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INTRODUCTION

In the 2018 fiscal year, the Department of Justice collected $2.8 billion from settlements and judgments involving fraudulent and false claims against the government.[1] $2.5 billion of that sum was attributable to fraudulent billing in the healthcare industry.[2] The False Claims Act (FCA) is the government's primary tool to address issues of fraudulent and false claims.[3] One of the principal uses of the FCA is to address false claims submitted to the Centers for Medicare and Medicaid Services (CMS) by healthcare providers.[4] The statute grants authority to private citizens, often called

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1. Press Release, U.S. Dep't of Justice, Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 [https://perma.cc/ETT4-HL8Q].

2. *Id*.

3. Martin Merritt & Rachel V. Rose, *Pleading "Healthcare Fraud and Abuse" Under the False Claims Act*, 60 FED. LAW., May 2013, at 62, 63.

4. Sara A. Smoter, Note, *Relaxing Rule 9(b): Why False Claims Act Relators Should Be Held to a Flexible Pleading Standard*, 66 CASE WESTERN RES. L. REV. 235, 238 (2015).

relators (or whistleblowers), to file *qui tam* claims reporting attempts to defraud the government.[5] *Qui tam* claims account for the majority of FCA litigation.[6] Such claims, however, are often difficult to plead because they are subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure (FRCP).[7]

There is a circuit split regarding pleading standards under Rule 9(b) which has resulted in different outcomes depending on where the suit is brought as to whether the case is allowed to proceed.[8] Notably, the First,[9] Fourth[10] and Eleventh Circuits[11] apply a strict standard for *qui tam* claims, while other circuits apply a more lenient standard.[12] Courts in circuits that dismiss these *qui tam* actions before even preliminary discovery can occur may be depriving the government of recovery of funds. Dismissal of claims prior to discovery is contradictory to public policy as the government, through CMS, is meant to pay only medical claims that are legitimate and necessary. By denying the potential for recoupment of these funds, the government is wastefully spending resources to pay for healthcare that is either not needed or that never even occurred. CMS states, "[a]lthough no precise measure of health care fraud exists, those who exploit federal health care programs can cost taxpayers billions of dollars while putting beneficiaries' health and welfare at risk."[13] If a provider bills for services that were never provided or "up-codes" services by billing at an inflated rate, taxpayers suffer monetarily. A more egregious situation occurs if a provider is overutilizing care, resulting in a

5. *Id*. at 238, 238 n.12; Merritt & Rose, *supra* note 3, at 63.

6. Merritt & Rose, *supra* note 3, at 63.

7. *Id*. at 63–64.

8. Smoter, *supra* note 4, at 241.

9. *Id*. at 243–44, 244 n.47; *e.g.*, United States *ex rel*. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2004).

10. Smoter, *supra* note 4, at 243; *e.g.*, United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457–58 (4th Cir. 2013).

11. Smoter, *supra* note 4, at 241–43, 242 n.35; *e.g.*, United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002).

12. Smoter, *supra* note 4, at 244–48.

13. CTR. FOR MEDICARE & MEDICAID SERV., MEDICARE FRAUD & ABUSE: PREVENT, DETECT, REPORT 4 (2019), https://www.cms.gov/outreach-and-education/medicare-learning-network-MLN/MLNproducts/downloads/fraud-abuse-MLN4649244.pdf [https://perma.cc/P3QJ-KRRG].

patient suffering physically and emotionally, in addition to taxpayers suffering monetarily.

For those reasons, it is in the best interest of the government, taxpayers, and healthcare consumers to allow credible *qui tam* claims to survive, at least through the discovery phase. After studying both the most stringent and the most lenient jurisdictions, this Article will suggest a solution to the circuit split. This solution offers an alternative means for resolving *qui tam* claims. That solution would take the form of an amendment to the FCA that would allow for administrative organizations to step in where the government decides not to pursue a *qui tam* claim or where a court dismisses a *qui tam* claim before it can be fully heard. Such an approach would better protect innocent healthcare organizations and providers from unnecessary litigation while bringing entities engaged in fraudulent billing practices to task for their unlawful conduct.

Part I of this Article will lay out the law of the FCA, *qui tam* actions, and relevant provisions of the FRCP. Part II will provide a discussion of how the current law poses problems of pleading fraud with particularity for *qui tam* relators with representative examples from both strict and lenient circuits. Part III will discuss solutions that scholars have put forth to resolve the problem and advance this author's alternative solution. Finally, this Article will conclude by providing a summary of this important and timely problem.

I. BACKGROUND

A. *The False Claims Act*

For the government to successfully recoup funding from a healthcare organization or provider, it must find evidence that the provider or organization violated the FCA.[14] Examples of violations include billing for services that a patient did not receive or overbilling for services that were provided, but not to the degree of accuracy as stated in the claim.[15]

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14. *See* 31 U.S.C. §§ 3729–3733 (2012).

15. CTR. FOR MEDICARE & MEDICAID SERV., *supra* note 13, at 7; *see* Michael W. Youtt et al., *False Claims Act Actions–The Developing Case Law Regarding if and When Opinions of Medical Necessity Can Be Fraudulent*, 27 HEALTH LAW., Apr. 2015, at 36, 36.

The first category of claims that the FCA covers are "factually false" claims, which impose liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[16] The FCA defines "knowing" and "knowingly," in respect to a person with information, as "[one who] (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information" and "require[s] no proof of specific intent to defraud."[17] It is important to recognize the wide spectrum of knowledge that qualifies under the statute, from actual knowledge to a reckless disregard for the truth, or even conscious avoidance of the truth. Additionally, intent to defraud is not required, which allows for significantly more claims than if the statute included a scienter element. Section 3729(a)(1)(A) is useful in litigation involving providers "padding" their bills with services that they never rendered, since the action need be predicated only on the actual submission of these "factually false" claims.

The second category of claims that the FCA covers are "legally false" claims.[18] The statute imposes liability on "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[19] The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[20] This section of the legislation is illustrated in *United States ex. rel. Mikes v. Straus*, where a pulmonologist pursued a claim against a physician practice for failing to calibrate a piece of machinery, rendering their tests so unreliable as to be "false."[21] These "legally false" claims are common in the healthcare industry.

16. § 3729(a)(1)(A); *see also* United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) ("In a run-of-the mill 'factually false' case, proving falsehood is relatively straightforward: A relator must generally show that the government payee has submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'").

17. § 3729(b)(1).

18. *Conner*, 543 F.3d at 1217.

19. § 3729(a)(1)(B).

20. § 3729(b)(4).

21. 274 F.3d 687, 692–93 (2d Cir. 2001).

Lastly, the statute provides for additional damages when one "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[22] That occurs when providers or organizations discover that they have incorrectly or mistakenly billed CMS and do not initiate a refund process back to the government in a prompt manner. If a provider is found liable, the statute allows the government to recover a civil penalty plus treble damages for the loss which the government sustained as a result of the provider's actions.[23] That portion of the statute was reinforced as the "reverse false claims act" provision within the Fraud Enforcement and Recovery Act of 2009.[24] Additionally, the passage of the Patient Protection and Affordable Care Act in 2010 set parameters to ensure that any falsely billed claims, upon identification, were to be returned within sixty days of discovery of the overpayment.[25]

B. *Qui Tam Actions*

While the United States government has significant resources, its dependence on private citizens to effectively police corporations is demonstrated in section 3730, entitled "Civil Actions for False Claims." To assist in gauging the vast scope of these claims, the Department of Justice reported that recovery from *qui tam* actions related to healthcare under the FCA in 2018 amounted to over $2.1 billion of the $2.8 billion collected for all FCA claims.[26] Of that amount, relators earned approximately $301 million in 645 *qui tam* actions.[27]

Qui tam relators are often referred to as "whistleblowers," as the information that they assert and provide to the government as the basis of their claims often comes from their relationship with a former or current employer.[28] The statute permits a relator to bring a civil action for a violation of the FCA in his or her name and

22. § 3729(a)(1)(G).
23. *Id.*
24. Youtt et al., *supra* note 15, at 36.
25. 42 U.S.C. § 1320a–7k(d)(2) (2012).
26. U.S. Dep't of Justice, *supra* note 1.
27. *Id.*
28. Brianna Bloodgood, Comment, *Particularity Discovery in* Qui Tam *Actions: A Middle Ground Approach to Pleading Fraud in the Health Care Sector*, 165 U. PA. L. REV. 1435, 1439 (2017).

on behalf of the government.[29] The relator's action is filed *in camera* with the court and sealed for at least sixty days to allow the government adequate time to review the claim.[30] The government may decide to take the case and formally prosecute, utilizing its own resources to pursue the claim.[31] If the government decides to not take up the case and does not recommend dismissal to the court, the relator is free to pursue the claim using his or her own resources (funding, attorney guidance, etc.).[32]

The monetary motives for relators seeing successful claims through to judgment cannot be ignored. Under section 3730(d), depending on the relator's status—ranging from mere informant to a wrongdoer who has turned himself over to the authorities—relators stand to gain between ten and twenty-five percent of the total damages recouped by the government. As the FCA authorizes penalties *per claim* in the amount of "not less than $5,000 and not more than $10,000 . . . plus 3 times the amount of damages which the government sustains because of the act of that person," it is apparent why *qui tam* lawsuits are a popular means of ferreting out fraud.[33] Compensation for risk is also appropriate when a relator's claim is pursued either by the government or the relator, especially when the relator is a current employee.[34] There are protections for "whistleblowers" as outlined in section 3730(h), providing for additional compensation for lost wages and damages if the whistleblower lost his or her job or suffered discrimination at his or her employment site.

C. *Pleading Standards Under the Federal Rules of Civil Procedure*

At the complaint stage, most civil claims need only comply with FRCP Rule 8(a) which states that the complainant must assert "a short and plain statement of the claim showing that the pleader is

29. 31 U.S.C. § 3730(b)(1) (2012).
30. § 3730(b)(2).
31. § 3730(b)(4)(A).
32. § 3730(b)(1), (b)(4)(B).
33. § 3729(a)(1)(G).
34. Sean Elameto, *Guarding the Guardians: Accountability in* Qui Tam *Litigation Under the Civil False Claims Act*, 41 PUB. CONT. L.J. 813, 818–19 (2012).

entitled to relief."[35] In federal courts, the scope of Rule 8(a) has been further defined by the Supreme Court's landmark decisions in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*. *Twombly* dealt with potential collusion in the telecommunications industry in a claim brought by subscribers to telecommunications services.[36] Effectively, the Supreme Court stated that all of the details of the claim need not be known at the time of pleading, but enough facts must be present so that it is "plausible" that the fraudulent conduct could have occurred. [37] Thus, *Twombly* established the plausibility standard of pleading.[38]

Further elucidating the meaning of "plausibility," the Supreme Court again took up this issue in *Ashcroft v. Iqbal*, in the context of the deprivation of constitutional liberties for a prisoner in the aftermath of the terrorist attacks on September 11, 2001.[39] The Supreme Court's ruling in *Iqbal* stated that "[w]hile legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief."[40]

When pleading a fraud-related claim under the FCA, complainants must also comply with the heightened pleading requirements articulated in FRCP Rule 9. Specifically, Rule 9(b) states, in relevant part, that: "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."[41] Accordingly, a relator must comply with pleading requirements of both Rules 8 and 9. However, this raises the question of just how much "particularity" is necessary at the pleading stage. Further complicating this issue, the circuits are split on interpreting "particularity" as it relates to *qui tam* litigation in healthcare.

Thus, when a relator brings a *qui tam* action under the FCA, it is not enough to assert fraud generally, but rather the complaint

35. FED. R. CIV. P. 8(a)(2).
36. 550 U.S. 544, 550–51 (2007).
37. *Id.* at 556.
38. *Id.* at 544.
39. 556 U.S. 662, 666 (2009).
40. *Id*. at 679.
41. FED. R. CIV. P. 9(b).

must contain plausible factual assertions that support the legal allegations. Regardless of whether the pleading standards have been met in an FCA *qui tam* action, the likelihood of the complaint withstanding a motion to dismiss depends largely upon the circuit in which the action was filed.

II. THE PROBLEM OF *QUI TAM* PLEADING WITH PARTICULARITY

Each circuit court has chosen either a strict or lenient standard when deciding whether to allow *qui tam* relator claims to proceed to discovery, leading to widely varied and inconsistent results.[42] For *qui tam* relators, the strict standard poses a unique challenge in their attempts to have their cases heard before a court.[43] The Supreme Court has denied writs of certiorari to resolve this circuit split. Consequently, it is important to understand the different approaches that circuit courts use in deciding these difficult cases.[44]

A. *Circuit Courts that Apply Stringent Rule 9(b) Pleading Standards*

Circuits that strictly apply the Rule 9(b) standard[45] maintain that the Rule "require[s] a relator's complaint to identify representative samples of the allegedly false claims."[46] The rationale motivating this strict approach is that it protects the defendant's reputation in the market against vexatious claims and deters *qui tam* relators from making frivolous claims if they know there is little chance of success.[47] Additionally, some argue that "[m]eritless FCA suits impose significant financial burdens on the taxpayer by wasting the [Department of Justice]'s investigative resources and increasing the costs of government programs and contracts."[48] Merely stating that a relator knows of a scheme or fraud without more detailed information will most likely not

42. Smoter, *supra* note 4, at 237.
43. *Id*.
44. *Id*.
45. *See* cases cited *supra* notes 9–11.
46. *See* Michael Lockman, Comment, *In Defense of a Strict Pleading Standard for False Claims Act Whistleblowers*, 82 U. CHI. L. REV. 1559, 1559–60 (2015).
47. *Id*. at 1566.
48. *Id*. at 1567.

survive a Rule 12(b)(6) motion filed by the defendant in those circuits that take a stricter approach to Rule 9(b) pleading standards.[49]

In one of the most cited cases on this topic, *United States ex rel. Clausen v. Laboratory Corp. of America*, the Eleventh Circuit upheld the district court's opinion that the relator did not plead enough facts with particularity to allow the claim to pass to the discovery phase.[50] The relator, Jeffrey Clausen, was not an employee of the defendant Laboratory Corporation of America, Inc. (LabCorp), but "identified himself as a current competitor" in the laboratory industry.[51] Clausen alleged in his complaint that LabCorp, which provided diagnostic services to patients residing in long-term care facilities, was fraudulently billing Medicare.[52] To support his allegations, he stated that he had knowledge of six different schemes in which LabCorp was receiving funds from Medicare that were inappropriate, including: standing orders for laboratory tests that were not ordered by physicians; random draws for laboratory tests without a physician's order; unbundling of blood testing to allow for duplicative billing; charging multiple times for travel to long-term care facilities where multiple patients were seen on the same service date; and for patients with multiple co-morbidities, charging for the same test multiple times corresponding to each chronic condition, despite the test only being performed once.[53] Clausen filed an initial complaint, followed by two amended complaints, both of which were dismissed by the district court, thus prompting Clausen to appeal to the Eleventh Circuit.[54]

The initial complaint failed to "identify any [long-term care facilities] by name, include any documentary exhibits or explain the origin of its information," and eventually, after conducting its own investigation, the government "declined to intervene."[55] Clausen proceeded to file his first amended complaint, which included further details, such as information regarding conversations

49. *See id.* at 1570.
50. 290 F.3d 1301, 1302 (11th Cir. 2002).
51. *Id.* at 1302–03.
52. *Id.*
53. *Id.* at 1303.
54. *Id.* at 1302.
55. *Id.* at 1303–04.

between Clausen and LabCorp employees (identified by specific names) regarding LabCorp policies, codes that would have been used falsely by LabCorp to bill the government, and the medical history of three patients in two named facilities.[56] Nevertheless, the district court dismissed count one of the complaint, finding that Clausen failed to meet the pleading standard under Rule 9(b), thus requiring him to file a second amended complaint.[57] Clausen's second amended complaint included more detailed information concerning the three patients identified in the first amended complaint and a blank claim form that was routinely used to bill the government for services rendered to patients.[58] The district court subsequently granted LabCorp's second motion to dismiss, stating that Clausen's amended complaint "'suffer[ed] from the same defect as the [First] Amended Complaint' in that it did not 'identif[y] a single fraudulent claim by date filed, amount or claim number that was actually submitted to the government.'"[59]

The Eleventh Circuit ultimately affirmed the district court's decision to dismiss Clausen's complaint.[60] The court explained that, in order to allow the claim to pass through to the discovery phase, a pleading must contain facts alleging statements or documents that were made in pursuit of the fraud, the time and place of those statements, the person or persons responsible for making the statements or composing the documents, the manner in which the statements or documents misled the government to induce payment, and what the defendants gained by making the false statements.[61] The court further stated that "Clausen merely offer[ed] conclusory statements, and [did] not adequately allege when—or even if—the schemes were brought to fruition."[62] Hence, the Eleventh Circuit took a firm stance regarding pleading healthcare fraud with particularity, setting a high bar for *qui tam* relators.

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56. *Id*. at 1304.

57. *Id*. at 1305.

58. *Id*. at 1305–06, 1306 n.10.

59. *Id*. at 1306–07.

60. *Id*. at 1315.

61. *See id*. at 1310 (citing Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001) and United States *ex rel.* Cooper v. Blue Cross & Blue Shield of Fla., 19 F.3d 562, 567–68 (11th Cir. 1994)).

62. *Clausen,* 290 F.3d at 1312.

The Fourth Circuit reached a similar result in *United States ex rel. Nathan v. Takeda Pharmacies North America, Inc.* There, Noah Nathan, a sales manager for the pharmaceutical company Takeda Pharmaceuticals (Takeda), brought a *qui tam* action under the FCA.[63] Nathan provided three amended complaints pursuant to the court's requests which alleged that Takeda employed marketing tactics that ultimately led to the government paying for prescriptions that were inappropriately prescribed to patients.[64] Nathan asserted that sales representatives were encouraged to promote a newly approved gastrointestinal drug, Kapidex, to physicians who did not regularly prescribe this type of drug, thus encouraging "off-label" use that could not be reimbursed.[65] He also asserted that sales representatives only provided samples of the sixty milligram tablet of Kapidex to physicians, despite the fact that the thirty milligram tablet was FDA-approved for a more common condition, and without considering whether the thirty milligram tablet was better suited to each physician's needs.[66] In short, Nathan alleged that Takeda effectively induced the government to pay for prescription claims that were technically not reimbursable in violation of the FCA.[67]

The district court dismissed Nathan's complaint in response to a Rule 12(b)(6) motion filed by Takeda.[68] The Fourth Circuit affirmed the district court's ruling, stating that "when a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment."[69] While the suit seemed plausible on its face (which would allow the suit to meet the Rule 8(a) standard), the court mentioned various ways in which the relator's argument failed to meet the heightened Rule 9(b) standard, namely that even though Nathan had supplied the court with numbers of prescriptions written or filled, he did not provide the diagnoses associated with

63. 707 F.3d 451, 453 (4th Cir. 2013).
64. *See id*. at 454.
65. *Id*.
66. *Id*.
67. *See id.*
68. *Id.* at 453.
69. *Id*. at 457.

each prescription, which was required to validate the doses.[70] The court was unwilling to allow the claim to proceed to discovery based on inferences "draw[n] . . . from general facts."[71]

Both the *Clausen* and *Nathan* opinions led to the dismissal of *qui tam* actions and are used to illustrate how some courts apply a strict standard to Rule 9(b) pleadings.

B. *Circuit Courts that Apply Lenient Rule 9(b) Pleading Standards*

On the other side of the split, courts allow a more lenient application of the Rule 9(b) standard. These circuits require pleading fraud with particularity without specific details, which can be accomplished when the pleading is supported by "reliable indicia" that bolsters the inference that a healthcare provider supplied false claims to the government.[72] This standard is flexible enough to allow claims to survive a Rule 12(b)(6) motion in order to accomplish the true purpose of the FCA—capture providers that are defrauding the government. Knowledge of the scheme, as well as the indicia of reliability, allows relators to pursue and recoup funding that was incorrectly and fraudulently paid to healthcare organizations or providers not deserving of the reimbursement.

In *Foglia v. Renal Ventures Management, LLC*, the Third Circuit reversed the district court's grant of a Rule 12(b)(6)motion.[73] In that case, Thomas Foglia, a registered nurse at Renal Ventures from 2007 to 2008, alleged that Renal Ventures was not in compliance with quality regulations and was charging Medicare inappropriately as a result.[74] The complaint centered around the use of the drug Zemplar, which at the time was available in three different vial sizes.[75] Renal Ventures exclusively used the 5 mcg single-use vials for its patients with chronic kidney disease.[76] When using the 5 mcg vials, most patients did not require the full dose in the vial, leaving the remaining product to be discarded at

70. *See id*. at 459–60.
71. *Id*. at 460.
72. *E.g.*, United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009).
73. 754 F.3d 153, 158 (3d Cir. 2014).
74. *See id*. at 155.
75. *Id*. at 157.
76. *Id*.

the directive of the manufacturer.[77] Even though the whole vial was not used, Renal Ventures nevertheless billed Medicare for the whole vial.[78] If the unused portion of the drug was discarded, this practice would have fallen within the acceptable use standards for the medication.[79] However, Foglia alleged that the unused product was not discarded, but rather it was "harvested" for other patients—leading Renal Ventures to charge Medicare for the full vial—while actually only using portions and taking advantage of the remainder.[80] Foglia supported these allegations with his testimony as well as with medication logs that showed, given patient volume, approximately fifty vials should have been used each day (with the overage discarded), but instead only twenty-nine to thirty-five vials were being used each day.[81] Even though the district court found that this information did not comply with the particularity standards required by Rule 9(b), the Third Circuit stated that it would follow the approach used by the First, Fifth, and Ninth Circuits; that is, "it is sufficient for a plaintiff to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'"[82] On these grounds, the court reasoned that there were enough facts to allow the case to proceed to discovery, showing a clear divergence from those circuits that apply a more stringent standard.[83]

The Fifth Circuit took a similar approach in *United States ex rel. Grubbs v. Kanneganti*.[84] Dr. Grubbs, a psychiatrist, alleged that the Chairman of the Medical Staff of the hospital's Psychiatric Subsection and several other doctors were involved in a scheme to defraud Medicare.[85] The alleged fraud arose when the doctors

77. *See id*.

78. *See id*.

79. *Id*. The Department of Health and Human Services did allow for multiple use of vials, but only under certain conditions that Renal Ventures was not meeting. *Id.*

80. *Id*.

81. *Id*. at 158.

82. *Id*. at 156–157 (citing Ebeid *ex rel.* United States v. Lungwitz, 616 F.3d 993, 998–99 (9th Cir. 2010) and United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

83. *See id*. at 158.

84. 565 F.3d 180, 190 (5th Cir. 2009).

85. *Id*.

would record "face-to-face physician visits that had not occurred and that were based solely on information obtained through nursing contacts with the patients."[86] Upon reporting that practice to the general hospital administrator, Dr. Grubbs was dismissed and the alleged fraudulent billing practices continued.[87] Dr. Grubbs filed a *qui tam* action in which he asserted at least one distinct false claim for each physician involved in the fraud.[88] The district court held that the evidence of fraud presented by Dr. Grubbs was insufficient to satisfy the particularity requirement set forth under Rule 9(b).[89]

The Fifth Circuit reversed, allowing Dr. Grubbs to advance his suit against the hospital and doctors involved. The court recognized the traditional judicial construct that a relator's pleading must include "the time, place, and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby."[90] However, the court also acknowledged that "Rule 9(b)'s ultimate meaning is context-specific."[91] Ultimately, the court concluded that strict adherence to the traditional construct would make it exceedingly difficult for a Rule 9(b) pleading to move forward, which would be contrary to the spirit of the FCA.[92]

The Fifth Circuit, through *Grubbs*, adopted a flexible pleading standard under Rule 9(b), stating that "a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."[93] Under this approach, Dr. Grubbs's claims against the doctors were permitted to move forward, but the claim against the hospital was dismissed because the billing originated from the doctors and the hospital

86. *Id.* at 184.
87. *See id.*
88. *Id.* at 184–85.
89. *See id.*
90. *Id.* at 188. (quoting United States *ex rel.* Russell v. Epic Healthcare Mgmt. Grp., 193 F.3d 304, 308 (5th Cir. 1999)).
91. *Id.* (quoting Williams v. WMX Techs., Inc., 112 F.3d 175, 178 (5th Cir. 1997)).
92. *Id.* at 190.
93. *Id.*

lacked the requisite intent for liability under the FCA.[94] Most importantly, the court in *Grubbs* recognized that allowing claims to move forward both permits *qui tam* relators to access, through discovery, the particular information required to adequately plead their claims (i.e., billing records, clinical records, etc.), while protecting organizations and providers from frivolous litigation by scrutinizing each relator claim to ensure plausibility.[95]

A similar scenario on a much grander scale occurred in the oft-cited Eighth Circuit case, *United States ex rel. Thayer v. Planned Parenthood of the Heartland*.[96] Susan Thayer was a center manager at Planned Parenthood's Storm Lake, Iowa location from 1991 to 2008, and served as a center manager for a second location in Iowa for four years during this time.[97] Thayer alleged that Planned Parenthood (operating seventeen clinics in Iowa) engaged in the following schemes: obtaining reimbursement from Medicaid for contraceptives that were prescribed without a necessary examination or were not actually received by patients; obtaining prohibited reimbursements based on federal law for abortion services; filing claims for services that had already been paid for by philanthropic funding; and "upcoding" for services.[98] While the district court dismissed Thayer's claim for failure to meet the Rule 9(b) standard, the Eighth Circuit reversed.[99]

The Eighth Circuit looked to both the allegations that Thayer brought in her claim and the base of knowledge that she acquired as an employee and manager during her lengthy tenure with Planned Parenthood.[100] The court found that Thayer had satisfied the heightened pleading requirement because she identified the names of Planned Parenthood employees who directed her participation in these schemes, the time period during which the schemes were carried out (two years), the actual clinics that

94. *Id*. at 191–92.

95. *See id*. at 191.

96. 765 F.3d 914 (8th Cir. 2014).

97. *Id*. at 915.

98. *Id*. at 915–16. "Upcoding" is a process by which a medical facility "file[s] claims for more expensive services than were actually performed." *Id.* at 916.

99. *Id*. at 915.

100. *See id*. at 917, 919.

participated in the billing schemes, and the methods used to achieve the object of the schemes.[101]

In its discussion, the court noted that the Eighth Circuit does not require a representative sample approach whereby a relator must cite specific instances of fraud within his or her complaint.[102] Instead, the court stated that "to satisfy Rule 9(b)'s particularity requirement, 'the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.'"[103] Given Thayer's long tenure with Planned Parenthood, access to and management of the billing and claims system, and intimate knowledge of the inner workings of the organization, her complaint satisfied the court's standard for particularity.[104]

III. SOLUTIONS TO THE CIRCUIT SPLIT

Pleading fraud with particularity to satisfy Rule 9(b) in relation to the FCA is a subject that has been discussed at length in several law journal articles and the cases themselves.[105] The Supreme Court has denied at least three writs of certiorari from plaintiffs attempting to resolve the confusion regarding what, in fact, is a sufficiently well-pleaded complaint from a *qui tam* relator in the healthcare forum.[106] There are three approaches of note that have been advanced but have not yet been adopted by the courts. The first approach proposes that when two medical professionals disagree on the medically appropriate course of treatment, there cannot be a false claim.[107] Disagreement about care that yields a claim billed to CMS is not a sufficient basis for a *qui tam* suit so long as both courses of treatment are reasonable in relation to what

101. *Id*. at 919.

102. *See id*. at 918 (quoting United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

103. *Id*. at 916–17 (quoting United States *ex rel.* Joshi v. St. Luke's Hospital, Inc., 441 F.3d 552, 556 (8th Cir. 2006)).

104. *See id.* at 917.

105. *See generally Grubbs*, 565 F.3d 180; United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301 (11th Cir. 2002); Bloodgood, *supra* note 28; Smoter, *supra* note 4.

106. Lockman, *supra* note 46, at 1560.

107. Youtt et al., *supra* note 15, at 43.

is in the best interest of the patient.[108] The second approach advances a more moderate pleading standard rather than the inflexible approach applied by courts such as the Eleventh Circuit.[109] The last approach advocates for relators to have the opportunity for discovery prior to advancing their claim, which would allow them to meet the particularity pleading standard.[110]

Recognizing the limitations inherent in these approaches, this Article will propose a solution that diverts from a purely judicial remedy handled strictly within the courts. The proposal includes the usage of administrative government agencies to pursue *qui tam* actions in lieu of the court system, thus requiring a change to the FCA.

A. *Existing Proposed Solutions*

For attorney-scholars Robison, Thomas, and Youtt, one of the problems giving rise to the circuit split relates to claims regarding differing opinions of medical necessity; different circuits appear to have contradictory understandings of when pleadings are sufficient to demonstrate lack of medical necessity.[111] In their view, any claim that does not fall into the category of medical necessity—that is, billing patients for services they do not need—should remain subject to the FCA.[112] However, depending on provider preference, knowledge, and skill, as well as patient autonomy, what is considered medically necessary may vary.[113] For example, two physicians reasonably disagreeing on a course of treatment does not necessarily render that treatment objectively false in violation of the FCA.[114] Courts agree that cases involving claims arising from incorrect or negligent medical acts are not actionable under the FCA.[115] In those instances, a physician who supported a course of treatment that was actually wrong for the patient or carried out the treatment negligently is not violating the FCA so long as the

108. *See id.* at 38 (quoting United States *ex rel.* Hockett v. Columbia/HCA, 498 F. Supp. 2d 25, 65, n. 29 (D.D.C. 2007)).
109. *See* Smoter, *supra* note 4, at 236–37.
110. Bloodgood, *supra* note 28, at 1435–36.
111. *See* Youtt et al., *supra* note 15, at 40.
112. *See id.* at 37.
113. *See id.*
114. *See id.* at 38.
115. *See id.*

provider acted with the reasonable belief that the service was necessary, and not in a manner that amounts to *knowingly* defrauding the government.[116] Thus, as long as a provider does not knowingly defraud the government, the provider does not violate the FCA where reasonable medical minds may differ over the proposed course of treatment.[117]

While that is a well-reasoned suggestion for courts evaluating FCA claims, it only addresses one type of claim under the FCA. The unnecessary treatment or services rendered to a patient is only one of the potential ways a provider could defraud the government. Those types of claims are not part of a greater scheme to defraud the government such as the scheme in *Foglia*, where there was clear abuse of billing for medications.[118] They address only cases where there is a difference of opinion, not a difference in treatment standards, which will not cover the majority of FCA claims.

The second argument that has been advanced is one that is critical of the "representative samples" approach, where a *qui tam* relator provides a CMS claim, or evidence of a CMS claim submission, that the court can use to substantiate the pleadings.[119] Supporters of this approach assert that those relators who file in districts that strictly adhere to the representative sample approach may be deprived of their day in court, as they may not have access to the documents that would provide the representative sample needed for the court to find enough particularity in the complaint.[120] Additionally, for those *qui tam* relators who *do* have evidence on hand, a more flexible approach will not be detrimental to their case.[121] In lieu of the representative samples approach, this theory mimics the approach that the more lenient circuits have adopted to decide whether a *qui tam* complaint meets the Rule 9(b) threshold.[122] Proponent of this approach assert that "[w]hen

116. *See id.*; *see also* Luckey v. Baxter Healthcare Corp., F. Supp. 2d 1034, 1047 (N.D. Ill. 1998) ("The requisite intent [under the FCA] is the knowing presentation of what is known to be false, as opposed to innocent mistakes or mere negligence.").

117. *See* Youtt et al., *supra* note 15, at 38.

118. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153 (3d Cir. 2014).

119. *See* Lockman, *supra*, note 46, at 1559-60.

120. *See* Smoter, *supra* note 4, at 245.

121. *See id.*

122. *Id.* at 259.

evaluating a relator's complaint, every court should consider whether the relator sufficiently alleged: (1) details of the overall fraudulent scheme and (2) indicia of reliability."[123] Because this method has already been adopted by the lenient circuit courts,[124] it does nothing to resolve the existing circuit split.

A final proposed solution—which perhaps may be the least disruptive—is to set a pleading standard that allows for a limited, court-controlled discovery process after the filing of a relator complaint.[125] This solution would allow a limited pretrial discovery period conducted under court-imposed parameters giving relators access to information that could substantiate their claims, and at the same time, control court and defendant costs.[126] Courts could ensure that patient privacy is secure by placing requested records under seal and controlling the number of records reviewed.[127] Although this solution is workable, it would still not provide the government with a robust ability to recoup funds fraudulently paid and it would only offer a solution for a portion of healthcare fraud cases. As such, this author proffers the solution below.

B. *Proposed Solution*

After duly considering the case law and opinions of other authors, this Article suggests that a change in legislation is needed. As proposed, new FCA legislation would allow administrative agencies, such as CMS or healthcare fraud task forces, to work with a *qui tam* relator should the court decide that the relator has not pleaded fraud with sufficient particularity. Under the FCA, the government currently can

> elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty . . . . [T]he person initiating the action shall have the same rights in

123. *Id.*

124. *See id.* at 244.

125. Bloodgood, *supra* note 28, at 1464 ("Provided that judges can be persuaded that the peculiarities of fraud in the health care sector warrant an alternative framework for decisionmaking during the pre-trial phase, particularity discovery designed to help a qui tam plaintiff satisfy a stricter reading of Rule 9(b) is a feasible middle ground to resolve the circuit split.").

126. *Id.* at 1456–58.

127. *See id.*

> such a proceeding as such a person would have had if the action had continued under [section 3730].[128]

While it may seem that the law already covers this proposed solution, there is a complication in the nexus between the FCA and the *qui tam* statute—administrative agencies cannot enforce the FCA:

> The FCA is a *litigation* statute, which is distinct from the other fraud and abuse statutes such as the Civil Monetary Penalties Law in two important ways: (1) FCA cases will always be prosecuted in federal court, where the express language of a statute will be strictly construed in accordance with the rules of civil procedure; and (2) unlike the four other major Medicare fraud and abuse statutes (Stark Law, the Anti-Kickback Statute, Civil Monetary Penalties Law (CMPL), and the Exclusionary Statute), Congress did not "enable" the so-called alphabet agencies (e.g., the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), DOJ, and the OIG) to adopt *U.S. Code of Federal Regulations* concerning the FCA . . . . Interpretation of the elements of the FCA, if any, must come from the courts, or amendments to the Act by Congress.[129]

Thus, even though under section 3730 relators should be able to pursue their claims in the administrative arena, the statute under which they are bringing their claims prohibits them from doing so by making the judicial system the exclusive means of resolving such disputes.

Amending the FCA would be a great departure from the current state of the law. However, given the rampant amount of fraud throughout our healthcare system, it is imperative that tax dollars not go to waste in paying providers for fraudulent CMS claims. While the proposed solution may invite additional claims, it would allow administrative agencies to pursue such suits, and the recoupment of funds by the government cannot be overlooked. This Article's proposed solution would work well in cases such as *Clausen* and *Nathan* where the claims likely would have survived

128. 31 U.S.C. § 3730 (2012).

129. Merritt & Rose, *supra* note 3, at 63.

in a more lenient circuit and potentially resulted in millions of dollars returned to the government.

While CMS and other administrative agencies have limited resources in their ability to *find* fraud, their discretion in pursuing actions against those committing fraud would be much more robust under the proposed solution. By allowing relators to bring their concerns to the courts, or in the alternative, an administrative agency that is designed to safeguard the integrity of our healthcare system, taxpayers and patients both stand to benefit.

CONCLUSION

Unfortunately, healthcare fraud is rampant throughout the United States healthcare system. Hospitals, pharmaceutical companies, medical supply companies, medical technology companies, and even doctors and nurses have a valid interest in maintaining their revenue and profit streams. Nevertheless, companies and providers that cross the line from legitimate care to fraudulent billing should be held accountable for their actions. As the Supreme Court has declined to resolve the discord among the circuits concerning the appropriate pleading standard for alleged healthcare fraud under the FCA, a change is necessary to ensure that relators have alternative means to rectify the injustice that they witness in the system.

An extrajudicial process would provide such an alternative avenue for redress in the event that a court declines to review a relator's claim for failure to plead with particularity pursuant to Rule 9(b). This would maximize recoupment of government funds thus benefitting all interested parties.