IN THE

SUPREME COURT OF THE UNITED STATES

Docket No. 21-1967

KEEGAN MASON,

Petitioner,

v.

SOUTHERN AMERICAN METROPOLITAN CLINICS, INC.

Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the Fifteenth Circuit

BRIEF FOR RESPONDENT

Team 3010
Attorneys for Respondent

QUESTIONS PRESENTED

1. Whether the first-to-file provision in the False Claims Act (FCA) merely bears on whether a claim has been stated, or does it serve as a jurisdictional bar, where until recently well-settled consensus based on the plain and unambiguous reading of the statute honored Congress's use of the jurisdictional bar to prompt the initiation of claims for fraud and discourage repetitive claims.

2. Whether Mason has adequately supported a false claim if she can demonstrate that the treating physician's opinion was incorrect, or must she demonstrate objective falsity, when this Court has established a more demanding framework, beyond a mere difference of opinion, to be false including an opinion the speaker knows is false or has no reason to believe is true.

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The Decision and Order of the United States District Court for the District of Lincoln is unreported and set out in the Record. R. at 1-19. The opinion of the United States Court of Appeals for the Fifteenth Circuit is also unreported and provided in the Record. R. at 20-28.

RELEVANT PROVISIONS

This case involves the False Claims Act (31 U.S.C. § 3729). The False Claims Act (FCA) encourages private citizens, known as relators, to bring qui tam suits by allowing them to share in any recovery obtained for the government. President Abraham Lincoln signed the FCA into law in 1863. It was originally intended "to combat rampant fraud in Civil War defense contracts." S. Rep. No. 99-345, at 8 (1986).

In 1986, Congress amended the FCA to include the "First-to-File rule" which is an attempt to balance encouraging prompt filing and litigation to deter fraudulent acts against preventing opportunistic citizens from filing "copycat" lawsuits.

Today, the FCA is the federal government's "primary litigative tool for combating fraud." *Id*. at 2. Civil actions for false claims are addressed in 31 U.S.C. § 3730.

This case also addresses Federal Rules of Civil Procedure (FRCP) 8(a) and 9(b). FRCP 8(a) states a pleading only requires a "short and plain statement" regarding the grounds of the claim. Fed. R. Civ. P. 8(a). FRCP 9(b), however, requires allegations of fraud to be plead with particularity. Fed. R. Civ. P. 9(b).

STATEMENT OF THE CASE

STATEMENT OF THE FACTS

Southern American Metropolitan Clinics, Inc. ("SAM") provides medical care for patients with non-healing wounds and burns in fourteen clinics in Lincoln. R. at 2. SAM has

been providing care to patients in Lincoln since 1956. *Id.* John O'Keefe is the current CEO of SAM. R. at 4. Approximately seventy-five percent of SAM's revenue comes from programs that serve the elderly (Medicare) and the poor (Medicaid) for reimbursement for treatment provided to patients. R. at 2.

SAM specializes in treating chronic wounds. *Id.* A chronic wound is one that is "unresponsive to initial therapy or persistent in the face of appropriate care." *Id.* Common types of wounds occur from vascular or neuropathic origins or as a result of pressure ulcers. *Id.* While most wounds can be successfully treated with non-surgical procedures, debridement may be necessary. R. at 2-3.

Debridement is the removal of the unhealthy tissue found in a wound. R. at 3. Debridement can be either selective or surgical/excisional. *Id.* Surgical debridement involves the removal of subcutaneous tissue, fat, or bone. *Id.* Selective debridement does not involve the removal of these tissues. *Id.* SAM performs both types of debridement in their clinics. *Id.* Both types of debridement are reimbursable under guidelines established by the Center for Medicare and Medicaid Services (CMS). *Id.*

If a wound does not respond to the normal standard of care, which includes debridement, Hyperbaric Oxygen (HBO) therapy is appropriate. *Id.* HBO therapy exposes a patient to an increase in atmospheric conditions while inhaling 100 percent oxygen. *Id.* This treatment is compensable under CMS guidelines, but usually requires other types of treatment first. *Id.* As part of its reimbursement analysis, CMS uses the Meggitt-Wagner system to grade wounds. *Id*.

The Meggitt-Wagner system has five grades of wounds [1]. These grades vary from a wound with only associated pain to a wound that has progressed to include full gangrene. *Id.* HBO therapy is permitted for grade III wounds and higher. *Id.*

A comprehensive list of other covered and non-covered treatments is available on the CMS website [2].

In 2017, Petitioner began working at SAM Clinics as a clinical nurse. R. at 4. Even though in her previous role Petitioner was permitted to diagnose and order HBO therapy, she is not qualified or licensed to do so in the State of Lincoln. *Id.* Clinical nurses, according to Lincoln law, are permitted only to supervise HBO therapy. *Id.* HBO therapy must be ordered by a physician. *Id.* Prior to working at SAM Clinics, Petitioner worked as a clinical nurse in another state. *Id.*

In her current role, Petitioner sees patients at multiple clinics within the State of Lincoln. *Id.* Petitioner claims she was aware of the criteria CMS uses for reimbursing HBO therapy. *Id.* Petitioner was also aware that HBO therapy had to be certified to CMS prior to HBO therapy being reimbursed. R. at 4-5.

In February of 2019, Petitioner claims to have noticed an increase in HBO therapy treatments at SAM clinics. R. at 5. Petitioner alleges that treatment was performed that was medically unnecessary for a variety of reasons, including some patient's wounds were responding to regular treatment and they still received HBO therapy. *Id.*

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[1] https://jdfc.org/2012/volume-4-issue-1/a-new-classification-of-diabetic-foot-complications-a-simple-and-effective-teaching-tool/

[2] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=12&ver=3

Petitioner claimed she heard management "pushing" physicians to meet quotas. *Id.* Petitioner also claimed she observed a physician alter a Meggitt-Wagner grade for a wound in an apparent effort to qualify for Medicare reimbursement. *Id.*

Also, in February of 2019, Petitioner claims to have noticed an increase in HBO therapy treatments at SAM clinics. *Id.* Petitioner alleges that treatment was performed that was medically unnecessary for a variety of reasons, including some patient's wounds were responding to regular treatment and they still received HBO therapy. *Id.*

On or about September 24, 2019, Petitioner alleged she overheard a conversation between Dr. William Drake, a doctor at SAM, and John O'Keefe about keeping the HBO treatment "numbers up," and that if the clinic did so, it could be a "win-win-win." *Id.* Due to her suspicion of potential fraud, Petitioner contacted an attorney about filing a *qui tam* suit. *Id.*

On October 14, 2019, Dr. Elizabeth Cobb, a SAM employee in Washington City, filed a *qui tam* suit in the District Court for the State of Lincoln [3]. *Id.* Dr. Cobb's complaint was initially filed under seal. *Id.* In her complaint, Dr. Cobb alleged she was terminated by SAM for refusing to certify the medical necessity of a debridement. *Id.* After Dr. Cobb's refusal, she alleges O'Keefe found another doctor to falsely certify the necessity of the procedure. *Id.*

PROCEDURAL HISTORY

On December 16, 2019, Dr. Cobb's complaint was unsealed. R. at 6. On January 20, 2020, her complaint was dismissed for failure to state a claim. *Id.* The district court dismissed the case for failing to plead fraud with the requisite particularity. *Id.* The court stated FRCP 9(b) prevents "speculative suits against innocent actors for fraud . . . must include facts as to time,

[3] *Cobb v. Southern America Metropolitan Clinic Inc.,* No. CV-2019-213 *3 (D. Linc. Jan. 20, 2020)

place, and substance of the defendant's alleged fraud." *Cobb v. Southern America Metropolitan Clinic Inc.,* No. CV-2019-213*3 (D. Linc. Jan. 20, 2020).

The court concluded that Dr. Cobb's complaint had only general allegations of pressure from Mr. O'Keefe, there was no fraud plead with particularity regarding CMS certifications. R. at 6. As a result, the court determined Dr. Cobb's complaint did not meet the requirements of FRCP 9(b). *Id.* at 4.

On November 22, 2019, approximately fifty-two days *after* Dr. Cobb, Petitioner filed a complaint alleging SAM of Medicare fraud. *Id.* Of note, at the time of Petitioner's filing, Dr. Cobb's complaint was still sealed. Petitioner's claim was correctly unsealed on January 24, 2020. R. at 1.

In her complaint, Petitioner alleged instances of Respondent's patients receiving HBO therapy that they were not qualified to receive. R. at 7. The complaint also included an affidavit that Respondent's treatment went against established CMS guidelines. *Id.*

Respondent filed a 12(b)(1) motion asserting the court's lack of subject matter jurisdiction. *Id.* Respondent asserted subject matter jurisdiction did not exist due to the "first-to-file" rule under the FCA. R. at 8. Respondent also filed a 12(b)(6) motion for failing to state a claim for which relief could be granted. *Id.* at 9.

According to the court, "[t]he False Claims Act provides that when a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." *Id.*

The District Court denied the Respondent's motion to dismiss under 12(b)(1), since the court claimed it had subject matter jurisdiction. R. at 9. The District Court granted Respondent's motion under 12(b)(6) for failure to state a claim upon which relief can be granted. *Id.*

The United States Court of Appeals for the Fifteenth Circuit reviewed the appeal *de novo*. R. at 20. Petitioner appealed the dismissal of her complaint to the court. *Id.*

The Court of Appeals determined Dr. Cobb had put the government on sufficient notice of Respondent's potential fraud in her original complaint. R. at 23. The Court of Appeals stated, "Mason's claim did not provide *additional or new information* about SAM Clinics 'practices that could not have been discovered by the government when it investigated Dr. Cobb's allegation." *Id.* (Emphasis added.)

As a result, the Court of Appeals determined Petitioner's claim was jurisdictionally barred under the first-to-file provision of the FCA. R. at 24.

The Court of Appeals also addressed the FRCP 9(b) argument presented by Respondent at the District Court. *Id.* The Court of Appeals ruled, "Both Dr. Cobb's claim and Mason's claim alleged SAM Clinics was defrauding Medicare by prescribing patients certain wound treatments when they were not medically necessary. Both complaints identified John O'Keefe as involved in the alleged false certifications." R. at 24-25.

The Court of Appeals correctly affirmed the decision of the district court. R. at 25. This Honorable Court subsequently granted certiorari. R. at 29.

<u>STANDARD OF REVIEW</u>

In reviewing motions for summary judgment, courts apply a *de novo* standard of review. *B&G Enters., Ltd. v. United States*, 220 F.3d 1318, 1322 (11th Cir. 2000).

<u>SUMMARY OF THE ARGUMENT</u>

The Court should deny Petitioner's appeal because the Fifteenth Circuit Court of Appeals properly found that the First-to-File rule is a jurisdictional bar to petitioner's claim. Additionally, as recognized by the District Court but not addressed by the 15th Circuit in its decision, the

Petitioner's claim failed to identify an objective falsity which this court has established as the standard for determining if an opinion is false.

The FCA effectively deputizes every private citizen in the country to report fraudulent acts against the government. The FCA encourages this action by offering citizens an opportunity to bring a civil action on behalf of the government and share with the government any recovery from defendants who commit fraud. Congress included the "First-to-File" Rule in the FCA in an attempt to balance between encouraging prompt filing and litigation to deter fraudulent acts and preventing opportunistic citizens from filing "copycat" suits.

A former employee of the Respondent, Dr. Elizabeth Cobb, was the first to file a complaint on October 14, 2019. Her complaint alleged Respondent pressured her to upcode a patient's chart to certify for a Medicare patient the medical necessity of what she believed to be an unnecessary surgical debridement of a wound.

According to the Office of the Inspector General, upcoding is defined as: "using billing codes that reflect a more severe illness than actually existed, or a more expensive treatment than was provided, which includes billing for services that were not medically necessary." [4]Dr. Cobb claimed that when she refused, she was fired, and another physician falsely certified the medical necessity and performed the surgery. Several weeks later, Petitioner alleged SAM was engaged in a plan to defraud Medicare with the same essential elements by certifying as medically necessary HBO therapy that was allegedly unnecessary.

Because the FCA precludes another person from bringing an action based on the facts underlying the pending action, the Petitioner's claim was jurisdictionally barred because Cobb's

[4] https://oig.hhs.gov/compliance/physician-education/02payers.asp#:~:text=A%20common%20type%20of%20false,expensive%20treatment%20than%20was%20provided

claim was pending when the Petitioner first filed her claim. Prior to 2015, the first-to-file rule was uniformly adopted as a jurisdictional bar. Since 2015 a split among the circuits has developed. Resolving this issue simply requires accepting the statute as it was plainly written. As the Ninth Circuit explained, "[s]ection 3730(b) (5)'s plain language unambiguously establishes a first-to-file bar, preventing successive plaintiffs from bringing related actions based on the same underlying facts.... [and]… stops repetitive claims." *United States ex rel. Lujan v. Hughes Aircraft Co.,* 243 F.3d 1181 (9th Cir. 2001). This rule promotes judicial efficiency and maintains the intent and success of Congress's 1986 amendments to the FCA, "which from 1986-2021 led to more than $64 billion in recovery to the United States Justice Department." DOJ, *Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020* (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

Regardless of how this court determines the outcome of the jurisdictional bar question, the Respondent further contends that the Petitioner still was not the first to file and her case must be dismissed, if not on 12(b)(1) grounds for a lack of subject matter jurisdiction, then for the failure to state a claim under 12(b)(6) because Petitioner remains barred because she was not the first to file.

After Petitioner's claim was filed, Dr. Cobb's claim was dismissed for failure to plead with particularity according to FRCP 9(b). While the 9(b) standard must be met to prevail on an FCA action, that level of particularity is not necessary to serve the pleading's purpose in the FCA of providing *notice* to the government and to the Defendant. Despite how a previously filed action concludes, a Petitioner cannot "get back in the action" if they file while another claim alleging the same essential acts is pending.

This Court has established the framework for determining if an opinion may be false and has held in its decision in *Omnicare* that a sincerely held statement of belief cannot be. Each of the Circuits to recently address what constitutes "false" or "fraud" in the FCA adopts this Court's holding from *Omnicare* but applies it in a variety of ways. The Eleventh Circuit in its decision in *Aseracare* conforms most closely to this Court's holding in *Omnicare* and held that objective falsity is the proper standard for pleading a claim under the FCA. Petitioner failed to plead sufficiently to establish objective falsity.

Assuming arguendo that Petitioner is not required to demonstrate objective falsity, her claim still fails because it lacks the particularity the FRCP 9(b) standard demands. Assuming also that Petitioner demonstrates that Respondent submitted inaccurate certification of medical necessity, that alone does not inflate the submission for reimbursement beyond a claim for breach of contract into a fraudulent act susceptible to recovery under the FCA.

ARGUMENT

I. THIS COURT SHOULD AFFIRM THE UNITED STATES COURT OF APPEALS FOR THE FIFTEENTH CIRCUIT'S HOLDING BECAUSE CONGRESS, BY ITS PLAIN LANGUAGE, INTENDED THE FIRST-TO-FILE RULE IN THE FALSE CLAIMS ACT TO SERVE AS A JURISDICTIONAL BAR.

This court should affirm the Fifteenth Circuit's holding that petitioner's claim is barred because of the False Claims Act's first-to-file rule. The first-to-file provision of the False Claims Act, 31 U.S.C. § 3730(b)(5), prohibits later-filed actions alleging the same material elements of fraud described in an earlier suit, regardless of whether the allegations incorporate somewhat different details. *United States ex rel. St. John LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227 (3rd Cir. 1998). This has been well-settled precedent throughout the federal circuits until two recent diverging opinions from the Second and D.C. Circuits. The Petitioner

alleges that the Respondent violated the False Claims Act by knowingly submitting false certifications of medical necessity for Hyperbaric Oxygen (HBO) therapy to receive federal reimbursements through Medicare. *Cobb v. Southern America Metropolitan Clinic Inc.*, No. CV-2019-213 *3 (D. Linc. Jan. 20, 2020). Petitioner alleged the same essential acts by SAM that Cobb did — submission of false certifications of medical necessity for procedures to collect reimbursement from Medicare. Cobb's claim, which was subsequently dismissed for a lack of particularity, was sufficient to satisfy the first-to-file rule because it provided the government notice of the scheme to "upcode" claims. Cobb's claim satisfied this Court's definition of pending and therefore bars Petitioner's claim from proceeding.

A. This Court should affirm the lower court's holding that by the plain language of the FCA, the first-to-file rule serves as a jurisdictional bar.

Over a hundred years after the FCA was enacted, Congress amended the Act to include the First-to-File Rule language which states: When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action. 31 U.S.C. § 3730(b)(5)

""If a court finds that the particular action before it is barred by the first-to-file rule, the court lacks subject matter jurisdiction over the later-filed matter," and dismissal is therefore required." *United States ex rel. Carter v. Halliburton Co*., 866 F.3d 199, 203 (4th Cir. 2017).

Of the six circuits to address this issue, several implicitly assumed that the rule affected subject matter jurisdiction. The First, Fifth, and Sixth Circuits, however, provided slightly more detailed analyses in *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 108 750 F.3d 111 (1st Cir. 2014), *United States ex rel. Branch Consultants v. Allstate Insurance Co*.,109 560 F.3d 371 (5th Cir. 2009) and *Walburn v. Lockheed Martin Corp*.,110 431 F.3d 966 (6th Cir. 2005), respectively. In each of these cases, the district court had dismissed the relator's complaints for

lack of subject matter jurisdiction due to the first-to-file rule. *Wilson*, 750 F.3d at 120; *Branch Consultants*, 560 F.3d at 373; *Walburn*, 431 F.3d at 969.

These courts recognized that the jurisdictional rule served to balance two competing policy goals: (1) providing sufficient incentives to encourage private parties to bring suits for the public good, and (2) preventing duplicative lawsuits that do little to serve the public interest because a previously filed claim already provided the government with sufficient notice of the alleged fraud. *Wilson*, 750 F.3d at 117; *Branch Consultants*, 560 F.3d at 376; *Walburn*, 431 F.3d at 970

Once an initial *qui tam* complaint puts the government and the defendants on notice of its essential claim, all interested parties can expect to resolve that claim in a single lawsuit. *Grynberg v Koch Gateway Pipeline Co*., 390 F.3d 1276 (10th Cir. 2004).

Prior to 2015, violating the first-to-file rule was unanimously regarded as a jurisdictional bar by circuit courts. *United States ex rel. Todd Heath v. AT&T, Inc*.,791 F.3d 112 (D.C. Cir. 2015). However, the *Heath* court joined the Second Circuit and held that the first-to-file rule was not a jurisdictional bar. *Id.* The Court reasoned that Congress would have explicitly added this language to the FCA if they sought a jurisdictional bar. *Id.* The *Heath* court's rationale for its holding that the first-to-file rule to not be a jurisdictional bar runs counter to the congressional intent of the rule and sharply and errantly diverges with the majority of the circuit courts over the last 30 years. *Id.*

In *Heath*, Petitioner asserted that Respondent (AT&T and one of its nineteen subsidiaries, Wisconsin Bell) were committing two very distinct types of fraud against the federal government. The Wisconsin Bell Complaint alerted the federal government only to a limited scheme by Wisconsin Bell to defraud the E–Rate program within Wisconsin. *Id*. In

contrast, the AT&T Nationwide Complaint alleges a different and more far-reaching scheme to defraud the federal government through service contracts entered into across the Nation, and then to cover up that fraud. *Id*.

Nothing in the complaint would have alerted the United States government to a nationwide scheme centered in AT&T's corporate headquarters of mischarging the E–Rate program and subsequently concealing those overpayments. *Id*. Nor, given the affirmative misrepresentations at issue, would the Wisconsin Bell complaint have pointed the federal government to AT&T's systematic refusal to institutionalize compliance by employees with the lowest-corresponding-price requirement. *Id*. The fraud thus manifested itself in sufficiently distinct ways in the two cases that the material elements of the fraud differ. *Id*.

Respondent maintains that the Court's rationale for deeming the first-to-file rule as non-jurisdictional actually strengthens the argument in *favor* of the jurisdictional bar. The intent behind the rule is to provide incentives to relators to efficiently and effectively alert the government to the essential facts of a fraudulent scheme. *See Aseracare*. In Heath, based on the court's opinion, Respondent agrees that the federal government was not sufficiently put on notice from either of the two claims that were brought forward, independently. Both involved very concealed schemes that were materially different from their counterpart's actions.

> "To hold, as AT & T suggests, that the first-to-file bar kicks in every time an initial complaint alleges that a subsidiary of a national company violated a national law would erase a broad swath of False Claims Act coverage. The point of the first-to-file bar is not to allow isolated misconduct to inoculate large companies against comprehensive fraud liability. The point, instead, is to prevent copycat litigation, which tells the government nothing it does not already know. Because Heath's complaints go after two materially distinct fraud schemes, the first-to-file bar does not apply."
>
> *Id*.

The Court's response in holding that the first-to-file rule didn't apply in this case given the very distinct separation between the complaints was proper. These claims did not assert the same essential facts. In fact, this further justifies why the court should have left undisturbed the jurisdictional bar, particularly when the majority of circuit courts have adopted the bar. When the rule is applied properly, it is effective in encouraging differing claims but also prevents burdensome repeat claims. This component of the Act has been extremely successful in helping claimants and ultimately the United States Justice Department receive just compensation for fraud against the government. Courts addressing the issue after the Heath ruling have held that the violation of the first-to-file rule should remain a jurisdictional bar. Therefore, the first to file rule should continue to be treated as a jurisdictional bar and adopted by this Court.

B. Because meeting the FRCP 9(b) standard is not required for the notice provision of the FCA, Dr. Cobb's claim is sufficient to be found the first to file.

A claim that doesn't meet the standard of FRCP 9(b) is still sufficient to put the government on notice of an alleged fraudulent action. This allows a relator to achieve status as the first to file, even if the claim is later dismissed. Dr. Cobb filed her claim 52 days before Petitioner filed her claim. Dr. Cobb alleged the same material facts in her complaint as Petitioner later claimed, namely that SAM was inappropriately upcoding by falsifying the medical necessity of wound care procedures.

> "Congress's reference to FRCP 9(b) in some of False Claims Act's provisions, particularly subsections under 31 USCS 3730(b), and omission of any FRCP 9(b) requirement from 31 USCS 3730(b)(5), tells courts that Congress did not intend first-to-file rule to incorporate FRCP 9(b)'s heightened pleading standard." "Allegations of preclusive first-filed complaint under 31 USCS 3730(b)(5) need not comport with FRCP 9(b)'s pleading requirements to provide government with sufficient notice of potential fraud." "For purposes of False Claims Act's 31 USCS 3729, et seq. first-to-file rule, earlier-filed complaint need not meet heightened pleading standard of FRCP 9(b) to provide sufficient notice to government of alleged fraud and bar later-filed complaint under 31

> USCS 3730(b)(5); earlier-filed complaints must provide only essential facts to give government notice to initiate investigation into allegedly fraudulent practices."
>
> See *Heineman-Guta v. Guidant Corp.,* 718 F.3d 28 (2013).

The First Circuit reasoned that the court must start with the statutory language of the provision when evaluating whether § 3730(b)(5) imposes Rule 9(b)'s pleading standard on earlier-filed complaints alleging FCA violations. *United States v. Armstrong*, 706 F.3d 1, 5 (1st Cir. 2013). "Where the language of the statute is plain and the meaning unambiguous, we will do no more than enforce the statute in accordance with those plain terms." *United States v. Booker*, 644 F.3d 12, 17 (1st Cir. 2011). Section 3730(b)(5) says "no person other than the Government" can "bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). Nothing in the language of § 3730(b)(5) references Rule 9(b)'s particularity requirements.

The language is plain and simple: an action is barred if it is a "related action" that is "based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). Section 3730(b)(5) contains no exceptions, and certainly not one requiring that the "pending" earlier-filed action comply with Rule 9(b)'s heightened pleading standard. *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28 (1st Cir. 2013).

The court under *Heineman-Guta* held, for the purposes of the first-to-file rule, the earlier-filed complaint need not meet the heightened pleading standard of Rule 9(b) to provide sufficient notice to the government of the alleged fraud and bar a later-filed complaint under § 3730(b)(5); earlier-filed complaints must provide only the essential facts to give the government sufficient notice to initiate an investigation into allegedly fraudulent practices. *Id.*

Because Cobb was the first to file her claim and meeting the particularity requirements of FRCP 9(b) is not required to provide sufficient notice to the government under the FCA, the Petitioner's claim is barred because of the first to file rule. *See LaCorte* and *Grynberg* . More than 50 days before the Petitioner filed her claim, Cobb filed and put the government on notice of an alleged Medicare scheme through Respondent's upcoding practices. R. at 2-3.

The scheme alleged false certification of medical necessity for the advanced and profitable treatment of patients with wound conditions that did not warrant such treatment. When Petitioner filed her complaint, she added some additional information to this scheme from her personal experience, however, her claim was based on the same essential acts of fraudulent conduct and was filed during Cobb's pending action.

After Cobb's claim was dismissed, she should have been given the opportunity to amend her claim and provide the necessary specificity required by 9(b), before Petitioner had an opportunity of her claim being heard. This courtesy has been provided by courts in the past that relate to original *qui tam* suits that do not meet the heightened 9(b) standard. "If a case filed by a *qui tam* relator does not meet the heightened 9(b) standard, the relator must be provided with an opportunity to amend their complaint". "[Plaintiff] made general compulsory allegations of fraud. But as [Defendant] concedes, [Plaintiff] is entitled to one chance to amend the complaint and bring it into compliance with the rule. *Bank v. Pitt*, 928 F.2d, 1108 (11th Cir. 1991). Thus, we instruct the district court to allow [Plaintiff] to amend his complaint." *Cooper v. Blue Cross & Blue Shield*, 19 F.3d 562 (11th Cir. 1994).

C. Petitioner's claim is jurisdictionally barred because Courts have broadened the ban on subsequent FCA complaints from claims that allege "identical acts" to complaints that allege "substantially similar" acts.

The similarity of claims is assessed in a first-to-file analysis by comparing the complaints side-by-side and asking whether the later complaint "alleges a fraudulent scheme the government already would be equipped to investigate based on [the first] [c]omplaint." *Batiste v. SLM Corp*., 659 F.3d 1204, 1209, 398 U.S. App. D.C. 110 (D.C. Cir. 2011) A side-by-side comparison has persuaded us that, although the complaints allege somewhat different facts, [the first] complaint suffices to put the U.S. government on notice of allegedly fraudulent forbearance practices. *Id*.

Without first looking at the merits of this case, this court must review, "if there were earlier filed actions alleging the same material elements of fraud, notwithstanding the fact the allegation may have somewhat different details." *LaCorte* at 233. Because Cobb filed her claim almost two months before the Petitioner filed her nearly identical claim, the Government was already on notice there were claims of Medicare billing fraud from Cobb stemming from the Respondent's upcoding of medical necessity. "The pendency of the initial *qui tam* action consequently blocks other private relators from filing copycat suits that do no more than assert the same material elements of fraud, regardless of whether those later complaints are able to marshal additional factual support for the claim". *Grynberg v Koch Gateway Pipeline Co*., 390 F.3d 1276 (10th Cir. 2004). See also *LaCorte.*

While Petitioner stated additional facts regarding the billing practices and verbal exchanges she claimed to overhear about the wound healing therapies, the material facts and essential elements remained unchanged from the Cobb's fraud claim. "Every other circuit to have addressed this issue has also rejected a narrow "identical facts" test in favor of a broader "essential claim" or "same material elements" standard. *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.,* 355 U.S. App. D.C. 23, 318 F.3d 214, 217-18 (D.C. Cir. 2003). ("We … hold that § 3730(b)(5) bars any action incorporating the same material elements

of fraud as an action filed earlier. In doing so we reject another possible test, one barring claims based on 'identical facts.'"); *Lujan*, 243 F.3d at 1189. *See also Grynberg.*

Limiting § 3730(b)(5) to only bar actions with identical facts, and permitting slight variations on the same fraudulent tale, would be contrary to the plain language and legislative intent of Congress. Allowing these copycat suits would impact the effectiveness of the FCA by: (1) using a narrow jurisdictional bar, such as an identical facts test, would decrease incentives to promptly bring qui tam actions; (2) multiple relators would expect a recovery for the same conduct, thereby decreasing the total amount each relator would potentially receive and incentives to bring the suit; and (3) a narrow identical facts bar would encourage piggyback claims, which would have no additional benefit for the government," since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *LaCorte* at 234. *See also Lujan.*

D. Because Cobb's complaint had not been decided at the time Respondent filed her claim, it was pending regardless of how the claim was subsequently resolved.

The first-to-file provision provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). This Court has defined "pending" to mean "[r]emaining undecided; awaiting decision," thereby finding that the first-to-file rule bars later actions if their earlier-filed counterparts are pending. *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 575 U.S. 650, 663 (2015). Following § 3730(b)(5)'s plain language, an action is barred if the claim is pending. To hold that a later dismissed action was not a then-pending action would be contrary to the plain language of the statute and the legislative intent. *United States v. Rutherford*, 442 U.S. 544, 551-52 (1979).

The Petitioner filed claims alleging the same core material facts and Medicare scheme that was previously filed and still pending by Cobb. In the case before us, had the petitioner waited until Cobb's complaint was resolved before filing her complaint, she would have been given the opportunity for her claim to be reviewed, however, since she has not done that, the first-to-file rule would disallow subject matter jurisdiction to consider the later filed action and requires the claim to be dismissed.

II. THE LINCOLN DISTRICT COURT'S DECISION THAT PETITIONER FAILED TO STATE A CLAIM FOR WHICH RELIEF CAN BE GRANTED SHOULD BE AFFIRMED BECAUSE PETITIONER'S PLEADINGS DID NOT DEMONSTRATE THE OBJECTIVE FALSITY OR SUFFICIENT PARTICULARITY REQUIRED BY THE FALSE CLAIMS ACT.

The Fifteenth Circuit did not rule on the requirement of objective falsity in this case. R. at 20. The District Court of Lincoln held that Petitioner's claim required dismissal in part because of the failure to plead that SAM submitted objectively false medical certifications. R. at 16-19. This Court should affirm the lower Court's ruling because the framework for analyzing falsity, established by this Court in *Omnicare*, was properly applied by the District Court to a claim under the False Claims Act. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 183 (2015).*

Petitioner has failed to meet the requisite standard of objective falsity. *See United States ex rel. Berkowitz v. Automation Aids, Inc., 896 F.3d 834 (7th Cir. 2018), see also Smith v. Clark/Smoot/Russell, A JV, 796 F.3d 424 (4th Cir. 2015).* Petitioner's claim boils down to overhearing a troubling conversation and her expert witness, a physician, disagreed with the treating SAM physicians that the treatments provided to just four patients complied with CMS guidelines. R. at 5-6. However, under the FCA "[e]xpressions of opinion, scientific judgments, or

statements as to conclusions about which reasonable minds may differ cannot be false." *United States ex rel. Morton v. A Plus Benefits, Inc.,* 139 Fed. Appx. 980, 983 (10th Cir. 2005). Like in the case at hand, reasonable minds can differ on an opinion (such as a clinical classification) and just because they do, it does not make one opinion fraudulent. *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019). *See also Omnicare at 175*.

As noted earlier, this case is governed by the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *United States ex rel. Riley v. St. Luke's Episcopal Hosp*., 355 F.3d 370, 381 (5th Cir. 2004). In alleging fraud or mistake under Rule 9(b), a party must state with particularity the circumstances constituting fraud or mistake. *United States ex rel. Gross v. Aids Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005). The burden of particularity is on Petitioner to specifically identify the "who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990). Even if the Court accepts Petitioner's relaxed falsity standard, she has failed to plead with the particularity required to allow her complaint to proceed.

Petitioner fails to meet the heightened pleading standard of FRCP 9(b) because she fails to adequately demonstrate the nexus between the allegedly fraudulent claims, the actors involved, and a scheme to defraud. *United States v. Lockheed-Martin Corp*., 328 F.3d 374, 376 (6th Cir. 2005). No individual physicians are specifically linked to the examples of allegedly fraudulent behavior. Petitioner allegedly overheard a conversation with a specific physician, William Drake, but he is not identified as one of the physicians who allegedly submitted a false claim. R. at 5. Petitioner's allegations are overly broad and vary wildly: from patients with underlying conditions insufficient to qualify for HBO therapy to patients with so many conditions that HBO therapy would no longer be appropriate; from patients trying to stave off an

amputation to physicians being forced to upgrade the characterization of a patient's qualifying condition simply to qualify for initial therapy. R. at 7.

A. This Court should affirm the District Court's ruling on the necessity of pleading objective falsity in claims alleging violation of the False Claims Act because it properly follows the analytical framework this Court established in *Omnicare*.

The Court is being asked to answer: "[w]hat is false or fraudulent in the context of the FCA?" The Circuit Courts do not speak with one voice on this issue. The root of this split is found in the first of the following elements of the FCA: (1) a *false* statement or *fraudulent* course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due. *United States v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2016). (Emphasis added) Congress did not define false in the FCA. *United States ex rel. Schutte v. SuperValu Inc.,* 2021 U.S. App. LEXIS 24018, *14.

Proponents of the objective falsity standard would not find the first element to be satisfied by a clinical judgment that turns out to be false so long as it is the clinician's genuinely held belief. *United States v. Persaud*, 866 F.3d 371, 372 (6th Cir. 2017). Therefore, whether an opinion "trigger[s] liability for fraud" is determined by whether the views are "not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion." *Id*.

Alternatively, the petitioner is asking this Court to establish a rule that holds that a treating doctor's sincerely held medical opinion can be the basis of liability for "falsity" merely if another witness disagrees with the doctor's opinion. R. at 17. This level of permissiveness would dramatically tip the scales in favor of plaintiffs in FCA cases. *See Aseracare* at 1299. Such a rule runs counter to this court's precedent and the common law. Failing to heed to the precedent established by this Court in *Omnicare*, the Third and Ninth Circuits have allowed this

dangerously permissive standard. *See Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1113, (9th Cir. 2020), see also United States ex rel. Druding v. Druding, 952 F.3d 89, 95 (3rd Cir. 2020).*

Conversely, the Fourth, Seventh, & Eleventh Circuits hold that a simple difference of medical opinion is insufficient to establish liability and what is required is an "objective falsehood." *See United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008), see also United States ex rel. Yannacopoulos v. General Dynamics, 652 F.3d 818, 836 (7th Cir. 2011), see also* United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008).*

Congress has failed to define "false" or "falsity" in the FCA. *United States ex rel. Schutte v. SuperValu Inc.,* 2021 U.S. App. LEXIS 24018, *14. In the absence of a statutory definition, courts rely on the common law as a gap filler. *See United States EEOC v. Global Horizons, Inc.,* 915 F.3d 631, 638 (9th Cir. 2019)*, see also Nationwide Mut. Ins. Co. v. Darden,* 503 U.S. 318, 322 (1992).

This Court specifically addressed falsity in its holding in Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund. *Omnicare at 183.*

Omnicare issued public securities and in the required registration statements stated *inter alia* "*we believe* our contract arrangements….are in compliance with applicable federal and state laws." *Id*. at 179. (Emphasis added) The federal government later sued under an anti-kickback provision and a pension fund that invested in the securities offering subsequently sued Omnicare for materially false representations. *Id.* This Court rejected the argument that a statement of opinion that is ultimately found incorrect — even if believed at the time made — may count as an "untrue statement of a material fact." *Id*. at 182.

In rejecting the plaintiff's argument, this Court reasoned that the argument that expressing a belief ("we believe X") is ultimately a statement of fact ("X is in fact true") wrongly melds facts and opinions. And although a plaintiff could later prove the opinion erroneous, the words "I believe" themselves admitted that possibility, thus precluding liability for an untrue statement of fact. *Id*. at 184.

While holding that a sincerely held opinion that ultimately proves to be false isn't a false statement of fact, this Court did not permanently shut the door to opinions being false. *Id*. This Court left open to falsity situations where expressed opinions could reach the falsity threshold, including if the speaker: (1) does not hold the stated belief, (2) expresses within the opinion an embedded fact that is false, (3) expresses the opinion without some meaningful knowledge or inquiry, or (4) knows facts that would preclude the opinion from being correct. *Id*. at 184-188. Admittedly, *Omnicare* addressed securities fraud and not the False Claims Act. However, the guidepost regarding "falsity" established by the Court in this case has been referenced by the Circuit courts to reach divergent opinions in three recent FCA suits.

B. The Eleventh Circuit's Approach to Objective Falsity Is Correct, Follows the Common Law As Created by This Court, and Should Be Expressly Adopted For Application to FCA Claims.

1. The Eleventh Circuit Court properly utilized this Court's falsity analysis from *Omnicare* in *AseraCare* to adjudicate a False Claims Act dispute.

In this FCA suit, the government asserted that a network of hospice facilities falsely billed Medicare for end-of-life care provided to elderly patients on the basis of erroneous clinical judgments that the patients were terminally ill based on the opinion of its expert witness. *AseraCare* at 1281. The Eleventh Circuit, citing this Court's holding in *Omnicare*, stated that a "properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong." *Id.* at 1297. The Eleventh Circuit clearly utilized this

Court's falsity framework from *Omnicare* to articulate what may qualify as objectively false claims in a medical setting:

> Where, for instance a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting ….[a medical opinion then] ….his ill-formed "clinical judgment" reflects an objective falsehood. The same is true where a plaintiff proves that a physician did not, in fact, subjectively believe that his patient …[had the condition being certified]… at the time of certification. A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient ….[had the condition]…given the relevant medical records. In each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."
>
> *Id.*

Clearly the Eleventh Circuit was mindful of how an opinion could be objectively false according to this Court's holding in *Omnicare*. Ultimately, the court held that since there was no showing that the expressed opinion was inconsistent with proper clinical judgment within the Court's falsity analysis, the claim failed as a matter of law. *Id.* at 1304.

The Court noted that it appreciated the government's argument that the objective falsity standard could create a more challenging environment for plaintiffs to prevail. *Id*. at 1301. While recognizing the concern, the Court suggested that the Centers for Medicare & Medicaid Services or Congress could address this issue and noted that they failed to do so when they had the chance. *Id*. Instead, Congress chose to keep the physician at the center of medical judgments regarding appropriateness of levels of care. *Id*.

2. The Ninth Circuit Court incorrectly denied the need for objective falsity but correctly applied this Court's analytical framework from *Omnicare* to identify expressed opinions that were objectively false.

In this case from the Ninth Circuit Court of Appeals, a former hospital director of care management alleged that the hospital submitted, or caused to be submitted, Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary. *Winter* at

1113. Early in its opinion, the Ninth Circuit stated that "Congress imposed no requirement of proving 'objective falsity,' and we have no authority to rewrite the statute to add such a requirement." *Id.* Despite that pronouncement, the court proceeded to apply the same factors to determine falsity as this Court did in *Omnicare* or the Eleventh Circuit did in *AseraCare*: " a subjective opinion is *fraudulent if it implies the existence of facts that do not exist, or if it is not honestly held*….[or it carries] with it an implied assertion, not only that the speaker knows no facts wh*ich would preclude such an opinion, but that he does know facts which justify it." Id*. at 1117. (Emphasis added)

Here the plaintiff properly alleged far more than a simple difference of opinion between two physicians regarding the medical necessity of the inpatient admission. *Id*. at 1115. Tellingly, the Court found liability not merely because an expert pronounced that the medical admissions criteria were fraudulent. *Id*. at 1120. The Court applied the criteria and found that the plaintiff pled *more than just a reasonable difference of opinion*. (Emphasis added) *Id*. The Court's disagreement with "objective falsity" is mostly semantic, because while denying a need for "objective falsity" to be present for liability for a false claim under the FCA, the Ninth Circuit fully embraced this Court's holding in *Omnicare* as to the threshold requirements for an opinion to be deemed false.

3. The Third Circuit Court of Appeals failed to appreciate the distinction between sincerely held opinions and objectively false statements this Court recognized in *Omnicare* and wrongfully blended falsity and scienter to craft a rule that fails to honor the precedent established by this court and has detrimental policy implications.

In a case similar to *Winter*, Plaintiffs in the Third Circuit in *United States ex rel. Druding v. Druding,* 952 F.3d 89 (3rd Cir. 2020) brought an FCA action alleging that the defendants admitted patients who were ineligible for hospice care and directed its employee to improperly

alter those patients' Medicare certifications to reflect eligibility. The Court held that by requiring "objective" falsity (consistent with this Court's requirements in *Omnicare*), the District Court conflated scienter and falsity in a manner that was inconsistent with the text and application of the FCA. *Id*. at 96.

While the Third Circuit criticized the District Court in that case for conflating scienter and falsity, it was guilty of the same sin in its search for a definition of "false" or "fraudulent." *Id*. The Court cited common law rules to identify the well-settled meaning of "false" or "fraudulent." *Id*. at 95. The Court noted in part the same rules this Court held in *Omnicare*, namely that "an opinion or projection . . . will be deemed untrue for purposes of the federal securities laws if it is issued *without reasonable genuine belief or if it has no basis*" (Emphasis added) (*Herskowitz v. Nutri/Sys*., Inc., 857 F.2d 179, 184 (3d Cir. 1988)) and that "an opinion may be false when the speaker makes an express statement *contrary to the opinion he or she actually holds*." (Emphasis added) *Restatement (Second) of Torts* §§ 525 cmt. c, 539 cmt. a (1977). Each of these references freely blends elements of scienter and falsity and, if proven, would satisfy an objective falsity standard. *Druding* at 96. The AseraCare court agreed that an opinion can be objectively false if it isn't truly held. *Aseracare* at 1297. "The FCA does not define "false" or "fraudulent," but its falsity and scienter requirements are inseparable." *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. Appx. 980, 982 (10th Cir. 2005).

The Third Circuit opportunistically used this blended approach — one that incorporates significant definitional elements of scienter — to say that since some opinions can be false, the District Court was wrong to hold that a sincerely held opinion cannot be false. *Druding* at 95. The Court then provides examples which all incorporate expression of opinions not sincerely held. *Id*. That directly contradicts this Court's *Omnicare* holding. *Omnicare* at 1297.

The Third Circuit fails to appreciate this court's view in the *Omnicare* ruling that there is a clear difference between a sincerely held belief, which the Court found *could not be false*, and one that is unfounded or conveyed knowing that in some manner it is not true. (Emphasis added)

The Third Circuit justifies this permissive definition of "falsity" by stating that the scienter element will serve to limit practitioner exposure to lawsuits because it is "rigorous." *Druding* at 96. "Scienter helps to limit the possibility that hospice providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis." *Id.*

This further conflates two separate elements of an FCA claim. From a policy perspective, questions of scienter are inherently fact bound "plaintiffs in ... fraud cases must plead facts giving rise to a "strong inference" of scienter. *City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1249 (10th Cir. 2001). Therefore, claims like the petitioners that would be dismissed for a lack of objective falsity would more routinely go to the jury (or produce forced settlements) in an effort to determine scienter.

C. Petitioner Failed to Meet "Objective Falsity" Standard Articulated by This Court in *Omnicare*

Under the objective falsity standard, "vague allegations of debatably improper therapy provided to unidentified patients do not create a material issue of fact for an FCA action." (*United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2015 U.S. Dist. LEXIS 45221, *32-33). Petitioner fails to plead with particularity how the claims were false or fraudulent under this Court's *Omnicare* standard.

1. No pleading asserts the treating physician had no meaningful knowledge of the case.

Petitioner does not allege at any time or in any manner that any treating physician had no knowledge of their own cases being submitted for certification. R. at 7.

2. No pleading expressly asserted that the treating physicians did not believe their claims.

Petitioner's explanations for Patients #2 and #4 do not mention any physician. R. at 7. Clearly no lack of belief on the part of the treating physician was pleaded with particularity for those patients.

Patient #1 was not classified as a Wagner III initially and was not prescribed HBO treatment. *Id*. Petitioner is likely to attribute the subsequent change as evidence of a lack of the physician's belief in the modified classification. However, she fails to plead with particularity any connection between the physician and any dialogue demonstrating they were part of the alleged "scheme" or that they did not believe in the certification. *Id*.

Similarly, Patient #3 identifies the treating physician as encouraging Petitioner to "talk to O'Keefe about it." *Id*. As much as Petitioner would like the Court to seize on that comment, it remains a far cry from a pleading of particularity demonstrating that the physician did not believe in the indicators supporting HBO therapy.

3. No pleading demonstrates the expression of an opinion with an embedded fact that is false.

Petitioner is not qualified in Lincoln to assess patient conditions and prescribe or deny HBO therapy. R. at 4. Doing so requires a degree of clinical judgment. Petitioner seeks to turn these judgments (Is it refractory? Is it a stage II or stage III? Is the patient responding?, etc.) into matters of fact that can be armchair quarterbacked on Monday morning by a paid expert.

Medicine is both an art and a science. These judgments are just that — judgments — and are part of the healing art. They don't always easily lend themselves to definitive, "yes" or "no", "A" or "B", answers.

Regardless of that challenge, Petitioner again fails to particularly plead that any fact embedded in the physician's opinion was false and is the basis for her claim.

4. No pleading asserts the treating physician had facts that would preclude her from believing her opinion to be true.

Petitioner does not plead with particularity that there are facts known to the treating physicians to be false that would preclude them from holding their opinion regarding medical necessity. "The phrase 'known to be false' in that sentence does not mean 'scientifically untrue'; it means 'a lie.'" *Chen-Cheng Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992).

Utilizing the framework from this Court in *Omnicare*, neither SAM Clinics nor any of its physicians conveyed an objective falsehood to the government.

D. Assuming Petitioner is not required to demonstrate objective falsity, her claim still fails for the lack of particularity the FRCP 9(b) standard for FCA pleadings require.

Because Petitioner alleges violations of the FCA, she must, and cannot, demonstrate that she has satisfied the two pleading requirements of the FCA. First, the claim must, if accepted as true, provide enough factual matter to make a plausible case for relief under FRCP 8(a). *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Plaintiff's obligation to provide the "grounds" of his "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*.

However, the usual notice-pleading standards are not all that is required in a case alleging fraud: every circuit to consider the issue has held that, because the False Claims Act is self-

evidently an anti-fraud statute, complaints brought under it must also comply with Rule 9(b). *United States ex rel. Totten v. Bombardier Corp*., 286 F.3d 542, 551-552 (D.C. Cir. 2002).

Rule 9(b) states that "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." USCS Fed Rules Civ Proc R 9. Rule 9 "does not require the impossible…[because]…courts do not require voluminous documentation substantiating fraud at the pleading stage." *United States v. Molina Healthcare of Ill., Inc*., 2021 U.S. App. LEXIS 24775, *13. However, what is required is "sufficiently detailed allegations." *Id*.

Petitioner fails to sufficiently detail her allegations to satisfy the standard in FRCP 9(b). In order to do so, she must "specify the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990). "The purpose of the heightened pleading requirement in fraud cases is to force the plaintiff to do more than the usual investigation before filing his complaint." *Ackerman v. Northwestern Mut. Life Ins. Co.,* 172 F.3d 467, 469 (7th Cir. 1999). The specific information Petitioner provides about the four patients does not reflect an adequate investigation that would satisfy this standard. 9(b) allegations must be evaluated as they appear in the complaint. *Id*.

1. **Claim for Patient 1 does not meet the 9(b) standard.**

Petitioner states that Patient 1 received HBO therapy after O'Keefe pulled the patient's chart, spoke to the physician, and the physician then changed the wound classification from a Wagner II to a Wagner III. This change was required to be eligible for HBO therapy.

Pleading with particularity requires specificity. There is no specific reference to the identity of the treating physician in the complaint. There is no evidence offered as to what O'Keefe said to the physician or that the physician was involved in any way in the alleged scheme. There is no evidence that this patient's case was discussed at all. Even if it was discussed, there is no evidence that there was any pressure brought to bear on the physician. Clinical judgments are often changed in good faith after discussions with colleagues. There is no evidence provided that the patient's wound was actually a Wagner grade II rather than a grade III, as submitted. In this complaint the court is left without knowledge of the identity of the physician, no evidence what was said to the physician — if anything at all — and what the actual status of the patient was.

2. **Claim for Patient 2 does not meet the 9(b) standard.**

There is absolutely no actor identified in the complaint other than the patient — who performed the allegedly fraudulent act. Additionally, the complaint fails to indicate the duration of the patient's infection. Additionally, there is no documentation that the bone infection, resulting from the wound, *was responding* to conventional treatments. The failure to address each of these issues in the complaint represents a failure to plead with particularity.

3. **Claim for Patient 3 does not meet the 9(b) standard.**

Petitioner asks the unnamed physician about indicators for HBO therapy, does not get a specific answer, and therefore asserts the claim was not medically necessary. Petitioner fails to assert what the certification of medical necessity was for and only states how it could not have been for one of many covered conditions. The complaint states that amputation was indicated for the patient's condition. Having an indication for one course of treatment, in this case amputation, does not automatically preclude other therapies. Once again, Petitioner's failure to

clearly identify that the patient had no other indicators for HBO therapy demands that the court "fill in the blanks" in a manner not permitted by FRCP 9(b).

4. **Claim for Patient 4 does not meet the 9(b) standard.**

Once again, Petitioner fails to plead with particularity the identity of the person who actually submitted the allegedly fraudulent claim. She makes no connection to the alleged scheme and why the clinician may have reason to participate in it. Once again, Petitioner has incompletely challenged the classification of the wound based merely on her opinion. The attending physician may have noted the presence of joint sepsis, a condition which qualifies for a Wagner III classification, which Petitioner does not address in her pleading.

E. Even if Petitioner demonstrates that SAM Clinic submitted inaccurate medical records, that alone does not make the submission of the claims fraudulent.

Petitioner has made vague and inconclusive allegations regarding both the inaccurate certification of medical necessity and a scheme to defraud the federal government. Petitioner cites an "unexpected increase" in HBO treatment at SAM as evidence of fraud but fails to state with any particularity the alleged scheme behind the increase. An equally plausible explanation for the increase in HBO therapy is the doubling of the rate of diabetes in this country between 1999 and 2015. [5]

Diabetes is the key factor in chronic wound development. "Patients who suffer from diabetes have a 15–25% chance of developing a chronic wound. Chronic wounds associated with diabetes include foot, venous and pressure ulcers." [6]

[5] https://www.cdc.gov/diabetes/statistics/slides/long_term_trends.pdf.
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6163915/

Absent a showing of particularity by the Petitioner and the multitude of plausible alternative explanations for the increase in HBO therapy, Petitioner is urging this Court to make a finding of fraudulent conduct unsupported by a requisite showing evidence.

As noted earlier, the classification of a patient's clinical status is often a judgment that is subject to good faith disagreement among physicians. Should the court find that the inaccurate certification of the status of some patient's medical necessity occurred, that does not allow petitioner to claim any more than a breach of contract without satisfying the FRCP 9(b) standard. *See United States ex rel. Berkowitz v. Automation Aids, Inc.,* 896 F.3d 834, 842.

"[F]raud requires more than [a] breach of promise: fraud entails making a false representation, such as a statement that the speaker will do something it plans not to do. "Tripping up on a regulatory complexity does not entail a knowingly false representation. Without any specific allegations regarding the particularities of the fraud scheme, [a relator] cannot satisfy the requirements of Rule 9(b) for these claims." *Id.*

While the "phrase 'false or fraudulent claim' in the False Claims Act should be construed broadly," id. at 788, it just as surely cannot be construed to include a run-of-the-mill breach of contract action that is devoid of any objective falsehood. An FCA relator cannot base a fraud claim on nothing more than his own interpretation of an imprecise contractual provision. To hold otherwise would render meaningless the fundamental distinction between actions for fraud and breach of contract. See *Strum v. Exxon Co*., 15 F.3d 327, 329-30 (4th Cir. 1994). This we refuse to do. *Wilson v. Kellogg Brown & Root, Inc*. at 378.

CONCLUSION

For the reasons stated above, the decision of the Fifteenth Circuit Court of Appeals should be affirmed. Dr. Cobb's complaint imposed a jurisdictional bar on Petitioner's complaint.

Petitioner also failed to plead any allegations with the requisite objective falsity required for a claim to be false or particularity in accordance with FRCP 9(b). Permitting claims of similar allegations, and not requiring the claim to be plead under FRCP 9(b), will encourage copycat complaints and fails to honor congressional intent.