STEMMING THE FEDERAL TORT FOUNTAIN: WHY FEDERAL COURTS SHOULD MAINTAIN IMPLIED CERTIFICATION LIMITATIONS ON *QUI TAM* SUITS AGAINST NONCLAIMANT DEFENDANTS

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I. INTRODUCTION

> "[A]ny government is potentially the worst client in the world you could . . . want to have."[1]

Amgen is a pharmaceutical and biotechnology company that markets drugs for "cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses."[2] On September 17, 2001, the Food and Drug Administration approved a new drug, Aranesp, for the treatment of anemia in patients with "chronic renal failure," an approval that was extended to patients with chemotherapy-related anemia in 2002.[3] The drug became a huge success, with over $11 billion in sales between 2001 and 2008.[4] The Food and Drug Administration eventually issued a black box warning against the drug in 2007 after clinical studies revealed that it increased the growth rate of tumors and led to a higher risk of serious health problems,[5] but the drug has remained on the market.[6]

Amgen had developed a similar drug called EPO in the 1980s and had entered into a marketing agreement with Johnson & Johnson for that drug.[7] Amgen marketed the drug as Epogen, and Johnson & Johnson marketed it as Procrit; Epogen was used to treat patients with renal problems, while Procrit was used to treat patients with other conditions, including cancer.[8] Aranesp was

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[1] Thomas Heatherwick, *Thomas Heatherwick: Building the Seed Cathedral*, TED (May 2011), http://www.ted.com/talks/thomas_heatherwick.html.

[2] *About Amgen*, AMGEN, http://www.amgen.com/about/amgen.html (last visited Feb. 22, 2013).

[3] Relator's Fourth Amended Complaint at 20, United States *ex rel.* Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010) (No. 06-10972-WGY), 2010 WL 3236078, at *20.

[4] *Id.* at 21.

[5] *Id.*

[6] *See* Larry Husten, *Amgen Trial Fails To Show Benefit of Anemia Drug in Heart Failure Patients*, FORBES (Jan. 16, 2013, 5:45 PM) (stating that Aranesp is approved for use "for the treatment of anemia associated with chronic renal failure"), http://www.forbes.com/sites/larryhusten/2013/01/16/amgen-trial-fails-to-show-benefit-of-anemia-drug-in-heart-failure-patients/.

[7] Relator's Fourth Amended Complaint, *supra* note 3, at 23.

[8] *Id.*

marketed by Amgen as an alternative to Procrit and to the company's own Epogen,[9] with the company noting that Aranesp could be taken less frequently by patients.[10]

In 2006, a former employee of Amgen filed a *qui tam* action against Amgen with the Department of Health and Human Services.[11] The employee claimed that Amgen engaged in a scheme to sell Aranesp by "cannibaliz[ing]" the market share of Epogen and Procrit.[12] Slight overfills are recommended for intravenous administration of Aranesp so that the patient receives the full amount of medication through the injection.[13] Amgen typically provided quite generous overfills in the vials it manufactured for both Epogen and Aranesp; both were initially overfilled by 16.8%.[14] Around 2001, however, Amgen temporarily increased the overfill of Aranesp to 19%[15] and gradually decreased the overfill for Epogen to 11.1% by 2004;[16] both of which were still higher than the 10% overfill recommended by medical authorities.[17]

The plaintiff claimed that this generous overfill was part of a scheme to provide kickbacks to doctors by providing more medication than Amgen was charging for.[18] Federal law prohibits furnishing "any remuneration . . . in cash or kind" to a physician for prescribing medical services or products.[19] The plaintiff claimed that Amgen remunerated doctors by encouraging them to seek reimbursement for the overfilled amount of medication while not paying for the extra medication and despite the fact that the

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[9] *Id.* at 24.

[10] Gretchen Henkel, *Anemia Hard Choices: Comparing Procrit vs. Aranesp*, ONCOLOGY TIMES, Mar. 25, 2003, at 29, 29.

[11] Relator's Fourth Amended Complaint, *supra* note 3, at 3.

[12] *Id.* at 24; *see also* United States *ex rel.* Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 137 (D. Mass. 2010), *aff'd in part and rev'd in part sub nom.* New York v. Amgen, Inc., 652 F.3d 103 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011) (providing date when suit was originally brought).

[13] Relator's Fourth Amended Complaint, *supra* note 3, at 25.

[14] *Id.* at 26.

[15] *Id.* at 27.

[16] *Id.* at 26.

[17] *Id.* at 25.

[18] *Id.* at 29–30.

[19] 42 U.S.C. § 1320a-7b(b)(1) (2006).

use of the overfill was medically unnecessary.[20] After three years of investigation, the federal government decided not to intervene in the case, but several states entered the lawsuit and alleged claims under their states' False Claims Acts.[21] The district court granted the defendants' motion to dismiss,[22] but the First Circuit overruled and reinstated the case, finding that there is a claim against parties who provide a kickback that leads to claims against Medicare or Medicaid.[23]

This Note argues that a reasonable interpretation of the Federal False Claims Act (FCA or the Act), in conjunction with the Anti-Kickback Statute, should not provide a cause of action against an alleged provider of a kickback where that provider has no contract with a federal government agency requiring compliance with the Anti-Kickback Statute and submits no claims to a federal government agency. The FCA specifies certain per-claim fines and punitive damages for knowingly defrauding the government.[24] It gives a right of action to certain relators, who are private individuals with independent knowledge of the wrongful act, in exchange for information about the alleged fraud.[25] The Anti-Kickback Statute criminalizes providing a valuable benefit to a medical professional for recommending certain services.[26] The Note argues that the First Circuit wrongly decided to permit the claims to move past the motion-to-dismiss stage because limitations on the "false or fraudulent claim" are necessary due to amendments to the Anti-Kickback Statute that limit protections such as scienter and materiality. Furthermore, permitting such claims contravenes the enforcement scheme of the Anti-Kickback

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[20] Relator's Fourth Amended Complaint, *supra* note 3, at 33–34.

[21] *See* United States *ex rel.* Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 137 (D. Mass. 2010), *aff'd in part and rev'd in part sub nom.* New York v. Amgen, Inc., 652 F.3d 103 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011) (explaining prior history of lawsuit before motion to dismiss).

[22] *Id.* at 140.

[23] *Amgen, Inc.*, 652 F.3d at 106.

[24] *See* 31 U.S.C. § 3729(a) (Supp. IV 2011) (providing for per-claim fines as well as treble damages for harm caused to the government).

[25] *Id.* § 3730(b) (2006).

[26] 42 U.S.C. § 1320a-7b (Supp. V 2012).

Statute as well as prosecutorial discretion for other health-care crimes such as health-care fraud.

In Part II, this Note first examines the FCA and its use in the context of health-care law. The FCA has morphed in the last twenty years from a statute designed to combat fraud among defense contractors to a statute primarily used against health-care contractors.[27] Second, this Note outlines the circuit split that has developed over implied certification of compliance with applicable statutes and regulations. Since the Act requires a "false or fraudulent" claim,[28] courts have developed a theory that certain claims include an implied warranty by the claimant that it is complying with certain laws.[29] While the majority of circuits have recognized this theory, they disagree over when the theory can be applied to a specific statute or regulation.[30]

Third, this Note provides three examples of how the FCA has been applied against medical providers who allegedly provided kickbacks to doctors who then made claims to Medicare or Medicaid. Each case held that the defendants fell within the FCA's scope of liability,[31] but two of those cases used the Act's broadest theory of liability for implied certification.[32] The third case dismissed a similar charge against the defendant for violations of Medicare marketing rules, but the court in that case failed to apply similar logic to the violation of the Anti-Kickback Statute.[33]

Next, in Part III, this Note explains the reasons for applying a constrained interpretation of the FCA. First, amendments in the

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[27] *See infra* notes 62–67 and accompanying text.

[28] 31 U.S.C. § 3729(a)(1)–(2).

[29] *See, e.g.*, Ab-Tech Constr. v. United States, 31 Fed. Cl. 429 (1994) (finding a potential case under the FCA where the defendant failed to comply with terms of special federal funding), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decision).

[30] *See infra* Part II.C.

[31] United States *ex. rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295 (3d Cir. 2011); New York v. Amgen, Inc., 652 F.3d 103 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011); United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 380 (1st Cir.), *cert. denied*, 132 S. Ct. 815 (2011).

[32] See *Amgen*, 652 F.3d at 110, and *Hutcheson*, 647 F.3d at 387–88, describing the First Circuit's expansive view of implied certification.

[33] *Wilkins*, 659 F.3d at 315.

Patient Protection and Affordable Care Act limit the protections of materiality and scienter when the Anti-Kickback Statute is applied to the FCA while not requiring compliance with the Act as a precondition of payment. Second, the enforcement scheme of the FCA conflicts with the enforcement scheme of the Anti-Kickback Statute. Administrative and criminal agencies have been created to investigate and prosecute these claims selectively, and the comprehensive scheme is disrupted when private enforcement is permitted.

Qui tam actions are especially suspect in the health-care field where a wide set of regulations covers health-care professionals. This Note argues that prosecutions of nonsubmitting parties accused of providing kickbacks violate the purpose of the punitive scheme created in the original FCA and should only be permitted after the nonsubmitting party has been convicted of violating the Anti-Kickback Statute.

II. REVIEW OF THE FALSE CLAIMS ACT AND RECENT CASES CONCERNING NONCLAIMANT DEFENDANTS

A. *QUI TAM*

The Informer's Act, the precursor to the current Federal False Claims Act, was enacted by Congress in 1863 following several notable cases of supplier fraud during the Civil War.[34] In its current form, the FCA punishes several forms of fraudulent conduct: (1) knowingly presenting or causing a presentation of a false claim to the federal government; (2) knowingly using or causing the use of a false statement material to a false claim to the federal government; (3) conspiring to submit a false claim; (4) knowingly failing to deliver all of the property or money to be used by the federal government; (5) knowingly certifying receipt of property without actually receiving the property; (6) knowingly buying or receiving as collateral property from a member of the

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[34] Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 458 (1998); *see also id.* at 458 n.29 (describing testimony that mules "unfit for service" were bought for $119).

government who is not authorized to sell that property; and (7) knowingly making or using a false record material to the government's obligation to pay a claim.[35]

The FCA requires a penalty of $5,500 to $11,000 for each violation of the Act in addition to treble damages for "damages which the Government sustains because of the act of that person."[36] Damages may be reduced by the court to double damages in limited circumstances if the liable party reports the violation and cooperates with the investigation.[37] The Supreme Court has likened the FCA to an enactment of punitive damages,[38] and it has defended punitive damages as a measure required to combat fraud.[39]

The FCA also gives private individuals, called relators, the right to pursue the claim on behalf of the federal government.[40] Such actions, called *qui tam* actions, are based on English common law rights.[41] In exchange for bringing the suit, the relator receives

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[35] 31 U.S.C. § 3729(a)(1) (Supp. IV 2011).

[36] *Id.* As initially passed, the FCA provided for a minimum civil monetary penalty of $5,000 and a maximum penalty of $10,000. *See infra* note 46 and accompanying text. But under the Federal Civil Penalties Inflation Adjustment Act of 1990, every five years, starting in 1995, federal agencies must adjust the minimum and maximum civil monetary penalties to account for changes to the cost of living and to "maintain the deterrent effect of civil monetary penalties and promote compliance with the law." Pub. L. 101-410, §§ 2(b)(1)–(2), 5(a), 104 Stat. 890, 890, 891. For all offenses occurring after September 29, 1999, the FCA provides a minimum penalty of $5,500 and a maximum penalty of $11,000 per violation. Adjustments to Penalties, 28 C.F.R. § 85.3(9) (2012).

[37] 31 U.S.C. § 3729(a)(2).

[38] *See* Vt. Agency of Natural Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 784–85 (2000) (noting that "the current version of the [FCA] imposes damages that are essentially punitive in nature" with both "treble damages and a civil penalty of up to $10,000 per claim"); *see also* Smith v. Wade, 461 U.S. 30, 85 (1983) (Rehnquist, J., dissenting) (using the FCA as an example of Congress's ability to clearly articulate a right to recover punitive damages); Tex. Indus., Inc. v. Radcliff Materials, Inc., 451 U.S. 630, 639 (1981) ("The very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers.").

[39] *See, e.g.*, United States v. Halper, 490 U.S. 435, 450 (1989), *abrogated by* Hudson v. United States, 522 U.S. 93 (1997) (reaffirming the government's right to punish fraudsters through punitive damages when the government has not already sanctioned the individual).

[40] 31 U.S.C. § 3730(b)(1) (2006) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government.").

[41] *See* Note, *The History and Development of* Qui Tam, 1972 WASH. U. L.Q. 81, 83 ("*Qui tam* has roots in the formative stages of English law."). For a full history of English *qui tam* law, see J. Randy Beck, *The False Claims Act and the English Eradication of* Qui Tam

part of the proceeds from any penalty placed on the defendant.[42] If the government does not intervene, the relator receives 25%–30% of the proceeds as well as "reasonable expenses," including attorneys' fees.[43] If the government does intervene, the relator may still receive 15%–25% of the proceeds plus "reasonable expenses," including attorneys' fees.[44] Defendants are protected from "clearly frivolous" or "clearly vexatious" actions by a provision granting them reasonable attorneys' fees and expenses should the court find the suit frivolous or vexatious after the government declines to intervene.[45]

The FCA has undergone two major modifications in the last thirty years. In 1986, Congress amended the FCA, imposing civil penalties of $5,000–$10,000 per violation and treble damages.[46] It also defined "knowing" and "claim" for purposes of the FCA[47] and created the current remuneration scheme for relators.[48] These amendments were designed to facilitate the expansion of claims to protect the integrity of federal programs and punish fraudsters who take advantage of federal funding.[49] In 2009, Congress again amended the FCA via the Fraud Enforcement and Recovery Act (FERA),[50] which permits claims against not only those who are

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Legislation, 78 N.C. L. REV. 539, 565–608 (2000), discussing the original intent of *qui tam* suits as a means of enforcing national law in the face of contrary local interests and the eventual legislative abolition of *qui tam* suits.

[42] *See* 31 U.S.C. § 3730(d)(1)–(2) (requiring that the relator who brought the *qui tam* action be awarded 15%–25% of the proceeds of an action in which the government intervenes and 25%–30% in an action in which the government does not).

[43] *Id.* § 3730(d)(2).

[44] *Id.* § 3730(d)(1).

[45] *Id.* § 3730(d)(4).

[46] *See* Pub. L. No. 99-562, § 2(7), 100 Stat. 3153 (codified as amended at 31 U.S.C. § 3729(a)(1) (Supp. IV 2011)). As explained in the text accompanying note 36 *supra*, the current minimum and maximum civil monetary penalties are $5,500 and $11,000, respectively.

[47] *See* Pub. L. No. 99-562, § 2(7) (codified as amended at 31 U.S.C. § 3729(b) (Supp. IV 2011)).

[48] *See id.* § 3 (codified as amended at 31 U.S.C. § 3730 (2006 & Supp. IV 2011)).

[49] *See* Meador & Warren, *supra* note 34, at 461 (identifying the purposes of the FCA as protecting the public fisc and the integrity of federal programs, recovering government losses due to fraud, and punishing parties who make false claims).

[50] Pub. L. No. 111-21, 123 Stat. 1617 (codified as amended in scattered sections of 18 & 31 U.S.C.).

compensated directly by the federal government on a false claim but also those who present a false claim to someone eventually reimbursed by the federal government.[51] FERA also includes a requirement that a claim under the FCA predicated on a false statement be based on a statement that is "material" to the approval or denial of the claim.[52]

To successfully prosecute a *qui tam* case, the plaintiff must prove that the defendant "(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury."[53] Congress has defined "knowing" to include actual knowledge, deliberate ignorance, and reckless disregard.[54] A factually false claim is one including "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."[55] Legally false claims, on the other hand, do not involve a misstatement of fact; instead, these claims are "predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term."[56] While factually false claims have not created much controversy, circuit courts have split as to when legally false claims create liability under the FCA.

B. *QUI TAM* AND HEALTH-CARE LAW

Fraudulent claims pose a significant problem in health-care law because multiple public programs provide support for health care. One commentator suggests that 3% of health-care funding is lost

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[51] *See* Justin P. Tschoepe, Comment, *A Fraud Against One Is Apparently a Fraud Against All: The Fraud Enforcement and Recovery Act's Unprecedented Expansion of Liability Under the False Claims Act*, 47 HOUS. L. REV. 741, 760 (2010) ("These amendments clarify that liability can arise from the submission of a false claim to anyone who is eventually reimbursed with federal funds . . . ."). Tschoepe describes the FERA amendments as a drastic expansion of the FCA, removing "judicial limitations which rationally prevented the reach of the statute from encroaching into the entire commercial marketplace." *Id.* at 761.

[52] Pub L. No. 111-21, § 4(a)(1), 123 Stat. 1617, 1621 (2009) (codified as amended at 31 U.S.C. § 3729(a)(1)(B) (Supp. IV 2011)).

[53] Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001).

[54] 31 U.S.C. § 3729(b)(1)(A).

[55] *Mikes*, 274 F.3d at 697.

[56] *Id.* at 696.

to fraudulent claims,[57] leading to estimated losses of "tens of billions of dollars each year."[58] Error rates are over 10% for Medicare payments and over 14% for privately run Medicare Advantage programs.[59] While health-care fraud is often considered a white-collar crime,[60] organized crime participated in some instances of health-care fraud in the 1990s, especially in the area of managed care.[61] Large economic losses caused by health-care fraud, waste, and abuse have led the federal government to increase its efforts to combat health-care fraud.[62]

The largest category of *qui tam* suits are health-care suits—the Department of Health and Human Services received 417 *qui tam* matters in 2011 while all other federal departments combined only received 221 new *qui tam* matters in the same year.[63] Although

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[57] Timothy Stoltzfus Jost, *Optimizing* Qui Tam *Litigation and Minimizing Fraud and Abuse: A Comment on Christopher Alexion's* Open the Door, Not the Floodgates, 69 WASH. & LEE L. REV. 419, 419 (2012).

[58] National Health Care Anti-Fraud Association, *The Challenge of Health Care Fraud*, NHCAA, http://www.nhcaa.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud.aspx (last visited Apr. 21, 2013).

[59] Jost, *supra* note 57, at 419 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-278, HIGH-RISK SERIES: AN UPDATE 186 (2011), *available at* http://www.gao.gov/new.items/d11278.pdf).

[60] *See, e.g.*, Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 855, 870 (1989) ("Clearly, fraud by health care providers fits either an 'actor' or 'conduct' definition of white collar crime. When a health care provider obtains reimbursement by misrepresenting what health care services were provided, the provider has used its position of trust as a professional to obtain an illegal gain.").

[61] *See* MALCOLM K. SPARROW, LICENSE TO STEAL: HOW FRAUD BLEEDS AMERICA'S HEALTH CARE SYSTEM 19 (2d ed. 2000) (claiming that drug traffickers and the Mafia have become involved in health-care fraud because it is safer, more lucrative, and the "punishments . . . are likely to be much less severe than those for drug dealing").

[62] A recent example of increased federal enforcement is the Health Care Fraud Prevention and Enforcement Action Team, a collaboration between the Department of Justice and the Department of Health and Human Services designed to combat health-care fraud. This initiative focuses primarily on criminal prosecutions rather than civil actions. Joan H. Krause, Skilling *and the Pursuit of Healthcare Fraud*, 66 U. MIAMI L. REV. 363, 369–70 (2012).

[63] *Compare* CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—OVERVIEW 2 (2012), *available at* http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf (noting that the total number of qui tam matters received by the federal government in 2011 was 638), *with* CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—HEALTH AND HUMAN SERVICES 2 (2012) (noting that the Department of Health and Human Services alone received 417 new *qui tam* matters in 2011).

the FCA was initially enacted to combat fraud among defense contractors, the Department of Defense only received forty-six *qui tam* matters in 2011.[64] Of the $2.8 billion the government recovered in *qui tam* suits in 2011,[65] over $2.2 billion resulted from damages collected by the Department of Health and Human Services.[66]

Qui tam suits against health-care companies are attractive for several reasons. First, health-care providers often make hundreds or thousands of small claims for routine tests and procedures, and the FCA provides a penalty of $5,500 to $11,000 for each violation.[67] Second, the risk that a conviction could potentially bankrupt a company forces many companies to settle with the plaintiff in a FCA case.[68] Lastly, the government bears a lower burden of proof in a civil suit under the FCA than in a criminal trial.[69] For these reasons, *qui tam* cases represent a more lucrative method of regulating and preventing health-care fraud.

C. IMPLICIT CERTIFICATION

A successful claim for a violation of the FCA requires the plaintiff to prove that a false or fraudulent request for payment was made against the federal government.[70] Factually false claims are much more common[71] and have not resulted in a circuit split since a false statement of fact in a claim for payment is facially a "false . . . claim for payment or approval."[72] It becomes harder to

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[64] CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—DEPARTMENT OF DEFENSE 2 (2012).

[65] FRAUD STATISTICS—OVERVIEW, *supra* note 63, at 2.

[66] FRAUD STATISTICS—HEALTH AND HUMAN SERVICES, *supra* note 63, at 2.

[67] *See* DEAN M. HARRIS, CONTEMPORARY ISSUES IN HEALTHCARE LAW AND ETHICS 145 (3d ed. 2008) (explaining that the numerosity of small claims combined with the per-violation penalty results in excessive liability for health-care companies).

[68] *Id.* at 146.

[69] *See id.* at 145 (noting that the government only has to prove fraud by a preponderance of the evidence rather than beyond a reasonable doubt under the FCA).

[70] Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001).

[71] 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, 134 (2008).

[72] 31 U.S.C. § 3729(a) (Supp. IV 2011).

determine whether a claim is false or fraudulent under the FCA as a legally false claim when such a claim only violates an express or implied condition of payment.[73] For example, a company violates the FCA when it expressly certifies compliance with a statute or regulation while submitting a claim for payment without actually having complied with that statute or regulation.[74] The case is more difficult, though, when the defendant is sued for failing to comply with a statute and has not certified compliance with that statute in the submission of the claim.[75]

The U.S. Court of Federal Claims took the first step in establishing implied certification of statutory or regulatory compliance as a basis for FCA liability.[76] In *Ab-Tech Construction v. United States*, the Army Corps of Engineers contracted with the defendant corporation under § 8(a) of the Small Business Act, which is designed to facilitate government contracts with businesses owned by minorities.[77] The defendant then entered into an agreement with a nonminority-owned company, which gained significant control over the defendant.[78] The Court of Federal Claims found that the continued claims for payment under the original contract constituted a violation of the FCA because they "represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the

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[73] *See* Levy et al., *supra* note 71, at 134 (explaining that a "legally false" claim involves "a false representation or certification of compliance with some governing law, statute, or regulation or with a prescribed contractual term").

[74] *See id.* (describing an example of a party who makes a false claim to the Department of Housing and Urban Development expressly certifying compliance with its regulations when the party has not actually complied); *see also* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997) (explaining the relator's claim that the defendant violated the FCA by expressly certifying compliance with the Anti-Kickback Statute when the defendant had violated it).

[75] *See* Levy et al., *supra* note 71, at 135 ("In light of the plain language of the [FCA], [implied certification] is often difficult to legitimize as it tries to circumvent a crucial element under [the FCA]: that a *false claim* was knowingly submitted to the Government.").

[76] Michael Holt & Gregory Klass, *Implied Certification Under the False Claims Act*, 41 PUB. CONT. L.J. 1, 18 (2011).

[77] 31 Fed. Cl. 429, 431–32 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decision). Under § 8(a), businesses are required to sign a "Statement of Cooperation" certifying compliance with the program's requirements. *Id.* at 432.

[78] *Id.* at 432–33.

8(a) program."[79] This holding was based on a wide interpretation of the purpose of the FCA: to deter and punish "all fraudulent attempts to cause the Government to pay out sums of money."[80] Ab-Tech's deliberate withholding of information about the contract with the nonminority-owned company "caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program."[81] Because such information was "critical to the decision to pay" funds to the government contractors, the failure to disclose it constituted a violation of the FCA.[82]

The Tenth Circuit considered this wide rule of implied certification a few years later. In *Shaw v. AAA Engineering & Drafting, Inc.*, the court found that the defendant violated the FCA by submitting a claim for equitable adjustment of a contract with a false certification that the data on work orders were accurate where in reality the defendant had altered the work orders.[83] The Tenth Circuit noted a difference between § 3729(a)(1) and § 3729(a)(2) of the FCA: subsection (a)(1) creates liability for presenting false claim for payment, while subsection (a)(2) creates liability for the presentation of a false record or statement to facilitate payment of a false or fraudulent claim.[84] Because these are distinct violations, the Tenth Circuit held that liability under the Act could not require "an affirmative or express false statement by the government contractor," since such a statement is only required for a claim under subsection (a)(2).[85]

Other courts, however, have found that implied statements of legal compliance cannot create liability under the FCA. For example, in *United States ex rel. Hopper v. Anton*, the Ninth Circuit stated that "[i]t is the false *certification* of compliance which creates liability when certification is a prerequisite to

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[79] *Id.* at 434.
[80] *Id.* at 433 (quoting United States v. Neifert–White Co., 390 U.S. 228, 233 (1968)).
[81] *Id.* at 434.
[82] *Id.*
[83] 213 F.3d 525–26, 533 (10th Cir. 2000).
[84] *Id.* at 531.
[85] *Id.* at 532.

obtaining a government benefit."[86] The court stated that this rule is especially true "where regulatory compliance [is] not a *sine qua non* of receipt of state funding."[87] The Ninth Circuit also mentioned the administrative remedies available for violations of education regulation, which the relator pursued before filing the FCA action.[88] The Fifth Circuit cited *Hopper* with approval in *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.* in considering a claim based on violations of the Anti-Kickback Statute and the Stark Acts, which criminalize a physician referring patients to other medical facilities in which the physician has an ownership interest.[89] The Fifth Circuit noted that previous cases found that "claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the [FCA]."[90] The court did not determine, however, whether the claim could be properly dismissed because there were insufficient facts in the record to determine if Medicare required certification of compliance with the Anti-Kickback Statute in order to receive payment.[91]

In *Mikes v. Straus*, the Second Circuit took a middle approach, finding a violation of the FCA with no express certification "only when a statute or regulation . . . *expressly* states the provider must comply" in order to have the claim processed and paid.[92] The relator in that case alleged that the defendant doctors defrauded Medicare by submitting claims for spirometry tests that were inaccurate due to the doctors' failure to calibrate the machines in line with medical guidelines.[93] The Second Circuit argued that the FCA's original intent was "restitutionary," noncompliance could not create liability where it "would not have influenced the

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[86] 91 F.3d 1261, 1266 (9th Cir. 1996).

[87] *Id.* at 1267.

[88] *See id.* at 1263–64, 1267 (describing the California Department of Education's process of reviewing and curing violations of the California Education Code).

[89] 125 F.3d 899, 901–02 (5th Cir. 1997).

[90] *Id.* at 902.

[91] *Id.* at 902–03.

[92] 274 F.3d 687, 700 (2d Cir. 2001).

[93] *Id.* at 694.

government's decision to pay."[94] The court also noted that this particular type of claim could lead to a federalization of medical malpractice law by predicating FCA liability on a failure to meet a standard of care supposedly contained in federal regulations.[95] The Second Circuit went on to state that a rule allowing FCA prosecutions when a statute or regulation expressly requires compliance for payment of claims against the government properly balances the need to prosecute fraud with the need to grant deference to administrative agencies such as the Center for Medicare and Medicaid Services.[96] Some courts use yet another middle approach holding that implied certification of compliance with a statute or regulation can create liability under the FCA when the statute or regulation is material to the government's decision to pay the claim even if the statute or regulation does not expressly require compliance.[97]

D. IMPLIED CERTIFICATION IN *QUI TAM* ACTIONS FOR ALLEGED KICKBACKS

1. United States *ex rel.* Hutcheson v. Blackstone Medical, Inc. *United States ex rel. Hutcheson v. Blackstone Medical, Inc.* involved a complaint against a pharmaceutical company under the FCA.[98] The relator, Susan Hutcheson, was employed as a Regional Manager at Blackstone until she was fired in January 2006.[99] Eight months later, she filed a *qui tam* action against her former

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[94] *Id.* at 697. The court distinguished the case from *United States v. Neifert–White Co.*, 390 U.S. 228 (1968), because the regulations in question in *Mikes* were not material to the government's decision to pay the defendants' claims made by defendants. *Id.*

[95] *Id.* at 700 (citing Patrick A. Scheiderer, Note, *Medical Malpractice as a Basis for a False Claims Action?*, 33 IND. L. REV. 1077, 1098–99 (2000)).

[96] *See id.* at 699–700 ("[A] limited application of implied certification in the health-care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met.").

[97] *See, e.g.*, New York v. Amgen, Inc., 652 F.3d 103, 110 (1st Cir.) (stating that to survive a motion to dismiss, the plaintiff "must show that the claims at issue in this litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent"), *cert. denied*, 132 S. Ct. 993 (2011).

[98] 647 F.3d 377, 380 (1st Cir.), *cert. denied*, 132 S. Ct. 815 (2011).

[99] *Id.*

employer, claiming "that Blackstone engaged in a nationwide kickback scheme to induce physicians to use its medical devices in spinal surgeries."[100] Hutchenson alleged that the defendant compensated doctors through "sham consulting agreements; paid development projects; research grants; . . . and other illegal incentives."[101] Furthermore, Hutcheson alleged that Blackstone executives "supervised the kickback scheme" with full knowledge that many patients used Medicare and other federal programs to fund procedures for which doctors would use Blackstone's devices "as a result of the kickbacks."[102]

The relator alleged that this conduct constituted a violation of the FCA because the Anti-Kickback Statute prohibits payments from Medicare to physicians who have received kickbacks.[103] She identified two documents that Medicare providers must sign which require compliance with the Anti-Kickback Statute.[104] First, the Medicare Provider Agreement explicitly states that "payment of a claim by Medicare is conditioned upon . . . compl[iance] with such laws, regulations, and program instructions (including . . . the Federal anti-kickback statute)."[105] Second, hospitals must sign a Hospital Cost Report, which cautions that "fines and/or imprisonment may result" from use of a kickback and which must be signed by a person certifying "that the services identified in this cost report were provided in compliance with such laws and regulations."[106]

The District Court of Massachusetts dismissed the complaint for failure to state a claim.[107] Articulating the First Circuit's test, the court found that the plaintiff must show that the defendant knowingly presented a material false or fraudulent claim to the government or caused another to knowingly present such a

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[100] *Id.* at 378.
[101] *Id.* at 380.
[102] *Id.* at 380–81.
[103] *Id.* at 381.
[104] *Id.*
[105] *Id.*
[106] *Id.* at 381–82.
[107] *Id.* at 382.

claim.[108] The court found that a third party causes a false or fraudulent claim to be presented "when the submission was the reasonably foreseeable result of a defendant's actions."[109] The court dismissed the claim against Blackstone Medical, however, because the Provider Agreement signed by the individual providers "create[d] no obligation on the part of the signatory to determine whether the entire transaction complied with the Anti-Kickback Statute."[110] Furthermore, the court argued that express statutory certification is required to bring about an action under the FCA, and the Provider Agreement in question did not qualify since "such a precondition cannot be hidden in an enrollment form."[111] The court also held that any false statements of the doctors were immaterial even if they were knowingly made because the doctors sought reimbursement for their services, not for use of the product itself.[112] Therefore, the Medicare claims submitted by the doctors for their own services were not "tainted" by the alleged kickbacks for purchasing the medical device.[113]

The First Circuit reversed the decision of the district court and remanded the case for trial.[114] The court determined that the two issues were: (1) whether claims can be "false or fraudulent for failure to meet an implied legal condition of payment that is found in a source other than a statute or regulation" and (2) whether representations made by the submitting party regarding its own compliance can be binding on nonparties to the transaction between the provider and the federal government.[115]

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[108] United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 61 (D. Mass. 2010) (citing United States *ex rel.* Karvelas v. Melrose–Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004); United States v. Data Translation, Inc., 984 F.2d 1256, 1267 (1st Cir. 1992)), *rev'd*, 647 F.3d 377 (1st Cir.), *cert. denied*, 132 S. Ct. 815 (2011).

[109] *Id.* (citing United States *ex rel.* Rost v. Pfizer, Inc., 507 F.3d 720, 733 n.9 (1st Cir. 2007)).

[110] *Id.* at 66.

[111] *Id.*

[112] *Id.* at 66–67.

[113] *Id.* at 67. The court further stated that its conclusion would have been different if "Blackstone induced doctors to perform medically unnecessary surgeries for which they sought reimbursement from Medicare." *Id.*

[114] 647 F.3d 377, 395 (1st Cir.), *cert. denied*, 132 S. Ct. 815 (2011).

[115] *Id.* at 384.

The First Circuit began its analysis by criticizing the distinction between "factually false" and "legally false" claims.[116] It noted that while such categorical distinctions "sometimes can help carry out a statute's requirements, . . . they can also create artificial barriers that obscure and distort those requirements," thereby harming congressional intent.[117] The court recognized the circuit split on the question of when a government contractor implicitly certifies compliance with a federal statute.[118] The court accepted the broad definition of implied certification created by the D.C. Circuit in *United States v. Science Applications International Corp.*,[119] noting that Congress indicated no intent to limit the scope of the FCA based on the nature of the certified compliance.[120] According to the First Circuit in *Hutcheson*, individuals falsely accused of violating the FCA are better protected by materiality and scienter requirements than limitations on the scope of FCA violations.[121]

The court next stated that a nonsubmitting party may be held liable under the FCA for the implied certifications of the submitting party.[122] The FCA states that liability extends to anyone who causes a false claim to be presented to the federal

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[116] *Id.* at 385.

[117] *Id.* The court also pointed out that the statutory language of the FCA does not create any "certification" requirement. *Id.* (citing United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006)).

[118] The First Circuit found a three-way circuit split on the question of implied certification. The Second and Ninth Circuits have only allowed FCA suits based on implied certification of prerequisites to payment expressly stated in statutes or regulations. The Tenth Circuit expanded that rule to allow consideration of contractual terms when determining if compliance was a prerequisite to payment. The D.C. Circuit has expanded the concept of implied certification the furthest, holding that noncompliance with contractual terms can lead to a claim even if the contract did not specifically state that compliance was a prerequisite to payment. *Id.* at 387–88.

[119] 626 F.3d 1257 (D.C. Cir. 2010).

[120] *See Hutcheson*, 647 F.3d at 387–88 (arguing that the FCA gives no indication of "a circumscribed view of what it means for a claim to be false or fraudulent" (quoting *Sci. Applications Int'l Corp.*, 626 F.3d at 1270)).

[121] *See id.* at 388 (noting that measures other than limitations on certification "exist to cabin the breadth" of false or fraudulent claims).

[122] *See id.* at 389 (finding that "[t]he statue makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent").

government.[123] The First Circuit also noted that the Supreme Court has expressly allowed FCA prosecutions against nonsubmitting parties,[124] although most of those actions involved factually false rather than legally false claims.[125] The First Circuit stated that it refused to "rewrite statutes" and that "the policy concerns are overblown," as other limitations exist in the FCA.[126]

Unlike the District Court of Massachusetts, the First Circuit found sufficient evidence of misrepresentation for the plaintiff to survive the motion to dismiss for failure to state a claim.[127] The Provider Agreement and Hospital Cost Report submitted by the hospital were sufficient certifications of compliance with relevant Medicare statutes and regulations.[128] In addition, the Provider Agreement alone was sufficient evidence of misrepresentation for claims against Blackstone with respect to doctor kickbacks, since the "underlying transaction" violated the Anti-Kickback Statute and thus the FCA.[129] The court also stated that the complaint was sufficient regarding the materiality of the defendant's fraud because it was legally uncertain that the misrepresentations "were not capable of influencing Medicare's decision to pay the claims."[130]

On November 2, 2012, Orthofix International, the parent company of Blackstone Medical, agreed to pay $30 million to settle the case.[131] The whistleblower, Susan Hutcheson, received $8 million from the settlement, approximately 27% of the total

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[123] *Id.* (citing 31 U.S.C. § 3729(a)(1) (Supp. IV 2011)).

[124] *Id.* at 390 (citing *United States v. Bornstein*, 423 U.S. 303 (1976), which held a subcontractor liable for mistakes that caused the contractor to make a false claim).

[125] The court cites two cases where implied certification was imputed to a nonsubmitting party. *See id.* at 390–91 (citing United States *ex rel.* Marcus v. Hess, 317 U.S. 537 (1943); Murray & Sorenson v. United States, 207 F.2d 119 (1st Cir. 1953)). Both cases are over fifty-years-old and neither is directly related to claims submitted by a health-care provider.

[126] *Id.* at 391–92.

[127] *Id.* at 393.

[128] *Id.* The court ignored the defendant's "formalistic reading" that sought to "divert attention from th[e] clear language" to "avoid the conclusion that these forms recognize[d] this precondition of Medicare payment." *Id.*

[129] *Id.*

[130] *Id.* at 394.

[131] Press Release, Dep't of Justice, Office of Pub. Affairs, Orthofix Subsidiary, Blackstone Medical, Pays U.S. $30 Million to Settle False Claims Act Allegations (Nov. 2, 2012), *available at* http://www.justice.gov/opa/pr/2012/November/12-civ-1309.html.

amount.[132] The claim was settled with no determination of liability.[133]

2. New York v. Amgen, Inc. Approximately two months after the First Circuit's decision in *Hutcheson*, the court decided a similar suit based on comparable state False Claims Acts from several states in *New York v. Amgen, Inc.*[134] The relator worked for Amgen, Inc. from 2002 to 2005[135] and alleged that the defendant gave kickbacks to doctors through a scheme of overfilling vials of one drug, Aranesp, while reducing the overfill of another drug, Procrit.[136] The plaintiff also alleged that the defendant provided other financial benefits to doctors.[137] Seven states joined the relator in the suit: California, Georgia, Illinois, Indiana, Massachusetts, New Mexico, and New York.[138] The First Circuit found that the state statutes were almost identical to the federal FCA, prohibiting the same activities and defining *knowingly* in the same manner.[139]

As in *Hutcheson*, the District Court of Massachusetts dismissed this case based on the plaintiffs' failure to state a claim.[140] The district court rejected an express certification theory of liability based on providers signing a document certifying "compliance with applicable state and federal laws" and containing an agreement "to not engage in or commit fraud or abuse."[141] The court also rejected a theory of implied certification of compliance because no statute

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[132] *Id.*

[133] *Id.*

[134] 652 F.3d 103, 106 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011).

[135] *Id.*

[136] *See id.* at 107 (alleging that the defendant overfilled the Aranesp vials by 19% when the maximum suggested amount was only 10% while reducing the overfill in Procrit until the Aranesp overfill was 50% greater than the Procrit overfill).

[137] *See id.* (listing benefits provided to doctors, including "free weekend retreats, lavish advisory board meetings, sham honoraria, [and] consulting fees").

[138] *Id.* at 108.

[139] *See id.* (noting that the New Mexico statute "does not itself define" *knowingly*).

[140] United States *ex rel.* Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 137 (D. Mass. 2010), *aff'd in part and rev'd in part sub nom.* New York v. Amgen, Inc., 652 F.3d 103 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011).

[141] *See id.* at 136–37 (citation omitted) ("Such broad language requiring compliance with 'all applicable state and federal laws' is insufficient to constitute an express certification of compliance with anti-kickback statutes.").

or regulation expressly required compliance with anti-kickback statutes as a prerequisite to payment.[142] The court distinguished this case from *Ab-Tech Construction, Inc. v. United States*, stating that in that case, the defendant concealed "the fact that it had contracted with a non-minority business, contrary to the entire purpose of the [federal small business] program."[143] The court emphasized that compliance with the Anti-Kickback Statute was not the primary purpose of the Medicare statute.[144]

The First Circuit found that the state statutes in question in this case were similar enough to apply the federal framework to the dispute.[145] Citing *Hutcheson*, the court rejected the rule that implied certification requires an express prerequisite of payment in a statute or regulation.[146] Instead, the court held that the plaintiffs had to show that: (1) the claims "misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent," and (2) "the defendants knowingly caused the submission" of said claims.[147] The court also rejected the plaintiffs' argument that kickbacks have been widely accepted as fraudulent because such an argument failed to consider differences in individual state laws.[148] The court found that the laws of Illinois, Indiana, Massachusetts, and New York expressly allowed denial of payments to providers guilty of fraud or misrepresentation, including kickbacks.[149] Thus, the claims brought under those states' laws could proceed.[150]

The court allowed the claims by California and New Mexico against Amgen to proceed based on provider agreements that

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[142] *Id.* at 137. The court stated that limitations like requiring an express requirement are necessary for "adequate notice" of compliance as a precondition to payment. *Id.*

[143] *Id.* at 138.

[144] *Id.*

[145] *Amgen, Inc.*, 652 F.3d at 109 n.6. The court also explained that using the federal framework does not require that the exact same claims be considered fraudulent under federal and state law. *Id.*

[146] *Id.* at 110.

[147] *Id.*

[148] *See id.* at 111 (describing such an argument as a "generalit[y]" that "cannot control").

[149] *See id.* at 112–13 ("We begin with the four states whose statutes and regulations make clear that the kickbacks alleged in this case preclude Medicare payment.").

[150] *Id.* at 113.

clearly classified kickbacks as fraudulent.[151] The First Circuit rejected Amgen's argument that it never certified compliance with any of these statutes, finding that such a question was "of no moment" as to whether the claims at issue were false in a material manner at the time of submission.[152] The court found, however, that no provisions of Georgia law or the provider agreement with Georgia's Medicaid program required compliance with any anti-kickback statute at the time of the suit.[153] Thus, the relator's claims against Amgen under Georgia law were dismissed.[154]

3. United States *ex rel.* Wilkins v. United Health Group, Inc. The Third Circuit considered a similar prosecution against a medical provider who allegedly gave kickbacks to patients for signing up for prescription drug plans.[155] The relators, a marketing supervisor and a sales representative who worked for United Health Group and AmeriChoice, claimed that the defendants provided physicians with kickbacks in violation of the Anti-Kickback Statute and violated Medicare Advantage marketing rules.[156] The federal government decided not to intervene on May 26, 2009,[157] and the district court granted the defendants' motion to dismiss for failure to state a claim.[158] The district court found that Third Circuit precedent did not allow for FCA prosecutions based on implied certification, and it refused to allow such prosecutions in the present case because it would create

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[151] *Id.* at 114.

[152] *Id.* at 114–15.

[153] *Id.* at 115–16. The court also emphasized that "Georgia, unlike the other six states involved in this litigation, does not have a state law analogue to the federal AKS." *Id.* at 116.

[154] *Id.* at 116.

[155] United States *ex. rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 298 (3d Cir. 2011).

[156] *Id.* at 300. The court cited eleven examples of marketing violations, including "us[ing] marketing flyers that [the Center for Medicare and Medicaid Services] did not approve beforehand," "engag[ing] in marketing activities in the waiting rooms of clinics and doctors' offices," and "g[iving] out prizes at Medicare presentations in excess of $15 in value contrary to CMS guidelines."

[157] *Id.*

[158] United States *ex rel.* Wilkins v. United Health Grp., Inc., No. 08-3425 (RBK/JS), 2010 WL 1931134, at *1 (D.N.J. May 13, 2010), *aff'd in part and rev'd in part*, 659 F.3d 295 (3d Cir. 2011).

"a breathtakingly expansive view of liability" for Medicare contractors:[159] "If Relators' theory were correct, the [FCA] would become a federal tort fountain, flowing claims for every trivial violation of Medicare/Medicaid regulations."[160] The district court also focused on the lack of connection between the alleged violations of the Medicare marketing statutes or the Anti-Kickback Statute and the government's decision to pay the claims.[161]

The Third Circuit held that the implied certification test set out by the Second Circuit in *Mikes* was the proper test for implied certification,[162] affirmed the dismissal of claims based on the Medicare marketing violations, and reversed the dismissal of claims based on violations of the Anti-Kickback Statute.[163] The court found that the Medicare marketing violations were not a proper basis for a FCA action because compliance with the marketing plans was not a condition of payment of the Medicare claims.[164] The court approvingly noted that Medicare regulations allow for a grace period to fix marketing problems before shutting down the Medicare Advantage program and that an administrative scheme exists to enforce the regulations.[165] The court also considered the complexity of the Medicate regulations, which could cause "the best intentioned plan participant" to make mistakes, as well as the possible short-circuiting of the intended remedial scheme for marketing violations if the court allowed the FCA claim to go forward based on such violations.[166]

On the other hand, the court found a cognizable claim under the FCA for the defendants' alleged violation of the Anti-Kickback Statute.[167] As evidence of the defendants' implied certification of compliance with the Anti-Kickback Statute, the court noted that

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[159] *Id.* at *5 (citation omitted) (noting that "conditions of *participation*" are not "conditions of "*payment*").

[160] *Id.*

[161] *See id.* at *5–6 (explaining that implied certification at least requires that the statute or regulation violated is relevant to the government's decision to pay the claim).

[162] *See Wilkins*, 659 F.3d at 309.

[163] *Id.* at 315.

[164] *Id.* at 308.

[165] *Id.* at 309.

[166] *Id.* at 310.

[167] *Id.* at 314.

(1) the defendants had to agree to comply with the law to become providers for Medicare Advantage, (2) compliance with these guidelines was an express condition of payment, (3) a false certification of compliance with the Anti-Kickback Statute is an actionable claim under FCA precedent, and (4) other limitations are sufficient to prevent a reading of the FCA as a strict liability statute.[168] The regulation cited by the court[169] does require that organizations agree to comply with "[f]ederal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including . . . the anti-kickback statute,"[170] but the provider does not have to certify compliance with this contractual promise in order to receive payment from Medicare.[171]

In analyzing this claim, the court did not consider the strong punishment scheme under the Anti-Kickback Statute nor the government's discretion in prosecuting violations of that statute. Overall, the First Circuit found that the FCA merely requires that the statute or regulation be material to the government's decision to pay,[172] while the Third Circuit held that it must be a condition of payment.[173] The Third Circuit, however, held that a bare allegation that a regulation is a condition of payment is sufficient to survive a motion to dismiss.[174]

III. DISCUSSION

The First and Third Circuits have recently decided that the FCA can be applied against pharmaceutical and medical device

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[168] *Id.* at 312–14.

[169] *Id.* at 314.

[170] 42 C.F.R. § 422.504(h)(1) (2012).

[171] *See id.* § 422.504(a) ("As a condition for receiving a monthly payment . . . the [Medicare Advantage] organization . . . certifies . . . the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify."). This subchapter of the regulation requires certification of facts, but it does not appear to require certification of compliance with any laws mentioned in the regulation.

[172] New York v. Amgen, Inc., 652 F.3d 103, 110 (1st Cir.), *cert. denied*, 132 S. Ct. 993 (2011).

[173] *Wilkins*, 659 F.3d at 313.

[174] *See id.* (distinguishing *Wilkins* from prior case where plaintiff failed to allege that compliance with antifraud laws was a precondition of payment).

companies for alleged violations of the Anti-Kickback Statute. The First Circuit, though, used an expansive interpretation of the implied certification theory to allow these claims to survive motions to dismiss based on a determination that the alleged violations of the Anti-Kickback Statute would have been material to the government's decision to pay the claim.[175] The Third Circuit accepted the implied certification rule based on materiality from *Mikes*,[176] but it found that the plaintiffs in *Wilkins* properly claimed that the defendants violated a precondition of payment stated in an applicable regulation.[177] This Note argues that the First and Third Circuits were incorrect in finding that the FCA applies to violations of the Anti-Kickback Statute by persons or entities who do not file claims with the federal government, especially when that person or entity has no contractual relationship with the government. *Mikes v. Straus* correctly requires that compliance with the Anti-Kickback Statute be a precondition of payment, and Congress has failed to make compliance with this law such a precondition.

First, the First Circuit incorrectly argued that nonmeritorious claims can be prevented through materiality and scienter requirements—recent legislation has significantly watered down scienter requirements and has eliminated materiality requirements. Such protections are vital in ensuring that the FCA

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[175] *See*, *e.g.*, *Amgen, Inc.*, 652 F.3d at 110 (requiring that the plaintiff "show that the claims at issue in this litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent" in order to survive a motion to dismiss); United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 386 (1st Cir.) ("[T]he district court held both that implied conditions of payment can only be found in statutes and regulations, and that these sources must expressly state the obligation. We reject both requirements."), *cert. denied*, 132 S. Ct. 815 (2011).

[176] *See Wilkins*, 659 F.3d at 307 ("[U]nder this theory [of implied certification] a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's [FCA] claims, it would not have paid the defendant's claims.").

[177] *See id.* at 311 (stating that "Medicare regulations require MA and Prescription Drug Plan ("PDP") organizations to operate under agreements with CMS which include a provision requiring that the organization comply with the [Anti-Kickback Statute]"). This regulation is merely part of the contract between the prescription plan provider and Medicare, however; it does not require certification of compliance with the Anti-Kickback Statute for payment. *See supra* note 161 and accompanying text.

is applied only to those who intentionally defraud the federal government through the submission of false claims. Second, privatization of Anti-Kickback Statute prosecution significantly harms the comprehensive regulatory and enforcement scheme for health-care fraud and abuse, as shown by the small percentage of *qui tam* actions in which the federal government actually intervenes. This comprehensive scheme of enforcement is vital to the protection of the public interest in a financially viable health-care system because it provides discretion to determine which financial arrangements are fraudulent and which are acceptable. Unlimited private prosecution under the FCA significantly harms this balance, especially when the federal government refuses to intervene in *qui tam* actions.

A. THE EFFECTS OF AMENDMENTS TO THE ANTI-KICKBACK STATUTE IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

In March 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA).[178] The law is a comprehensive scheme designed "to increase the number of Americans covered by health insurance and decrease the cost of health care."[179] It contains 10 titles and over 900 total pages.[180] Title VI of PPACA is entitled "Transparency and Program Integrity" and is meant to enhance protections against health-care fraud.[181] Section 6402, entitled "Enhanced Medicare and Medicaid Program Integrity Provisions,"[182] strengthened the Anti-Kickback Statute in two ways. First, it added a provision stating, "In addition to the penalties provided for in this section . . . a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31," the FCA.[183] Second, the intent requirement was modified to note that "a person need not have

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[178] Pub. L. No. 111-148, 124 Stat. 119 (2010).
[179] Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2580 (2012).
[180] *Id.*
[181] Pub. L. No. 111-148, § 1(b), 124 Stat. 119, 126.
[182] *Id.* § 6402, 124 Stat. at 753.
[183] 42 U.S.C. § 1320a-7b(g) (Supp. V 2012).

actual knowledge of this section or specific intent to commit a violation of this section."[184]

These provisions clearly indicate that Congress intended some violations of the Anti-Kickback Statute to lead to liability under the FCA. This statute undercuts the Fifth Circuit's holding in *Thompson* that a claim that allegedly violates the Anti-Kickback Statute does not constitute a "false or fraudulent claim" by law.[185] The statute fails to clearly supersede *Mikes v. Straus*, however, because it does not condition payments to providers on compliance with the Anti-Kickback Statute.[186] Congress had the ability to do this, as demonstrated by the fact that it made compliance with other portions of PPACA a "material condition" of receiving payment.[187] Congress has shown no clear intent to abrogate the limitations created by implied certification, as the PPACA does not require the claimant to certify compliance with the statute in order to receive payment. Rather, a finding of a violation of the statute after payment can lead to additional penalties under the FCA.[188] The introductory clause in 42 U.S.C. § 1320a-7b(g), stating that such penalties are "[i]n addition" to the penalties of the Anti-Kickback Statute, shows that Congress intended for enforcement of the FCA to follow criminal enforcement against a violator of the Anti-Kickback Statute. Since the Anti-Kickback Statute cannot be enforced by private relators,[189] the amendment in the PPACA keeps control of the scope of the Anti-Kickback Statute within the federal government.

The amendment in PPACA § 6402(f)(2) is designed to ensure that specific intent rules that apply to highly technical statutes

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[184] *Id*. § 1320a-7b(h).

[185] *See supra* note 90 and accompanying text.

[186] *See supra* note 92 and accompanying text.

[187] *See, e.g.*, 42 U.S.C. § 18033(a)(6)(A) (Supp. V 2012) ("Compliance with the requirements of [PPACA] concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an issuer's entitlement to receive payments, including payments of premium tax credits and cost-sharing reductions, through the Exchange.").

[188] *See supra* note 183 and accompanying text. *But see* Jost, *supra* note 57, at 429 (claiming, without explanation, that 42 U.S.C. § 1320a-7b(g) resolves the circuit split concerning implied certification).

[189] United States *ex. rel.* Roy v. Anthony, 914 F. Supp. 1504, 1506 (S.D. Ohio 1994).

such as tax laws are not applied to violations of the Anti-Kickback Statute.[190] This amendment codifies case law concerning the Anti-Kickback Statute, which generally found that the Anti-Kickback Statute is not technical enough to warrant requiring specific intent to violate the statute.[191]

In *Hutcheson*, decided before the amendments to the Anti-Kickback Statute took effect, the First Circuit rejected the argument that implied certification is only valid when a statute or regulation expressly makes compliance a condition of payment.[192] The court argued that "other means exist to cabin the breadth of the phrase 'false or fraudulent' as used in the [FCA]."[193] Specifically, the FCA requires that a defendant have acted "knowingly" and that "the claim's defect [be] material."[194] The amendments to the Anti-Kickback Statute, however, weaken these protections for defendants in *qui tam* suits involving kickbacks. The definition of knowingly has been statutorily defined to include actions taken without knowledge of the law.[195] Furthermore, the amendments potentially eliminate materiality as an element of FCA cases based on a violation of the Anti-Kickback Statute.[196] While the First Circuit did not consider the amendments in PPACA, these amendments significantly dilute protections against FCA liability and show the importance of maintaining judicial limitations on FCA liability based on implied certification.

Even if the materiality requirement used in *Hutcheson* and *New York v. Amgen, Inc.* is not eliminated by PPACA, the court in

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[190] *See* Krause, *supra* note 62, at 371.

[191] *See, e.g.*, United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) ("Section 1320a-7b is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct. Indeed, the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal . . . .").

[192] United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 388 (1st Cir.), *cert. denied*, 132 S. Ct. 815 (2011).

[193] *Id.*

[194] *Id.*

[195] 42 U.S.C. § 1320a-7b(h) (Supp. V 2012) ("[A] person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

[196] *Id.* § 1320a-7b(g) states that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim." And the FCA does not require that false or fraudulent claims be material to the government's decision to pay. 31 U.S.C. § 3729(a)(1) (Supp. IV 2011).

Hutcheson was incorrect to suggest that materiality provides sufficient protection for defendants in FCA cases. Determining whether a statute or regulation is material to the government's decision to pay a claim is a fact-intensive question that may hinder a court's ability to rule on a motion to dismiss.[197] Indeed, such a question would almost certainly preclude granting a motion to dismiss because it is a factual question regarding what a government agency considers in deciding whether to approve a claim for payment. Concerns about adjudicating motions to dismiss FCA claims are important, especially in the health-care field. Because the FCA contains a mandatory per-claim fine,[198] settlements are especially common once a motion to dismiss fails.[199] These settlements may be based on the strength of the claim, but they may also be based on the relator's ability to plead just enough facts to survive a motion to dismiss and the defendant's fear of "betting the company" on a single case.[200] Furthermore, motions to dismiss should be encouraged because they end 78% of FCA cases and thus tend to weed out "many frivolous claims."[201] Dismissal is especially likely when the

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[197] *Cf.* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902–03 (5th Cir. 1997) (denying a motion to dismiss and remanding the case because the court was "unable to determine from the record . . . whether . . . payment for services identified in defendants' annual cost reports was conditioned on defendants' certifications of compliance" and thus needed "further factual development").

[198] 31 U.S.C. § 3729(a) (Supp. IV 2011).

[199] *See supra* notes 67–68 and accompanying text.

[200] There is a scholarly debate about the extent to which the merits of litigation matter in determining a proper settlement for a case. For the argument that many settlements are not voluntary as a practical matter and do not reflect the merits of the litigation, see Janet Cooper Alexander, *Do the Merits Matter? A Study of Settlements in Securities Class Actions*, 43 STAN. L. REV. 497, 566–68 (1991). For the argument that the merits of litigation are the primary factor in settlements, see William S. Lerach, *"The Private Securities Litigation Reform Act of 1995—27 Months Later": Securities Class Action Litigation Under the Private Securities Litigation Reform Act's Brave New World*, 76 WASH. U. L.Q. 597, 601–02 (1998) ("All experienced practitioners know that strong cases generally settle for more than weak cases, other things being equal. Those who actually litigate and settle securities class actions know that the strength of a case is often the first matter discussed . . . .").

[201] Christina Orsini Broderick, Note, Qui Tam *Provisions and the Public Interest: An Empirical Analysis*, 107 COLUM. L. REV. 949, 975 (2007) (arguing that the rate of dismissed claims suggests that *qui tam* suits harm the public interest and that new methods of prosecuting such suits may be necessary).

government decides not to intervene, like in *Hutcheson* and *New York v. Amgen Inc.*[202] Therefore, promoting a limitation on the FCA based on the government's reaction to alleged violations will lead some innocent defendants to settle rather than face the costs of discovery in a frivolous suit, and frivolous suits will waste more judicial resources.

One recent commentator suggests that the First Circuit's test is superior because it is more closely aligned with the goals of the FCA.[203] This argument contradicts itself, however, by claiming both that the First Circuit test is "simpler" and that it allows the judge the power to determine "what constitutes a precondition of payment . . . based on the totality of the circumstances."[204] To the contrary, a *qui tam* claim based on the FCA is often adjudicated on a motion to dismiss or settled by the defendant, so this "simpler" standard threatens to provide an effective windfall to plaintiffs since it is a fact-intensive standard and makes a motion to dismiss much harder to receive. The commentator also claims that a standard focusing on factors other than implied certification is more closely aligned with the goal of "deterring all falsely or fraudulently obtained funds from the government."[205] Nonsubmitting defendants accused of violating the Anti-Kickback Statute, however, do not obtain funds from the government. Rather, they obtain funds from the doctor or provider who purchases the material and subsequently makes a claim for payment to the federal government. Finally, the commentator raises the possibility of an unscrupulous defendant tricking innocent providers into accepting remuneration and then submitting a false claim, but the citation given is to court decisions reciting facts from a plaintiff's complaint.[206] This argument shows

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[202] *Id.* (showing that 92% of FCA cases from 1987 to 2004 were dismissed after the government declined to intervene in the case).

[203] Lonie Kim, Note, *Am I Liable? The Problem of Defining Falsity Under the False Claims Act*, 39 AM. J.L. & MED. 160, 162 (2013).

[204] *Id.* at 177, 178.

[205] *Id.* at 180.

[206] *See id.* at 179 & n.196 (citing *Blackstone* and *Amgen* as examples where "innocent" doctors were induced to join illegal scheme when both cases were adjudicating a motion to dismiss).

how a plaintiff can creatively present a *qui tam* action to highlight the actions of a third party and effectively force a settlement once the case gets past a motion to dismiss and into the fact-intensive standard proposed by the First Circuit.

B. PRIVATIZATION OF ANTI-KICKBACK ENFORCEMENT AND EFFECTS ON THE PROSECUTORIAL STRUCTURE

Several commentators have noted that strong enforcement mechanisms exist to enforce the Anti-Kickback Statute and to punish those who violate it. The Anti-Kickback Statute provides for criminal penalties of up to five years in prison and up to $25,000 in fines.[207] Additionally, the Civil Monetary Penalties Law states that any person who commits a violation of the Anti-Kickback Statute is liable for $50,000 in fines "for each such act" as well as treble damages.[208] The Civil Monetary Penalties Law was designed to be "akin to the [FCA], indicating that Congress found the [FCA] insufficient" to punish those guilty of violating the Anti-Kickback Statute.[209] The Law is enforced through the Department of Health and Human Services pursuant to regulations agreed to by the Attorney General,[210] but no prosecution can take place more than six years after the event.[211] It allows for enforcement through administrative proceedings with a right of appeal to the United States Courts of Appeals.[212] Lisa Michelle Phelps argues that this remedial scheme is sufficiently comprehensive to preclude *qui tam* suits under the FCA.[213] She finds that (1) the Anti-Kickback Statute gives no right of action to private parties, (2) the truly injured party—the government—has

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[207] 42 U.S.C. § 1320a-7b(a) (2006).

[208] *Id.* § 1320a-7a(a).

[209] Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations To Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1037 (1998) (footnote omitted).

[210] *See* 42 U.S.C. § 1320a-7a(j)(1) (granting the Secretary of Health and Human Services the authority to delegate prosecution to the Inspector General of the Department of Health and Human services).

[211] *Id.* § 1320a-7a(c)(1).

[212] *Id.* § 1320a-7a(e).

[213] Phelps, *supra* note 209, at 1038.

a right of action available, and (3) relief under the FCA is inconsistent with the relief available under the Civil Monetary Penalties Act and the Anti-Kickback Statute, which indicates that "Congress did not intend to leave [FCA] remedies available to qui tam plaintiffs."[214]

The FCA and the remedial provisions in Title 42 of the United States Code conflict in several ways. First, the scienter requirement for the Anti-Kickback Statute is higher than the scienter requirement for the FCA, which could lead to mistaken application of a lower scienter requirement when an actual violation of the Anti-Kickback Statute must be proven in order for the FCA claim to succeed.[215]

Second, permitting prosecution under both the FCA and the Civil Monetary Penalties Act could lead to damages larger than those anticipated by Congress. The FCA provides for damages of $11,000 per claim as well as treble damages for harm caused to the United States.[216] Therefore, a relator could bring a claim against someone who allegedly provided kickbacks and the government could recover the per-claim fines and treble damages. Then the Department of Health and Human Services could bring an action under the Civil Monetary Penalties Law, fine the person for the act of providing the kickback itself, and receive treble damages again for the value of the claims caused by the kickback. Even if treble damages are meant to protect the public fisc, sextuple damages for the value of each claim appears to merely enrich the government at the expense of those who violate a highly complex statute with several safe harbors and hundreds of advisory opinions providing narrower exceptions.

Finally, the importance of prosecution by relators is reduced by the multiple bodies that investigate health-care fraud and violations of health-care statutes. New health-care fraud investigatory units have been created in recent years. In fact, one

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[214] *Id.* at 1038–43.

[215] *See id.* at 1041 (arguing that "allowing plaintiffs to pursue anti-kickback claims in connection with the [FCA's] lower scienter standard . . . undermines . . . congressional intent to provide a 'uniform' scienter standard for [FCA] prosecution").

[216] 31 U.S.C. § 3729(a)(1) (Supp. IV 2011).

of these programs, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), was involved in the investigation of Blackstone Medical, although they declined to intervene in that case.[217] Because more resources are being placed into government investigation of fraud, thereby reducing the fact-finding purpose of the *qui tam* law, tighter rules on FCA provisions should be accepted. These government agencies possess resources and discretion to investigate fraud and to determine which instances of fraud should be prosecuted, and this process should not be interfered with when the complex regulatory scheme makes a wide range of *qui tam* actions possible.[218]

Professor Timothy Jost has argued against the proposition that private relators in the health-care industry should be subject to strict limitations due to the possibility of frivolous or parasitic *qui tam* actions. First, he points out the large amount of fraud and abuse present in the health-care system[219] and notes the potential for significant savings through tightened enforcement of the health-care fraud and abuse statutes.[220] He minimizes the threat of frivolous and parasitic *qui tam* suits lessening the financial benefits of policing fraud and abuse claims by noting that such suits have costs for the private relator.[221] For instance, such private relators are "unlikely to find future employment in the health-care industry," and they may face "hostility from colleagues and coworkers" and possibly criminal indictment if they took part in the fraud.[222]

Two problems exist with this argument. First, the potential loss of employment in the health-care industry is of little concern to those employed in areas such as pharmaceutical sales who have

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[217] Press Release, *supra* note 131.

[218] *Cf.* Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001) ("[P]ermitting *qui tam* plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice . . . .").

[219] *See supra* notes 58–59 and accompanying text.

[220] Jost, *supra* note 57, at 419–20 (explaining the difficulties of cutting public-health expenditures in the United States and outlining support for "eliminating health care fraud").

[221] *Id.* at 425–26.

[222] *Id.* at 426.

skills that are transferable to other industries.[223] While such limitations on a relator's incentive to sue are valid for employees like doctors and nurses who rely on the goodwill of the local health-care industry, they are less relevant to sales employees who commonly bring *qui tam* suits against nonclaimant defendants. Jost also argues that limitations on the relator's recovery from the ultimate damages against the defendant reduce the incentive to file frivolous suits and that many relators ultimately regret bringing such lawsuits.[224] However, hindsight regrets have no effect on the relator's original decision to bring a *qui tam* action, and because a vast majority of health-care *qui tam* actions do not get to discovery,[225] the time and resources that Department of Justice allocates to researching the claim are wasted. There are practical reasons to be less skeptical of *qui tam* actions brought by health-care professionals, but these reasons do not extend to the average relator in a FCA suit against a nonclaimant defendant.

IV. CONCLUSION

As mentioned at the beginning of this Note, the government can be a terrible client for a contractor.[226] The FCA has given the government, along with private citizens working on its behalf, the power to impose treble damages for any fraud committed against it. This liability can fairly be placed on the contractors since they are presumed to know the legal terms on which they contract with the government. However, a broad interpretation of liability under the Anti-Kickback Statute has widened the potential scope of FCA liability to parties who never signed a contract with the government—a practice that threatens to impose treble damages on any party that transacts business with health-care entities in a slightly improper, but legal, fashion.

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[223] *See* Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH J.L. REFORM 281, 309 (2007) (describing pharmaceutical fraud suit brought by former vice president of sales for pharmaceutical company).

[224] Jost, *supra* note 57, at 427.

[225] *See supra* notes 199–202 and accompanying text.

[226] *See supra* note 1 and accompanying text.

American citizens are understandably upset when fraud and abuse cost the United States government millions of dollars that could have been spent elsewhere. So is the desire to punish those who waste government resources in such a way. This is the purpose of the Anti-Kickback Statute: to criminalize providing kickbacks in exchange for referrals or providing products to doctors that may cause them to unreasonably favor the provider. The criminal statute contains several protections for the defendant, however, and it grants the government a strong degree of discretion in determining who will be held criminally liable. These safeguards appear fair when the wide scope of the Anti-Kickback Statute is considered—it arguably criminalizes both paying off doctors for patient referrals and adjusting the dose of intravenous medication provided in a dial in such a way that is found, *post hoc*, to be unreasonable.

Enforcement under the FCA, on the other hand, provides none of these protections. Instead, it is subject to the whims of relators, private parties who often bring pointless claims hoping for an eventual settlement. The FCA intrudes on a scheme of administrative and criminal enforcement, a scheme designed to balance the goals of preventing fraud and abuse while allowing health-care companies and professionals to conduct business in a profitable manner. Yet Congress has indicated that the FCA is to be used in connection with some claims tainted by implied certifications of compliance with the Anti-Kickback Statute. Congress has the right to do so, but the courts should realize that Congress is essentially co-opting the civil FCA as another form of penalty for the criminal Anti-Kickback Statute and thus should interpret the FCA restrictively.

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