No. 25A___

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. ET AL.,

Respondents.

APPLICATION TO EXTEND TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI FROM NOVEMBER 17, 2025, TO JANUARY 16, 2026

To the Honorable Justice Clarence Thomas, as Circuit Justice for the U.S. Court of Appeals for the Eleventh Circuit:

Under 28 U.S.C. § 2101(c) and Supreme Court Rules 13.5, 22, and 30.3, petitioner the United States of America and the State of Georgia ex rel. Barbara Senters respectfully requests that the time to file a petition for a writ of certiorari be extended 60 days from November 17, 2025, to and including Friday, January 16, 2026. The Eleventh Circuit affirmed the District Court's dismissal of petitioner's complaint on July 16, 2025, Add. 4-5, and denied a timely rehearing petition on August 19, 2025, Add. 2. Without an extension, the petition for a writ of certiorari would be due November 17, 2025. This application is being filed at least 10 days before that date. *See* Sup. Ct. R. 13.5. This Court will have jurisdiction to review the petition under 28 U.S.C. § 1254.

1. This case presents an important question that deeply divides the circuits: Whether Federal Rule of Civil Procedure 9(b)'s heightened pleading standard requires False Claims Act plaintiffs who plead a fraudulent billing scheme with particularity to also identify specific false claim submissions to avoid dismissal.

The False Claims Act empowers private individuals (relators) to bring fraud actions on the Government's behalf. *See* 31 U.S.C. § 3729 *et seq.* The statute imposes liability when a person knowingly, with reckless disregard, or with deliberate indifference, presents a false or fraudulent claim to the Government for payment or approval. *See ibid.* Because it is an anti-fraud statute, FCA claims are subject to Rule 9(b)'s heightened pleading standard, which requires that a party "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

2. Petitioner Barbara Senters began at respondent Quest Diagnostics as a human resources generalist in 2005 and was promoted to compliance officer in 2007. Add. 4. Quest sells diagnostic laboratory tests to various medical practices and providers. *Ibid.*

As part of her job "making sure that Quest was billing the government, namely Medicare and Medicaid, for tests eligible for reimbursement," petitioner observed Quest's automated system intentionally cause doctors to unknowingly order tests they had not deliberately chosen or authorized for Government-insured patients. Add. 4. Quest then falsely certified that the tests "'were medically indicated and necessary for the health of the patient'" when submitting reimbursement claims to Medicare and Medicaid. *See* Add. 4-6 (quoting CMS Form 1500). Petitioner sued

Quest on behalf of the United States and the State of Georgia in July 2010. *Ibid.* After nearly a decade of investigation, the United States declined to intervene and the complaint was unsealed. *Ibid.*

3. Respondent moved to dismiss. The District Court granted the motion solely because petitioner failed to 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.'" *See* Add. 7 (panel quoting District Court).

The Eleventh Circuit affirmed, confirming the circuit's precedent: "'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.'" Add. 9 (quoting *Olhausen v. Arriva Med., LLC*, 124 F.4th 851, 860-61 (11th Cir. 2024) (per curiam); internal quotation marks omitted); *see also ibid.* (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005), for proposition that "a relator must 'allege the "who," "what," "when," and "how" of fraudulent submissions to the government'"); *Corsello* 428 F.3d at 1014 ("Underlying improper practices alone are insufficient to state a claim under the False Claims Act absent allegations that a specific fraudulent claim was in fact submitted to the government.").

The panel acknowledged that petitioner's job "gave her access to the claims being submitted to the government and that she reviewed the claims billed to the

government." Add. 10-11. Yet even though she described the fraud scheme in detail and identified specific dates, amounts, and patients connected to the false claims, the panel concluded that she had not plausibly alleged an FCA claim. *Ibid.* The panel reasoned that, "even with 'direct knowledge of the defendants' billing and patient records,' [she] '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.'" *Ibid.* (quoting *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam)).

This timely application follows.

REASONS FOR GRANTING AN EXTENSION OF TIME

The time to file a petition for a writ of certiorari should be extended for 60 days for three reasons:

1. The forthcoming petition is likely to be granted.

First, there is a well-recognized circuit division over whether Rule 9(b) requires plaintiffs in False Claims Act cases who plead a fraudulent scheme with particularity to also plead specific details of false claims, or whether the existence of false claims can be inferred from circumstances including the scheme itself. *See, e.g.*, Cert. Pet., *United States of America and State of Michigan ex rel. Olsen v. Tenet Healthcare Corp.*, No. 25-347 (U.S. Sept. 19, 2025) (pending), at i (presenting parallel Question over which "circuits are intractably divided": "Whether Rule 9(b) requires False Claims Act relators who plead detailed firsthand knowledge of a fraudulent billing

scheme to identify specific false claims when billing records remain exclusively within defendants' control.").

As many as six circuits do not require specific details of a particular false submission. *See United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 89 (2d Cir. 2017) (describing the "Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits" as having "overtly adopted a 'more lenient' pleading standard" than Sixth, Eighth, and Eleventh Circuits). "Those courts have allowed a complaint that does not allege the details of an actually submitted false claim to pass Rule 9(b) muster by 'alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *See ibid.* (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014), as "agreeing with *Grubbs*"; *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) (same); *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010) (same); *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015) (same); also citing *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit.")). As the Seventh Circuit explained, "a plaintiff does not need to present, or even include allegations about, a specific document or bill that the defendants submitted to the Government" to satisfy Rule 9(b). *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 777 (7th Cir. 2016). These courts

reason that Rule 9(b)'s text and purpose are satisfied when relators provide sufficient factual detail to support a strong inference of fraudulent conduct.

In contrast, at least six other circuits require relators to plead specific details of false submissions in addition to details of fraudulent schemes. Here, the Eleventh Circuit reaffirmed its entrenched rule that even when relators have "access to the claims being submitted to the government and [have] reviewed the claims billed to the government," they "must still provide particular facts about a representative false claim" to avoid Rule 9(b) dismissal. Add. 10-11 (citing *Carrel v. AIDS Healthcare Foundation, Inc.*, 898 F.3d 1267, 1277-78 (11th Cir. 2018)). The Second Circuit similarly requires that when, as here, the plaintiff has some access to billing and thus "*can* identify examples of actual claims," she "*must* do so at the pleading stage." *Chorches*, 865 F.3d at 86 (citing *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1314 n.25 (11th Cir. 2002), as "rejecting argument for a 'more lenient pleading standard'"). The First, Fourth, Sixth, and Eighth Circuits agree. *See, e.g.*, *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 38-39 (1st Cir. 2017); *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 197 (4th Cir. 2018); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007); *United States ex rel. Strubbe v. Crawford County Mem'l Hospital*, 915 F.3d 1158, 1163, 1165 (8th Cir. 2019). *Cf.* Cert. Pet., *Tenet Healthcare Corp.*, *supra*, at 12-24 (pending cert. petition arguing that circuits are intractably divided and that split "has calcified since this Court last sought the Solicitor General's views").

Second, the Eleventh Circuit's side of the split is wrong. Rule 9(b)'s text requires only that "a party must state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), and the Eleventh Circuit's categorical bar ignores the Rule's core purpose: providing defendants adequate notice of the claims against them. As the Government has argued, a "per se rule that a relator must plead the details of particular false claims" is "unsupported by Rule 9(b) and undermines the FCA's effectiveness as a tool to combat fraud against the United States." U.S. Cert. Amicus Br., *United States ex rel. Nathan v. Takeda Pharmaceuticals N. Am., Inc.*, No. 12-1349, 2014 WL 709660, at *10 (U.S. Feb. 25, 2014).

The Eleventh Circuit's contrary approach allows fraudsters to escape liability through compartmentalization. In most cases, relators will not have specific details of actual false claims—either because the relator's role does not give them access to that information, or because the defendant has effectively concealed it. As the Second Circuit observed in *Chorches*, defendants' billing procedures often "ma[k]e it virtually impossible for most employees to have access to all of the information necessary to certify on personal knowledge both that a particular invoice was submitted for payment and that the facts stated to justify the invoice were false." 865 F.3d at 82. A rule requiring plaintiffs to allege details about both the scheme and the bills thus allows fraudsters to stymie FCA enforcement by compartmentalizing relevant knowledge. *See id.* at 82, 86. The inevitable result is that more fraud on the Government will go unchecked.

Take this case. Petitioner's "job included making sure that Quest was billing the government, namely Medicare and Medicaid, for tests eligible for reimbursement." Add. 4. The Eleventh Circuit did not dispute her allegation that "Quest's sales representatives [created custom lab panels] to be implemented in doctors' offices by Quest employees," which caused tests to be ordered that were neither authorized by physicians nor "determined to be medically necessary for their patients." Add. 5. The Court of Appeals also acknowledged that Quest, as the entity submitting the reimbursement claim to the Government, was required to "expressly certify" on submission "that the services listed on the [certification] form 'were medically indicated and necessary for the health of the patient.'" Add. 5-6. But even though this case presents a classic false-certification theory that turns on the submitter's intent at the time of certification (here, Quest's), the Eleventh Circuit held that petitioner's fraud claims were not even plausible. The court reasoned that, for the specific representative bills described in her complaint, petitioner failed to allege that the "doctors later discovered, or even now believe, that they were tricked or confused into ordering medically unnecessary tests or tests that they did not intent to order." *Ibid.* *But see Heath*, 791 F.3d at 126 (Rule 9(b) does not "require relators, before discovery, to prove more than the law requires to be established at trial"); *Foglia*, 743 F.3d at 156 (requiring detailed billing information at the pleading stage "would be 'one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial.'" (quoting *Grubbs*, 565 F.3d at 190)). But petitioner did not claim the *doctors* were falsely certifying that medical necessity of

tests they ordered; their later understanding or belief is irrelevant to whether *Quest*'s certifications to the Government were knowingly false or submitted with deliberate indifference or reckless disregard for the truth.

Third, this case provides a good vehicle to finally resolve the long-recognized split. Unlike other circuits on the Eleventh Circuit's side of the split, which sometime allow plaintiffs who do not plead specific false claims to overcome dismissal if they allege "specific personal knowledge that relates directly to billing practices," *see, e.g.*, *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 769 (6th Cir. 2016) (only instance of Sixth Circuit applying a limited "personal knowledge" exception to its similar requirement that specific false claims be alleged), the Eleventh Circuit requires all relators to "still provide particular facts about a representative false claim," no exception, Add. 11.

And while the Government suggested previously that the circuit split was unripe for this Court's review, that rested on the premise that the circuits were converging on the flexible approach the panel rejected here. *See* U.S. Cert. Amicus Br., *Takeda Pharmaceuticals*, *supra*, 2014 WL 709660, at *10 (arguing that the "extent of the disagreement among the lower courts" was "uncertain" and might "be capable of resolution without this Court's intervention"); *see also* U.S. Cert. Amicus Br., *Johnson v. Bethany Hospice*, No. 21-462, 2022 WL 1715610, at *15 (May 24, 2022) (suggesting that "the courts of appeals have largely converged on a more flexible standard" and predicting that the split would resolve itself). But the Government's prediction failed. The panel here reaffirmed the Eleventh Circuit's per se pleading requirement,

entrenching the categorical bar the circuit has maintained since at least 2005. *But see* U.S. Cert. Amicus Br., *Takeda Pharmaceuticals*, *supra*, 2014 WL 709660, at *10 (opposing "a per se rule that a relator must plead the details of particular false claims" because such a rule "is unsupported by Rule 9(b) and undermines the FCA's effectiveness as a tool to combat fraud against the United States").

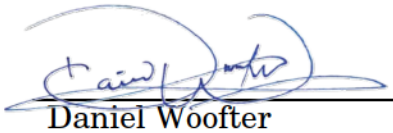
2. The press of other matters before this and other courts makes the existing November 17, 2025 deadline exceedingly difficult to meet. Petitioner only recently retained undersigned counsel to prepare the petition. Counsel needs more time to study the issues and prepare a concise petition. Meanwhile, among various other matters, undersigned counsel has a merits amicus brief due in this Court on November 20, 2025, in *Chevron US Inc. v. Plaquemines Par.*, No. 24-813, an Opening Brief and Appendix due in the Sixth Circuit on December 11, 2025, in *In re: Nat'l Prescription Opiate Litig.*, No. 24-3739, and a Reply Brief due in the Fourth Circuit shortly thereafter in *United States v. Windom*, No. 25-4217. These obligations are in addition to helping others prepare filings and present oral argument, as well as managing personal commitments related to the Thanksgiving and end-of-year holidays.

3. Whether or not the extension is granted, the petition will be considered this Term. Thus, the extension will not substantially delay the resolution of this case or prejudice any party.

CONCLUSION

For the preceding reasons, the time to file a petition for a writ of certiorari should be extended for 60 days to and including January 16, 2026.

Respectfully submitted,



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November 6, 2025

ADDENDUM

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.

[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

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.

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

[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.

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.

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

UNITED STATES OF AMERICA, *ex rel.* BARBARA SENTERS and THE STATE OF GEORGIA, *ex rel.* BARBARA SENTERS, Relator, v. QUEST DIAGNOSTICS, INC., Defendant.	:	CIVIL ACTION NO. 1:10-cv-2202-AT

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 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.

[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.

(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

[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).

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 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

[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.*

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]

[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

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 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

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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.").

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 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

[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.

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]

[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

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 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

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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. 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.

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 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 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

[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.

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]

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

[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 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.

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 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 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.

Honorable Amy Totenberg
United States District Judge

[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.**