No. 25-___

In the
Supreme Court of the United States

THE UNITED STATES OF AMERICA AND THE STATE OF GEORGIA EX REL. BARBARA SENTERS,

Petitioner,

v.

QUEST DIAGNOSTICS INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Federal Rule of Civil Procedure 9(b) provides that "circumstances constituting fraud" must be "state[d] with particularity." The circuits are divided over what Rule 9(b) requires in *qui tam* cases arising under the False Claims Act, 31 U.S.C. § 3729, which prohibits the submission of false or fraudulent claims for payment to the Government. Six circuits allow *qui tam* plaintiffs to proceed if the submission of false claims can reasonably be inferred from other well-pleaded facts. Three circuits, including the Eleventh, hold that the submission of claims cannot be inferred from other circumstances; plaintiffs must plead direct, firsthand knowledge of actual false claims submitted to the Government to overcome dismissal. Three others generally require the plaintiff to plead the details of a specific false invoice submitted to the Government.

This Court has thrice sought the views of the United States. Each time, the Government argued that a *qui tam* complaint satisfies Rule 9(b) if it pleads "other sufficiently reliable indicia supporting a strong inference that false claims were submitted to the government," but predicted that the circuit conflict would resolve itself. It has not. A complementary petition presenting the same issue is pending before this Court in *United States ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347.

The Question Presented is:

Whether a *qui tam* complaint satisfies Federal Rule of Civil Procedure 9(b) when it alleges detailed firsthand knowledge of a fraudulent billing scheme paired with reliable indicia supporting a strong inference that false claims were submitted to the Government, or whether relators must also plead direct knowledge of actual false claim submissions.

PARTIES TO THE PROCEEDING

The parties to the proceeding are:

1. Petitioner Barbara Senters, who was the plaintiff in the District Court and appellant in the Court of Appeals.

2. Respondent Quest Diagnostics Inc., who was the defendant in the District Court and appellee in the Court of Appeals.

RELATED PROCEEDINGS

There are no related proceedings.

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PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully petitions this Court for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Eleventh Circuit. Alternatively, this case should be held for resolution of the Question Presented in *United States ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347 (distributed for Conference of January 9, 2026).

OPINIONS BELOW

The Court of Appeals' opinion (Pet. App. A) is unreported but available at 2025 WL 1951196. The District Court's opinion (Pet. App. B) is unpublished but available at 2024 WL 4297469.

JURISDICTION

The Eleventh Circuit issued its judgment July 16, 2025, Pet. App. A, and denied a timely rehearing petition on August 19, 2025, Pet. App. C. Justice Thomas granted an extension of the time to file this petition to December 17, 2025. No. 25A541. This Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT LEGAL PROVISIONS

The relevant rule and statutory provisions are reproduced in Appendix D to this Petition.

INTRODUCTION

Respondent's fraud is one the Government has prosecuted before. In 1998, the Department of Justice recovered over $800 million from clinical laboratories, including $325 million from Quest's predecessor, for bundling tests into custom "panels" that caused physicians to order tests they did not specifically intend to order, then billing Medicare for each test with false certifications of medical necessity. The Government dubbed the requisition forms used to select those panels the "instrument of the crime." Quest inherited the resulting compliance agreement when it acquired the fraudster in 1999. Quest's own training materials identified the scheme as illegal.

As petitioner alleged, Quest's response was to modernize the instrument of the crime. It substituted electronic panel selection for paper requisition forms while deliberately bypassing every compliance safeguard it had implemented for paper-based panels. The courts below did not doubt any of this. The Eleventh Circuit accepted petitioner's allegations that Quest employees "implemented" custom panels "in doctors' offices" and that "Quest made it difficult for doctors to know which tests were included." Pet. App. 2a. The District Court acknowledged that petitioner's complaint plausibly alleged an actual example allowing "the inference that the ordering doctor was confused or did not know what was in" a panel he selected because he separately prescribed an individual test already contained in the same panel on the same requisition form. *Id.* 22a n.7. And neither court questioned that Quest's system automatically billed every test in a selected panel, with Quest certifying on each claim submitted to Medicare that the services were "medically indicated and necessary."

The Eleventh Circuit affirmed dismissal anyway, holding that no matter how the alleged fraud scheme operates, a relator "must still" plead firsthand knowledge of false claim submissions by "provid[ing] particular facts about a representative false claim," or alleging that she "observed the submission of an actual false claim," or "personally participate[d] in submitting false claims." Pet. App. 7a-8a. The Sixth and Eighth Circuits require the same showing. Three others demand the details of a specific false invoice subject to ad hoc exceptions that do not apply here.

In contrast, six circuits permit *qui tam* plaintiffs to proceed when the well-pleaded facts of a fraudulent billing scheme support a strong inference that false claims were submitted to the Government. Because "much knowledge is inferential," complaints satisfy Rule 9(b) in those circuits if the submission of false claims is a "plausible" "inference" of the alleged fraud scheme. *See United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (same).

In 2022, this Court called for the views of the United States in *Johnson v. Bethany Hospice & Palliative Care LLC*, No. 21-462 (U.S.), an Eleventh Circuit case presenting the same question. The Solicitor General agreed with petitioner's rule but predicted the circuits were "converging," so she recommended denial. Every development has proven that prediction wrong. A petition presenting the same issue is pending before the Court in *United States ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347 (U.S.). This case removes all doubt. The Court should grant certiorari here and in *Tenet Healthcare* to resolve the cases together. Alternatively, it should grant one and hold the other. Either way, it is time to end the conflict.

STATEMENT OF THE CASE

I. Statutory Background

The False Claims Act imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim" to the Government, or who makes or uses a false "record" or statement material to such a claim. 31 U.S.C. § 3729(a). The FCA is designed "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quotation marks omitted).

Congress overhauled the statute in "1986 amendments [intended] to make the FCA a 'more useful tool against fraud in modern times.'" *Chandler*, 538 U.S. at 133 (quoting S. Rep. No. 99-345, at 2 (1986)). The Act's *qui tam* provisions are central to its enforcement scheme. The FCA authorizes private citizens, known as *qui tam* relators, to sue for the Government those who defraud federal programs and to keep a share of any successful recovery. *See* 31 U.S.C. § 3730(b), (d). The *qui tam* provisions seek to "encourage any individual knowing of Government fraud to bring that information forward." S. Rep. No. 99-345, at 2.

The FCA's most common application is redressing healthcare fraud. Since 1986, approximately $54 billion recovered under the Act related to fraud against federal healthcare programs—70% of the more than $78 billion total in recoveries under the modern statute. U.S. Dep't of Justice, *Fraud Statistics – Overview, October 1, 1986 – September 30, 2024*, at 3, 6 (2025), https://tinyurl.com/3fypz6cw.

When healthcare providers seek reimbursement from Medicare or Medicaid, they must submit claims using CMS Form 1500, which requires the claimant to certify that the services "were medically indicated and necessary for the health of the patient." Pet. App. 7a. Medicare and Medicaid reimbursement is available only for diagnostic tests "ordered by the physician who is treating the beneficiary"; tests ordered by non-treating providers are deemed "not reasonable or necessary" and therefore not reimbursable. 42 C.F.R. § 410.32(a).

II. Factual Allegations

A. The Alleged Scheme

Quest Diagnostics is the nation's largest provider of clinical laboratory testing. *See* Pet. App. 2a. It sells services to provide diagnostic testing for physicians, hospitals, and medical practices that order testing for their patients. *See ibid.* When Quest performs a test for a Medicare beneficiary, "Quest, not the doctor's offices or hospitals," submits the claim for reimbursement to the Government. *See id.* 3a. To obtain payment, Quest must certify on each claim that the services were "medically indicated and necessary for the health of the patient," which it does so long as the physician checks the box for a test on a requisition form. *See ibid.*

Quest's sales representatives "created custom lab panels containing multiple lab tests" under a single name, then "implemented" those panels "in doctors' offices" across the country using the company's "software platform, Care360." Pet. App. 2a-3a, 11a. Physicians would select custom panels on paper requisition forms that did not identify the individual tests included in the panel; those forms were then provided to Quest's phlebotomists for entry into

Quest's Care360 software system, where Quest's sales representatives—not the physicians—had configured the panels and chosen the included tests.

Moreover, physicians "were mistakenly led to believe that the tests included in custom panels were billed at bundled rates." Pet. App. 11a. In fact, Quest's billing software "unbundled" each panel and billed each component test individually, and when the bill was submitted to the Government for reimbursement, Quest invariably certified on every claim that the test was medically indicated and necessary based solely on the fact that it was within the custom panel created by Quest's sales representatives. Fourth Amended Complaint ("FAC") ¶¶6, 175. And when a physician selected a panel, Quest performed every test it contained, whether the physician knew every individual test included within it, and then "billed each test individually to the Government." *Ibid.* As a result, Quest sometimes billed the Government for tests that were not affirmatively or intentionally ordered by the treating physicians, as required by 42 C.F.R. § 410.32(a).

The billing was automatic. When Quest's phlebotomists selected a panel in Care360, the system generated an electronic requisition listing every test in the panel, printed a barcode for the patient's specimen, and transmitted the test list to Quest's billing system. FAC ¶¶175, 213-14; *see also id.* ¶222 (Quest's "testing instruments" read the barcode and "caused each individual test on the electronic requisition ... to be performed, and communicated with Quest's billing system to bill for each individual test that was performed.").

B. Quest's Knowledge Of The Fraud

Quest knew this scheme was illegal. In 1998, the Department of Justice recovered over $325 million from Quest's predecessor SmithKline Beecham Clinical Laboratories for the same basic fraud: bundling tests into custom panels that caused physicians to order tests without knowing what they were ordering, then billing Medicare for each test with false certifications of medical necessity. FAC ¶¶14-15. The paper requisition forms used to select the panels were the "instrument of the crime." FAC ¶14. Quest acquired SmithKline Beecham in 1999 and became subject to its Corporate Integrity Agreement. FAC ¶15. And Quest's compliance training "specifically instructed that the Government's enforcement initiative ... was based on the defendant labs' having their clients order tests in conveniently named customized groupings or panels of tests rather than ordering them individually." FAC ¶16.

For paper-based custom panels, Quest maintained extensive compliance safeguards to ensure physician awareness and choice. Before activating a paper panel, Quest required physicians to sign authorization forms verifying that they knew the panel's contents, the codes for each component test, and the Medicare reimbursement rate for each. FAC ¶¶153, 157-59. Quest sent annual notification letters to every physician using a paper panel, listing every test included. FAC ¶160. Quest's policy stated that custom panels could be offered "only with rigorous controls emphasizing physician choice, proper disclosure and client education." FAC ¶153.

For electronic "ease of order" custom panels in Care360, Quest abandoned all these safeguards and actively trained its sales representatives to bypass

them—sales reps who were financially rewarded based on the amount of test revenue generated from each client. FAC ¶¶5, 37-38, 161, 173, 182. At corporate training programs, Quest taught sales representatives to create custom panels directly in the electronic Care360 ordering system in physicians' offices, without any physician authorization or verification that doctors knew the panels' contents. FAC ¶¶173, 182.

Physicians continued to order tests using paper "script pads" that listed only the names of custom panels (not their component tests) alongside any separate individual tests the physician might need to order, whether included in a custom panel or not; a Quest employee would "handle[] it from there"—entering the physician's paper requisition into Quest's electronic Care360 ordering system by selecting the pre-created custom panels along with any separately listed tests. FAC ¶¶40, 218-21, 229-31. In this process, the physician never selected or ordered the individual component tests within the panels; the Quest employee did, and the physician had no access to see what those components were. FAC ¶180.[1] And Quest took "no steps to determine whether every Provider selecting a Care360 ease of order panel knew what tests were in the panel when he or she selected it." FAC ¶174. The complaint includes an example of an actual paper order form in which the doctor was confused into ordering a duplicate test that was already included in one of the custom panels created and implemented by a Quest employee. *See, e.g.*, FAC

[1] Even when electronic order forms replaced paper scripts, Quest's custom panels did not expire in the Care360 system, which Quest "designed" to be "'laborious and difficult'" for treating physicians to navigate. FAC ¶¶5, 176, 180.

¶¶217, 219 (treating physician "ordered the 'Arthritis Panel' as well as a 'CBC' test for Patient X, unaware that a 'CBC' test was one of the seven individual tests included in the 'Arthritis Panel'").

"Quest knew its Care360 ease of order panel process was resulting in Quest submitting false claims." FAC ¶178. In 2007, Quest even "created procedures that were designed to verify that each provider utilizing an ease of order panel actually knew of and intended to order each individual test included in the panel for his or her patient for a specific medical condition on the date the panel was selected," just as the company required for paper panels, calling these "draft set of policies and forms 'Alternative Care360.'" FAC ¶¶178, 189-94. But as "Quest's Vice President of Compliance and Chief Compliance Officer, Tim Sharpe, told Relator," the "business unit did not want to implement it." FAC ¶194.

III. Procedural History

Petitioner filed this *qui tam* suit under seal in July 2010. Pet. App. 2a. The Government investigated for over nine years. *Id.* 13a. In 2020, the Government declined to intervene and the complaint was unsealed. *Ibid.* After petitioner filed the operative Fourth Amended Complaint, the parties "engaged in efforts to resolve the case" for "approximately a year thereafter." *Ibid.* "Those efforts were ultimately unsuccessful," and respondent moved to dismiss. *Ibid.*

The District Court granted the motion. The court was "sympathetic" and "cognizant of the potential difficulty of amassing information and facts to show that the doctors were tricked into ordering medically unnecessary tests." Pet. App. 26a. And the court credited the complaint's example physician order form as sufficient to plead "the inference that the ordering

doctor was confused or did not know what was in the Arthritis Panel" he had ordered. *Id.* 22a n.7. But the court held that, "at least in this Circuit," a relator cannot survive a motion to dismiss by "'describing a private scheme in detail' and stating that 'claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted' to the government." *Id.* 23a (quoting *84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1360-61 (11th Cir. 2023)) (brackets removed). "[R]ecent ... Eleventh Circuit authority," the District Court explained, "has clarified ... the absolute requirement that a relator must plead an actual *false* claim with particularity, regardless of other indicia of reliability, *see 84Partners LLC*, 79 F.4th at 1360." *Id.* 26a n.9.

The Eleventh Circuit affirmed, confirming the court's view that "submission cannot be inferred from the circumstances." Pet. App. 6a (quoting *Olhausen v. Arriva Med., LLC*, 124 F.4th 851, 860-61 (11th Cir. 2024) (per curiam)). Even a relator with "direct knowledge of the defendants' billing and patient records" must provide allegations to establish her firsthand knowledge that false claims were submitted to the Government. *See id.* 7a-8a. This means providing the "'specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose treatment served as the basis for the claims,'" *id.* 8a (quoting *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam)), or alleging that the relator "observed the submission of an actual false claim" or "personally participate[d] in submitting false claims," *ibid.* (citing *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012)). Because petitioner had not shown her direct,

firsthand knowledge of actual false claim submissions by detailing a specific false Medicare invoice or alleging that she directly witnessed or participated in a fraudulent request for Government reimbursement, the Eleventh Circuit held that she failed to plausibly allege her claims. *Id.* 7a-9a.

The panel denied rehearing on August 19, 2025. Pet. App. 30a.

This petition follows.

REASONS FOR GRANTING THE WRIT

I. The Circuits Are Intractably Divided Over What Rule 9(b) Requires Of *Qui Tam* Plaintiffs.

The circuits are divided three ways over the Question Presented.

The Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits hold that direct knowledge of submitted false bills is not required, and that the existence of false submissions can be inferred from circumstances, including from the existence of a fraud scheme that naturally would lead to the submission of false claims.

That is not sufficient in the Sixth, Eighth, and Eleventh Circuits, which require all relators to allege particularized firsthand knowledge that false claims were actually submitted—either by pleading the details of a specific false invoice submitted to the Government or by plausibly alleging that they witnessed or participated in an actual false request for payment.

The First, Second, and Fourth Circuits generally require identifying specific false bills that were in fact submitted to the Government for reimbursement, although they have sometimes adopted ad hoc

exceptions that would not apply in this case. Accordingly, these circuits would have dismissed petitioner's complaint for failing to identify an example false claim submitted to the Government, in conflict with the law in six other circuits. These courts of appeals' ad hoc carveouts underscore the untenable arbitrariness of the present division in the lower courts.

A. Six Circuits Permit Plaintiffs To Proceed Based On Reliable Indicia Supporting A Strong Inference That False Claims Were Submitted To The Government.

The **Seventh Circuit** recognizes that "much knowledge is inferential," and permits complaints to proceed if the allegations that false claims were submitted is a "plausible" "inference" from the scheme alleged. *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009). Thus, in *Lusby*, an employee who alleged a fraudulent scheme to provide noncompliant products to the Government, but had never seen the defendant's actual bills and certifications of compliance, could proceed because it was reasonable to infer the defendant had certified its compliance when it sought payment. *See ibid.*

In later cases, the Seventh Circuit has confirmed that "a plaintiff does not need to present, or even include allegations about, a specific document or bill that the defendants submitted to the Government." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 777 (7th Cir. 2016) (citing *Lusby*, 570 F.3d at 853-54, and *Leveski v. ITT Educ. Servs., Inc.*, 719 F.3d 818, 839 (7th Cir. 2013)).

In a recent case, the Seventh Circuit reaffirmed that a relator can satisfy Rule 9(b) if her allegations

"plausibly support[] the inference that [the defendant] included false information" in its communications with the Government, even if the allegations only provide "circumstantial evidence" of an FCA violation. *United States ex rel. Prose v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732, 741 (7th Cir. 2021). The defense side of the *qui tam* bar sought this Court's intervention to resolve the circuit split in that case and was supported by the Chamber of Commerce of the United States and Washington Legal Foundation—all of whom acknowledged that the split is important and outcome determinative to real cases. *See infra* Part V.

The **Fifth Circuit** also does not require firsthand knowledge of false claim submissions. For example, in *United States ex rel. Colquitt v. Abbott Laboratories*, 858 F.3d 365, 371 (5th Cir. 2017), the court of appeals considered a case involving alleged kickbacks between a stent manufacturer and the hospitals and physicians that used the stents. The district court held that although the relator "had identified some specific hospitals and doctors that allegedly received kickbacks, he did not plead that any of [the] hospitals or doctors signed up to be Medicare providers or submitted certified claims for reimbursement for procedures using Abbott's stents." *Ibid.* The Fifth Circuit determined that this was "too rigid an application of Rule 9(b)," which "'is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act.'" *Id.* at 371-72 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). It suffices 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.'" *Ibid.* (quoting *Grubbs*, 565 F.3d at 191).

Applying this rule, the Fifth Circuit determined that the relator's allegations permitted "[a] strong inference that the named hospitals submitted claims to Medicare" because "[n]early every hospital in America participates in Medicare and would most likely have billed Medicare had they performed procedures using Abbott's stents on a person over age 65," a practice the complaint alleged was "common." *Colquitt*, 858 F.3d at 372. Given the nature of the scheme, probability and circumstantial evidence were enough to infer the existence of claims for repayment.

In *Grubbs*, the seminal case quoted in *Colquitt*, the Fifth Circuit explained that emphasis on details of claims is misplaced because "[s]tating 'with particularity the circumstances constituting fraud' does not necessarily and always mean stating the contents of a bill. The particular circumstances constituting the fraudulent presentment are often harbored in the scheme," and not the bills themselves. *Grubbs*, 565 F.3d at 190. Thus, when "the logical conclusion of the particular allegations" in a complaint is that "fraudulent bills were presented to the Government," the complaint survives Rule 9(b) even if it does not include details of the bills themselves. *Id.* at 192. "It would stretch the imagination to infer the inverse; that the defendant[s]" would "go through the charade ... only for the scheme to deviate from the regular billing track at the last moment so that the recorded, but unprovided, services never get billed." *See ibid.* The court also recognized that to require details about claims "at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Id.* at 190.

The **Ninth Circuit** has "join[ed] the Fifth Circuit," and expressly rejected the stricter approaches to Rule 9(b) that courts on the other sides of the split have adopted. *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) (contrasting the Fifth Circuit's approach with that of the First, Sixth, Eighth, and Eleventh Circuits).

In *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667 (9th Cir. 2018), allegations were similar to the allegations here: The relator alleged that the defendant Medicare Advantage organizations contracted with a third party to assess their beneficiaries and code their conditions to determine reimbursement—and that the contractor's approach was to overstate the beneficiaries' health problems, thus increasing the amount of money the Medicare Advantage organizations could seek from the Government for those beneficiaries' care. *Id.* at 679. Despite lacking any allegations of direct knowledge that actual false claims were submitted, the Ninth Circuit held that there was "ample circumstantial evidence from which to infer that the defendant organizations submitted [the contractor's] risk adjustment data and certified the data's validity to CMS." *Ibid.* Even though it was "possible that some Medicare Advantage organizations, after paying for [the contractor's] services, might have discovered the fraud and then cut ties with the company and thrown out its data," the allegations were enough to support the contrary inference; "it would stretch the imagination to infer the inverse." *Ibid.* (quoting *Grubbs*, 565 F.3d at 192) (brackets omitted).

More broadly, the Ninth Circuit has held that Rule 9(b) "does not require absolute particularity or recital of the evidence," and therefore does not require a complaint to allege "a precise time frame, describe

in detail a single specific transaction or identify the precise method used to carry out the fraud." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) (quotation marks omitted). Instead, if the complaint is specific enough to give the defendant notice of the allegations, and to dispel an inference that the allegations are spurious, it satisfies Rule 9(b). *See id.* at 1183 n.11.

The **Third Circuit** acknowledged the circuit conflict, and then held that Rule 9(b) is satisfied if the plaintiff can 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." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quoting *Grubbs*, 565 F.3d at 190, and contrasting Fifth Circuit's approach with that taken by the Fourth, Sixth, Eighth, and Eleventh Circuits). In *Foglia*, the Third Circuit reaffirmed its precedent holding that a plaintiff need not "identify a specific claim for payment *at the pleading stage* of the case." *Ibid.* (quoting *United States ex Rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 308 (3d Cir. 2011)) (emphasis in original). And as the Third Circuit later explained, "Rule 9(b) does not require the relators to plead" any direct knowledge of actual false submissions because "falsity" doesn't always come "from a particular misrepresentation, but" sometimes "from a set of circumstances that, if true, makes a whole set of claims at least prima facie false." *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019). "It is enough" in such instances "to allege those circumstances with particularity." *Ibid.*

The **Tenth Circuit** has likewise adopted the Fifth Circuit's approach, holding that "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a

reasonable inference that false claims were submitted as part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010). The court also "excuse[s] deficiencies that result from the plaintiff's inability to obtain information within the defendant's exclusive control," including details about claims and billing procedures. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 (10th Cir. 2018). "Rule 9(b) does not require omniscience," the court of appeals explained; "rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." *Ibid.* (quotation marks omitted). Telling defendants what they already know is not essential to providing notice.

The **D.C. Circuit** has "join[ed] [these] sister circuits in holding that the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint." *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015). "The central question, instead, is whether the complaint alleges 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* at 126 (quoting *Grubbs*, 565 F.3d at 190). And echoing the Fifth and Seventh Circuits' concerns, the D.C. Circuit admonished that Rule 9(b) does not "require relators, before discovery, to prove more than the law requires to be established at trial." *Ibid.* (citing *Lusby*, 570 F.3d at 854-55; *Grubbs*, 565 F.3d at 188-89).

B. Three Circuits Require Relators To Allege Direct, Firsthand Knowledge Of Actual False Claims That Were Submitted To The Government.

The **Eleventh Circuit**'s "requirement that a relator must plead an actual *false* claim with particularity, regardless of other indicia of reliability," is "absolute." *See* Pet. App. 26a n.9 (citing *84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1360 (11th Cir. 2023)). Thus, all relators must establish their direct knowledge of actual false bills, either by "provid[ing] particular facts about a representative false claim," or alleging that she "observed the submission of an actual false claim" or "personally participate[d] in submitting false claims." *Id.* 8a (citing *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1277-78 (11th Cir. 2018); *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam); *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012)).

In *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005) (per curiam), the Eleventh Circuit held that even though the plaintiff was an insider at the company who claimed to be "'aware' of the manner by which the defendants submitted fraudulent claims and had 'learned from his colleagues the national reach of the schemes,'" his complaint was inadequate because it did not show "that a specific fraudulent claim was in fact submitted to the government." *Id.* at 1013-14. And in *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), the court held that even though the plaintiff described the fraud scheme in detail, including identifying "particular patients, dates and corresponding medical records for services that he contends were not eligible for

government reimbursement," the claim still failed because the plaintiff was "a psychiatrist responsible for the provision of medical care, not a billing and coding administrator responsible for filing and submitting the defendants' claims for reimbursement"—and therefore not privy to the submission of actual false claims. *Id.* at 1359. And in *Lymphatx*, the Eleventh Circuit dismissed the relator's claims despite his "direct knowledge of the defendants' billing and patient records" because he failed to provide "at least some examples of actual false claims." 596 F.3d at 1302 (quotation marks omitted).

In one of the cases in which this Court requested the United States' views in 2022, the Eleventh Circuit held that a complaint failed to satisfy Rule 9(b) even though the plaintiffs alleged that all or nearly all of the defendant's patients were covered by Government insurance programs, that a large fraction of the patients were receiving care tainted by kickbacks (which would cause the resulting claims for payment to be false per se), and that Medicare claims data showed that the defendant was submitting claims for reimbursement for patients referred by the doctors who received kickbacks. *See Est. of Helmly v. Bethany Hospice & Palliative Care of Coastal Georgia, LLC*, 853 F. App'x 496, 502 (11th Cir. 2021). The court held there what the panel held here: Short of providing the details of specific false invoices, a relator must plead her "'personal knowledge or participation in the fraudulent conduct,'" which the plaintiffs in *Bethany Hospice* had failed to do. *See id.* at 501-02 (quoting *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012)).

And in the post-CVSG opinion discussed by the District Court, the Eleventh Circuit reaffirmed its

view that, "[s]tanding alone, a fraudulent scheme, no matter how egregious, is not enough; there must be an actual false claim." *See United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1360 (11th Cir. 2023). The Eleventh Circuit emphasized that allegations of "improper practices, even if fraudulent and so widespread as to constitute standard operating procedure, are not enough; a complaint must allege with particularity a connection between those practices and one or more actual claims." *Id.* at 1362. The court even acknowledged that one of the relators "participated in some of" the alleged fraud, but rejected his allegation as "fall[ing] far short of the required particularity" for failing to describe "who did what, who said what, and where and when they did or said it." *Ibid.* The District Court thus acknowledged that, "as made abundantly clear in *84Partners*," Pet. App. 19a, the Eleventh Circuit has an "absolute requirement that a relator must plead an actual *false* claim with particularity," *id.* 26a n.9 (citing *84Partners*, 79 F.4th at 1360).

The panel below agreed, holding that a relator, even one like petitioner, "must still provide particular facts about a representative false claim" or otherwise demonstrate her firsthand observation of or involvement in the scheme. *See* Pet. App. 8a. The Circuit's pleading barrier admits no exception. Because petitioner did not allege "to have observed the submission of an actual false claim" or to "personally participate in submitting false claims," her "access and knowledge [did] not help [her] satisfy the heightened particularity requirement" imposed by the court below. *See ibid.*

The **Sixth Circuit** has also long imposed what it calls a "'clear and unequivocal requirement that a relator allege specific false claims when pleading a

violation of the FCA.'" *See United States v. Tenet Healthcare Corp.*, 2025 WL 1166894, at *4 (6th Cir. Apr. 22, 2025), *cert. petition pending*, No. 25-347 (U.S.) (quoting *United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 411 (6th Cir. 2016)). Under that rule, a plaintiff must identify a "representative example" of a false claim that was in fact submitted to the government. *See United States ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192, 196 (6th Cir. 2021). Thus, in the Sixth Circuit, even "where a relator pleads a complete and far-reaching fraudulent scheme with particularity," the relator must also "provide[] examples of specific false claims submitted to the government pursuant to that scheme." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007). "[I]t is insufficient to simply plead the scheme;" the relator "must identify a representative false claim that was actually submitted to the government." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 470 (6th Cir. 2011).

The Sixth Circuit also permits some relators with personal "billing-related" knowledge to meet this requirement without presenting the particulars of an example false invoice. *See United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 769-73 (6th Cir. 2016). But the court still requires the allegations to establish that the relator observed or participated in the submission of actual false claims for Government payment. As the Sixth Circuit later explained, that maneuver only worked for the relator in *Prather* because she "reviewed allegedly false claims themselves." *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 915 (6th Cir. 2017) (citing *Prather*, 838 F.3d at 768). "In fact," the Sixth Circuit confessed, "the only time this court has ever applied a personal knowledge exception" to the

Circuit's requirement that the relator describe a representative example "was in *Prather* itself." *Ibid.*

The **Eighth Circuit** also requires direct knowledge of actual false claim submission. *See United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp.*, 915 F.3d 1158, 1163, 1165 (8th Cir. 2019) (holding that relators who were paramedics and EMTs who "did not have access to the billing department" and who did not allege "personal knowledge of the billing system or the submission of false claims" failed to plausibly allege that false claims were submitted even though their complaint alleged a "wide-ranging fraudulent scheme"); *United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 740 (8th Cir. 2020) (holding that trauma surgeon could not satisfy Rule 9(b), and refusing to hold that inference of false claims was reasonable when the plaintiff alleged that over a quarter of a hospital's revenue came from Medicare, and that every claim submitted by certain physicians was false due to Stark Act and Anti-Kickback Statute violations).

Like the Sixth Circuit, the Eighth Circuit once excused a relator who "concede[d] that she did not provide any representative examples of the false claims in the complaint," because she alleged direct, firsthand knowledge that actual false claims were submitted. *See United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 917 (8th Cir. 2014). In *Thayer*, the relator "was the center manager for two of [defendant] Planned Parenthood's clinics, oversaw Planned Parenthood's billing and claims systems, and was able to plead personal, first-hand knowledge of Planned Parenthood's submission of false claims. *Ibid.*

Thus, the Sixth and Eight Circuits, like the court below, would have rejected petitioner's claims because she did not allege that she "observed the submission of an actual false claim" or "personally participate[d] in submitting false claims." *See* Pet. App. 8a.

C. Three Circuits Also Generally Require Relators To Identify A Specific False Claim Submitted To The Government, Subject To Limited Exceptions Not Applicable Here.

The **First Circuit** holds that examples of false claims are required in most cases. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). In *Karvelas*, the court dismissed a hospital employee's allegations of a scheme to bill Medicare for medically unnecessary services because he could not identify the "dates or content of any particular false or fraudulent claim submitted for reimbursement," "identification numbers or amounts charged in individual claims for specific tests, supplies, or services," "the individuals involved in the improper billing," or "certification of compliance with federal regulations in order to obtain payments." *Id.* at 233.

The Circuit recognizes an exception, however, when the plaintiff alleges that the defendant caused a third party to submit the false claims. *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 38-39 (1st Cir. 2017). In that circumstance, the court "appl[ies] a more flexible standard," under which "a relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond the possibility without necessarily

providing details as to each false claim." *Id.* at 39 (quotation marks omitted). Only then may the complaint "pair the details of the scheme with reliable indicia that lead to a strong inference that claims were actually submitted." *Ibid.* (quotation marks omitted).

The **Fourth Circuit** also generally requires a complaint to describe a specific false claim in detail. *See United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013). The court "hold[s] 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." *Ibid.* (emphasis in original). "To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances," the Fourth Circuit held that "we disagree with that approach." *Id.* at 457-58. The possibility or even probability that the Government was billed is not enough; the fact must be certain. *See United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 197 (4th Cir. 2018). In *Grant*, the Fourth Circuit thus held that although the relator "allege[d] with specificity some instances of United's fraudulent conduct, the complaint" failed because it "ma[de] no specific allegation as to whether or how any statement containing a false claim was presented to or paid for by the government, as it must." *Id.* at 199.

The **Second Circuit** generally requires the plaintiff to describe an actual false claim that was submitted to the Government for payment as well. In *United States ex rel. Chorches v. American Medical Response, Inc.*, 865 F.3d 71 (2d Cir. 2017), the court held that when a relator "*can* identify examples of actual claims," she "*must* do so at the pleading stage."

Id. at 86. The court cited the Eleventh Circuit's caselaw approvingly, noting that the Eleventh Circuit has rejected "a 'more lenient pleading standard.'" *Ibid.* (citing *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1314 n.25 (11th Cir. 2002)). Yet unlike the other circuits, the Second Circuit excuses this requirement when the "information regarding the particular bills that were submitted for reimbursement is peculiarly within [the defendant's] knowledge." *Id.* at 82. (quotation marks omitted); *see also id.* at 81-82 ("Despite the generally rigid requirement of Rule 9(b), allegations may be based on information and belief when facts are peculiarly within the opposing party's knowledge." (quoting *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990)) (brackets omitted)).

None of these ad hoc exceptions would save petitioner's complaint. Quest itself submitted the claims (unlike *Nargol*). Petitioner had billing access (unlike *Chorches*). And the scheme made false claims all but certain (unlike *Grant*).

II. The Question Presented Is Important.

The FCA generates billions in annual recoveries for the federal treasury, with healthcare fraud comprising 70% of all FCA recoveries since 1986. *See supra* p.4. The question presented arises in virtually every *qui tam* case—yet the circuits apply fundamentally different standards to determine which cases may proceed past the pleading stage.

Multiple circuits recognize that modern healthcare compartmentalizes billing from clinical care. Those witnessing fraud often do not personally submit claims. *See, e.g.*, *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1359 (11th Cir. 2006) (rejecting relator's claim because he was "a

psychiatrist responsible for the provision of medical care, not a billing and coding administrator responsible for filing and submitting the defendants' claims for reimbursement"); *see also* Pet. 25, *United State ex rel. Olsen v. Tenet Healthcare Corp*, No. 25-347 (U.S. 2025) (distributed for Conference of January 9, 2026) (discussing compartmentalization in healthcare industry). And those processing claims, for example, do not see patients—as here. Indeed, this is true for any provider who uses respondent Quest's services as the nation's largest provider of third-party clinical laboratory testing.

As the Second Circuit recognized in *Chorches*, this siloing means that "by simply insulating its accounting department from personnel with operational knowledge, a corporate fraudster could ensure that few employee relators could successfully plead both the falsity of recorded information and the presentment of a claim containing those falsehoods." 865 F.3d at 86. *Chorches* was concerned with physicians not having access to the bills, but this case demonstrates the opposite problem. Petitioner's job was to review the Medicare and Medicaid submissions for eligibility, but because she lacked access to the patients and doctors themselves, the Eleventh Circuit rejected her claims as implausible. *See* Pet. App. 7a. The Circuit's "absolute" requirement thus immunizes the very compartmentalization that makes fraud difficult to detect.

This Court has thrice called for the Solicitor General's views on this question, reflecting its recognized importance. And although the Government recommended denial then, its interests diverge from other FCA stakeholders on this issue. "FCA claims litigated by the United States should rarely if ever present" this question because the Government "will

typically have access to any claims for payment that the defendant submitted." U.S. *Amicus Curiae* Br. 22, *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, No. 21-936 (U.S. 2022). But "[t]he vast majority of FCA cases are brought by *qui tam* relators, not the United States," and the Government "declines to intervene in approximately 75% of those cases." Petr. Second Supp. Br. 7, *Molina Healthcare of Illinois, Inc. v. Prose*, No. 21-1145 (U.S. 2022); *see also* Petr. First Supp. Br. 7, *Molina Healthcare of Illinois, Inc. v. Prose*, No. 21-1145 (U.S. 2022) ("It appears that in the twelve FCA cases since October Term 1996 in which the Court has called for the views of the Solicitor General, the Solicitor General has recommended denial in all but one. Notably, the Court granted certiorari in three of those cases despite the Solicitor General's denial recommendation." (footnotes omitted)).

III. This Case Is An Ideal Vehicle.

This case cleanly presents the question. The Eleventh Circuit affirmed dismissal solely because petitioner did not allege direct, firsthand knowledge of actual false claims submissions. Pet. App. 6a-8a. The panel did not reach any alternative ground for affirmance, *ibid.*, and the District Court dismissed on the same basis, *id.* 18a-19a.

The District Court's candor confirms the split is outcome-determinative. It expressed "sympath[y]" for her "predicament." *See* Pet. App. 26a. But "at least in this Circuit," the court held, *84Partners* required dismissal "regardless of other indicia of reliability." *Id.* 23a, 26a n.9.

This case also demonstrates that the Eleventh Circuit's rule is categorical. Petitioner had direct knowledge of Quest's billing practices and patient records. The panel held that this "access and

knowledge does not help Relator satisfy the heightened particularity requirement" without further alleging that she directly "observed the submission of an actual false claim" or "personally participate[d] in submitting false claims." Pet. App. 8a. The requirement for direct, firsthand knowledge of actual false claim submission admits no exception.

This case thus complements the pending petition in *United States ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347 (distributed for Conference of January 9, 2026). *Tenet Healthcare* arises from the Sixth Circuit and frames the question around billing access—whether relators who lack access to billing records may proceed without identifying specific claims. *See id.*, Pet. i. As discussed above, several circuits have highlighted billing access as a relevant consideration. But that billing-related access did not help petitioner. Granting both petitions would therefore present the full range of circumstances in which the question arises. Alternatively, if the Court grants only one of the petitions, it should hold the other pending resolution. Either way, the conflict is entrenched and warrants this Court's review.

IV. The Decision Below Is Wrong.

Federal Rule of Civil Procedure 9(b) requires a party to "state with particularity the circumstances constituting fraud." It does not require a plaintiff to produce the defendant's billing records or prove falsity before discovery.

The Eleventh Circuit's rule cannot be squared with this text. The "circumstances constituting fraud" here are the deceptive panels Quest created, the automatic billing system that submitted claims every time a Quest employee entered a physician's paper requisition selecting a Quest customized panel into

Quest's electronic Care360 ordering system, and Quest's certification on each claim for reimbursement that the tests were in fact "medically indicated and necessary." Petitioner alleged all of this with particularity. What she did not allege were the specific contents of an actual false claim form automatically submitted for Medicare reimbursement through Quest's Care360 system. Rule 9(b) does not demand that level of detail. As six circuits have recognized, requiring such allegations practically requires the "production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see also United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015) (same).

The Eleventh Circuit's rule also serves no function except to prematurely kick well-pleaded *qui tam* suits out at the pleading stage. The panel did not doubt that Quest's scheme was designed to cause physicians to order tests they did not intend to order, which in turn caused Quest's automated system to bill Medicare for those tests with certifications of medical necessity regardless of whether doctors were confused. Submission of false claims was not merely probable; it was the scheme's purpose. Requiring petitioner to also identify the specific contents of a false Medicare invoice or to have directly witnessed or participated in actual false billing isn't necessary for Quest to defend itself. Quest knows what it is accused of doing and has the contents of each bill it submitted. The Government also has that data. *See supra* pp.26-27.

The Eleventh Circuit's rule also conflicts with the FCA's text. Everyone agrees the FCA is not limited to

insider whistleblowers. Requiring relators to plead direct, firsthand knowledge of actual false claims submissions doesn't just arbitrarily hamstring insiders like petitioner, it largely disqualifies many outsiders who learn of a fraudster's scheme to overbill the Government but cannot allege firsthand knowledge of the actual false invoices that were submitted for reimbursement.

Finally, the United States agrees with petitioner's answer to the Question Presented. The Solicitor General has consistently argued that "a *qui tam* complaint satisfies Rule 9(b) if it contains detailed allegations supporting a plausible inference that false claims were submitted," even if it "does not identify specific requests for payment" or otherwise allege the relator's direct observation of or involvement in actual false claim submission. *See* U.S. *Amicus Curiae* Br. 10, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 12-1349 (U.S. 2014).

V. At A Minimum, The Court Should Call For The Views Of The Solicitor General.

If the Court is not prepared to grant certiorari outright, it should invite the views of the United States.

When the Solicitor General twice urged denial of certiorari in 2022, she concluded that the circuits were converging toward rejecting hard-and-fast rules that invariably require relators to show their direct, firsthand knowledge of actual false claim submission. *See* U.S. *Amicus Curiae* Br. 14-19, *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, No. 21-936 (U.S. 2022); U.S. *Amicus Curiae* Br. 13-14, *Johnson v. Bethany Hospice & Palliative Care LLC*, No. 21-462 (U.S. 2022). That prediction has proven spectacularly wrong. Indeed, all other stakeholders disagreed with the

Solicitor General at the time and continue to plead for this Court's intervention.

1. Just this year, the Eleventh Circuit permitted only one of several fraud claims to proceed where the relators had "audited patient files—including billing correspondence and authorizations for payment" providing "specific instances of upcoding" with "dates, amounts, and billing codes"—but dismissed three other fraud theories against the *same defendant* for failure to identify specific false claims or direct knowledge of actual false submissions. *Vargas v. Lincare*, 134 F.4th 1150, 1159-62 (11th Cir. 2025). In other words, the Eleventh Circuit only permitted the claims to go forward where the relators had "hands-on access to primary records" that "[gave] them the type of inside information that are sufficient at the pleading stage." *Id.* at 1159. And again, the Eleventh Circuit held in 2023 that "a fraudulent scheme, no matter how egregious, is not enough," and that "underlying improper practices, even if fraudulent and so widespread as to constitute standard operating procedure, are not enough." *See 84Partners*, 79 F.4th at 1360, 1362. That "recent ... Eleventh Circuit authority," the District Court explained, "clarified ... the absolute requirement that a relator must plead an actual false claim with particularity, regardless of other indicia of reliability." *See* Pet. App. 26a n.9 (citing *84Partners*, 79 F.4th at 1360)).

The Sixth Circuit continues to require direct personal knowledge of false claims submission as well, applying the rule in *United States ex rel. VIB Partners v. LHC Grp., Inc.*, 2025 WL 1103997 (6th Cir. Apr. 14, 2025), where it dismissed detailed scheme allegations from a nurse and data manager who witnessed OASIS score manipulation because "relators cannot survive a Rule 9(b) challenge by alleging a systemic scheme

alone." *Id.* at *3. The Sixth Circuit applied the rule again in *United States v. Tenet Healthcare Corp.*, 2025 WL 1166894, at *4 (6th Cir. Apr. 22, 2025), *cert. petition pending*, No. 25-347 (U.S.).

The First Circuit also maintains its requirement that relators generally must allege the details of specific false billing submissions. *Flanagan v. Fresenius Med. Care Holdings, Inc.*, 142 F.4th 25, 37 (1st Cir. 2025) (dismissing false certification claims for failure to specify what was submitted in compliance reports). Meanwhile, circuits rejecting the requirement permit similarly situated healthcare whistleblowers to proceed. *See, e.g.*, *United States ex rel. Ellis v. CVS Health Corp.*, 671 F. Supp. 3d 580, 589-92 (E.D. Pa. 2023) (allowing "worthless services" claim to proceed based on relator's knowledge of shipping problems and manufacturers' warnings against freezing, not the description of any direct, firsthand knowledge of the false claim submissions).

2. The Solicitor General's 2022 claim that the split was resolving itself has been uniformly rejected by all other stakeholders.

After the Solicitor General argued in *Owsley* that courts were merely reaching "divergent results across cases involving a wide range of factual allegations," U.S. *Amicus Curiae* Br. 19-20, relators, defendants, and amici united in opposition. "Bluntly put, no, they haven't," the *qui tam* defendant-petitioner explained in *Molina Healthcare of Illinois, Inc. v. Thomas Prose*, No. 21-1145 (U.S. 2022). *See* Petr. Second Supp. Br. 1. The Chamber of Commerce of the United States supported certiorari review in that case, arguing the split has "far-reaching consequences." U.S. Chamber of Commerce *Amicus Curiae* Br. 2. The Washington Legal Foundation agreed that the circuit split "cries

out for this Court's review." WLF *Amicus Curiae* Br. 3; *see also* America's Health Insurance Plans *Amicus Curiae* Br. 5-6 & n.3 (noting "split on this question is acknowledged and deep" and urging review).

As the *Molina Healthcare* defendant pointed out, the Solicitor General herself conceded that "different circuits have *not* articulated 'the same standard for applying Rule 9(b) in FCA cases.'" *See Molina Healthcare*, Petr. Second Supp. Br. 2 (quoting *Bethany Hospice* and *Owsley* CVSGs). "Different results based on the application of the same rule to different facts are how law is supposed to work. Different results based on the application of different rules to the same facts are not." *Id.* at 1. The defense side of the *qui tam* bar was right when it urged back then that "[t]his Court should grant certiorari." *Ibid.*

Legal observers continue to document the split and plead for this Court to intervene. In 2023, Gibson Dunn put out an alert warning clients that the circuits' standards "exist on a spectrum, ranging from the Eleventh Circuit and Sixth Circuit," to "the Seventh Circuit (and others such as the Third, Fifth, Ninth, Tenth, and D.C. Circuits)." Gibson Dunn, *2022 Year-End False Claims Act Update* (Feb. 8, 2023), https://tinyurl.com/36xc2sv2. "By denying the petitions for writ of certiorari in *Bethany Hospice*, [*Molina Healthcare*], and *Owsley*," the firm cautioned, this "Court ha[d] effectively declined to resolve this circuit split ... and as a result left open the possibility that plaintiffs will forum-shop for the most favorable pleading standard when pursuing FCA cases." *Ibid.*

Troutman Pepper Locke similarly cautioned that "the continued lack of uniformity in pleading requirements poses problems for companies that face increased risk of finding themselves subject to FCA

lawsuits and concomitant federal investigations." Callan G. Stein et al., *Cos. Need Clarity on Divergent FCA Pleading Standard*, Troutman Pepper Locke (Mar. 20, 2023), https://tinyurl.com/2zmd2b4a. "Notwithstanding the government's [2022] position, there is, indeed, an outcome-determinative circuit split that needs to be addressed, even if it is not as well-defined as it was previously." *See* Kenneth M. Abell & Katherine Kulkarni, *Justices Should Resolve FCA Cases' Rule 9(b) Circuit Split*, AEL Law (June 28, 2022), https://tinyurl.com/2swjne3c.

CONCLUSION

The petition should be granted. Alternatively, the Court should hold the petition for resolution of the Question Presented in *United States ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347 (U.S.) (distributed for Conference of January 9, 2026).

Respectfully submitted,

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December 17, 2025

APPENDIX

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APPENDIX A: ELEVENTH CIRCUIT OPINION, FILED JULY 16, 2025

[DO NOT PUBLISH]

In the

United States Court of Appeals

for the Eleventh Circuit

No. 24-12998

Non-Argument Calendar

UNITED STATES OF AMERICA, ex. rel. et al.,

Plaintiffs,

BARBARA SENTERS,

Plaintiff-Appellant,

versus

QUEST DIAGNOSTICS INC.,

Defendant-Appellee,

JOHN DOE FLORIDA CORPORATIONS 1-1000, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
D.C. Docket No. 1:10-cv-02202-AT

OPINION

Before: JILL PRYOR, BRASHER, and WILSON, Circuit Judges.

PER CURIAM:

In this qui tam action, Barbara Senters (Relator) appeals the district court's dismissal of her fourth amended complaint (FAC). The district court found that Relator failed to plead with particularity that a false claim had been submitted. After careful review, we affirm.

I. Background

Quest Diagnostics sells diagnostic laboratory tests to a variety of different type of medical entities, including hospitals and medical practices. Relator started working for Quest in 2005 as a human resources generalist. In 2007, Relator was promoted to a compliance officer for the Southeastern Business Unit, which cover multiple states including Georgia. Part of Relator's job included making sure that Quest was billing the government, namely Medicare and Medicaid, for tests eligible for reimbursement. In July 2010, after uncovering an alleged fraudulent billing scheme, Relator sued Quest under seal on behalf of the United States and the State of Georgia, alleging that Quest violated the False Claims Act (FCA), 31 U.S.C. § 3729, the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168.1, and the Georgia Medical Assistance Act, O.C.G.A. § 49-4-146.1.

As Relator alleged, the scheme involved custom lab panels created by Quest's sales representatives to be implemented in doctors' offices by Quest employees. Relator further alleges that in creating these custom panels, Quest made it difficult for doctors to know which tests were included in the custom panel and thus difficult to understand what tests were ordered. As a result, when the physicians selected the custom panels, they unknowingly ordered tests that were not determined to be medically necessary for their

patients, and then Quest billed the government for those unnecessary tests.

Because Quest, not the doctor's offices or hospitals, submits the claim for reimbursement to the government, it must submit a Center for Medicare & Medicaid Services Form 1500 (CMS Form 1500). CMS Form 1500 requires a provider, here Quest, to expressly certify that the claim being submitted "complies with all Medicare and/or Medicaid laws, regulations" and that the services listed on the form "were medically indicated and necessary for the health of the patient." To submit the CMS Form 1500, Quest had to submit a Medicare Enrollment Application, Form CMS-855B, which requires that Quest agree to abide by federal laws and regulations along with certifying that Quest would not "knowingly present . . . a false or fraudulent claim for payment by Medicare."

In July 2011, Relator's action was administratively closed pending the United States's decision on whether to intervene. Very little activity occurred on the district court docket, but investigations occurred. In October 2020, the United States declined to intervene. In February 2021, Relator filed a third amended complaint (TAC) that was not under seal. In the TAC, the crux of Relator's claim was that Quest submitted false claims and false statements that lab tests were medically necessary and eligible for reimbursement and that Quest certified on its CMS Form 1500 that it complied with all Medicare laws for payment.

Quest moved to dismiss. The district court granted the motion because under Federal Rule of Civil Procedure 9(b), it found that Relator had not pled with particularity that "a specific fraudulent claim

was in fact submitted to the government." But based on Relator's representations that she had 75 hours of investigative recording that would allow her to plead her claims with more detail, the district court granted Relator leave to file the FAC.

Unlike in the TAC, Relator alleged in the FAC that Quest submitted requests for payment of services, that Quest did not know whether the lab tests were medically necessary, and that despite this lack of knowledge, Quest certified on its CMS Form 1500 that it complied with all Medicare laws for payment. Quest again moved to dismiss.

The district court granted Quest's motion to dismiss, finding that "Relator fail[ed] to plead the falsity element with particularity and so fail[ed] to plead that an actual *false* claim was submitted to the government." In relying on the express certification theory, the court explained that "Relator must plead a representative false claim in which the services rendered were not 'medically indicated and necessary for the health of the patient' and where the claim was submitted to the government for payment." And Relator failed to do so because the FAC does not provide any particular details about the only representative claim submitted to the government. Instead, Relator used inferences because of the alleged "shady nature of the scheme." At the end, the district court explained that "this case must come to a close" and did not give Relator leave to amend.[1] Relator timely appealed.

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[1] Relator did not file a separate motion for leave to amend, but she asked for leave in her response to Quest's motion to dismiss.

II. Standard of Review

"We review a dismissal with prejudice for failure to state a claim under the False Claims Act *de novo*." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015). We take the allegations in the complaint as true and draw all reasonable inferences in Relator's favor. *Id.*

III. Analysis

On appeal, Relator argues that the district court erred in dismissing the FAC because it alleged with the requisite particularity a false claim violation under 31 U.S.C. § 3729. Relator also argues that the district court should have allowed Relator to amend her complaint. We address each argument in turn.

A. Dismissal of FAC

"The FCA imposes liability on any person who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017) (quoting 31 U.S.C. § 3729(a)(1)(A)–(B)). Section 3729(a)(1) imposes liability for various acts, and relevant for our purposes, it imposes liability for *presentment* and *false statements*. 31 U.S.C. § 3729(a)(1)(A)–(B).

"To state a § 3729(a)(1)(A) *presentment* claim, a complaint must allege (1) a false claim, (2) that the defendant presented, or caused to be presented, for payment or approval, (3) with knowledge that the claim was false. *United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1359 (11th Cir. 2023) (emphasis added). "To state a § 3729(a)(1)(B) *false-*

statement claim, a complaint must allege (1) the defendant made, or caused to be made, a false statement, (2) the defendant knew the statement was false, and (3) the statement was material to a false claim." *Id.* (emphasis added). "[A]n essential element that must be alleged in a False Claims Act complaint is the actual presentment or payment of a *false* claim." *Id.* at 1360 (emphasis added). "Standing alone, a fraudulent scheme, no matter how egregious, is not enough; there must be an actual false claim." *Id.*

When alleging an FCA violation, a relator's complaint must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). Rule 9 (b) requires that a party "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." "[T]he particularity standard in qui tam actions requires the relator to allege the actual submission of a false claim." *Olhausen v. Arriva Med.*, LLC, 124 F.4th 851, 860 (11th Cir. 2024) (per curiam) (internal quotation marks omitted and alteration adopted). "It is not enough to plead generally that false claims were submitted, nor may a relator merely "point to 'improper practices of the defendant' to support 'the inference that fraudulent claims were submitted' because 'submission cannot be inferred from the circumstances.'" *Id.* at 860–61 (alterations adopted). Rather, a relator must "allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (per curiam).

Here, Relator asserts that the FAC contained an exemplar sample of a false claim that shows a violation under 31 U.S.C. § 3729, under three theories of liability: (1) express false certification theory, (2)

implied false certification theory, and (3) fraudulent inducement theory. Relator expends considerable ink on these different theories. But she misses the mark. No matter which theory she pursues, her FAC rises and falls with the fact that she failed to plead with particularity that a *false* claim was submitted to the government.

As an example, Relator's exemplar sample for Patient Y shows that the doctor ordered a custom panel and that panel was submitted to the government for reimbursement using the CMS Form 1500, which required a certification that the services listed on the form "were medically indicated and necessary for the health of the patient." Then Relator alleges that Quest did not know if the services were medically necessary. But that is a blanket allegation with no particular facts to show why the custom panel for Patient Y was not medically necessary and why, therefore, any certification to the contrary was false. Like the district court noted, "Relator provided no factual allegations to indicate that doctors later discovered, or even now believe, that they were tricked or confused into ordering medically unnecessary tests or tests that they did not intend to order."

Relator tries to work around this issue by pointing to personal knowledge about the alleged fraudulent claims, including Patient Y's custom panel. *See United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012) ("[W]e are more tolerant toward complaints that leave out some particularities of the submissions of a false claim if the complaint also alleges personal knowledge or participation in the fraudulent conduct."). We recognize that Relator's job gave her access to the claims being submitted to the government and that she reviewed the claims billed to the government, but

Relator must still provide particular facts about a representative false claim. Previously, we found that relators with "managerial positions" who attended "monthly financial review meetings" could not satisfy the Rule 9(b) particularity requirements because "the relators failed to explain how their access to possibly relevant information translated to knowledge of actual tainted claims presented to the government." *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1277–78 (11th Cir. 2018).

Relator's complaint suffers from the same flaw. The FAC alleged that Relator had access to Quest's billing system and confirmed from her review of those systems that Quest was submitting claims to the government, but she does not allege any facts that show those label panels "were medically indicated and necessary for the health of the patient." Those allegations cannot satisfy Rule 9(b)'s particularity requirement because even with "direct knowledge of the defendants' billing and patient records," Relator "failed to provide any specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose treatment served as the basis for the claims." *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam). Nor did Relator claim to have observed the submission of an actual false claim; nor did she personally participate in submitting false claims. *See Matheny*, 671 F.3d at 1230. Thus, Relator's access and knowledge does not help Relator satisfy the heightened particularity requirement.

Although we construe all facts in favor of Relator, we "decline to make inferences about the submission of fraudulent claims because such an assumption would strip all meaning from Rule 9(b)'s requirements

of specificity." *Corsello*, 428 F.3d at 1013 (internal quotation marks omitted and alteration adopted).

B. Leave to Amend

Relator did not file a motion asking for leave to file a fifth amended complaint but asked in her response to Quest's motion to dismiss. The district court did not address this request but dismissed the case with prejudice. On appeal, Relator argues that the district court erred in entering a dismissal with prejudice because the district court did not make a finding of delay or willful conduct such that lesser sanctions were not appropriate. But as Quest notes, the district court did not dismiss the case as a sanction for litigation misconduct. The district court dismissed the case with prejudice because the case had been happening for over fourteen years with several complaints where Relator ultimately failed to plead a false claim with particularity as required. The district court did not err. *See Corsello*, 428 F.3d at 1014.

IV. Conclusion

The district court's dismissal of the FAC with prejudice is affirmed.

AFFIRMED.

APPENDIX B: DISTRICT COURT OPINION, FILED AUGUST 23, 2024

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CIVIL ACTION NO. 1:10-cv-2202-AT

UNITED STATES OF AMERICA, *ex rel.* BARBARA SENTERS and THE STATE OF GEORGRIA, *ex rel.* BARBARA SENTERS,

Relator,

v.

QUEST DIAGNOSTICS, INC.,

Defendant.

ORDER

This *qui tam* case, originally filed in 2010, involves allegations that Defendant Quest Diagnostics, Inc. ("Quest") engaged in a fraudulent scheme to encourage doctors to over-order lab tests that Quest then completed and, as alleged, wrongfully billed to the government. Before the Court is Defendant's Motion to Dismiss the Fourth Amended Complaint. [Doc. 108]. After careful review, the Court finds that Relator fails to plead her claims with the particularity required under Rule 9(b) and so **GRANTS** Defendant's Motion.

I. Background

In prior orders, the Court has outlined the relevant procedural and factual background and so provides only a brief recap here, highlighting Relator's core theory as well as changes made in the Fourth Amended Complaint ("FAC"). For a comprehensive review of the relevant facts and procedural history, see the Court's Order on Defendant's Motion to Dismiss the Third Amended Complaint (Doc. 77) and the Court's Order on Defendant's Motion to Unseal (Doc. 125).

Broadly speaking, Relator alleges that Quest engaged in the following fraudulent scheme:

- that Quest created custom lab panels containing multiple lab tests in each panel (*see, e.g.*, FAC, Doc. 80 ¶ 5);
- that Quest employees (sales representatives and phlebotomists) surreptitiously implemented these custom lab panels at doctor's offices across the country using Quest's software platform, Care360 (*id.* ¶ 7);
- that the script pads or electronic order forms did not clearly indicate — or made it difficult to determine — which particular lab tests were included in a given custom panel (*id.*; *id.* ¶ 180);
- that doctors were encouraged (by Quest personnel) to use the custom panels and that doctors were mistakenly led to believe that the tests included in custom panels were billed at bundled rates, as with American Medical Association approved panels (*id.* ¶¶ 183-84);

- that Quest then completed each test included in the custom lab panels (as ordered by the doctors when the doctors checked the form to order the custom panel) (*id.* ¶ 185);
- that Quest then billed government payors for each separate lab test completed (*id.*); and
- that Quest submitted claim forms attesting that the lab tests performed were medically indicated and necessary (*id.*; *id.* ¶ 244).

As her primary example, Relator points to an Arthritis Panel, containing seven lab tests, that was implemented by Quest employees at a doctor's office in Snellville, Georgia. (*Id.* ¶ 217). As alleged, doctors at the Snellville office ordered the Arthritis Panel for two exemplar patients, Patients X and Y. (*Id.* ¶¶ 219-224). For Patient X, the doctor separately ordered both a CBC test and the Arthritis Panel, which included the CBC test as one of the seven included tests. (*Id.*) Relator argues that this demonstrates that the doctor was not aware of the contents of the Arthritis Panel.[1] Relator alleges that thousands of different custom

[1] As discussed in prior briefing and at the prior hearing, Relator does not allege that the lab tests completed for Patient X were billed to a government payor. Instead, Relator provides the example of Patient X to demonstrate the nature of the scheme. (*See* Resp. to MTD the TAC, Doc. 55 at ECF 14; Hearing Tr., Doc. 75 p. 46). Conversely, Relator does allege that the tests conducted for Patient Y were submitted to government payors. However, Relator does not allege either a similar duplicate test order for Patient Y or any information to suggest that the tests were not medically necessary.

panels were created and implemented in doctors' offices across the country.

Relator is a former Quest employee. She worked as a Senior Human Resources Generalist from 2005 to 2008 and worked as Compliance Officer for the Southeastern Business Unit (serving Georgia, North Carolina, South Carolina, Tennessee, and Alabama) from 2008 until 2010, when she left Quest. (*Id.* ¶ 26).

This case was originally filed in 2010 (Doc. 1) but was then administratively closed for over nine years, from 2011 to 2020, while the government investigated the case. In 2020, the government declined to intervene, the case was reopened, and the Third Amended Complaint ("TAC") was filed and served on Defendant. After Defendant moved to dismiss and that motion was briefed, the case was transferred to the undersigned. After hearing oral argument, the Court granted Defendant's motion to dismiss without prejudice. In its Order granting the motion to dismiss, the Court found that the TAC did not include sufficient indicia of reliability to support Relator's claims, particularly in light of the age of the case. (Doc. 77 at 21). However, Relator asserted that she had recently been provided with 75 hours of investigative recordings (that had been presumed to be lost) and that these recordings would allow her to plead her claims in more detail. Accordingly, the Court allowed Relator an opportunity to amend her complaint.

In October of 2022, Relator filed a Fourth Amended Complaint ("FAC"). (Doc. 80). For approximately a year thereafter, the parties sought various extensions and stays while they engaged in efforts to resolve the case without the need for further litigation. Those efforts were ultimately unsuccessful. On November 30, 2023, Defendant moved to dismiss

the FAC, (Doc. 108), and the briefing on the motion was completed in January 2024.

In the FAC, Relator makes some notable modifications. In the TAC, Relator previously alleged that:

- "Quest caused bills to be submitted to Government payors for services that had not been ordered by the treating physician and *were not necessary*" (Doc. 37 ¶ 143) (emphasis added); and
- Quest submitted bills and false certifications to government payors for lab services that "were not medically necessary." (*Id.* ¶ 157).

Consistent with these and other similar allegations, Relator previously emphasized and argued that Quest submitted bills for reimbursement where the lab tests *were not medically necessary*. (*See* Resp to MTD the TAC, Doc. 55 at ECF 2, 5, 12.)

However, Relator appears to have somewhat shifted her theory in the FAC and in her response to Defendant's new motion to dismiss. In the FAC, Relator modifies the allegations in some paragraphs to state that Quest *did not know* whether the lab tests were medically necessary, rather than stating that the tests were in fact not medically necessary, as follows:

- "Quest billed Government payors for services that Quest *did not know were* medically necessary and lied about its lack of knowledge to obtain payment of each claim." (Doc. 80 ¶ 185); and
- "But Quest did not know and indeed made it impossible for it to know if tests included in Care360 [custom] panels were

> known to and intended by each provider selecting a panel." (*id.* ¶ 196).

In her response to Quest's motion to dismiss the FAC, Relator clarifies her theory by arguing:

> Relator's case is not about what doctors might say about a given test or what was or is in their patients' medical records; it is about what Quest knew or did not know about who ordered the tests in a custom profile in Care360 at the time Quest unbundled and billed each test in the profile.

(Resp. to MTD the FAC, Doc. 109 at ECF 18). In this way, Relator contends that it does not matter whether the lab tests were medically necessary or not and, instead, what matters is that Quest's certifications to the government were (as alleged) false because of Quest's lack of confirmation or knowledge regarding the medical necessity of the tests. (*Id.* at ECF 8). The Court discusses this morphed, or solidified, theory in the discussion section below.

In another relevant change in the FAC, Relator adds new allegations about a third example patient, Patient A. Patient A was a patient at the Highlands Center for Women in South Carolina. (FAC, Doc. 80 ¶ 228). A doctor ordered a custom panel (named a "PCOS panel") for Patient A. The PCOS panel had been created by a Quest employee and contained 16 lab tests. (*Id.* ¶¶ 228-233). Quest completed the tests for Patient A. (*Id.*) The FAC does not include allegations indicating who was billed for Patient A's lab tests (whether a government provider, a private insurer, or the patient). The FAC also adds some new allegations about the nature of the alleged fraudulent scheme, such as providing examples of other custom panels. (*See, e.g.*, *id.* ¶ 235-37) (detailing the

"LPTREAT" panel, containing six tests, created by a Quest employee for a doctor's office in Memphis, Tennessee and the "12345" custom panel, containing nine tests, created for the Nashville Fertility Center).

Since the Court's prior decision (dismissing the TAC), the Eleventh Circuit and the Supreme Court have issued relevant decisions in False Claims Act cases. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023); *United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353 (11th Cir. 2023). These decisions provide further guidance about what exactly Realtor must plead and prove to establish FCA claims.

Having provided this updated backdrop, the Court outlines the legal standard and addresses the merits of Defendant's motion to dismiss below.

II. Legal Standard

To survive a motion to dismiss for failure to state a claim, a complaint must include "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In assessing such a motion, a court must accept the complaint's factual allegations, though not its legal conclusions, as true. *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Under Federal Rule of Civil Procedure 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." When a complaint alleges fraud or mistake, as in a *qui tam* case like this one, the complaint must satisfy Federal Rule of Civil Procedure 9(b). *84Partners, LLC*, 79 F.4th at 1358-59. Rule 9(b) requires the complaint to "state with particularity the circumstances constituting fraud or mistake."

However, under Rule 9(b), malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

III. Discussion

The False Claims Act ("FCA") creates a cause of action in favor of the United States against any person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim[2] for payment or approval" or "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A) & (B). The FCA also creates a cause of action for a "reverse false claim" against any person who "(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* § 3729(a)(1)(G). Relator asserts these three causes of action.[3]

The Court begins with Relator's false presentment claim, brought under § 3729(a)(1)(A). As the Supreme Court recently explained when addressing an FCA false presentment claim: "two essential elements of an FCA violation are (1) the

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[2] A "claim" as defined by these provisions includes a request or demand for payment presented to the United States. *Id.* § 3729(b)(2)(A)(i).

[3] Relator asserts claims under the False Claims Act and the Georgia False Medical Claims Act. The Georgia False Medical Claims Act is "modeled after, and contains nearly identical language to the FCA." *United States ex rel. Galuten v. Emory Healthcare, Inc.*, 2018 WL 11336042, at n.3 (N.D. Ga. May 15, 2018). Thus, for purposes of the Court's Rule 9(b) analysis, the FCA and GMFCA are effectively the same. *Id.*

falsity of the claim and (2) the defendant's knowledge of the claim's falsity." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 747 (2023). The Eleventh Circuit has articulated similar elemental requirements for a false presentment claim. *See United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1359 (11th Cir. 2023) ("To state a § 3729(a)(1)(A) presentment claim, a complaint must allege (1) a false claim, (2) that the defendant presented, or caused to be presented, for payment or approval, (3) with knowledge that the claim was false.") (internal citations omitted).

This recent binding authority emphasizes what is perhaps obvious: an essential element of a false presentment claim is the *falsity* of the claim. This falsity requirement is separate and distinct from any question of the defendant's knowledge of the falsity or the overall scheme. *SuperValu Inc.*, 598 U.S. at 747.

Also emphasized in Eleventh Circuit's recent *84Partners* decision, a relator must allege "the actual presentment or payment of a false claim" in order to survive a motion to dismiss. 79 F.4th at 1360. For purposes of a presentment claim, Rule 9(b) requires that that both the false claim and its presentment be alleged with particularity. *Id.* This is because, "[s]tanding alone, a fraudulent scheme, no matter how egregious, is not enough; there must be an actual false claim." *Id.* at 1360, 1362 ("[U]nderlying improper practices, even if fraudulent and so widespread as to constitute standard operating procedure, are not enough; a complaint must allege with particularity a connection between those practices and one or more actual claims."). All in all, a *qui tam* relator must "specifically plead the minimum elements of their allegation." *Id.* at 1360 (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313,

n. 24 (11th Cir. 2002)). As falsity is an "essential element" of an FCA claim, *see SuperValu Inc.*, 598 U.S. 739 at 747, a relator must plead the *falsity of the claim* with particularity. *See 84Partners LLC*, 79 F.4th at 1360.

Here, Relator fails to plead the falsity element with particularity and so fails to plead that an actual *false* claim was submitted to the government.

As alleged in the FAC, Defendant submitted claims — i.e., requests for reimbursement for covered lab services — to the government using a claim form called the CMS Form 1500. (FAC, Doc. 80 ¶ 55). When submitting the claims, Defendant expressly certified, among other things, that the services rendered were "medically indicated and necessary for the health of the patient." (*Id.* ¶ 56).[4] Accordingly, to establish that this express certification was false, Relator must plead with particularity that the services rendered were *not* "medically indicated and necessary for the health of the patient." And, as made abundantly clear in *84Partners*, Relator must plead a representative false claim in which the services rendered were not "medically indicated and necessary for the health of the patient" and where the claim was submitted to the government for payment.

While Relator alleges in a single paragraph in the FAC that the claims submitted by Quest were not medically necessary (*see*, Doc. 80 ¶ 244), she does not

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[4] Relator has reiterated that she proceeds on an express certification theory, not an implied certification theory. (*See* Hearing Tr., Doc. 75 p. 8) ("[T]he case is very squarely an express fa[lse] certification on the CMS-1500 claim form. Every time that Quest submits the claim for a test that is conducted because the test was part of a custom panel of tests, they are falsely certifying that the test was medically necessary.").

plead so with particularity. Indeed, she modified allegations in the FAC to shy away from this contention and instead pled that Quest *did not know* whether the claims it was submitting were medically necessary. (*Compare* TAC, Doc. 37 ¶ 143 ("Quest caused bills to be submitted to Government payors for services that had not been ordered by the treating physician and were not medically necessary.") *with* FAC, Doc. 80 ¶ 185 ("Quest billed Government payors for services that Quest *did not know* were medically necessary and lied about its lack of knowledge to obtain payment of each claim.") (emphasis added)).

Put another way, in order for Quest's express certification to have been *false*, the tests must *not* have been "medically indicated and necessary for the health of the patient." Despite the decade-long investigation in this case, Relator has provided no factual allegations to indicate that doctors later discovered, or even now believe, that they were tricked or confused into ordering medically unnecessary tests or tests they did not intend to order.[5] And while Relator repeatedly cites Medicare and Medicaid requirements and regulations stating that tests not ordered by a physician are not medically necessary (*see, e.g.*, FAC, Doc. 80 ¶ 121, 123; Resp. to MTD, Doc. 109 at ECF 10), she provides no factual allegation of Quest billing for a lab test that was not ordered by a physician. Notably, governing legal authority acknowledges — and Relator agrees (*see* FAC, Doc. 80 ¶ 1) — that Quest had no obligation to make an independent determination of medical necessity or

[5] While Relator alleges in the FAC that doctors were wrongfully led to believe that the labs in Quest's custom panels were billed at a bundled rate (Doc. 80 ¶ 184), she does not explicitly allege that the doctors were misled into ordering tests that they did not intend to order.

second guess doctors' medical determinations. *See, e.g.*, *United States ex rel. Groat v. Boston Heart Diagnostics Corp.* ("*Groat II*"), 296 F. Supp. 3d 155, 163 (D.D.C. 2017).

There are cases involving similar alleged schemes which have survived motions to dismiss. But in those cases, the relators provided specific factual allegations to support that the tests ordered were not in fact medically necessary. For example, relators in these cases relied on medical literature, physician opinions, or the nature of specific tests (e.g. tests typically conducted only for rare conditions) to support that the tests were unnecessary. In a leading case cited by Relator, *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, the court found that the relator adequately pled that 13 specifically listed tests were not medically necessary for patients with four particular diagnostic codes based on, an array of scientific information, e.g., government manuals, scientific medical authority, relator's experience as a physician, and specific exemplar tests ordered for a particular patient. 255 F. Supp. 3d 13, 24-25 (D.D.C. 2017) *reconsidered in part*, 296 F. Supp. 3d 155 (D.D.C. 2017). Similarly, in *United States ex. rel. Lutz v. Berkeley Heartlab, Inc.*, the court found that the relator adequately pled that tests done on blood samples held in storage were medically unnecessary where the tests were specific genetic tests that were not necessary for the vast majority of the population. 225 F. Supp. 3d 487, 497, 500 (D.S.C. 2016).

But here, Relator does not rely on medical literature, physician opinions, or the nature of particular tests to support a finding that the tests ordered (and billed) were medically unnecessary. If Relator had alleged and argued that the tests were not medically necessary based on these types of

information (e.g., physician opinions, medical literature), her complaint might well have stated a claim. But she does not. As a result, the Court has no factual basis that would allow it to infer that the tests ordered and billed to the government were medically unnecessary.[6]

And, crucially, Relator does not provide an exemplar false claim that was submitted to the government for a lab test that was not "medically indicated and necessary for the health of the patient." As for the examples of Patients X and A, there is no allegation that the tests ordered for these patients were ever submitted to the government for reimbursement.[7] The FAC does allege that tests in a

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[6] Relator argues that the Court previously recognized the viability of its false certification of lab tests theory based on other similar cases. As demonstrated above, the comparable cases that survived motions to dismiss (at least on some claims) all involve more particular pleadings and information demonstrating how and why the over-ordered tests were medically unnecessary. *See, e.g.*, *Groat*, 255 F. Supp. 3d at 24-25 (13 specific tests were medically unnecessary for patients with particular diagnostic codes); *Berkeley Heartlab, Inc.*, 225 F. Supp. 3d at 497, 500 (specific genetic tests not necessary for most of population); *Allen*, 334 F. Supp. 3d 349 at 364 (particular at-home blood tests that were ordered more frequently than necessary, as indicated in medical literature); *United States v. Patel*, 2021 WL 2550477, at *1, (S.D. Fla. June 22, 2021) (alleging kickback scheme involving specific cancer genomic DNA testing that was not medically necessary for many patients). Thus, in those cases, the government or relator pled the falsity element (i.e., the lack of medical necessity) with sufficient detail. Relator has not provided comparably particular allegations here about the lack of medical necessity of the allegedly over-ordered tests.

[7] The example of Patient X does show that a duplicate test was ordered and so allows the inference that the ordering doctor was confused or did not know what was in the Arthritis Panel. But again, the billing for Patient X was not to the government.

custom panel were submitted to the government for Patient Y. But there are no factual allegations supporting that the tests in Patient Y's Arthritis Panel were not ordered by the doctor or were not "medically indicated and necessary" for Patient Y.

At the end of the day, the government would have wrongfully paid out claims if it reimbursed Quest for lab tests that *were not* "medically indicated and necessary." But, if the lab tests *were* medically indicated and necessary, then there is no false certification that caused the government to make wrongful payments. Relator's position appears to be that, because of the (alleged) shady nature of the scheme — and the high number of tests completed and amounts billed as Quest began implementing more and more custom panels in doctors' offices — some of the tests *must have been* unnecessary and that doctors *must have* ordered unnecessary tests. But, at least in this Circuit, "describ[ing] a private scheme in detail" and stating that "claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted" to the government is insufficient absent an "actual false claim for payment being made." *84Partners, LLC*, 79 F.4th at 1360-61 (citing *Clausen*, 290 F.3d at 1311).

In another case involving the alleged over-ordering of tests through pre-printed forms, a district court found that the relator failed to state a claim (against certain defendants) because he provided no example of an actual claim that was not medically necessary (submitted by those defendants). *United States ex rel. Allen v. Alere Home Monitoring, Inc.*, 334

As Relator does not allege that the tests for Patient X were billed to the government, the Patient X example – standing alone – is not enough to meet the Rule 9(b) pleading requirements.

F. Supp. 3d 349, 258-59 (D. Mass. 2018). The *Allen* Court explained that, while the scheme regarding the pre-printed forms was generally plausible, all "tests at issue here were approved by a treating physician" and, even according to the complaint, many were necessary. *Id.* The relator in that case failed to offer any way to distinguish medically necessary from unnecessary tests, and "[w]ithout such details," Relator's claim lacked the requisite specificity to show that unnecessary tests were actually ordered. *Id.* at 358-59 ("The physicians' intervening medical judgment is the main impediment to Relator's theory . . . . [T]he forms, by themselves, may create a possibility of fraud by pressuring doctors into prescribing medically unnecessary tests . . . . But they do not give rise to a strong inference that false claims were actually submitted.") (internal quotation omitted).

In briefing, Relator primarily ignores the question of falsity (i.e., whether the tests were medically necessary or not) and instead focuses on Quest's knowledge at the time it submitted claims.[8] Relator repeatedly argues that Quest's certification was false because Quest submitted the claims when it *did not know* one way or the other whether they were true. But in so arguing, Relator conflates the two distinct requirements of falsity and knowledge — which are separate elements, *see SuperValu Inc.*, 598 U.S. 739 at 747. Indeed, Relator responds to Quest's contention

[8] As noted previously, Relator argues in briefing that her case is not about what doctors might say about whether a given test was medically necessary or not and that her case is not about what information is in the tested patient's medical records. (Resp. to MTD the FAC, Doc. 109 at ECF 18). Yet, this information is critically important to the determination of whether tests were medically necessary and thus whether submissions for payment were false or not.

that she fails to adequately plead falsity by citing to legal authority that addresses the separate issue of knowledge. (*See* Resp. to MTD the FAC, Doc. 109 at ECF 8 (quoting *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1299 (11th Cir. 2021) (describing pleading requirement for establishing scienter, specifically noting that the scienter "question is whether [the defendant] acted with, at least reckless disregard [for] the truth or falsity of the certification")).

The express certifications raised by Relator here are Quest's certifications that the tests were "medically indicated and necessary." If the tests *were* medically indicated and necessary, then the billing claim certification was true regardless of Quest's knowledge or lack thereof regarding the tests' medical necessity. Under Relator's revised pleadings and theory (that Quest's lack of knowledge regarding the verity of the medical certification provides a sufficient factual basis to meet the falsity element), the separate and distinct falsity requirement would be rendered meaningless. Such a reading runs contrary to the most recent Supreme Court authority. *SuperValu Inc.*, 598 U.S. 739 at 747 (stating that knowledge and falsity are separate elements of an FCA claim). So, even assuming the sufficiency of Relator's allegations about Quest's knowledge of the scheme to encourage over-ordering of tests and ensuing billing, she does plead any colorable, concrete, or particularized facts to support that the claims were actually false.[9]

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[9] Throughout her response brief, Relator points to the Court's prior Order dismissing the TAC (Doc. 77) for the proposition that the Court already ruled that her theory was viable. But, as discussed, Relator has altered her allegations and presents a morphed theory in the FAC and related briefing. In

The Court is sympathetic to Relator's predicament. After more than a decade, establishing which lab tests were "medically indicated and necessary" and which, if any, were not may be impossible. *See supra Allen*, 334 F. Supp. 3d at 358-59 (noting that relator provided no way to distinguish a claim involving medical judgment and one that was medically unnecessary). The Court is cognizant of the potential difficulty of amassing information and facts to show that the doctors were tricked into ordering medically unnecessary tests. Yet, despite the years of investigation and hours of audio recordings, there is a real gap in Relator's allegations. Relator has not shown even one exemplar claim that was submitted to the government for a lab test that was not "medically indicated and necessary." Relator has not provided factual allegations that would allow the Court to infer that tests ordered by doctors were in fact medically unnecessary (for example, allegations supporting that testing for rare conditions was ordered for patients with no risk factors). And Relator has not alleged facts that would allow the Court to distinguish between medically necessary and potentially unnecessary tests (and related billing). Without these types of factual

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particular, Relator did not previously allege or argue that the medical necessity of the lab tests was immaterial. Instead, she previously asserted that the lab tests Quest billed to the government were *not* medically necessary. Nowhere in the prior Order did the Court endorse Relator's present theory and contention that she can state a claim regardless of the medical necessity of the tests ordered. In addition, recent Supreme Court and Eleventh Circuit authority has clarified both the distinction between the falsity and knowledge requirements, *see SuperValu Inc.*, 598 U.S. at 747, and the absolute requirement that a relator must plead an actual *false* claim with particularity, regardless of other indicia of reliability, *see 84Partners LLC*, 79 F.4th at 1360.

allegations to support the falsity requirement, Relator fails to state a false presentment claim.

Further, because Relator fails to plead an actual false claim with particularity, her § 3729(a)(1)(B) false statement claim also fails. Although the elements are slightly different, the *84Partners* explained that "[a] false claim is essential not only under § 3729(a)(1)(A), which deals directly with false claims, but also under § 3729(a)(1)(B) . . . which deal[s] with false records or statements." 79 F.4th at 1360. Without an actual false claim — that is, an exemplar claim for which the allegations demonstrate with particularity that the test(s) were not medically indicated and necessary — Relator fails to adequately plead her § 3729(a)(1)(B) claim.

Finally, without a presentment or false statement claim, Relator's reverse false claim, brought under § 3729(a)(1)(G), also fails. For a reverse false claim, liability results from avoiding the payment of money owed to the government, as opposed to submitting a false claim to the government. *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012). To establish a reverse false claim, a relator must establish that the defendant owed an obligation to pay money to the government. That obligation can arise from a contractual relationship, from a statute or regulation, or from retention of an overpayment. *United States ex rel. Stepe v. RS Compounding LLC*, 304 F.Supp.3d 1216, 1226 (M.D. Fla. 2018). However, as Relator has not adequately pled false statements or certifications with particularity, she cannot sustain a reverse false claim. *Id.* (dismissing reverse false claim where "it remains unclear how pre-printing a refill number on a script pad, which physicians were free to mark out, qualifies as false. . . . [Relator] never alleges [that] the

physicians acknowledged that they had mistakenly ordered [excess] refills because of the pre-printed script pads."). Put differently, as relator here has not sufficiently plead the existence of a false claim, her reverse false claim counts fail because those causes of action are "based on false claims having been paid that [defendant] failed to repay." *See United States ex rel. Mastej v. Health Mgmt. Assoc., Inc.*, 591 F. App'x 693, 706 n.20 (11th Cir. 2014). In addition, to the extent Relator relies on the Cape Fear example pled in the FAC, Relator alleges that Medicaid already recouped the alleged overpayments from Cape Fear. (FAC, Doc. 80 ¶¶ 238-39). Therefore, none of the alleged facts support that Quest failed to repay the government for an overpayment. As a result, Relator fails to plead that Quest owed an obligation to pay money to the government.

In sum, because Relator fails to plead a *false* claim with particularity, she fails to state a claim under the governing legal standard, and the FAC is due to be dismissed.

IV. Conclusion

After over 14 years, this case must come to a close. The government's significant delay in deciding whether to intervene no doubt harmed the viability of the overall case. Yet, with the fruits of the lengthy recordings as well as likely some other documents collected by the government, Relator still fails to state a claim as required by the current, stringent governing legal standards. Accordingly, Defendant's Motion to Dismiss [Doc. 108] is **GRANTED**. Relator's claims are **DISMISSED WITH PREJUDICE**.[10] The

[10] As the Court dismisses Relator's claims with prejudice, Quest's Motion to Dismiss Under Rule 41(b) [Doc. 127] is **DENIED AS MOOT**.

Clerk is **DIRECTED** to close the case. If the United States believes for any reason that the case should not be closed, it is **DIRECTED** to file any objection (and the basis for such objection) within 12 days of this Order.

IT IS SO ORDERED this 23rd day of August 2024.

[SIGNATURE OMITTED]
Honorable Amy Totenberg
United States District Judge

APPENDIX C: ELEVENTH CIRCUIT ORDER, FILED AUGUST 19, 2025

In the
United States Court of Appeals
for the Eleventh Circuit

No. 24-12998

UNITED STATES OF AMERICA, ex. rel. et al.,

Plaintiffs,

BARBARA SENTERS,

Plaintiff-Appellant,

versus

QUEST DIAGNOSTICS INC.,

Defendant-Appellee,

JOHN DOE FLORIDA CORPORATIONS 1-1000, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
D.C. Docket No. 1:10-cv-02202-AT

Before JILL PRYOR, BRASHER, and WILSON, Circuit Judges.

PER CURIAM:

The Petition for Panel Rehearing filed by Appellant Barbara Senters is DENIED.

APPENDIX D: RELEVANT RULES AND STATUTORY PROVISIONS

Federal Rule of Civil Procedure 9 provides in relevant part:

Rule 9. Pleading Special Matters

* * *

(b) Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

* * *

The False Claims Act provides in relevant part:

31 U.S.C. § 3729. False claims

(a) LIABILITY FOR CERTAIN ACTS.—

(1) IN GENERAL.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) REDUCED DAMAGES.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

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[1] So in original. Probably should read "Public Law 101-410".

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) COSTS OF CIVIL ACTIONS.— A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

* * *