COMMENT

PARTICULARITY DISCOVERY IN QUI TAM ACTIONS: A MIDDLE GROUND APPROACH TO PLEADING FRAUD IN THE HEALTH CARE SECTOR

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Health care fraud in the United States is policed in a unique enforcement landscape. The False Claims Act, one major piece of that landscape, grants private citizen whistleblowers the ability to sue on behalf of the government to remedy fraud. Plaintiffs in these qui tam actions are subject to procedural requirements characteristic of any federal civil fraud lawsuit, including the rigid pleading standard of Federal Rule of Civil Procedure 9(b). The Supreme Court has repeatedly declined to resolve a circuit split as to the precise particularity of the claim required under the rule; some circuits require a representative sample of false claims for a complaint to survive a motion to dismiss, while others relax the requirement and hold that general allegations supporting a strong inference of fraud will suffice. Ample literature exists in support of the latter, more lenient approach to evaluating a complaint, but little, if any, explores the possibility that a resolution outside the existing dichotomy could optimize results in the health care fraud qui tam context.

This Comment explores one such solution: pre-merits "particularity discovery" designed to allow a qui tam plaintiff to plead a representative sample of false claims in her complaint. By exploring the merits and shortfalls of the particularity requirement as it applies to False Claims Act qui tam plaintiffs, this Comment first

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suggests that health care fraud cases may warrant special considerations at the pleadings stage. Then, this Comment uses examples of pre-merits discovery in other contexts, namely class certification and jurisdictional disputes, to illustrate relevant, albeit imperfect, blueprints for a particularity discovery procedure. Finally, this Comment proposes a framework for ruling on a qui tam plaintiff's motion for particularity discovery that could operate within the district court's existing discretion. Because of the importance of remedying health care fraud, this middle ground could provide opportunities for plaintiffs to bring meritorious claims to court without sacrificing the benefits and purpose of the particularity requirement. This Comment will hopefully encourage courts to consider adopting the more rigid representative sample standard for particularity pleading, recognizing that the addition of targeted particularity discovery to the procedure creates a viable middle ground between the two existing approaches to pleading.

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INTRODUCTION

Policing fraud in the health care industry should be a goal that unites the government and individual citizens. When individuals and organizations engage in fraudulent practices, consumers, patients, and the government bear the financial cost,[1] and the integrity of clinical decisionmaking and patient wellness[2] may be threatened. New technologies and the massive increase in the volume of data in the health care industry make for an increasingly complex enforcement landscape.[3] The False Claims Act (FCA) provides one important vehicle for the government and private citizens to combat fraud.

Despite the desirability of detecting and remedying fraud, private citizens, called "relators," who sue under the FCA's qui tam provision without the help of the government, must overcome a number of rigid procedural hurdles. Not only must a relator satisfactorily plead with plausibility under Rule 8's jurisprudential standard,[4] but she must also state her allegations with sufficient specificity, or "particularity," as required by Rule 9(b).[5] Currently, there is a circuit split regarding the proper stringency a court should use in assessing the sufficiency of a plaintiff's FCA complaint under Rule 9(b). One approach requires that a plaintiff plead a representative sample of fraudulent claims, including identifying at least one claim by time, place, and persons involved. The other allows a plaintiff to satisfy her pleading burden with more general allegations that support a strong inference of fraudulent activity. The Supreme Court has declined to resolve the existing split multiple times, but an increasing number of courts favor the more relaxed "strong inference" standard. In this Comment, I challenge the potential for either standard to produce the optimal result in health care fraud cases.

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1 *See* Press Release, U.S. Dep't of Justice, Fact Sheet: The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud (Feb. 26, 2016), https://www.justice.gov/opa/pr/fact-sheet-health-care-fraud-and-abuse-control-program-protects-conusmers-and-taxpayers [https://perma.cc/BD9V-56M5] (detailing the Justice Department's successes at recovering government payments of American tax dollars that were incurred by fraudulent practices).

2 *See Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, CTRS. FOR MEDICARE & MEDICAID SERVS. 3 (Oct. 2016), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf [https://perma.cc/EPA2-N6PP] (stating that abuse of federal health care programs puts "beneficiaries' health and welfare at risk").

3 *See* Basel Kayyali, David Knott & Steve Van Kuiken, *The Big-Data Revolution in US Health Care: Accelerating Value and Innovation*, MCKINSEY & CO. (Apr. 2013), http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/the-big-data-revolution-in-us-health-care [https://perma.cc/Q9T6-JWPA] (describing a dramatic increase in data in the health care field).

4 *See* FED. R. CIV. P. 8(a)(2) (providing that a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief"); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (clarifying that a claim for relief must be "plausible on its face").

5 *See* FED. R. CIV. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.").

While a qui tam relator may possess credible information of a fraudulent scheme, that information alone may not be sufficient to satisfy a strict pleading requirement. Discovery may provide an important cure. Regardless, the allure of assisting relators must be balanced against the principal purposes of Rule 9(b): providing notice to defendants and preventing frivolous suits. Here, I argue that the solution is a combination of the representative sample standard with limited particularity discovery[6]—discovery designed to help a relator state her claim with particularity. This framework is an optimal middle ground between the existing alternatives. It provides the procedural value of the representative sample approach—namely, that a pleading with mere general allegations will not survive dismissal—with an adequate opportunity for some relators to satisfy it.

In Part I, I provide background information on the FCA, qui tam procedure, and the Rule 9(b) inquiry. In Part II, I explore the circuit split on the particularity requirement as it relates to notice, frivolous suits, informational disparities, and the policy goals of the FCA. Finally, in Part III, I outline the procedure a court may use during the pleadings stage of an FCA suit, including a proposed standard by which the court may decide on a relator's motion for particularity discovery.

I. BACKGROUND

A. *The False Claims Act*

The False Claims Act[7] is the primary tool that the government uses to protect taxpayers from fraud. Known to some as the "Informer's Law," it was enacted during the Civil War to combat widespread fraud by government contractors.[8] Such contractors often supplied the Union Army with faulty weapons, spoiled food, and sickly mules.[9] This behavior, President Abraham Lincoln and Congress decided, was sufficiently unpatriotic to warrant both civil and criminal penalties.[10]

Under the FCA, any person who knowingly presents, makes, or uses a materially false or fraudulent claim, or who delivers or certifies a materially

6 As discussed below, some literature refers to pre-merits discovery designed to allow a plaintiff to survive a motion to dismiss as "plausibility discovery." Because this Comment focuses on pre-merits discovery to allow a plaintiff to satisfy a more stringent standard under Rule 9(b)'s particularity requirement, I use the phrase "particularity discovery."

7 31 U.S.C. §§ 3729–32 (2012).

8 United States v. Bornstein, 423 U.S. 303, 309 (1976).

9 David L. Haron, Mercedes Varasteh Dordeski & Larry D. Lahman, *Bad Mules: A Primer on the Federal and Michigan False Claims Acts*, 88 MICH. B.J., Nov. 2009, at 22, 22.

10 *See id.* (quoting President Lincoln saying, "Worse than traitors in arms are the men who pretend loyalty to the flag, [and] feast and fatten on the misfortunes of the nation . . . .").

false record or statement to the federal government, can be held liable in a civil action.[11] The statute's legislative history and the sentiment surrounding its passage support the notion that the law was intended to apply broadly.[12]

By providing a mechanism to hold defendants accountable for money wrongfully taken from the government, the FCA helps return billions of dollars each year to programs funded by taxpayer dollars.[13] Health care fraud cases form a significant portion of the FCA enforcement landscape. Indeed, over half of the $3.5 billion recovered under the FCA in 2015 was derived from health care fraud claims.[14]

B. *Mechanics of a False Claims Act Qui Tam Suit*

In setting and executing investigative priorities, the Attorney General decides whether to bring a civil action against a person for a False Claims Act violation.[15] However, the FCA also grants standing to private citizens to sue on behalf of themselves and the United States government.[16] Qui tam actions are colloquially referred to as "whistleblower" suits because the relator[17] is often a current or former employee or affiliate of a defendant organization. When such a relator brings an FCA suit, she is effectively "blowing the whistle" on the defendant's illegal behavior.

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11 31 U.S.C. § 3729(a)(1) (2012). Such behavior may also give rise to criminal charges, but that is beyond the scope of this Comment. *See* 18 U.S.C. § 287 (2012) (providing that making a "false, fictitious, or fraudulent" claim to the government may result in imprisonment of up to five years).

12 *See* CONG. GLOBE, 37th Cong., 3rd Sess. 956 (1863) (statement of Sen. Davis) (arguing that because there are no individuals "who deserve more certain and speedy punishment than . . . [those] who have failed to perform their duties in the execution of contracts made with the Government," the proposed jurisdiction of the FCA should be expanded from military courts to include civil courts); Alan Levins & Alison Cubre, *Pleading a Claim Under the False Claims Act*, ABA (May 23, 2014), http://apps.americanbar.org/litigation/committees/trialpractice/articles/spring2014-0414-pleading-claim-under-false-claims-act.html [https://perma.cc/29SA-6DP3] (noting that subsequent amendments to the FCA have expanded its scope).

13 *See Justice Department Recovers over $3.5 Billion from False Claims Act Cases in Fiscal Year 2015*, U.S. DEP'T JUST. (Dec. 3, 2015), https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015 [https://perma.cc/DL5B-LJEV] (quantifying taxpayer recoveries from FCA claims in one recent year).

14 *See id.* (noting that of the $3.5 billion recovered from FCA cases in 2015, "$1.9 billion came from companies and individuals in the health care industry").

15 31 U.S.C. § 3730(a) (2012).

16 *Id.* § 3730(b). The term "qui tam" comes from the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning "who as well for the king as for himself sues in this matter." *Qui Tam Action*, BLACK'S LAW DICTIONARY (10th ed. 2014).

17 A "relator" is an informer who furnishes information to the government. *Relator*, BLACK'S LAW DICTIONARY (10th ed. 2014).

FCA qui tam complaints are filed in camera[18] and remain under seal for at least sixty days.[19] While the complaint is under seal, the government has an opportunity to review it and to determine the extent of its involvement in the case. It may decide to prosecute the case, move to dismiss, settle the case, or decline to intervene altogether.[20] The qui tam plaintiff's potential recovery will depend on this decision.[21] Eventually, if the court does not dismiss and the parties do not settle, the court lifts the seal and the case proceeds as an ordinary civil case under the Federal Rules of Civil Procedure. This Comment will focus principally on cases in which the Department of Justice declines to intervene.

Once the court lifts the seal, the complaint is served on the defendant, who may then move to dismiss in accordance with ordinary federal civil practice.[22] To survive the defendant's motion, the plaintiff's complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief"[23] that is "plausible on its face."[24] Claims of fraud require a more nuanced level of pleading. Under Rule 9(b), a plaintiff alleging fraud must "state with particularity the circumstances constituting fraud."[25] The purpose of this particularity requirement is to place the defendant on notice of the allegations and to protect the defendant against conclusory and unfounded claims of fraud.[26] There is no dispute that Rule 9(b) applies to qui tam relators.[27]

Notably, the circuits are divided as to what constitutes a sufficiently particular complaint in the FCA context. One approach requires that the plaintiff's complaint identify at least one false claim by time, place, content

18 "In camera" means in private chambers, or in a courtroom without public access. *In Camera*, BLACK'S LAW DICTIONARY (10th ed. 2014).

19 31 U.S.C. § 3730(b)(2). On motion, the government can ask the court to delay the unsealing for good cause. *Id.* § 3730(b)(3).

20 *See id.* § 3730(c) (listing these options).

21 Subject to certain conditions that are beyond the scope of this Comment, relators are entitled to receive fifteen to twenty-five percent of the proceeds of the action or settlement of the claim. *Id.* § 3730(d).

22 *See id.* § 3731 (outlining special procedures in false claims actions but indicating no unique dismissal features); FED. R. CIV. P. 12(b)(6) (stating that a defendant may assert by motion the defense of "failure to state a claim upon which relief can be granted").

23 FED. R. CIV. P. 8(a)(2).

24 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). The *Twombly* plausibility standard was further clarified in *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009), in which the Supreme Court instructed courts not to grant conclusory allegations the assumption of truth.

25 FED. R. CIV. P. 9(b).

26 *See* United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1310 (11th Cir. 2002) ("The particularity rule serves an important purpose in fraud actions by alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral and fraudulent behavior." (internal quotation marks omitted) (quoting Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001))).

27 2 JOHN T. BOESE, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS § 5.04[A][2], at 5-48 (3d ed. 2010).

of the action, and names of actors.[28] Defendants favor this "representative sample" approach because it places the onus on the private citizen relator to present specific factual details of the alleged fraudulent activity. This is often a heavy burden for a relator who, absent ordinary civil discovery, lacks the investigative resources of the government.

Under this standard, private plaintiffs may face difficulties pleading a representative sample of facts in a way that ensures the claim is not conclusory—in other words, that it does not require the court to make any logical leaps from the facts to find that the claim for fraud is plausible.[29] For example, in *United States ex rel. Nathan v. Takeda Pharmaceuticals*, the complaint alleged that ninety-eight non-reimbursable prescriptions for sixty milligrams of a drug called Kapidex (samples of which Takeda provided to doctors) were submitted to the Centers for Medicare & Medicaid Services for reimbursement.[30] The sixty milligram dose for Kapidex is not eligible for federal reimbursement for certain uses that are off-label.[31] The relator, a sales manager for Takeda, also alleged two additional facts: the names of sixteen doctors who wrote prescriptions for Kapidex (at unknown dosages) and submitted them for reimbursement, and the fact that ninety-three percent of all prescriptions for Kapidex are for a sixty milligram dose.[32] Nonetheless, the court dismissed the claim on Takeda's Rule 12(b)(6) motion. Allowing the case to proceed would have required the court to speculate that the specific Kapidex prescriptions of the sixteen identified doctors were in fact for sixty milligrams; such a logical leap indicated a lack of plausibility.[33] The *Takeda* case illustrates that even a relator with specific information suggesting a strong possibility of fraud will struggle under the strict representative sample pleading standard given the interrelationship among Rule 8(a), Rule 9(b), and the *Twombly–Iqbal* plausibility standard.

The government's amicus curiae brief[34] in *Takeda* asserted that a "strong inference" approach to pleading an FCA violation is preferable to a heightened

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28 *See, e.g.*, United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 455-56 (4th Cir. 2013) (outlining this requirement).

29 *See* Brief for the United States as Amicus Curiae at 12, United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 134 S. Ct. 1759 (2014) (No. 12-1349) [hereinafter Brief for United States—Takeda] (articulating the complicated and varied approaches used to assess the interrelationship between the particularity of the pleaded facts and the plausibility of the claim).

30 *Takeda*, 707 F.3d at 459.

31 *See id.* at 454 (explaining that the FDA had approved a sixty milligram dose of Kapidex only for the treatment of erosive esophagitis, making the prescription of a sixty milligram dose for the treatment of other conditions off-label).

32 *Id.* at 459.

33 *Id.*

34 The United States declined to intervene in the relator's suit against Takeda, and thus submitted an amicus curiae brief. Government's Notice of Election to Decline Intervention, United

requirement,[35] and, in 2014, the Third Circuit joined several other circuits in adopting that more relaxed pleading standard.[36] In courts that have adopted this approach, a plaintiff can survive a motion to dismiss by pleading facts that support a strong inference that the defendant violated the FCA.[37] A general description of the alleged fraudulent scheme combined with such reliable indicia of fraudulent activity will suffice.[38]

In *United States ex rel. Foglia v. Renal Ventures Management*, the United States decided not to intervene in the relator's lawsuit.[39] The complaint alleged that defendant Renal, a dialysis care services company, had falsely certified to the government that it was in compliance with certain quality of care regulations and had submitted false claims regarding the use of and reimbursement for the drug Zemplar.[40] Specifically, Foglia alleged that Renal's inventory logs indicated that the company used a maximum of thirty-four vials of Zemplar per day, but that its patient logs indicated that fifty vials would have been necessary if such vials were only used once.[41] The court reasoned that financial motivation existed for Renal to charge the government as if it were "using vials of Zemplar in the single use fashion while actually harvesting and using 'extra' Zemplar from the vials."[42] While this was not the only possible explanation of the facts, the court reversed the dismissal of the case, noting that the hypothesis presented in the complaint was sufficient to give Renal notice, especially since only Renal had evidence in its possession to prove or disprove the claim.[43]

The *Takeda* and *Foglia* cases illustrate different treatment of Rule 9(b)'s particularity standard and different views of how health care fraud allegations fit within FCA motion to dismiss framework. While the Supreme Court has yet to grant certiorari to resolve the circuit split,[44] circuits now tend to apply

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States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., No. 1:09-cv-01086-AJT-JFA (E.D. Va. Dec. 13, 2010), ECF No. 36.

35 *See* Brief for United States—Takeda, *supra* note 29, at 11-12 (discussing the circuit courts that do not require a plaintiff to plead the details of a specific false claim).

36 *See* United States *ex rel.* Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156 (3d Cir. 2014) (citing approvingly the approach of the Fifth and Ninth Circuits).

37 *See id.* at 156-57 (citing similar holdings in First, Fifth, and Ninth Circuit decisions).

38 *See id*. at 157-58 (noting that to satisfy the standards of Rule 9(b), the plaintiff must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" (internal quotation marks omitted) (quoting United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009))).

39 *Id.* at 155.

40 *Id.* at 158.

41 *Id.*

42 *Id.*

43 *Id.*

44 *See* George B. Breen et al., *Supreme Court Declines to Opine on Circuit Split over Rule 9(b) Pleading Requirements for FCA Claims*, HEALTH CARE & LIFE SCI. CLIENT ALERT (Epstein Becker & Green, P.C., New York, N.Y.), June 2014, at 1, http://www.ebglaw.com/content/uploads/2014/09/

a more relaxed understanding of the particularity requirement.[45] This Comment will focus on the reasons why, when combined with the use of particularity discovery, adhering to a strict reading of Rule 9(b) provides the proper balance between defendant protection and government enforcement.

II. ANALYSIS OF THE EXISTING APPROACHES

Both courts and scholars have identified strengths and weaknesses of the representative sample and strong inference approaches. A survey of the existing law and literature is appropriate to understand the distinctive procedural and substantive elements of health care fraud cases that warrant special consideration and frame the existing debate.

Advocates of the strict representative sample approach articulate a number of rationales: to give sufficient notice to the defendant of the allegations; to prevent frivolous lawsuits; to eliminate fraud actions in which all facts are learned in discovery; to protect the defendant from reputational harm; and to prevent plaintiffs from imposing costs on the court, the defendant, and the government without a factual basis.[46] Critics of the representative sample approach focus on the difficulty of surviving a motion to dismiss under that standard. As the *Foglia* court described, the representative sample approach appears to be "one small step shy of requiring production of actual documentation with the complaint."[47] The strong inference standard's lenient pleading approach accommodates a relator's informational disparity against the typical corporate defendant, arguably better supporting the goals of the FCA.

The concerns raised by scholars on both sides explain why Rule 9(b) requires some form of a heightened pleading standard. I focus on three considerations that inform the particularity discovery proposal in the health care fraud context: achieving the proper degree of notice to the defendant; balancing the need to prevent frivolous suits with plaintiffs' access to the

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HCLS-Client-Alert_Supreme-Court-Declines-to-Opine-on-Circuit-Split-Over-Rule9b.pdf [https://perma.cc/FR5D-Q9TS] (reporting that the Supreme Court declined to review the decision in *Takeda* in early 2014). Last summer, the Court denied certiorari on another case on this subject. *See* AT&T, Inc. v. United States *ex rel.* Heath, 136 S. Ct. 2505 (2016).

45 *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) ("A strict interpretation of Rule 9(b)—requiring a relator's complaint to identify representative samples of the allegedly false claims—is falling out of fashion across the circuits."); Sara A. Smoter, Note, *Relaxing Rule 9(b): Why False Claims Act Relators Should Be Held to a Flexible Pleading Standard*, 66 CASE W. RES. L. REV. 235, 242-44 (2015) (noting that a minority of circuits continue to rigidly apply Rule 9(b)). That the Supreme Court has again declined certiorari on the issue suggests that the trend toward relaxation will continue.

46 2 BOESE, *supra* note 27, § 5.04.

47 754 F.3d at 156 (quoting United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

courts; and addressing the informational disparity. I conclude with reference to the goals of health care fraud enforcement and the potential impact of the particularity requirement in realizing those goals.

A. *Notice to Defendant*

A fundamental principle of procedural law is that a defendant must be given sufficient notice to defend the charges against him.[48] In FCA cases, Rule 9(b)'s particularity requirement "demands a higher degree of notice than that required for other [non-fraud] claims"[49] for a number of reasons. The Rule is designed to "enable the defendant to respond *specifically* and *quickly* to the potentially damaging allegations."[50]

Specificity in a health care fraud complaint is indispensable. In health care fraud cases, the financial stake for any given defendant is extraordinarily high: the statutory penalty for FCA violations ranges from $5,500 to $10,000 *per claim* (as adjusted by law for inflation), plus treble damages.[51] Moreover, a typical health care fraud case rarely involves a single false claim; rather, common fraudulent conduct involves recordkeeping practices like up-coding, bundling payments, inflating cost reports, or false certification that services were completed in the manner making them eligible for reimbursement.[52] Such practices can involve dozens, hundreds, or even thousands of individually recoverable claims, *each* of which carries its own statutory penalty. FCA lawsuits indeed recover billions of dollars per year.[53] The specificity demanded by Rule 9(b) is clearly necessary for proper notice.

Rule 9(b)'s requirement also demands that a defendant be allowed to respond expediently to allegations of fraud. When the government disburses payments for health care claims that turn out to be fraudulent, taxpayer dollars are wasted on illegal payments.[54] This magnifies defendants' potential reputational harm as compared to that in other fraud lawsuits, where, for example, one corporation may allege fraud by another in an action not

48 *See* Walling v. Beverly Enters., 476 F.2d 393, 397 (9th Cir. 1973) ("[Rule 9(b)] only requires the identification of the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations.").

49 United States *ex rel.* Costner v. United States, 317 F.3d 883, 888 (8th Cir. 2003).

50 *Id.* (emphasis added).

51 31 U.S.C. § 3729(a)(1) (2012).

52 For a more detailed description of the typical ways companies and individuals in the health care sector defraud the government, see Pietragallo Gordon Alfano Bosick & Raspanti, LLP, *Health Care Fraud and False Claims*, FALSE CLAIMS ACT RESOURCE CTR., http://www.falseclaimsact.com/common-types-of-fraud/health-care-fraud [https://perma.cc/LQ32-5LTN].

53 *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FISCAL YEAR 2016 (2017).

54 As a jurisdictional matter, the FCA prohibits only claims that are submitted to the government for payment such that taxpayer dollars are at stake. *See* 31 U.S.C. § 3729 (a)(1).

implicating tax dollars vis-à-vis the government. Fraud on the government naturally requires defendants to defend against both the lawsuit itself and potential bad publicity. Because an FCA defendant stands to suffer from public disfavor, heightened notice consistent with the intent of Rule 9(b) is necessary so that the defendant can respond quickly and efficiently to the allegations.

B. *Frivolous Suits and Access to the Courts*

In light of the threat that an FCA qui tam suit may pose to a defendant, frivolous suits aimed to force a settlement are a natural worry. The Rules Committee addressed the fear of defamatory fraud allegations based in scant facts in the very construction of Rule 9(b);[55] given the clear intent of the rule, access to full discovery without any meaningful analysis of the sufficiency of a complaint is clearly undesirable. Defendants' worries must be considered alongside plaintiffs' ability to access the remedial power of the court through discovery.

In *Twombly* and *Iqbal*, the Supreme Court balanced similar considerations to those at play in the Rule 9(b) split.[56] Plausibility pleading, as conceived in the *Twombly* and *Iqbal* decisions, serves as a middle ground between possibility and probability.[57] This pleading framework has negatively affected plaintiffs as they now survive the motion to dismiss stage and move on to discovery less often.[58] However, the tension remains between "spar[ing]" defendants from "costly and complex discovery" and dismissing potentially meritorious suits before the plaintiff has an adequate opportunity to investigate.[59] Indeed, as the Fifth Circuit has described (albeit, in adopting a more lenient approach to pleading), "Rule 9(b)'s ultimate meaning is context-specific,"[60] and a complaint's ability to satisfy the particularity requirement may vary depending on the nature and complexity of the case.[61] Making this analysis even harder, facts that support a claim that is "plausible on its face"[62] in one context may be wholly insufficient in another. Therefore, the frivolity

55 *See* United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1310 (11th Cir. 2002) (expressing disfavor toward allegations of fraud based on spurious factual reasoning).

56 *See* Ashcroft v. Iqbal, 556 U.S. 662, 684-85 (2009) (examining the connection between the potential invasiveness of discovery and the motion to dismiss inquiry); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 569 n.14 (2007) (distinguishing between a claim's overall plausibility and the particularization of the complaint's allegations).

57 *Iqbal*, 556 U.S. at 678.

58 *See generally* Jonah B. Gelbach, Note, *Locking the Doors to Discovery? Assessing the Effects of* Twombly *and* Iqbal *on Access to Discovery*, 121 YALE. L.J. 2270 (2012).

59 Suzette M. Malveaux, *Front Loading and Heavy Lifting: How Pre-Dismissal Discovery Can Address the Detrimental Effect of* Iqbal *on Civil Rights Cases*, 14 LEWIS & CLARK L. REV. 65, 68 (2010).

60 United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 188 (5th Cir. 2009).

61 2 BOESE, *supra* note 27, § 5.04[B][1], at 5-57.

62 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

of a complaint, and thus the desirability of a complainant's access to the court, is difficult to predict in the abstract.

This difficulty naturally engenders fear that private citizens may take advantage of publicly available information, including pleadings and briefs in other cases, to string together complaints that are only facially plausible and to force defendants with deep pockets to settle. However, strike suits are less of a concern in FCA qui tam cases than in other contexts for a number of procedural and practical reasons.

While the text of the FCA does not say so, it is widely accepted that qui tam relators may not proceed pro se.[63] Because the claim in an FCA suit ultimately belongs to the United States, the relator is not the true party in interest.[64] Such "ownership" of the claim remains even if the government declines to intervene in the suit.[65] In this regard, the case does not "belong to" the relator.[66] She may not represent herself in a qui tam action because the case is not truly her own,[67] and she must first find a lawyer willing to represent her. Because members of the qui tam bar and firms who represent relators often specialize in whistleblower suits and have experience identifying meritorious allegations, this creates a built-in screening process for frivolous suits before a relator is able to file a complaint.

Further, the original source rule limits a relator's ability to rely on public information to construct a qui tam complaint that will survive a motion to dismiss. The FCA provides that a whistleblower "who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing" is an "'original source.'"[68] Once the original source of information brings forth such information, the only remaining party that may intervene is the United States.[69] A circuit split exists as to whether a second relator's action is barred if the first relator failed to plead the same

63 *See Whistleblowers Not Permitted to Litigate Cases Under False Claims Act Without Counsel*, BERGER & MONTAGUE, P.C., http://www.bergermontague.com/practice-areas/whistleblowers,-qui-tam-false-claims-act/whistleblowers,-qui-tam-false-claims-act-legal-blog/whistleblowers-not-permitted-to-litigate-cases-under-false-claims-act-without-counsel [https://perma.cc/78JU-L4P5] (providing an overview of the law and policy considerations that support this rule).

64 United States *ex rel.* Mergent Servs. v. Flaherty, 540 F.3d 89, 93 (2d Cir. 2008).

65 *See id*. (discussing ownership of a claim without distinguishing among cases based on the United States' choice to intervene).

66 *Id*.

67 *See* 28 U.S.C. § 1654 (2012) ("[T]he parties may plead and conduct *their own* cases personally . . . ." (emphasis added)). *But see* Vt. Agency of Nat. Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 773-74 (2000) (acknowledging that "[t]he FCA can reasonably be regarded as effecting a partial assignment of the Government's damages claim").

68 31 U.S.C. § 3730(e)(4)(B) (2012).

69 *Id*. § 3730(b)(5).

facts with enough particularity to satisfy Rule 9(b).[70] As a practical matter, once a relator is deemed to be an original source, all other suits based on the same facts are barred. This rule shields the defendant from facing numerous lawsuits based on the same publicly available information. The resolution of the circuit split on the connection between the Rule 9(b) pleading standard and the first-to-file bar will determine the degree of such potential protection.[71] Nonetheless, the original source rule supports the notion that strike suits will not necessarily follow from using anything other than a strict approach to pleading with particularity.

Similarly, the FCA's statute of limitations indicates Congress's intent to discourage plaintiffs from sitting on their claims to maximize their potential recovery.[72] By linking the expiration of the limitations period to the time when facts material to the claim should have been known to the government,[73] the statute demands expediency in fraud recovery. The circuits are also split as to whether the statute of limitations provision of § 3731 also applies to relators.[74] However, courts generally give effect to statutory goals in interpreting the ambiguity of the statute of limitations language,[75] indicating their willingness to weed out claimants with frivolous purposes.

Finally, the government's failure to intervene should not be indicative of the sufficiency of the allegations at the motion to dismiss stage. Indeed, in determining when to bring suit, the government considers numerous factors that speak to the government's enforcement priorities and not to the adequacy of a specific complaint.[76] For example, the government factors into its decision

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70 *Compare* Walburn v. Lockheed Martin Corp., 431 F.3d 966, 972 (6th Cir. 2005) (requiring a relator to satisfy Rule 9(b) to be considered an original source), *with* United States *ex rel.* Batiste v. SLM Corp., 659 F.3d 1204, 1210 (D.C. Cir. 2011) (not requiring the initial relator to survive a Rule 9(b) challenge before imposing a bar on suits by other relators).

71 *See* Karin Lee, Note, *Linking Rule 9(b) Pleading and the First-to-File Rule to Advance the Goals of the False Claims Act*, 108 NW. U. L. REV. 1423, 1427 (2014) ("[T]he more claims that are allowed to survive 9(b), the bigger the pool of claims defendants can draw from to bar later-filed claims.").

72 *See* United States *ex rel.* Sanders v. N. Am. Bus Indus., Inc., 546 F.3d 288, 295 (4th Cir. 2008) (finding that a reading of the statute of limitations in the FCA that incentivizes relators to sit on their claims before filing to increase their own potential recovery is inconsistent with congressional intent).

73 *See* 31 U.S.C. § 3731(b)(2) (2012) (stating that an action may not be brought "more than 3 years after the date when facts material to the right of action are known or reasonably should have been known").

74 For an in-depth analysis of the varying interpretations of the text of the FCA statute of limitations, see generally Stephen S. Stallings & Lauren E. Caravello, *Wait Not, Want Not: The Importance of the Statute of Limitations in* Qui Tam *False Claims Act Cases*, 7 PITT. J. ENVTL. & PUB. HEALTH L. 245 (2013).

75 *See, e.g.*, *Sanders*, 546 F.3d at 295-96 (finding that a majority of circuits hold that the FCA's statute of limitations is extended only in cases where the United States is a party).

76 *See generally* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., WORK PLAN: FISCAL YEAR 2016 (2016) (describing the governments's enforcement activities). In addition, one might look to certain government actions as indicators of the government's position

the influence of an alleged fraudulent activity on health care access and quality, patient autonomy, and clinical decisionmaking.[77] Moreover, the government's failure to intervene could simply be a symptom of too many suits and not enough resources. This is especially likely in the health care sector, where fraud abounds.[78]

In sum, the peculiarities of health care fraud cases add color to the traditional conflict between protecting defendants from frivolous suits and giving plaintiffs sufficient access to court. In subsection III.B.1, I address how the court should weigh such considerations when determining whether a case warrants particularity discovery.

C. *The Relator's Informational Disparity*

Congress's choice to grant standing to private citizens in FCA matters suggests that the proper approach to assessing the sufficiency of a complaint may depend on the relator's practical ability to plead with sufficient particularity.[79] When the government declines to intervene and qui tam plaintiffs are left to their own investigatory resources, the informational disparity they face warrants taking a critical look at the court's dismissal analysis under Rule 9(b). Indeed, the representative sample approach is "[r]iddled with [e]xceptions"[80] in health care fraud cases across the circuits, suggesting that certain contexts and certain kinds of relators warrant special consideration by the court.

For example, at least one court has granted a whistleblower leniency under the representative sample approach when the relator was able to plead the reasons why she believed the defendant submitted false claims.[81] In *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, the relator was a

on a case or its merits, such as the time it took to make the decision not to intervene, or the subject matter of its briefings to the court as a party in interest. However, it is unlikely that such indicators are proxies that tell the whole story about how the government views a case.

77 Some experts refer to these considerations as "prudential factors." Arnold & Porter LLP, Connecting Through mHealth Solutions: Fraud & Abuse Implications for Patient, Physician, ACO, Hospital and Industry Partner Engagement Models (June 10, 2015), http://files.arnoldporter.com/ebookconnectingthroughmhealthsolutions.pdf [https://perma.cc/AMV2-255N].

78 At the close of the last fiscal year, the Department of Justice had over 1400 civil health care fraud matters pending. U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF JUSTICE, *supra* note 53, at 71.

79 *But see* 2 BOESE, *supra* note 27, § 5.04[A][2] ("Although a few early cases allowed some leniency in *qui tam* complaints, because the relator had no investigatory power, that exception has been discredited."); Smoter, *supra* note 45, at 255 (arguing that a relator's insider status should not affect the standard a court uses to assess the sufficiency of her complaint).

80 Fisher K. Law, Note, *Proper Pleading or Premature Proof? Rule 9(b)'s Particularity Requirement and the False Claims Act*, 49 GA. L. REV. 855, 871 (2015).

81 United States *ex rel.* Walker v. R&F Props. of Lake Cty., Inc., 433 F.3d 1349, 1360 (11th Cir. 2005).

nurse practitioner (NP) employed by the defendant family medical practice.[82] The standard practice for billing federal payers for NP services involves one of two alternatives: either the NP directly bills with a certification that her services were "incident to the service of a physician,"[83] or she bills through a particular doctor.[84] The former requires the NP to use her own Unique Provider Identification Number (UPIN); the latter requires the use of the physician's UPIN and an implied certification that the services were performed under that physician's supervision.[85] The complaint alleged that the relator was never given her own UPIN number (thus eliminating her ability to bill under the first alternative), and that, each day, she received instructions as to which doctor's UPIN to use for billing, even if she was not actually being supervised by that doctor.[86] She also alleged that billing within the practice had never occurred in any other manner.[87] Even without a literal representative "sample," the court found the complaint to be sufficient because the relator was able to plead beyond mere speculation of fraudulent activity based on her experience within the practice.[88]

Even the Sixth Circuit, which has yet to relax the stringent representative sample approach, has left open the possibility that knowledge akin to the relator's in *Walker* could provide the basis for an adequate pleading. In *Chesbrough v. VPA, P.C.*, the relators were two doctor-owners of a radiology services business that contracted with the defendant, VPA, to interpret radiological images.[89] Based on their difficulty reading the defendant's scans, the relators concluded and alleged that VPA must have billed the government for tests performed with improper equipment, by personnel with inadequate training, or for clinical indications that were not properly documented.[90] Despite such detailed information and medical expertise, including references to specific scans, the court affirmed the dismissal of the relators' claim because it failed to satisfy Rule 9(b).[91] The relators' personal knowledge was an important consideration for the court but insufficient in this case: their knowledge related to a general scheme, not to billing procedures or the nature of VPA's government contracts.[92] The latter kind of personal knowledge, the

82 *Id.* at 1353.
83 42 C.F.R. § 410.26(b) (2015).
84 *Walker*, 433 F.3d at 1352-53.
85 *Id.* at 1353.
86 *Id.* at 1360.
87 *Id.*
88 *Id.*
89 655 F.3d 461, 464 (6th Cir. 2011).
90 *Id.* at 465.
91 *Id.* at 472.
92 *Id.* at 471.

court said, would likely be persuasive to dispense with the representative sample approach in that case.[93]

Finally, in the Eighth Circuit, at least one set of facts led the court to use the strong inference approach even though it would otherwise demand a representative sample of fraudulent claims. In *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, an insider relator was able to plead sufficient details of an alleged fraudulent scheme by Planned Parenthood to file false claims for certain birth control and abortion services:

> Thayer adequately alleges the particular details of these schemes, such as the names of the individuals that instructed her to carry out these schemes, the two-year time period in which these schemes took place, the clinics that participated in these schemes, and the methods by which these schemes were perpetrated. Moreover, she alleges that her position as center manager gave her access to Planned Parenthood's centralized billing system, pleads specific details about Planned Parenthood's billing systems and practices, and alleges that she had personal knowledge of Planned Parenthood's submission of false claims.[94]

Such details sufficed for these allegations to survive the defendant's motion to dismiss.[95] The *Thayer* decision supports the notion that while relators necessarily operate with an informational disadvantage as plaintiffs, courts can be convinced of the credibility of a relator's knowledge of fraudulent claims when her information on a defendant's practices reaches some threshold level of specificity.

These cases illustrate that even relators in the health care fraud context who are sophisticated whistleblowers with a great deal of valuable inside information may not always have the right information for the purpose of satisfying Rule 9(b). As I argue below, such knowledge can more optimally be used to evaluate a motion for particularity discovery than to rule on a motion to dismiss.

D. *Goals of the False Claims Act*

The Department of Justice and Department of Health & Human Services have repeatedly indicated that health care fraud enforcement is a high priority. As discussed above, the staggeringly high annual recovery amounts per year make this an area ripe for protecting taxpayer dollars and the integrity of government-funded programs.[96] Further, Congress's intent to

93 *Id.*

94 765 F.3d 914, 919 (8th Cir. 2014).

95 *Id.*

96 *See supra* Section I.A.

prosecute disloyalty and dishonesty to the United States is clear from the legislative history of the FCA.[97]

Beyond these original goals, the FCA has become an important mechanism for policing activities in the clinical context that can be harmful to patients. Indeed, the federal government has undertaken the role of protecting the public's health since at least the mid-1800s.[98] Through the FCA and other statutes and regulations,[99] the government directly and indirectly evaluates the safety and efficacy of drugs and medical procedures that are available for consumers. Notably, lawmakers were attuned to the importance of policing fraud in the health care sector as far back as the passage of the Federal Food, Drug, and Cosmetic Act of 1938, which created the foundation of the modern regulatory framework for pharmaceuticals.[100] Senators carefully calculated the implications of requiring scientific data to back up claims of a drug's effectiveness; after significant debate, they decided that in the absence of such scientific foundation, a claim of effectiveness should be considered fraudulent.[101] The FCA's current use as an additional mechanism to impose liability for health care fraud is therefore consistent with congressional intent to police fraud in the health care space.

A strict, unwavering particularity pleading standard prevents potentially meritorious allegations from proceeding to discovery, which interferes with the goals of policing both fraud against the government and fraud that results in unsafe or ineffective practices.[102] Especially when defendants are promoting potentially dangerous uses for drugs or medical devices, FCA relators play an important role in bringing those defendants to court for recovery. The seriousness of a false claim, particularly as characterized by its relation to unsafe medical practices, should be an important consideration for courts in

97 *See supra* text accompanying notes 7–9, 12.

98 *See About FDA: History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History [https://perma.cc/66C6-2KXC] (describing the origins of the Food & Drug Administration).

99 For both civil and criminal offenses, these include the Federal Food, Drug, and Cosmetic Act of 1938, the Anti-Kickback Statute, and the Stark Law, along with their related regulations.

100 *See generally* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

101 *See* 81 CONG. REC. 2004 (1937) (statements of Sens. Robinson & Copeland) (discussing the practical effects of imposing fraud liability for lack of scientific evidence).

102 *See, e.g.*, Brief for United States—Takeda, *supra* note 29, at 14-15 (stating that a strict, unwavering application of the representative sample approach would prevent whistleblowers from assisting the government in policing fraud in the health care sector as Congress intended them to do); Emily T. Chen, Note, *Depressing Diagnosis: Stringent Particularity Requirement of the Rule 9(b) Pleading Standard as a Critical Bar to Off-Label Promotion Fraud Whistleblowers*, 36 CARDOZO L. REV. 333, 365 (2014) ("The heightened pleading standard, then, would bar many nonfrivolous *qui tam* lawsuits at the very start and would thus undermine congressional intent . . . .").

evaluating the sufficiency of an FCA complaint, and that analysis that can be inserted into a decision on particularity discovery, as I outline in Part III.

E. *Summary*

Courts' willingness to permit exceptions to the representative sample standard, relators' informational inequities, and the goals of the FCA point in favor of an approach more lenient than the strict representative sample approach. However, because Rule 9(b)'s requirements are firmly rooted in defendant protection—a particularly compelling goal in FCA cases—this new approach should require more than the strong inference standard. Indeed, successfully alleging a false claim requires a high degree of specificity, and relaxing the standard detracts from the important balance that the Rules Committee and the Supreme Court have already addressed in the construction of Rule 9(b) and the *Twombly–Iqbal* framework.

An optimal resolution of the circuit split involves reframing the dismissal stage to address the unique circumstances of typical health care fraud relators and to give them a chance to meet a strict pleading standard. In Part III, I argue that particularity discovery provides a solution that addresses the procedural, substantive, and policy arguments on both sides of the debate.

III. PROPOSAL: PARTICULARITY DISCOVERY

Particularity discovery combined with the strict representative sample standard would provide a workable and optimal balance between the two existing approaches to pleading and would align with the practical realities of whistleblower suits. As described in Part II, the distinctive features of health care fraud qui tam suits suggest a need for a critical eye toward existing FCA pleading practices.

Pre-merits discovery for the purpose of surviving a motion to dismiss is not a novel concept. Following the decision in *Iqbal*, at least one scholar has explored using such discovery to assist plaintiffs in satisfying the plausibility pleading standard.[103] This Comment proposes an extension of the use of pre-merits discovery to allow relators to satisfy the particularity requirement in health care fraud cases.

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103 *See* Malveaux, *supra* note 59, at 108 ("Courts should consider narrow, targeted plausibility discovery at the pleadings stage to insure that the trans-substantive application of the Rules does not work an injustice against those cases involving informational inequities."). *But see* Bratton v. Town of Fortville, No. 1:09-cv-1391-SEB-JMS, 2010 WL 2291853, at *3 n.3 (S.D. Ind. June 2, 2010) ("The Supreme Court has clearly rejected the availability of [plausibility discovery] . . . where the plaintiff's allegations simply fail to state a plausible claim." (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557-58 (2007))).

Courts already have the authority to permit pre-merits discovery and indeed do so in other contexts, including class certification and threshold jurisdictional questions.[104] The use of particularity discovery in health care fraud whistleblower cases would be consistent with the government's position that Rule 9(b) should not be an insurmountable barrier to relators' role in fraud enforcement. In fact, it would likely further current enforcement goals. Limiting and targeting the scope of pre-merits discovery would provide defendants with notice and reputational protection while resolving the problem of relators' distinct type of informational inequity. Finally, incorporating particularity discovery in accordance with this framework would optimize the selection of cases proceeding to full-fledged discovery. Plaintiffs would still be required to meet the representative sample particularity standard to survive a motion to dismiss, but the court's analysis would be structured to grant relators an opportunity to satisfy that standard in an amended complaint.

A. *Pre-Merits Discovery in Other Contexts*

In this Section, I will outline the use of pre-merits discovery in class certification and jurisdictional disputes. My goal here is to extrapolate principles from these contexts that can inform the proposal that I outline in Section III.B. I weave these principles into the mechanics of particularity discovery below.

1. Class Certification Discovery

In class action lawsuits, the court may use pre-merits discovery to determine whether the four prerequisites for certifying a class of Rule 23(a) are met and whether the proposed class falls within one of the enumerated categories of Rule 23(b).[105] The plaintiff bears the burden not just of pleading the prerequisites at this pretrial phase, but also of proving them.[106] Generally,

104 For a discussion of the court's discretion to permit discovery prior to ruling on a 12(b)(6) motion, see Edward A. Hartnett, *Taming* Twombly*, Even After* Iqbal, 158 U. PA. L. REV. 473 (2010), and subsection III.B.2.

105 *See* Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 161 (1982) (restating the requirement that the court must undergo a rigorous analysis before certifying a class). The four elements required by Rule 23(a) are numerosity, commonality, typicality, and adequacy of representation. FED. R. CIV. P. 23(a). Rule 23(b) requires the court to assess whether (1) prosecuting separate actions would result in incompatible standards of conduct for the defendant or would substantially impede other individuals from protecting their interests; (2) injunctive relief or declaratory relief would be appropriate given that the defendant has acted or refused to act in a way that applies generally to the entire class; or (3) that common questions of law or fact predominate over any questions affecting individual members. FED. R. CIV. P. 23(b). A court must determine whether the plaintiff has proven all four elements of Rule 23(a) and that one category in Rule 23(b) applies to the proposed class action.

106 Halliburton Co. v. Erica P. John Fund, Inc., 134 S. Ct. 2398, 2412 (2014).

pre-certification discovery is necessary when the parties dispute any facts related to any of the prerequisites.[107] In 2003, the Rules Committee revised Rule 23 to require that certification occur at "an early practicable time,"[108] suggesting its desire to permit more discovery when making the certification determination.[109]

Pre-merits discovery requires that a plaintiff first make a prima facie showing that discovery is likely to show that the prerequisites for class certification are met.[110] The court then undertakes a difficult balance when determining the extent to which it will permit pre-certification discovery. Indeed, the court must answer questions of access and resources similar to the concerns it faces when deciding a motion to dismiss in a qui tam suit. A plaintiff typically succeeds on her discovery motion when information that would later be discoverable within the scope of Rule 26 is relevant to the question of certification and the defendant has exclusive control over that information.[111] Similarly, a whistleblower will likely know which information she needs from the defendant, even though she does not have access to it.

At present, the court may consider the merits of the case during pre-certification discovery only to the extent that they relate to the question of certification.[112] Particularly when determining commonality, typicality, and adequacy of representation, it would seem nearly impossible to disregard the merits inquiry altogether. Although the posture will differ, the court must consider the same questions of law and fact during the certification process as in any proceeding involving the merits.

While admittedly "[t]he class certification determination is more about the scope and structure of the lawsuit than its very existence,"[113] it is instructive that the rules permit pre-certification discovery despite difficulties in bifurcating the merits determination. In class action pre-certification discovery motions, the court must determine whether the complaint on its face alleges a case that satisfies Rule 23(a). Similarly, in Rule 9(b) decisions, the court must decide whether the relator has sufficiently pled the particulars of an FCA violation that is plausible on its face without delving too far into the details of the alleged fraudulent activity. A plaintiff's motion for

107 *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 21.14 (2004) (discussing when discovery may be necessary in this context).

108 FED. R. CIV. P. 23(c)(1)(A).

109 FED. R. CIV. P. 23 advisory committee's note to 2003 amendment.

110 *See, e.g.*, Perez v. Safelite Grp. Inc., 553 Fed. App'x 667, 668-69 (9th Cir. 2014) (noting that the plaintiff bears the burden of proving that discovery will substantiate the Rule 23(a) elements).

111 *See* 8 ALBA CONTE & HERBERT NEWBERG, NEWBERG ON CLASS ACTIONS § 24.80, at 309-10 (4th ed. 2002) (noting that in the context of employment discrimination class actions, the informational inequity between the parties is a relevant consideration for the court).

112 Amgen Inc. v. Conn. Ret. Plans & Tr. Funds, 133 S. Ct. 1184, 1195 (2013).

113 Malveaux, *supra* note 59, at 112.

particularity discovery would require her to allege that a fraudulent scheme exists and that targeted, pre-merits discovery would provide a representative sample of false claims.

2. Jurisdictional Discovery

Neither in personam nor subject matter jurisdiction discovery provide exact guides for structuring particularity discovery because they are inherently substantive inquiries; only a facial challenge to jurisdiction would be precisely analogous to a Rule 12(b)(6) motion.[114] As Malveaux theorizes, however, certain discrete aspects of jurisdictional discovery are potentially illustrative on this topic.[115]

Complex issues in litigation do not lend themselves to universal, catchall understandings of procedure. The court's inquiry regarding jurisdictional discovery must begin with "clearly understand[ing] the plaintiff's jurisdictional claim."[116] Similarly, where a relator seeks discovery under the proposed scheme, the court must first understand the sufficiency of the original complaint; the relator's identity, knowledge of the defendant's operations, and potential information inequity; and the degree to which a plaintiff can narrowly identify the minimum information necessary to allege a representative sample of false claims. To determine the latter, the court may even consider the potential effectiveness of ordering a meet-and-confer conference.[117]

Further, as with class certification, the court has discretion to consider whether the plaintiff has met her initial burden prior to her jurisdictional discovery motion. The plaintiff must first make a colorable case for jurisdiction; otherwise, the court may have no basis to believe that any amount of discovery will establish jurisdiction over the claim.[118] Similarly, in this Comment's proposed Rule 9(b) particularity discovery analysis, the relator must first allege a colorable claim for an FCA violation by pleading enough details of the alleged fraudulent activity that make it plausible that the defendant submitted at least one false claim. If the plaintiff fails to meet

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114 *Id.* at 119-20.

115 *See id.* at 117-22 (analogizing jurisdictional discovery to other forms of pre-merits discovery).

116 Steven R. Swanson, *Jurisdictional Discovery Under the Foreign Sovereign Immunities Act*, 13 EMORY INT'L L. REV. 445, 482 (1999).

117 *See* Malveaux, *supra* note 59, at 120 ("To facilitate [jurisdictional] discovery, a court may order the parties to meet, confer, and formulate a discovery plan."). Concededly, the fundamental difference between a substantive jurisdictional inquiry and a facial challenge to the plausibility of the complaint will likely affect a defendant's willingness to cooperate in such a conference. Nonetheless, the authority to order the parties to meet and confer may prove useful in certain cases.

118 *See, e.g.*, Compagnie des Bauxites de Guinee v. L'Union Atlantique S.A. d'Assurances, 723 F.2d 357, 362 (3d Cir. 1983) (directing the district court to allow discovery on jurisdiction where the plaintiff's claim is "not clearly frivolous").

this burden, the district court would have the discretion to deny pre-merits discovery, just as it would have discretion to deny jurisdictional discovery.[119] Because a motion for particularity discovery would not be granted as a matter of course to whistleblowers, this proposal ensures that the court will not be flooded with qui tam fishing expeditions.

Finally, the proposed particularity discovery can be limited in scope, not unlike jurisdictional discovery. Courts generally will deny vague requests for jurisdictional discovery,[120] but the precise boundaries of the appropriate inquiry are unknown.[121] That the definition of "limited" jurisdictional discovery has not been identified does not foreclose the court's ability to assess the scope of pre-merits discovery on a case-by-case basis. One possibility, proposed by Strong, is that the scope of pre-merits discovery remain limited compared to the broader scope of merits discovery.[122] In other words, the discovery sought must be relevant to the disposition of the particular inquiry at hand—in the context of jurisdiction, the 12(b)(1) or 12(b)(2) motion, or in the context of a whistleblower's request for particularity discovery, the 12(b)(6) motion. As described above, the court may limit discovery in kind or degree depending on the particular case at hand and the relevant facts necessary for the plaintiff to meet her burden.[123] Again, the court must tailor the scope of discovery granted to its understanding of the pleadings.

B. *Mechanics of the Proposal*

In this Section, I propose a procedure for incorporating particularity discovery into the motion to dismiss stage of health care fraud qui tam lawsuits in which the government declines to intervene. Bearing in mind the concerns raised by proponents of both existing approaches and the examples provided by pre-certification and jurisdictional discovery, I propose this procedure and analysis of a motion for particularity discovery as a middle ground.

Once the court lifts the seal from an FCA complaint, the defendant generally moves to dismiss under Rule 12(b)(6) for failure to state a claim. In

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119 *See id.* (emphasizing that in this context the court has discretion over whether to permit discovery to proceed).

120 *See, e.g.*, Freeman v. United States, 556 F.3d 326, 341-42 (5th Cir. 2009) (stating that a party "may not simply rely on vague assertions that additional discovery will produce needed, but unspecified, facts" (internal quotation marks omitted) (quoting SEC v. Spence & Green Chem. Co., 612 F.2d 896, 901 (5th Cir. 1980))).

121 *See* S.I. Strong, *Jurisdictional Discovery in United States Federal Courts*, 67 WASH. & LEE L. REV. 489, 532 (2010) (noting that "there is no real understanding of what [scope of discovery] is appropriate in any particular set of circumstances").

122 *Id.* at 532-33.

123 *See id.* at 536-57 (outlining the types of facts that may be relevant for determining legislative or constitutional authority for jurisdiction).

recognition of her need to identify specific examples of fraudulent claims to satisfy the "representative sample" approach and avoid dismissal, the plaintiff may seek specific facts or information from the defendant. It is unlikely that the defendant will be willing to turn over such information at this stage in the litigation without a court order, and she may even move to stay discovery.

At this point, the plaintiff will make a motion for particularity discovery under Rule 7(b).[124] The burden will be on the plaintiff to demonstrate relevant facts and circumstances, outlined below, that warrant particularity discovery. This is not inconsistent with Rule 26, which states that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case."[125] The motion should explain the basis for the request by pointing to specific information in the complaint.

This is the point of divergence from the court's standard motion to dismiss inquiry. In the plaintiff's brief on behalf of himself and the United States in *Foglia*, the relator argued that "Rule 9(b) may be satisfied by pleading fraud on information and belief, if the pleader *identifies the available information on which the allegation of fraud is founded*."[126] Alternatively, under the representative sample approach, the court looks to see if the plaintiff has identified at least one claim by time, place, content, and names of actors. Regardless of the complaint's sufficiency under either existing approach, the court at this point has enough information to decide on the motion for particularity discovery, and should do so rather than immediately rule on the defendant's motion to dismiss.

To satisfy her initial burden under this proposed framework, the plaintiff must first plead sufficiently detailed allegations of a fraudulent scheme that suggest it is plausible that the defendant submitted a false claim. In other words, a claim that does not satisfy the *Twombly–Iqbal* pleading standard will not suffice,[127] but the plaintiff need not satisfy Rule 9(b)'s representative sample standard in the initial complaint as a condition for particularity discovery. Rather, the court will consider the allegations in the initial complaint combined with other factors, discussed here, to make its ruling. These factors are consistent with the proportionality requirement in Rule 26(b)(1) because

124 *See* FED. R. CIV. P. 7(b) (requiring that a motion state the relief sought).

125 FED. R. CIV. P. 26(b)(1). Rule 26 was revised in 2015, and the scope of permissible discovery now includes a proportionality requirement.

126 Brief with Joint Appendix 1-23 Volume I on Behalf of Appellant at 18, Foglia *ex rel.* United States v. Renal Ventures Mgmt., LLC, No. 12-4050 (3d Cir. Mar. 12, 2013) (emphasis added).

127 *See* Hartnett, *supra* note 104, at 511 (noting *Iqbal*'s determination that a complaint's lack of plausibility precludes even cabined pre-merits discovery).

they help the court determine the appropriate scope of discovery based on the facts and circumstances of the case and the pre-merits posture.[128]

If the court grants particularity discovery, discovery should proceed according to an order limiting its scope. The plaintiff may employ any typical discovery mechanisms, including interrogatories, depositions or document requests, within the boundaries outlined in the discovery order.

After discovery, the plaintiff may seek leave to amend her complaint under Rule 15,[129] and the court is likely to grant this request to the extent that the proposed amendments seek to remedy the deficiencies identified in the defendant's motion to dismiss. Assuming the plaintiff is able to identify a false claim through discovery, the relator should have everything she needs to satisfy a strict reading of Rule 9(b)'s particularity requirement.[130] The court should then evaluate the sufficiency of the amended complaint under the representative sample approach.

1. Ruling on the Particularity Discovery Motion

Relevant considerations for the court when deciding on the particularity discovery motion include the identity and characteristics of the relator(s); the characteristics of the case and the degree of sufficiency of the initial complaint; and the seriousness of the allegations. Scholars have proposed that courts use similar factors to address motions to stay discovery when a motion to dismiss is pending.[131] I address each of these considerations in turn.

a. *Relators*

Rule 9(b) applies to qui tam relators despite information inequities.[132] In fact, John T. Boese contends that because of relators' intimate knowledge of the defendant's practices, the court should demand *more* of them than the

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128 *See* FED. R. CIV. P. 26(b)(1) (directing the court to determine the scope of discovery based on "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit").

129 *See* FED. R. CIV. P. 15(a)(2) ("The court should freely give leave when justice so requires.").

130 The plaintiff still bears the burden of pleading an FCA violation that is plausible on its face, in accordance with *Twombly* and *Iqbal*. While particularity discovery may also allow the plaintiff to satisfy that requirement, it does not follow that finding a "sample" to plead through pre-merits discovery will automatically save the complaint from dismissal. *See, e.g.*, United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013) (dismissing for lack of plausibility even though the plaintiff pled a representative sample).

131 *See* Kevin J. Lynch, *When Staying Discovery Stays Justice: Analyzing Motions to Stay Discovery When a Motion to Dismiss Is Pending*, 47 WAKE FOREST L. REV. 71, 90-91 (2012) (outlining eight considerations that echo the Rule 26(b)(1) factors for the court to weigh when ruling on a pre-merits discovery motion).

132 2 BOESE, *supra* note 27, § 5.04[B][1].

average plaintiff, instead of granting them leniency.[133] Indeed, modern relators are often compliance officers, managers, doctors, nurses, or in-house counsel who have a high level of access and understanding of the defendant's conduct in the health care space.[134]

However, to hold that all qui tam relators should conduct their cases within the same rigid framework ignores the modern reality of fraud in the health care sector. In small qui tam actions, the relator could potentially be a low-level employee who has credible knowledge of a fraudulent scheme but limited access to concrete data to support it.[135] For example, in *United States ex rel. Lee v. SmithKline Beecham, Inc.*, the court determined that the relator could not fairly allege that proof of fraud was solely in the possession of the defendant when the relator had been employed there for twenty years.[136] On these grounds, the court found that the relator failed to satisfy Rule 9(b), and his complaint was dismissed.[137] But, the *Lee* court's disposition rests on a false premise regarding the sophistication of a relator; a relator's insider status should warrant a demand for her to know how and where to find information within the defendant's control, not to actually have that information.

Despite the relator's inside knowledge, the high level of complexity of health care billing and claims management renders it unwise for us to hold every plaintiff to a strict pleading standard without assessing her individual characteristics. To meet her burden of showing "good cause" for particularity discovery, the relator must be able to identify what she is looking for and where she believes she will find it. When evaluating the whistleblower's motion, the court should avoid a premature merits inquiry by assessing the relator's degree of familiarity with the defendant's business practices in conjunction with her ability to articulate how she will target her discovery efforts. The court should anticipate this degree of sophistication to be reflected in the detail provided in the initial complaint, which I will turn to next.

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133 *Id.*

134 *See* Kathleen M. Boozang, Comment, *The New Relators: In-House Counsel and Compliance Officers*, 6 J. HEALTH & LIFE SCI. L. 16, 18 (2012) (discussing an increase in licensed attorneys bringing cases as FCA relators in recent years).

135 *See, e.g.*, Amended Complaint, United States *ex rel.* Cashi v. Fox Hollow Techs. Inc., No. 1:09-cv-01066-WMS (W.D.N.Y. Feb. 19, 2010).

136 245 F.3d 1048, 1052 (9th Cir. 2001).

137 The Ninth Circuit ultimately found that the district court should have granted Lee leave to amend his complaint because it could be construed to allege a claim based on worthless services fraudulently provided to the government. *Id.* at 1053.

b. *Characteristics of the Case and the Sufficiency of the Initial Complaint*

The cases outlined in Parts I and II illustrate the method the court should use to assess the allegations in a complaint facing a motion to dismiss. I consider each of them in turn.

Cases in which the discovery inquiry can be limited to a single, discrete fact are strong candidates for particularity discovery. For example, in *Foglia*, information as to whether Renal was charging the government as if it were using vials of Zemplar in a certain way was not in the relator's control; this information alone would have plainly shown either the existence or absence of false claims.[138] In the event that Renal was using vials of Zemplar properly, the court's resources and the defendant's reputation would have been spared in favor of other enforcement actions with greater merit. In *Walker*, the court made an exception to its ordinarily stringent requirement because the NP relator's pleading was sufficient to illustrate why she believed the defendant had committed fraud.[139] Alternatively, her detailed knowledge would have lent itself well to a discovery inquiry. For example, she could have requested specific billing records for particular days she believed the defendant was billing the government fraudulently.

Chesbrough would have been a closer call, but ultimately would also have been a case ripe for particularity discovery.[140] There, the relators had detailed knowledge of radiology scans and standards for equipment and personnel, but, as independent contractors rather than employees, they did not have the same intimate familiarity with the defendant's billing practices as did the *Walker* relator.[141] While the complaint may have contained sufficient detail to grant a motion for particularity discovery, the relators may not have had the sophistication to find what they needed to generate a representative sample. The court may likely have ended up granting a motion to dismiss for failure to plead with particularity in the amended complaint. Even though the ultimate disposition of the case would have been the same, the decision to dismiss would have been more informed with the addition of particularity discovery.

In some cases, the discovery inquiry might rest entirely on the detail provided in the complaint. Recall that in *Thayer*, the court found the relator's knowledge of the defendant's billing practices and fraudulent scheme to be so specific that it, in effect, waived the requirement of a representative sample because the "strong inference" was so compelling.[142] As a policy matter, this relator had a strong case for access to the courts—it is desirable for such

138 *See supra* text accompanying notes 40–43.
139 *See supra* text accompanying notes 81–88.
140 *See supra* text accompanying notes 89–93.
141 *See supra* text accompanying notes 89–93.
142 *See supra* text accompanying notes 94–95.

detailed allegations to proceed to full discovery. Particularity discovery nonetheless plays a role in the pre-merits phase to help identify the particular claims at issue, thereby placing the defendant on proper notice. Rather than simply denying the motion to dismiss outright, the court may, at its discretion, permit targeted particularity discovery to further these goals and assess the "correctness" of its inclination to deny the motion.

Finally, the use of discovery to resolve a complaint's deficiency under Rule 9(b) should be distinguished from its use to cure a *Twombly–Iqbal* plausibility problem. In *Takeda*, for example, the relator's pleading contained one key deficiency preventing the case from surviving the motion to dismiss: whether the sixteen doctors in question in fact prescribed Kapidex at sixty-milligram doses.[143] In its brief, however, the United States took the position that the *Takeda* case was an inappropriate vehicle for addressing the Rule 9(b) circuit split because the complaint failed for lack of plausibility under the *Twombly–Iqbal* framework *despite* a representative sample of names and false claims.[144] Although the court could have sufficiently cabined the inquiry to give the plaintiff a chance to identify at least one prescription by one of the identified doctors at the off-label dose (assuming it existed), the plausibility problem is distinct from a sample deficiency. Thus, *Takeda* would not necessarily have been a case ripe for particularity discovery under the proposed framework.

c. *Seriousness of the Allegations*

The government's position on the proper interpretation of Rule 9(b) is not inconsistent with allowing particularity discovery during the pre-dismissal stage. In the Solicitor General's amicus brief in *Takeda*, the United States noted the numerous exceptions to the representative sample approach, some of which are described in Section II.C, and advocated for a more relaxed pleading standard to support the policy goals of the FCA.[145] In recognizing the informational inequity of relators, the Solicitor General articulated,

> Subjecting *qui tam* relators to a per se rule requiring the identification of specific false claims is especially unwarranted because it attaches dispositive significance to the relator's awareness of details that in most instances are already known to the government. . . . Requiring *qui tam* complaints to identify specific false claims thus would not meaningfully assist the government's enforcement efforts. To the contrary, the likely effect of such a requirement would be to discourage the filing of *qui tam* suits by relators . . .

143 United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 458-59 (4th Cir. 2013).

144 Brief for United States—Takeda, *supra* note 29, at 10-11.

145 *Id.* at 11-12.

> who would otherwise have the means and the incentive to expose frauds against the United States.[146]

The government does not misstate the tension between relators' inability to plead certain facts with specificity and the potential harm that fewer qui tam actions would provide. However, the government ignores the possible role of pre-merits discovery, which might further its goals while still requiring plaintiffs to plead specific false claims.

The proposed framework for particularity discovery allows the court to use its discretion to give effect to this tension and the goals of the government in FCA enforcement. The more serious the alleged violation, the more willing the court should be to grant pre-merits discovery to allow the relator an opportunity to "meaningfully assist the government's enforcement efforts."[147] Particularity discovery does not simply subject relators to a per se rule requiring them to identify false claims; it also gives them an adequate opportunity to meet that burden with the assistance of a court order.

2. Authority and Discretion of the District Court to Order Pre-Merits Discovery

The discretion to oversee discovery, including to order or deny pre-merits discovery, lies within the existing authority of the district court.[148] Indeed, the procedure described here mirrors what could theoretically already occur in a court that has adopted the representative sample approach; except in certain cases,[149] discovery is not automatically stayed pending a motion to dismiss.[150] In a court demanding a representative sample of false claims to satisfy Rule 9(b), the judge maintains discretion to order discovery prior to the disposition of the 12(b)(6) motion and will not routinely order a stay.[151] This proposal thus leaves much discretion in the hands of the judge, and there are a number of possible procedural outcomes: a denial of particularity discovery followed by the grant of a motion to dismiss; a denial of particularity

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146 *Id.* at 16.

147 *Id.*

148 *See* Parker v. Time Warner Entm't Co., 331 F.3d 13, 21 (2d Cir. 2003) (reviewing for abuse of discretion the district court's decision to deny class certification without allowing discovery of factual information necessary to that decision).

149 *See, e.g.*, *In re* AOL Time Warner, Inc. Sec. Litig., No. 06 Civ. 0695 (SWK), 2006 U.S. Dist. LEXIS 49162 (S.D.N.Y. July 13, 2006) (ruling on a motion to lift the automatic stay of discovery imposed by the Private Securities Litigation Reform Act).

150 *See* SK Hand Tool Corp. v. Dresser Indus., Inc., 852 F.2d 936, 945 n.11 (7th Cir. 1988) (noting that the mere filing of a motion to dismiss does not automatically preclude discovery pending a ruling on the motion).

151 *See* Hartnett, *supra* note 104, at 507-08 (stating that it is "not routine" for a district court to order a stay in this context).

discovery followed by denial of a motion to dismiss; a grant of particularity discovery and a subsequent grant of a motion to dismiss; and a grant of particularity discovery and a subsequent denial of a motion to dismiss.[152]

This proposal does not cabin the discretion of the district court to stay or otherwise deny pre-merits discovery.[153] This is because it does not *require* that courts grant pre-merits discovery in certain circumstances, but rather encourages courts to adopt a more rigid standard for assessing the particularity of a complaint in recognition of the likely appropriateness of targeted discovery to identify a sample of false claims. Relators' counsel must thus remain diligent and mindful of the court's ultimate discretion to decide against them on a pre-merits discovery motion. The decision to grant or deny discovery is reviewable for abuse of discretion,[154] whereas a 12(b)(6) ruling is reviewable de novo.[155] The proposed framework in essence conflates the two decisions, giving the ruling on a motion for pre-merits discovery the weight of a ruling on a motion to dismiss. As such, a pre-merits discovery motion denial that effectively becomes dispositive (by precluding a plaintiff's ability to plead a representative sample) would seem to increase the discretion available to the district court judge. This proposal merely suggests to the court a framework for understanding a particularity discovery motion; short of the incorporation of particularity discovery through binding jurisprudence or an amendment to the Federal Rules of Civil Procedure, this structure provides no additional protection on appeal for relators operating under the representative sample standard.

3. Final Considerations

The proposal for particularity discovery gives effect to the pros and cons of both existing approaches while considering the peculiarities of whistleblowers in the health care context, the oddities of health care fraud fact patterns, and the role of the government's enforcement goals in helping cases to proceed. Judicial rulings on motions to compel and other ordinary discovery disputes in qui tam cases illustrate the capacity of courts to craft limited, targeted discovery plans. In *Dalitz v. AmSurg Corp.*, the defendant, a treatment facility, failed to perform certain reimbursement requirements prior to performing surgical procedures, and then submitted claims for those surgeries to state

152 *See id.* at 509-10 (discussing these permutations).

153 For a proposal on how the court should exercise this discretion that echoes the factors outlined here, see generally Lynch, *supra* note 131.

154 *See* Glickenhaus & Co. v. Household Int'l, Inc., 787 F.3d 408, 414 (7th Cir. 2015) ("We review discovery rulings for abuse of discretion.").

155 *See* United States *ex rel.* Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 154 n.1 (3d Cir. 2014) ("We review *de novo* a district court's grant of a motion to dismiss for failure to state a claim . . . .").

and federal payers.[156] Viewing the allegations through the lens of the amended Rule 26(b)(1), the district court cabined discovery geographically, but widened its scope temporally in recognition of the size and scope of the billing volume of the defendant corporation.[157]

Further, courts continue to indicate that the ability to consider more information at the pleading stage is preferable. In *Cardiac Devices*, the court found that where the plaintiffs served patient and procedure lists on the defendants separately from the complaint, the purpose of Rule 9(b) had been satisfied.[158] While in that case the purpose of the separate documents was to protect patient privacy, the court's message is clear: certain health care fraud actions warrant distinctive considerations in the context of Rule 9(b). Particularity discovery is one attractive avenue for addressing these kinds of peculiarities.

CONCLUSION

Courts and scholars should be open to the idea of modified discovery practices in health care fraud litigation. Both a more relaxed approach—the strong inference standard—and a stricter approach—the representative sample standard—to the Rule 9(b) particularity requirement have pros and cons, but neither adequately addresses the uniqueness of qui tam FCA lawsuits. 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. Because it captures the benefits of both the strict and lenient standards to address the unique factual features of a typical health care fraud qui tam case, it provides a better result than either standard alone.

156 No. 2:12-cv-2218-TLN-CKD, 2015 WL 8717398, at *1 (E.D. Cal. Dec. 15, 2015).

157 *Id.* at *3-4.

158 *In re* Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 338 (D. Conn. 2004).