Docket No. 21-1967

In The

Supreme Court of the United States

October Term, 2021

United States *ex rel.* 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 PETITIONER

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QUESTIONS PRESENTED

I. Should the False Claims Act's first-to-file rule be read as jurisdictional when the plain language of the provision does not speak to jurisdiction, thereby barring a later claim alleging different essential facts from a previous insufficiently particular claim?

II. Must a relator under the False Claims Act show that certification of a medical opinion regarding medical necessity was objectively false when additional facts and circumstances demonstrate the physician did not honesty hold that opinion?

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The opinion 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 and order of the United States Court of Appeals for the Fifteenth Circuit is also unreported and set out in the record. R. at 20–28.

STATUTORY PROVISIONS

The following provisions of the False Claims Act are relevant to this case: 31 U.S.C. §§ 3729(a)(1), (b); 3730(b); 3730(e)(2)(A). These provisions are reproduced in Appendix A.

RULES PROVISIONS

The following provision of the Centers for Medicare and Medicaid Services, Medicare National Determinations (NCD) Manual is relevant to this case: § 20.29 Hyperbaric Oxygen Therapy. This provision is reproduced in Appendix B.

The following provisions of the Federal Rules of Civil Procedure are relevant to this case: Fed. R. Civ. P. 9(b); Fed. R. Civ. P. 12(b)(1), (6); Fed. R. Civ. P. 56(a). These provisions are reproduced in Appendix B.

STATEMENT OF THE CASE

Factual Background

SAM Clinics and Its Operations. In 2017, Keegan Mason began work as an experienced nurse specialist at Southern American Metropolitan Clinics, Inc. (SAM Clinics). R. at 4. Operating fourteen care centers throughout Lincoln, SAM Clinics is the largest for-profit wound care provider in the state of Lincoln and specializes in chronic wound treatment. R. at 2. The vast majority, approximately seventy-five percent, of SAM Clinic's revenue comes from Medicare and Medicaid reimbursements. R. at 2.

SAM Clinics offers wound care services including wound debridement and Hyperbaric Oxygen (HBO) therapy. R. at 3. Debridement is the removal of unhealthy tissue to promote healing while HBO therapy is inhalation of pure oxygen at increased atmospheric pressure designed to promote healing of certain diabetic wounds. R. at 3. Both kinds of therapy are eligible for reimbursement from Medicare and Medicaid when certain Center for Medicare and Medicaid Services (CMS) conditions are satisfied. R. at 3. In particular, to qualify for reimbursement of HBO therapy, CMS requires a wound to be classified as grade III or above on the Wagner scale, a system for determining the severity of diabetic lower extremity wounds. R. at 3-4. For a wound to qualify as a Wagner grade III, there must be an ulcer with an abscess, osteomyelitis, joint sepsis, or other bone involvement from the wound. R. at 4. While nurse specialists are not permitted to diagnose and order treatment in Lincoln, Mason, who had previously worked in a state that did allow such practice,

was already familiar with CMS standards for HBO therapy reimbursement when she began working for SAM Clinics. R. at 4.

The Quota System. Two years after Mason began working for SAM Clinics, the corporation hired a new CEO, James O'Keefe, in January 2019. R. at 4. Within a month, Mason observed a surprising increase in the number of HBO therapy treatments the clinic was performing. R. at 4. Mason observed at least four instances in which SAM Clinics certified to CMS the medical necessity of HBO therapy when the treatment was inappropriate, either because the treatment conflicted with the patient's diagnosis and CMS guidelines or because it appeared unnecessary. R. at 6–7. For example, one diabetic patient exhibited osteomyelitis and a Wagner grade III wound; however, the osteomyelitis promptly responded to conventional wound treatment, so HBO therapy was unnecessary under CMS guidelines. R. at 7. Further, two diabetic patients had lower extremity wounds classified as Wagner grade III. Their medical charts, however, indicated no sign of an ulcer with an abscess, osteomyelitis, joint sepsis, or other bone involvement from the wound. R. at 7. At the same time, Mason became aware that clinical management was pressuring physicians to meet reimbursement quotas. R. at 5. For instance, in July 2019, when Mason questioned why a non-diabetic patient with end-stage vascular disease was administered HBO therapy when the condition necessitated amputation, the responsible physician merely said, "[T]alk to O'Keefe about it." R. at 7. Then, on September 24, 2019, Mason overheard a conversation in which O'Keefe reminded a

physician, "Got to keep those numbers up," to which the doctor replied, "I'm good. Almost got that Tesla down payment." R. at 5.

Mason was convinced that SAM Clinics was perpetrating a scheme in which physicians were financially rewarded for submitting false certifications of the medical necessity of HBO therapy to Medicare for reimbursement. R. at 6. Consequently, she sought legal counsel on filing a False Claims Act (FCA) suit and obtained an affidavit from an expert witness confirming that SAM Clinics was certifying HBO therapy contrary to CMS guidelines. R. at 5, 7.

Cobb's Complaint. Unbeknownst to Mason, on October 24, 2019, Dr. Elizabeth Cobb filed a *qui tam* action under the FCA against SAM Clinics. R. at 5. Dr. Cobb was a plastic surgeon who had been fired from a different SAM Clinic. R. at 5. She alleged that O'Keefe dismissed her for refusing to perform a surgical debridement or to certify the medical necessity of the procedure because she believed it was unnecessary. R. at 5. While Dr. Cobb alleged that O'Keefe had another physician perform the procedure, she did not plead with particularity that the clinic knowingly submitted a false certification of medical necessity. R. at 6. Dr. Cobb's complaint was dismissed by the district court on January 20, 2020 as insufficiently specific under Federal Rule of Civil Procedure 9(b). R. at 6.

Procedural History

District of Lincoln. Keegan Mason filed suit on behalf of the United States under seal against SAM Clinics on November 22, 2019 for knowingly submitting false certifications of the medical necessity of HBO therapy in violation of FCA, §

3729(a)(1). R. at 1. The United States declined to intervene but did not seek dismissal, and Mason's complaint was unsealed on January 24, 2020. R. at 1. On January 30, 2020, SAM Clinics responded with two procedural motions. First, under Federal Rule of Civil Procedure 12(b)(1), SAM Clinics argued that the district court lacked jurisdiction to hear the claim because another claim, Dr. Cobb's, was still pending at the time. R. at 11. Second, SAM Clinics asserted under Rule 12(b)(6) that Mason failed to a state claim on the theory that she had not established that SAM Clinics submitted objectively false certifications of medical necessity. R. at 16. Because the first-to-file rule is not jurisdictional, the district court denied SAM Clinic's 12(b)(1) motion, holding that even if the rule was jurisdictional Mason's suit would not be barred because it alleges different essential facts than Cobb's complaint. R. at 15. Under the Eleventh Circuit's objective falsity standard, the court granted SAM Clinic's 12(b)(6) motion. R. at 19.

Fifteenth Circuit. Mason appealed the district court's dismissal of her complaint under Federal Rule of Civil Procedure 12(b)(6) to the United States Court of Appeals for the Fifteenth Circuit. R. at 20. The Fifteenth Circuit affirmed the district court's dismissal of the case but reversed and remanded the jurisdictional question. R. at 25. The circuit court did not address the question of objective falsity. R. at 20. Judge Askins dissented, arguing that the district court was correct in finding that the first-to-file rule is nonjurisdictional and that Mason and Dr. Cobb allege different essential facts. R. at 25. Moreover, Judge Askins argued that the district court was right to reach the question of falsity but erred in adopting an objective

falsity standard rather than remaining faithful to the FCA's plain language. R. at 26. Even so, he reasoned, Mason pleaded sufficient facts to raise a jury question, rendering dismissal improper. R. at 27.

SUMMARY OF THE ARGUMENT

Properly interpreted, the False Claims Act's first-to-file rule is nonjurisdictional. The FCA has the dual purposes of empowering private whistleblowers to alert the government to frauds being perpetrated against it by filing *qui tam* actions in exchange for a share of the award if successful while preventing duplicative claims. In balancing these dual purposes, Congress included in the FCA a first-to-file rule which bars relators from filing a related, follow-on claim while an earlier-filed claim is still pending. Some circuits have assumed without argument that this means the existence of a previously filed claim denies district courts the power to hear related, later-filed claims. This view, however, contradicts this Court's precedent that absent a "clear expression" of jurisdiction, a rule is nonjurisdictional. Further, when some provisions of an act are explicitly jurisdictional while others are not, courts must interpret the inclusion and exclusion of such language as intentional. In this case, the first-to-file rule is silent as to jurisdiction while other provisions of the FCA are explicitly jurisdictional, meaning that, properly interpreted, the rule is nonjurisdictional. Therefore, the district court possessed the power to hear Mason's claim despite the existence of a pending, previously filed claim at the time.

Moreover, even if the first-to-file rule were jurisdictional, it would not bar Mason's claim because Dr. Cobb's claim, failing to plead with specificity the nature of the fraud she alleged, did not constitute a genuine claim under even the most permissive interpretation of Federal Rule of Civil Procedure 9(b). Mason's complaint, in contrast, included the time, place, and content of the fraud she alleged and, consequently, was properly pleaded under Rule 9(b). To deny the necessity of FCA claims satisfying 9(b) would be to disregard the authority of the Federal Rules of Civil Procedure.

Finally, because Mason alleges, in significant detail, a far broader scheme of fraud involving a method of treatment and a kickback scheme totally absent from Dr. Cobb's claim, her claim was not sufficient to alert the Government to the content of Mason's complaint. That is, Mason's claim includes not only somewhat different details but different essential facts than Cobb's. Therefore, Mason's claim should not be barred by the first-to-file rule because it was the first claim filed alleging these particular facts.

Requiring proof of "objective falsity" to reveal a medically necessary certification as fraudulent contradicts the plain text of the FCA. The district court erred when it adopted the Eleventh Circuit's "objective falsity" test which requires independently verifiable facts to prove a certification of medical necessity as false. It was an error because the plain text indicates Congress's intent that "false" be read under its common law definition, which allows that a subjective opinion may be false if it implies facts which do not exist or is not honestly held by its speaker.

More narrowly, the FCA does not distinguish between objective and subjective falsity, but rather imposes liability for all false or fraudulent claims without requiring a specific intent to defraud. While some argue this allows medical professionals to be sued for merely holding a different medical opinion than another, this fear is misplaced because the scienter and materiality requirements under the FCA offer sufficient protection to physicians. To constitute fraud, the FCA still requires an actor to know the government would be entitled to refuse payment if it were aware the request violated its standards. Because the physicians at SAM Clinics knew they were certifying treatment as a "medical necessity" in contradiction of CMS standards, Mason was able to meet this burden of proof.

Nevertheless, even if this Court were to adopt the objective falsity standard, Mason could prove that SAM Clinics violated it. In particular, Mason identified four cases in which clinic physicians certified the medical necessity of treatments objectively inappropriate for those patients. For example, one physician certified the medical necessity of HBO treatment for a non-diabetic patient's wound, when that treatment is specifically authorized only for diabetic wounds. As a result, Mason identifies more than a "reasonable difference of opinion" as to the medical necessity of HBO therapy for the patients she identified. Thus, regardless of the definition of "false" this Court adopts, Mason's claims are capable of meeting it and the district court erred by dismissing her claim.

STANDARD OF REVIEW

When a claim is dismissed under Federal Rule of Civil Procedure 12(b)(6), the appellate court reviews the decision de novo. *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1116 (9th Cir. 2020). Facts in a plaintiff's complaint must be accepted as true and "state a claim to relief that is plausible on its face" with every reasonable inference made in favor of the nonmovant. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A plaintiff must plead FCA claims, like all fraud claims, with particularity. *Winter*, 953 F.3d at 1116; Fed. R. Civ. P. 9(b).

ARGUMENT

I. Under this Court's interpretive rules and the plain language of the text, the False Claims Act's first-to-file rule is nonjurisdictional.

As its primary tool for combatting fraud, the False Claims Act (FCA) imposes civil penalties on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A); *see* S. Rep. No. 99-345, at 2 (1986). In furtherance of this policy, the FCA empowers private citizens to bring *qui tam* actions as "relators" on behalf of the government. *See* 31 U.S.C. § 3730(b). Such actions are filed under seal to provide the government an opportunity either to assume responsibility for the suit or allow the relator to continue the suit in the government's name. *See id. at* § 3730(b)(2). One variety of FCA claims is the "certification theory" of liability under which, "(1) a false statement or fraudulent course of conduct, [is] (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006).

The FCA includes a first-to-file rule barring others from bringing claims based on the same underlying facts as another action while the first is still pending. *See* 31 U.S.C. § 3730(b)(5) ("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."). The rule serves dual purposes: to encourage whistleblowers with knowledge of fraud to bring meritorious claims to the government's attention while preventing opportunistic plaintiffs from filing duplicative claims. *See, e.g., United States ex rel. LaCorte v. SmithKline Beecham*

Clinical Lab'ys, Inc., 149 F.3d 227, 233 (3d Cir. 1998). However, as this Court held in *Kellogg Brown & Root Services v. United States ex rel. Carter*, the first-to-file rule bars new claims only while related claims are still "pending." 575 U.S. 650, 664 (2015). Thus, once a claim is dismissed, a new claim, even one pleading related facts, is no longer barred by the rule. *See id.*

A. The language of the first-to-file rule is nonjurisdictional because other provisions of the FCA do speak jursidictionally, meaning under this Court's precedent the rule is not a jurisdictional bar.

"Jurisdiction" means the power of a court to adjudicate a case. *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004). A jurisdictional rule, then, "defines whether a court can exercise power to hear and resolve a case." *See* Howard M. Wasserman, *Jurisdiction, Merits, and Procedure: Thoughts on A Trichotomy*, 102 Nw. U. L. Rev. 1547, 1552 (2008). In contrast, a "merits rule" describes who may sue whom, when, and on what grounds; thus, limiting the ability of claimants to bring suit but not the power of courts to hear such claims. *Id.* at 1548.

1. Under the "clear statement" rule, the first-to-file rule is nonjurisdictional.

Under this Court's canons of construction, unless Congress "clearly states" that a rule is jurisdictional, "courts should treat the restriction as nonjurisdictional." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013) (quoting *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 516 (2006)). The Court adopted this "readily administrable bright line" test in order to "ward off profligate use of the term 'jurisdiction.'" *Id.* at 153 (quoting *Arbaugh*, 546 U.S. at 515–16). For example, in *Sebelius v. Auburn Regional Medical Center*, a provision of the Social Security Act required healthcare providers

who objected to the Medicare reimbursements they received to appeal the administrative decision within 180 days. *Id.* at 148. At issue was whether the 180-day limit was jurisdictional, thereby preventing the Secretary of Health and Human Services from extending the period for good cause. *Id.* at 148–49. The Court held that because the code section did not "speak in jurisdictional terms," the filing deadline was not jurisdictional. *Id.* at 154 (quoting *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982)).

Like the code section in *Auburn Regional*, the first-to-file rule does not speak in jurisdictional terms, but rather discusses who may bring an FCA claim and when, not the power of the court to consider the claim. *See* § 3730(b)(5). Consequently, under the clear statement rule, § 3730(b)(5) is not jurisdictional. *See id.* The Fifteenth Circuit, therefore, erred in holding that the first-to-file rule jurisdictionally barred Mason's claim. R. at 23.

2. Congress intended the first-to-file to be nonjurisdictional.

In addition to its clear statement rule, this Court has held that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Kucana v. Holder*, 558 U.S. 233, 249 (2010) (quoting *Nken v. Holder*, 556 U.S. 418, 430 (2009)). To illustrate, in *United States ex rel Heath v. AT&T*, relator Heath brought an FCA claim against AT&T which resembled his own earlier claim against Wisconsin Bell, a subsidiary of AT&T. 791 F.3d 112, 117-18. The district court found that the first-

to-file rule was jurisdictional and, therefore, barred Heath's second claim. *Id.* at 118–19. The D.C. Circuit, however, broke with the majority of courts of appeals at the time in holding that the rule was nonjurisdictional. *Id.* at 121. The court reasoned that because Congress used clear jurisdictional language in some provisions of the FCA—e.g., "No court shall have jurisdiction over an action brought against a Member of Congress . . . if the action is based on evidence or information known to the Government when the action was brought"—Congress "knew how to reference 'jurisdiction expressly' in the False Claims Act." *Id.* at 120–21 (quoting § 3730(e)(2)). As a result, its decision not to include jurisdictional language in § 3730(b)(5) must be interpreted as intentional. *See id.* Therefore, the D.C. Circuit concluded, the first-to-file rule is not jurisdictional. *Id.*; *accord United States v. Millennium Lab'ys, Inc.*, 923 F.3d 240, 248 (1st Cir. 2019); *United States ex rel. Hanks v. United States*, 961 F.3d 131, 137 (2d Cir. 2020); *In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, 974 F.3d 228, 234 (3d Cir. 2020). To hold otherwise would not only contradict the text of the FCA but also Congress's intentions. *See Heath*, 791 F.3d at 120–21.

3. The plain text and proper interpretation of the first-to-file rule demonstrates that it is nonjurisdictional and, therefore, the Fifteenth Circuit erred in holding that it barred Mason's claim.

Contrary to this Court's interpretive rules, some circuits have held that the first-to-file rule is jurisdictional. *See*, e.*g.*, *United States ex rel. Wilson v. Bristol-Meyers Squibb, Inc.*, 750 F.3d 111 (1st Cir. 2014); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966 (6th Cir. 2005). Each of these courts emphasized the

competing goals of a jurisdictional rule: incentivizing whistleblowing for the public good while preventing duplicative suits. *See Wilson*, 750 F.3d at 117; *Branch Consultants*, 560 F.3d at 376; *Walburn*, 431 F.3d at 970. Beyond referencing these policy goals, however, none of the courts offered "more analysis to explain why the first-to-file rule divested the district court of jurisdiction to hear follow-on relator-filed FCA complaints." Scott Glass, Note, *Is the False Claims Act's First-to-File Rule Jurisdictional?*, 118 Colum. L. Rev. 2361, 2377 (2018). For example, in *United States ex rel. Carter v. Halliburton*, the Fourth Circuit assumed without argument that if a court finds a given action is barred by the first-to-file rule "the court lacks subject-matter jurisdiction over the later-filed matter." 866 F.3d 199, 203, n.1 (quoting *United States ex rel. Carson v. Manor Care, Inc.*, 851 F.3d 293, 303 (4th Cir. 2017)) (noting that the D.C. and Second Circuits have held otherwise without attempting to revisit the issue).

For three reasons, the courts treating the first-to-file rule as jurisdictional are in error. First, to read the first-to-file rule as jurisdictional when the text of the provision does not speak in jurisdictional terms, while other provisions of the statute do, contradicts the clear statement and intent rules of interpretation this Court has articulated. *See Heath*, 791 F.3d at 120–21. Moreover, the text of the first-to-file rule implies a merits rule rather than a jurisdictional one. *See* Howard M. Wasserman, *The Demise of "Drive-by Jurisdictional Rulings"*, 105 Nw. U. L. Rev. 947, 950 (2011). That is, the rule speaks to who may sue whom, when, and on what grounds, but not the power of courts to hear such claims. *See id.* The purpose and legislative history

behind the first-to-file rule and the FCA overall is "unilluminating" on this issue and only serves to reinforce that there is no reason to depart from the conclusion the text of the rule and the structure of the FCA suggest. Glass, *supra*, at 2388 (describing the legislative history of the first-to-file rules as uninformative).

Finally, a nonjurisdictional rule provides sufficient protection to FCA defendants. *Id.* at 2391. While construing the first-to-file rule as jurisdictional effectively prohibits duplicative suits, a nonjurisdictional, merits rule provides ample protection under the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 9(b), 12(b)(6), 56(a). For instance, FCA relators must satisfy Rule 9(b)'s heightened pleading standard for claims of fraud, and defendants may bring Rule 12(b)(6) motions to dismiss and Rule 56(a) summary judgment motions against meritless claims. *Id.* These are no small barriers to relators' claims and effectively serve the first-to-file rule's purpose of barring duplicative, and thereby unmeritorious, claims. *See* Glass, *supra*, at 2391. Therefore, this Court should hold that the FCA's first-to-file rule is nonjurisdictional and, consequently, did not bar Mason's claim.

B. Even if jurisdictional, Cobb's claim fails to preempt Mason's because Cobb's is legally insufficient and the essential facts of their claims differ.

1. Cobb's claim fails to allege with particularity the circumstances constituting SAM Clinic's fraud.

Federal Rule of Civil Procedure 9(b) requires that, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Given that all claims brought under the FCA necessarily allege fraud, relators must meet the heightened pleading requirements of

Rule 9(b). *See* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for anyone who "knowingly presents, or causes to be presented, a *false or fraudulent claim* for payment or approval") (emphasis added). This Court confirmed this reasoning in *Universal Health Services v. United States*, noting that, "False Claims Act plaintiffs must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." 136 S. Ct. 1989, 2003 n.6 (2016).

Where disagreement arises among the circuit courts is not *whether* FCA plaintiffs must meet the standard of Rule 9(b) but *what* is required to meet that standard. *Compare United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (holding broadly that only a strong inference was required) *with United States ex rel. Nathan v. Takeda Pharms.*, 707 F.3d 451, 457 (4th Cir. 2013) (holding narrowly that allegations must be pleaded with particularity and specificity). For example, in *United States ex rel. Grubbs v. Kanneganti*, the relator, Dr. Grubbs, alleged that coworkers at his hospital attempted to involve him in an ongoing scheme to defraud Medicare and Medicaid by submitting fraudulent bills for reimbursement. 565 F.3d at 192. As a doctor, however, Grubbs lacked access to the actual bills the hospital submitted. *Id.* The Fifth Circuit held, nevertheless, that Grubbs's complaint was sufficient under Rule 9(b) because it "[led] to a strong inference that [false] claims were actually submitted." *Id.* at 190. In contrast, the Fourth Circuit held in *United States ex rel. Nathan v. Takeda Pharmaceuticals* that a relator alleging a similar scheme to defraud Medicare was required to "allege with particularity that specific

false claims actually were presented to the government for payment" to satisfy Rule 9(b). 707 F.3d at 457.

In the present case, Cobb's complaint fails to meet the particularity requirement under either the Fifth Circuit's permissive interpretation or the Fourth Circuit's more restrictive view of Rule 9(b). *See* Karin Lee, Note, *Linking Rule 9(b) Pleading and the First-to-File Rule to Advance the Goals of the False Claims Act*, 108 Nw. U. L. Rev. 1423, 1428-32 (2014) (describing the Fifth Circuit's view as "most permissive" and the Fourth Circuit's as "most restrictive"). Dr. Cobb alleged only: (1) that she was pressured to certify the medical necessity of a Medicare patient's treatment she believed was unwarranted; (2) she refused to certify the necessity of a surgical debridement or to perform the procedure; and (3) she was fired as a result. R. at 5–6. Dr. Cobb's allegations are insufficient under the Fourth Circuit's restrictive interpretation of Rule 9(b) because she fails to allege that any false claims were actually presented to the government. R. at 5–6; *See Nathan*, 707 F.3d at 457. However, her allegations are also insufficient under the Fifth Circuit's most permissive view because that she was fired for refusing to perform a medically unnecessary procedure does not, without more, "lead to a strong inference" that SAM Clinics actually submitted a false claim. *See Grubbs*, 546 F.3d at 190.

2. Because Cobb's allegations fail to constitute a complaint under Federal Rule of Civil Procedure 9(b), they are incapable of barring Mason's claim.

Stemming from the disagreement over the standards of Rule 9(b), circuit courts are also divided over whether the first-to-file rule requires a complaint to satisfy 9(b)

to bar related, later-filed complaints. *Compare Walburn*, 431 F.3d at 973 (holding that if a complaint is dismissed, it does not bar future complaints under the first-to-file rule) *with United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011) (holding that if a complaint is dismissed, it provides "sufficient notice" to the government and subsequent claims are barred under the first-to-file rule). In *Walburn v. Lockheed Martin*, a private citizen filed an FCA suit alleging similar facts as a previous relator. 431 F.3d at 969. The second relator argued that the first-filed suit should not bar the later-filed suit under the first-to-file rule because the original complaint was insufficiently particular. *Id. a*t 972. The Sixth Circuit agreed, finding that a "fatally-broad complaint" that did not satisfy Rule 9(b) was not a complaint and the court, therefore, could not exclude later complaints under § 3730(b)(5). *Id.* at 973. The D.C. Circuit reached the opposite conclusion in *United States ex rel. Batiste v. SLM Corporation*, holding that a complaint need not meet 9(b)'s particularity requirement to bar subsequent complaints. 659 F.3d at 1210. Rather, an original complaint need provide only "sufficient notice" for the government to be apprised of the alleged fraud, rendering later-filed complaints duplicative. *Id.*

The purposes of both Rule 9(b) and the FCA demonstrate that this Court should hold a first-filed complaint must satisfy Rule 9(b)'s heightened standards to bar a related later-filed complaint. *Walburn*, 431 F.3d at 973; Fed. R. Civ. P. 9(b). The purpose of Rule 9(b) is to provide defendants with fair notice of a plaintiff's claims as well as their factual grounds. *See United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010). Meanwhile, the purpose of the FCA is to

encourage whistleblowers to come forward and alert the government of potential fraud. *Walburn*, 431 F.3d at 973. Neither purpose is well-served by allowing an insufficiently particular claim to bar related later-filed claims. *See id.* As the Sixth Circuit noted, a claim which cannot meet 9(b)'s particularity standard fails to provide "notice of the essential facts of a fraudulent scheme, and therefore would not enable the government to uncover related frauds." *Id.* To hold otherwise incentivizes relators to allege broad and unspecific complaints in order to bar as many potentially related later-filed actions as possible. *See id.* Moreover, because this Court's interpretive rules demonstrate that the first-to-file rule is nonjurisdictional, Rule 9(b) is a critical check against meritless claims. *See* Fed. R. Civ. P. 9(b). Consequently, because Cobb's allegations were insufficiently particular to constitute a complaint, they should not bar Mason's claim even if their facts are substantially similar. R. at 5–6.

3. Mason was first to file under the FCA because her claim states different essential facts than Cobb's, whose allegations failed to put the government on notice of the fraudulent scheme Mason alleges.

The first-to-file rule specifies that once a party files a *qui tam* action under the FCA, no party but the government may bring "a related action based on the facts underlying the pending action." § 3730(b)(5). The plain language of this rule does not bar all related actions, only related actions that are also based on the same essential facts as the pending action. *See United States ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 363 (7th Cir. 2010). Thus, similarity to a pending action alone is not enough to trigger the first-to-file ban. *See id.* The question is what it means for a related action to be "based on the facts underlying" another claim. 31 U.S.C §

3730(b)(5). One interpretation is that this language bars only claims based on identical facts. *See* Joel Deuth, *The False Claims Act's First-to-File Bar: How the Particularity Requirement of Civil Procedure Militates Against Combating Fraud*, 62 Cath. U. L. Rev. 795, 802-03 (2013). Such a reading, however, renders the word "related" irrelevant. *Id.* Instead, the majority of circuit courts have interpreted "facts" to mean "material" or "essential facts". *See Chovanec*, 606 F.3d at 363.

Under the essential facts test, a complaint alleging a lesser fraud does not, by itself, encompass a greater fraud. *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 122 (D.C. Cir. 2015). To illustrate, in *Duxbury v. Ortho Biotech Products*, two relators brought FCA claims against the maker of an anemia medication. 579 F.3d 13, 15–16 (1st Cir. 2009). Both complaints alleged (1) an unapproved, "off-label" dosing scheme, (2) promoted for the purpose of increasing Medicare reimbursements, and (3) resulting in the company submitting false reimbursement claims. *Id.* at 33. The only crucial difference between the complaints was that the second alleged off-label use and the company's promotion efforts "in significant detail," while the original complaint alleged only one method of off-label promotion *Id.* Despite their similarities, the First Circuit held that because the original complaint failed to encompass all the allegations made in the second, the complaints did not plead the same essential facts. *Id.* The later-filed complaint, therefore, was not barred by the first-to-file rule. *Id.*

In this case, the original complaint brought by Dr. Cobb includes only one discrete allegation: that, despite pressure from O'Keefe, she refused to perform or

certify the medical necessity of a surgical debridement on a Medicare patient because she believed it was unnecessary and was fired as a result. R. at 5. Meanwhile, Mason's complaint includes multiple observations of SAM Clinics violating CMS treatment guidelines, four specific instances in which SAM Clinics submitted false certifications of medical necessity, and a scheme by which physicians received kickbacks for submitting those false certifications. R. at 6–8. Thus, like the original complaint in *Duxbury*, Dr. Cobb's complaint alleges only one instance of fraud, while Mason's later-filed complaint alleges a larger fraud in significant detail. *See* 579 F.3d at 33. Consequently, Mason's claim is not trumped by Dr. Cobb's under the first-to-file rule's essential facts test. R. at 5–6.

The conclusion that Dr. Cobb's claim does not block Mason's is supported by the caselaw even of those courts that find a later complaint may be barred by the first-to-file rule despite "incorporat[ing] somewhat different details" *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-33 (3d Cir.1998). For example, in *United States ex rel. Poteet v. Medtronic*, successive relators claimed that a medical technology company had used illegal kickbacks to induce physicians to use its products and submit ineligible claims for Medicare and Medicaid reimbursement. 552 F.3d 503, 508-09 (6th Cir. 2009), *abrogated on other grounds by United States ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813 (6th Cir. 2021). The Sixth Circuit found that the later-filed complaint alleged Medtronic had violated the same federal laws, using the same methods and means, and leading to the same results as the earlier-filed complaint. *Id.* at 517. The only difference was that the later

complaint implicated different physicians than the earlier one. *Id.* The circuit court found this was not a difference of essential facts and the earlier complaint was sufficient to put the government on notice of Medtronic's potential fraud. *Id.* at 516.

Here, however, the facts of Mason's complaint are critically unlike the second relator's in *Poteet*. *See id.* at 517; R. at 5–6. Mason does not simply describe the same fraudulent scheme as Dr. Cobb but with different physicians, she alleges a different and broader scheme: that SAM Clinics instituted a quota system, illegally awarding physicians based on the number of HBO treatments they certified. R. at 4–7. Even if Dr. Cobb had properly alleged SAM Clinics perpetrated a fraud, her claim is, at most, that it submitted one false certification of medical necessity for a surgical debridement. *See Cobb*, No. CV-2019-213 at *4 (finding that Dr. Cobb failed to allege with particularity that SAM Clinics submitted false certifications of medical necessity). That is not a matter of "somewhat different details," but of essential facts. *Id.* One allegation that SAM Clinics potentially submitted a fraudulent reimbursement claim for a surgical debridement does not put the government on notice of a company-wide illegal kickback scheme for physicians falsely certifying the medical necessity of HBO therapy. R. at 4–7. As a result, Dr. Cobb's claim was not sufficient to alert the government to Mason's allegations against SAM Clinics. R. at 5–6. Mason's complaint was, therefore, the first claim filed on these facts. R. at 5–6.

II. Under the FCA, certification of a medical opinion may be false and Mason's claim met the requisite standard to withstand a dismissal.

The FCA imposes liability on any person who knowingly submits or conspires to submit a "false or fraudulent claim for payment" to the government or makes "a

false record or statement material to" such a claim. 31 U.S.C. § 3729(1)(A)–(C). Thus, to bring a claim under the FCA, a plaintiff must allege: "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing, (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). Where courts diverge is whether physicians' clinical judgments, and thereby their certifications of medical necessity, may be "false or fraudulent" under the FCA. *Compare United States v. AseraCare, Inc.*, 983 F.3d 1278, 1281 (11th Cir. 2019) (holding that objective falsehood is required for certified medical opinions to be considered fraudulent) *with Winter ex rel. United States v. Gardens Reg'l Hosp. and Med. Ctr., Inc.*, 953 F.3d 1108, 1117 (9th Cir. 2020) (holding that objective falsity is not required by the FCA to show fraudulent medical necessity certification). While all federal complaints of fraud must be pleaded with particularity, this Court has refused to accept a rigid definition of "fraudulent" under the FCA and has cautioned against adopting a circumscribed view when considering whether a claim is false or fraudulent to preserve Congress's intent "to reach all types of fraud, without qualification, that might result in financial loss to the government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968); *Univ. Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (U.S. 2016).

A. The text of the FCA is silent as to the definition of "false," meaning Congress intended the common law definition.

When Congress does not indicate another interpretation, it is the settled precedent of this Court that Congress's intent was to rely on the common law meaning of the term. *Universal Health Servs.*, 136 S. Ct. at 1999. Consequently, in

interpreting the FCA which does not define "false or fraudulent," courts must turn to common law definitions. *Id.* Under common law, a subjective opinion is not totally insulated from liability. *United States v. Paulus*, 894 F.3d 267, 275–76 (6th Cir. 2018). For instance, the Restatement of Torts acknowledges that "[a] statement of opinion as to facts not disclosed and not otherwise known to the recipient" may sometimes be reasonably interpreted as implying the speaker "knows facts sufficient to justify him in forming it," or at least that the facts he does know are not incompatible with that opinion. Restatement (Second) of Torts § 539. Thus, as this Court has held, a statement need not include an "express falsehood" to be fraudulent. *Universal Health Servs.*, 136 S. Ct. at 1999.

To demonstrate Congress's intent to interpret the FCA even more broadly than common law in at least one respect, the FCA explains that "'[k]nowingly' . . . require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). The language within the FCA imposes liability for all false or fraudulent claims and does not create a distinction between "objective" or "subjective" falsity. *Winter*, 953 F.3d at 1117. Further, there is no specific language in the statute creating an exception for clinical judgments and opinions requiring them to be objectively false. *Id*; 31 U.S.C. § 3729(b)(1)(B).

The FCA requires the knowing presentation of a falsehood, and "[t]he phrase, 'known to be false' . . . does not mean 'scientifically untrue'; it means 'a lie'" *Winter*, 953 F.3d at 1117-18 (quoting *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992)). This was the Ninth Circuit's conclusion in *Winter ex rel. United States v.*

Gardens Regional Hospital and Medical Center, *Inc. Id.* In that case, a former hospital director alleged that Gardens Regional Hospital and Medical Center (Gardens Regional) had falsely certified the medical necessity of certain inpatient hospitalizations when medical records and the hospital's admissions policies demonstrated that inpatient hospitalization was unnecessary. *Id.* at 1112–13. The district court dismissed the relator's complaint reasoning that she failed to show that the hospital made an "objectively false representation" and that "subjective medical opinions . . . cannot be proven to be objectively false." *Id.* at 1113. The Ninth Circuit reversed, however, holding that a relator does not need to plead an objective falsehood to state a claim under the FCA. *Id.* at 1119. Rather, a physician's certification of medical necessity "can be false or fraudulent for the same reasons any opinion can be false or fraudulent," including that their opinion was not honestly held or implied the existence of facts that did not exist. *Id.* at 1122.

The Ninth Circuit concluded that Winter's allegations met this standard. *Id.* at 1119–20. First, her complaint not only alleged a scheme connoting misconduct because the hospital relied on Medicare reimbursements for revenue but also demonstrated that the number of Medicare patients admitted spiked after new management took over. *Id.* Second, her allegations as to each Medicare claim were detailed and supported an inference of falsity because she identified specific patients who were admitted in contradiction to medical standards. *Id.* Finally, the court also noted that the evidence of management pressuring doctors to recommend

unnecessary treatments supported not only an inference of scienter but also of falsity. *Id*.

Like the relator in *Winter*, Mason has plausibly alleged that SAM Clinic's physicians submitted false certifications of medical necessity. *Id.* at 119; *Iqbal*, 556 U.S. at 681 (holding factual allegations in a complaint only need to "plausibly suggest an entitlement to relief"). First, as in *Winter*, Mason's allegations suggest a scheme of misconduct because SAM Clinics relies on Medicare for seventy-five percent of its revenue, and she documented a spike in the number of HBO therapy treatments ordered for Medicare patients after O'Keefe became CEO. R. at 4. Second, not only does Mason identify suspect trends in treatment orders, but she also details evidence of four specific patients being prescribed unnecessary treatment. R. at 7. For example, Patient D's lower extremity wound from diabetes was classified as Wagner grade III, despite no signs of osteitis, abscess, or osteomyelitis which are required for Wagner grade III classification. R. at 7. This supports an inference of falsity because the physician's certification that HBO therapy was medically necessary implies the existence of facts that did not exist. R. at 7; *Winter*, 953 F.3d at 1122. Finally, the conversation Mason overheard between O'Keefe and Dr. Drake and the instance in which a physician told her to "talk to O'Keefe about it" when she questioned the medical necessity of the physician's treatment order not only suggests scienter but that the doctor did not honestly believe his prescribed treatments were necessary. R. at 5, 7. Thus, Mason, like Winter, has plausibly alleged that SAM Clinics submitted false certifications of medical necessity to the government to receive Medicare

funding. R. At 4–7. It is unnecessary to require her to plead the clinic submitted objectively false certifications and would read a requirement into the FCA which is not in its plain text and Congress did not intend. *Universal Health Servs.*, 136 S. Ct. at 2002.

B. The FCA's scienter and materiality requirements are sufficient to protect medical professionals from undue liability.

In addition to alleging fraudulent conduct, a relator is required to allege that the conduct was material and made with scienter. *Campie*, 862 F.3d at 899. These two requirements are rigorous safeguards to address concerns about fair notice and open liability without having to enforce an objective falsehood standard. *Universal Health Servs.*, 136 S. Ct. at 2002. By strictly enforcing these two requirements, unsubstantial and ordinary breaches of contract will not satisfy conditions to bring a claim under the FCA. *United States v. Sci. Applications Int'l. Corp.*, 626 F.3d 1257, 1271 (D.C. Cir. 2010).

1. Mason's complaint satisfies the materiality requirement because the scheme she alleges is central to the government's decision to pay SAM Clinics for HBO therapy.

As defined by the FCA, "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). To satisfy this element, relators must demonstrate that a mispresentation of compliance with a statutory, regulatory, or contractual requirement influenced the government's decision to pay out a claim. *Univ. Health Services, Inc.*, 136 S. Ct. at 2002. However, demonstrating that a provision is a condition of payment is relevant but, alone, not enough to prove materiality. *Id.* at

2001. "For a false statement to be material, a plaintiff must plausibly allege that the statutory violations are 'so central' to the claims that the government 'would not have paid these claims had it known of these violations.'" *Winters*, 953 F.3d at 1121 (quoting *Universal Health Servs.*, 136 S. Ct. at 2004).

Mason's complaint satisfies the materiality requirement. R. at 5–6. CMS's guideline is that "[t]he use of HBO therapy is covered as an adjunctive therapy *only after* there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be in addition to standard wound care." Ctrs. for Medicare & Medicaid Servs., Medicare National Determination (NCD) Manual § 20.29 (emphasis added). Further, diabetic wounds to the lower extremities only qualify for HBO therapy if standard wound therapy has failed and the wound is classified as a Wagner grade III or higher. *Id*. Mason pleaded in her complaint four specific instances of fraud by SAM Clinics. R. at 7. In the first instance, O'Keefe had Patient A's wound classification prescribed by another physician changed from Wagner grade II to Wagner grade III in order to be eligble for Medicare reimbursement. R. at 7. Next, Patient B's osteomyelitis showed improvement after using standard wound therapy; nevertheless, she was diagnosed with chronic refractory osteomyelitis to satisfy the CMS requirements for HBO treatment. R. at 7. Further, Patient C was not diabetic, and it was indicated the patient needed an amputation, but HBO treatment was prescribed anyway though there was no indication that the patient qualified. R. at 7. Finally, Patient D's lower extremity wound from diabetes was classified as a Wagner grade III, despite no signs of osteitis,

abscess, or osteomyelitis which are required to be classified as a Wagner grade III. R. at 7. In each of these instances, the alleged fraudulent acts were changes to material requirements the government had imposed for Medicare funding of HBO therapy. R. at 7; Ctrs. for Medicare & Medicaid Servs., Medicare National Determination (NCD) Manual § 20.29. In other words, had these patients been certified with the correct classification, the government would not have given SAM Clinics Medicare funding for their procedures. R. at 7; *Universal Health Servs.*, 136 S. Ct. at 2002.

2. Mason's complaint satisfies the scienter requirement because it includes facts and circumstances demonstrating that SAM Clinics physicians knowingly committed fraud.

Mason's complaint also satisfied the requirement of scienter. R. at 5. For the purposes of § 3729, the FCA specifies the level of scienter as "knowing." 31 U.S.C. § 3729(b)(1)(A)(i)–(iii). In doing so, the Act imposes liability on any person acting with "actual knowledge," "in deliberate ignorance," or "in reckless disregard of the truth or falsity of the information." *Id.* It does not, however, require proof of specific intent to defraud. 31 U.S.C. § 3729(b)(1)(B). Moreover, under Federal Rule of Civil Procedure 9(b), scienter may be alleged generally. Fed. R. Civ. P. 9(b). While this is not an invitation to make conclusory allegations, a complaint need only allege facts sufficient to support a plausible claim of scienter. *See United States v. Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011).

In her complaint, Mason alleged that SAM Clinics management was pressuring its physicians to meet a quota system for HBO therapy in exchange for financial kickbacks as evidenced by the conversation she overheard between O'Keefe

and Dr. Drake. R. at 4. Further, she observed a physician change a wound classification to a level that qualified for HBO therapy after a meeting with O'Keefe about the patient's chart. R. at 7. Regarding Patients B, C, and D, Mason observed physicians prescribe treatments contraindicated by CMS standards and the patients' diagnoses. R. at 7. Finally, Mason also obtained an expert opinion from a physician that the treatment regimens for these four patients contradicted CMS guidelines. R. at 5. These allegations are enough to satisfy the requirement that the certifying physicians knew what they were doing and that it was wrongful. *See Universal Health Servs.*, 136 S. Ct. at 2002.

Worries that without the objective falsity standard physicians will be liable any time a peer disagrees with their medical opinion are misplaced. *Id*. According to the district court in this case, the objective falsity test should be adopted to allow "healthcare providers to continue to make clinic[al] judgments without fear that the government will come knocking for every case with a challenging call." R. at 18. The district court erred in relying on this policy argument because the FCA's demanding materiality and scienter requirements ensure that a case is not brought every time physicians disagree. *Universal Health Servs.*, 136 S. Ct. at 2002. Moreover, as this Court has held, "policy arguments cannot supersede clear statutory text." *Id*.

C. Even under the "objective falsity" standard, Mason pleaded a viable claim.

The objective falsehood standard adopted by the district court requires that the relator show "something more than the mere difference of reasonable opinion concerning the prognosis of a patient" to prove a certification of medical necessity

false. *United States v. AseraCare, Inc.*, 983 F.3d 1278, 1281 (11th Cir. 2019). This was the Eleventh Circuit's conclusion in *United States v. AseraCare*. *Id.* at 1281. In that case, the government intervened in an FCA action brought by former employees against AseraCare, the operator of a network of hospice facilities. *Id*. at 1281. Allegedly, AseraCare classified patients as eligible for hospice care and billed Medicare though these individuals did not, in fact, qualify for hospice. *Id.* at 1282. To be eligible for hospice care, a provider must supply written certification that the individual is terminally ill, meaning that the patient's life expectancy is six months or less based on the physician's medical judgment. 42 U.S.C. §§ 1395f(7)(A), 1395x(dd)(3)(A). At trial, the government relied on expert witnesses who disagreed with AseraCare's techniques in assessing whether a patient was terminally ill. *AseraCare*, 983 F.3d at 1288.

The Eleventh Circuit held that it could not deem a clinical judgment of terminal illness warranting hospice benefits under Medicare as false when there was "only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment." *Id*. at 1281. The court reasoned that predicting end-of-life is not an exact science, and that the legal framework under CMS simply asks physicians to use their best judgment and document their reasoning. *See id.* at 1294. Therefore, to prove a physician's opinion is false requires additional facts and circumstances surrounding the patient's certification that is inconsistent with the physician's clinical judgment. *Id*. at 1290, 1297. In elucidating this standard, the court explained that a certification of medical

necessity is objectively false when a physician (1) fails to review a patient's medical records before certifying a diagnosis, (2) does not subjectively believe her own diagnosis at the time of certification, or (3) certifies a diagnosis when no reasonable physician could have reached that conclusion. *Id.* at 1297.

In this case, Mason has satisfied the objective falsehood pleading standards set out in *AseraCare*. R. at 4–5, 7. First, Mason has pleaded facts which plausibly imply that SAM Clinic's physicians did not honestly hold the medical opinions they certified. R. at 4–5, 7. This is suggested by the pressure that management placed on physicians to reach quotas of HBO treatments as evidenced by the conversation Mason overheard between O'Keefe and Dr. Drake. R. at 5, 7. In particular, one physician's only explanation for certifying the medical necessity of HBO therapy for Patient C, whose condition necessitated amputation, was that Mason should "talk to O'Keefe about it." R. at 7.

Moreover, there is ample evidence that no reasonable physician could have reached the diagnoses SAM Clinic's physicians certified in several cases. R. at 7. Unlike an end-of-life estimate, CMS guidelines for the appropriateness of HBO therapy are concrete and objective. *See* Ctrs. for Medicare & Medicaid Servs., Medicare National Determination (NCD) Manual § 20.29. For example, Patient B was diagnosed with chronic refractory osteomyelitis, a bone infection that persists despite appropriate treatment, yet it was shown that the patient responded well to a short course of conventional treatment in direct contradiction with her diagnosis. R. at 7. Further, Patient D's wound was certified Wagner grade III, requiring there to

be osteitis, abscess, or osteomyelitis, and there were no signs of any of the conditions that would make the wound a Wagner grade III. R. at 7. The expert medical testimony Mason secured only reinforces the plausibility of her claim that no reasonable physician could come to the conclusions that SAM Clinic's physicians reached. R. at 7. Consequently, Mason demonstrated more than a "reasonable difference of opinion" among physicians. *AseraCare*, 983 F.3d at 1297. She identified verifiable facts suggesting that the medical opinions SAM Clinic's physicians certified were not honestly held and were unreasonable which satisfies the objective falsehood standard. R. at 7.

CONCLUSION

The plain language of the text and this Court's clear statement and intent rules demonstrate that the FCA's first-to-file rule is a nonjursidictional merits rule. Under this standard, Mason's complaint should not have been dismissed because it was based on different essential facts and alleged in significantly greater detail than Dr. Cobb's previously-filed complaint. Because Mason alleged a broader scheme of false certification in signficantly greater detail than the previously-filed complaint, the Court of Appeals for the Fifteenth Circuit erred when it dismissed Mason's claim on jurisdictional grounds.

Further, a certification of medical opinion may be false under the FCA without proof that the certification was objectively false. The text of the statute demonstrates Congress's intent to apply the common law meaning of "false" which does not require proof that an opinion includes an express falsehood for that opinion to be false. Evidence supporting an inference that an opinion was not honestly held by its

speaker is sufficient to demonstrate the falsity of that opinion. Because Mason's complaint met this standard, the Fifteenth Circuit also erred in affirming the district court's dismissal.

It is for these reasons that that this Court should reverse the Court of Appeals for the Fifteenth Circuit and remand the case for further proceedings.

Respectfully submitted,

/s/ 3011

Attorneys for Petitioner

CERTIFICATE OF SERVICE

We certify that a copy of Petitioner's brief was served upon Respondent, Southern American Metropolitcan Clinics, Inc., through the counsel of record by certified U.S. mail return receipt requested, on this, the 16th day of September, 2021.

/s/ 3011

Attorneys for Petitioner

APPENDIX A

Statutory Provisions

False Claims Act

31 U.S.C. § 3729(a)(1), (b). False Claims

(a) Liability for certain acts.—

(1) In general.—Subject to paragraph (2), any person who—

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

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

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

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

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

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

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(b) Definitions.—For purposes of this section—

(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3730(b), (e)(2)(A). Civil Actions for False Claims

(b) Actions by private persons.

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name

of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure.1 The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) 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.

(e) Certain Actions Barred.—(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

APPENDIX B

Rules Provisions

Ctrs. For Medicare & Medicaid Servs., Medicare National Determinations (NCD) Manual § 20.29 (2017). Hyperbaric Oxygen Therapy

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication,

2. Decompression illness,

3. Gas embolism,

4. Gas gangrene,

5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.

6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.

7. Progressive necrotizing infections (necrotizing fasciitis), 8. Acute peripheral arterial insufficiency,

9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),

10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,

11. Osteoradionecrosis as an adjunct to conventional treatment,

12. Soft tissue radionecrosis as an adjunct to conventional treatment,

13. Cyanide poisoning,

14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,

15. Diabetic wounds of the lower extremities in patients who meet the following three criteria: a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; b. Patient has a wound classified as Wagner grade III or higher; and c. Patient has failed an adequate course of standard wound therapy. The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that

might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Non-covered Conditions All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A). No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility. 6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.

13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).

14. Tetanus.

15. Systemic aerobic infection.

16. Organ transplantation.

17. Organ storage.

18. Pulmonary emphysema.

19. Exceptional blood loss anemia.

20. Multiple Sclerosis.

21. Arthritic Diseases.

22. Acute cerebral edema.

Fed. R. Civ. P. 9(b) Pleading Special Matters

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

Fed. R. Civ. P. 12(b)(1), 12(b)(6) Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses;

(b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(1) lack of subject-matter jurisdiction;

(2) lack of personal jurisdiction;

(3) improper venue;

(4) insufficient process;

(5) insufficient service of process;

(6) failure to state a claim upon which relief can be granted; and

(7) failure to join a party under Rule 19.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.

Fed. R. Civ. P. 56(a) Summary Judgment

(a) Motion for Summary Judgment or Partial Summary Judgment. A party may move for summary judgment, identifying each claim or defense — or the part of

each claim or defense — on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.