ex rel.* Dan Abrams Co. v. Medtronic, Inc., 2017 WL 4023092, at *8 (C.D. Cal. Sept. 11, 2017) ("Medicare or Medicaid may allow coverage of a cleared device used off label, when the use is 'medically necessary,' or 'reasonable and necessary' to treat a given patient."); Elliott-Lewis v. Abbott Lab'ys, Inc., 2017 WL 1826627, at *4 (D. Mass. May 5, 2017).

167. *Polansky*, 2009 WL 1456582, at *7.

168. *Id*.

169. U.S. *ex rel.* Keeler v. Eisai, Inc., No. 09-22302, slip op. at 21–22 n.18 (S.D. Fla. Jan. 31, 2013) (noting that relator failed to demonstrate falsity because he did not "contend that a prescribing physician falsely represented that the treatment was for an indicated condition when seeking reimbursement from the government" and because he did not allege "that a claim for reimbursement is the equivalent of a representation that the requested service is covered, that submission of off-label claims runs afoul of any of the certifications that prescribers make, or that the government would not have reimbursed the claim had it known of the off-label nature of the use or the fact of the promotion").

it had no credible evidence of efficacy.[170] The lack of credible efficacy evidence made each use ineligible for reimbursement (because the use was not reasonable or necessary).[171] Essentially, the court found an impliedly false certification that the off-label use was reasonable and necessary in each submitted claim that resulted from the drug company's conduct.[172] The issue of falsity will undoubtedly be further tested in litigated off-label cases.

§ 11:5.2 Anti-Kickback Violations

The government has brought FCA cases based on claims submitted by healthcare providers who allegedly had received kickbacks or referral fees in exchange for prescribing a drug. These cases put at issue pharmaceutical companies' provision of grant money, samples, honoraria, or other things of value to healthcare providers as potential payments to induce the provider to prescribe the companies' drugs. Similar issues arise regarding the provision of services and things of value to managed care companies, pharmaceutical benefits managers, and other entities involved in paying for pharmaceuticals. The anti-kickback statute (AKS) also prohibits remuneration for patient referrals, which the Seventh Circuit held is broadly defined as "encapsulating both direct and indirect means of connecting a patient with a provider."[173]

Criminal exposure for alleged kickbacks to providers has long been found in the AKS, which makes it a felony under certain circumstances to solicit, receive, or provide remuneration knowingly and willfully in return for: (i) referring a person to a person for a service reimbursed by Medicare/Medicaid, or (ii) purchasing a good or service that is to be paid by Medicare/Medicaid.[174] The Second Circuit recently held that willfulness necessary to support an FCA case alleging kickback violations requires allegations that defendant acted with "a bad purpose," that is, with knowledge that its conduct was unlawful.[175]

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170. *Scios*, 676 F. Supp. 2d at 891.
171. *Id*. at 891–92.
172. *See also* U.S. *ex rel.* Carpenter v. Abbott Lab'ys, Inc., 723 F. Supp. 2d 395, 409 (D. Mass. 2010) (finding a claim for reimbursement impliedly certifies that it is for a medically accepted indication).
173. Stop Ill. Health Care Fraud, LLC v. Sayeed, 957 F.3d 743, 750 (7th Cir. 2020). *But see Martin*, 63 F.4th at 1048 (holding that remuneration "covers just payments and other transfers of value" in holding that hospital decision not to hire a doctor competing with another doctor providing referrals was not remuneration).
174. 42 U.S.C. § 1320a-7b(b).
175. U.S. *ex rel*. Hart v. McKesson Corp., ___ F.4th ___, 2024 WL 1056936 (2d Cir. Mar. 12, 2024) (affirming dismissal of FCA case premised on

Kickback cases can present interesting issues regarding the level of pleading necessary to satisfy Rule 9(b). For example, in *In re Pharmaceutical Industry Average Wholesale Price (AWP) Litigation*, the district court rejected a Rule 9(b) challenge to an anti-kickback FCA claim where plaintiff had detailed at least one particular payoff in the form of a discount and had sufficiently detailed descriptions of "the alleged schemes, including names of particular doctors and hospitals, to satisfy the particularity requirement."[176] Those detailed allegations of the underlying payoff scheme made it "probable that the payments . . . led to the submission of false certifications of compliance with the Anti-Kickback statute."[177] Moreover, because the pharmaceutical company did not directly submit the claims, the court ruled that the relator "need not plead the details of specific false claims."[178] In *Duxbury*, the First Circuit found that Rule 9(b) was met in a kickback case—although it was a "close call"—where the relator identified eight providers who allegedly submitted false claims because of kickbacks, which the court found supported a "strong inference that such claims were also filed nationwide."[179] In contrast, in *U.S. ex rel. Laucirica v. Stryker Corp.*,[180] the court held that a relator failed to meet Rule 9(b) where he failed to identify any specific claim tainted by a kickback or to specify the time period over which improper reimbursements were sought, despite specifically alleging that a doctor was motivated to use defendant's products because of research grants he received.

Challenging causation is also a key defense to a kickback case based on statutory language in the 2010 amendment to the AKS specifying that claims "resulting from" AKS violations are false. In 2022, the Eighth Circuit held that language requires FCA plaintiffs to establish but-for causation—that is, that an item or service would not have been included in a claim "but for the illegal kickbacks," rejecting the government's "taint" theory.[181] The Sixth Circuit followed suit, holding that the "when it comes to violations of the Anti-Kickback

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kickbacks where relator's complaint lacked allegations showing defendant's willfulness).

176. *In re* Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367, 391 (D. Mass. 2008).

177. *Id*.

178. *Id*.

179. *Duxbury*, 579 F.3d at 30–31.

180. U.S. *ex rel.* Laucirica v. Stryker Corp., 2010 WL 1798321 (W.D. Mich. May 3, 2010).

181. U.S. *ex rel.* Cairns v. D.S. Med., LLC, 44 F.4th 828, 2022 WL 2930946 (8th Cir. July 26, 2022).

Statute, only submitted claims 'resulting from' the violations are covered by the False Claims Act" and that the "resulting from" standard requires but-for causation.[182] In 2024, the Seventh Circuit declined to decide whether but-for causality was required but held that plaintiff's suggestion that "every claim for payment following an anti-kickback violation is automatically false" is inconsistent with the statutory language that a false claim "must result" from a kickback.[183]

§ 11:5.3 Pharmaceutical Pricing Cases

Relators and the government have also brought cases under the FCA regarding the prices for drugs that pharmaceutical companies report to privately published drug price compendia that the government uses as a basis to reimburse providers. The government alleges

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182. U.S. *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1052 (6th Cir. 2023); *see also Regeneron*, 2023 WL 6296393, at *21 ("[t]he adoption by Congress of the 'resulting from' language in the statute requires a finding that the appropriate standard is but-for causation, and the Court will follow that approach here"). *But see* U.S. *ex rel*. Fitzer v. Allergan, 2024 WL 3015364 (D. Md. June 3, 2024) (affirming its "middle-of-the-road" approach even after contrary decisions from the Sixth and Eighth Circuits were issued, and outlining the causal elements it would require in case alleging kickbacks to doctors by placing them on a doctor-locator screen on defendant's website); United States v. Teva Pharm. USA, Inc., 2023 WL 4565105 (D. Mass. July 14, 2023) ("[t]he government need not prove 'but-for' causation"); U.S. *ex rel.* Fitzer v. Allergan, Inc., 2022 WL 846211 (D. Md. Mar. 22, 2022) (rejecting but-for causation in favor of a "middle of the road" approach and collecting cases); U.S. *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 97 (3d Cir. 2018) (no requirement that kickback "actually influenced a provider's judgment"). Even in a "but-for" causation jurisdiction, the government claims it can rely on a "taint" theory because it need not rely on the 2010 amendment in asserting an FCA claim based on alleged kickbacks, contending that the government pays only for "conflict-free medical care that is provided in the best interest of the patient and that is not potentially affected by financial considerations." United States' Statement of Interest, U.S. *ex rel.* Louderback v. Sunovion Pharm., Inc., No. 17-cv-01719-ECT/ECW (D. Minn. July 10, 2023). That theory was accepted in one district court case in Minnesota, *see* U.S. *ex rel*. Fesenhaier v. Cameron-Ehlen Grp., Inc., 2023 WL 36174 (D. Minn. Jan. 4, 2023), but rejected by another court in that same district in U.S. *ex rel*. Louderback v. Sumitomo Pharma Am., Inc., 2024 WL 4151357 (D. Minn. Sept. 11, 2024) (dismissing case with prejudice for failure to plausibly allege that alleged kickbacks in the form of conditional rebates to pharmacies were the but-for cause of claims).

183. Stop Ill. Health Care Fraud, LLC v. Sayeed, 100 F.4th 899 (7th Cir. 2024) (remanding to district court to determine which unlawful referrals were caused by an illicit data mining scheme).

that the companies report a falsely high price—known as the Average Wholesale Price (AWP)—to those compendia knowing that the government will overpay providers. The government's theory is that the pharmaceutical company benefits by increased demand for its product from providers, who benefit from the spread between the higher reimbursement price and their lower actual price. Relators, in addition to federal and state government entities, have secured sizable settlements in pricing-based FCA cases.[184] Pricing cases also have generated substantial litigation, which has, in large part, been consolidated into a multi-district litigation in the District of Massachusetts. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, the district court denied a motion to dismiss a claim under the California False Claims Act "that the drug manufacturers report false prices for a particular drug to MediCal via the publishing compendium knowing full well that the provider will be reimbursed based on that inflated price when he submits his claim to Medi-Cal for a particular drug."[185] The court disposed of several challenges by defendant to the charges on the ground of a lack of falsity, finding that: (i) the fact that the provider did not include the AWP in the submitted claim did not require dismissal, as the claim "is predicated on an underlying fraudulent pricing scheme," and (ii) that the ambiguity of the term AWP did not foreclose a falsity finding, particularly where the reported prices could be so grossly inflated to be "by their very nature fraudulent."[186]

The court, however, entertained a government knowledge defense, acknowledging that reports of the HHS Inspector General's office that reported AWPs were artificially high presented a "difficult legal question."[187] Ultimately, the court did not dismiss on that ground, holding that government knowledge is not an automatic bar. In another pharmaceutical pricing case, *Commonwealth of Massachusetts v. Mylan Laboratories*,[188] interpreting the Massachusetts false claims

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184. For example, since 2000, whistleblower specialty pharmacy Ven-A-Care of the Florida Keys, Inc. has settled more than two dozen pricing-based FCA cases for over $3 billion. David Voreacos, *Mylan to Pay $57 Million to Settle Drug Overpricing Claims*, BLOOMBERG (Feb. 28, 2012), www.bloomberg.com/news/2012-02-28/mylan-to-pay-57-million-to-settle-drug-overpricing-claims-1-.html.

185. *In re* Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 173 (D. Mass. 2007) (denying motion to dismiss under California version of FCA).

186. *Id*. at 173–74.

187. *Id*. at 174.

188. Commonwealth of Massachusetts v. Mylan Lab'ys, Civ. Action No. 03-11865, slip op. at 54 (D. Mass. Dec. 23, 2008).

act, the court stated that a government knowledge defense was "viable" where a state agency knew that a drug reimbursement reference price did not reflect discounts "because the government decided to continue using [the reference price] as a policy."[189] Government knowledge of the problems with AWP-based reimbursements also was the basis for the reversal of jury verdicts in favor of the State of Alabama claiming that pharmaceutical companies' reported AWPs constituted fraud.[190] A well-documented record of government knowledge of the nature of reported prices may fare better on summary judgment or in a case brought or joined in by the federal government.

§ 11:5.4 Concealment of Safety Data and Risk Minimization

A few recent cases have addressed FCA qui tams premised on the alleged concealment of safety data from the FDA by pharmaceutical manufacturers or minimization of drug or device risks in the promotion of these products. Relators have argued that the claims for reimbursement submitted to the government for these drugs were false because, had the safety information or risks been properly disclosed, the government would have paid for fewer prescriptions of the drugs at issue. Relators contend that fewer government reimbursements would have resulted, either because doctors would have written fewer prescriptions in light of the additional or correct safety information or because the FDA would have withdrawn approval for the drugs. Relators pursuing FCA suits based on this theory have faced difficulties, as courts—including the Third, Fourth, and First Circuits—have dismissed their complaints for failure to state a claim under the FCA or for failure to satisfy Rule 9(b)'s heightened pleading standard.

In *Petratos*, the Third Circuit held that a claim that a pharmaceutical manufacturer suppressed the safety risks of a drug were not material under *Escobar* because the FDA continued to approve the drug after learning of relator's allegations.[191] The Third Circuit also pointed out that DOJ had taken no action, and declined intervention, suggesting a different result could be obtained in an intervened case.[192] In *Rostholder*, the Fourth Circuit rejected relator's allegations

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189. *Accord In re* Pharm. Indus. Average Wholesale Price Litig., 685 F. Supp. 2d 186, 205 (D. Mass. 2010) (noting that to prevail on a government knowledge defense, defendants must produce admissible evidence that the government "knew the actual true facts, and that they ordered, asked for, approved, or decided as a policy matter to acquiesce in the Defendants' reporting of false prices").
190. AstraZeneca LP v. Alabama, 41 So. 3d 15, 33 (Ala. 2009).
191. U.S. *ex rel.* Petratos v. Genentech, 855 F.3d 481, 490 (3d Cir. 2017).
192. *Id*.

that a pharmacy violated the FCA by selling to government programs drugs that violated regulations prohibiting the cross-contamination of penicillin and non-penicillin drugs. The court reasoned, "[w]ere we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct."[193] The First Circuit also upheld the dismissal of a claim that a device manufacturer had fraudulently obtained FDA approval, noting that the government had not denied reimbursement for uses of the device nor had the FDA demanded a recall.[194] In dismissing the case, the court stated that "[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so."[195] Other courts have similarly dismissed safety-based FCA claims given FDA oversight of that issue.[196] The Ninth Circuit issued a contrary

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193. U.S. *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694, 702 (4th Cir. 2014).

194. D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016).

195. *Id.*; *see also* U.S. *ex rel.* Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 34 (1st Cir. 2017) (failure of FDA to withdraw or suspend approval after allegations of defendant's misrepresentations in approval process "renders a claim of materiality implausible," but court allowed claims that defendant sold products to physicians that did not meet FDA specifications); In U.S. *ex rel.* Ge v. Takeda Pharm. Co., 737 F.3d 116 (1st Cir. 2013), the First Circuit affirmed a dismissal of an FCA claim based on improper reporting of adverse events to the FDA on Rule 9(b) grounds because relator failed to allege with particularity that defendant's alleged misconduct regarding adverse events resulted in the submission of false claims. The district court in *Takeda* explained that citizens are able to petition the FDA to bring enforcement actions against pharmaceutical manufacturers for not properly reporting adverse events and stated that "[i]t is through that mechanism, rather than an FCA lawsuit, that relator should have brought the reporting issues illuminated in the complaints to the attention of the FDA." U.S. *ex rel.* Ge v. Takeda Pharm. Co., 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012).

196. *See* U.S. *ex rel.* Walterspiel v. Bayer AG, 639 F. App'x 164, 168 (4th Cir. 2016) (dismissing claim that defendant falsified study data that it submitted to the FDA because the complaint failed to identify "what claims Bayer AG made to the Government, the amount of the claims, or the extent to which Bayer AG benefited from the alleged fraud it perpetrated on the Government"); U.S. *ex rel.* Thornton v. Pfizer, Inc., 2019 WL 1200753 (N.D. Ill. Mar. 14, 2019) (dismissing claim of "silent recall" of medical devices in violation of FDA regulations noting that there was no change to government reimbursement of device in response to suit);

ruling concerning compliance with FDA-approved manufacturing practices.[197] Other courts have also allowed claims that companies

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Elliott-Lewis, 2017 WL 1826627, at *3 (applying *D'Agostino* to dismiss fraud-in-inducement claim based on allegedly false Premarket Approval Application filed with FDA); U.S. *ex rel.* Tessitore v. Infomedics, Inc., 847 F. Supp. 2d 256, 264–66 (D. Mass. 2012) (dismissing on Rule 9(b) grounds relator's claims that defendant's failure to report adverse drug experiences resulted in the submission of false claims because relator failed to provide any details regarding the alleged false certifications the company submitted to the FDA or any factual support that submitting the adverse reports would have hastened the FDA's decision to require warnings and that such warnings would have resulted in doctors writing fewer prescriptions for the drug).

In U.S. *ex rel.* Simpson v. Bayer Healthcare Pharm., 732 F.3d 869 (8th Cir. 2013), the Eighth Circuit took a split approach to whether risk minimization leads to false claims. The court affirmed the dismissal of relator's claim that a manufacturer's downplaying of drug risk led to the submission of false claims to government healthcare programs because the relator failed to identify any representative examples of actual false claims that were submitted due to the risk minimization marketing scheme or show "how such reimbursement claims were false in and of themselves." *Id*. at 878–80. The court, however, reversed the dismissal as to the purchase of the subject drugs by the U.S. Department of Defense (DoD), finding that relator had stated a viable fraud in the inducement claim based on specific discussions between the manufacturer and DoD regarding DoD's safety concerns about the drug. *Id*. at 875–77. *But see* U.S. *ex rel*. Bennett v. Bayer Corp., 2024 WL 1507689 (D.N.J. Apr. 4, 2024) (rejecting fraud-in-the-inducement theory regarding allegations that defendant concealed side effects when obtaining FDA approval because of an absence of a contractual relationship between the government and defendant). *See also* U.S. *ex rel.* Bennett v. Bayer Corp., 2022 WL 970219 (D.N.J. Mar. 31, 2022) (granting motion to dismiss noting that FDA conspicuously declined to include side effects that plaintiff claims should have been included); U.S. *ex rel*. Jefferson v. Roche Holding AG, 2020 WL 5759779 (D. Md. Sept. 28, 2020) (denying motion to dismiss claim that defendant fraudulently induced government to purchase drug for pandemic stockpile based on claim that it "purposefully orchestrated studies with unsound methodologies in order to generate support for an FDA indication that it had previously been denied").

197. U.S. *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890 (9th Cir. 2017) (reversing dismissal of complaint holding that use of unapproved source for active ingredient of drug as material to government reimbursement). The government, however, has since sought dismissal of the case on the ground that discovery would disrupt the mission of FDA and other government agencies. *See also* U.S. *ex rel*. Wallace v. Exactech, Inc., 2020 WL 4500493 (N.D. Ala. Aug. 5, 2020) (allowing claims to proceed that alleged that medical device claims were false under a misbranding theory because of defendant's failure to report adverse events and manufacturing defects rendering product not reasonable and necessary for use). *See*

misled the medical community, underreported adverse events, or otherwise withheld safety data to proceed beyond a motion to dismiss.[198] The government's amicus briefs take the position that a failure to report adverse events could support an FCA case in "rare" circumstances such as "if the unreported adverse events are so serious that the FDA would have withdrawn a drug's approval for all indications had these events been properly reported."[199] Although some courts have expressed skepticism about the FCA being the proper remedy for product safety issues, actions taken by DOJ pursuant to the FCA and by state attorneys general pursuant to their state FCA statutes or consumer protection statutes have resulted in settlements and jury verdicts against pharmaceutical manufacturers for concealing or minimizing drug safety issues.[200]

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also Dan Abrams Co. v. Medtronic Inc., 850 F. App'x 508 (9th Cir. 2021) (following *Campie* in allowing fraud-on-FDA claim to proceed); United States v. Medtronic, 2024 WL 1699558 (C.D. Cal. Feb. 16, 2024) (allowing claims that defendant made misrepresentations to FDA in order to secure approval of a medical device to proceed past summary judgment).

198. U.S. *ex rel.* Higgins v. Bos. Sci. Corp., 2017 WL 6389671, at *2 (D. Minn. Dec. 13, 2017) (denying motion to dismiss claims that device maker failed to inform FDA of product defects). *But see* U.S. *ex rel.* Higgins v. Bos. Sci. Corp., 2021 WL 3604848 (D. Minn. Aug. 12, 2021) (in which the same court later granted defendant summary judgment finding no materiality based on FDA's awareness of the allegedly misrepresented matters); United States v. Pfizer, Inc., 2016 WL 807363 (E.D. Pa. Mar. 1, 2016) (allowing claims that defendant misrepresented study to FDA in new drug application to proceed); *In re* Plavix Mktg., Sales Practices & Prods. Liab. Litig., 2015 WL 4997077, at *21 (D.N.J. Aug. 20, 2015) (rejecting most claims, but permitting claims that company misrepresented effectiveness of Plavix to proceed as to Medicaid states that provide that treatments must be cost-effective to be reimbursed); U.S. *ex rel.* Krahling v. Merck & Co., 44 F. Supp. 3d 581 (E.D. Pa. 2014) (allegations that company withheld vaccine safety data from government can state a claim).

199. Brief for United States of America as Amicus Curiae in Support of Neither Party at 11, U.S. Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint at 8, U.S. *ex rel.* Ge v. Takeda Pharm. Co., No. 13-1088 (1st Cir. Aug. 1, 2013); *see also* Brief for United States of America as Amici Curiae in Support of Neither Party at 26, U.S. *ex rel.* Petratos v. Genentech, No. 15-3805, 2016 WL 3012033 (3d Cir. May 23, 2016) (FCA liability is possible "in the (rare) circumstances in which the defendant's false statements masked problems that were so serious that FDA would have (for example) withheld or withdrawn its approval of the drug application for all indications had it known the truth . . .").

200. For example, in 2012, GlaxoSmithKline's $3 billion settlement resolved, among other misconduct, allegations that GSK had made misleading

§ 11:5.5 Rule 9(b) Issues Involving Providers and Manufacturers

FCA actions must meet the heightened pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure.[201] The difficulties in linking a reimbursement claim to defendant's conduct, including promotional activity by pharmaceutical manufacturers, can lead to dismissal of FCA healthcare fraud cases under Rule 9(b). The plaintiff should have details in hand when bringing the complaint, as one appellate court struck an amended complaint reflecting information relator learned in discovery, holding that plaintiffs should not be permitted to bolster threadbare allegations with discovery.[202] As to identifying false claims, courts are split as to whether Rule 9(b) requires an FCA plaintiff to specifically identify some or all of them or whether detailed allegations regarding the allegedly fraudulent off-label marketing scheme suffice without any identification of allegedly false claims.

Many courts have allowed plaintiffs to survive Rule 9(b) dismissal by pleading the details of a fraudulent scheme along with some reliable indicia that false claims were submitted. In *U.S. ex rel. Rost v. Pfizer, Inc.*,[203] the First Circuit, after noting that relators failed to identify false claims, recognized a lower Rule 9(b) pleading standard in FCA cases where claims are not submitted to the government by the defendant. The court found that Rule 9(b) could be met in such cases where there is "factual or statistical evidence to strengthen the inference of fraud *beyond possibility*," and permitted the relator to amend his complaint.[204] The Ninth Circuit has similarly held that

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statements to healthcare providers about the safety profile for Avandia. A $950 million settlement by Merck in 2011 also resolved, among other misconduct, allegations that Merck made misleading statements about Vioxx's cardiovascular safety to healthcare providers and to state Medicaid agencies.

201. *See, e.g.*, U.S. *ex rel.* Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004). The 2009 amendments to the FCA did not eliminate the requirement that fraud be pled with particularity. *See* U.S. *ex rel.* Lacy v. New Horizons, Inc., 348 F. App'x 421, 424 n.2 (10th Cir. 2009); *see also* U.S. *ex rel.* Burroughs v. Cent. Ark. Dev. Council, 2010 WL 1875580 (E.D. Ark. May 10, 2010).

202. Bingham v. HCA, Inc., 783 F. App'x 868, (11th Cir. July 31, 2019) (reasoning that the government should decide whether or not to intervene with complete information).

203. U.S. *ex rel.* Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007).

204. *Id*. at 732–33 (emphasis added). The relator's amended complaint in *Rost* survived a Rule 9(b) motion to dismiss only as to claims arising in two states. Those claims were later dismissed on summary judgment

plaintiffs need not identify false claims as long as they allege details of a scheme "paired with reliable indicia that claims were actually submitted."[205] The D.C. Circuit stated that "the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable [FCA] complaint," especially where claims are submitted by a third party.[206]

There have been varied approaches by courts in delineating what constitutes reliable evidence that false claims were submitted. Some have found such evidence from a representative sample of false claims.[207] Other courts have focused on whether the relator has pled that he or she has personal knowledge of the submission of claims to the government.[208] In a number of decisions dismissing claims

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for insufficient proof of a violation of the FCA. U.S. *ex rel.* Rost v. Pfizer, Inc., 736 F. Supp. 2d 367 (D. Mass. 2010). The First Circuit reiterated this rule in U.S. *ex rel.* Duxbury v. Ortho Biotech Prods., LP, 579 F.3d 13, 29 (1st Cir. 2009), stating that, in a case alleging the submission of false claims by a third party, a relator could satisfy Rule 9(b) through factual or statistical evidence establishing fraud "beyond possibility," "without necessarily providing details as to each false claim."

205. United States v. United Healthcare Ins. Co., 2016 WL 7378731, at *14 (9th Cir. Dec. 16, 2016); *cf.* United States v. Carolina Liquid Chemistries, Corp., 2019 WL 3207851 (N.D. Cal. July 16, 2019) (dismissing on 9(b) grounds where complaint did not allege sufficient details to show that the allegedly fraudulent scheme "took place").

206. U.S. *ex rel.* Heath v. AT&T, Inc., 791 F.3d 112, 126 (D.C. Cir. 2015); *see also* U.S. *ex rel.* Chorches v. Am. Med. Response, Inc., 865 F.3d 71, 93 (2d Cir. 2017) ("details of actual bills or invoices" are not required as long as "relator makes plausible allegations . . . that lead to a strong inference that specific claims were indeed submitted"); U.S. *ex rel.* Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153 (3d Cir. 2014) (finding that Rule 9(b) is satisfied where the complaint contains "details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

207. *See Duxbury*, 579 F.3d 13 (plaintiff met 9(b) by identifying eight providers alleged to have submitted false claims); U.S. *ex rel.* Dunn v. N. Mem'l HealthCare, 739 F.3d 417 (8th Cir. 2014) (the plaintiff "must provide some representative examples of [the defendant's] fraudulent conduct" under Rule 9(b)). *See also* U.S. *ex rel.* Sibley v. Univ. of Chi. Med. Ctr., 44 F.4th 646 (7th Cir. 2022) (dismissing claim against one defendant where no specific examples of false claims provided).

208. Estate of Debbie Helmly v. Bethany Hospice & Palliative Care of Coastal Ga., LLC, 853 F. App'x 496 (11th Cir. 2021) (affirming dismissal where relators did not claim "to have observed the submission of an actual false claim; nor did they personally participate in the submission of false claims"); U.S. *ex rel.* Strubbe v. Crawford Cnty. Mem'l Hosp., 95 F.3d 1158 (8th Cir. 2019) (no strong inference of false claims where realtors did not have access to the billing department and complaint included no

on Rule 9(b) grounds, the First Circuit has described the types of evidence that would meet Rule 9(b), stating that a complaint that does not identify claims should nevertheless identify "who submitted false claims to the government, how many false claims were submitted to the government, or how the Defendants' actions resulted in the submission of false claims."[209]

While the majority of courts allow for a complaint to proceed without identification of claims, the Fourth Circuit continues to require that false claims be identified or plausible allegations that the conduct necessarily led to the submission of a false claim. In *U.S. ex rel.*

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details about defendant's billing practices); U.S. *ex rel.* Grant v. United Airlines Inc., 912 F.3d 190 (4th Cir. 2018) (without specific false claims identified, relator must at least describe billing structure); Carrel v. AIDS Healthcare Found., Inc., 898 F.3d 1267 (11th Cir. 2018) (dismissal where relators had no knowledge of tainted claims; could not rely on "mathematical probability" that there must have been a false claim); U.S. *ex rel.* Eberhard v. Physicians Choice Lab'y Servs., LLC, 642 F. App'x 547, 552 (6th Cir. 2016) (allowing an exception from the strict requirement that actual claims be identified where plaintiff alleges "specific information about the filing of the claims themselves"); *see also* U.S. *ex rel.* Hirt v. Walgreen Co., 846 F.3d 879 (6th Cir. 2017) (noting that the Sixth Circuit has relaxed the pleading standard only once where relator had "sufficient personal knowledge of the defendant's claim submission and billing process"); U.S. *ex rel.* Mastej v. Health Mgmt. Assocs., Inc., 591 F. App'x 693 (11th Cir. 2014) (sufficient indicia of reliability based on personal knowledge of the former CEO that claims were actually submitted to the government); U.S. *ex rel*. O'Toole v. Cmty. Living Corp., 2020 WL 2512099 (S.D.N.Y. May 14, 2020) (dismissing on 9(b) grounds where no false claim identified and relator had "at least some access to information" about submitted claims). One court noted that as a general rule treating doctors would not be in a position to have the requisite knowledge about the claims submitted based on their treatment. *See* United States v. Nw. Eye Ctr., P.A., 2017 WL 758572 (D. Minn. Feb. 27, 2017). *See also* U.S. *ex rel*. Benaissa v. Trinity Health, 963 F.3d 733 (8th Cir. 2020) (affirming dismissal on 9(b) grounds where relator did not have firsthand knowledge of defendant's billing practices, but also noting that there is no requirement that relator be a member of a defendant's billing or financial-services department); U.S. *ex rel.* Owsley v. Fazzi Assocs., Inc., 16 F.4th 192 (6th Cir. 2021) (without a "representative claim," plaintiff can meet Fed. R. Civ. P. 9(b) based on personal knowledge of billing practices).

209. Lawton *ex rel.* U.S. v. Takeda Pharm. Co., 842 F.3d 125, 131 (1st Cir. 2016); *see also* U.S. *ex rel.* Kelly v. Novartis Pharm. Corp., 827 F.3d 5 (1st Cir. 2016) (plaintiff needs to identify doctors who submitted claims, rough time periods, locations and amounts of false claims and specific government programs); Hagerty *ex rel.* U.S. v. Cyberonics, Inc., 844 F.3d 26 (1st Cir. 2016) (same).

Nathan v. Takeda Pharmaceuticals North America, Inc.,[210] the Fourth Circuit affirmed the dismissal of an off-label case against a pharmaceutical manufacturer because the relator did not "allege with particularity that specific false claims actually were presented to the government for payment."[211] The court stated that "when a defendant's actions, as alleged and as reasonably inferred from the allegations, could have led, but need not necessarily have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." But in a recent case, the Fourth Circuit seems to allow for a case to proceed beyond dismissal without sample claims.[212]

The Sixth Circuit, while allowing for a relaxed pleading standard in limited circumstances, notes that its decisions have "continued to affirm that we impose a strict requirement that relators identify actual false claims[.]"[213] Demonstrating its strict approach, the Sixth Circuit held that a representative claim in an off-label case must be described "with specificity as to each necessary component of the alleged scheme," that is, a prescription by a specific provider to whom the defendants promoted off label.[214]

The circuits' divergent views in these cases demonstrate that Rule 9(b) will continue to be an important issue in FCA healthcare fraud cases, and dismissal will likely be more challenging where the government intervenes or where relator identifies at least some of the allegedly fraudulent claims.

§ 11:5.6 Causation, Individualized Proof, and Damage Issues Involving Providers and Manufacturers

Causation and damages quantification also present hurdles for the government in FCA healthcare cases because of the difficulties

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210. U.S. *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013); *see also* U.S. *ex rel.* Branscome v. Blue Ridge Home Health Servs., Inc., 2018 WL 1309734, at *3–4 (W.D. Va. Mar. 13, 2018).

211. *Id*.

212. *See* U.S. *ex rel.* Nicholson v. Medcom Carolinas, Inc., 42 F.4th 185, 194 (4th Cir. 2022) (describing two ways to show presentment of a false claim with particularity: a representative sample of claims or a pattern of conduct that necessarily would have led to the submission of false claims).

213. U.S. *ex rel.* Eberhard v. Physicians Choice Lab'y Servs., LLC, 642 F. App'x 547 (6th Cir. 2016) (quotation omitted).

214. U.S. *ex rel.* Ibanez v. Bristol-Myers Squibb Co., 874 F.3d 905, 920 (6th Cir. 2017) (citation omitted); *see also* U.S. *ex rel.* Roycroft v. Geo Grp., 722 F. App'x 404 (6th Cir 2018) (dismissing case where relator failed to "identify what is false in the representative claims, so as to connect the claims to the broader scheme" and to identify which "facet" of the scheme was implicated) (citation omitted).

of proving that promotional activities caused a particular provider to submit a false claim. For example, in an off-label case, *Parke-Davis*, the district court denied summary judgment on the causation issue, finding that plaintiff need only prove that the off-label promotion was foreseeable and a substantial factor in submission of a claim. The court found enough evidence to overcome summary judgment based on an increased rate of off-label prescriptions after promotional activities, and evidence in the record of the state of mind of doctors following promotional meetings.[215] While enough to defend summary judgment, this evidence may not be sufficient to prove causation at trial. Therefore, an early focus on causation can prove worthwhile in the defense of FCA claims in the healthcare area.

Another potential pitfall for plaintiffs is proof of falsity of individual claims and damage quantification. In one case, the Fifth Circuit affirmed the dismissal of a complaint premised on statistical data inferences where that data was also consistent with a "legal and obvious alternative explanation."[216] Other courts have confronted the issue of using statistical analyses as proof beyond the pleading stage. In 2014, a district court addressed the issue of whether liability could be premised on extrapolation from a sample. In that case, the government alleged that defendant skilled nursing facility overbilled for longer patient stays, and proposed proving its case as to the amount of false claims at issue by extrapolating from a sample. The district court denied defendant's motion for partial summary judgment on the limited issue of whether statistical extrapolation is appropriate for demonstrating FCA liability. The court found that statistical extrapolation is sufficient for this purpose and, more specifically, for purposes of demonstrating falsity and identifying specific claims submitted for government reimbursement.[217] In another case, after allowing sampling, the court threw out the resulting $347 million jury verdict

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215. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *13; *see also Carpenter*, 723 F. Supp. 2d 395. *But see* U.S. *ex rel*. Calderon v. Carrington Mortg. Servs., LLC, 2020 WL 1320894 (S.D. Ind., Mar. 12, 2020) (holding that at summary judgment stage relator must have evidence to support that each loan was fraudulent).

216. U.S. *ex rel*. Integra Med Analytics, L.L.C. v. Baylor, 2020 WL 2787652 (5th Cir. May 28, 2020).

217. U.S. *ex rel.* Martin v. Life Care Ctrs. of Am., Inc., 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014). Notably, the district court denied defendant's motion to certify the issue for interlocutory appeal. *See* Order, U.S. *ex rel.* Martin v. Life Care Ctrs. of Am., Inc., No. 1:08-cv-251 (E.D. Tenn. Nov. 24, 2014) (denying motion to certify order for immediate interlocutory appeal); *see also* U.S. *ex rel.* Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 714 (7th Cir. 2014) ("there has to be some evidence—statistical or otherwise—from which the jury could determine

finding the disputed practices not material as a matter of law and commenting that evidence of a widespread scheme was premised on "the diciest possible form of sparse and attenuated statistical sampling . . . ."[218] Other courts have reached different conclusions about whether to allow statistical sampling to prove an FCA case.[219]

Sampling issues will likely arise as to damage quantification as well. In off-label and kickback cases, for example, the plaintiff will have to develop a method of proving which of thousands of prescriptions, some not induced by improper promotion, were unlawful. Few cases have proceeded this far down the litigation road, and therefore

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(at least approximately) how many of [defendant's] documents contained false certifications").

218. U.S. *ex rel.* Ruckh v. Salus Rehab., LLC, 304 F. Supp. 3d 1258, 1267–68 (M.D. Fla. 2018); *rev'd in part on other grounds*, 963 F.3d 1089 (11th Cir. 2020).

219. *Compare* Grant v. Zorn, 107 F.4th 782 (8th Cir. 2024) (no abuse of discretion by district court in allowing plaintiff expert to extrapolate from a sample of thirty-one patients to all of defendant's billing practices); U.S. *ex rel.* Heath v. Wis. Bell, Inc., 75 F.4th 778 (7th Cir. 2023) ("[w]e have recognized that statistical analyses may be used to support False Claims Act cases"); U.S. *ex rel*. Schmuckley v. Rite Aid Corp., 2020 WL 3970201 (E.D. Cal. July 14, 2020) (allowing expert testimony using statistical sampling to prove falsity of claims); U.S. *ex rel*. Scott v. Ariz. Ctr. for Hematology & Oncology PLC, 2020 WL 2059926 (D. Ariz. Apr. 29, 2020) (denying defendants' summary judgment on claims proved by sampling, stating that "if sufficiently reliable to be admitted under Rule 702," statistical evidence may be used to prove an FCA case); United States v. Americus Mortg. Corp., 2017 WL 4083589, at *4 (S.D. Tex. Sept. 14, 2017) (allowing sampling and extrapolation to determine the number of ineligible loans and associated damages), *and* United States v. Robinson, 2015 WL 1479396, at *10 (E.D. Ky. Mar. 31, 2015) ("statistical sampling methods and extrapolation" are "reliable and acceptable evidence in determining facts related to FCA claims"), *with* U.S. *ex rel.* Conroy v. Select Med. Corp., 307 F. Supp. 3d 896 (S.D. Ind. 2018) (denying relator request for broad discovery on the ground that it was necessary for sampling analysis, stating that fraud based on lack of medical necessity cannot "be done by a random-sampling method that does not evaluate whether each particular claim for which the plaintiffs seek relief was actually knowingly false within the meaning of the FCA"); U.S. *ex rel.* Michaels v. Agape Senior Cmty., Inc., 2015 WL 3903675, at *8 (D.S.C. June 25, 2015), *order corrected*, 2015 WL 4128919 (D.S.C. July 6, 2015) (rejecting sampling where each claim involves a "highly fact-intensive inquiry involving medical testimony"); U.S. *ex rel*. Dolan v. Long Grove Manor, Inc., 2019 WL 2774149 (N.D. Ill. July 2, 2019) (granting summary judgment to defendants where plaintiff relied only on statistical analyses and could not provide "individualized evidence of at least one claim involving the provision of medically unnecessary care").

it is difficult to predict what evidence will suffice at trial. In *Parke-Davis*, the district court, in denying summary judgment, deferred to a later date the "daunting task of determining whether a reliable statistical method exists for measuring nation-wide damages."[220] The viability of methods measuring causation and damages by aggregate proof remains uncertain.[221]

§ 11:6 FCA Issues Regarding Government Contractors

Claims against traditional government contractors have been a significant focus of qui tam relators and the government dating back to the FCA's passage during the Civil War as a means to address rampant fraud by contractors supplying the Union Army.

§ 11:6.1 Government Contractor Risks

Traditional bases of FCA liability for government contractors have included, but are not limited to, the following types of allegations:

(i) defective products or services;[222]

(ii) overbilling and inflation of labor or supply costs;[223]

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220. *Parke-Davis*, 2003 WL 22048255, at *5.

221. *Compare In re* Zyprexa Prods. Liab. Litig., 671 F. Supp. 2d 397, 434 (E.D.N.Y. 2009) (noting large body of law holding that "statistical proof is in most instances insufficient to show reliance, loss-causation, or injury"), *with* United States v. Fadul, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (noting that courts "have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical"), *and In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 51 (1st Cir. 2013) (finding summary judgment inappropriate because it "should have been left to a jury to weigh the aggregate and circumstantial evidence of causation presented by [plaintiff] against any failure to present individualized testimony from doctors").

222. *See, e.g.*, U.S. *ex rel.* Roby v. Boeing Co., 100 F. Supp. 2d 619 (S.D. Ohio 2000), *aff'd*, 302 F.3d 637 (6th Cir. 2002) (denying defendant's motion for summary judgment on claims alleging delivery of defective helicopters, transmissions, and gears); Press Release No. 15-304, U.S. Dep't of Just., Manhattan U.S. Attorney Files and Simultaneously Settles False Claims Act Lawsuit Against Defense Contractor and Its President for Multi-Year Fraud Involving Sale of Defective Weapons Sights to U.S. Military and Other Agencies (Nov. 25, 2015), www.justice.gov/usao-sdny/pr/manhattan-us-attorney-files-and-simultaneously-settles-false-claims-act-lawsuit-against (settling claim that L-3 Communications, through its subsidiary EOTech, allegedly "sold defective holographic weapon sights to the U.S. Department of Defense").

223. *See, e.g.*, Press Release, Navmar to Pay $4.4 Million to Settle False Claims Act Allegations Regarding Double-Billing and Cost-Shifting

(iii) misrepresentations regarding qualifications or eligibility, such as small business status;[224]

(iv) misrepresentations regarding compliance with contract requirements[225] or applicable laws in performance of a

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(Sept. 15, 2023), www.justice.gov/opa/pr/navmar-pay-44-million-settle-false-claims-act-allegations-regarding-double-billing-and-cost (resolving allegations that Navmar "knowingly billed certain labor and material costs on one Navy contract" and "subsequently billed the same costs on another contract" such that it was paid twice for the same costs); Press Release 17-906, U.S. Dep't of Just., Defense Contractor Agrees to Pay $9.2 Million to Settle False Billing Allegations (Aug. 15, 2017), www.justice.gov/opa/pr/defense-contractor-agrees-pay-92-million-settle-false-billing-allegations (settling allegations that Huntington Ingalls Industries "knowingly overbilled the Government for labor on U.S. Navy and Coast Guard ships at its shipyards in Pascagoula, Mississippi").

224. *See, e.g.*, Gose v. Native Am. Servs. Corp., 109 F.4th 1297 (10th Cir. 2024) (graduates of Minority Small Business and Capital Ownership Development Program subject to program requirements as long as they continue to perform existing contracts); Press Release, Government Contractors Agree to Pay $3.9 Million to Resolve Clams of Misrepresenting Women-Owned Small Business Status (Jan. 30, 2024), www.justice.gov/usao-edva/pr/government-contractors-agree-pay-39-million-resolve-claims-misrepresenting-women-owned (resolving allegations that QuarterLine Consulting Services made false statements about its women-owned small business status to obtain a Defense Health Agency task order that was set aside for those businesses); Press Release No. 17-895, U.S. Dep't of Just., Defense Contractor ADS Inc. Agrees to Pay $16 Million to Settle False Claims Act Allegations Concerning Fraudulently Obtained Small Business Contracts (Aug. 10, 2017), www.justice.gov/opa/pr/defense-contractor-ads-inc-agrees-pay-16-million-settle-false-claims-act-allegations (settling "allegations that ADS, together with several purported small businesses that it controlled, fraudulently induced the government to award certain small business set-aside contracts by misrepresenting eligibility requirements"). Note that misrepresentations of small business size status can be a trap for the unwary. When certifying status in the System for Award Management, a contractor should consider the effect of the limitations on subcontracting rule, *see* 13 C.F.R. § 125.6; 48 C.F.R. § 52.219-14, as well as the ostensible subcontractor rule and all affiliates that could be aggregated for purposes of determining the contractor's size status, *see* 13 C.F.R. § 121.103.

225. *See, e.g.*, Press Release No. 21-1293, Justice Department Announces Global Resolution of Criminal and Civil Investigations with Privatized Military Housing Contractor for Defrauding U.S. Military (Dec. 22, 2021), www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-privatized (settling allegations that Balfour Beatty Communities manipulated data and falsely certified that it had met its performance objectives in order to get the incentive fee); Press Release No. 24-917, Prysmian Cables Settles Allegations of Falsified

contract;[226]

(v) failure to comply with the "price reductions clause" in GSA schedule contracts;[227]

(vi) false certifications of contract cost and pricing data under the Truthful Cost or Pricing Data Act;[228] and

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Test Results and Failure to Test Cable Used in Military Vehicles (July 23, 2024), www.justice.gov/opa/pr/prysmian-cables-settles-allegations-falsified-test-results-and-failure-test-cable-used (resolving allegations that Prysmian prepared and submitted falsified test results and certifications of compliance to the government for its cable used in military vehicles); Press Release No. 17-193, U.S. Dep't of Just., Pacific Architects and Engineers, LLC to Pay $5 Million in False Claims Act Settlement (Sept. 13, 2017), www.justice.gov/usao-dc/pr/pacific-architects-and-engineers-llc-pay-5-million-false-claims-act-settlement (resolving allegations that PAE "knowingly failed to follow vetting requirements for personnel working in Afghanistan under a State Department contract for labor services").

226. *See, e.g.*, U.S. *ex rel.* Wall v. Circle C Constr., LLC, 697 F.3d 345 (6th Cir. 2012) (affirming summary judgment against contractor on claims alleging false payroll certifications where subcontractor did not comply with Davis-Bacon Act prevailing wage requirements); Press Release No. 16-226, U.S. Dep't of Just., Lockheed Martin Agrees to Pay $5 Million to Settle Alleged Violations of the False Claims Act and the Resource Conservation and Recovery Act (Feb. 29, 2016), www.justice.gov/opa/pr/lockheed-martin-agrees-pay-5-million-settle-alleged-violations-false-claims-act-and-resource (settling FCA claim that Lockheed Martin violated the Resource Conservation and Recovery Act in its performance of a Department of Energy contract at the Paducah diffusion facility "by failing to identify and report hazardous waste produced and stored at the facility, and failing to properly handle and dispose of the waste").

227. *See, e.g.*, Press Release No. 16-631, U.S. Dep't of Just., Deloitte Consulting LLP Agrees to Pay $11 Million for Alleged False Claims Related to General Services Administration Contract (May 31, 2016), www.justice.gov/opa/pr/deloitte-consulting-llp-agrees-pay-11-million-alleged-false-claims-related-general-services (settling claim that, between 2006 and 2012, Deloitte Consulting allegedly "failed to comply with the price reductions clause in its contract," which required it "to reduce the prices it charged the government if it offered lower prices to specific commercial customers during the course of the contract"). Note that GSA eliminated the price reductions clause requirement in mid-2016. *See* GSA Final Rule, 81 Fed. Reg. 41,104 (June 23, 2016). FCA claims grounded in price reductions clause noncompliance should cease to be an issue for contractors in future years as the applicable statutes of limitations and contracts containing the clause run their course.

228. *See, e.g.*, Press Release No. 13-751, U.S. Dep't of Just., CyTerra Corporation Agrees to Pay $1.9 Million to Resolve False Claims Act Allegations (July 2, 2013), www.justice.gov/opa/pr/cyterra-corporation-agrees-pay-19-million-resolve-false-claims-act-allegations (settling claim that, during

(vii) false certifications of compliance with the Trade Agreements Act[229] or domestic preference statutes,[230] such as the Buy American Act.

Additional FCA risks are posed by noncompliance with regulatory policies specific to government contracting, especially Department of Defense (DoD) contracting. These policies are regularly, and often required to be, included as Federal Acquisition Regulation (FAR)-prescribed clauses in government contracts. For example, a Defense Federal Acquisition Regulation Supplement (DFARS) clause requires DoD contractors to "mitigate supply chain risk in the provision of supplies and services to the Government."[231] Another DFARS clause requires DoD contractors to safeguard "covered defense information" by implementing the protocols specified in National Institute of Standards and Technology (NIST) Special Publication 800-171

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contract negotiations, CyTerra allegedly "knowingly failed to provide the Army with [its] most recent cost or pricing data on the number of labor hours needed to produce a mine detector" despite the Truthful Cost or Pricing Data Act requirement that it provide "accurate, complete and current" cost and pricing data). Note that the Truthful Cost or Pricing Data Act was formerly known as the Truth in Negotiations Act. FCA claims grounded in violations of the statute are relatively rare as it only applies to negotiated procurements above an inflation-adjusted threshold, presently set at $750,000. *See* 48 C.F.R. § 15.403-4. These larger awards are generally sought by established contractors with sophisticated compliance and proposal teams experienced with government cost and pricing principles.

229. *See, e.g.*, Press Release No. 14-875, U.S. Dep't of Just., Samsung Electronics America Agrees to Pay $2.3 Million to Resolve False Claims Act Allegations (Aug. 19, 2014), www.justice.gov/opa/pr/samsung-electronics-america-agrees-pay-23-million-resolve-false-claims-act-allegations (settling claim that Samsung Electronics America allegedly "caused the submission of false claims for products sold on General Service Administration . . . Multiple Award Schedule . . . contracts" by "knowingly providing inaccurate information to [authorized] resellers regarding the country of origin" of Samsung products sold on the resellers' Schedule contracts).

230. *See, e.g.*, Press Release No. 16-008, U.S. Dep't of Just., Wisconsin Architectural Firm to Plead Guilty and Pay $3 Million to Resolve Criminal and Civil Claims (Jan. 5, 2016), www.justice.gov/opa/pr/wisconsin-architectural-firm-plead-guilty-and-pay-3-million-resolve-criminal-and-civil-claims (settling claim that architectural firm Novum Structures allegedly "caused false claims by knowingly—and in violation of its contractual obligations—using noncompliant foreign materials on several federally funded construction projects from Jan. 1, 2004 through July 11, 2013").

231. *See* 48 C.F.R. § 252.239-7018(b).

(as revised December 2016), and to "rapidly report" the "discovery of any cyber incident."[232] Finally, a FAR clause requires DoD and civilian contractors to put in place various processes to combat and report human trafficking.[233] Contractor certifications of compliance with these and other FAR clauses pose risks of FCA liability, and the potential for treble damages (in addition to breach of contract liability), to the extent a post-*Escobar* court rules that compliance was material to the government's decision to pay.

Contractors should also be on guard for FCA claims predicated on a "fraud in the inducement" theory. Under such a theory, a contractor can be liable for initial misrepresentations that induce a contract, even if the contractor properly performs work under the contract and claims for payment submitted under the contract are entirely accurate.[234] Fraud in the inducement FCA claims likely will present questions regarding both post-*Escobar* materiality and but-for causation.[235]

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232. *See id*. § 252.204-7012; *see also id.* § 252.204-7008 (related solicitation provision); NIST Special Publication 800-171, rev. 1, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations (Dec. 2016), https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-171r1.pdf. Compliance with NIST 800-171 will be enforced by Defense Contract Management Agency (DCMA) audits of contractor business systems, among other methods. Contractors should actively monitor this rapidly evolving area, as there is a strong possibility an analogue clause requiring full NIST 800-171 compliance for civilian agency contracts could be adopted by the FAR Council, or finalized in other agency-specific FAR Supplements, in the near future. Additionally, note that 48 C.F.R. § 252.204-7012 is a mandatory flowdown clause to all subcontractors not supplying commercial off-the-shelf (COTS) items. Prime contractors should require documented, on-file System Security Plans and Plans of Action for all non-COTS subcontractors on DoD contracts. Also, to the extent subcontractors do not require access to systems storing, transmitting, or processing covered defense information—or controlled unclassified information generally—such access should be restricted. Finally, commercial companies (or civilian contractors) engaging in only a limited number of DoD contracts should heed caution as a cyber incident on a non-segregated system could conceivably trigger reporting obligations, and resultant FCA exposure, if the company also stores, transmits, or processes covered defense information on the system.

233. *See* 48 C.F.R. § 52.222-50.

234. The Supreme Court first applied this common law theory to the FCA in U.S. *ex rel*. Marcus v. Hess, 317 U.S. 537 (1943). Recently, some courts have questioned whether the theory can be extended beyond the traditional contract context. *See, e.g.*, *In re* Plavix Mktg., Sales Prac. & Prods. Liab. Litig., 332 F. Supp. 3d 927 (D.N.J. 2017).

235. *See* U.S. *ex rel*. Cimino v. Int'l Bus. Machs. Corp., 3 F.4th 412 (D.C. Cir. 2021) (holding fraudulent inducement theory requires proof of but-for causation).

Additionally, the FAR prescribes a "mandatory disclosure rule," which requires contractors to "[h]ave a written code of business ethics and conduct,"[236] "[m]ake a copy of the code available to each employee engaged in performance of the contract,"[237] and establish both an "ongoing business ethics awareness and compliance program,"[238] and an "internal control system."[239] It also requires contractors to report to the Inspector General and the contracting officer whenever the contractor has "credible evidence" that a violation of the FCA or certain specified criminal laws has occurred in connection with the award, performance, or closeout of a government contract or subcontract.[240] The mandatory disclosure rule is a required clause in all prime contracts and subcontracts where the expected value is greater than $5.5 million and the expected period of performance is at least 120 days.[241] "The disclosure requirement for an individual contract continues until at least 3 years after final payment on the contract."[242] Failure to comply with mandatory disclosure, and attendant internal investigation obligations, could be a predicate for FCA liability if post-*Escobar* materiality is satisfied. Moreover, materials disclosed pursuant to mandatory disclosure could themselves trigger information retention requirements and become bases for future FCA claims.[243] Likewise, various FAR "overpayment" clauses, which

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236. 48 C.F.R. § 52.203-13(b)(1)(i).
237. *Id*. § 52.203-13(b)(1)(ii).
238. *Id*. § 52.203-13(c)(1).
239. *Id*. § 52.203-13(c)(2).
240. *Id*. § 52.203-13(b)(3)(i).
241. *See id*. §§ 3.1004(a), 52.203-13(d). Note that there is a slight distinction in the drafting of the prime contracts regulation at section 3.1004(a) and the subcontracts regulation at section 52.203-13(d), which is material to contracts and subcontracts with a period of performance of exactly 120 days. The prime contracts regulation states that the mandatory disclosure clause is required where the period of performance is "120 days or more" (inclusive of 120 days) while the subcontracts regulation states that the clause is required where the period of performance is "more than 120 days" (exclusive of 120 days). It is unclear how a court would interpret this apparent drafting error. Additionally, note that GSA has taken the position that the $5.5 million threshold is calculated for Schedule contracts by considering "the total estimated value of all contracts on the particular Schedule." ABA SEC. OF PUB. CONTRACT LAW, REPORT OF THE TASK FORCE ON IMPLEMENTATION OF THE CONTRACTOR CODE OF BUSINESS ETHICS AND CONDUCT AND MANDATORY DISCLOSURE RULE, at 11 n.12 (2010) (emphasis omitted). As a practical matter, almost any schedule contract would meet the $5.5 million threshold under this approach. *See id*.
242. 48 C.F.R. § 52.203-13(c)(2)(ii)(F)(3).
243. *See, e.g.*, Press Release, U.S. Att'y's Off., E. Dist. of Va., Government Contractor to Pay $142,500 to Settle Civil Fraud Allegations Resulting

apply depending on the type of contract involved, require the prompt disclosure and remittance of government overpayments.[244] Failure to comply with these requirements could be a predicate for reverse FCA liability. The potential for FCA liability is in addition to potential suspension or debarment, which can apply whether or not mandatory disclosure and overpayment clauses are included in the contract.[245]

§ 11:6.2 Combating Risk and Defending Claims

In light of the above, prime contractors in particular would be wise to protect themselves by:

(i) confirming and documenting the qualifications, business reputation, and responsibility of subcontractors and suppliers;

(ii) including meaningful audit and inspection rights in subcontracts and supplier agreements, extending to the audit and inspection of quality assurance/quality control policies;

(iii) flowing down all FAR clauses requiring certification of regulatory compliance (including cybersecurity compliance) to all subcontracts and supplier agreements, whether or not flow down is mandatory, in order to protect against lability for subcontractor or supplier noncompliance; and

(iv) determining whether it is necessary to provide controlled unclassified information to subcontractors or suppliers and, where unnecessary, excluding access to controlled systems.

The subcontractor/supplier would itself remain liable for FCA claims if the conduct occurred after the 2009 FERA amendments, which eliminated the FCA's "presentment requirement."[246]

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from Its Disclosure of Conduct (Aug. 25, 2016), www.justice.gov/usao-edva/pr/government-contractor-pay-142500-settle-civil-fraud-allegations-resulting-its (settling claims resulting from disclosed conduct that Fairbanks Morse Engine employees had allegedly "engaged in labor mischarging" on a Navy subcontract).

244. *See* 48 C.F.R. §§ 52.212-4(i)(5), 52.232-25(d), 52.232-26(c), 52.232-27(l).

245. *See id*. §§ 3.1003(a)(2), 9.406-2(b)(1)(vi)(C), 9.407-2(a)(8)(iii).

246. As discussed previously in this chapter, the FCA had required that a claim be "presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States." 31 U.S.C. § 3729(a)(2). Among other conduct, the 2009 FERA amendments extended the Act's ambit to "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" *Id*. § 3729(a)(1). Elimination of the presentment requirement has substantially increased the liability exposure of companies working as subcontractors or suppliers, which

On a final note, *Escobar* may provide unique materiality defenses in the government contracting context pertaining to the issue of "continued payments."[247] In requesting payment from the government,

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themselves lack direct privity of contract with the federal government. *See, e.g.*, Press Release No. 13-668, U.S. Dep't of Just., Science Applications International Corporation Pays $11.75 Million to Settle False Claims Allegations (June 13, 2013), www.justice.gov/opa/pr/science-applications-international-corporation-pays-1175-million-settle-false-claims (settling claim that SAIC, acting as a subcontractor to the New Mexico Institute of Mining and Technology, allegedly "charg[ed] inflated prices . . . to train first responder personnel to prevent and respond to terrorism attacks").

247. *See* U.S. *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 663–64 (5th Cir. 2017) ("[T]hough not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality. . . . Further, this case is not about inferring governmental approval from continued payment. Here, the [federal] government has never retracted its explicit approval [of allegedly nonconforming products sold to states and reimbursed under a federal program]."); *id.* at 665 ("While we agree with our sister circuits that no single factor is outcome determinative, the 'very strong evidence' here of [the federal government's] continued payment remains unrebutted." (quoting *Escobar*, 579 U.S. 195)); *id.* at 668–69 ("Congress enacted the FCA to vindicate fraud on the federal government, not [to] second guess decisions made by those empowered through the democratic process to shape public policy."); U.S. *ex rel.* McBride v. Halliburton Co., 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("Moreover, we have the benefit of hindsight and should not ignore what actually occurred: the DCAA investigated McBride's allegations and did not disallow any charged costs. In fact, KBR continued to receive an award fee for exceptional performance under [the applicable task order] even after the Government learned of the allegations. This is very strong evidence that the requirements allegedly violated by the maintenance of inflated headcounts are not material." (internal quotation marks omitted)); U.S. *ex rel.* Kelly v. Serco, Inc., 846 F.3d 325, 334 (9th Cir. 2017) ("Given the demanding standard required for materiality under the FCA, the government's acceptance of Serco's reports despite their non-compliance with [relevant guidelines], and the government's payment of Serco's public vouchers for its work under [applicable contract orders], we conclude that no reasonable jury could return a verdict for Kelly on his implied false certification claim." (citation omitted)); U.S. *ex rel.* Ruckh v. Salus Rehab., LLC, No. 8:11-cv-1303, 2018 WL 375720, at *5 (M.D. Fla. Jan. 11, 2018) (granting motion under Rules 50 and 59 for judgment as matter of law and new trial because jury verdict "effect[ed] an unwarranted, unjustified, unconscionable, and probably unconstitutional forfeiture—times three—sufficient in proportion and irrationality to deter any prudent business from providing services and products to a government armed with the untethered and hair-trigger artillery of a False Claims Act invoked by a heavily invested relator"); *id.* at *4 ("Treble damages plus $11,000

contractors are not simply coding a procedure relative to a diagnosis, as may sometimes be the case in the circumstance of medical claims.[248] Rather, the contractor, contracting officer, contracting officer's technical representative, DCMA representative, and Defense Contract Audit Agency (DCAA) auditor are often interacting together onsite. As the post-*Escobar* case law develops, it warrants monitoring whether the government will be able to say "if only we knew, we

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(after adjusting for inflation) per false claim is not a remedy lawfully imposed on a supplier who delivers substantially compliant goods or services that are received and accepted by a government with knowledge of, or with indifference toward, some immaterial, formalistic, or technical non-compliance."); *id.* ("The record suffers an entire absence of evidence of the kind a disinterested observer, fully informed and fairly guided by *Escobar*, would confidently expect on the question of materiality . . . evidence of whether governments are content—assisted by a regime of rigorous and regular inspections, audits, and accounting—to permit record-keeping practices that largely achieve the ends of, but differ from, the prescribed record-keeping." (discussing *Escobar*, 579 U.S. at 193–95 (footnote omitted))). *But see* U.S. *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 906–07 (9th Cir. 2017) (reversing Rule 12(b)(6) dismissal where questions relating to materiality remained, including whether FDA approval had been fraudulently induced because defendant pharmaceutical company supplying the government allegedly sourced active ingredient from unapproved manufacturer in China, and whether FDA's failure to withdraw its prior approval was grounded in reasons besides the payments to defendant (citations omitted)); United States v. Triple Canopy, Inc., 857 F.3d 174, 179 (4th Cir. 2017) ("[I]n discussing the types of evidence the Government could introduce to show materiality, the [Supreme] Court referenced whether the Government typically paid claims that violated the particular requirement. Here, the Government did not renew its contract for base security with Triple Canopy and immediately intervened in the litigation. Both of these actions are evidence that Triple Canopy's falsehood affected the Government's decision to pay." (referencing *Escobar*, 579 U.S. at 193–95 (footnote omitted))).

248. That said, a continued payments materiality defense has also been successful in the context of medical claims implicating prior FDA approvals. *See, e.g.*, D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016) ("[T]he FCA requires that the fraudulent representation be material to the government's payment decision itself. The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges." (citing *Escobar*, 579 U.S. at 193–95)); *id.* at 8 ("If the FDA would have approved Onyx notwithstanding the alleged fraudulent representations, then the connection between those representations to the FDA and a payment by CMS relying on FDA approval disappears."); *id.* ("The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." (citations omitted)).

would not have paid" where the government was in regular proximity to the contractor interacting about contract performance at the time the contractor submitted claims and the government paid on those claims.[249]

Relatedly, it is questionable whether the government will be able to assert materiality or a causal link to its decision to pay where a contractor has documented regular contemporaneous documentation of its compliance with mandatory disclosure obligations under 48 C.F.R. § 52.203-13. After all, each mandatory disclosure submission arguably asks the government, "Should we continue performing and will you continue paying?" If the government does not say "no," that could prove to be a strong materiality and causation defense and, in a sense, turn mandatory disclosure into an asset rather than a liability for contractors.[250]

§ 11:6.3 Confronting Concurrent Proceedings

As the above discussion demonstrates, FCA issues in the government contracts context can be particularly complex. This complexity is further aggravated by the potential for multiple layers of civil proceedings, even aside from the potential for parallel criminal enforcement. Civil proceedings and pre-proceedings might include:

(i) pre-claim investigations by the contractor, such as internal risk assessments or investigations by outside counsel to comply with mandatory disclosure obligations;

(ii) pre-claim investigations by government contracting personnel, such as audits by the DCAA or investigations by the applicable contracting officer;

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249. *See* U.S. *ex rel.* McBride v. Halliburton Co., 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("Moreover, we have the benefit of hindsight and should not ignore what actually occurred: the DCAA investigated McBride's allegations and did not disallow any charged costs. In fact, KBR continued to receive an award fee for exceptional performance under Task Order 59 even after the Government learned of the allegations. This is 'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material." (quoting *Escobar*, 579 U.S. at 195)).

250. More generally, the creation and maintenance of written policies and procedures to ensure compliance with the FAR and other applicable regulations (including, potentially, the implementation of automated systems if contractor scale or federal work volume justifies) is a best practice that also could be used as an asset in defending against FCA claims.

(iii) pre-claim demands for documents by the government, such as DOJ civil investigative demands or agency subpoenas following the filing of a sealed qui tam complaint;

(iv) the potential for qui tam or government claims even where the DCAA and the contracting officer did not find a violation;

(v) the potential for companion common law fraud claims, as well as breach of contract claims litigated in the U.S. Court of Federal Claims (COFC) or before a board of contract appeals;[251]

(vi) the potential for government FCA counterclaims in COFC contract litigation for money damages; and

(vii) the potential for immediate contract termination or suspension or debarment, which can financially cripple a contractor's ability to mount a robust FCA defense or otherwise induce settlement.[252]

Furthermore, divergent interests between a prime contractor and subcontractor in defending FCA claims brought against both can magnify complexity.

Companies contracting with the government, or even acting as subcontractors or suppliers to others contracting with the government, are well served to consult with experienced government

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251. *See, e.g.*, United States v. Bae Sys. Tactical Vehicle Sys., LP, No. 2:15-cv-12225, ECF No. 20 (E.D. Mich. Mar. 9, 2016) (denying in relevant part defendant's motion to dismiss FCA claim alleging defective cost or pricing data under the Truth in Negotiations Act); BAE Sys. Tactical Vehicle Sys. LP, ASBCA No. 59491, 17-1 BCA ¶ 36,585; ASBCA No. 60433, 16-1 BCA ¶ 36,450 (July 25, 2016) (denying government motion to stay or suspend Board proceedings pending outcome of related FCA action). The Armed Services Board of Contract Appeals subsequently dismissed the board matter as moot following the contracting officer's rescission of the final decision that had asserted the government's claim. *See* ASBCA No. 59491, 17-1 BCA ¶ 36,585 (Dec. 5, 2016). The parties ultimately settled the FCA claim. *See* No. 2:15-cv-12225, ECF No. 52 (E.D. Mich. June 1, 2017) (joint stipulation of dismissal with prejudice).

252. *See, e.g.*, Press Release No. 17-582, U.S. Dep't of Just., Defense Contractor Resolves Criminal, Civil and Administrative Liability Related to Food Contracts (May 26, 2017), www.justice.gov/opa/pr/defense-contractor-resolves-criminal-civil-and-administrative-liability-related-food (agreeing to pay $95 million, forego $249 million in payments, and plead guilty to criminal misdemeanor "to globally resolve criminal, civil, and administrative cases," including suspension of contractor, "arising from allegations that Agility [Public Warehousing Co.] overcharged the United States when performing contracts with the [Defense Logistics Agency] . . . to supply food for U.S. troops from 2003 through 2010").

contracts counsel from the moment they receive notice of any government or relator-initiated proceedings. Furthermore, contractors and subcontractors are best served by engaging outside counsel for regular internal risk assessments and investigations to detect potential FCA exposure before a complaint is filed or civil investigative demand is made. Regular due diligence can maximize compliance with mandatory disclosure obligations and substantially increase the likelihood of detecting companion exposure issues, such as Procurement Integrity Act violations or potential antitrust liability for failure to propose an independently derived price.

§ 11:7 Defenses

§ 11:7.1 Statute of Limitations

The FCA supplies its own limitations period of either: (i) six years after the date of the alleged FCA violation, or (ii) three years after the government official "charged with responsibility to act in the circumstances" knows or should have known of the material facts (but in no event more than ten years after the violation).[253] Regarding the latter period, some courts have held that the responsible government official means the responsible official in the Department of Justice,[254]

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253. 31 U.S.C. § 3731(b). The statute of limitations in a criminal case is governed by 18 U.S.C. § 3282, which provides for a limitations period of five years after the date of the alleged offense. The limitations period of the FCA for submitting a false claim begins when the claim is made, or if paid, when the government pays the claim. U.S. *ex rel.* Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1157 (2d Cir. 1993). But courts have found that the limitations period for an FCA conspiracy claim is triggered when the conspiracy is entered into even if claims that are part of the conspiracy are submitted within the limitations period. *See* U.S. v. Spectrum Painting Corp., 2020 WL 5026815 (S.D.N.Y. Aug. 25, 2020).

254. *See, e.g.*, U.S. *ex rel.* Reeves v. Mercer Transp. Co., 253 F. Supp. 3d 1242, 1251 (M.D. Ga. 2017) ("[O]nly Department of Justice officials are deemed to be officials 'charged with knowledge to act in the circumstances.'"); United States v. Kellogg Brown & Root Servs., Inc., 2016 WL 5344419, at *4 (C.D. Ill. Sept. 16, 2016) (responsible government official "means the Attorney General or her designees"); United States v. R.J. Zavoral & Sons, Inc., 2014 WL 5361991 (D. Minn. Oct. 21, 2014) (the relevant official is someone who has authority to initiate an action under the FCA); United States v. Incorporated Village of Island Park, 791 F. Supp. 354, 363 (E.D.N.Y. 1992); United States v. Tech Refrigeration, 143 F. Supp. 2d 1006, 1009 (N.D. Ill. 2001); U.S. *ex rel.* Jordan v. Northrop Grumman Corp., 2002 U.S. Dist. LEXIS 26616, at *11–12 (C.D. Cal. 2002) ("Based upon the legislative history, the Court finds that the relevant official is one within the Department of Justice.").

although a minority has held that an official of another relevant government agency can qualify as the responsible official to trigger the running of the limitations period.[255] In applying a nearly identical provision governing the statute of limitations for common-law fraud claims (which are often pursued in tandem with FCA claims), some courts have held that the responsible official may come from another agency.[256]

The issue of whether the tolling period applies where the relator pursues the case alone drew the attention of the Supreme Court in the *Cochise Consultancy* case. The Eleventh Circuit had held that the tolling period applies to an action litigated by a relator alone,[257] and that the three-year period is triggered by knowledge of the underlying fraud by the government, not the relator.[258] The Supreme Court granted certiorari given the circuit split, with the Fourth, Fifth and Tenth Circuits holding that the tolling provision does not apply to relator actions, and the Ninth holding that is does and is based on the knowledge of the relator.[259] The Supreme Court ruled that, based on the plain language of the FCA, the tolling provision applies to relator actions but the three-year tolling provision is premised on when a government official (not a relator) knew or should have known about the alleged fraud.[260]

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255. *Kreindler*, 985 F.2d at 1156 (senior army officials in charge of a helicopter project); *see also* United States v. Intrados/Int'l Mgmt. Grp., 265 F. Supp. 2d 1, 12 n.8 (D.D.C. 2002) (questioning in dicta whether the responsible official must be from the DOJ and citing *Kreindler*).

256. *See* 28 U.S.C. § 2416(c); *see also* U.S. *ex rel.* Wilkins v. N. Am. Constr. Corp., 2001 WL 34109383, at *4 (S.D. Tex. Sept. 26, 2001) ("responsible official" under section 2416 was Army Corps of Engineers' Administrative Contracting Officer, not just DOJ officials with authority to initiate litigation); United States v. Kensington Hosp., 1993 WL 21446, at *12 (E.D. Pa. Jan. 14, 1993) (rejecting government position that responsible official under section 2416 must come from Civil Division of the Department of Justice, and finding that IRS and FBI agents had notice of the material facts).

257. U.S. *ex rel.* Hunt v. Cochise Consultancy, Inc., 887 F.3d 1081 (11th Cir. 2018).

258. *Id*.

259. U.S. *ex rel.* Sanders v. N. Am. Bus. Indus., Inc., 546 F.3d 288, 293 (4th Cir. 2008); U.S. *ex rel.* Jackson v. Univ. of N. Tex., 673 F. App'x 384 (5th Cir. 2016); U.S. *ex rel.* Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 726 (10th Cir. 2006); U.S. *ex rel.* Hyatt v. Northrup Corp., 91 F.3d 1211, 1217 (9th Cir. 1996).

260. Cochise Consultancy, Inc. v. U.S. *ex rel*. Hunt, 139 S. Ct. 1507 (2019).

Some courts had held that the FCA's statute of limitations may be extended by the Wartime Suspension of Limitations Act (WSLA),[261] which was amended by the Wartime Enforcement of Fraud Act of 2008 (WEFA) to extend the tolling provisions of the WSLA to time periods during which Congress has authorized use of the armed forces, which includes the current use of the armed forces in Afghanistan and Iraq. In one case, the Fourth Circuit applied the WSLA to extend the statute of limitations in a relator's civil FCA case involving false claims submitted in 2005.[262] The Supreme Court reversed, holding that the WSLA is inapplicable to any civil fraud claim and applies only to criminal "offenses,"[263] thus settling the issue.

Courts generally do not allow plaintiffs to extend the statute of limitations by arguing that a continuing course of conduct connects violations outside of the limitations period with those within. Although the continuing course of conduct theory has gained traction in other contexts, in FCA litigation each fraudulent claim starts the clock on a separate statute of limitations period.[264] However, in one case the Eighth Circuit upheld a district court's dismissal because the relator "failed to tie the allegations [outside of the period] into a continuous pattern of conduct."[265] Although the court did not explain

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261. The WSLA suspends "the running of any statute of limitations applicable to any offense . . . involving fraud or attempted fraud against the government." 18 U.S.C. § 3287.

262. *See* U.S. *ex rel.* Carter v. Halliburton Co., 710 F.3d 171, 176 (4th Cir. 2013), *petition for cert. filed*, 82 U.S.L.W. 3178 (U.S. June 24, 2013) (No. 12-1497) (argued on Jan. 13, 2015); *see also* United States v. Witherspoon, 211 F.2d 858 (6th Cir. 1954) (same). Some district courts found the same. *See, e.g.*, United States v. Movtady, 2014 WL 1357330 (S.D.N.Y. Apr. 7, 2014); United States v. Arnold, 2014 WL 66754 (S.D. Ga. Jan. 7, 2014); United States v. Wells Fargo Bank, N.A., 2013 WL 5312564, at *14 (S.D.N.Y. Sept. 24, 2013) (applying WSLA to extend the statute of limitations in the government's civil FCA case involving false claims related to mortgage fraud submitted between 2002 and 2010); United States v. BNP Paribas SA, 884 F. Supp. 2d 589, 603, 606–07 (S.D. Tex. 2012). Other courts held that the WSLA does not toll the FCA's statute of limitations on claims brought by the relator alone. *See, e.g.*, Hericks v. Lincare, Inc., 2014 WL 1225660 (E.D. Pa. Mar. 25, 2014).

263. Kellogg Brown & Root Servs., Inc. v. U.S. *ex rel.* Carter, 135 S. Ct. 1970, 1978 (2015) ("the term 'offense' [in the WSLA] must be construed to refer only to crimes. Because this case involves civil claims, the WSLA does not suspend the applicable statute of limitations").

264. *See, e.g.*, *Kreindler & Kreindler*, 985 F.2d at 1157; United States v. Incorporated Village of Island Park, 888 F. Supp. 419, 441–42 (E.D.N.Y. 1995).

265. U.S. *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 558 (8th Cir. 2006).

why this fact was relevant, the comment suggests at least the possibility that some courts may entertain the theory in the future.

In FCA cases where the government intervenes years after the relator filed the sealed complaint, issues could arise as to whether the action is time-barred or whether the intervention is governed by Rule 15(c)(2) of the Federal Rules of Civil Procedure, which allows relation back of new allegations in an amended complaint where the new claims arise out of the conduct alleged in the original complaint.[266] In 2006, in *United States v. Baylor University Medical Center*, the Second Circuit dismissed a government complaint in intervention as time-barred, finding that the complaint did not relate back under Rule 15(c)(2) to the relator's original qui tam complaint filed eight years before.[267] The holding in *Baylor* was not widely followed.[268] Congress overturned *Baylor* in the 2009 amendments by specifying that any government complaint in intervention "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."[269] Congress stated that this amendment applies to cases pending as of the May 2009 enactment of the amendments.[270]

Although Congress has overturned *Baylor*, it behooves an FCA defendant to seek dismissal under the statute of limitations where government allegations are unrelated to those in the original complaint.[271] As Judge Saris noted, albeit in the course of rejecting a

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266. U.S. *ex rel*. Gurion v. Guff, 2024 WL 3344673, at *9–10 (S.D.N.Y. July 8, 2024) (dismissing claims as time-barred because the relation back provision benefits only the government and does not apply to save new claims by relators).

267. United States v. Baylor Univ. Med. Ctr., 469 F.3d 263 (2d Cir. 2006).

268. *See* U.S. *ex rel.* Miller v. Bill Harbert Int'l Constr., Inc., 2007 WL 851855 (D.D.C. Mar. 14, 2007) (rejecting *Baylor* in favor of prior precedent in D.C. federal court finding relation back under FED. R. CIV. P. 15(c)(2)); U.S. *ex rel.* Parikh v. Premera Blue Cross, 2007 WL 1031724 (W.D. Wash. Apr. 3, 2007) (holding that limitations period in FCA is tied to when the action is brought, not unsealed, and imposes no limit on government extensions of the seal period); U.S. *ex rel.* Cericola v. Fannie Mae, 529 F. Supp. 2d 1139, 1149 (C.D. Cal. 2007) ("the Court finds nothing in the FCA legislation that precludes application of the relation back doctrine to qui tam complaints").

269. 31 U.S.C. § 3731(c).

270. FERA § 4(f)(2).

271. *In re* Pharm. Indus. Average Wholesale Price Litig., 2007 WL 4287572, at *3 (dismissing claims in an amended complaint relating to drugs not included in earlier claims against pharmaceutical company of

limitations defense, "long delays" by the government in investigating FCA allegations are "troubling," as "[e]vidence spoils, memories fade, and prejudice may result."[272]

§ 11:7.2 Tax Code Cases

The FCA explicitly excludes liability for claims, statements, or records made under the tax code.[273] Courts have dismissed claims based on such statements for lack of subject-matter jurisdiction.[274] In 2006, Congress enacted a whistleblower statute regarding tax claims.[275]

§ 11:8 Special Defenses Against a Qui Tam Relator

If the government declines to intervene, a defendant can assert jurisdictional defenses to dispose of an entire case if it is based largely upon the prior public disclosure of allegations in the qui tam complaint or if the case was filed when another FCA case alleging the same fraud was pending. Some defenses can also be used in certain circumstances to remove a relator if the government does intervene, which can spare a defendant exposure to relator attorney fees.[276]

§ 11:8.1 Public Disclosure Bar

The FCA does not permit suits by relators where allegations are similar to those in the public domain unless the government joins

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fraudulently reported drug prices); U.S. *ex rel*. Aldridge v. Corp. Mgmt. Inc., No. 21-60568 (5th Cir. Aug. 21, 2023) (concluding that government's claims presented new allegations not mentioned in the relator's complaint and thus the claims did not relate back to relator's complaint).

272. *In re* Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 399 n.6 (D. Mass. 2007).

273. 31 U.S.C. § 3729(e). In 2010, New York amended its false claims act to include liability for claims, records, or statements made under the tax law in certain circumstances. *See* N.Y. STATE FIN. LAW § 189(4).

274. *See, e.g.*, Barber v. Paychex Inc., 439 F. App'x 841, 842 (11th Cir. 2011) (affirming dismissal of claims involving records or statements made under the Tax Code for lack of subject-matter jurisdiction), *cert. denied*, 132 S. Ct. 1146 (2012); U.S. *ex rel.* Lissack v. Sakura Glob. Cap. Mkts., Inc., 377 F.3d 145, 157 (2d Cir. 2004) (same). *But see* U.S. *ex rel.* Calilung v. Ormat Indus., Ltd., 2015 WL 1321029, at *11 (D. Nev. Mar. 24, 2015) (grant in lieu of tax credit is not subject to FCA tax exemption).

275. *See infra* section 11:10.

276. For an example, see the procedural history of the *Rockwell* case in which defendant moved to dismiss relators' complaint on public disclosure grounds even after the government had intervened and obtained a verdict against it. Rockwell Int'l Corp. v. United States, 549 U.S. 457 (2007).

the suit.[277] The FCA, as amended as part of the 2010 healthcare law, provides that a court "shall dismiss" an action, "unless opposed by the government, if substantially the same allegations or transactions as alleged in the action" have been previously disclosed, except if: (1) the action is brought by DOJ, or (2) the relator qualifies as the "original source" of the publicly disclosed information.[278] The terms "allegations" and "transactions" are not defined, but "[c]ourts have interpreted 'allegation' to refer to a direct claim of fraud, and 'transaction' to refer to facts from which fraud can be inferred."[279] The type of public disclosures that can serve as the basis for dismissal under this provision includes federal court or administrative hearings in which the government is a party; congressional or federal hearings, audits, investigations, or reports;[280] or disclosure "from the news

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277. If the government joins a suit that is found to be primarily based on disclosures from a prior government investigation or the news media, the relator's share of the recovery is reduced to not more than 10%. 31 U.S.C. § 3730(d)(1).

278. *Id*. § 3730(e)(4)(A).

279. U.S. *ex rel.* Mateski v. Raytheon Co., 816 F.3d 565, 570–71 (9th Cir. 2018); *see also* U.S. *ex rel.* 3729, LLC v. Express Scripts Holding Co., 2023 WL 4056042 (S.D. Cal. June 16, 2023).

280. In Graham Cnty. Soil & Water Conservation Dist. v. U.S. *ex rel.* Wilson, 559 U.S. 280 (2010), the Supreme Court held that "administrative" includes state and local administrative reports, hearings and investigations—a decision that was rendered moot when Congress amended the statute to drop the word "administrative" as a modifier for reports, thereby limiting the public disclosure bar to only "congressional, Government Accountability Office, or other Federal" reports. The court also opined on reports that trigger the public disclosure bar in Schindler Elevator Corp. v. U.S. *ex rel.* Kirk, 536 U.S. 401 (2011), where the Court held, in a 5-3 decision, that the government response to a FOIA request is a "report" under the public disclosure bar. Additionally, information considered to be public disclosure has been held to include the full range of proceedings in criminal, civil, or administrative litigation, encompassing all the pleadings and even non-confidential discovery. *See* U.S. *ex rel.* Paranich v. Sorgnard, 396 F.3d 326, 333 (3d Cir. 2005). Some courts have been more restrictive, limiting what is considered to be public material to information actually filed with a court. *See* U.S. *ex rel.* Stinson v. Prudential Ins. Co., 944 F.2d 1149, 1168–69 (3d Cir. 1991); U.S. *ex rel.* McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 939 (6th Cir. 1997). In addition, SEC filings can qualify as a "type of federal report." U.S. *ex rel.* Calilung v. Ormat Indus., Ltd., 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015); *see also* United States v. Allergan, 46 F.4th 991, 2022 WL 3652967 (9th Cir. Aug. 25, 2022) (provision applies to "a wide range of investigatory processes," including ex parte patent prosecutions). *But see* Silbersher v. Valeant Pharm. Int'l, 76 F.4th 843 (9th Cir. 2023) (holding that *inter partes review* by patent office, a trial-like proceeding

media."[281] The 2010 amendment altered the public disclosure bar by:

(1) deleting the provision that made the bar jurisdictional,[282]

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in which a private party challenges another party's patent, is not a federal hearing or investigation for purposes of the public disclosure bar).

281. Courts have held that the "news media" category of statutory disclosures has a broad scope. *Kirk*, 563 U.S. at 408 ("The other sources of public disclosure in § 3730(e)(4)(A), especially 'news media,' suggest that the public disclosure bar provides a 'broa[d] sweep.'") (quoting *Wilson*, 559 U.S. at 290); U.S. *ex rel.* Ping Chen v. EMSL Analytical, Inc., 2013 WL 4441509, at *11–12 (S.D.N.Y. Aug. 16, 2013) (finding that a press release from a U.S. Attorney's Office and articles posted online were "news media" under the public disclosure bar). But courts have grappled with the extent to which information on the Internet constitutes "news media." In U.S. *ex rel.* Customs Fraud Investigations, LLC v. Victaulic Co., 2014 WL 4375638, at *8 (E.D. Pa. Sept. 4, 2014), the court determined that information on a website can be news media "where the information provided is to some extent curated," meaning that there is some editorial control or analysis. *See also* U.S. *ex rel*. Integra Med Analytics LLC v. Providence Health & Servs., 2019 WL 3282619 (C.D. Cal. July 16, 2019) (holding that news media does not include everything on the Internet but only "information about recent events or that would otherwise be commonly found in a newspaper, news broadcast or other news source," and setting out five factors to evaluate whether online information is from the news media); U.S. *ex rel.* Colquitt v. Abbott Lab'ys, 864 F. Supp. 2d 499, 518 (N.D. Tex. 2012) (finding that, "[a]lthough this Court is not inclined to conclude that in the age of basement blogging and ease of publishing, any medium that disseminates information to the public in a periodic manner is part of the 'news media,'" scholarly and scientific articles, technical periodicals, trade journals, and advertisements contained in these publications are statutory disclosures); U.S. *ex rel.* Osheroff v. Humana, Inc., 776 F.3d 805, 813 (11th Cir. 2015) (holding that newspaper articles and a clinic's websites "which are intended to disseminate information about the clinic's programs" are considered news media); U.S. *ex rel.* Moore & Co. v. Majestic Blue Fisheries, 69 F. Supp. 3d 416 (D. Del. 2014) (posting to CNN website of first-person iReports is not news media because the postings are not verified); U.S. *ex rel.* Oliver v. Philip Morris USA, Inc., 101 F. Supp. 3d 111, 124 (D.D.C. 2015) (government web pages qualify as administrative reports and news media); U.S. *ex rel*. Jacobs v. JP Morgan Chase Bank, N.A., 2024 WL 3928931 (11th Cir. Aug. 26, 2024) (finding blog articles qualify as news media).

282. Where previously the statute commanded that "No court shall have jurisdiction . . . ," the statute now states that "The court shall dismiss . . ." 31 U.S.C. § 3730(e)(4). Thus, while the public disclosure bar was a jurisdictional defense under Rule 12(b)(1) for pre-PPACA cases (that is, those filed prior to March 23, 2010), this bar has become a substantive defense under Rule 12(b)(6) for post-PPACA cases. U.S. *ex rel.* May v. Purdue Pharma L.P., 737 F.3d 908, 916 (4th Cir. 2013); U.S. *ex rel.* Siegel v. Roche Diagnostics Corp., 2013 WL 6847689, at *3 (E.D.N.Y. Dec. 30, 2013).

(2) allowing the government a seeming veto power over the defense,[283]

(3) limiting prior public disclosure to prior federal cases in which the government is a party,[284] and to federal—not state or local—reports, hearings, investigations and audits,[285] and

(4) clarifying that the bar applies where the relator's allegations are similar to prior disclosures even if they were not actually derived from them.[286]

Because the Supreme Court has held that the 2010 amendment to the public disclosure bar is not retroactive,[287] defendants will need

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283. Courts have been rejecting public disclosure defenses where the government opposes it. In U.S. *ex rel.* Sanchez v. Abuabara, 2012 WL 1999527, at *2 (S.D. Fla. June 4, 2012), the district court recognized that under the amended FCA, "Congress eliminated an absolute jurisdictional bar in favor of a jurisdictional bar that can be lifted by government discretion." A different district court held that it could not consider a public disclosure defense as to post-March 2010 allegations because the government opposed dismissal on that basis. U.S. *ex rel.* Szymoniak v. Ace Sec. Corp., 2014 WL 1910876 (D.S.C. May 12, 2014); *see also* U.S. *ex rel.* Griffith v. Conn, 2015 WL 779047 (E.D. Ky. Feb. 24, 2015) (holding that because the public disclosure bar is no longer jurisdictional, allowing the government to quash that defense is not a violation of the separation of powers doctrine); U.S. *ex rel.* Conroy v. Select Med. Corp., 2016 WL 5661566 (S.D. Ind. Sept. 30, 2016) (holding that government veto power over public disclosure defense passes constitutional muster).

284. Courts are split on whether a non-intervened qui tam is a prior public disclosure because the government was not a party. In U.S. *ex rel*. Holloway v. Heartland Hospice, Inc., 960 F.3d 836 (6th Cir. 2019), the Sixth Circuit held that under agency principles a declined qui tam is a prior disclosure in which the government was a party. *But see* U.S. *ex rel.* Forney v. Medtronic, Inc., 327 F. Supp. 3d 831 (E.D. Pa. 2018).

285. *See May*, 737 F.3d at 917 ("After the amendments . . . only disclosures in federal trials and hearings and in federal reports and investigations qualify as public disclosures.").

286. *See id*. ("As amended . . . the public-disclosure bar no longer requires actual knowledge of the public disclosure, but instead applies 'if substantially the same allegations or transactions were publicly disclosed.'") (quoting 31 U.S.C. § 3730(e)(4)(A) (2010)); U.S. *ex rel.* Stratienko v. Chattanooga-Hamilton Cnty. Hosp. Auth., 2013 WL 3912571, at *7 (E.D. Tenn. July 29, 2013).

287. Graham Cnty. Soil & Water Conservation Dist. v. U.S. *ex rel.* Wilson, 559 U.S. 280 (2010); *see also* U.S. *ex rel.* Saldivar v. Fresenius Med. Care Holdings, Inc., 841 F.3d 927, 933 n.1 (11th Cir. 2016); Prather v. AT&T, Inc., 847 F.3d 1097 (9th Cir. 2017). Some courts have held that the amendments to the original source provision are clarifying rather

to continue to evaluate this defense regarding conduct that occurred prior to March 2010.[288]

The reason for the public disclosure bar is to discourage "'parasitic' or 'free-loading' qui tam suits while also encouraging productive private enforcement suits."[289] Stated differently by another court, the public disclosure bar precludes qui tam suits "based on information that would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator."[290] Given this bar, a defendant faced with an FCA suit should scour the possible sources of public disclosure, especially the news media, for any references to the allegations that are at issue in the complaint.[291]

The D.C. Court of Appeals set forth the following analytical framework for a public disclosure defense: "If X + Y = Z, Z represents the *allegation* of fraud and X and Y represent its essential elements," a public disclosure has occurred when either *Z* (the fraud allegation), or both *X* and *Y*—a misrepresented state of facts *and* a true state of facts—are public.[292] Courts have also held that the disclosures supporting a public disclosure dismissal motion may be culled from disparate sources and do not need to be found in a single source, such as a newspaper article.[293] And the public disclosure bar applies even if

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than substantive and therefore apply retroactively. U.S. *ex rel.* Bogina v. Medline Indus., Inc., 809 F.3d 365, 369 (7th Cir. 2016); United States v. McMahon, 2016 WL 5404598 (N.D. Ill. Sept. 28, 2016).

288. *See* U.S. *ex rel.* Scutellaro v. Capitol Supply, Inc., 2017 WL 1422364, at *13 (D.D.C. Apr. 19, 2017) (collecting appellate cases holding that conduct prior to March 23, 2010, is subject to the pre-2010 FCA).

289. *Rost*, 507 F.3d at 729.

290. *Stinson*, 944 F.2d at 1155–56.

291. As discussed above, non-traditional media may qualify as public disclosures. One court has held that even widely disseminated advertisements of customer coupons alleged to violate the FCA can constitute public disclosure. Carmel v. CVS Caremark Corp., 2015 WL 3962532, at *4 (N.D. Ill. June 26, 2015), *appeal dismissed* (Sept. 17, 2015).

292. U.S. *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654–55 (D.C. Cir. 1994). For example, the posting of an allegedly fraudulent contract to a government website does not trigger the public disclosure bar. U.S. *ex rel.* Heath v. Wis. Bell, Inc., 760 F.3d 688 (7th Cir. 2014).

293. *See* U.S. *ex rel.* Dingle v. Bioport Corp., 388 F.3d 209, 214 (6th Cir. 2004) (in determining whether there was a public disclosure "[t]he fact that the information comes from different disclosures is irrelevant"); *see also* U.S. *ex rel.* Solomon v. Lockheed Martin Corp., 878 F.3d 139, 145 (5th Cir. 2017) (public disclosure if relator "could have synthesized an inference of fraud from the public disclosures") (citation omitted); *Holloway*, 960 F.3d at 844 ("a disclosure can arise from multiple documents taken together, rather than a single document"). *But see* U.S. *ex rel*. Silbersher v. Valeant Pharm. Int'l, Inc., 89 F.4th 1154, 1168 (9th Cir. 2024) (no

the complaint is based "in part" on prior public disclosures,[294] and has no requirement that the prior disclosure "use magic words or specifically label the disclosed conduct as fraudulent."[295]

Courts are split on whether disclosure to government officials constitutes prior public disclosure, with most courts holding that it does not.[296] Disclosures prompted by defendants may also qualify: One court has found that emails that the defendant attached to a complaint against a competitor, which suggested the defendant engaged in fraudulent billing practices, constituted prior public disclosure, despite concerns that a person committing fraud "could theoretically

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public disclosure where "the scattered qualifying public disclosures may each contain a piece of the puzzle, but when pieced together, they fail to present the full picture of fraud").

294. U.S. *ex rel.* Hirt v. Walgreen Co., 2016 WL 815512, at *6 (M.D. Tenn. Mar. 2, 2016) (quoting U.S. *ex rel.* Poteet v. Medtronic, Inc., 552 F.3d 503, 514 (6th Cir. 2009)); *see also* Seikel v. Alvarez, 2024 WL 1315869, at *4 (N.D. W. Va. Mar. 27, 2024) (relators' reliance on publicly available information triggered public disclosure bar "even if [the disclosures] only form[ed] part of their claims").

295. U.S. *ex rel.* Winkelman v. CVS Caremark Corp., 827 F.3d 201, 209 (1st Cir. 2016); *see also* U.S. *ex rel.* Sanders, 2021 WL 3513663 (W.D. W. Va. Aug. 10, 2021) (dismissing on public disclosure grounds, stating "it matters not that the conduct was not specifically labeled as fraudulent").

296. *Compare* U.S. *ex rel.* Fowler v. Caremark RX, LLC, 496 F.3d 730, 736 (7th Cir. 2007) ("disclosure of information to the U.S. Attorney's Office during the government's investigation . . . qualifies as a public disclosure of Relators' allegations"), *cert. denied*, 552 U.S. 1183 (2008), *and* Cause of Action v. Chi. Transit Auth., 815 F.3d 267, 277 (7th Cir.), *cert. denied sub nom.* U.S. *ex rel.* Cause of Action v. Chi. Transit Auth., 137 S. Ct. 205 (2016) (letter sent to government was a prior public disclosure, but recognizing that the contrary view of other circuits has "significant force"), *and* U.S. *ex rel*. Howard v. KBR, Inc., 2020 WL 3865725 (C.D. Ill. July 9, 2020 ("the Seventh Circuit has repeatedly held that facts are in the public domain if they are in the possession of the government"); U.S. *ex rel.* Lisitza v. Par Pharm. Cos., 276 F. Supp. 3d 779, 782–83 (N.D. Ill. 2017) (same), *with* Berg v. Honeywell Int'l, Inc., 2012 WL 6759950, at *1 (9th Cir. Dec. 19, 2012) (declining to apply the public disclosure bar where "no member of the public requested the [government audit] reports or received them from the government prior to the date Relators filed their action"), *and Rost*, 507 F.3d at 728 ("[i]n our view, a 'public disclosure' requires that there be some act of disclosure to the public outside of the government"), *and* U.S. *ex rel.* Whipple v. Chattanooga-Hamilton, 782 F.3d 260 (6th Cir. 2015) (rejecting the Seventh Circuit view as inconsistent with the plain text of the statute), *and* U.S. *ex rel.* Wilson v. Graham County, 777 F.3d 691 (4th Cir. 2015) (audit report given only to government officials does not trigger the public disclosure bar).

shield itself from a *qui tam* action through preemptively filing its own action." The court noted that the Supreme Court has found concerns about abuses from such self-disclosure to be unwarranted, particularly as the government can still sue based on the disclosures.[297]

Prior to the 2010 amendment, the FCA required that the relator's allegations be "based upon" the public disclosures. Most jurisdictions did not require an FCA defendant to demonstrate that the relator's suit was derived from the public disclosure. Rather, it was sufficient to demonstrate that the substance of the relator's allegations appeared publicly prior to the relator's filing of the complaint under seal. Eleven federal courts of appeals had held that a relator's lawsuit is "based upon" a public disclosure where the allegations are similar to, supported by, or the same as those that have been publicly disclosed, "regardless of where the relator obtained his information."[298]

In contrast, only the Fourth Circuit had held that public disclosures were a jurisdictional bar only where the allegations in a relator's complaint were "actually derived" from the publicly disclosed information.[299]

Another important consideration in searching for prior public disclosures is that such disclosures do not necessarily have to identify

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297. U.S. *ex rel.* Estate of Cunningham v. Millennium Lab'ys of Cal., Inc., 713 F.3d 662, 672 (1st Cir. 2013).

298. **First Circuit:** U.S. *ex rel.* Ondis v. City of Woonsocket, 587 F.3d 49, 57 (1st Cir. 2009); **Second Circuit:** U.S. *ex rel.* Doe v. John Doe Corp., 960 F.2d 318, 324 (2d Cir. 1992); **Third Circuit:** *Paranich*, 396 F.3d at 334–35; **Fifth Circuit:** Fed. Recovery Servs., Inc. v. United States, 72 F.3d 447, 451 (5th Cir. 1995); **Sixth Circuit:** Walburn v. Lockheed Martin Corp., 431 F.3d 966, 975 (6th Cir. 2005); **Seventh Circuit:** Glaser v. Wound Care Consultants, Inc., 570 F.3d 907, 920 (7th Cir. 2009); **Eighth Circuit:** U.S. *ex rel.* Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1044–45 (8th Cir. 2002); **Ninth Circuit:** U.S. *ex rel.* Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ., 161 F.3d 533, 537–40 (9th Cir. 1998); **Tenth Circuit:** U.S. *ex rel.* King v. Hillcrest Health Ctr., Inc., 264 F.3d 1271, 1279 (10th Cir. 2001); **Eleventh Circuit:** U.S. *ex rel.* Cooper v. Blue Cross & Blue Shield of Fla., Inc., 19 F.3d 562, 565–69 (11th Cir. 1994); **D.C. Circuit:** U.S. *ex rel.* Findley v. FPC-Boron Emps.' Club, 105 F.3d 675, 682–85 (D.C. Cir. 1997).

299. U.S. *ex rel.* Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994). In 2016, the Fourth Circuit reaffirmed the "actually derived" standard for pre-2010 conduct cases. U.S. *ex rel.* May v. Purdue Pharma L.P., 811 F.3d 636, 640 (4th Cir. 2016); *see* U.S. *ex rel*. Fitzer v. Allergan, Inc., 2024 WL 3344627, at *4–5 (D. Md. July 9, 2024) (concluding that public disclosure bar did not apply where relator's allegations of fraud were not "actually derive[d]" from public information about government payments under Medicare).

the defendant targeted in the FCA suit specifically. For example, the Fifth Circuit found a prior public disclosure arose from a public lawsuit against the defendant's predecessor entity.[300] In other cases, it may be enough that the prior public disclosures identify an industry-wide practice that would include the now-sued FCA defendant. In *U.S. ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, the court of appeals found that nationwide press coverage that teaching hospitals double-billed Medicare for services by residents barred a relator action against a hospital charged with such double-billing.[301] The court stated that there is no need for "the specific defendants named in the lawsuit [to] have been identified in the public records." Rather, "[i]ndustry-wide public disclosures bar qui tam actions against any defendant who is directly identifiable from the public disclosures."[302] Other circuits have adopted similar industry-wide theories where public disclosures have provided an "easily identifiable" group of potential perpetrators or have provided "easily accessible notice" to likely defendants.[303] Notably, some circuit courts—even courts that have recognized an industry-wide public disclosure theory—have cautioned against its broad application because such disclosures inform the government "on a general level that fraud is taking place," but do not identify all of the actors—a task with which relators could still help.[304] Despite limitations, district courts have dismissed claims

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300. U.S. *ex rel.* Schwizer v. Canon, Inc., 2021 WL 3560911 (4th Cir. 2021).

301. U.S. *ex rel.* Gear v. Emergency Med. Assocs. of Ill., Inc., 436 F.3d 726, 727–29 (7th Cir. 2006).

302. *Id*.

303. U.S. *ex rel.* Black v. Health & Hosp. Corp. of Marion Cnty., 494 F. App'x 285, 294 (4th Cir. 2012) (holding that, despite "not specifically identify[ing] the Defendant," public hearings and news articles provided "easily accessible notice" and "clearly show[ed] that the government was aware" of the fraud); United States v. CSL Behring, L.L.C., 855 F.3d 935, 946 (8th Cir. 2017) (finding prior public disclosure in OIG's report about pricing issues as to a "narrow class" of drugs from which one could identify the manufacturer-defendant); U.S. *ex rel.* Fine v. Sandia Corp., 70 F.3d 568, 571–72 (10th Cir. 1995) (holding that disclosures of the "mechanics" of the allegedly fraudulent practices combined with a small number of "easily identifiable" potential perpetrators can bar a relator's claim because the prior disclosure "set the government squarely on the trail of fraud").

304. U.S. *ex rel.* Jamison v. McKesson Corp., 649 F.3d 322, 330 (5th Cir. 2011); *see also* U.S. *ex rel.* Baltazar v. Warden, 635 F.3d 866, 868–69 (7th Cir. 2011) (holding that public disclosure regarding only a portion of an industry did not bar suits against all members of the industry because "no court of appeals supports the view that a report documenting widespread false claims, but not attributing them to anyone in particular, blocks qui tam litigation against every member of the entire industry").

based on the industry-wide public disclosure theory, providing yet another means by which defendants can shake off relators in appropriate circumstances.[305]

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305. *See* U.S. *ex rel.* Hogget v. Univ. of Phx., 2014 WL 3689764 (E.D. Cal. July 24, 2014) (disclosure of fraudulent practices by for-profit colleges sufficed as to claim against a particular college); U.S. *ex rel.* Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 328–30 (D. Mass. 2011) (dismissing relator's false certification claims because industry-wide allegations in FDA warning letters and meetings—in connection with a *New York Times* article stating that Medtronic's device was cleared through a certification-required process despite concerns of off-label promotion—provided "enough evidence to identify Medtronic as a perpetrator of the allegedly industry-wide fraud"); U.S. *ex rel.* Branch Consultants, LLC v. Allstate Ins. Co., 668 F. Supp. 2d 780, 794 (E.D. La. 2009) (finding public disclosure of fraud by Hurricane Katrina insurers because "the government would not face great difficulty in identifying possible perpetrators from these disclosures"). In the pharmaceutical pricing cases, Judge Saris applied the public disclosure bar to dismiss FCA claims against a pharmaceutical defendant not named in an earlier public lawsuit alleging similar fraud, finding that the previous complaints could easily have led the government to identify that defendant as a "potential wrongdoer." *In re* Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d at 383 n.10; *see also* U.S. *ex rel.* Law Project for Psychiatric Rights v. Matsutani, No. 09-80 (D. Alaska Sept. 24, 2010) (finding prior public disclosure where "'broad categories' of fraud have been disclosed and the relator merely fills in the details"). *But see* U.S. *ex rel.* Silver v. Omnicare, 903 F.3d 78 (3d Cir. 2018) (no industry-wide prior disclosure of swapping by nursing home pharmacies; notes that the prior disclosure should meet Rule 9(b) pleading standards); U.S. *ex rel.* Rahimi v. Zydus Pharm. (USA), Inc., 2017 WL 1503986, at *7–8 (D.N.J. Apr. 26, 2017) (generic drug company not readily identifiable in prior disclosures of industry-wide fraud given the size of the generic industry), *denying in part and granting in part reconsideration on other grounds*, 2018 WL 515943 (D.N.J. Jan. 23, 2018); U.S. *ex rel.* Fisher v. Homeward Residential, Inc., 2015 WL 3776444, at *3–4 (E.D. Tex. June 17, 2015) (prior disclosures that do not name defendant or cite to an industry-wide scheme are not sufficient); U.S. *ex rel.* Fox Rx, Inc. v. Omnicare, Inc., 2013 WL 2303768, at *9 (N.D. Ga. May 17, 2013) ("A public disclosure, sufficient to bar a relator's FCA action, must identify the particular defendant as having engaged in the fraudulent scheme."); U.S. *ex rel.* Colquitt v. Abbott Lab'ys, 864 F. Supp. 2d 499, 522–23 (N.D. Tex. 2012) (finding that an untitled FDA letter alleging that "many" medical device manufacturers had engaged in the alleged fraud was insufficient to trigger the public disclosure bar against defendants because the letter disclosed allegations only against a subset of industry members and not "every member of the industry," which *Gear* requires for application of its industry-wide theory); U.S. *ex rel.* Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 292 (D. Mass. June 1, 2012) ("Generalized claims of industry-wide fraud . . . will not trigger the public disclosure bar.").

§ 11:8.2 Original Source

As mentioned, the public disclosure bar is inapplicable if the relator is an original source of the information. To qualify as an original source under the FCA as amended in 2010, a relator must have (i) voluntarily disclosed to the government the information on which his claims are based prior to the public disclosure, or (ii) have voluntarily disclosed information that is independent of, and materially adds to, the publicly disclosed information prior to filing the action.[306] Prior to the 2010 amendment, to be an original source, a relator must have had "direct and independent knowledge of the information on which the allegations are based," *and* must have "voluntarily provided this information to the government before filing an action under this section which is based on the information." Direct knowledge is not knowledge gained by reviewing documents and discussing them with relevant individuals.[307]

The Supreme Court has held under the old statute that the relator must be the original source of the "information underlying the allegations of the relator's action," as opposed to the "information on which the publicly disclosed allegations that triggered the public-disclosure bar are based."[308] Moreover, the relator must be the original source of all the allegations in the complaint, including amendments, and, where a case proceeds to trial, factual averments in trial documents such as a pretrial order.[309]

Courts have diverged on the extent of knowledge required to be an original source. The Eighth Circuit stated that a relator need not have knowledge of "*all* of the vital ingredients to a fraudulent *transaction*" and can be an original source with knowledge of "*any* essential

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306. 31 U.S.C. § 3730(e)(4)(B).

307. U.S. *ex rel.* Schumann v. Astrazeneca Pharm. L.P., 769 F.3d 837 (3d Cir. 2014); *see also* U.S. *ex rel.* Rahimi, 3 F.4th 813, 829 (6th Cir. 2021) ("direct knowledge is knowledge gained by the relator's own efforts and not acquired from the labor of other people"); U.S. *ex rel.* Banigan v. Pharmerica, Inc., 950 F.3d 154 (1st Cir. 2020) (direct knowledge is "marked by an absence of intervening agency"); U.S. *ex rel*. Denis v. Medco Health Sols. Inc., 2019 WL 2513790 (3d Cir. June 18, 2019) (dismissing where relator's knowledge came from reviewing documents and discussing them with colleagues); U.S. *ex rel.* Saldivar v. Fresenius Med. Care Holdings, Inc., 841 F.3d 927 (11th Cir. 2016) (no direct knowledge if obtained from secondhand sources); *see also* U.S. *ex rel*. Solis v. Millennium Pharma. Inc., 2020 WL 1547439 (E.D. Cal. Apr. 1, 2020) (relator needs to have "direct knowledge of instances where a defendant caused a false claim to be submitted").

308. *Rockwell*, 549 U.S. at 470–71.

309. *Id*. at 473.

element of the underlying fraud transaction."[310] But the Fifth Circuit took a more stringent view, stating that in addition to having knowledge of the underlying fraud, an original source must have knowledge that "suggests that false claims were made to the government."[311]

Under both the new and old versions of the original source provision,[312] interesting issues can arise if a relator claiming to be an original source has provided information to the government as a result of a subpoena. The FCA requires that, to be an original source, a relator must have provided information to the government "voluntarily" before filing suit. A relator who has been swept up in government subpoenas may find that he or she is not an original source because information was not provided to the government voluntarily. Plainly, if the only information provided by a relator to the government was pursuant to subpoena, the "voluntariness" standard would not be met and the relator could not be an original source. But even if the relator later provides information different than that called for in a subpoena, he may still not qualify as an original source. In *U.S. ex rel. Paranich v. Sorgnard*, a relator claimed to have "voluntarily" provided information to the government about matters beyond the scope of an earlier-served government subpoena to him. The court held that there is no voluntariness when "the government has identified the putative relator as being involved in the fraudulent activity and has initiated contact with a subpoena demanding information fundamental to the putative relator's action."[313]

Similarly, some courts have held that federal employees whose jobs compel them to disclose fraud cannot qualify as original sources

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310. U.S. *ex rel.* Simpson v. Bayer Healthcare (*In re* Baycol Prods. Litig.), 870 F.3d 960, 962 (8th Cir. 2017) (emphasis in original).

311. U.S. *ex rel.* King v. Solvay Pharm., Inc., 871 F.3d 318, 326 (5th Cir. 2017) (citation omitted).

312. The Seventh Circuit has held that the 2010 amendment to the original-source definition is retroactive because it clarified the "inscrutable" prior definition. U.S. *ex rel.* Bogina v. Medline Indus., Inc., 809 F.3d 365, 368 (7th Cir. 2016); *see also* Bellevue v. Univ. Health Servs. of Hartgrove, Inc., 867 F.3d 712, 718 (7th Cir. 2017).

313. *Paranich*, 396 F.3d at 340; *see also* City of Chicago *ex rel.* Rosenberg v. Redflex Traffic Sys., Inc., 884 F.3d 798, 804–06 (7th Cir. 2018) (relator who provided information to government investigator in exchange for an immunity agreement not an original source); U.S. *ex rel.* Hendrickson v. Bank of Am. N.A., 2018 WL 5313932 (N.D. Tex. Oct. 26, 2018) (disclosure not voluntary where relator was an employee of the Office of Inspector General); U.S. *ex rel.* Solomon v. Lockheed Martin Corp., 2016 WL 7188298 (N.D. Tex. Dec. 12, 2016) (private employee who had an affirmative duty as an auditor to report fraud to the government not an original source).

because such disclosures are not voluntary.[314] Thus, an FCA defendant seeking dismissal of a suit on public disclosure grounds should make every effort to determine whether the relator has been the target of a government subpoena concerning the subject matter of the FCA suit and whether a government relator's job description involves the disclosure of fraud.

To the extent the relator can demonstrate that the information was provided to the government voluntarily but cannot demonstrate that the information was provided prior to the public disclosure, under the amended statute, the relator must show that his or her "knowledge . . . is independent of and materially adds to the publicly disclosed allegations or transactions."[315] The Third Circuit imported Rule 9(b)'s heightened pleading requirement into its analysis.[316] The court stated that the 2010 amendment to the original source provision "lower[ed] the bar for relators," holding that "direct knowledge" of the fraud was no longer required.[317] Instead, hewing to the language of the amended statute, the court held that a relator is an original source

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314. *See, e.g.*, Prather v. AT&T, Inc., 847 F.3d 1097 (9th Cir. 2017) (government attorney not an original source); U.S. *ex rel.* Little v. Shell Expl. & Prod. Co., 690 F.3d 282, 294 (5th Cir. 2012); U.S. *ex rel.* Fine v. Chevron, U.S.A., Inc., 72 F.3d 740, 743–44 (9th Cir. 1995) ("[Relator] was no volunteer. He was a salaried government employee, compelled to disclose fraud by the very terms of his employment. He no more voluntarily provided information to the government than we, as federal judges, voluntarily hear arguments and draft dispositions."); U.S. *ex rel.* Griffith v. Conn, 2015 WL 779047, at *6 (E.D. Ky. Feb. 24, 2015) (Social Security administration employees' reports to the government of the rigging of disability cases was not voluntary).

315. 31 U.S.C. § 3730(e)(4)(B).

316. *See* U.S. *ex rel.* Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294 (3d Cir. 2016). Additionally, in a case decided under the pre-amended version of the original source provision, the U.S. Court of Appeals for the District of Columbia Circuit referenced the new language, explaining that it permits suits in which relator's allegations "do[ ] in fact mirror the publicly disclosed information" but only where the newly alleged information "adds value." U.S. *ex rel.* Davis v. District of Columbia, 679 F.3d 832, 839 n.4 (D.C. Cir. 2012); U.S. *ex rel.* Judd v. Quest Diagnostics Inc., 2015 WL 5025447, at *6 (3d Cir. Aug. 26, 2015) (relator's allegations of the same fraud occurring in a different time frame did not "materially add" to or establish a "new fraud" under the post-amendment public disclosure bar); *see also* U.S. *ex rel.* 3729, LLC v. Express Scripts Holding Co., 2023 WL 4056042, at *29 (S.D. Cal. June 16, 2023) (noting that allegations must "add value to what the government already knew" and not merely contain details and additional color regarding prior disclosures).

317. *Moore*, 2016 WL 386087, at *3–4.

if he "contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'"[318] The First Circuit has held that information that "materially adds" falls into a "narrow category" and does not include information about other allegedly defrauded government programs, information as to a different temporal scope of the fraud, and information that "merely adds detail or color."[319] The Tenth Circuit exhaustively reviewed the issue concluding that "materially adds" means that the new information is "sufficiently significant or important that it would be capable of 'influenc[ing] the behavior of the recipient'—i.e., the government."[320] Other courts applying this amended original-source standard have made fact-based inquiries comparing relator's allegations to the prior public disclosure.[321]

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318. *Id*. at *11 (quoting *In re* Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002)).

319. U.S. *ex rel.* Winkelman v. CVS Caremark Corp., 827 F.3d 201, 213 (1st Cir. 2016); *see also In re* Syngenta AG Mir 162 Corn Litig., 2016 WL 5851795, at *3 (D. Kan. Oct. 6, 2016) (adopting *Winkelman* formulation). *But see Niazi*, 2018 WL 654289, at *5 (relator materially added by alleging fraud continued over a later time period and providing different examples of misconduct).

320. U.S. *ex rel.* Reed v. Keypoint Gov't Sols., 2019 WL 1907853 (10th Cir. Apr. 30, 2019); *see also* Vierczhalek v. Medimmune, Inc., 2020 WL 1289100 (2d Cir. Mar. 18, 2020) (for new allegations to "materially add" to public disclosures they must "substantially" or "considerably" add to information that is already public).

321. *See* U.S. *ex rel.* Ven-A-Care of Fla. Keys, Inc. v. Baxter Healthcare Corp., 772 F.3d 932 (1st Cir. 2014) (affirming dismissal of a later-filed qui tam complaint because an earlier-filed complaint had already disclosed the "essential facts" of the alleged fraud, even though the later suit supplied "far more detail"); U.S. *ex rel.* Johnson v. Planned Parenthood of Houston & Se. Tex., Inc., 570 F. App'x 386, 389 (5th Cir. 2014) (finding that earlier-filed case alleging improperly coded billing barred later-filed case alleging billing for un-performed tests because "an investigation into the first claim would uncover the same fraudulent activity alleged in the second claim" and the second relator failed to provide the government with "genuinely valuable information"); U.S. *ex rel.* Beauchamp v. Academi Training Ctr., Inc., 933 F. Supp. 2d 825, 843 (E.D. Va. 2013) (finding relator's complaint "to add only illustrative examples of the specific behavior" that was previously disclosed and, therefore, "does not materially add to the already disclosed allegations"); U.S. *ex rel.* Lockey v. City of Dallas, 2013 WL 268371, at *16 (N.D. Tex. Jan. 23, 2013) (finding that relators' new information did not materially add to prior disclosures because the new information was not "qualitatively different"; was "merely the product and outgrowth of publicly disclosed" information; did not provide "some additional compelling fact"; and did

§ 11:8.3 First-to-File Bar

Another potential defense to an FCA suit prosecuted by a relator alone is the first-to-file bar—a bar that precludes later-filed suits that arise "from events that are already the subject of existing suits."[322] With relators frequently bringing fraud claims, an FCA defendant may benefit from having been on the receiving end of a prior FCA claim alleging fraud similar to that in a current action. The first-to-file bar is based on 31 U.S.C. § 3730(b)(5), which provides that, "[w]hen 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*" (emphasis added). Courts interpreting this provision have rejected an "identical facts" test advocated by relators, under which a later-filed suit is barred only if it alleges facts identical to the earlier-filed suit.[323] Instead, courts will dismiss a later-filed complaint that "states all the essential facts" or the "same elements of a fraud" as an earlier-filed suit, even if the later suit "incorporates somewhat different details."[324]

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not demonstrate "a new and undisclosed relationship between the disclosed facts"); U.S. *ex rel.* Osheroff v. Humana, Inc., 2012 WL 4479072, at *12 (S.D. Fla. Sept. 28, 2012) (finding that relator's addition of details including the value of meals provided to clinic patients and the number of passengers given free transportation to the defendant clinics did not materially add to the information already publicly disclosed regarding the alleged kickback-based fraud). *But see* U.S. *ex rel.* Hoggett v. Univ. of Phx., 2012 WL 2681817, at *4 (E.D. Cal. July 6, 2012) (finding that relators' qui tam—alleging that "new procedures cover[ed] up a continuation" of a previously settled case involving fraudulent payments to online education recruiters—materially added to the prior publicly disclosed suit, and therefore relators were the original sources of the continued fraud).

322. U.S. *ex rel.* LaCorte v. SmithKline Beecham, 149 F.3d 227, 233–34 (3d Cir. 1998). The D.C. Circuit has held that the first-to-file bar is not jurisdictional because the statute does not explicitly state that the bar is jurisdictional. U.S. *ex rel.* Heath v. AT&T, Inc., 791 F.3d 112, 120 (D.C. Cir. 2015); *see also* U.S. *ex rel.* Hayes v. Allstate Ins. Co., 853 F.3d 80, 86 (2d Cir. 2017) (same); *In re* Plavix Mktg., 2020 WL 5200681 (3d Cir. Sept. 1, 2020) (same); Stein v. Kaiser Found. Health Plan, Inc., 2024 WL 4271950 (9th Cir. Sept. 24, 2024) (same). *But see* U.S. *ex rel.* Carson v. Manor Care, Inc., 851 F.3d 293, 303 (4th Cir. 2017) (if first-to-file bar applies, "the court lacks subject matter jurisdiction over the later-filed matter"); U.S. *ex rel.* Little v. Triumph Gear Sys, Inc., 870 F.3d 1242, 1249–50 (10th Cir. 2017) (same).

323. *E.g.*, *LaCorte*, 149 F.3d at 232; *see also Stein*, 2024 WL 107099 (applying the first-to-file bar where later action relates to fraud within the broad scheme alleged in the earlier-filed actions).

324. *See LaCorte*, 149 F.3d at 232–33; *accord* Branch Consultants v. Allstate Ins. Co., 560 F.3d 371, 377–78 (5th Cir. 2009) (collecting cases). *But see* U.S. *ex rel*. McGuire v. Millenium Labs, Inc., 923 F.3d 240 (1st Cir.

A key rationale for the bar is that, because a first-filed complaint gave notice of the potential fraud to the government, the second complaint is unnecessary under the FCA regime.[325] As courts have pointed out, it is not relevant whether the government actually put the facts in the first complaint to its best use; rather, the question is whether a government investigation launched in direct consequence of the prior complaint would have revealed the details alleged in the later-filed qui tam.[326] Because of this rationale, courts dismiss second suits even where the first suit was brought by the same relator.[327]

Interesting issues arise where the first-filed complaint has been dismissed after the second suit was filed. Some courts examine the circumstances of the dismissal of the first action—even if it overlaps with the fraud alleged in the second action—and hold that a first action dismissed for failure to plead fraud with particularity or for lack of jurisdiction cannot bar a second complaint.[328] Other courts reject these theories because the plain language of the first-to-file bar makes it exception-free and the government has notice of the alleged fraud even if the first complaint was later dismissed.[329]

2019) (first complaint needs to disclose same "mechanism" of fraud; mere notice "is not enough").

325. *LaCorte*, 149 F.3d at 234 ("duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds"); U.S. *ex rel.* Heineman-Guta v. Guidant Corp., 718 F.3d 28, 35 (1st Cir. 2013) ("[I]f the first-filed complaint contains enough material information (the essential facts) about the potential fraud, the government has sufficient notice to launch its investigation."); *see also* U.S. *ex rel.* Batiste v. SLM Corp., 740 F. Supp. 2d 98, 105 n.3 (D.D.C. 2010), *aff'd*, 659 F.3d 1204 (D.C. Cir. 2011). *But see* U.S. *ex rel.* Heath v. AT&T, Inc., 791 F.3d 112, 122 (D.C. Cir. 2015) (no first-to-file bar where first suit alleged fraud by "rogue" actors in local area and second suit alleged nationwide fraud).

326. United States v. Planned Parenthood of Houston, 570 F. App'x 386 (5th Cir. 2014); U.S. *ex rel.* Batiste v. SLM Corp., 659 F.3d 1204, 1209 (D.C. Cir. 2011); U.S. *ex rel.* Folliard v. Synnex Corp., 798 F. Supp. 2d 66, 74 (D.D.C. 2011).

327. U.S. *ex rel.* Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 11 (1st Cir. 2016) (the first to file bar is "plainly stated and exception-free") (quotation omitted).

328. Walburn v. Lockheed Martin Corp., 431 F.3d 966, 975 (6th Cir. 2005); Campbell v. Redding Med. Ctr., 421 F.3d 817 (9th Cir. 2005).

329. *See, e.g.*, *Heineman-Guta*, 718 F.3d at 35–36; *Batiste*, 659 F.3d at 1210; U.S. *ex rel.* Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 287 n.17 (D. Mass. June 1, 2012); U.S. *ex rel.* Sandager v. Dell Mktg., L.P., 872 F. Supp. 2d 801, 810–12; U.S. *ex rel.* Piacentile v. Sanofi Synthelabo, Inc., No. 05-2927, 2010 WL 5466043, at *4 (D.N.J. Dec. 30, 2010); *see also* U.S. *ex rel.* Wickliffe v. EMC Corp., 473 F. App'x 849, 851 (10th Cir.

Courts have also grappled with the statutory language that the first suit be "pending" to bar a later similar suit in determining whether to apply the bar where the first-filed complaint had been dismissed *before* the second suit was filed. Circuit courts had split on the issue. The majority had held, or at least indicated in dicta, that an earlier-filed qui tam suit did not have preclusive effect where it had been dismissed before the filing of the second suit because the earlier suit was no longer "pending" for purposes of the first-to-file bar.[330] The D.C. Circuit had taken the opposite view, holding that the first-to-file rule barred later-filed suits "even if the initial action is no longer pending."[331] The D.C. Circuit reasoned that the first complaint, whether dismissed or not, satisfied the chief purpose of the first-to-file bar, which is to put the government on notice of the alleged fraud.[332] Rejecting the D.C. Circuit's view, the Supreme Court resolved the split in 2015, holding that the ordinary meaning of the statutory term "pending" controls and the bar applies only where the first suit is actually pending when the second suit is filed.[333]

Courts have also reached differing conclusions on the issue of whether an amendment can cure the jurisdictional defect of a first-to-file bar if the first case is dismissed at some point *after* the second case is filed. The First Circuit has opined that a federal rule allowing supplemental pleadings to cure jurisdictional defects can revive a barred suit, while other circuits and lower courts have held that jurisdiction must be determined at the time the second case is filed, not as of any amendment.[334]

2012) (affirming dismissal of qui tam on other grounds but "admit[ting] to being uneasy with the parties' suggestion that Rule 9(b)'s particularity requirement should be applied to the first-to-file bar").

330. *See, e.g.*, U.S. *ex rel.* Carter v. Halliburton Co., 710 F.3d 171, 183 ("[O]nce a case is no longer pending the first-to-file bar does not stop a relator from filing a related case."); U.S. *ex rel.* Chovanec v. Apria Healthcare Grp., Inc., 606 F.3d 361, 365 (7th Cir. 2010) ("[Section] 3730(b)(5) applies only while the initial complaint is 'pending'"); *In re* Nat. Gas Royalties Qui Tam Litig., 566 F.3d 956, 964 (10th Cir. 2009) ("[Section] 3730(b)(5) applies only when another qui tam action is 'pending'").

331. U.S. *ex rel.* Shea v. Cellco P'ship, 748 F.3d 338, 343 (D.C. Cir. 2014).

332. *Id*.

333. Kellogg Brown & Root Servs., Inc. v. U.S. *ex rel.* Carter, 135 S. Ct. 1970, 1979 (2015).

334. *Compare* U.S. *ex rel.* Gadbois v. PharMerica Corp., 809 F.3d 1, 7 (1st Cir. 2015) (reversing first-to-file dismissal and allowing relator to move to supplement to allege that the first-filed case had been dismissed), United States v. Pfizer, Inc., 2016 WL 807363 (E.D. Pa. Mar. 1, 2016) (allowing amendment to cure first to file bar), *and* U.S. *ex rel.* Kurnik v. PharMerica Corp.,

§ 11:9 Protection of Whistleblower

FCA section 3730(h) protects employees, contractors, and agents from retaliation in their employment because of conduct "in furtherance of an action under [section 3730] or other efforts to stop 1 or more violations of this subchapter."[335] The original version of the FCA covered only acts "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 [the FCA]." The scope of this section was twice expanded by Congress in a span of less than two years. The Fraud Enforcement and Recovery Act of 2009 (FERA)[336] and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010[337] amended section 3730(h) by expanding the class of potential plaintiffs to include contractors and agents, broadening the scope of protected conduct, extending the section's protections to individuals "associated" with whistleblowers, and setting a statute of limitations period for anti-retaliation suits.

Whistleblowers who prevail under section 3730(h) are entitled to be made whole, which includes reinstatement, two times the amount of back pay, interest on the back pay, litigation costs, reasonable attorney fees, and compensation for any special damages, which may

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2015 WL 1524402, at *6 (D.S.C. Apr. 2, 2015) (denying first-to-file motion when amended complaint filed after the first action had been dismissed), *with* U.S. *ex rel.* Wood v. Allergan, Inc., 899 F.3d 163 (2d Cir. 2018) (amended pleading cannot cure fact that action originally brought in violation of first-to-file bar); U.S. *ex rel.* Shea v. Cellco P'ship, 863 F.3d 923, 928–29 (D.C. Cir. 2017) (holding that amendment cannot cure a first-to-file defect that existed when the second suit was filed); U.S. *ex rel.* Carter v. Halliburton Co., 866 F.3d 199, 210 (4th Cir. 2017) (same); U.S. *ex rel*. Cho v. Baker, 2020 WL 5076712 (M.D. Fla. Aug. 26, 2020) (declining to follow *Gadbois*); United States v. Medco Health Sols., Inc., 2017 WL 63006 (D. Del. Jan. 5, 2017) (declining to follow *Gadbois* and dismissing even if first action dismissed after second action filed), U.S. *ex rel.* Palmieri v. Alpharma, Inc., 2016 WL 7324629 (D. Md. Dec. 16, 2016) (same), U.S. *ex rel.* Soodavar v. Unisys Corp., 178 F. Supp. 3d 358 (E.D. Va. 2016), U.S. *ex rel.* Moore v. Pennrose Props., LLC, 2015 WL 1358034, at *13 (S.D. Ohio Mar. 24, 2015) (amendment filed after the first action had been dismissed does not impact the first-to-file bar because jurisdiction is determined as of the date the second case is filed), *and* U.S. *ex rel.* Carter v. Halliburton Co., 2015 WL 7012542, at *7 (E.D. Va. Nov. 12, 2015) ("The temporal focus of the first-to-file bar remains the time a later suit is *filed*.").

335. 31 U.S.C. § 3730(h).

336. Pub. L. No. 111-21, 123 Stat. 1617.

337. Pub. L. No. 111-203 (Dodd-Frank), 124 Stat. 1376 (2010).

include damages for emotional distress.[338] Where reinstatement is not feasible, front pay may be available.[339]

Plaintiffs may prevail under this section if they prove:

(1) that they engaged in conduct protected by the False Claims Act,[340]

(2) that the employer knew of this conduct, and

(3) that the employer took discriminatory actions because of that conduct.[341]

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338. 31 U.S.C. § 3730(h)(2); *see also* Neal v. Honeywell, Inc., 191 F.3d 827, 832 (7th Cir. 1999) (awarding damages for emotional distress where manager threatened to physically injure whistleblower).

339. *See* Wilkins v. St. Louis Hous. Auth., 198 F. Supp. 2d 1080, 1091 (E.D. Mo. 2001), *aff'd*, 314 F.3d 927, 934 (8th Cir. 2002); *see also* Thompson v. Quorum Health Res., LLC, 485 F. App'x 783, 788, 793 (6th Cir. 2012) (unpublished) (affirming judgment that included award of front pay).

340. To determine whether an employee's conduct is protected under the whistleblower provision, courts consider whether (1) the employee in good faith believed, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer committed fraud against the government. In assessing the second, "objective" prong, courts look to the facts known to the employee at the time of the alleged protected activity. *See* U.S. *ex rel.* Uhlig v. Fluor Corp., 839 F.3d 628, 635 (7th Cir. 2016); *accord* Jones-McNamara v. Holzer Health Sys., 630 F. App'x 394, 399–400 (6th Cir. 2015) (unpublished).

341. *See* Mann v. Heckler & Koch Def., Inc., 630 F.3d 338, 343–44 (4th Cir. 2010); *see also* Harrington v. Aggregate Indus. Ne. Region, Inc., 668 F.3d 25, 32 (1st Cir. 2012) (holding that evidence that high-level executives at the company were aware of the protected conduct is sufficient to satisfy the knowledge prong even absent evidence that the employee's direct supervisors were aware of protected conduct, and finding causation based on the temporal proximity between when the employee settled his FCA suit and when he was terminated). The Eighth Circuit has held that the discriminatory acts must be "motivated solely" by the plaintiff's protected activity. *See, e.g.*, Elkharwily v. Mayo Holding Co., 823 F.3d 462, 470–71 (8th Cir. 2016); Sherman v. Berkadia Com. Mortg. LLC, 956 F.3d 526 (8th Cir. 2020). The First, Third, Fifth, and Eleventh Circuits similarly require that the protected conduct be the "but-for" cause of the adverse employment action. *See* Lestage v. Coloplast, 982 F.3d 37, 46 (1st Cir. 2020) ("retaliation claims under the False Claims Act must be evaluated under the but-for causation standard"); DiFiore v. CSL Behring, LLC, 879 F.3d 71, 76–78 (3d Cir. 2018) (not sufficient for protected activity to be merely a "motivating factor" for the adverse action); U.S. *ex rel.* King v. Solvay Pharm., Inc., 871 F.3d 318, 333 (5th Cir. 2017) (applying "but-for" standard); Nesbitt v. Candler County, 945 F.3d 1355 (11th Cir. 2020). *But see* Singletary v. Howard Univ., 939 F.3d 287 (D.C. Cir. 2019) (holding that adverse employment action be motivated "at least in part" by protected activity).

Proving a violation of the FCA is not an element of a section 3730(h) cause of action for retaliation.[342] Accordingly, at the pleading stage, the allegations of a whistleblower retaliation claim need only satisfy the notice-pleading requirements of Rule 8(a) of the Federal Rules of Civil Procedure, rather than the heightened requirements of Rule 9(b).[343]

Where a plaintiff establishes the above three elements, a presumption of retaliation arises, and the burden shifts to the defendant to prove that the plaintiff would have been subjected to adverse action even if he or she had not engaged in the protected conduct.[344] If the defendant then presents a legitimate, non-retaliatory reason, the burden shifts back to the plaintiff to prove by a preponderance of the evidence that the defendant's stated reason was a pretext for retaliation.[345]

FERA expanded the class of potential plaintiffs under section 3730(h) to include contractors and agents, in addition to "employees."[346] Even under this amended language, though, an employment-like relationship is still required, and the provision's protections will not reach so far as to non-employee applicants.[347] There is a split among the circuit courts as to whether the plaintiff must have been an employee at the time the retaliation took place: the Tenth Circuit has held that the plaintiff must be a current employee,[348] but the Sixth Circuit

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342. Graham Cnty. Soil & Water Conservation Dist. v. U.S. *ex rel.* Wilson, 545 U.S. 409, 416 n.1 (2005); U.S. *ex rel.* Crockett v. Complete Fitness Rehab., Inc., 721 F. App'x 451 (6th Cir. 2018); Miller v. Abbott Lab'ys, 648 F. App'x 555, 560 (6th Cir. 2016) (unpublished) (plaintiff "need not establish that [the employer] actually violated the FCA"). Relatedly, the first-to-file rule for FCA fraud claims does not apply to bar retaliation claims, which are "personal to the plaintiff." *Carson*, 851 F.3d at 306–07.

343. Smith v. Clark/Smoot/Russell, 796 F.3d 424, 433 (4th Cir. 2015); Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1103 (9th Cir. 2008).

344. *See* Kakeh v. United Planning Org., Inc., 655 F. Supp. 2d 107, 115 (D.D.C. 2009).

345. *Id.*; *see, e.g.*, Diaz v. Kaplan Higher Educ., LLC, 820 F.3d 172, 175 n.3 (5th Cir. 2016) (applying the *McDonnell Douglas* burden-shifting framework to the FCA's anti-retaliation provision and observing that the First, Third, Sixth, Eighth, and D.C. Circuits have done the same).

346. *See* U.S. *ex rel.* Bias v. Tangipahoa Par. Sch. Bd., 816 F.3d 315, 323 & n.4 (5th Cir. 2016).

347. *See* Vander Boegh v. EnergySolutions, Inc., 772 F.3d 1056, 1062–64 (6th Cir. 2014); U.S. *ex rel.* Abou-Hussein v. Sci. Applications Int'l Corp., 2012 WL 6892716, at *3–4 (D.S.C. May 3, 2012), *aff'd*, 475 F. App'x 851 (4th Cir. 2012) (per curiam).

348. Potts v. Ctr. for Excellence in Higher Educ., Inc., 908 F.3d 610 (10th Cir. 2018).

held that retaliation protections extend to former employees.[349] A bill introduced in the Senate would amend the FCA to adopt the latter view and extend protections to former employees.[350]

In expanding section 3730(h) to encompass contractors and agents, the amendment removed an express reference to "employer" from the retaliation provision.[351] However, courts have found that the term was removed in order to account for the broadening of the class of FCA plaintiffs, not to expand liability to defendants other than those by whom plaintiffs are employed, with whom they contract, or for whom they are agents.[352]

Some cases hold that the FCA's anti-retaliation provision applies to any employer, irrespective of whether that employer is the target of the FCA action or investigation that the employee has acted in furtherance of.[353] Thus, an employee who engaged in protected activity regarding a false claim while with one employer maintains the cloak of 3730(h) protection from any subsequent employers who learn of the conduct.[354]

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349. U.S. *ex rel.* Felten v. William Beaumont Hosp., 993 F.3d 428 (6th Cir. 2021).

350. False Claims Amendments Act of 2021, S. 2428, 107th Cong. (2021).

351. *See Bias*, 816 F.3d at 323 & n.4.

352. *See id*. at 324; Howell v. Town of Ball, 827 F.3d 515, 529–30 (5th Cir. 2016) (holding that former police officer could pursue retaliation claims only against the town, and not against individual town officials, where it was undisputed that the town was his "employer"); *Abou-Hussein*, 2012 WL 6892716, at *3 n.4 (holding that removal of the term "employer" was not intended to include "potential defendants who have no employer type relationship with plaintiffs").

353. *See* O'Hara v. Nika Techs., Inc., 878 F.3d 470, 475 (4th Cir. 2017) (rejecting the district court's holding that § 3730(h) only protects whistleblowing activity directed at the whistleblower's employer); *see also* Hill v. Booz Allen Hamilton, Inc., 2009 WL 1620403, at *5 (D. Guam June 9, 2009); U.S. *ex rel.* Lang v. Nw. Univ., 2005 WL 670612, at *2 (N.D. Ill. Mar. 22, 2005); U.S. *ex rel.* Satalich v. Los Angeles, 160 F. Supp. 2d 1092, 1107–09 (C.D. Cal. 2001); Nguyen v. Cleveland, 121 F. Supp. 2d 643, 648–49 (N.D. Ohio 2000).

354. Although these cases often involve allegations of concerted action by a plaintiff's current employer (who is alleged to have retaliated) and plaintiff's former employer or other third party (who is the target of the FCA investigation), the case law indicates this is not required to find liability under section 3730(h). *See* United States v. Bon Secours Cottage Health Servs., 665 F. Supp. 2d 782, 786 (E.D. Mich. 2008) (suggesting that the FCA protects a plaintiff-relator from being "retaliated against by her current employer [who is the subject of the qui tam suit] or future employers for filing th[e] qui tam action"); *Hill*, 2009 WL 1620403, at *6 (rejecting defendant's interpretation of the case law as requiring an allegation of a

In the amended statute, Congress also expanded the scope of protected activity to include conduct "to stop" a violation of the act. The amended language therefore protects not only actions taken in furtherance of a potential or actual qui tam action, but also steps taken to remedy fraud through other means.[355] Thus, individuals who refuse to participate in unlawful activity or who internally report violations to supervisors or compliance officers can now be protected from retaliation under the FCA.[356] Complainants need not even be aware of the FCA at the time they engage in the relevant activity.[357]

The amended language, however, is not without its limitations. For example, the plaintiff's "efforts" must be sufficiently connected to exposing or stopping a violation of the FCA, rather than mere attempts to avoid personal liability[358] or expose other unlawful conduct.[359] Refusal to participate in the alleged fraud, standing alone, is

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conspiracy between the plaintiff's employer and the third party alleged to have violated the FCA).

355. *See* Carlson v. DynCorp Int'l LLC, 657 F. App'x 168, 171 (4th Cir. 2016) (unpublished) (finding that "[w]hile the first prong [of protected activity under § 3730(h)] refers to activity associated with an action under the FCA, the second prong specifically encompasses 'other efforts'" and is therefore "explicitly untethered from any such action"); *Smith*, 796 F.3d at 434 (holding that the "other efforts" encompass "more than just activities undertaken in furtherance of a False Claims Act lawsuit").

356. *See, e.g.*, U.S. *ex rel.* Gobble v. Forest Lab'ys, Inc., 729 F. Supp. 2d 446, 449–50 (D. Mass. 2010) (declining to dismiss plaintiff's claim that he was retaliated against for complaining to his supervisors about illegal kickbacks and off-label promotions); Thomas v. ITT Educ. Servs., Inc., 2011 WL 3490081, at *1–2, *4 (E.D. La. Aug. 10, 2011) (denying defendant's motion to dismiss plaintiff's section 3730(h) claim, which was based on plaintiff's refusal to falsely inflate student grade records); Pilat v. Amedisys, Inc., 2024 WL 177990 (2d Cir. Jan. 17, 2024) (finding relator engaged in protected conduct by refusing to certify patients for home health care on ethical grounds).

357. *See, e.g.*, McKenzie v. BellSouth Telecomms., Inc., 219 F.3d 508, 516 (6th Cir. 2000) ("An employee, however, need not expressly know that the FCA allows qui tam actions to be filed against their employer, or have already filed such an action to be protected from retaliation under § 3730(h)." (citation omitted)).

358. *See* Smith v. CR Bard, Inc., 730 F. Supp. 2d 783, 803 (M.D. Tenn. 2010).

359. *See* U.S. *ex rel.* Booker v. Pfizer, Inc., 847 F.3d 52, 60 (1st Cir. 2017) ("Evidence that an employee objected to or reported receipt of instructions to promote a drug's off-label use, absent any evidence that those objections or reports concerned FCA-violating activity such as the submission of false claims, cannot show . . . that the employee engaged in conduct protected by the FCA."); Farmer v. Eagle Sys. & Servs., Inc., 654 F. App'x 157, 159 (4th Cir. 2016) (unpublished) (holding that "a single report of theft, without any facts suggesting an underlying fraud,"

insufficient to demonstrate a protected activity.[360] In addition, where a plaintiff's job requires him or her to investigate or report FCA violations, there is no retaliation claim when he or she merely raises the FCA issue, without more to put the defendant on notice that the plaintiff was engaging in a protected activity.[361]

FERA also expanded the group of individuals who are protected by the FCA's anti-retaliation provision to include "associated others." This ambiguous term was clarified in the *Congressional Record* by Congressman Berman, who explained that this language is intended to deter and penalize indirect retaliation against colleagues and family members of the person who acts to stop the violations of the FCA.[362] Thus, this subsection, as amended, offers some degree of protection to individuals beyond those who engage in protected conduct.[363] This expanded coverage, however, is not retroactive and applies only to conduct on or after the date of FERA's enactment, May 20, 2009.[364]

Dodd-Frank changed the applicable statute of limitations periods for FCA retaliation actions. Prior to the passage of Dodd-Frank in 2010, the statute of limitations for an FCA retaliation claim was the analogous state statute of limitations for wrongful discharge

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was insufficient to constitute protected activity); U.S. *ex rel.* Ziebell v. Fox Valley Workforce Dev. Bd., Inc., 806 F.3d 946, 951, 953 (7th Cir. 2015) (rejecting FCA retaliation claim where the record did not show "any fraudulent-claims activity" but showed "at most . . . regulatory noncompliance").

360. U.S. *ex rel.* Tran v. Comput. Scis. Corp., 53 F. Supp. 3d 104, 136 (D.D.C. 2014).

361. *See* Mahony v. Universal Pediatric Servs., Inc., 753 F. Supp. 2d 839, 850–51 (S.D. Iowa 2010) ("Employees whose responsibilities include investigation of fraud against the government must meet heightened requirements to establish an FCA retaliation claim by making it clear to the employer that the employee's actions went beyond the employee's assigned tasks."); *accord* U.S. *ex rel.* Reed v. Keypoint Gov't Sols., 2019 WL 1907853 (10th Cir. Apr. 30, 2019); U.S. *ex rel.* Schweizer v. Océ N.V., 677 F.3d 1228, 1238–39 (D.C. Cir. 2012).

362. 155 CONG. REC. E1295–1300, at E1300 (daily ed. June 3, 2009) (statement of Rep. Berman).

363. *See* Bechtel v. St. Joseph Med. Ctr., Inc., 2012 WL 1476079, at *8–9 (D. Md. Apr. 26, 2012) (interpreting the term "associated others" to protect a physician assistant from retaliation for actions taken by her physician-mentor); *cf.* Thompson v. N. Am. Stainless, L.P., 562 U.S. 170, 177–78 (2011) (holding, in the context of the Title VII anti-retaliation provision, that a worker who was terminated because his fiancée had filed an EEOC charge could sue for retaliation because he fell within the "zone of interests" sought to be protected by the statutory provision).

364. FERA § 4; *see* U.S. *ex rel.* Cox v. Smith & Nephew, Inc., 749 F. Supp. 2d 773, 786 n.13 (W.D. Tenn. 2010).

actions.[365] Dodd-Frank, however, provides for a statute of limitations for FCA retaliation claims of three years from the date on which the retaliation occurred.[366] This new statute of limitations is not retroactive, as it applies only to conduct that occurred after the date of enactment, July 21, 2010.[367]

§ 11:10 Other Whistleblower Laws

§ 11:10.1 Tax Whistleblower Law

In 2006, Congress enacted a tax false claim analogue that took effect in December 2006 and was designed to duplicate the success of the FCA qui tam provisions.[368] The new IRS provision targets not only violations of internal revenue laws leading to trial and punishment, but also simple underpayments of tax. Like the FCA, the IRS provision grants whistleblowers 15–30% of the collected proceeds, depending on "the extent to which the individual substantially contributed to such action."[369] The exact amount is decided by the IRS Whistleblower Office but may be appealed to the U.S. Tax Court. The new IRS provision is limited to cases of large tax fraud where (i) the tax, penalties, and interest in dispute exceed $2 million, and

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365. *See Wilson*, 545 U.S. at 419, 422.

366. *See* Dodd-Frank § 1079A(c); 31 U.S.C. § 3730(h)(3).

367. Dodd-Frank § 4; *see* U.S. *ex rel.* Sefen v. Animas Corp., 607 F. App'x 165, 167 (3d Cir. 2015) (unpublished) (rejecting retroactive application of Dodd-Frank's amended statute of limitations for retaliation claims); *Schweizer*, 677 F.3d at 1231 n.3 (recognizing that Congress has amended the FCA several times recently, including as part of Dodd-Frank, and except for "one exception not relevant here, none of the changes apply retroactively").

Although Dodd-Frank amended the whistleblower provisions of the Commodity Exchange Act and Sarbanes-Oxley to make any predispute arbitration clauses for disputes arising under those whistleblower sections unenforceable, it did not similarly amend the FCA's anti-retaliation provision. *See* James v. Conceptus, Inc., 851 F. Supp. 2d 1020, 1028–29 (S.D. Tex. 2010) (holding that Dodd-Frank's anti-arbitration amendments to other statutes cannot be extended by implication to the anti-retaliation provisions of the FCA). Courts may nonetheless find reasons not to enforce an arbitration clause in a retaliation suit under the FCA. *See* Winston v. Academi Training Ctr., Inc., 2013 WL 989999, at *2–4 (E.D. Va. Mar. 13, 2013) (refusing to enforce arbitration clause because it prohibited discovery and required plaintiff to bear all arbitration fees and costs regardless of the outcome, which the court found unconscionable).

368. *See* 26 U.S.C. § 7623(b).

369. *See id.* § 7623(b)(1).

(ii) if brought against an individual taxpayer, that individual's gross income exceeds $200,000.[370]

Unlike the FCA, which grants anti-retaliation protection to whistleblowers,[371] the IRS statute does not include a specific provision outlawing retaliatory employment decisions against a reporting employee. However, other whistleblower protection statutes may apply, such as the Sarbanes-Oxley Act or various state statutes.[372] Furthermore, courts have found implied whistleblower protection in some statutes, even in the absence of explicit statutory language.[373]

§ 11:10.2 Securities Whistleblower Law

In 2010, Congress added whistleblower incentives and protections in the securities fraud arena as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.[374] To qualify for whistleblower awards under Dodd-Frank, a party must provide "original information" to the SEC that leads to a successful judicial or administrative action that results in monetary sanctions, including penalties, interest, and disgorgement, in excess of $1 million.[375] The statute defines "original information" as information derived from "independent knowledge *or analysis*" that the SEC does not know from another source.[376] That information cannot be "exclusively derived" from prior "allegation[s]" in hearings, government reports or the news media—a standard similar to the FCA public disclosure bar that may generate decisions applicable to the FCA's public disclosure bar.[377] The disclosure can be anonymous provided that the disclosure is made through counsel.[378]

Under Dodd-Frank, whistleblowers are entitled to 10% to 30% of the government's recovery, with individual determinations left to

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370. *See id*. § 7623(b)(5); there is no such income threshold as to non-individual taxpayers. Therefore, the tax whistleblower provisions apply to tax underpayments by a business in excess of $2 million.
371. *See* 31 U.S.C. § 3730(h).
372. *See, e.g.*, 18 U.S.C. § 1514A.
373. *See, e.g.*, CBOCS W., Inc. v. Humphries, 553 U.S. 442 (2008) (finding that 42 U.S.C. § 1981 encompasses retaliation claims); Gomez-Perez v. Potter, 553 U.S. 474 (2008) (ADEA implicitly includes retaliation protection).
374. *See* Dodd-Frank § 922.
375. *See id*. (§ 21F(a)(1) as added to 15 U.S.C. § 78).
376. *See id*. (emphasis added) (§ 21F(a)(3)).
377. *Id*.
378. *Id*. (§ 21F(d)(2)).

the SEC's discretion.[379] In Congress's effort to protect informants, Dodd-Frank creates a cause of action for whistleblowers in cases of employer retaliation, providing for reinstatement, two times back pay with interest, and attorney fees and costs.[380]

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379. *Id*. (§ 21F(b)(1)). Parties supplying information obtained through an audit mandated by securities law are explicitly excluded from receiving awards. *See id*. (§ 21F(c)(2)(C)).

380. *See id*. § 21F(h)(1) (the prohibition against retaliation states that "(n)o employer may discharge, demote, suspend, threaten, harass, directly or indirectly, or in any other manner discriminate against, a whistleblower . . . because of any lawful act done by the whistleblower"). In 2018, the Supreme Court held that this provision applies only to persons who report violations to the SEC and not to those who report only internally at the company. Digit. Realty Tr., Inc. v. Somers, 138 S. Ct. 767, 778 (2018).