

THE IMPLIED CERTIFICATION THEORY: WHEN SHOULD THE FALSE CLAIMS ACT REACH STATEMENTS NEVER SPOKEN OR COMMUNICATED, BUT ONLY IMPLIED?

Susan C. Levy, Daniel J. Winters, and John R. Richards

- I. Introduction 132
- II. Background Regarding the False Claims Act 133
 - A. Elements of an FCA Claim 133
 - B. Historical Perspective 134
- III. Emergence of the Implied Certification Theory 135
 - A. Scenario #1: Implied Certification of Continued Compliance with Prior Express Certification 136
 - B. Scenario #2: Submitting Invoices for Payment Impliedly Certifies Compliance with a Governing Statute, Regulation, or Government Policy 139
 - 1. The Seminal Cases—*Hopper* and *Mikes* 140
 - 2. Requirement #1: Violation of Law or Regulation Setting Forth Express Condition of Payment 143
 - 3. Requirement #2: Existence of Statute or Regulation 147
 - C. Scenario #3: Compliance with Contractual Terms 150
- IV. Conclusion 152

How expansively should the False Claims Act (FCA or the Act) be interpreted in order to deter and remedy alleged fraudulent conduct committed against the Government? Should the FCA reach not just false statements (its traditional target), but also false implied statements? When, if at all, is it appropriate for a court to put words in a person’s mouth, and then hold that person liable for fraud (and subject to treble damages) for words he or she never actually communicated? If implied statements are fair game, how should courts determine which unspoken words should be attributed to the defendant for purposes of FCA liability? All of these questions—plus a host of

Susan C. Levy is a partner in Jenner & Block’s Chicago office. She is the firm’s Managing Partner, and serves on the firm’s Policy Committee, Management Committee, and Litigation Executive & Strategy Committee and is a member of the firm’s Litigation Department and Business Litigation, Government Contracts, and Insurance Litigation and Counseling Practices. Daniel J. Winters is a partner in Jenner & Block’s Chicago office and a member of the firm’s Litigation Department and Business Litigation, Defense & Aerospace, and Trade Secrets and Unfair Competition Practices. John R. Richards is an attorney practicing in Chicago and, at the time the article was written, was an associate in Jenner & Block’s Chicago office.

other academic and real-world issues—arise in connection with the increasing use of the implied certification theory in FCA cases.

I. INTRODUCTION

The FCA, 31 U.S.C. §§ 3729–3733 (2000), is primarily an antifraud statute. Under the FCA, a private individual (referred to as a “relator”) may bring an action on behalf of the U.S. Government, which may or may not elect to intervene. The relator’s FCA claim is often referred to as a “*qui tam*” action.¹ Under the FCA, relators who prosecute meritorious *qui tam* actions are entitled to between 15 and 30 percent of the proceeds of a judgment or settlement award, in addition to reasonable expenses, attorney fees, and costs pursuant to 31 U.S.C. § 3729(a).² The FCA also provides for both treble damages and fines of between \$5,550 and \$11,000 per claim.³

A typical FCA case arises when an entity, often a defense contractor or health care provider, enters into a contract to perform services or supply goods in exchange for federal funds. Legal issues arise when someone—usually an insider (or “whistleblower”)—alleges that the contractor submitted false invoices or false certifications in order to receive payment from the Government. Traditionally, the alleged false statements triggering the relator’s FCA claim have been clear. They typically have included, for example, a representation on an invoice as to the quantity of goods being delivered, a representation on a certification that the company was authorized to participate in the underlying government program, or a representation that the medical services were actually performed. Although these cases often concern hotly contested legal and factual issues as to whether the statements are false and whether they are actionable under the FCA, there is typically no dispute that the underlying statements were made.

The implied certification theory has emerged in recent years as an expansion of the scope of the FCA. Now, instead of just complaining about alleged false statements that the defendant actually made, relators are increasingly bringing FCA claims based on alleged false statements that the defendant *impliedly* made. Under the implied certification theory, courts will read certain implied terms into a defendant’s invoices or certifications.⁴ And if those implied words are deemed false (and the other elements of the FCA are satisfied), then the defendant is held liable under the FCA. In recent years, this novel theory of liability has been advanced in FCA cases involving defense contractors, health care

1. “*Qui tam*” comes from the Latin phrase “*Qui tam pro domino rege quam pro si ipso in hac parte sequitur*,” which means “[w]ho sues on behalf of the King as well as for himself.” *United States v. Fla.-Vanderbilt Dev. Corp.*, 326 F. Supp. 289, 290 (S.D. Fla. 1971) (internal quotation omitted).

2. See also 31 U.S.C. § 3730(c)(1), (d)(1), (d)(2) (2000).

3. *Id.* § 3729(a) (2000); see also Civil Monetary Penalties Inflation Adjustment, 28 C.F.R. § 85.3(a)(9) (2008).

4. See introduction to Part III, *infra*.

providers (especially those involved with the Medicare system), and schools, especially for-profit schools.⁵

This Article discusses three scenarios in which relators have attempted to apply the implied certification theory: (i) where a party previously and expressly certified compliance with certain government regulations in order to participate in a federal program; (ii) where a party participating in a federal program has allegedly violated some law, regulation, or government policy governing participation in a program; and (iii) where a party has allegedly failed to comply with some provision in its contract with the Government. As to each scenario, this Article analyzes and synthesizes the reported case law and explains how courts have limited relators' attempts to apply the implied certification theory in an unbounded manner. Finally, this Article discusses the authors' views regarding the proper scope and application of the theory. As discussed below, without proper restraints and limitations, contractors and other providers will legitimately fear being charged with fraud for implied statements they never made or intended to make.

II. BACKGROUND REGARDING THE FALSE CLAIMS ACT

A. *Elements of an FCA Claim*

The FCA prohibits a person from (1) knowingly presenting or causing to be presented false or fraudulent claims to the United States; (2) knowingly making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim paid; (3) conspiring to defraud the Government by getting a false or fraudulent claim paid; (4) falsely certifying the type or amount of property to be used by the Government; (5) certifying receipt of property on a document without knowing that the information is true; (6) knowingly buying government property from an unauthorized officer of the Government; or (7) knowingly making, using, or causing to be made or used a false record to avoid or decrease an obligation to pay or transmit property to the Government.⁶

The most common violation of the FCA is the knowing presentation of a false or fraudulent claim.⁷ This type of FCA violation occurs when (1) the defendant presented or caused to be presented, for payment or approval, to the Government of the United States a claim upon or against the United States; (2) the claim was false; and (3) the defendant knew that the claim was false.⁸ The word "claim" means

5. See, e.g., *Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173–74 (9th Cir. 2006) (for-profit school); *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (Medicare); *United States ex rel. Coppock v. Northrop Grumman Corp.*, No. Civ.A. 3:98-CV-2143-D, 2003 WL 21730668 (N.D. Tex. July 22, 2003) (defense contractor renting a facility from the Navy).

6. 31 U.S.C. § 3729(a) (2000).

7. As distinguished from an implied certification claim. See *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265–66 (9th Cir. 1996).

8. See *Mikes*, 274 F.3d at 695; *United States ex rel. Gross v. Aids Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005).

any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.⁹

As to the falsity requirement, the FCA reaches both “factually false” and “legally false” statements.¹⁰ A “factually false” statement is the more common type of false statement involved in FCA cases.¹¹ This is where the Government (or the relator) alleges that the defendant incorrectly described the goods or services it provided or requested reimbursement for goods or services that it never provided.¹² For example, a health provider may submit forms under Medicaid and other government-funded programs representing that a medical physician or licensed professional performed services when it did not.¹³ In contrast, a “legally false” statement under the FCA is a false representation or certification of compliance with some governing law, statute, or regulation or with a prescribed contractual term.¹⁴ For instance, a legally false statement is a statement made to the U.S. Department of Housing and Urban Development that expressly certifies compliance with its regulations, despite failing to comply with them.¹⁵

B. Historical Perspective

A primary purpose of the FCA is to provide restitution to the Government for money taken by fraud.¹⁶ *Qui tam* suits have been part of the FCA scheme to prevent fraud against the Federal Government since the Civil War, when the Federal Government was inundated with fraudulent claims for goods never delivered.¹⁷ In *United States v. McNinch*, the Supreme Court discussed how congressional testimony at the time painted “a sordid picture of how the

9. 31 U.S.C. § 3729(c).

10. See *Mikes*, 274 F.3d at 696–97.

11. See *Hopper*, 91 F.3d at 1266.

12. See *Mikes*, 274 F.3d at 697.

13. *United States ex rel. Woodruff v. Hawaii Pac. Health*, No. 05-00521, 2007 WL 1500275, at *1–2 (D. Haw. May 21, 2007) (involving a defendant who allegedly violated the FCA by submitting forms to the Government that were factually false); see also *United States v. Krizek*, 7 F. Supp. 2d 56, 57 (D.D.C. 1998) (involving a relator who alleged that the defendant submitted factually false claims for psychiatric services under Medicare and Medicaid when it presented claims for more than twenty-four hours of care in a single day).

14. See *Mikes*, 274 F.3d at 697.

15. *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977); see also *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997) (involving a defendant alleged to have submitted false claims by failing to comply with the antikickback provision of the Medicare statute (42 U.S.C. § 1320a-7b(b)), after it had expressly certified compliance with that provision).

16. *United States ex rel. Augustine v. Century Health Servs. Inc.*, 289 F.3d 409, 413 (6th Cir. 2002) (referring to restitution as the purpose of the FCA).

17. *Mikes*, 274 F.3d at 692.

United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and [was] generally robbed in purchasing the necessities of war.”¹⁸

Since its beginnings during the Civil War, *qui tam* litigation has ebbed and flowed, with Congress and courts providing checks, balances, and incentives to ensure the proper detection of fraudulent conduct, but avoid overreaching by relators.¹⁹ For example, in 1986, Congress enacted certain amendments to the FCA that sought to achieve “the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute on their own.”²⁰ Courts too have historically acted to ensure that relators’ aggressive prosecution of *qui tam* claims was bounded within the letter and spirit of the FCA, and that the FCA was not converted into a weapon to challenge every alleged regulatory violation or every alleged act of misconduct in relation to the Government.²¹

III. EMERGENCE OF THE IMPLIED CERTIFICATION THEORY

The implied certification theory has emerged in recent years as an attempt to expand significantly the scope of what constitutes a false statement under the FCA. In light of the plain language of the FCA, this theory is often difficult to legitimize as it tries to circumvent a crucial element under FCA: that a *false claim* was knowingly submitted to the Government.²² Rather, such cases are based on the general theory that claims submitted to the Government contain unspoken, unwritten, or implicit certifications of compliance. To understand and synthesize the reported case law in this emerging area of FCA law, it is useful to segregate the cases into the following three scenarios that reflect the most common contexts in which the implied certification theory arises: (i) where the relator alleges that the defendant violated an implied certification of continued compliance with some prior express certification submitted by the defendant; (ii) where the relator alleges that the defendant’s invoices impliedly certified the defendant’s compliance with the statutes or regulations governing the government program at issue; and (iii) where the relator alleges that the defendant violated an implied certification in its invoices that it had complied with all of the terms of the contract executed by the defendant under which payment was sought. Each of these scenarios is discussed below.

18. 356 U.S. 595, 599 (1958).

19. See generally JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 1.01[A] (Supp. 2008-2).

20. United States *ex rel.* Lamers v. Green Bay, 168 F.3d 1013, 1016–17 (7th Cir. 1999) (quoting United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 649 (D.C. Cir. 1994)).

21. See United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1265 (9th Cir. 1996).

22. See generally BOESE, *supra* note 19, § 2.02[B].

A. Scenario #1: Implied Certification of Continued Compliance with Prior Express Certification

First, courts have employed the implied certification theory to hold that a party that expressly certifies its compliance with certain conditions of payment impliedly certifies its continued compliance with those conditions each time it later submits an invoice for payment.²³ In these cases, a relator brings an FCA claim when the defendant continues to seek payments after it ceases to be in compliance with its prior express certifications (which permitted it to participate in the government program in the first instance). Relators need to resort to the implied certification theory because the defendant's invoices—the alleged false claims—may not have repeated the earlier representations made by the defendant that it was in compliance with certain government requirements. This scenario typically arises in cases where there is a federal program that requires companies to submit a certification attesting to certain facts in order to participate in a federal program and receive federal funding. For example, the implied certification doctrine has been applied in the Medicare arena and under the Small Business Administration (SBA) Act. Three illustrative cases analyzing the application of the implied certification theory in this context are: *Ab-Tech Construction, Inc. v. United States*,²⁴ *United States ex rel. Augustine v. Century Health Services Inc.*,²⁵ and *United States ex rel. Main v. Oakland City University*.²⁶

In *Ab-Tech Construction, Inc. v. United States*,²⁷ a construction company participated in an SBA program that promoted minority-owned businesses. In order to participate in this federal program, Ab-Tech was required to submit an express certification form (a "Statement of Cooperation") attesting to its compliance with numerous conditions of participation, including its promised compliance with the program's requirements for continuing eligibility.²⁸ Ab-Tech subsequently submitted a number of payment vouchers to the SBA.²⁹ When

23. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (holding that the "government can state a claim under the FCA for an antecedent violation of the Anti-Kickback Statute for claims submitted through the Medicare program" because the program requires providers to affirmatively certify that they have complied with the Anti-Kickback Statute); *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 91 (D. Conn. 2006) ("Medicare Regulations and the CMS (formerly HCFA)-1500 and HCFA-1450 forms expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms on the form."); *Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347, 355 (D. Mass. 1999) (annual reports included expressed certifications); cf. *United States ex rel. Stebner v. Stewart & Stevenson Servs., Inc.*, 305 F. Supp. 2d 694, 698–99 (S.D. Tex. 2004) (stating that contractor providing trucks to Government did not submit expressly false claims when it submitted forms seeking payment for completed trucks and progress payments on others, which did not mention that trucks did not meet specifications regarding corrosion).

24. 31 Fed. Cl. 429 (1994).

25. 289 F.3d 409 (6th Cir. 2002).

26. 425 F.3d 914 (7th Cir. 2005).

27. 31 Fed. Cl. at 431–32.

28. *Id.* at 432.

29. *Id.* at 433.

the SBA discovered that Ab-Tech had a relationship with a non-minority-owned enterprise that allegedly rendered Ab-Tech ineligible to participate in the program, the Government filed an FCA lawsuit to recover payments made to Ab-Tech in the period after Ab-Tech ceased to be in compliance.³⁰ Although the payment vouchers that Ab-Tech submitted to the SBA did not contain any express misrepresentation, the court held that each invoice it submitted included an implied certification that it was in continued compliance with the express certification it had previously submitted (promising continued compliance with the SBA's minority-owned business requirements).³¹ At trial, the court held that Ab-Tech's failure to comply with the terms of this implied certification rendered its claims for payment false.³²

*United States ex rel. Augustine v. Century Health Services Inc.*³³ involved an implied certification claim against a home health care agency and its officers for submitting false cost reports to obtain Medicare funds. Each cost report submitted by the defendants included an express representation that the funds were being requested for reimbursement of Employee Stock Ownership Plan (ESOP) contribution costs and were in accordance with the governing Medicare regulations.³⁴ Upon receipt, the defendants properly deposited the Medicare funds into an ESOP account; but, shortly thereafter, the defendants transferred the funds to the company for its general corporate use without notifying the Government.³⁵ Because the express representations in defendants' cost reports were true at the time they were submitted, defendants could not be held liable under a traditional FCA theory of liability. Instead, the lower court relied on the implied certification theory, and held that each cost report—which expressly certified that the payment was in accordance with the Medicare regulations governing the allowability of ESOP expenses—included an implied certification that defendants would “continue to comply” with that certification.³⁶ After being found liable for submitting false claims under the FCA, the defendants appealed. The Sixth Circuit affirmed, and approved the application of the implied certification theory under these circumstances.³⁷ The Sixth Circuit explained: “[L]iability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned.”³⁸

More recently, in *United States ex rel. Main v. Oakland City University*,³⁹ the Seventh Circuit appeared to address a similar issue, although it did not

30. *Id.* at 432–33.

31. *Id.* at 434.

32. *Id.*

33. 289 F.3d 409, 411 (6th Cir. 2002).

34. *Id.* at 412.

35. *Id.*

36. *Id.* at 414–15.

37. *Id.* at 415.

38. *Id.*

39. 426 F.3d 914, 916 (7th Cir. 2005).

refer to the implied certification theory by name. In *Main*, a relator brought a multiphase fraud claim under the FCA against a university.⁴⁰ In phase one, in order to obtain a certification of eligibility for government subsidies, the university expressly certified its compliance with the applicable contingent fee provisions, 20 U.S.C. § 1094 and 34 C.F.R. § 668.14(b)(22)(i), which “condition institutional eligibility on a commitment to refrain from paying recruiters contingent fees for enrolling students.”⁴¹ In phase two, the university and its students applied for grants and loans covered by the FCA but did not repeat the assurances that it had not paid contingent fees.⁴² The Seventh Circuit, in an opinion by Judge Easterbrook, analyzed the claim under a promissory fraud theory and held that the phase two disbursements were contingent upon the certificate of eligibility in phase one.⁴³ The court held that under such a theory, liability will attach to each claim submitted to the Government under a contract, when the contract or some extension of a government benefit was originally obtained through false statements or fraudulent conduct.⁴⁴

Therefore, the university had essentially impliedly certified that it had complied with the phase one requirements when it submitted requests for subsidies in phase two, and thereby fraudulently induced the Government to pay.⁴⁵ The court explained that “[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.”⁴⁶

This first application of the implied certification theory appears noncontroversial in that it works to hold a defendant liable for express certifications it actually made in order to be eligible to receive federal funds. The law simply implies that the defendant repeats those certifications each time it submits an invoice for payment as a participant in that federal program. In these types of circumstances, it is fair for the Government to assume that once a party expressly certifies compliance with certain funding prerequisites (e.g., that it will not pay recruiters, will remain a minority-owned business, or will comply with Medicare cost report regulations), it will continue to comply with those requirements. The use of the implied certification theory in this context does not improperly expand the breadth of the FCA. Rather, it is consistent with the Act’s purpose to indemnify the Government for fraud committed against it.

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.* at 916–17; *see also* United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1173–74 (9th Cir. 2006) (discussing the case at length).

44. *Main*, 426 F.3d at 916–17; *see also* Hendow, 461 F.3d at 1173–74 (“[U]nder either the false certification theory or the promissory fraud theory, the essential elements of [FCA] liability remain the same . . .”).

45. United States *ex rel.* Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005); *see also* Hendow, 461 F.3d at 1174.

46. *Main*, 426 F.3d at 916; *see also* Hendow, 461 F.3d at 1174 (quoting *Main*).

B. *Scenario #2: Submitting Invoices for Payment
Impliedly Certifies Compliance with a Governing Statute,
Regulation, or Government Policy*

The second scenario in which the implied certification theory has been used is where a defendant is participating in some federal program and is alleged to have violated some law, regulation, or government policy governing participation in that program. The Government and relators resort to the implied certification theory when the defendant has made no express representation on its invoices or requests for payment certifying compliance with the law, regulation, or policy it is alleged to have violated. The cases discussed below show that relators rely on the implied certification theory to allege that the submission of a claim for payment is itself an implied representation that the defendant is in compliance with the laws and regulations governing the federal program. These types of implied certification claims are often raised in cases relating to Medicare, where relators rely on some alleged violation of one of the vast number of complex rules and regulations relating to that program as the basis for an FCA claim.⁴⁷

Some relators have been particularly aggressive in their attempted use of the implied certification theory in these circumstances. For example, some relators have brought claims alleging that the defendants have violated laws or regulations that are unrelated to the conditions of payment for that government program.⁴⁸ Also, some relators have sought to extend the implied

47. See, e.g., *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001) (holding, in a case involving alleged violations of the Medicare Act, 42 U.S.C. §§ 1320c-5(a), 1395y(a)(1)(A), that “[s]ince [42 U.S.C.] § 1395y(a)(1)(A) expressly prohibits payment if a [Medicare] provider fails to comply with its terms, defendants’ submission of the claim forms implicitly certifies compliance with its provisions”); *United States ex rel. Lee v. Fairview Health Sys.*, No. Civ.02-270 RHK/SRN, 2004 WL 1638252, at *3 (D. Minn. July 22, 2004) (involving alleged violation by Medicare provider of implied certification of compliance with 42 C.F.R. § 416.60(c)(1)(i) requiring physical therapists to practice within the scope of their license); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 346 (D. Conn. 2004) (“[I]n submitting the claim forms, defendants implicitly certified compliance with the Medicare Act [42 U.S.C.] § 1395y(a)(1)(A), that they were only seeking payment for services that were reasonable and necessary. To the extent the forms included requests for payment of services that were not reasonable and necessary, the claims were legally false under an implied certification theory.”); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) (discussing kickback certifications under Medicare and holding that failure to comply with the kickback laws implicates the FCA); *United States ex rel. Sharp v. Consol. Med. Transp., Inc.*, No. 96-C-6502, 2001 WL 1035720, at *2 (N.D. Ill. Sept. 4, 2001) (involving alleged Medicare kickback scheme in violation of 42 U.S.C. § 1320a-7(b)(2) prohibiting payments of money to induce referrals of Medicare patients).

48. See, e.g., *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) (holding that compliance with the regulations that the defendant allegedly violated was not a *condition of payment* where, in the event of noncompliance, “the Government is merely authorized to suspend future enrollment, suspend *future* payments, or impose monetary penalties, rather than withhold payment for those already enrolled”); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 68–71 (D.D.C. 2007) (granting summary judgment because the relator did not identify a regulation or law that specifically conditioned payment on compliance with a law, regulation, or other requirement that the defendant violated); *United States ex rel. Gay v. Lincoln Technical Inst., Inc.*, No. Civ.A. 301CV505K, 2003 WL 22474586, at *4 (N.D. Tex. Sept. 3, 2003) (finding that the relators’ claims for implied and

certification theory to reach not only alleged violations of governing laws or regulations, but also nonbinding guidelines, manuals, and policies.⁴⁹

This aggressive use of the implied certification theory is illustrated in *United States ex rel. Hopper v. Anton*⁵⁰ and *United States ex rel. Mikes v. Straus*.⁵¹ In these two decisions, the courts have reined in relators' attempts to use the implied certification theory in this manner. In doing so, they have set forth two important criteria that a relator must establish before the implied certification is applied: (i) the provision of the law or regulation at issue must set forth an express condition of payment and (ii) the law or regulation must be binding, and not just an informal government rule, guideline, or manual provision.

1. The Seminal Cases—*Hopper* and *Mikes*

In *Hopper*, the relator, a special education teacher, filed an FCA claim against the Los Angeles School District (the District).⁵² The relator alleged that the District made false statements in certain forms (J-50 forms and J-380 forms) that it submitted to the California State Department of Education, which she contended permitted it to improperly receive federal funds under the Individuals with Disabilities Education Act (IDEA) for special education programs.⁵³ The relator further averred that at the time these forms were submitted, the District was not in compliance with the controlling federal and state regulations, including California Education Code section 56341(b)(2)

express false certification failed because they did not establish that the defendant knowingly made a false statement of compliance with a regulation or statute that was a *condition of government payment*); *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 501 (S.D. Tex. 2003) (stating that “[t]he statute or regulation at issue must *expressly* state that certification of compliance is a *condition of payment*” and finding relators failed to state an FCA action because “the regulation does not expressly condition the delivery or disbursement of funds ... [on] certification of compliance”) (emphasis added); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) (granting defendant's motion for summary judgment because the relator introduced no evidence to demonstrate that the defendant certified compliance with the applicable Medicare regulations *as a condition to receiving federal payment*); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 831 (W.D. Mich. 2000), *aff'd*, 24 Fed. Appx. 491 (6th Cir. 2001), *cert. denied*, 535 U.S. 1096 (2002) (citing *Luckey v. Baxter Health Corp.*, 183 F.3d 730 (7th Cir. 1999)) (“*Luckey* has been interpreted to stand for the proposition that an implied false certification theory can succeed only where the defendant's compliance with statutory or regulatory authority is so essential for reimbursement that, if the government had been aware of the defendant's non-compliance, it would have refused payment.”).

49. See, e.g., *Mikes*, 274 F.3d at 701–02 (rejecting implied certification claim based on alleged violation of certain Medicare guidelines); *United States ex rel. Yannacopoulos v. Gen. Dynamics*, No. 03 C 3012, 2007 WL 495257, at *3–4 (N.D. Ill. Feb. 13, 2007) (rejecting implied certification claim premised on alleged violation of DSAA guidelines); *Swafford*, 98 F. Supp. 2d at 828–29, 833 (granting defendants' motion for summary judgment on the FCA claim and rejecting plaintiff's argument that the Medicare Carriers Manual was an appropriate guide for determining whether Medicare claims submitted by physicians for venous ultrasound reports were false or fraudulent in violation of the FCA).

50. 91 F.3d 1261 (9th Cir. 1996).

51. 274 F.3d 687 (2d Cir. 2001).

52. 91 F.3d at 1263.

53. *Id.* at 1265.

and 34 C.F.R. § 300.344(a), which discuss the manner in which evaluations of special education children are to be conducted.⁵⁴ Although not couched in terms of the implied certification theory, the relator argued that the J-50 and J-380 forms contained false implied certifications of compliance with all the governing federal and state regulations relating to special education programs. The district court granted summary judgment in favor of the District, finding that even if the District had failed to comply with certain regulations, it made no false statements actionable under the FCA in the J-50 and J-350 forms it submitted to the Government.⁵⁵ In refusing to accept the relator's expansive theory as to the scope of the implied representations made in the District's forms, the district court explained that the relator had a deep misunderstanding of the scope of the FCA:

It is not the case that any breach of contract, or violation of regulations or law, or receipt of money from the government where one is not entitled to receive the money, automatically gives rise to a claim under the FCA. . . . The FCA is far narrower. It requires a false claim. Thus, some request for payment containing falsities made with scienter . . . must exist. This does not mean that other types of violations of regulations, or contracts, or conditions set for the receipt of moneys, or of other federal laws and regulations are not remediable; it merely means that such are not remediable under the FCA or the citizen's suit provisions contained therein.⁵⁶

The Ninth Circuit affirmed the dismissal of the relator's FCA claims and agreed that the teacher had misinterpreted the breadth of the Act.⁵⁷ The Ninth Circuit explained that "violations of laws, rules, or regulations alone do not create a cause of action under the FCA."⁵⁸ Rather, the court held: "[i]t is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit."⁵⁹ The court also refused to read a certification of compliance with any laws or regulations into the District's J-50 and J-380 forms because the IDEA did not expressly require funding recipients to certify compliance with any specific federal laws or regulations.⁶⁰

In *Mikes*, a relator filed suit against a medical partnership claiming that it had submitted false reimbursement requests to the Federal Government for spirometry testing services, a pulmonary function test used to detect lung disease.⁶¹ The relator alleged that the partnership did not perform the spirometry

54. *Id.* at 1264.

55. *Id.* at 1264–65.

56. *Id.* at 1265.

57. *Id.* at 1265, 1270.

58. *Id.* at 1266.

59. *Id.*

60. *Id.* at 1267. See also *United States ex rel. Holder v. Special Devices, Inc.*, 296 F. Supp. 2d 1167, 1174 (C.D. Cal. 2003) ("No matter how *Hopper* is interpreted, it could not be more clear that the defendant in *Hopper* did not have comply [*sic*] with regulations in order to receive government funds."); cf. *Holder*, 296 F. Supp. 2d at 1175 (then distinguishing *Hopper* and noting that the contracts entered into between the Federal Government and the company in *Holder* unequivocally stated that the company had to comply with all applicable federal, state, and local laws and required the company to comply with such laws as a condition of payment).

61. *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 692, 694 (2d Cir. 2001).

services in compliance with the standard of care contained in the American Thoracic Society (ATS) guidelines.⁶² The guidelines were included by reference in regulations promulgated by the Social Security Act and Medicare statute, 42 U.S.C. § 1320c-5(a).⁶³ Relying on the implied certification theory, the relator argued that the partnership's submissions for reimbursement impliedly certified compliance with the ATS guidelines.⁶⁴ The court rejected the relator's argument and found that the defendants' submissions did not impliedly certify that their performance of spirometry conformed to any qualitative standard set forth in the ATS guidelines.⁶⁵ Moreover, the court concluded that "even were the Medicare claims objectively false, plaintiff had not shown [that the] defendants submitted the claims with the requisite scienter."⁶⁶ The district court then granted defendants' motion for summary judgment, ruling that "submitting a claim for a service that was not provided in accordance with the relevant standard of care" set forth in the ATS guidelines did not make that claim false under the FCA.⁶⁷

On appeal, the Second Circuit agreed and cautioned against reading the implied certification theory too expansively or out of context.⁶⁸ Though the spirometry tests may not have complied with guidelines referenced in certain acts, and though the guidelines may constitute a "professionally recognized standard of health care," the Second Circuit focused on the fact that compliance with the guidelines was not a precondition of payment.⁶⁹ Instead, the federal statute simply stated that "[i]t shall be the obligation of any health care practitioner . . . who provides health care services for which payment may be made" to assure compliance with the statute.⁷⁰ Hence, according to *Mikes*, the statutory provision acted prospectively by setting forth conditions of eligibility to participate.⁷¹ In light of the guidelines, the court then explained: "[the] implied false certification [theory] is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid."⁷² Thus, because the Medicare statute did not explicitly condition payment on compliance with § 1320c-5(a), the court rejected the relator's proposed application of the implied certification theory.⁷³

Mikes serves as a warning to relators—especially in the Medicare context where FCA actions are often brought given the large number of governing

62. *Id.* at 693–94.

63. *Id.* at 694.

64. *Id.* at 701.

65. *Id.*

66. *Id.* at 693.

67. *Id.*

68. *Id.* at 699 (citing *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 433 (S.D.N.Y. 1999)).

69. *Id.* at 699–700.

70. *Id.* at 701 (quoting 42 U.S.C. § 1320c-5(a)).

71. *Id.*

72. *Id.* at 700.

73. *Id.* at 701–02.

statutes and regulations—not to read the implied certification theory expansively and out of context. The presence of numerous governing statutes and regulations should not necessarily multiply and expand the scope of the FCA. Rather, *Mikes* makes clear that the FCA “was not designed for use as a blunt instrument to enforce compliance with all medical regulations.”⁷⁴

2. Requirement #1: Violation of Law or Regulation Setting Forth Express Condition of Payment

As demonstrated in *Hopper* and *Mikes*, a relator may not rely on the implied certification theory to establish liability under the FCA for every alleged statutory or regulatory violation. A claim for reimbursement is not false simply because the service furnished did not comply with the mandates of a statute, regulation, or contractual term that is tangential to that service.⁷⁵ Rather, the hurdle to pursue an implied certification claim under the FCA is much higher. As *Mikes* correctly stressed, the FCA is primarily aimed at retrieving falsely obtained government funds.⁷⁶ To find liability when the alleged noncompliance would not have influenced the Government’s decision to pay would be inconsistent with the Act’s purpose and thereby improperly broaden the Act’s reach.⁷⁷ The relator, therefore, must establish the violation of a law or regulation setting forth an express condition of payment.⁷⁸ Indeed,

74. *Id.* at 699, 700 (stating further that “permitting *qui tam* plaintiffs to assert that defendants’ quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff”).

75. *Id.* at 697.

76. *Id.*

77. *Id.*

78. *Id.* at 700; see also *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, No. 2:99-CV-00086, 2007 WL 2713913, at *2 (D. Utah Sept. 12, 2007) (citing *Mikes* and stating that the plaintiff “must identify a statute, regulation, or contractual term that she claims Defendants violated and that expressly makes compliance a prerequisite for payment”) (emphasis added); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 663 (N.D. Ill. 2006) (“[T]he plaintiffs must plead (and ultimately prove) that had the government known about the kickback scheme, it would have refused payment of the claims and, further, that the defendants were aware that this was the case when they engaged in their fraudulent conduct.”); *United States ex rel. Cooper v. Gentiva Health Servs., Inc.*, No. 01-508, 2003 WL 22495607, at *3 (W.D. Pa. Nov. 4, 2003) (finding *Mikes* limitation on implied certification theory “to be a well-reasoned and accurate statement of the law”); *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 501 (S.D. Tex. 2003) (citing *Mikes*, stating that “[t]he statute or regulation at issue must expressly state that certification of compliance is a condition of payment,” and finding relators failed to state an FCA action because “the regulation does not expressly condition the delivery or disbursement of funds ... [on] certification of compliance”) (emphasis added); *United States ex rel. Watson v. Conn. Gen. Life Ins. Co.*, No. Civ.A. 98-6698, 2003 WL 303142, at *10 (E.D. Pa., Feb. 11, 2003) (citing *Mikes* and stating that “[l]iability under the FCA for a false or fraudulent certification of compliance [with the regulations at issue], whether the certification was express or implied, exists only if certification of such compliance influenced the government’s payment decision”); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002) (“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.”).

an essential element of any FCA claim premised on the alleged false certification of compliance with statutory or regulatory requirements is that the certification of compliance be an express condition to government payment.⁷⁹ A relator may not simply argue that where a contractor impliedly certifies compliance with a statute or regulation, the condition of payment set forth in the statute or regulation also may be implied.⁸⁰ Rather, courts distinguish between the underlying statute or regulation, which is impliedly complied with, and the condition of payment set forth in it, which must be expressly stated.⁸¹ Thus, the fact that a contractor impliedly certified compliance with an underlying statute or regulation is only relevant to an FCA claim if that provision contains an express condition of payment. For all other alleged regulatory violations, there are administrative and other remedies.⁸²

A survey of the reported case law indicates that courts have uniformly embraced this requirement. For example, in the Medicare context, a court has held that the alleged violation of Medicare's antikickback and self-referral statute (42 U.S.C. § 1320a-7(b)) satisfied this requirement because Medicare expressly conditioned payment on compliance, and there was evidence that the Government would not have paid the claims in the absence of compliance.⁸³

79. United States *ex rel.* Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 605 (7th Cir. 2005); *see also* United States *ex rel.* Bowan v. Educ. Am., Inc., 116 Fed. Appx. 531 (5th Cir. 2004) (per curiam) (holding that false certifications of compliance with applicable regulations and statutes governing participation in federal student financial aid programs did not constitute a basis for imposing liability under the FCA, absent allegation of certifications of compliance with particular regulations on which payment was conditioned); United States *ex rel.* Schmidt v. Zimmer, Inc., 386 F.3d 235, 245 (3d Cir. 2004) (finding that the relator did state a valid FCA claim as the relator alleged that "certification of compliance with health care law is a prerequisite to entitlement to Medicare payments and that false certifications of compliance were necessary consequences of [the defendant's] marketing scheme"); United States *ex rel.* Costner v. United States, 317 F.3d 883, 887 (8th Cir. 2003) ("[T]he plaintiffs have failed to produce evidence . . . as to whether the allegedly withheld information was even relevant to the EPA's payment decision."); United States *ex rel.* Gay v. Lincoln Technical Inst., Inc., No. Civ. A. 301CV505K, 2003 WL 22474586, at *4 (N.D. Tex. Sept. 3, 2003) (finding that the relators' claims for implied and express false certification fail because they did not establish that defendant knowingly made a false statement of compliance with a regulation or statute that was a condition of government payment); United States *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) (granting defendant's motion for summary judgment because the relator introduced no evidence to demonstrate that the defendant certified compliance with the applicable Medicare regulations as a prerequisite to receiving federal payment); United States v. Estate of Rogers, No. 1:97CV461, 2001 WL 818160, at *6 (E.D. Tenn. June 28, 2001) ("FCA liability may not be based merely on noncompliance with statutes and regulations. FCA liability for a false certification will lie only if compliance with a statute or regulation was a prerequisite to gaining a benefit, and the defendant affirmatively certifies such compliance.").

80. United States *ex rel.* Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 70 (D.D.C. 2007).

81. *Id.*

82. *See, e.g.,* United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1267 (9th Cir. 1996) ("There are administrative and other remedies for regulatory violations. [Relator] knows this. She has pursued many of them.").

83. United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902-03 (5th Cir. 1997).

In reaching this conclusion, the court properly focused on the provision in the Medicare statute providing: “No payment may be made under this subchapter for a designated health service which is provided in violation of [self-referral statute defendant alleged to have been violated].”⁸⁴

There are several other cases in which courts have rejected implied certification claims premised on the alleged violation of statutory or regulatory provisions that were not express conditions of government payment. For example:

- In *United States ex rel. Willard v. Humana Health Plan of Texas*,⁸⁵ a former employee of a health maintenance organization (HMO) alleged that the HMO engaged in a scheme that discouraged rural and less affluent persons from joining, in violation of government statutes prohibiting discrimination. The relator argued that the HMO’s submissions to the Government impliedly certified compliance with the governing antidiscrimination statutes (42 U.S.C. § 1395mm(i)(6) and 42 C.F.R. § 417.428(b)(1)).⁸⁶ The lower court dismissed the implied certification claims, and the Fifth Circuit affirmed because the Health Care Financing Administration did not “*conditio[n] its payment* to [defendant] on any implied certification of compliance with the anti-discriminatory regulations.”⁸⁷
- In *Harrison v. Westinghouse Savannah River Co.*,⁸⁸ a relator brought a *qui tam* action against a government contractor, alleging that the contractor made false and fraudulent statements to the Government in connection with claims for payment to a subcontractor hired by the contractor. The Fourth Circuit affirmed the district court’s dismissal of the relator’s FCA claim because the relator “never asserted that such implied certifications were in any way related to, let alone prerequisites for, receiving continued funding.”⁸⁹
- In *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*,⁹⁰ the relator alleged that certain Medicare forms submitted to the Government were false under the implied certification theory. The court granted summary judgment in favor of the defendant because the relator did not identify a regulation or law that specifically conditioned payment on compliance with a law, regulation, or other requirement that the defendant violated.⁹¹

84. 42 U.S.C. § 1395nn(g)(1) (2000); *Thompson*, 125 F.3d at 902.

85. 336 F.3d 375, 378–79 (5th Cir. 2003).

86. *Id.* at 380.

87. *Id.* at 382.

88. 176 F.3d 776, 780 (4th Cir. 1999).

89. *Id.* at 793.

90. 498 F. Supp. 2d 25, 68–70 (D.D.C. 2007).

91. *Id.* at 70.

In determining whether the law or regulation at issue is an express condition of payment, courts consider whether the Government has any discretion in the event of noncompliance, or whether denial of payment is required. Where the Government has discretion to fashion a remedy (even if the options include denial of payment), courts have properly found that compliance with the law or regulation is not a condition of payment.⁹² *United States ex rel. Lamers v. City of Green Bay* illustrates this point.⁹³ In *Lamers*, a relator “alleged that in order to remain eligible for annual federal transit grants the City of Green Bay lied to the Federal Transit Administration (FTA) about its efforts to transport local school children on public buses.”⁹⁴ The relator tried to use the FCA to supplant the FTA’s decision not to implement regulatory penalties against the city.⁹⁵ The court properly rejected such efforts and affirmed summary judgment against the plaintiff.⁹⁶ The court emphasized that “the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations.”⁹⁷ This conclusion makes sense not just within the analytical framework of *Mikes* and *Hopper*, but also because the FCA should not supplant a federal agency’s discretion to determine the proper penalty for regulatory noncompliance.⁹⁸

Finally, in analyzing whether the law or regulation at issue is an express condition of payment, courts distinguish between conditions of payment and mere conditions of participation in the underlying federal program.⁹⁹ This principle follows from the FCA’s primary rationale, in that no fraud is committed if the Government would have paid the contractor notwithstanding the alleged violation of the condition of participation.¹⁰⁰ For example, in

92. See *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 382–83 (5th Cir. 2003) (holding that compliance with the regulations that the defendant allegedly violated was not a condition of payment where in the event of noncompliance “the Government is merely authorized to suspend future enrollment, suspend *future* payments, or impose monetary penalties, rather than withhold payment for those already enrolled”); *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 459 F. Supp. 2d 1081, 1088–89 (D. Kan. 2006) (dismissing relator’s FCA claims based on defendant’s alleged violations of certain Medicare regulations because federal agency responsible for enforcing regulations had discretion over what sanctions, if any, to impose for such violations).

93. 168 F.3d 1013, 1019–20 (7th Cir. 1999).

94. *Id.* at 1014.

95. *Id.* at 1015.

96. *Id.* at 1020.

97. *Id.*; see also *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) (stating that it is improper for *qui tam* relator to supplant agency’s discretion “where [the agency] may choose to . . . impose a less drastic sanction than full denial of payment”).

98. *Lamers*, 168 F.3d at 1020.

99. See, e.g., *United States ex rel. Woodruff v. Haw. Pac. Health, No. 05-00521 JMS/LEK*, 2007 WL 1500275, at *7–8 (D. Haw. May 21, 2007). But see *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 414–15 (6th Cir. 2002) (holding that liability may attach when a claimant violates a condition of participation after it had expressly certified compliance with it, which included an implied certification to continue to comply with those conditions).

100. See *Augustine*, 289 F.3d at 413.

United States ex rel. Woodruff v. Hawaii Pacific Health,¹⁰¹ the relator alleged that the defendants falsely certified compliance with certain Medicaid statutes and regulations, including several regulations entitled “Conditions of Participation for Hospitals.” The defendants did not, however, initially expressly certify their compliance with the conditions of participation.¹⁰² Rather, the relator attempted to use the implied certification theory to read into the invoices the defendants’ implied certified compliance with the conditions of participation.¹⁰³ The court rejected the argument that any alleged violation of the conditions of participation would give rise to liability under the FCA and explained that such a conclusion would be an “impermissibly broad expansion” of the FCA.¹⁰⁴ The court emphasized that it had “not found any case holding that violations of conditions of participation are sufficient to state a claim under the FCA based on false certification of Medicare or Medicaid claims.”¹⁰⁵

3. Requirement #2: Existence of Statute or Regulation

The second requirement for the proper application of the implied certification theory is that the relator establishes a violation of a binding law or regulation (which, as discussed above, contains an express condition of payment).¹⁰⁶

101. 2007 WL 1500275, at *8 & n.10 (referring to 42 C.F.R. pt. 482, ch. IV).

102. *Id.* at *7–8.

103. *Id.*

104. *Id.* at *7.

105. *Id.*

106. *See, e.g.*, *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (referencing requirement of an “underlying *statute or regulation* ... [which] states the provider must comply in order to be paid”) (emphasis added); *United States ex rel. Herndon v. Sci. Applications Int’l Corp.*, No. 05CV2269–BEN (RBB), 2007 WL 2019653, at *5 (S.D. Cal. July 10, 2007) (dismissing relator’s FCA claim because relator did not identify any *laws or regulations* that defendant allegedly violated where compliance was a condition of government payment); *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 2007 WL 495257, at *3 (N.D. Ill. Feb. 13, 2007) (stating that “[t]o succeed under this [implied certification] theory, plaintiff must show that compliance with the relevant *statutes and regulations* was a condition of receiving payment”) (emphasis added); *United States ex rel. Erickson v. Uintah Special Servs. Dist.*, 395 F. Supp. 2d 1088, 1097 (D. Utah 2005) (finding that quasi-municipal corporation did not make “false claim” to obtain mineral lease funds because relators did not identify any *statute, rule, or regulation* requiring the submission of any claim, request, demand, or report for defendants’ receipt of those funds); *United States ex rel. Cooper v. Gentiva Health Servs., Inc.*, No. 01-508, 2003 WL 22495607, at *2 (W.D. Pa. Nov. 4, 2003) (granting the defendant’s motion for summary judgment on the plaintiff’s *qui tam* claims because they failed to certify “compliance with a *statute or regulation* as a condition to governmental payment”) (emphasis added); *United States ex rel. Bailey v. Ector County Hosp.*, 386 F. Supp. 2d 759, 765 (W.D. Tex. 2004) (granting the defendants’ motion for summary judgment on the FCA claim because the relator failed to establish that the defendants “made a knowingly false certification of compliance with a *statute or regulation*”) (emphasis added); *United States ex rel. King v. F.E. Moran, Inc.*, No. 00-C-3877, 2002 WL 2003219, at *11 (N.D. Ill. Aug. 22, 2002) (stating that a relator must show that “compliance with the relevant *statutes and regulations* was a condition of receiving payment”) (emphasis added); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998) (noting that the relator had failed to demonstrate that defendant’s “compliance with any *statutes or regulations* was a material condition to receiving payment from the government”) (emphasis added).

The alleged violation of agency guidelines, manuals, or other nonbinding government publications is not sufficient to trigger application of the implied certification theory.¹⁰⁷ This requirement is important, among other reasons, because (1) guidelines and manuals do not have the force of law and (2) they allow the agency discretion, and therefore cannot constitute an express condition of payment. Guidelines are also not promulgated pursuant to an agency's rulemaking power or subject to rigorous public review. Consequently, they can be easily changed and are therefore extremely difficult for companies to track. To hold defendants liable for violating a mere guideline (of which they may not have even been aware) impermissibly broadens the scope of the Act and is inconsistent with the FCA's scienter requirement.

This second requirement is illustrated in *United States ex rel. Yannacopoulos v. General Dynamics*,¹⁰⁸ where the relator attempted to hold a defense contractor liable under the implied certification theory for the alleged violation of certain Defense Security Assistance Agency (DSAA) guidelines, which were not expressly incorporated in the contract (or the contractor's invoices or express certification). The court held that the DSAA guidelines were not binding statutes or regulations because they were not promulgated pursuant to any rulemaking power of the agency, nor were they subject to notice-and-comment rulemaking or the Administrative Procedure Act.¹⁰⁹ The court explained: "[The DSAA guidelines] do not have the force of law, and therefore evidence that General Dynamics may have failed to technically comply with a particular guideline not referenced in its Certification does not establish an FCA violation."¹¹⁰

United States ex rel. Swafford v. Borgess Medical Center is also illustrative.¹¹¹ In *Swafford*, a vascular technologist filed an FCA action alleging that various physicians and health care providers defrauded the Government by falsely charging for vascular ultrasound services that they did not provide.¹¹² The court rejected the relator's argument that the Medicare Carriers Manual published by the Health Care Financing Administration (HCFA) was an appropriate guide for determining whether Medicare claims submitted by physicians for venous ultrasound reports were false or fraudulent in violation of the FCA.¹¹³ The court declined to judge the truth or falsity of the defendants' representations in light of the manual and emphasized that the manual lacked

107. See *Mikes*, 274 F.3d at 701-02 (rejecting implied certification claim based on alleged violation of certain Medicare guidelines); *Yannacopoulos*, 2007 WL 495257, at *3 (rejecting implied certification claim premised on alleged violation of DSAA guidelines); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 827-28 (W.D. Mich. 2000) (granting defendants' motion for summary judgment on the FCA claim and rejecting plaintiff's argument that the Medicare Carriers Manual published by the Health Care Financing Administration (HCFA) was an appropriate guide for determining whether Medicare claims submitted by physicians for venous ultrasound reports were false or fraudulent in violation of the FCA).

108. No. 03 C 3012, 2007 WL 495257, at *1 (N.D. Ill. Feb. 13, 2007).

109. *Id.* at *3.

110. *Id.*

111. 98 F. Supp. 2d 822, 828-29 (W.D. Mich. 2000).

112. *Id.* at 824-25.

113. *Id.* at 828.

“the binding effect of law or regulation.”¹¹⁴ In granting the defendants’ motion for summary judgment, the court stressed that the HCFA had not promulgated specific regulations relating to the submission of reimbursement claims for venous ultrasounds and that the plaintiff failed to identify any controlling regulation.¹¹⁵ Thus, *Swafford* shows courts’ unwillingness to expand the scope of implied false certification to cases that do not involve binding statutes or regulations.

The authors of this Article are unaware of any FCA case in which a defendant has been held liable under the implied certification theory based solely on the violation of a government manual, agency guideline, or other nonbinding government publication without the force of law. Courts have, however, considered nonbinding manuals and guidelines, but only as necessary to determine whether a defendant violated some underlying statute or regulation.¹¹⁶ Although courts in these cases—which often arise in the Medicare context—discuss guidelines or government manuals, there is always an underlying statute or regulation that triggers the application of the implied certification theory.

For example, in *In re Cardiac Devices Qui Tam Litigation*,¹¹⁷ a relator brought a claim alleging that certain hospitals violated the FCA by submitting Medicare claims for hospital services provided to patients who elected to participate in clinical trials involving cardiac devices that the Food and Drug Administration (FDA) had not yet approved for marketing. The court held that the hospitals impliedly certified their compliance with section 1395y(a)(1)(A) of the Medicare Act, which provides that a service provider may only receive payment for services that were “reasonable and necessary.”¹¹⁸ In analyzing whether this implied certification was false (and, thus, actionable under the FCA), the court reviewed the accompanying Medicare manual that clarified what services were reasonable and necessary.¹¹⁹ Accordingly, although the court considered whether the hospitals complied with the manuals, the FCA claim was premised on the implied certification of the Medicare statute.

Thus, in the absence of some binding law or regulation, the implied certification theory is inapplicable.¹²⁰

114. *Id.* (quoting *Nat’l Med. Enters. v. Bowen*, 851 F.2d 291, 293 (9th Cir. 1988)).

115. *Id.*

116. *See, e.g., In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 323 (D. Conn. 2004).

117. *Id.*

118. *Id.* at 346 (citing 42 U.S.C. § 1395y(a)(1)(A)).

119. *Id.* at 347–51; *see also* *United States v. Napco Int’l, Inc.*, 835 F. Supp. 493, 496–98 (D. Minn. 1993) (considering DSAA guidelines to help assess whether defendant violated 22 U.S.C. § 2791 prohibition regarding non-U.S. content).

120. A somewhat comical view, courtesy of Hollywood, as to the difference between guidelines and binding laws was provided in the first *Pirates of the Caribbean* film. When Elizabeth (the character played by Keira Knightley) demanded that pursuant to the pirates’ code she be returned to shore and released, Barbosa (the pirate played by Geoffrey Rush) explained: “First, your return to shore was not part of our negotiations nor our agreement so I must do nothing. And secondly, you must be a pirate for the pirate’s code to apply and you’re not. And thirdly, the code is more what you’d call ‘guidelines’ than actual rules.” *THE PIRATES OF THE CARIBBEAN: THE CURSE OF THE BLACK PEARL* (Disney Studios 2003).

C. Scenario #3: Compliance with Contractual Terms

The third scenario in which the implied certification theory has been applied is where a defendant is alleged to have falsely submitted an invoice for payment in alleged violation of some provision in its contract with the Government. Here, relators allege that an invoice—the alleged false claim—implicitly certifies compliance with all of the terms of the underlying government contract.¹²¹ As with the cases arising in connection with statutes and regulations discussed above, courts have emphasized that not every breach of contract gives rise to an implied certification claim under the FCA.¹²² Rather, an invoice is only an implied certification of compliance with contract terms that are an express condition of payment.¹²³ Thus, in order for a breach of contract to be actionable under the FCA (assuming all other elements are satisfied), the breached contractual term must be an express condition of payment.¹²⁴ The application of this requirement is aptly illustrated in *United States ex rel. Coppock v. Northrop Grumman Corp.*¹²⁵ and in *United States ex rel. Marcy v. Rowan Cos.*¹²⁶

In *Coppock*, the defendant, Northrop Grumman Corp. (Grumman), leased a Naval Weapons Industrial Reserve Plant from the U.S. Navy.¹²⁷ Coppock alleged that Northrop had made false statements in toxic release inventory reports that Northrop was required under federal environmental laws to submit annually to the Environmental Protection Agency (EPA) in order to operate the facility.¹²⁸ Coppock also argued that Northrop made false implied certifications in its rent payments to the Navy for use of the property.¹²⁹ Specifically, Coppock alleged that Northrop knew about its violation of the environmental statutes and that it was “not substantially performing the material obligations of its contracts” at the time it made its rent payment.¹³⁰ According to Coppock, compliance with the various environmental statutes was a condition of payment because “had the Navy known that Northrop was violating the leases ... it would not have allowed Northrop to continue to use the property.”¹³¹

121. See, e.g., *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531–33 (10th Cir. 2000) (finding that defendant violated implied certification in invoices for full payment under a contract where defendant knew it had failed to comply with a mandatory contract requirement at the time the invoices were submitted); *United States ex rel. Bryant v. Williams Bldg. Corp.*, 158 F. Supp. 2d 1001, 1010 (D.S.D. 2001) (finding that payment invoices represented an implied certification of continued adherence to all *material* terms of the contract).

122. *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996).

123. *Bryant*, 158 F. Supp. 2d at 1010; see also *Shaw*, 213 F.3d at 531–33.

124. *United States ex rel. Coppock v. Northrop Grumman Corp.*, No. Civ.A. 3:98-CV-2143-D, 2003 WL 21730668, at *11–12 (N.D. Tex. July 22, 2003).

125. *Id.*

126. No. 03-3395, 2006 WL 2414349, at *1 (E.D. La. Aug. 17, 2006).

127. *Coppock*, 2003 WL 21730668, at *1–2.

128. *Id.* at *2.

129. *Id.*

130. *Id.*

131. *Id.*

Coppock alleged that “compliance with the environmental statutes and regulations and with maintenance requirements was expressly required by the contract” and further that compliance was a condition precedent to the Navy’s duty to continue providing the rented property.¹³² The court, however, found that the alleged breaches of contract did not constitute a viable FCA claim.¹³³ The court stated that “[e]ven if actionable in other contexts, not all violations of the law or of a contract constitute false claims against the government under the FCA.”¹³⁴ The court ultimately dismissed the case because Coppock did not allege that “compliance with these contract terms was a true prerequisite to acceptance of rent payments” and because the plaintiff also did not allege “that failure to certify . . . contractual compliance would *necessarily* have resulted in termination of the leases.”¹³⁵ The court concluded: “[e]ven if Coppock has sufficiently pleaded that Northrop engaged in conduct that breached the lease in question, that breach does not of itself constitute a viable FCA claim.”¹³⁶

Marcy involved an FCA claim against a company that operated off-shore oil rigs in the Gulf of Mexico.¹³⁷ The relator alleged that each time the company made its lease payments, it impliedly certified that it was in compliance with numerous environmental statutes and regulations.¹³⁸ The relator alleged the company violated these implied certifications by participating in illegal nighttime dumping of oil, oil waste, grease, trash, and other hazardous and solid waste into the Gulf.¹³⁹ The district court dismissed *Marcy*’s FCA claim, holding that *Marcy* failed to allege that “‘compliance with [the lease] terms [requiring compliance with environmental statutes and regulations] was a true prerequisite’ to Defendants’ continued use of the leased property.”¹⁴⁰ The court emphasized that *Marcy* did not “‘allege that failure to certify statutory or contractual compliance would *necessarily* have resulted in termination of the

132. *Id.* at *12.

133. *Id.*

134. *Id.* at *11.

135. *Id.* at *12.

136. *Id.*; see also *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998) (holding that the implied certification doctrine did not apply because there was no “regulation, statute or contract provision” requiring Baxter to comply with the blood testing procedures at issue).

137. *United States ex rel. Marcy v. Rowan Cos., Inc.*, No. 03-3395, 2006 WL 2414349, at *1 (E.D. La. Aug. 17, 2006).

138. *Id.* at *1. In particular, the relator alleged each lease payment impliedly certified compliance with Federal Water Pollution Control Act (the Clean Water Act), 33 U.S.C. §§ 1251–1387; the Act to Prevent Pollution from Ships (APPS), 33 U.S.C. §§ 1901–1915 (2000 & Supp. V 2005); the Oil Pollution Act of 1990 (OPA), 33 U.S.C.A. § 2701 *et seq.*; the Outer Continental Shelf Lands Act (OCSLA), 43 U.S.C. §§ 1331–1356; and 33 C.F.R. pt. 151.25. *Marcy*, 2006 WL 2414349, at *1.

139. *Marcy*, 2006 WL 2414349, at *1.

140. *Id.* at *11 (alteration in original) (quoting *United States ex rel. Coppock v. Northrop Grumman Corp.*, No. Civ.A. 3:98-CV-2143-D, 2003 WL 21730668, at *12 (N.D. Tex. July 22, 2003)).

lease[].’”¹⁴¹ Rather, the court found that “[a]ccording to Marcy’s allegations, termination of the lease upon violations of its terms is discretionary.”¹⁴² Thus, Marcy’s failure to allege facts showing that the Government conditioned its payment (or continuance of the lease) on the defendants’ certification of compliance was fatal to Marcy’s FCA claim.

Coppock and *Marcy* demonstrate how the implied certification theory should be properly applied in the contractual context. The purpose of the FCA is not to create a cause of action for every breach of contract, but to provide a remedy for false claims against the Government. This does not mean that other breaches of contract are not actionable; it merely means that such breaches are not actionable under the FCA.¹⁴³

IV. CONCLUSION

In recent years, courts have limited relators’ efforts to expand the scope and reach of the FCA via aggressive applications of the implied certification theory.¹⁴⁴ As relators seek to expand the scope of the FCA through the implied certification theory, it is instructive to return to the court’s admonition in *Hopper*: “It is not the case that any breach of contract, or violation of regulations or law, or receipt of money from the government where one is not entitled to receive the money, automatically gives rise to a claim under the FCA.... The FCA is far narrower.”¹⁴⁵ By narrowing the implied certification theory as discussed above, courts maintain a proper balance between permitting actions to prevent legitimate false and fraudulent claims against the Government and subjecting defendants to unlimited liability for statements and representations they never communicated or uttered. Otherwise, relators threaten to turn traditional FCA liability theory on its head.

141. *Id.* (alteration in original) (quoting *Coppock*, 2003 WL 21730668, at *12).

142. *Id.* at *12.

143. United States *ex rel.* *Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996).

144. See United States *ex rel.* *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (“[C]aution should be exercised not to read this [implied certification] theory expansively and out of context.”); BOESE, *supra* note 19, §§ 2-148 to 2-149 (“[T]he implied certification theory has the effect of putting words—false ones, at that—into the defendant’s mouth, and then penalizing the defendant for those alleged falsities....”).

145. *Hopper*, 91 F.3d at 1265.