IN THE

SUPREME COURT OF THE UNITED STATES

Docket No. 21-1967

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 RESPONDENT

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QUESTION PRESENTED

I. Whether § 3730(b)(5) of the False Claims Act (FCA) establishes a jurisdictional bar to a relator's qui tam action, where a jurisdictional application of the rule is supported by a majority of circuits, the first-filed suit remained pending in the district court, and the relator alleged the same general conduct as the first-filed suit in violation of a statutory mandate imposed by Congress?

II. Whether a relator must establish an objective falsehood to plausibly plead the "false" element of a medical certification theory of FCA liability where the certification reflects a mere subjective clinical opinion about the application of ambiguous standards, and whether Mason has plausibly pled verifiable facts to show an objective falsehood where the allegations suggest pure speculation about a possible scheme to increase patient numbers in a small but growing healthcare practice area.

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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 2-19. The opinion of the United States Court of Appeals for the Twelfth Circuit is also unreported and provided in the Record. R. at 19-27.

RELEVANT PROVISIONS

This case involves the statutory provisions of the False Claims Act. The first relevant provision, 31 U.S.C. § 3729(a)(1), imposes liability on "any person who knowingly presents or causes to be presented a false or fraudulent claim for payment." 31 U.S.C. § 3729(a)(1). The second provision, 31 U.S.C. § 3730(b)(5), provides in relevant part 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 case also implicates the Federal Rules of Civil Procedure. Fed. R. Civ. P. 9(b); 8(a).

STATEMENT OF THE CASE

STATEMENT OF THE FACTS

Background. Respondent, Southern America Metropolitan Clinics, Inc. ("SAM Clinics"), is a collection of clinics across the state of Lincoln dedicated to the treatment and care of wounds. Record at 2. Originally SAM Clinics started small in 1956, but the Clinic has seen considerable growth. R. at 2. SAM Clinics, now run by its CEO, John O'Keefe, operates 14 wound care centers treating a myriad of chronic and non-healing wounds from surgical wounds and burns to associated conditions

such as osteomyelitis or infection of the bone. R. at 2-4. But SAM Clinics' true area of expertise is treating those wounds which are unresponsive to initial therapy or persist in the face of appropriate care, i.e., chronic wounds.[1]

Wounds, in the ordinary course of events, are treated using non-surgical methods. R. at 2-3. Although, often, especially in the case of chronic wounds, debridement or even Hyperbaric Oxygen therapy (HBO) could be necessary for a wound to start the healing process. R. at 3.[2] Accordingly, SAM Clinics offers both treatments at its wound care centers to ensure no wound, no matter how persistent, goes untreated. R. at 3.

Appellant, Keegan Mason, is a clinical nurse specialist who started working for SAM Clinics in 2017. R. at 4. However, diagnosis by a SAM Clinics physician is required to determine the proper treatment. R. at 4. Especially in the case of HBO therapy because clinical nurse specialists can supervise HBO therapy under Lincoln law but cannot diagnose nor order treatment themself. R. at 4. Thus, a SAM Clinics physician will order the appropriate treatment being either non-surgical, surgical debridement, or HBO therapy, by measuring the severity of the wound. R. at 2-4.

Medicare and Medicaid. These treatments are reimbursable under the Center for Medicare and Medicaid Services (CMS) so long as the treatment is medically necessary under CMS guidelines. R. at 3. CMS guidelines use the Meggitt-

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[1] Robert Frykberg & Jaminelli Banks, *Challenges in the Treatment of Chronic Wounds, Advances in Wound Care*, Aug. 3, 2015, at 560, available at https://doi.org/10.1089/wound.2015.0635.

[2] Debridement is defined as the removal of unhealthy tissue from a wound to promote healing. Daniel R. Levinson, "Medicare Payments for Surgical Debridement Services in 2004" Dep't. Of Health and Human Serv., May 2007, 1, available at https://oig.hhs.gov/oei/reports/oei02-05-00390.pdf.; Gowri Raman et. al., A Horizon Scan: Uses of Hyperbaric Oxygen Therapy, Technology Assessment Rep., Oct. 5, 2005.)

Wagner system, also known as the Wagner grade, to determine whether treatment is reimbursable. R. at 3. Accordingly, if the treating doctor diagnoses the wound to be of a certain "Wagner grade," CMS approves the corresponding therapy. R. at 4.

The Complaints. On October 14, 2019, a SAMs Clinic plastic surgeon, Dr. Elizabeth Cobb, filed a *qui tam* FCA complaint against SAM Clinics in the District Court for the State of Lincoln. R. at 5. Dr. Cobb's complaint alleged that the CEO of SAM Clinic, John O'Keefe pressured her to certify a medically unnecessary surgical wound debridement as medically necessary for a Medicare patient at SAM Clinics. R. at 5. Cobb alleged that O'Keefe asked her to perform the medically unnecessary surgical debridement of the Medicare patient, and she refused. R. at 5. Lastly, Dr. Cobb alleged that because she refused, O'Keefe got another doctor to certify the procedure's medical necessity falsely, and O'Keefe fired Cobb. R. at 5.

The district court dismissed Dr. Cobb's action for failure to state a claim on January 20, 2020. R. at 2. *Cobb v. Southern America Metropolitan Clinic Inc.*, No. CV-2019-213 *3 (D. Linc. Jan. 20, 2020). R. at 5-6. The court concluded that although Dr. Cobb's complaint alleged that she had felt pressure from O'Keefe to perform a medically unnecessary surgical debridement, it failed to meet Federal Rule of Civil Procedure 9(b). *Id.* at *4. R. at 6.

Subsequently, on November 22, 2019, Petitioner Mason filed a *qui tam* action under seal in the District Court for the State of Lincoln against SAM Clinics. R. at 1. Mason's complaint alleged that SAM Clinics knowingly submitted Medicare claims to falsely certify HBO therapy as medically necessary for patients whose charts did

not meet CMS guidelines to qualify for such therapy. R. at 6. Mason further alleged that the physicians who falsely certified the medical necessity of the HBO therapy did so in exchange for monetary payment. R. at 7-8. Finally, Mason alleged that she overheard a discussion between CEO John O'Keefe and another SAM Clinics doctor, Dr. Drake, concerning HBO therapy procedures. R. at 5. Mason's complaint alleged she heard: O'Keefe say, "Got to keep those numbers up." Dr. Drake laughed and said, "I'm good. Almost got that Tesla down payment." O'Keefe then said, "Yep, CMS approves, you get that fancy new car, and the patients are happy. It's a win-win-win." R. at 5. Mason detailed four patients who received HBO therapy that SAM Clinics submitted a certification of medical necessity for and referenced an affidavit from a medical expert who concluded the identified treatments contradict CMS guidelines in her complaint as well. R. at 7. Mason's complaint was unsealed on January 24, 2020. R. at 1. The United States declined to intervene or seek dismissal of Mason's claims.

PROCEDURAL HISTORY

Plaintiff-Relator Keegan Mason ("Mason"), a citizen of the State of Lincoln, filed this proceeding *qui tam* under seal in the United States District Court for the District of Lincoln on November 22, 2019 against Defendant Southern American Metropolitan Clinics, Inc. ("SAM Clinics"). Mason alleges that SAM Clinics violated the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1), by knowingly submitting false certifications of the medical necessity of Hyperbaric Oxygen therapy to receive Medicare or Medicaid reimbursements. R. at 2.

Mason alleges that SAM Clinics falsely certified the medical necessity of HBO therapy despite information in the patients' charts, as well as general CMS guidelines, that did not establish the necessity of the treatments. R. at 5. Mason further alleges that she observed several instances of insufficient adherence to the treatment guidelines and instances where the patient's diagnosis did not appear to match her own medical observations. R. at 6. Mason included five specific instances of alleged unqualified HBO therapy. R. at 7. Mason also alleges that a sketchy conversation between a doctor and the hospital CEO took place in which the CEO applauded and encouraged the high volume of HBO patients. R. 7. Mason contends that this conversation, coupled with her other allegedly sketchy observations, established evidence of a scheme to falsify certificates. R. at 7.

On January 30, 2020, Respondent SAM Clinics filed, pursuant to the Federal Rules of Civil Procedure, two motions to dismiss: a 12(b)(1) motion to dismiss for lack of subject matter jurisdiction and a 12(b)(6) motion for failure to state claim. R. at 2.

SAM Clinics based the 12(b)(1) motion on the first-to-file rule, asserting the existence of another pending FCA action alleging the same essential facts. R. at 2. The other pending action refers to that filed under seal by Dr. Elizabeth Cobb on October 14, 2019. R. at 2. The complaint was unsealed on December 16, 2019. R. at 2. On January 20, 2020, the district court dismissed Dr. Cobb's complaint for failure to plead fraud with specificity as required under Federal Rule of Civil Procedure 9(b). R. at 5-6.

SAM Clinics based the 12(b)(6) motion on Mason's failure to plausibly allege the FCA's falsity element but rather merely established a reasonable difference in clinical opinion regarding the relevant treatment standards. R. at 10. SAM Clinics contends that, despite disagreements by Mason and an expert, its physicians exercised their best medical judgment in providing HBO therapy for these patients. R. at 10.

The District Court denied SAM Clinics' 12(b)(1) motion to dismiss, declaring that the first-to-file rule did not bar Mason's claim. R. at 19. SAM Clinics did not appeal the action but the United States Circuit Court of Appeals for the Twelfth Circuit raised the issue *sua sponte*. R. at 22. The Twelfth Circuit reversed and remanded the District Court's denial of the 12(b)(1) motion, finding that the first-to-file rule barred jurisdiction. R. at 21.

The District Court granted SAM Clinics' 12(b)(6) motion, finding that Mason did not plausibly plead that SAM Clinics falsely certified the medical necessity of HBO therapy in violation of the FCA. R. at 20. Mason appealed the dismissal to the United States Circuit Court of Appeals for the 12th Circuit. R. at 20. The Twelfth Circuit affirmed the District Court's decision to grant SAM Clinic's 12(b)(6) motion on the basis that the District Court lacked the jurisdiction to hear Mason's second argument regarding the falsity standard in the first place. R. at 25.

Mason petitioned for review of the decision affirming the dismissal of her FCA claim. R. at 30. This Court granted the petition for Writ of Certiorari to the United States Court of Appeals for the Twelfth Circuit, limited to the following

questions: (1) Does the FCA's first-to-file rule establish a rule of subject matter jurisdiction and was Petitioner's case barred by that rule?; and (2) Can certification of a medical opinion be false under the FCA or must the relator show the certification was objectively false, and did Petitioner in this case meet the requisite standard? R. at 30.

STANDARD OF REVIEW

The legal standard for reviewing a motion to dismiss for lack of subject matter jurisdiction is a question of law reviewed *de novo*. *Pillow v. Bechtel Const., Inc.*, 201 F.3d 1348, 1351 (11th Cir. 2000). Courts also apply a *de novo* standard of review when reviewing a motion to dismiss for failure to state a claim. *Harry v. Marchant*, 237 F.3d 1315, 1317 (11th Cir. 2000). On appeal, the Court should also accept all factual allegations as true. *See Leatherman v. Tarrant Cty.,* 507 U.S. 163, 164 (1993).

SUMMARY OF THE ARGUMENT

This Court should affirm the Fifteenth Circuit's decision to dismiss Mason's claim for lack of subject matter jurisdiction because Mason filed her related claim when Dr. Cobb's action remained pending in the district court.

This case presents two distinct issues sharing a common theme: the need for uniform legal consequences. Section 3730(b)(5)'s first-to-file rule is jurisdictional, notwithstanding Congress's silence on the matter, the consensus is that the courts apply it as a jurisdictional limit. The first-to-file rule imposed as a jurisdictional limit is the most logical conclusion because it restricts a district court from hearing

duplicative qui tam actions. Accordingly, § 3730(b)(5)'s jurisdictional bar more efficiently executes Congress' intent to limit unmeritorious claims and encourage prompt disclosure.

In contrast, the district court set a troublesome precedent when it justified incorporating 9(b)'s particularity requirement into § 3730(b)(5) in direct opposition to Congressional Intent. Similarly, a nonjurisdictional first-to-file rule will only decrease efficiency in the lower courts and cause unnecessary burdens on defendants. Therefore, a nonjurisdictional first-to-file rule and the incorporation of 9(b) will only add fuel to the FCA fire. In comparison, a jurisdictional bar perpetuates efficiency through the district courts and maintains equilibrium in the face of the FCA's conflicting goals.

Considering this Court's decision in *Arbaugh*, this Court may find characterizing the first-to-file bar as a jurisdictional rule unmanageable. However, no matter how the circuits characterize the rule, every circuit apply the same substantive analysis when making a first-to-file determination, and under that analysis, the first-to-file rule bars Mason's claim.

This Court should dismiss Mason's claim because Mason's improper filing violates a statutory mandate imposed by Congress. Congress plainly barred the bringing of qui tam actions while another related action is pending. Because Mason's initiation of this action failed to comply with § 3730(b)(5)'s statutory command, the required remedy is dismissal. This Court should, therefore, affirm the Fifteenth Circuit's dismissal of Mason's action.

Additionally, this Court should affirm the Fifteenth Circuit's decision to grant SAM Clinic's 12(b)(6) motion to dismiss because the "false" element of a false medical certificate theory of FCA liability requires an objective falsehood standard, and Mason has not plausibly pled facts to reflect objective falsity.

The FCA does not define "false." In a traditional FCA claim involving questions with clear "yes" or "no" answers that any layperson can answer, such as whether a product was delivered or not delivered, the meaning is not an issue. However, the medical certificate theory of FCA liability, where the question of falsity often centers on the veracity of a physician's subjective clinical opinion about a non-binary medical standard, has prompted courts to confront the meaning of "false." Fraud is inexcusable. Healthcare providers do not deserve blanket immunity. But they do deserve heightened respect. And the two ideals are not mutually exclusive with the Eleventh Circuit's objective falsehood standard.

With respect to a physician's clinical judgment, The Eleventh Circuit has held that a doctor's mere subjective clinical opinion about a medical standard is insufficient to give rise to FCA falsity. Recognizing the need to not only accord deference to healthcare providers as warranted by Medicare guidelines but also the need to promote uniformity in align with Medicare's purpose, the Eleventh Circuit set forth an objective falsehood standard. This standard, which we urge this Court to adopt, requires the government or relator to plead the FCA falsity element with verifiable facts.

In contrast, the Third, Ninth, and Tenth Circuits stand for the Petitioner's proposition that a doctor's mere subjective clinical opinion can trigger FCA falsity. These courts concede the policy concerns yet justify their stance on a short-sighted textual interpretation of the FCA. Based on statutory construction principles, the Ninth Circuit asserted that the lack of a definition for "false" in the FCA warrants the common-law definition of "fraud," which does not require an express falsehood. However, the Ninth Circuit erred in failing to consider the text of the applicable ancillary Medicare statutes and regulations, on which a theory of non-compliance with medical standards hinges. The Medicare statutes and regulations prioritize clinical deference and compel uniformity.

Just like the first-to-file rule concerns, the lack of an objective falsehood standard would encourage opportunistic forum shoppers and unfairly subject healthcare providers to rampant, frivolous litigation, thus imposing undue financial burdens on healthcare providers and delayed patient care on Americans.

In resolving the first-to-file rule issue and the "false" issue, the law—not just policy—prescribes uniform standards and respect for healthcare providers. Indeterminable medical standards warrant uniform legal standards and subjective clinical opinions warrant deference—not excessive litigation. It is time to halt opportunistic whistleblowers and hasten confident medical care. It is time for transparent legal standards.

ARGUMENT

I. THIS COURT SHOULD AFFIRM THE FIFTEENTH CIRCUIT'S DECISION TO DISMISS MASON'S CLAIM BECAUSE 3730(b)(5)'S FIRST-TO-FILE BAR ESTABLISHES A JURISDICTIONAL RULE THAT MASON'S CLAIM FAILED TO COMPLY WITH AND THE REQUIRED REMEDY IS MANDATORY DISMISSAL.

Congress crafted the False Claims Act to combat undisclosed fraud against the government. See 31 U.S.C. § 3730; S. REP. NO. 99-345. To further effectuate that goal, Congress implemented the *qui tam* provisions. See 31 U.S.C. § 3730. The *qui tam* provisions allow private individuals, known as relators, to bring a claim on behalf of the government. See 31 U.S.C. § 3730(b)(5). Although an undoubtedly effective tool, "the *qui tam* provision has historically been susceptible to abuse" by opportunistic relators who bring FCA claims based on information the relator did not uncover, in hopes to obtain a portion of the government's award. *See United States ex rel. Duxbury v. Ortho Biotech Prods.*, L.P., 579 F.3d 13 (1st Cir. 2009). Consequently, Congress has amended § 3730 multiple times in an effort to balance the need to incentivize whistleblowers with the need to impede the claims of parasitic relators. *See* S. REP. NO. 345, 99th Cong., 2d Sess. 8 (1986) (discussing prior amendment to FCA). Accordingly, the urgency to keep this balance is essential and can only be accomplished by the continued application of jurisdictional limits imposed by the FCA, specifically the first-to-file bar.

Section 3730(b)(5) 's first-to-file bar is jurisdictional because it possesses jurisdictional attributes and necessitates jurisdictional consequences. This Court has characterized Jurisdiction as "the court's statutory or constitutional power to adjudicate the case." *United States v. Cotton*, 535 U.S. 625, 630 (2002). The text of

the first-to-file bar invokes that power as it restricts a district court from hearing a *qui tam* action related to an action already pending. See 31 U.S.C. § 3730(b)(5). In general, this Court should not abandon the deep-rooted jurisdictional application of this rule. *See, e.g., United States ex rel. St. John LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 230 (3d Cir. 1998) (citing the first appellate case to discuss the first-to-file bar and finding it jurisdictional). The surrender of the jurisdictional bar has the practical effect of increasing confusion in the courts, and subsequently, the number of parasitic relators. On that basis, the Fifteenth Circuit's decision to raise the issue of subject matter jurisdiction *sua sponte* was proper.

In the present case, Mason's claim is jurisdictionally barred under § 3730(b)(5)'s first-to-file rule. Mason's claim is barred because Dr. Cobb's action was pending when Mason initiated this suit, and a subsequent dismissal does not cure Mason's improper filing. *See United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 200 (4th Cir. 2017) (holding relator's action mandated dismissal even after related pending actions were dismissed). Further, § 3730(b)(5) bars Mason's claim because Mason's claim relies on related facts underlying the first-filed claim. Even if this Court concludes that § 3730(b)(5) is not jurisdictional, Mason's claim is still barred because it does not comply with the statute. In *Hallstrom v. Tillamook County*, this court held that "if an action is barred by the terms of a statute, it must be dismissed." *Hallstrom v. Tillamook Cty.*, 493 U.S. 20, 31 (1989). For that reason, if this Court is reluctant to classify § 3730(b)(5) as a jurisdictional rule, the present

outcome cannot change. Because all courts that apply the first-to-file rule, jurisdictional and nonjurisdictional alike, use the same substantive analysis, under which Mason's claim cannot proceed. *Compare Carter*, 710 F.3d at 180 (applying a jurisdictional rule) *With United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 120-21, 416 U.S. App. D.C. 289 (D.C. Cir. 2015) (applying a nonjurisdictional rule). Accordingly, as a matter of law, Mason's claim is jurisdictionally and likewise statutorily barred. Therefore, this Court should affirm the Fifteenth Circuit's dismissal.

A. The FCA's First-to-File Bar Does Establish a Rule of Subject Matter Jurisdiction

The first-to-file bar does establish a rule of subject matter jurisdiction, as shown through its application in a majority of circuits and since the rule's inception. The first-to-file bar 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." 31 U.S.C. § 3730(b)(5). A jurisdictional bar furthers the FCA's purpose of supplying government notice while at the same time conserving judicial resources. In contrast, interpreting the rule as nonjurisdictional will only lead to less-efficient adjudication and an influx of non-meritorious claims.

1. The First-to-File Rule Establishes a Rule of Subject Matter Jurisdiction, as shown through its Long-Lived Application and Jurisdictional Attributes.

Congress implemented the current version of the first-to-file rule in the 1986 Amendment to the FCA. *See, e.g., LaCorte,* 149 F.3d at 227. The primary purpose of

the 1986 Amendment was "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 295 (2010). However, the rule found its origin in our appellate court system in *LaCorte*. *LaCorte,* 149 F.3d at n.6. In *LaCorte*, the Third Circuit correctly interpreted the first-to-file rule as a jurisdictional bar to *qui tam* actions. *See Id*. District and appellate courts have since followed suit.

At present, the majority of circuits still properly characterize the first-to-file bar as a jurisdictional rule. *See, e.g., United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 203 (4th Cir. 2017); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d371, 376-77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187-89 (9th Cir. 2001); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1278 (10th Cir. 2004). These circuits recognize that a first-to-file provision acts as a jurisdictional limit on a district court's authority to hear duplicative *qui tam* actions. *See Lujan*, 243 F.3d at 1183. Thus, these circuits have logically interpreted § 3730(b)(5) as a rule of subject matter jurisdiction.

Further, the first-to-file bar is jurisdictional by design. This Court has frequently set forth factors that indicate a rule should have jurisdictional attributes which necessitate jurisdictional consequences. *See Henderson v. Shinseki*, 562 U.S. 428, 438 (2011) (discussing attributes of jurisdictional rules); *Hamer v. Neighborhood Hous. Servs.*, 138 S. Ct. 13, 17 (2017); *Bowles v. Russell*, 551 U.S. 205,

210 (2007). As a jurisdictional bar, the first-to-file provision possesses such attributes. For instance, the first-to-file bar, like virtually all jurisdictional rules, is without exception. *See, e.g., U.S. ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 180 (4th Cir. 2013) (describing the first-to-file bar as an "absolute, unambiguous exception-free rule."); *Lujan*, 243 F.3d at 1188 (noting that the statute's plain language does not contain exceptions); *Duxbury*, 579 F.3d at 33 (noting that the "first-to-file" rule is "exception-free."). Further, §3730(b)(5) includes a temporal limitation enacted by Congress. *See Hamer*, 138 S. Ct. at 17-18; *See also United States ex rel. Chovanec v. Apria Healthcare Group, Inc.*, 606 F.3d 361, 362 (7th Cir. 2010) (noting the condition precedent to filing suit imposed by the language of §3730(b)(5)). Finally, like all jurisdictional rules, "failure to comply … deprives a court of adjudicatory authority over the case, necessitating dismissal." *See Hamer*, 138 S. Ct. at 17; *State Farm Fire & Cas. Co. v. U.S ex rel. Rigsby*, 137 S. Ct. 436, 440 (2016) (citing §3730(b)(5) as a provision "explicitly requiring dismissal."). Thus, although the first-to-file bar lacks express jurisdictional language, it is jurisdictional in nature.

Above all, this Court should remember that Congress is not required to "incant magic words" to establish a rule of subject matter jurisdiction. *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013). Accordingly, this Court is within its judicial purview to consider the rule's most efficient application. As this Court noted in *Bowles*, "[t]he accepted fact is that some time limits are jurisdictional even though expressed in a separate statutory section from jurisdictional grants."

Bowles, 551 U.S. at 210 (quoting *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 160, n. 6, (2003)).

2. The First-to-File Rule Establishes a Rule of Subject Matter Jurisdiction Which Promotes Judicial Efficiency and Furthers the Purpose of the FCA's Whistleblower Statute.

Section 3730(b)(5)'s jurisdictional bar achieves the purpose of the FCA while providing reliable outcomes and promoting judicial economy. The first-to-file rule's underlying purpose is to "reject suits which the government is capable of pursuing itself [and] promot[e] those which the government is not equipped to bring on its own." *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). The jurisdictional bar imposed by the first-to-file rule achieves this purpose efficiently, sets clear rules for district courts, and provides reliable outcomes. In practice, the first-to-file bar simply requires a side-by-side comparison of the complaints; if the later-filed claim is related to the pending action, the court lacks jurisdiction and must dismiss. *See Grynberg,* 390 F.3d at 1279; *LaCorte*, 149 F.3d at 235 n.6 (noting that further factual development is unnecessary need only compare the original and later complaints). Accordingly, the first-to-file jurisdictional bar yields clear and well-settled effects by allowing for determinations at the outset.

In stark contrast, interpreting the first-to-file provision as a nonjurisdictional rule will decrease the lower courts' efficiency. Foremost, the removal of the jurisdictional bar will displace the uniform legal consequences it provides. In other words, a nonjurisdictional rule would impose an obligation on district courts to grapple with, under which differing facts, noncompliance is justified. Although some circuits have adopted a nonjurisdictional rule, they have failed to specify how that

approach affects a party's pleadings. Scott Glass, *Is the False Claims Act's First-to-File Rule Jurisdictional?*, 118 Colum. L. Rev. 2361, 2399 (2018) (discussing flaws of a nonjurisdictional rule). Consequently, a nonjurisdictional rule wastes judicial resources that this Court could avoid by preserving the jurisdictional bar.

Further, concluding that the first-to-file bar is nonjurisdictional will unduly burden defendants. Without the jurisdictional bar in place, corporate defendants risk facing biased jurors who question how "related" the claims actually are when comparing the complaints. *See, e.g.,* Valerie P. Hans, *The Illusions and Realities of Jurors' Treatment of Corporate Defendants*, 48 DePaul L. Rev. 327 (1998). Moreover, a nonjurisdictional rule subjects defendants to unnecessary procedural burdens. For example, in some circumstances, the government requests that an action remain under seal for prolonged investigation. Such a request could result in a situation in which the defendant is unaware of the first-filed claim's existence yet is required to act in the later-filed claim. Consequently, the defendant would be unable to raise the bar, and under a nonjurisdictional rule, would waive the first-to-file defect entirely.

In sum, the current circuit split presents this Court with the opportunity to enforce the traditional application of the first-to-file bar and provide lower courts with clear rules that yield consistent outcomes. Likewise, when confronted with a case of first impression this Court should resist setting precedent that will decrease judicial efficiency and allow unmeritorious claims to slip through the cracks.

B. Mason's Claim is Jurisdictionally Barred by the First-to-File Rule.

To apply the first-to-file bar, a district court simply conducts a side-by-side comparison of the relator's complaint and the alleged first-filed complaint. Appropriately, if the two complaints are "related," the court must dismiss the later-filed case for lack of jurisdiction. *See Carter*, 710 F.3d at 180 (quoting *Walburn,* 431 F.3d at 970). However, courts must compare the relator's complaints at "a sufficiently high level of generality" to protect the first-filing relator's reward. *See, e.g., United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 217-18 (D.C. Cir. 2003). Thus, if the first-filed claim is sufficient to put the government on notice of potential fraud, a later related action is barred.

In the present case, the Fifteenth Circuit properly compared the complaints using a broad essential facts test. Moreover, Dr. Cobb's claim provided sufficient information for the government to investigate any potential fraud, and Mason's action was related to that claim. On that basis, this Court should affirm the Fifteenth Circuit's decision. Conversely, the district court's inclusion of 9(b) into its analysis was improper, and this Court should resist adopting an analysis squarely at odds with the policy goals of the FCA.

1. Mason's Complaint is Barred by the First-to-File Bar Because Dr. Cobb's Complaint Remained Pending at the Time Mason Filed, and was Sufficient to Put the Government on Notice.

In *Carter III*, this Court defined "pending" to mean "[r]emaining undecided; awaiting decision." *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter (Carter III)*, 575 U.S. 650, 654 (2015) (quoting Black's 1314 (10th ed. 2014). Further, this Court has explained that "a suit is brought when in law it is commenced."

Goldenberg v. Murphy, 108 U.S. 162, 163 (1883). Accordingly, the first-to-file bar effectively provides that no person may file a related action while a first-filed suit remains pending. *See, e.g., United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 929 (D.C. Cir. 2017). It follows that whether the jurisdictional limit applies is judged by looking at the facts as they existed when the relator filed the claim. *See Grynberg*, 390 F.3d at 1279; *Carter*, 866 F.3d at 199.

The Fifteenth Circuit was correct in finding that Dr. Cobb's claim was pending under this Court's holding in *Carter III*. *See Carter III*, 135 S. Ct. at 654. Here, Dr. Cobb filed her action on October 14, 2019. R. at 5. Subsequently, Mason filed her complaint on November 22, 2019. R. at 1. After that, the District Court dismissed Dr. Cobb's complaint on January 20, 2020. R. at 2. Thus, Dr. Cobb's action was undoubtedly still "pending" on November 22, 2019.

In contrast, the relator argues that, because the district court later dismissed Dr. Cobb's complaint, "the bar should not apply." However, Petitioner's assertion directly conflicts with the first-to-file bar's statutory text. 31 U.S.C. § 3730(b)(5). In fact, the Fourth Circuit, on remand of this Court's decision in *Carter III*, rejected this very same rationale advanced by Petitioner. *See Carter*, 866 F.3d at 205. The relator in *Carter* argued that the dismissal of the first-filed action cured the later-action's first-to-file defect. *Id.* The Fourth Circuit explained that, under Carter's interpretation, §3730(b)(5) would effectively bar "the *continuation* of a later suit while the earlier suit remains undecided, but cease to bar the *continuation* of the suit once it is dismissed." Relying on the statute's text, the court held that "the first-

to-file rule's statutory text … plainly bars the *bringing* of actions while related actions are pending and affords courts no flexibility to accommodate an improperly-filed action when its earlier-filed counterpart ceases to be pending." *See Id.*; *See also Lujan,* 243 F.3d at 1188 (considering the same facts and holding the same); *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163 (2d Cir. 2018); *United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923 (D.C. Cir. 2017). *United States ex rel. Chovanec v. Apria Healthcare Grp.*, Inc., 606 F.3d 361 (7th Cir.2010).

This Court should similarly decline to disregard the text of the statute. Under § 3730(b)(5)'s plain language a "pending" actions' later dismissal cannot revive actions that were barred at the time of filing. See § 3730(b)(5). The first-to-file bar's text leaves no room for exceptions. Therefore, because Dr. Cobb's claim was pending when Mason filed her related action, the first-to-file bar applies.

2. Mason's Complaint is Barred by the First-to-File Bar Because Dr. Cobb's Complaint Remained Pending at the Time Mason Filed and was Sufficient to Put the Government on Notice.

To escape the first-to-file bar, Mason's action must prove to be unrelated to Dr. Cobb's action. Circuit courts have uniformly rejected the idea that the complaints must be identical. Instead, courts apply the well-settled, broad "material elements" or "essential facts" test. *See, e.g., LaCorte*, 149 F.3d at 232-233 (noting § 3730(b)(5) bars later claims based on same "essential facts" or " elements of a fraud" as earlier claim); *Lujan*, 243 F.3d at 1188-1189; *Branch*, 560 F.3d at 378. In practice, a subsequent claim is related when it "raises the same" claim or is "a

related claim based in significant measure on the core fact or general conduct relied upon in the first qui tam action." *E.g., Grynberg*, 390 F.3d at 1279.

In the present case, both Dr. Cobb's complaint and Mason's complaint allege (1) the same general fraudulent conduct, (2) the same means of carrying out that fraud, and (3) identify the same wrongdoers. First, Dr. Cobb and Mason both alleged the same general fraudulent conduct. Both alleged the general fraudulent conduct of falsely certifying patient's treatment at SAM Clinics as medically necessary for Medicare purposes, which was not medically necessary. R. at 5-6. Second, Dr. Cobb and Mason alleged the same means of carrying out that fraud. Being: compelling physicians to make false certifications of treatments for wounds. R. at 5-6. Lastly, Dr. Cobb and Mason both identify CEO John O'Keefe as the wrongdoer and SAM Clinics' locations as the source of the wrongdoing locations as the source. in their complaints. R. at 5-6. Accordingly, both actions involve the same operative claim: that SAM Clinics defrauded Medicare by pressuring physicians to falsely certify the medical necessity of wound treatment. Therefore, Dr. Cobb's and Mason's claims constitute related actions under the meaning in the statute. As a result, Dr. Cobb's complaint provided sufficient notice to the government of the essential facts of the potential fraud, and Mason's complaint merely echoes that claim.

Despite the previous related allegations, Petitioner argues that the first-to-file bar does not apply because the essential facts of her claim are not the same as those raised in Dr. Cobbs. However, a relator cannot sidestep the first-to-file bar by

merely including additional factual details or variations of a previously disclosed fraud. *See, e.g., Branch*, 560 F.3d at 373; *Grynberg*, 390 F.3d at 1276; *United States ex rel. Folliard v. CDW Tech. Servs.*, 722 F. Supp. 2d 37, 40 (D.D.C. 2010). If this were the case, limitless complaints with only minor differences would be permitted to move forward, resulting in a split of the award between a surplus of relators and a diminished incentive to whistleblowers to follow. *See, e.g., Grynberg*, 390 F.3d at 1279 (noting original relators are less likely to act on the government's behalf if they had to share recovery). Consequently, the barring of a subsequent complaint is appropriate in cases where the later-filed complaint alleged additional facts as to how the defendant committed fraud, different instances of fraud in distinct locations, and even those naming different defendants.

For example, in *Grynberg*, the court held that 3730(b)(5) barred the later-filed complaint because the complaint raised the same essential facts of which the government already had notice. *See Grynberg,* 390 F.3d at 1280. In that case, the first-filed action alleged that the defendant utilized various fraudulent techniques to mismeasure the natural gas it produced to avoid its requirement to pay the government royalties. *Id*. The later-filed complaint also alleged fraudulent mismeasurement of natural gas. *Id*. However, it detailed additional facts about how the defendant specifically mismeasured the gas through a "wrongful analysis of the heating content" and "mismeasurement of the volume." *Id*. The court explained that although those specific allegations were not in the first complaint, the later complaint could not avoid the first-to-file bar by including additional facts. *Id*.

The D.C. Circuit came to the same conclusion in *U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp*. *See Hampton* 318 F.3d at 219. That case involved a first-filed complaint that alleged that the defendant's subsidiary fraudulently billed the government for "undocumented" home health care services, which did not meet the Medicare eligibility. *Id*. at 218-19. The later-filed claim also alleged that the defendant engaged in fraudulent Medicare billing for home health care. *Id*. However, the subsequent claim alleged a different type of billing fraud of "miscoded bills," and named a specific subsidiary and employees as defendants. *Id*. at 219. Although the subsequent claim detailed different occasions and mechanisms of unlawful billing in a different geographic area with additional defendants, the court barred the action. *Id*. The court affirmed the district court's dismissal. In doing so, the D.C. Circuit aligned itself with the other circuits which interpret 3730(b)(5) "to bar "actions alleging the same material elements of fraud" as an earlier suit—even if the allegations "incorporate somewhat different details." *Id*. at 217,219.

These cases demonstrate the purpose of 3730(b)(5): that is, to bar the filing of additional qui tam actions once the government has been made aware of the potential fraud against it. Indeed, "[O]nce the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds," fulfilling the rationale behind allowing *qui tam* suits. *LaCorte*, 149 F.3d at 234.

Likewise, Dr. Cobb's complaint promptly alerted the government to the essential facts of the Medicare fraud alleged in both complaints. Accordingly, it is immaterial that Mason's claim detailed four specific instances of fraud and a

different form of wound treatment and pressure on physicians. Where the first-to-file bar is concerned, Mason's claim merely mirrors Dr. Cobb's with additional examples of how the common defendant potentially defrauded the government. Above all, the additional specifications provided by Mason did not disclose anything that the government could not have discovered during its investigation into Dr. Cobb's complaint. Therefore, Mason's claim is jurisdictionally barred.

3. Petitioner's Argument that the First-to-File Bar Does Not Apply because Dr. Cobb's Claim Did Not Comply with Rule 9(b) Contradicts the Statutes Policy Goals and Congressional Intent.

Petitioner argues, and the district court agreed, that the first-filed proceeding is preemptive only if it was legally sufficient under Federal Rule of Civil Procedure 9(b). *See* Fed. R. Civ. P. 9(b). The district court improperly relies on the Sixth Circuit's framework put forth in *Walburn*. *See Walburn*, 431 F.3d at 972. However, most circuits have declined to follow the approach taken in the Sixth Circuit as it directly conflicts with the first-to-file rule's primary objectives. *See, e.g., United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 169 (2d Cir. 2018) (citing cases declining to follow Walburn); *Branch*, 560 F.3d at 377, n.10; *Batiste*, 659 F.3d at 1210. This Court should similarly decline to follow the district court's misguided imposition of Rule 9(b) on a first-filed action.

Three points are particularly prominent. First, requiring a first-filed complaint to meet 9(b)'s heightened pleading standard directly contradicts Congressional intent. "The FCA's first-to-file provision, 31 U.S.C. § 3730(b)(5), reflects Congress' explicit policy choice to encourage prompt filing and, in turn,

prompt recovery of defrauded funds by the United States." *See Graham,* 559 U.S. 280 at n.11 (Sotomayor, J., dissenting). However, if this Court chooses to throw 9(b) into the mix, the prompt disclosure that the first-to-file bar provides will be hindered by the need to craft a flawless complaint. Thus, imposing a 9(b)-pleading standard will only disincline relators to report fraud and simultaneously frustrates the first-to-file rules policy goals.

Second, the text of 3730(b)(5) does not warrant incorporating the particularity requirement of 9(b) into the statute. This Court has consistently held that it "ordinarily resists reading words or elements into a statute that do not appear on its face." *Bates v. United States*, 522 U.S. 23, 30 (1997). The first-to-file provision does not mention the Federal Rules, nor does its language mirror that of 9(b) in any regard. In contrast, Congress did not shy away from including the Federal Rules throughout the neighboring provisions of the FCA. See 31 U.S.C. § 3730(b)(2); § 3730(b)(3). Thus, the lack of any allusion to 9(b)'s particularity requirement, coupled with the statute's plain and unambiguous text, should caution this Court from reading 3730(b)(5) to require a heightened pleading standard.

Third, requiring 9(b) at the first-to-file stage will negatively impact the nature of judicial proceedings. The D.C. Circuit declined to do so for that very reason, explaining that incorporating 9(b) "would create a strange judicial dynamic." *Batiste*, 659 F.3d at 1210. To illustrate, it could create a situation where one district court must determine the sufficiency of a complaint filed in another, possibly creating a situation in which the two courts disagree on a complaint's

sufficiency. *Id*. Therefore, the ramifications of incorporating Rule 9(b) at the first-to-file stage does more harm than good.

Lastly, 9(b)'s purpose does not arise in the first-to-file stage. The *Folliard* court correctly noted that "it is entirely plausible that a complaint may provide sufficient information to cause the government to launch its own investigation of a fraudulent scheme without providing enough information under 9(b)." *Folliard*, 798 F. Supp. 2d at 75–76. Further, like the present case, a court will dismiss a relator's complaint at the pleading stage if it fails to comply with 9(b). Thus, the threat of an additional application of 9(b) at the first-to-file stage is unnecessary. *Batiste*, 659 F.3d at 1210. For that reason, a first-filed complaint need not satisfy 9(b) to bar later complaints; instead, the only relevant inquiry is whether the first-filed complaint provided the government sufficient notice.

The FCA's first-to-file provision establishes a rule of subject matter jurisdiction, that is exception-free, and limits a district court's authority to hear parasitic *qui tam* actions. Because Mason's claim formed a related action under § 3730(b)(5), the Fifteenth's Circuits decision should be affirmed.

C. Mason's Claim Violates the First-to-File Rule's Statutory Mandate and the Required Remedy is Dismissal.

"Section 3730(b)(5) is jurisdictional and if an action is later filed that is based on the facts underlying the pending case, the court must dismiss the later case for lack of jurisdiction." *Carter*, 710 F.3d at 180. However, even if this Court finds that the first-to-file rule does not establish a rule of subject matter jurisdiction, Mason's claim is still statutorily barred. *See*, *e.g., Yee v. City of Escondido, Cal.*, 503 U.S.

519, 534-35 (1992) (noting that a party can make any argument in support of its claim and are not limited to the arguments they made below). Because the general rule is that "when a statute specifies that an 'action shall not be instituted' and the plaintiff fails 'to heed that clear statutory command,' a district court properly dismisses the suit." *Shea*, 863 F.3d at 929 (quoting *McNeil v. United States*, 508 U.S. 106, 107 (1993)). Therefore, because Mason's filing failed to comply with 3730(b)(5)'s statutory command, the requisite remedy is to dismiss Mason's action.

Since this Court's decision in *Arbaugh*, various Circuits have resigned § 3730(b)(5)'s jurisdictional bar. *See Heath*, 791 F.3d at 120-21; *United States ex rel. McGuire v. Millennium Labs., Inc.*, 923 F.3d 240, 250-51 (1st Cir. 2019); *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85-86 (2d Cir. 2017) (per curiam); *United States v. Sanofi-Aventis U.S. LLC (In re Plavix Mktg.)*, 974 F.3d 228, 230 (3d Cir. 2020). These Circuits now decide if a case necessitates the first-to-file rule on a 12(b)(6) motion. If the bar applies, the relator has no cause of action. However, aside from these Circuits' renunciation of "calling" the first-to-file rule jurisdictional, the application remains unchanged. Put differently, while these Circuits may have rejected referencing § 3730(b)(5) as a jurisdictional rule and now adjudicate claims on the merits under 12(b)(6), these circuits still decide § 3730(b)(5) applies through the same "essential facts" or "material elements" test.

For example, in *Heath,* the D.C. Circuit was the first appellate court to double back and find the first-to-file rule is not jurisdictional. *See Heath*, 791 F.3d at 119 (quoting *Arbaugh v. Y&H Corp.,* 546 U.S. 500, 516 (2006)). Nevertheless, the

court in *Heath* still applied the same material elements test. *Id*. at 121; *See also Hampton*, 318 F.3d at 219; *Batiste*, 659 F.3d at 1211 (affirming dismissal in both for lack of jurisdiction). Specifically, the Second Circuit concluded that the first-to-file bar applies "if the claim incorporates "the same material elements of fraud" as the earlier action, even if the allegations incorporate additional or somewhat different facts or information.' *Heath*, 791 F.3d at 119. (citing *Hampton*, 318 F.3d at 217). The D.C. Circuit further explained that courts assess "similarity ... by asking whether the later complaint "alleges a fraudulent scheme the government … would be equipped to investigate based on [the first] [c]omplaint." *Id*. (quoting *Batiste*, 659 F.3d at 1209). Thus, although these circuits may no longer characterize the rule as jurisdictional, the substantive analysis remains unchanged. *See Id*.; *See also United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 169 (2d Cir. 2018) (citing *Heath* as the proper first-to-file framework); *Millenium*, 923 F.3d at 253, n.16 (applying the essential facts test and finding no difference between "this standard" and the one applied in *Heath*).

Here, as previously stated Mason initiated a "related" action while Dr. Cobb's first-filed action remained "pending." Accordingly, whether the first-to-file rule is jurisdictional or nonjurisdictional, Mason's suit violated § 3730(b)(5), and this Court should apply the requisite remedy. *See Rigsby*, 137 S. Ct. at 442-443.

This Court noted in *Rigsby* that the required remedy for a first-to-file violation is dismissal. *See Id*. In short, this Court specifically cited § 3730(b)(5)'s first-to-file rule as an FCA provision "requiring, in express terms, the dismissal of a

relator's action" for noncompliance. *Id*. Furthermore, requiring dismissal for noncompliance with a statutory mandate imposed by Congress is consistent with this Court's holdings concerning like provisions. *See Id*. (citing cases where this Court considered similar statutes and found dismissal was the required remedy); *McNeil,* 508 U.S. at 107, n.1 (" '[a]n action shall not be instituted upon a claim against the United States for money damages ... unless the claimant shall have first presented the claim to the appropriate Federal agency' "); *United States ex rel. Texas Portland Cement Co. v. McCord,* 233 U.S. 157, 161 (1914) (" 'if no suit should be brought by the United States within six months from the completion and final settlement of said contract' ").

For example, in *Hallstrom*, this Court dismissed an action that violated the 90-day statutory time period mandated by Title VII the Resource Conservation and Recovery Act. *See Hallstrom*, 493 U.S., at 25. In that case, the statute at issue stated that "no action may be commenced" until 60 days after the citizen has notified the EPA, the government, and the alleged violator of the waste disposal statute. *Id*. Like the statute in dispute here, the claimant failed to comply with the statute's mandatory provision. *Id*. This Court held that failure to meet the statute's requirement required dismissal. *Id*. at 33. Therefore, this Court should likewise dismiss Mason's action as the required remedy for Mason's statutory violation.

While Mason's claim might not divest a district court of subject matter jurisdiction, under either characterization of the rule, Mason's claim constitutes a related action under § 3730(b)(5) and must be barred as a matter of law. Therefore,

even if the first-to-file rule is not jurisdictional, this Court should dismiss Mason's action as it violates the statutory mandate imposed by Congress.

II. EVEN IF THE FIRST-TO-FILE RULE DOES NOT BAR MASON'S CLAIM, THIS COURT SHOULD AFFIRM THE FIFTEENTH CIRCUIT'S DECISION TO GRANT SAM CLINICS' 12(b)(6) MOTION TO DISMISS BECAUSE THE "FALSE" ELEMENT OF A FALSE MEDICAL CERTIFICATE THEORY OF FCA LIABILITY REQUIRES AN OBJECTIVE FALSEHOOD STANDARD, WHICH MASON HAS NOT SATISFIED.

A physician's mere subjective clinical opinion cannot be objectively false. It requires something more, and "something more" requires an objective standard, which Mason has not plausibly pled facts to satisfy.

The FCA plays an important role in combatting fraud. Despite playing an important role in combatting sickness and death, Healthcare providers should not be immune from liability. Yet, "[i]t is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1295 (11th Cir. 2019). Circuit courts, in determining the meaning of the FCA "false" element, resolve such tension in various ways.

Some circuit courts have established that a physician's mere subjective clinical opinion can be false. *See, e.g.*, *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 100-01 (3d Cir. 2020) (holding that "a physician's judgment may be scrutinized and considered 'false'"). These circuits equate FCA falsity with common-law fraud, relying on a shortsighted statutory construction of

the FCA's text. *Winter ex. rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.,* 953 F.3d 1108, 1117 (9th Cir. 2020) (concluding that the plain language of the statute does not distinguish between "objective" and "subjective" falsity or create an exception for clinical judgments).

Because the judicial interpretation of common law fraud allows for false opinions, these circuits hold that an objective falsehood standard is prohibited here. *Universal Health Services, Inc. v. United States*, 136 U.S. 1989, 1999 (2016) (applying the common law definition to hold that in *some* cases, misrepresentation by omission can violate the FCA). However, these circuits wholly fail to consider the ancillary CMS statutes and regulations on which a medical necessity theory of FCA liability is based. The ancillary framework compels an objective falsehood standard. *See AseraCare, Inc.*, 938 F.3d at 1293 (noting that the text of both the federal Medicare statute and its implementing regulation indicate the legislature's intent to accord substantial deference to clinical judgment in the hospice-eligibility context).

Other circuit courts, recognizing that a false certificate theory of FCA liability is distinct from traditional fraud, have logically established that differences in subjective opinion about the application of imprecise standards cannot give rise to FCA falsity. *See, e.g.*, *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370. (4th Cir. 2008). Accepted standards of medical care are particularly ambiguous, and medical experts can hold differing opinions that are both correct.

The Ninth Circuit recently offered a nuanced approach. *See generally Winter*, 953 F.3d at 1108. The Ninth Circuit recognized that a mere subjective clinical opinion *can* be false, but further suggested that "something more" is needed. *See Winter*, 953 F.3d at 1118-119 (endorsing *AseraCare* to the extent that a subjective opinion cannot be false "without more."

The Eleventh Circuit's objective falsehood standard provides a uniform solution to "something more." This Court should adopt this standard, in recognition that uniformity aligns with the intended purpose of Medicare and that a lack of uniformity unfairly subjects doctors to excessive litigation and financial burdens.

Petitioner has not satisfied the objective falsehood standard. The standard requires the government or the Relator to "identify facts and circumstances surrounding the patient's certifications that are inconsistent with the proper exercise of physicians." *Id.* at 1297. While this can be established in multiple ways, each way requires the Relator to plausibly plead a flaw that can be demonstrated through verifiable facts. *Id.* While Petitioner offers a conversation that invites potential speculation about a scheme, the Relator failed to plead facts that could plausibly verify the factual existence of the scheme. As such, Mason has failed to satisfy the objective falsehood standard.

A. For Purposes of an FCA Medical Necessity Claim, Satisfaction of the Falsity Element Should Require an Objective Falsehood Standard in the Interests of Practicality, Uniformity, and Fairness.

The application of the Eleventh Circuit's objective falsehood standard, authorized by the inexactitude of medical standards and the text of Medicare

guidelines, accords uniformity to a nationwide government enforcement system that necessitates it. Moreover, the standard grants deference to a country of healthcare providers who deserve it.

The existence of the scienter element as the purported remedy for the excessive litigation issue is sound in theory but weak in practice. The remaining scienter element provides cold comfort to the good-faith physician saddled with post-motion litigation costs and discovery burdens; and to the good-faith physician who, struck with fear of the FCA's punitive consequences, is forced to settle and thereby surrender to the unforgiving court of public opinion.

1. Medical Standards are Indeterminable by Nature, and Circuit Courts have Established that a Mere Difference in Subjective Opinion about the Application of Imprecise Standards cannot Give Rise to FCA Falsity.

"Two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." *AseraCare*, *Inc*., 938 F.3d at 1305 n. 6. This quote by Mary Jane Schultz, the former head of a medical review department, underscores a reality of medical judgment: a true false binary rarely exists. Indeed, no two patients are the same. Physicians undergo different training programs and are exposed to different views. Medical science evolves constantly, and with it, the contours of accepted healthcare standards. Put simply, medical standards are inherently indeterminable. As such, we urge this Court to align with the 4th and D.C. Circuits in recognizing that differing subjective interpretations of imprecise, ambiguous standards cannot trigger FCA falsity. *See Wilson.,* 525 F.3d

370, 377 (4th Cir. 2008); *U.S. ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983-84 (D.C. Cir. 2008).

In 2008, the Fourth Circuit in *Wilson,* prescribed the FCA falsity element an objective falsehood standard as a means to cabin liability where precise answers do not exist. *See Wilson*, 525 F.3d at 377. In *Wilson*, the Relators alleged that a contractor fraudulently represented in a special form that it would comply with the contract's general maintenance requirements. *Id.* at 374. The Relators and the contractor had different subjective opinions about the scope of the maintenance requirements. *Id.* at 377. In holding that the Relator's difference in opinion did not yield FCA falsity, the court relied principally on the imprecise nature of the general maintenance provision at issue. *See id.*

The D.C. Circuit in its 2008 *K & R* decision, similarly, accorded the defendant deference based on imprecise standards. *See K & R Ltd. P'ship*, 530 F.3d at 984. The court considered FCA allegations premised on non-compliance with certain mortgage notes. *Id.* at 981. Like the Fourth Circuit in *Wilson*, the court emphasized the ambiguity of the mortgage requirements. *Id.* at 983-84. The court affirmed dismissal of the claims, holding that a lack of falsity lies where a claim is based on a reasonable interpretation of underlying, ambiguous contract terms or regulations. *Id.* at 984.

Here, Mason's "certification theory of liability" is based, similar to the allegations in *Wilson* and *K & R*, on a theory of non-compliance with regulations. The medical necessity issue here centers on whether the doctors at SAM Clinics

exercised proper clinical judgment regarding what Wagner grades certain wounds should be assigned and their proper treatment moving forward. R. at 17. Under CMS guidelines, a claim is medically necessary if it meets "accepted standards of medicine." CMS, Medicare & You 2020: The Official U.S. Government Medicare Handbook 114 (2019). Accordingly, SAM Clinics' reimbursement claims are medically necessary if they comply with the accepted standards for Wagner Grade determinations, and more broadly, if they comply with the accepted standards of HBO therapy pursuant to both National and Local Coverage Determinations.

HBO therapy, is no exception to the general principle that accepted medical standards are inherently indeterminable. In fact, a 2016 peer-reviewed study in the *International Wound Journal* concluded that the Wagner Grade is "not reliable when scored by multiple physicians." TB Santema, *Comparing the Meggitt-Wagner and the University of Texas wound classification systems for diabetic foot ulcers: inter-observer analyses,* Int. Wound J., 1137-1141 (2016.) The report further noted the fallible nature of classifying wound grades by photograph as opposed to in-person. *Id.* This study highlights the imprecise nature of Wagner Grade determinations and, crucially, undermines the validity of an unaffiliated physician's second opinion. Thus, like in *Wilson* and *K & R*, falsity here should not lie in the absence of an objective falsehood standard.

Even the Ninth Circuit, a seminal circuit in Mason's toolkit, has required an objective falsehood standard. *See Hagood v Sonoma Cty. Water Agency,* 81 F.3d 1465, 1477-78 (9th Cir. 1996*)* (holding that reasonable disagreements about

applications of imprecise legal standards cannot trigger FCA falsity without an objective falsehood). Like several other courts, the district court in *Winter* interpreted *Hagood* to require the Relator to affirmatively allege that a "defendant knowingly made an objectively false representation to the Government." *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, No. CV 14-08850-JFW (EX), 2017 WL 8793222 (C.D. Cal. Dec. 29, 2017), *rev'd and remanded sub nom. Winter ex. rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.,* 953 F.3d 1108, 1117 (9th Cir. 2020). However, the *Winter* circuit court inexplicably departed from its lower court's interpretation. *See Winter*, 953 F.3d at 1117-118 (9th Cir. 2020). In doing so, the Ninth Circuit improperly divorced the FCA text from the applicable ancillary statutes and regulations.

2. The Ninth Circuit's Reliance on Statutory Construction to Prohibit an Objective Falsehood Standard Illogically Sequesters the Ancillary Medicare Framework from the FCA's Text.

In using the common law definition for "false" to prevent the adoption of an objective falsehood standard, the Ninth Circuit in *Winter* turned a blind eye to Medicare's regulatory framework, from which the FCA's text should not be divorced. The *Winter* court applied statutory construction principles to the plain language of the FCA as expressed in 31 U.S.C. 3729. *Winter*, 953 F.3d at 1117. Based on the absence of a statutory definition for "false" or "fraudulent," the court inferred Congress' intent to use the common-law definition, which the Supreme Court recently interpreted to not require an "express falsehood." *Id*; *see also Universal Health Services, Inc. v. United States*, 136 U.S. 1989, 1999 (2016) (applying the

common law definition to hold that in *some* cases, misrepresentation by omission can violate the FCA).

Although the court's rationale potentially sounds in a traditional FCA case, Mason asserts a distinct species of FCA liability: the "certification theory". R. at 10. Under this theory, liability arises from non-compliance with federal statutes and ancillary requirements, such as regulations and contractual provisions. R. at 10. Here, the applicable ancillary requirements include CMS Guidelines, National and Local Coverage Determinations, and Clinical Practice Guidelines. R. at 10. Under a non-compliance theory of falsity, a credible text-based interpretation of falsity logically requires a consideration of the foregoing requirements in conjunction with the FCA's text. *See Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 134 (2d Cir. 2002).

i. Nothing in the Medicare Regulatory Framework Suggests that a Physician's Clinical Judgment can be Second Guessed on the Mere Basis that an Unaffiliated Physician Reaches a Separate Conclusion.

While Judge Askin correctly noted in dissent that the plain language of the FCA statute does not distinguish between "objective" and "subjective" falsity or create an exception for clinical judgements, the judge withheld an equally instructive truth. That is, nowhere in the Medicare regulatory framework does Congress suggest that an unaffiliated physician's conflicting medical opinion can render the affiliated physicians' subjective opinion false.

ii. The Medicare Statute Emphasizes the Role of a Physician's Clinical Judgment.

Likewise, the CMS guidelines lack language requiring a physician to prove a clinical prognosis as a matter of medical fact. *See AseraCare, Inc.*, 938 F.3d at 1293 (noting instead that the text of both the federal Medicare statute and its implementing regulation indicate the legislature's intent to accord substantial deference to clinical judgment in the hospice-eligibility context); 42 U.S.C. § 1395f(a)(7)(A) (requiring hospice eligibility certificates to be "based on the physician's or medical director's clinical judgment"). Although the textual criteria for hospice care eligibility largely differs from HBO therapy, a Supreme Court decision involving HBO therapy, which represents a tiny fraction of medical services, could significantly impact FCA liability in giant areas like hospice care.

Importantly, the Eleventh Circuit's text-based recognition that a mere difference in clinical opinion cannot yield falsity prompted the court to elicit a standard that requires plaintiffs to show that a physician's clinical opinion about the medical necessity of treatment reflects an objective falsehood. *See AseraCare, Inc.*, 938 F.3d at 1297. We urge this Court to adopt this objective falsehood standard, pursuant to which the government must "identify facts and circumstances surround the patient's certifications that are inconsistent with the proper exercise of physicians." *Id.*

3. The Eleventh Circuit's objective falsehood standard promotes uniformity, which aligns with Medicare's design and discourages bad-faith whistleblowers from opportunistic forum-shopping.

The Eleventh Circuit's objective falsehood standard allows this Court to rectify the purpose of Medicare as a promoter of uniformity, which the confusing circuit court split undermines. A uniform standard for falsity aligns with Medicare's purpose. As the Second Circuit has recognized, Congress designed Medicare to function as a nationwide standard for uniform medical payments. *See Cmty. Health Ctr.*, F.3d at 134 (noting that Medicare "is administered . . . by intermediaries, who must apply uniform standards established by federal law") (citing 42 U.S.C. § 1395c (2000).). A circuit court split over the FCA false element frustrates this design. Consequently, the Ninth Circuit's 2020 *Winter* decision magnified the frustration.

The Ninth Circuit's 2020 *Winter* decision involving the medical necessity of inpatient hospitalizations brought more confusion than clarity to the meaning of false for FCA purposes. *See Winter*, 953 F.3d at 1118-119. On one hand, the court relied on the Third Circuit's decision in *Druding* to argue that a subjective clinical opinion *can* be false. *Winter*, 953 F.3d at 1118; (citing *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 100-01 (3d Cir. 2020)) (holding that "a physician's judgment may be scrutinized and considered 'false'"). On the other hand, the *Winter* court endorsed the Eleventh Circuit's *AseraCare* decision to the extent that a subjective cannot be false "without more." *See Winter*, 953 F.3d at 1118-119.

While the *Winter* court emphasized that the relator alleged "more than just a reasonable difference of opinion," the court refrained from establishing any sort of

uniform guideline for the meaning of "more." *See id.* at 1120. *Winter's* vague, nuanced reconciliation of an already-inconsistent circuit split lends this Court a prime opportunity to promote uniformity by requiring an objective falsehood standard. Furthermore, a uniform objective falsehood standard would discourage parasitic relators , enticed by whistleblower rewards that can reach 30% of the government's judgment, by strategically filing suit in plaintiff-friendly jurisdictions. See 31 U.S.C. § 3730(d). To the contrary, a lack of an objective falsehood standard would subject healthcare providers to a myriad of undue consequences.

4. The lack of an objective standard for falsity unfairly subjects healthcare providers to rampant, frivolous litigation, thus delaying patient care and imposing undue financial burdens.

If COVID-19 has taught us one thing on which we can all agree, it is that healthcare providers have a lot on their plates. They do not need increased exposure to frivolous Medicare litigation, especially with the number of Medicare beneficiaries projected to grow from around 55 million beneficiaries today to over 80 million by 2030. Medicare Payment Advisory Comm'n, *Health Care Spending and the Medicare Program, Chapter 2: The next generation of Medicare beneficiaries*, 37 (2015).

While the FCA is technically a remedial statute, FCA remedies are "essentially punitive in nature." *Universal Health Servs.*, 136 U.S. at 1996. FCA liability subjects' healthcare providers to treble damages, statutory penalties, and attorneys' fees—not to mention the immeasurable consequences of reputation damage. See 31 USCA Section 3729(a). In the year 2020 alone, the Department of

Justice recovered more than $2.2 billion in FCA judgments and settlements, $1.8 billion of which stemmed from health care fraud claims. Dep't of Justice, *Justice Department Recovers over $2.2 Billion from False Claims Acts Cases in Fiscal Year 2020*, (2021).

The FCA's spotlight on healthcare will surely increase in the Pandemic's wake, as the Department of Justice aims its weapons at an endless herd of COVID-19-related fraud claims. *See, e.g.*, Dept't of Justice, Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program, (Jan, 12, 2021).

Health care providers clearly have reason for fear, and such fear intensifies when an informed clinical judgment can be second-guessed by an unaffiliated, hired physician or layman in a liability proceeding. As the COVID-19 crisis has made evident, healthcare providers need to have the confidence to make critical decisions, often with expediency. The lack of an objective falsehood standard lessens that confidence, which would likely propel physicians to cling to conservative treatment plans where progressive alternatives could save lives. Furthermore, the fear of liability would likely propel healthcare providers to implement complicated systems of internal review for clinical decision-making, which would inevitably slow patient care and greatly increase costs.

The Third Circuit's assertion that the scienter element helps to curb frivolous liability might sound in theory, but it fails in practice. In holding that subjective clinical judgments can yield FCA falsity, the Third Circuit in *United States ex rel*

Druding v. Care Alternatives offered the existence of the scienter element as a safeguard to the unfair liability concerns. *Druding*, 952 F.3d at 98 (noting scienter requirements are "rigorous" and can be used to address excessive liability concerns) (citing *United States ex. Rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018).).

In practice, however, this safeguard fails to remedy the excessive litigation problem. The denial of a motion to dismiss for lack of falsity still subjects doctors to costly discovery and litigation proceedings. As a result, the imposing costs will force many innocent doctors, who could likely achieve justice at the summary judgment level, to instead settle—in the interest of their pocketbooks and to the detriment of an unruly court of public opinion.

B. Mason cannot satisfy the requisite objective falsehood standard because none of the clinical judgments underlying her claim contain a flaw that can be demonstrated through verifiable facts.

Mason has not plausibly pled any facts that satisfy the Eleventh Circuit's standard requiring a doctor's clinical judgment to reflect an obvious falsehood. The standard requires the government or the Relator to "identify facts and circumstances surround the patient's certifications that are inconsistent with the proper exercise of physicians." *AseraCare, Inc.*, 938 F.3d at 1297. The *AseraCare* court offered three ways to satisfy this standard. In each example, "[T]he clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts." *Id.*

First, the Relator can allege that the physicians failed to review the patients' medical charts or otherwise familiarize themselves with the patient's condition before the necessity determination. *See id.* Second, the Relator can prove that the physician did not subjectively believe that the treatment was necessary at the time of certification. *Id.* Third, the Relator can provide evidence to show that no reasonable physician could have concluded that the treatment was necessary based on the medical records. *Id.*

The record plainly fails to suggest that Mason can identify facts and circumstances surrounding any of the foregoing three examples. With respect to the second example, Mason does allege a scheme which could potentially show that Dr. Drake did not subjectively believe that the HBO therapy was necessary. However, the Record is devoid of any indication that Mason can demonstrate the existence of the scheme with verifiable facts. *See* R. at 5.

The Record indicates that a conversation between SAM Clinics' CEO Mr. O'Keefe and Dr. Drake "confirmed to Mason that . . . some kind of inappropriate scheme was in place." R. at 5. In this conversation, Mr. O'Keefe and Dr. Drake discussed their satisfaction with the clinic's HBO therapy numbers. R. at 5. Mr. O'Keefe stated to Dr. Drake, "…CMS approves, you get that fancy new car, and the patients are happy. It's a win-win-win." R. at 5.

While this conversation invites speculation, it does not verify with veracity the factual existence of a scheme. Accordingly, Mason cannot use the conversation to prove that Dr. Drake did not subjectively believe in the necessity of the HBO

therapy. Therefore, as a matter of law, Mason has not plausibly pled any facts to satisfy the objective falsehood standard.

CONCLUSION

For the aforesaid reasons, this Court should affirm the decision of the United States Court of Appeals for the Fifteenth Circuit to dismiss Mason's claim because her claim violates § 3730(b)(5) of the False Claims Act and Mason cannot satisfy the requisite objective falsehood standard.