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FOREWORD:

I am a joint J.D./M.P.H. student at the University of Minnesota, graduating in May 2013. My term paper for LAW 6919, Healthcare Fraud and Abuse, is reproduced in the following pages. The course was taught in the spring semester of 2012 by adjunct professor Margo Struthers. The paper concerns the use of implied certification theories under the federal False Claims Act.

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IMPLIED CERTIFICATION UNDER THE FALSE CLAIMS ACT: CRAFTING APPROPRIATE LIMITS

Rapidly rising healthcare costs have captured the national spotlight.[1] While policy strategies to contain costs are frequently politically divisive,[2] preventing and punishing healthcare fraud is a rare point of bipartisan agreement.[3] A focus on fraud is justified—in 2011, the federal government expected to recover $4.5 billion dollars as a result of investigating healthcare fraud.[4] Untold amounts are lost to undetected fraud. The most commonly-used legal method of controlling healthcare fraud and abuse is civil suits brought under the False Claims Act ("FCA").[5] The FCA prohibits any person from submitting false or fraudulent claims and from using false statements or records in connection with false or fraudulent claims.[6] The Act imposes severe sanctions including civil penalties between $5,500 and $11,000 per claim and treble damages.[7] The FCA allows the Government to proceed against defendants directly and permits individuals, called relators, to bring suit on behalf of the federal Government through qui tam suits.[8]

In its clearest form, the FCA protects the Government from factually false claims. This traditionally includes claims for services that were never provided.[9] In recent years, relators have sought to use the FCA to enforce compliance with a wide variety of healthcare regulations under the theory of

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[1] *See, e.g.*, Ezekiel J. Emanuel, *How Much Does Health Cost?*, N.Y. TIMES, Oct. 30, 2011, *available at* http://query.nytimes.com/gst/fullpage.html?res=9E06E7D9143DF933A05753C1A9679D8B63.

[2] *Compare* Stephen T. Parente, et al., *Evaluation of the Effect of a Consumer-Driven Health Plan on Medical Care Expenditures and Utilization*, 39 HSR: HEALTH SERVS. RESEARCH 1189, 1205 (2004) (arguing that increasing up-front costs for healthcare consumers drives utilization and costs down), *with* Jui-Fen Rachel Lu & William C. Hsiao, *Does Universal Health Insurance Make Healthcare Unaffordable? Lessons from Taiwan*, 22 HEALTH AFFAIRS 77, 86 (2003) ("It seems that the additional resources that had to be spent to cover the uninsured were largely offset by the savings resulting from reduced overcharges, duplication and overuse of health services and tests, transactions costs, and other costs.").

[3] John K. Iglehart, *The ACA's New Weapons Against Healthcare Fraud*, 363 NEW ENG. J. MED. 304, 304 (2010).

[4] OFFICE OF THE INSPECTOR GEN., HEALTH & HUM. SERVS., SEMIANNUAL REPORT TO CONGRESS (Sept. 2011), *available at* http://oig.hhs.gov/reports-and-publications/archives/semiannual/2011/fall/HH-OIG-SAR-Fall2011.pdf.

[5] MICHAEL K. LOUCKS & CAROL C. LAM, PROSECUTING AND DEFENDING HEALTHCARE FRAUD CASES 91 (2d ed. 2010) (noting that qui tam FCA suits make up the majority of healthcare fraud recoveries).

[6] 31 U.S.C. § 3729(a)(1)(A) & (B) (2006 & Supp. 2010).

[7] The False Claims Act allows for penalties of between $5,000 and $10,000 per claim, 31 U.S.C. § 3729(a)(1), but these penalties are increased to between $5,500 to $11,000 per claim under the Federal Civil Penalties Inflation Adjustment Act, 28 U.S.C. § 85.3(9) (2006).

[8] 31 U.S.C. § 3730(a) & (b).

[9] *See* United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001) (differentiating between legally and factually false claims).

implied certification.[10] In this type of case, the relator argues that the defendant's submission of claims to the Government impliedly certifies compliance with some obligation and the defendant's failure to so comply renders a claim false or fraudulent in violation of the FCA.[11] Although implied certification theoretically reaches a nearly endless variety of fact patterns, the Supreme Court is adamant that the FCA "was not designed to reach every kind of fraud practiced on the Government."[12] In this spirit, courts have rightly sought to constrain the application of implied certification, though their methods are frequently in conflict.[13]

This paper argues for a consistent framework to analyze FCA claims premised on implied certification. In particular, it argues that, while courts' desire to limit implied certification is understandable, the development of a vast array of uncertain legal tests encourages a proliferation of litigation and inhibits the efficient disposition of such cases to the detriment of health care providers and the general public.[14] Part I describes the text and purpose of the FCA and situates theories of implied certification in the Act. Part II explains the multitude of ways that courts have attempted to define principles to limit the application of the theory of implied certification. Part III analyzes the policy implications of the positions taken by courts and proposes an optimal solution, including suggested statutory revisions to the FCA.

I. The False Claims Act and the Theory of Implied Certification

In enacting key revisions to the FCA in 1986, Congress articulated the core purpose of the FCA as to "enhance the Government's ability to recover losses sustained as a result of fraud against the government."[15] Congress intended the FCA to apply broadly, stating that false claims are not just those for services never provided or materially misrepresented, but may be claims "for goods or services . . . provided in violation of contract terms, specification, statute, or regulation."[16] The following sections introduce the text and purpose of the FCA and explain the theory of implied certification.

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[10] *See, e.g.*, United States *ex rel.* Ebeid v. Lungwitz, 616 F.3d 993, 996 (9th Cir. 2010); United States *ex rel.* Conner v. Salina Reg'l Health Ctr., 543 F.3d 1211, 1218–19 (10th Cir. 2008).
[11] *E.g.*, United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011).
[12] United States v. McNinch, 356 U.S. 595, 599 (1958).
[13] *See infra* Part II.
[14] *See* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 15, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269) ("[B]usinesses need clear, predictable, and well-defined standards of liability.").
[15] S. REP. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266.
[16] *Id.* at 4.

A. The Text and Purpose of the False Claims Act

Since the birth of the theory of implied false certification, two relevant permutations of the FCA have been in effect. Although FCA including the amendments included in the Fraud Enforcement and Recovery Act of 2009 ("FERA")[17] has an effective date of May 20, 2009, the pre-FERA provisions continue to apply to some FCA cases still working their way through the system.[18] For this reason, it is vital to engage with both versions of the statute in order to understand the modern theory of implied certification.

Pre-FERA, the FCA included two provisions pertinent to implied certification. First, under § 3729(a)(1), those who "knowingly present[], or cause[] to be presented" to certain United States personnel "a false or fraudulent claim for payment or approval" are liable.[19] Second, § 3729(a)(2) makes liable individuals who "knowingly make[], use[], or cause[] to be made or used, a false record to get a false or fraudulent claim paid or approved by the Government."[20]

The FERA amendments adjusted the statutory language of § 3729(a)(1) by removing the requirement of presentment and by redesignating the section § 3729(a)(1)(A).[21] The amendments also renumbered § 3729(a)(2) as § 3729(a)(1)(B) and revised the subsection to impose liability on those who "make[], use[] or cause[] to be made or used, a false record or statement *material* to a false or fraudulent claim."[22] Both versions of the FCA require a defendant to have acted "knowingly," meaning that, with respect to the information alleged to be false, the defendant either had "actual knowledge; . . . act[ed] in deliberate ignorance of the truth or falsity of the information; or . . . act[ed] in reckless disregard of the truth or falsity of the information."[23] For the remainder of this paper, this statutorily-defined knowledge standard will be referenced as "FCA knowledge."

The FCA recognizes that the Government's ability to protect itself from fraud is subject to two major constraints. First, because the Government has limited ability to supervise its contractors, and because those committing fraud are likely to be secretive about their activities, the Government faces serious difficulty in detecting fraud in the first place.[24] Second, even if the Government successfully identifies incidents of fraud, it may lack the resources to

[17] Fraud Enforcement & Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617.
[18] LOUCKS & LAM, *supra* note 5, at 90–91.
[19] 31 U.S.C. § 3729(a)(1) (2006).
[20] *Id.* § 3729(a)(2).
[21] 31 U.S.C. § 3729(a)(1)(A) (2006 & Supp. 2010).
[22] § 3729(a)(1)(B) (emphasis added).
[23] *Id.* 31 U.S.C. § 3729(b)(1)(A) (2006 & Supp. 2010); 31 U.S.C. § 3729(b) (2006).
[24] CLAIRE M. SYLVIA, THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 1:4, at 6 (2d ed. 2010).

aggressively prosecute the fraud.[25] To address these barriers, the FCA allows private citizens to bring qui tam suits on behalf of the government against those who allegedly violate the Act.[26] These private citizens are frequently whistle-blowing employees of the defendant and are thus privy to superior information about possible fraud.[27] To encourage insiders to act as relators, the FCA allows them a portion of any recovery resulting from the suit as well as reimbursement for reasonable attorneys' fees.[28] Recognizing the lucrative potential of qui tam suits, lawyers are often willing to take on FCA cases on a contingent basis, meaning that the relator would incur no out-of-pocket costs related to legal fees.[29] Together, these financial incentives shift the Government's financial responsibilities for investigating and pursuing FCA cases to relators, relators' counsel, and defendant health care providers.[30] By setting up this scheme, Congress designed the FCA to root out fraud and to protect the public fisc.

B. The Theory of Implied Certification

Implied certification lies at the outer boundary of the FCA.[31] The theory takes multiple forms, but generally speaking, cases invoking the theory of implied certification can be split into two categories. In the first type of case, the defendant's submission of a claim impliedly certifies compliance with some set of obligations.[32] The second type of case arises when the defendant's prior express certification of compliance with an obligation "implie[s] certification of continued compliance" with that obligation.[33] At their core, FCA cases based on implied certification are like any other FCA case.[34] To prevail, the relator must show that the defendant knowingly presented or caused to be presented a false

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[25] *Id.* at § 1:5, at 9.
[26] 31 U.S.C. § 3730(b) (2006).
[27] *See, e.g.*, United States *ex rel.* Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377, 380 (1st Cir. 2011); United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 692 (2d Cir. 2001).
[28] 31 U.S.C. § 3730(d) (2006 & Supp. 2010).
[29] *See, e.g.,* Berger & Montague, P.C., *Berger & Montague's Whistleblower, Qui tam & False Claims Act Group Represents Whistleblowers Alleging Other Types of Fraud Against the United States and State Governments*, http://www.bergermontague.com/practice-areas/whistleblowers-qui-tam-false-claims-act/federal-and-state-whistleblower-laws/other-fraud-types (last visited Apr. 2, 2012) ("Berger & Montague's Whistleblower, Qui Tam & False Claims Act Group litigates cases on a contingent fee basis, so whistleblowers do not pay attorneys' fees or court costs unless there is a recovery.").
[30] *See* John T. Boese, *The Past, Present, and Future of "Materiality" Under the False Claims Act*, 3 ST. LOUIS U.J. HEALTH L. & POL'Y 291, 297–98 (noting that qui tam lawyers are "primarily interested in the greatest financial recovery for his or her individual client").
[31] *Cf.* Michael Holt & Gregory Klass, *Implied Certification Under the False Claims Act*, 41 PUB. CONT. L.J. 1, 2 (2011) ("[T]he implied certification doctrine is radical from the perspective of 'normal' contract law.").
[32] Marcia G. Madsen, *False Claims Act: What Government Contractors Should Know About the Implied Certification Theory of Liability*, 939 PLI/COMM. 471, 475 (2011).
[33] *Id.*
[34] SYLVIA, *supra* note 24, at § 4:33, at 180.

or fraudulent claim,[35] including claims made fraudulent by the use of a false record or statement.[36] Implied certification cases differ from garden variety FCA cases in their conception of "false or fraudulent." In an implied certification case, falsity or fraud is indirect; the defendant's violation of an ancillary obligation renders an entire claim false or fraudulent even if the services were provided precisely as billed.[37]

Because the statutory requirements are slightly different under the two subsections of the FCA, it is worth considering how the theory of implied certification fits into the text of the FCA. In particular, § 3729(a)(1)(B) of the post-FERA FCA requires that a false statement or record is material to the false or fraudulent claim, while § 3729(a)(1)(A) includes no materiality requirement.[38]

Courts apply typically § 3729(a)(1)(A) (formerly numbered § 3729(a)(1)) to cases in which the defendant's submission of a claim impliedly certifies the defendant's compliance with some obligation.[39] Courts support this conclusion by pointing out that § 3729(a)(1)(B) specifically references a "false record or statement" while § 3729(a)(1)(A) does not.[40] This omission in § 3729(a)(1)(A) indicates that an expressly false statement or record is not required under the subsection.[41] Therefore, those implied certification cases in which no express statement was ever made must be brought under § 3729(a)(1)(A). Courts further look to the FCA's legislative history to demonstrate Congress's intent to allow the FCA to reach beyond factually false claims to legally false claims.[42]

The second category of claims—those in which the defendant's prior express certification of compliance implies future compliance—present a more complicated question. Arguably, the prior express certification might be the "false record or statement" required by § 3729(a)(1)(B).[43] Or, under a line of reasoning similar to the one that places the submission of claims that falsely imply compliance through submission of a claim into § 3729(a)(1)(A), a prior express certification that falsely implies future compliance might be an

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[35] 31 U.S.C. § 3729(a)(1)(A) (2006 & Supp. 2010).
[36] *Id.* § 3729(a)(1)(B); *see* LOUCKS & LAM, *supra* note 5, at 105 (clarifying that § 3729(a)(1)(B) "does not require proof of both a false statement and a false claim" because the material false statement is what renders the entire claim false (citing United States *ex rel.* A+ Homecare Inc. v. Medshares Mgmt. Grp., 400 F.3d 428, 443 (6th Cir. 2005)).
[37] *See, e.g.*, Mikes v. Straus, 274 F.3d 687, 696–97 (2d Cir. 2001) (differentiating between factually and legally false claims).
[38] § 3729(a)(1)(A) & (B). The pre-FERA version of the FCA did not require materiality for either subsection of the statute. 31 U.S.C. § 3729(a)(1) & (2) (2006).
[39] United States *ex rel.* Wilkins v. United Health Grp., 659 F.3d 295, 306–07 (3d Cir. 2011) (citing Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000)).
[40] *Id.*
[41] *Id.*
[42] *Id.* at 306.
[43] *See* Holt & Klass, *supra* note 31, at 27.

inherently false or fraudulent claim properly analyzed under § 3729(a)(1)(A).[44] In fact, this potential overlap in statutory interpretation provides a potent argument that the statute was never meant to reach cases of false implied certification. The argument goes that if § 3729(a)(1)(A) is broad enough to reach implied false certifications of the first type, it certainly reaches the false statements and records referenced in § 3729(a)(1)(B)—effectively rendering § 3729(a)(1)(B) superfluous.[45] Because courts presume that Congress did not include surplusage in statute,[46] the natural conclusion is that § 3729(a)(1)(A) was not meant to include implied false certifications.[47] In spite of this, most,[48] but not all,[49] circuits have endorsed some version of implied certification. Because of the widespread judicial acceptance of the theory and because the legislative history supports it,[50] this paper presupposes the validity of at least some implied certification theories under the FCA.

II. Judicial Approaches to Constraining Implied Certification

Even among courts embracing implied certification, there is substantial variation in how the theory is applied. Across this variation, courts express a shared concern about establishing an appropriate limiting principle to constrain the applicability of the theory of implied certification.[51] Outside of the FCA context, courts have frequently noted that the statutes and regulations that govern the healthcare industry are incredibly complex.[52] These

[44] *See id.*
[45] *Id.* at 27–28.
[46] Astoria Federal Savings & Loan Ass'n v. Solimino, 501 U.S. 104, 112 (1991).
[47] Holt & Klass, *supra* note 31, at 28.
[48] *E.g.*, New York v. Amgen, Inc., 652 F.3d 103, 110 (1st Cir. 2011), *cert. denied* 132 S.Ct. 993 (2011); United States *ex rel.* Kirk v. Schindler Elevator Corp., 61 F.3d 94, 115 (2d Cir. 2010), *rev'd on other grounds*, 131 S.Ct. 1885 (2011); United States *ex rel.* Wilkins v. United Health Grp. Inc., 659 F.3d 295, 306 (3d Cir. 2011); United States *ex rel.* Augustine v. Century Health Servs., Inc., 289 F.3d 409, 415 (6th Cir. 2002); United States *ex rel.* Ebeid v. Lungwitz, 616 F.3d 993, 996 (9th Cir. 2010); United States *ex rel.* Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1168 (10th Cir. 2010); United States *ex rel.* McNutt v. Haleyville Medical Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005); United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1261 (D.C. Cir. 2010).
[49] *E.g.*, Harrison & United States v. Westinghouse Savannah River Co., 176 F.3d 776, 786–87 (4th Cir. 1999); *see, e.g.*, United States *ex rel.* Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010) (declining to decide whether the theory of implied certification is valid under the FCA because the facts of the case at hand do not warrant such a finding); United States *ex rel.* Yannacopoulos v. Gen. Dynamics, 652 F.3d 818, 824 n.4 (7th Cir. 2011) (declining to find FCA liability when the defendant never expressly certified compliance with the applicable statute).
[50] S. REP. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266.
[51] For example, Keycite reveals twenty-two courts across the country have opined that the FCA is not a "blunt instrument" to enforce compliance citing the same language in *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001).
[52] *E.g.*, Shalala v. Ill. Council on Long Term Care, Inc, 529 U.S. 1, 13 (2000) (describing the Medicare program as "a massive complex health and safety program . . . embroiled in hundreds of pages of statutes and thousands of pages of often interrelated regulations"); Herweg v. Ray, 455 U.S. 265, 279 (1982) (Burger, J., dissenting) (noting that "the Medicaid program is a morass of bureaucratic complexity").

requirements and the enormous volume of associated administrative guidance[53] mean that perfect compliance with every requirement all the time simply is not possible.[54]

The exceptionally dense regulatory structure, in combination with the severe penalties imposed by the FCA, means that courts must have some mechanism for reining in the theory of implied certification. In implied certification cases, courts must articulate the point at which a "factually true claim[] become[s] legally false because of the violation of ancillary legal requirements."[55] The specific elements required by courts to establish an implied certification FCA claim might be understood as attempts to establish such limiting principles.[56] Courts' efforts to constrain implied certification under the FCA fall into two categories. First, courts interpret the parameters of "false or fraudulent" differently. Second, some courts have fallen back on the FCA's requirement of a "knowing" violation to limit liability. This section primarily focuses on various judicial permutations of "false or fraudulent."

Both of the relevant FCA sections require claims to be "false or fraudulent" before liability attaches.[57] The FCA does not provide a definition of

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[53] To illustrate, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), devoted about a page to healthcare privacy standards. *See id.* at § 262. The regulations hammering out the particulars of this so-called HIPAA Privacy Rule come in at around 100 pages of text. *See* 45 C.F.R. §§ 160.101–160.552, 162.100–162.1802, 164.102–164.534 (2011). A quick look at the Department of Health and Human Services website reveals dozens of guidance documents interpreting the Privacy Rule on topics ranging from "when a provider is allowed to share a patient's health information with the patient's family members, friends, or others," Office of Civil Rights, Dep't of Health & Human Servs., *A Health Care Provider's Guide to the HIPAA Privacy Rule: Communicating with a Patient's Family, Friends or Others Involved in the Patient's Care* 1, http://www.hhs .gov/ocr/privacy/hipaa/ understanding/coveredentities/provider_ffg.pdf (last visited Apr. 5, 2012), to describing how the HIPAA standards for de-identification affect research involving coded biological specimens, Office for Human Research Protections, *OHRP—Guidance on Research Involving Coded Private Information or Biological Specimens* (Oct. 16, 2008), http:// hhs.gov.ohrp/policy/cdebiol.html.

[54] *Cf.* Health Care for All, Inc. v. Romney, No. Civ.A 00-10833RWZ, 2005 WL 1660677, at *8 (D. Mass. July 14, 2005) ("While absolutely perfect compliance by defendants in the instant case may not be feasible, this fact does not excuse them from striving to comply as much as possible.").

[55] Boese, *supra* note 30, at 293.

[56] *See* United States *ex rel.* Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 344 (D. Mass. 2011) (arguing that "the FCA cabins the fraud that is actionable under the FCA" by requiring the plaintiff to show scienter and materiality).

[57] This is true in both the pre-FERA version of the statute, 31 U.S.C. § 3729(a)(1) (2006) (requiring a "false fraudulent claim"); *id.* § 3729(a)(2) (requiring a "false record or statement to get a false or fraudulent claim paid or approved by the Government"), and the post-FERA statute, 31 U.S.C. § 3729(a)(1)(A) (2006 & Supp. 2010) (requiring a "false or fraudulent claim"); *id.* § 3729(a)(1)(B) (requiring "a false record or statement material to a false or fraudulent claim").

"false or fraudulent."[58] As a result, courts hearing implied certification cases typically draw on dictionary definitions[59] or case law to determine if the claim is false.[60] At a basic level, under the implied certification theory, claims are made false or fraudulent because the defendant failed to meet some obligation and submitted claims to the government (or caused them to be submitted) in spite of this failure. Despite the facial simplicity of the previous statement, the details vary substantially. These variations occur along two axes: (1) the possible sources of obligations that might give rise to falsity if unfulfilled, and (2) the required relationship between the unmet obligation and the receipt of payment.

A. Sources of Unfulfilled Obligations that Might Give Rise to Falsity

Possible sources of obligations that might give rise to falsity differ court by court. Courts recognizing the theory of implied certification universally find that a violation of a statute or regulation might give rise to FCA liability in at least some circumstances.[61] By contrast, not all courts analyzing implied certification under the FCA allow liability to attach when the defendant's alleged violation is of an obligation found in interpretative agency guidance or of an obligation imposed by contract.

Courts divide on whether an unfulfilled obligation imposed by interpretative guidance might make a claim false.[62] Some courts have reasoned that because interpretative guidance does not carry the force and effect of law, "evidence of a failure to comply with administrative guidelines does not, on its own, establish that a defendant presented legally false claims."[63] Not all courts agree. For example, the District of Connecticut, in *In re Cardiac Devices Qui Tam Litigation*, found that the defendants' failure to comply with a provision of

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[58] Katie Bergstrom & Brian Dillon, *Quality of Care as a Basis for False Claims Act Liability: Is the Proof Insurmountable?*, 9 SEDONA CONF. J. 147, 147 (2008).

[59] United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citing WEBSTER'S THIRD INTERNATIONAL DICTIONARY 904 (1981)).

[60] *See, e.g.*, United States *ex rel.* Ebeid v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010) (citing United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266–67 (9th Cir. 1996)).

[61] *See, e.g.*, New York v. Amgen Inc., 652 F.3d 103, 105 (1st Cir. 2011); United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001); United States *ex rel.* Wilkins v. United Health Grp., 659 F.3d 295, 307 (3d Cir. 2011); United States ex rel. Augustine v. Century Health Services, Inc., 289 F.3d 409, 415 (6th Cir. 2002); United States *ex rel.* Ebeid v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010); United States *ex rel.* Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1168 (10th Cir. 2010); United States *ex rel.* McNutt v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005); United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010).

[62] *Contra* Susan C. Levy et al., *The Implied Certification Theory: When Should the False Claims Act Reach Statements Never Spoken or Communicated, But Only Implied?*, 38 PUB. CONT. L.J. 131, 147 (2008) ("The alleged violation of agency guidelines, manuals, or other nonbinding government publications is not sufficient to trigger application of the implied certification theory.").

[63] United States *ex rel.* Yannacopoulos v. Gen. Dynamics, No. 03 C 3012, 2007 WL 495257, at *3 (N.D. Ill. 2007).

the 1986 Medicare Manual ("Manual") formed the basis for a violation of the FCA.[64] Despite the court's specific ruling that the Manual contained interpretative rules rather than legislative rules, it ultimately found that the Manual was binding on defendants and so violating it made subsequent claims false in violation of the FCA.[65] The court's conclusion that the interpretative rule is binding is surprising because courts typically decide if a rule is legislative rather than interpretative by considering precisely whether the rule has the power to bind regulated parties.[66] Given the large volume of non-binding administrative guidance applicable to regulated entities in the healthcare industry,[67] a court's willingness to find a claim false for failure to comply with non-binding guidelines dramatically expands the scope of the FCA.[68]

Some courts recognize that a failure to meet a contractual obligation makes a claim false while others do not. Typically, such cases find that the defendant's prior express agreement to contractual terms implies the defendant will continue to comply with the terms in the future.[69] For example, in *United States ex rel. Conner v. Salina Regional Health Center*, the Tenth Circuit instructed that an implied certification analysis must focus on "underlying contracts, statutes, or regulations."[70] The First, Sixth, and D.C. Circuits have similarly examined contractual obligations when determining whether a claim is false.[71] By contrast, the Eleventh Circuit has not required examination of contractual language.[72]

Of course, any of these courts would still likely find defendants are obliged to comply with contractual obligations that incorporate statutory or regulatory standards, as is common in contracts between healthcare entities and the government.[73] In such cases, courts frequently consider the regulation or statute, rather than the contract, to be the source of the obligation.[74] Even

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[64] *In re* Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 354 (D. Conn. 2004).
[65] *Id.* at 353–54.
[66] *See, e.g.*, New York City Emp. Ret. Sys. v. S.E.C., 45 F.3d 7, 12–13 (2d Cir. 1995) (finding that an S.E.C. no-action letter was an interpretative rule rather than a legislative rule because it did not bind the parties or the courts).
[67] *See supra* note 53 and accompanying text.
[68] Levy, *supra* note 62, at 148.
[69] *E.g.*, United States *ex rel.* Augustine v. Century Health Services, Inc., 289 F.3d 409, 414–15 (6th Cir. 2002).
[70] 543 F.3d 1211, 1218 (10th Cir. 2008).
[71] United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010); *see* New York v. Amgen Inc., 652 F.3d 103, 112 (1st Cir. 2011) (examining obligations imposed by statute, regulation, and the Provider Agreement); *Augustine*, 289 F.3d at 414–15 (Sixth Circuit).
[72] *E.g.*, United States *ex rel.* Wilkins v. United Health Grp., 659 F.3d 295, 307 (3d Cir. 2011); United States *ex rel.* McNutt v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005).
[73] *E.g.*, *Augustine*, 289 F.3d at 414–15.
[74] *See McNutt*, 423 F.3d at 1258 (noting that the defendant entered a Provider Agreement which required compliance with the Anti-Kickback Statute).

so, whether a court considers the obligation to be contractual as opposed to statutory or regulatory is significant. Case law suggests that defendants have considerably more wiggle room if their behavior comports with a reasonable interpretation of a contractual term[75] than if their behavior comports with a reasonable interpretation of a regulation or statute with which the Government does not agree.[76]

B. Required Relationship Between the Unfulfilled Obligation and the Receipt of Payment

Prior to the FERA amendments, the text of the FCA did not require that an unmet obligation (or a statement or record declaring it fulfilled) be closely related to receiving payment for the claim.[77] Recognizing that not all violations of ancillary obligations make claims false, courts interpreting the pre-FERA FCA and its state analogs have generally required some level of connection between the ancillary obligation and the receipt of payment. Post-FERA, FCA cases alleging a violation of new § 3729(a)(1)(B) must establish, pursuant to the statutory text, that the "false statement or record" is "material to a false or fraudulent claim."[78] Under either version of the FCA, courts vary in how the relator must demonstrate the connection between the unmet obligation and the Government's decision to pay the claim.

1. Relationship Between the Unfulfilled Obligation and the Claim Under the Pre-FERA FCA

Despite the lack of a statutory requirement in the pre-FERA FCA that an unmet obligation or a false statement or record certifying fulfillment of such an obligation be related to the government's decision to pay, courts have generally required some relationship. Courts require a connection in implied certification cases brought under either § 3729(a)(1) or (2).[79] In fact, courts have occasionally declined to distinguish between the two subsections, arguing that

[75] *See* Burgin v. Office of Pers. Mgmt., 120 F.3d 494, 487–89 (4th Cir. 1997) (finding that the court need not defer to an agency's interpretation of a contract because contract interpretation is "within the competence of the courts"); Jicarilla Apache Tribe v. Fed. Energy Regulatory Comm'n, 578 F.2d 289, 292–93 (10th Cir. 1978) (finding that when an issue of interpretation is based on principles of contract law from the common law rather than on agency expertise, the agency is not entitled to judicial deference). *See generally* Timothy K. Armstrong, Chevron *Deference and Agency Self-Interest*, 13 CORNELL J.L. & PUB. POL'Y 203, 215–16 (noting that courts may be particularly reluctant to defer to agency interpretation of contracts when the agency is a party to the contract).

[76] *See* United States v. Bourseau, 531 F.3d 1159, 1165 n.2 (9th Cir. 2008) (rejecting the proposition that "the government must prove that a claim is false under any reasonable interpretation of applicable law").

[77] *See* 31 U.S.C. § 3729(a)(1) & (2) (2006).

[78] 31 U.S.C. § 3729(a)(1)(B) (2006 & Supp. 2010).

[79] United States *ex rel.* Wilkins v. United Health Grp., 659 F.3d 295, 304–07 (3d Cir. 2011).

their analysis applies equally to both subsections.[80] While courts have consistently required a showing of some relationship, the character and closeness of the relationship varies from court to court.

The First Circuit presents an example of a particularly expansive standard. In *New York v. Amgen*, the defendant allegedly overfilled single-dose vials of prescription drugs and then encouraged providers to bill the overfill (for which the providers were not charged) to state Medicaid programs.[81] This behavior, the relators alleged, amounted to a violation of the Anti-Kickback Statute ("AKS") and so the defendant had caused its provider-customers to submit false claims in violation of various state versions of the FCA.[82] The First Circuit decided whether an AKS violation rendered a claim false by examining whether the submission of the claims "misrepresented compliance with a material precondition of Medicaid payment."[83] The court looked to state Medicaid statutes and provider agreements to determine if AKS compliance was a precondition of payment and found that statutes or agreements explicitly requiring AKS compliance or indicating that payment "may" be withheld if a claim was tainted by an AKS violation demonstrated that compliance was indeed a precondition of payment.[84] Thus, the First Circuit held that preconditions of payment encompass both compliance with those obligations that, if unmet, would actually result in withheld payment and those which merely might.[85] This standard fails to distinguish between conditions of payment and mere conditions of participation.[86] Other courts have similarly minimized the distinction between conditions of participation and conditions of payment reasoning that an entity must comply with the conditions of participation to be eligible to participate in the program and program eligibility is required to receive payment.[87]

By contrast, the Second Circuit has taken a more limited view. In an early and oft-cited implied certification case, *United States ex rel. Mikes v. Straus*, the relators alleged that the defendants' claims for spirometry tests

[80] United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001); *see Wilkins*, 659 F.3d at 304.
[81] 652 F.3d 103, 105 (1st Cir. 2011).
[82] *Id.*
[83] *Id.* at 110.
[84] *Id.* at 111–12.
[85] *See id.*
[86] *Id.* at 115.
[87] *E.g.*, United States *ex rel.* Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1170 (10th Cir. 2010) (requiring the relator to show that had the Government known of the violation, it might not have paid); United States *ex rel.* Matheny v. Medco Health Solutions Inc., No. 10-15406, 2012 WL 555200, at *8 (11th Cir. Feb. 12, 2012) (defining materiality as having the "ability to influence the government's decision-making"). *See also* United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1176 (9th Cir. 2006). This particular holding in *Hendow* appears to have been abrogated by *United States* ex rel. *Ebeid v. Lungwitz* which explicitly differentiates between conditions of participation and conditions of payment. 616 F.3d 993, 1001 (9th Cir. 2010).

were impliedly false because the tests were not conducted according to the guidelines established by the American Thoracic Society.[88] The court reasoned that because the statute and regulation did not require providers to adhere to the guidelines, compliance could not have been a condition of payment.[89] The Third, Sixth, and Ninth Circuits take positions in accord with the Second Circuit and require the relator to show that compliance with the relevant obligation is a condition of payment such that the Government would not have paid had it known of the offense.[90] Courts justify this position by pointing out that statutes and regulations provide extensive administrative remedies less severe than withholding payment when regulated entities fail to comply with conditions of participation.[91] Qui tam litigation, the argument goes, ought not to displace these administrative mechanisms.[92]

2. Relationship Between a False Statement or Record and the Receipt of Payment Under the Post-FERA FCA

The FERA amendments inserted a materiality requirement into § 3729(a)(1)(B) (formerly § 3729(a)(2)) adjusting the subsection to impose liability on individuals who make, use, or cause another to make or use a "false record or statement material to a false or fraudulent claim."[93] Materiality is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[94] Because the amendments are relatively new, very few courts have analyzed how the new statutory requirement interacts with the prior case law on the required relationship between falsity and the receipt of payment.[95]

Among the few courts that have considered the issue, interpretations fall into two camps. The first group is made up of those courts finding that the amendment clarifies the pre-FERA judicially-imposed requirement that that the unmet obligation have a particular relationship with the payment decision.

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[88] 274 F.3d 687, 694 (2d Cir. 2001).
[89] *Id.* at 702.
[90] United States *ex rel.* Wilkins v United Health Grp., Inc., 659 F.3d 295, 308–09 (3d Cir. 2011); Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011) (citing United States *ex rel.* Augustine v. Century Health Servs., Inc., 289 F.3d 409, 415 (6th Cir. 2002)).
[91] *E.g.*, *Mikes*, 274 F.3d at 702; *Wilkins*, 659 F.3d at 311.
[92] *Wilkins*, 659 F.3d at 311. *See generally* Malcolm J. Harkins, *The Ubiquitous False Claims Act: The Incongruous Relationship Between a Civil War Era Fraud Statute and the Modern Administrative State*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 131, 151–55 (2007) (arguing that where Congress provides for an administrative enforcement mechanism, qui tam suits are not permitted because the issue has been committed to agency discretion and so is not justiciable).
[93] Fraud Enforcement & Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617.
[94] 31 U.S.C. § 3729(b)(4) (2006 & Supp. 2010).
[95] *See, e.g.*, United States *ex rel.* Walner v. NorthShore Univ. Healthsystem, 660 F. Supp. 2d 891, 896 n.4 (N.D. Ill. 2009) (noting that no Seventh Circuit court had interpreted the new materiality requirement).

This interpretation is consistent with legislative history.[96] For example, in *United States ex rel. Nowack v. Medtronic*, the District of Massachusetts found that the statutory addition did not alter its analysis[97] except to elucidate that a false statement renders a claim false if the statement "has a 'natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it is addressed.'"[98] Although this reasoning seems broader than the common pre-FERA "condition of payment" standard,[99] at least some courts recite the "tendency to influence" language and then go on to use to use the "condition of payment" standard by analyzing "whether the federal government would not have paid out the funds . . . had the claims been truthful."[100] John Boese argues this manipulation of "materiality" reflects courts' prudential efforts to balance controlling fraud with protecting healthcare entities providing necessary services.[101]

The second judicial approach to the amendment is to analyze materiality with reference to the FCA's requirement that a false statement be made "knowingly." The Northern District of Illinois illustrates this approach arguing that the post-FERA materiality language requires the false record or statement to have been made in order to get the claim paid—that is, the false statement is material if the defendant made it with the intention of inducing the Government to make a payment.[102] These divergent interpretations demonstrate that judicial analysis of the FERA amendments remains underdeveloped.

C. Demonstrating the Required Relationship

In addition to the differences articulated above, courts require different evidence to show the requisite relationship between an unmet obligation and the receipt of payment. Three distinct approaches appear in the case law. First, some courts take a holistic approach and examine contracts, statutes, and

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[96] S. REP.. 111-10, at 12 (Mar. 23, 2009) ("This definition is consistent with the Supreme Court definition [of materiality], as well as other courts interpreting the term as applied to the FCA.").
[97] 806 F. Supp. 310, 342 n.20 (D. Mass. 2011).
[98] *Id.* at 350 (quoting United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 394 (1st Cir. 2011)).
[99] Henry P. Wall, *What Construction Clients Need to Know About the False Claims Act*, NEWS & NOTES, Summer 2010, http://scbar.org/public/construction/const_aug10.html (noting "[s]cope and coverage of FCA with FERA is broad and even more plaintiff-relator friendly than in past years").
[100] United States *ex rel.* Baker v. Comm. Health Sys., Inc., 709 F. Supp. 2d 1084, 1120 (D.N.M. 2010)
[101] Boese, *supra* note 30, at 305 ("Most rational courts are . . . not going to allow a defendant to be bankrupted when it provides necessary services to eligible beneficiaries or when a contractor provides articles that meet all the specifications, just because some ancillary law was broken.").
[102] *Id.* at 896 & n.4; *accord* United States *ex rel.* Bennett v. Medtronic, Inc., 747 F. Supp. 2d 745, 766 (S.D. Tex. 2010); United States *ex rel.* Branch Consultants, L.L.C. v Allstate Ins. Co., 668 F. Supp. 780, 810–11 (E.D. La. 2009).

regulations to determine if the defendant's conduct implicates a close enough relationship between an unfulfilled obligation and the Government's decision to pay the claim.[103] Courts adopting the second approach look in the regulations and statutes for an indication that payment is conditioned on the defendant's certification of compliance with applicable obligations.[104] For example, the Western District of Tennessee found that submission of a claim did not imply certification with the AKS because the fact that the statutes and regulations did not require an express certification of compliance indicated that compliance was not relevant to the Government's decision to pay the claim.[105] Thus this court sought an indication in a statute or regulation that a certification of compliance was required before payment could be made in order to impose FCA liability under a theory of implied certification.[106] Finally, courts in the third category look for an express statement that compliance, rather than certification, is required by statute or regulation.[107] For these courts, failure to meet an obligation does not render a claim false unless statute or regulation *expressly* states that completion of the obligation is required for the defendant to be paid.

The variations described above lead to considerable unpredictability for defendants, relators, and the courts.[108] The complexities present in each of the foregoing areas are compounded when they are applied in combination with one another.[109] Further confusion is introduced by the differences between the pre- and post-FERA statutory language and the judicial opacity about which subsection of either version of the statute properly applies.

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[103] *E.g.*, United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1218 (10th Cir. 2008).

[104] *See* Holt & Klass, *supra* note 31, at 22–23.

[105] United States *ex rel.* Landers v. Baptist Mem. Health Care Corp., 525 F. Supp. 2d 972, 978–79 (W.D. Tenn. 2007); *accord* United States *ex rel.* Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000). Note that under this formulation, it is not clear that FCA liability could ever attach under a theory of implied certification falsity because liability only attaches when an express certification is explicitly required and inaccurately provided. *See* Holt & Klass, *supra* note 31, at 31.

[106] *See id.*

[107] *E.g.*, United States *ex rel.* Kirk v. Schindler Elevator Corp., 601 F.3d 94, 115 (2d Cir. 2011), *rev'd on other grounds* 131 S.Ct. 1885 (2011); United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001).

[108] *See* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 10–22, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269).

[109] Indeed, as-yet-unseen combinations of these approaches are likely because the implied certification jurisprudence is marked by cross-pollination between jurisdictions. *See, e.g.*, United States *ex rel.* Wilkins v. United Health Grp., 659 F.3d 295, 306–07 (3d. Cir. 2011) (relying on the Tenth Circuit's analysis of the difference between § 3729(a)(1) and § 3729(a)(2) (citing Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000)); Chesbrough v. VPA, P.C., 655 F.3d 461, 467 (6th Cir. 2011) (citing United States *ex rel.* Mikes v. Straus, 274 F.3d 687. 697–98 (2d Cir. 2001)).

III. Developing a Consistent Implied Certification Framework

The implied certification case law presents two different problems. First, the uneven application of standards makes the results of FCA litigation unpredictable, preventing regulated entities from efficiently conducting their businesses in compliance with the law.[110] The unpredictability also encourages relators and their counsel to employ theories on the ever-expanding frontier of implied certification.[111] Second, the extant standards fail to appropriately balance the Government's interest in protecting itself from fraud with the public good derived from allowing regulated parties to contract with the Government without fear of litigation.[112] This section analyzes some of the weaknesses in the current case law and proposes a consistent standard to be adopted. It then suggests simple statutory changes to clean up the analysis in implied certification cases.

A. Addressing Inconsistent and Inadequate Implied Certification Standards

The Supreme Court, the circuits, and district courts have all been clear that the reach of the FCA is not unlimited.[113] Therefore, courts must employ some mechanism to constrain the FCA. The line dividing acceptable claims from claims that are false or fraudulent under the framework of implied certification should not be drawn without reference to the policies implicated. A theory of implied certification should be designed to balance the major policies implicated by the theory. First, a theory of implied certification should be predictable in order to discourage relators from bringing suits that will ultimately be unsuccessful.[114] Second, the rule adopted should maintain the incentives that encourage relators to root out actionable fraud.[115] Third, the theory of implied certification should allow defendants who fail to meet

[110] *Cf.* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 2, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269).

[111] *See* Boese, *supra* note 30, at 297-98 (arguing that because "a legally false FCA case . . . is better than no FCA case at all" relators' counsel are more likely to "push the envelope" than the government would be if it directly pursuing the FCA case).

[112] *Cf.* Petition for a Writ of Certiorari at 26, Amgen Inc. v. New York, 132 S.Ct. 993 (2011) No. 11-363 ("[G]iving private parties the power to use the FCA to enforce obligations purportedly imposed on government contractors by their contracts, statutes or regulations would inevitably undermine the government's ability to administer its programs and contracts in a consistent and efficient manner.").

[113] *See, e.g.*, United States v. McNinch, 356 U.S. 595, 599 (1958); United States *ex rel.* Kirk v. Schindler, 601 F.3d 94, 114 (2d Cir. 2011); United States *ex rel.* Joslin v. Comm. Home Health of Md., Inc., 984 F. Supp. 374, 384 (D. Md. 1997).

[114] *See* Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 621 (1992) (arguing that rules set in advance are preferable to fact-specific standards when the rule is likely to be frequently applied).

[115] *See* S. REP. NO. 99-345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266 ("The purpose of . . . the False Claims Reform Act [] is to enhance the Government's ability to recover losses sustained as a result of fraud against the Government.").

relatively minor obligations to continue to provide beneficial services to the government and those eligible for government programs without incurring FCA liability.[116] Finally, a rule of implied certification should respect agency authority by reducing the possibility of FCA liability when the relevant agency is empowered to take other intermediate enforcement measures.[117]

The inconsistency of the implied certification case law has potentially "broad and deleterious" effects.[118] Regulated parties become possible defendants and are prevented from organizing their affairs to avoid liability because of unpredictable standards.[119] This is especially true for regulated entities operating on a national scale and thus conceivably subject to the jurisdiction of multiple circuits. As discussed above, healthcare entities are regulated by an ever-growing volume of statutory, regulatory and contractual obligations.[120] Because these entities are exceptionally unlikely to have the capacity to ensure perfect compliance by controlling all of their employees at all times, they necessarily set priorities for internal compliance efforts.[121] In addition, defending a possibly fruitless qui tam action may require substantial resources.[122] The costs associated with the uncertain risk of FCA liability, in addition to the severe nature of any resulting FCA penalties, divert resources from the issues most pressing to cost and quality. In short, unpredictable FCA case law allows qui tam litigants to play a larger informal regulatory role[123] than Congress anticipated when allowing for qui tam suits in the first place.[124] In the same way that inconsistent limits prevent defendants from conforming

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[116] *See* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 10–22, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269).

[117] *See* United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 309 (3d Cir. 2011).

[118] *See* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 11, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269).

[119] *Id.*

[120] *Id.* at 13. *See also supra* note 53 and accompanying text.

[121] Linda Baumann & Karl Thallner, *A Prescription for Compliance Programs*, PHYSICIAN'S NEWS DIGEST (May 1998), http://www.physiciansnews.com/law/598baumann.html (advising regulated entities to organize their compliance programs to focus on "those issues which OIG has identified as 'high risk').

[122] Although the FCA allows successful relators to recover attorneys' fees and expenses from the defendant, a successful defendant is only permitted to recover its costs if the Government declined to intervene in the suit and "the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4) (2006 & Supp. 2010).

[123] *See* United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001) ("[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations.").

[124] *See* S. REP. NO. 99-345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266 (noting the need to "adopt a more uniform standard").

their behavior to unknowable judicial standards, unclear case law encourages relators and their lawyers to push past the current boundaries of implied certification under the FCA.[125] The result is a high volume of litigation, an uncertain portion of which will not ultimately be viable, leading to wasted judicial and public resources.

Encouraging relators to root out actionable fraud and allowing defendants to conduct their business with minimal intrusion from over-aggressive relators are goals in tension with one another.[126] The existing judicial standards provide a useful range of possible balancing points. For example, the First Circuit's incredibly broad standard, which considers unmet obligations that merely may affect the Government's decision to pay to render claims false, weighs too far in favor of relators and too far against regulated entities.[127] Uniform adoption of this standard would hardly be better than the current haphazard case law. Particularly because the First Circuit standard does not require the Government to have ever indicated that particular conduct might result in withheld payment[128]—defendants effectively have no notice of sources of liability.[129] The unfortunate upshot of the First Circuit's standard is that it defines as "false or fraudulent" claims that the Government would have happily paid if fully informed of the defendant's conduct.[130] It is hard to believe that it is the proper place of a court to decide whether a claim is falsely or fraudulently made when the government agency paying the bills would not have considered it so.

The Third Circuit provides a better standard—a claim is falsely or fraudulently submitted if the Government would have refused to pay the claim had it been fully informed of the defendant's conduct.[131] Because adopting this standard does not disturb the incentives available for successful qui tam plaintiffs,[132] the value of providing for qui tam suits is preserved. By refraining from imposing liability unless the defendant's conduct actually implicates a condition of payment, the standard effectively identifies fraud which would

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[125] *See* Boese, *supra* note 30, at 297–98.
[126] *Compare* LOUCKS & LAM, *supra* note 5, at 91 (noting the majority of fraud recoveries happen through the qui tam provisions of the FCA) *with* Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 2, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269) ("[A] balance must be maintained, as contemplated by Congress, between enforcement and preventing vexatious and unnecessary litigation that does not serve the Act's purposes.").
[127] *See* Boese, *supra* note 30, at 305–06.
[128] *See* New York v. Amgen Inc., 652 F.3d 103, 112 (1st Cir. 2011).
[129] Brief for the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America as Amici Curiae Supporting Petitioner at 11, Blackstone Medical, Inc. v. United States *ex rel.* Hutcheson, 132 S.Ct. 815 (2011) (No. 11-269).
[130] *See id.*
[131] United States *ex rel.* Wilkins v. United Health Grp. Inc., 659 F.3d 295, 307 (3d Cir. 2011).
[132] *See supra* notes 26–29.

have actually caused damage to the Government.[133] Violations of nonbinding agency guidance that is not incorporated into a contract leaves the agency room to decide whether or not to pay the claim, so generally speaking, this standard would decline to find FCA liability for violations of nonbinding guidance.[134] Likewise, this standard effectuates the policy of respecting agency authority to impose penalties and sanctions short of withholding payment. This is so because a defendant's course of conduct that would result in sanctions short of the withholding of payment cannot be a condition of payment.[135]

However, this rule alone does not quite go far enough to protect health care providers. The standard must be modified to ensure that providers have adequate notice that a particular course of conduct will result in refused payment. To remedy this problem, courts should consider the falsity of the claim (arising from the defendant's unmet obligation) in close conjunction with the FCA's requirement that such a claim be made (or caused to be made) "knowingly."[136] That is, if a claim is made false because a defendant failed to meet an obligation implicating a condition of payment, the relator must show that the defendant knew that the obligation was unmet and knew that the obligation was a condition of payment within the meaning of the FCA.[137] Although the FCA does not require "proof of specific intent to defraud,"[138] requiring FCA knowledge of both an unmet obligation and of a condition of payment hinging on that obligation falls short of specific intent and so is consistent with the statute.[139]

Joint consideration of falsity and knowledge would similarly resolve one of the other circuit splits described above. Courts are split between those reserving FCA liability for defendants engaging in behavior which violates a provision identified *by statute* as a condition of payment and those who look

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[133] *See* John H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 127 (2001).

[134] *See* Levy, *supra* note 62, at 147–48 ("The alleged violation of agency guidelines, manuals, or other nonbinding government publications is not sufficient to trigger application of the implied certification theory . . . 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.").

[135] *See* Harkins, *supra* note 92, at 173 ("Payment for services when a healthcare provider violates one or more of the hundreds of Medicare and Medicaid requirements is rarely refused.").

[136] 31 U.S.C. § 3729(a)(1) & (2) (2006 & Supp. 2010).

[137] The FCA defines "knowing" and "knowingly" as actual knowledge, deliberate ignorance to truth or falsity, or reckless disregard of truth or falsity. § 3729(b)(1).

[138] *Id.* § 3729(b)(1)(B).

[139] *See* S. REP. NO. 99-345, at 6 to 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266 (citing, with disapproval, *United States v. Aerodex, Inc.* which found FCA liability requires not just knowledge by a "guilty knowledge of a *purpose* on the part of the defendant to cheat the Government," 469 F.2d 1003, 1007 (5th Cir. 1972) (emphasis added)).

more broadly.[140] Certainly, a defendant can reasonably be said to have FCA knowledge about conditions of payment expressed in the statute, regulations, or its own contracts with the government. This standard does not entirely rule out that a defendant's conduct might implicate a condition of payment not expressly articulated in statute, regulation, or contract, but a relator will face an uphill battle to establish that a defendant had FCA knowledge of such a condition.

Of course, under the present version of the FCA, courts must heed the statutory materiality requirement regardless of what their inclinations would otherwise have been because they are bound by the plain language of the statute.[141] Therefore, any radical deviation from the FERA standard must be made by statutory intervention as discussed below.

B. Proposed Statutory Changes

To simplify the application of the FCA to implied certification and to align the statutory requirements with the policy position described in the previous paragraphs, Congress should amend two provisions of the FCA. Namely, Congress should modify § 3729(a)(1)(B) both to eliminate the overlap between the subsection and § 3729(a)(1)(A), and to place implied certification squarely within § 3729(a)(1)(B). Congress should also amend the statutory definition of materiality in § 3729(b)(4) to reflect the policy position described above.

Section § 3729(a)(1)(B) currently imposes liability on an individual who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[142] To more clearly differentiate between this subsection and subsection (A), Congress should strike "false or fraudulent." Because a powerful argument against allowing implied certification at all is that situating the theory under § 3729(a)(1)(A) creates surplusage,[143] delineating these two subsections provides statutory support for recognizing implied certification in the first place. To further reinforce that implied certification is properly analyzed under the rubric of § 3729(a)(1)(B), Congress should strike "false record or statement" and replace it with "false statement (actual or implied) or record." This revision spells out that a statement need not actually be spoken, written, or expressly made in

[140] The third category of courts, which require that the statute expressly identifies the *certification* of compliance have entirely misapplied the theory of implied certification. Certification, while a useful concept in this case law, does not have "paramount and talismanic significance." United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006). Instead, the core issue in an implied certification case is the falsity arising from an unmet obligation and thus the violation itself ought to be connected to the decision to make payment rather than defendant's certification. *See* SYLVIA, *supra* note 24, at § 4:33, at 180.

[141] Lamie v. U.S. Trustee, 540 U.S. 526, 534 (2004) (citations omitted).

[142] § 3729(a)(1)(B).

[143] *See supra* notes text accompanying 45–47.

order to trigger FCA liability.[144] Placing implied certification in § 3729(a)(1)(B) is particularly important because only this subsection requires falsity to be material to a claim,[145] thus providing a clear statutory constraint on implied certification cases.

Congress should also adjust the statutory definition of "material" in § 3729(b)(4). Presently, the section defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[146] To protect the strong public policies described in the preceding section, this definition should be revised to read: "essential to the decision to make payment." The definition saves courts from having to dance around the broad statutory language of the materiality requirement when they determine public policy is not served by finding the defendant liable under the FCA despite the plain applicability of the current statutory definition.[147] Together, these two changes appropriately balance the risks of over-broad application of the theory of implied certification with the benefits of qui tam litigation.

CONCLUSION

The FCA's qui tam provisions are powerful weapons in the fight against healthcare fraud. However, their reach—through the theory of implied certification—cannot be endless. Regulated entities desperately need information on how far implied certification can stretch. The current case law is so divided and unclear that it prevents consistent administration of the FCA and fails to provide potential defendants with adequate notice of what types of conduct may result in liability. Although the FERA amendments' inclusion of a statutory materiality requirement represents a first step toward establishing appropriate limits on implied certification cases, the amendments fail to strike the optimal balance. Congress should again revisit the FCA to adjust the language to specifically place implied certification within the ambit of the statute. Congress should further revamp the statutory definition of "material" to include only that which is essential to the government's decision to pay the claim. Together these statutory changes would produce more consistent case law that better walks the line between protecting the Government's purse from fraud and preventing regulated entities from being subject to excess liability under the FCA.

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[144] Levy, *supra* note 62, at 131 ("Under the implied certification theory, courts will read certain implied terms into a defendant's invoices or certifications.").
[145] § 3729(a)(1)(A) & (B).
[146] § 3729(b)(4).
[147] Boese, *supra* note 30, at 305.