No. 17-4014

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

UNITED STATES OF AMERICA ex rel. GERALD POLUKOFF,

Plaintiff-Appellant,

v.

ST. MARK'S HOSPITAL; INTERMOUNTAIN HEALTHCARE, INC.; SHERMAN SORENSEN, M.D.; SORENSEN CARDIOVASCULAR GROUP; INTERMOUNTAIN MEDICAL CENTER; and HCA, INC.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Utah
[District Court Case No. 2:16-CV-304-JNP-EJF (Judge Jill N. Parrish)]

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF REVERSAL

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GLOSSARY

CMS	Centers for Medicare and Medicaid Services
FCA	False Claims Act
PFO	Patent foramen ovale

INTEREST OF THE UNITED STATES

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA. The district court committed errors in this case that undermine important government interests in remedying and deterring fraud and protecting patient safety. The court held that a certification that a procedure was medically necessary, for purposes of obtaining federal reimbursement, could not be "false" under the FCA. The court also stated that a corporation could be liable under the FCA only if its "managing agent" possessed the requisite scienter. The United States submits this amicus brief pursuant to Federal Rule of Appellate Procedure 29(a) to explain why both conclusions were incorrect.

STATEMENT OF ISSUES ADDRESSED

The United States submits this amicus brief to address the following issues:

1. Whether a defendant can be liable under the FCA for certifying that a procedure was medically necessary, knowing that certification to be untrue, for the purpose of obtaining reimbursement from a federal health care program.

2. Whether corporate liability under the FCA requires that a corporation's "managing agent" possess the requisite scienter.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background

1. The False Claims Act provides that "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is liable to the United States for treble damages and civil penalties. 31 U.S.C. § 3729(a)(1)(A).[1] The statute also imposes liability if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B). The FCA defines "knowingly" to "mean that a person, with respect to information," either "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). No proof of specific intent to defraud is required. *Id.* § 3729(b)(1)(B).

The Attorney General can bring a civil action to remedy a violation of the FCA. 31 U.S.C. § 3730(a). Alternatively, a private person (known as a *qui tam* relator) may bring a civil suit "for the person and for the United States Government." *Id.* § 3730(b)(1). If a relator files a *qui tam* action, the government may intervene and take

[1] The conduct alleged in this case occurred both before and after Congress amended the FCA through the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-25. *See* Am. Compl. ¶ 2 [Aplt. App. 506-07]. This brief refers only to the current version of the statute, which does not differ from its predecessor in any way relevant to this case.

over the case. *Id.* § 3730(b)(2). If the government declines to intervene, the relator conducts the litigation. *Id.* § 3730(c)(3). The government and the relator divide the monetary proceeds from a *qui tam* suit. *Id.* § 3730(d).

2. Medicare, the primary federal health care program at issue in this case, provides federally funded health insurance to eligible elderly and disabled persons. *See* 42 U.S.C. § 1395 *et seq.* In general, after a health care provider performs a covered service for an eligible patient, the Secretary of Health and Human Services, acting through a fiscal intermediary, reimburses the provider in accordance with the Medicare Act and the Secretary's regulations. *See id.* § 1395h; *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 450-51 (1999).

The Medicare Act provides that "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). A provider requesting reimbursement from Medicare must certify that the services at issue were "medically necessary." Centers for Medicare & Medicaid Servs. (CMS), Form 1500, https://go.usa.gov/xNGvF.

The Secretary of Health and Human Services can determine whether an item or service is reimbursable either "by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). If the Secretary chooses the former course, he can issue a "national coverage determination"

that announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). If there is no applicable national coverage determination, a Medicare contractor may issue a "local coverage determination" stating whether an item or service is covered within that contractor's jurisdiction. *Id.* § 1395ff(f)(2)(B).

Where there is no applicable national or local coverage determination, Medicare contractors "make individual claim determinations . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Contractors may reimburse providers for items and services that are "[s]afe and effective," "[n]ot experimental or investigational," and "[a]ppropriate." CMS, *Medicare Program Integrity Manual* § 13.5.1 (2015), https://go.usa.gov/xNGwE (addressing local coverage determinations); *see also id.* § 13.3 (applying these standards to individual claim determinations). One factor relevant to whether an item or service is "[a]ppropriate" is whether it is "[f]urnished in accordance with accepted standards of medical practice." *Id.* § 13.5.1.

B. Prior Proceedings

1. Defendants allegedly sought federal reimbursement for medically unnecessary cardiac procedures, including patent foramen ovale (PFO) closures. Am. Compl. ¶ 2 [Aplt. App. 506-07]. Although the federal government has not issued a national coverage determination regarding these procedures, the relator alleges that "[t]here has long been general agreement in the medical community that PFO closure is not medically necessary, except in the limited circumstances where there is a

confirmed diagnosis of a recurrent cryptogenic stroke or" transient ischemic attack. *Id.* ¶ 83 [Aplt. App. 524]. The relator cites industry guidance that assertedly supports his view, *see id.* ¶¶ 83-86 [Aplt. App. 524-25]; alleges that one of the defendant hospitals incorporated a similar standard into its internal policies, *id.* ¶¶ 87-90 [Aplt. App. 525-26]; and claims that Medicare contractors have taken the same position in local medical-review policies, *id.* ¶ 92 [Aplt. App. 526].

Defendant Sherman Sorensen allegedly departed from these standards by performing PFO closures on patients with migraines. Am. Compl. ¶ 137 [Aplt. App. 542-43]. The relator alleges that, because Dr. Sorensen knew "Medicare and Medicaid would not pay for PFO closures to treat migraines," he falsely indicated on patient records that he had performed the procedures based on "confirmed recurrent cryptogenic stroke." *Id.* He also allegedly performed the procedures at a high rate—for example, the relator claims that the Cleveland Clinic performed 37 PFO closures in 2010, while Dr. Sorensen performed 861. *Id.* ¶ 136 [Aplt. App. 542].

The relator asserts that the defendant hospitals encouraged Dr. Sorensen to perform these procedures "despite clear compliance red flags." Am. Compl. ¶ 3 [Aplt. App. 507]. Defendant Intermountain Medical Center allegedly suspended Dr. Sorensen's privileges in 2011, after concluding that he "had performed multiple, medically unnecessary PFO closures." *Id.* ¶ 115 [Aplt. App. 533]. Dr. Sorensen continued to practice at defendant St. Mark's Hospital, where the relator "personally observed Sorensen perform medically unnecessary PFO closures" and at least twice

saw him "*create* a PFO by puncture of the atrial septum in patients who were found to have an intact septum during surgery." *Id.* ¶ 124 [Aplt. App. 536-37]. The relator claims to have notified the CEO of St. Mark's of his concerns, but St. Mark's allegedly continued to allow Dr. Sorensen to perform PFO closures. *Id.* ¶ 133 [Aplt. App. 540-41].

Dr. Sorensen allegedly gave the relator records related to his practice, which the relator contends show specific false claims that defendants submitted to the government. Am. Compl. ¶¶ 141-44 [Aplt. App. 543-606].

2. Defendants moved to dismiss the relator's claims. In the decision under review, the district court granted the motions and dismissed the amended complaint with prejudice.

The district court first addressed whether the relator had pled his claims with the particularity that Federal Rule of Civil Procedure 9(b) requires. *See* Op. 7-15 [Aplt. App. 2515-23].[2] The court explained that Rule 9(b) does not require a relator to allege details regarding particular false invoices; the relator need only "show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." Op. 9-10 [Aplt. App. 2517-18] (emphasis omitted) (quoting *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)).

[2] The court also considered whether the relator had engaged in forum shopping, *see* Op. 6-7 [Aplt. App. 2514-15], but this brief does not discuss that issue.

Applying that standard, the district court held that the relator had adequately "pled the who, what, when, where, and how of an allegedly fraudulent scheme perpetrated by Dr. Sorensen." Op. 11-12 [Aplt. App. 2519-20]. As for the defendant hospitals, the court explained that the "essence" of the relator's claim was that the hospitals knew "Dr. Sorensen was performing allegedly medically unnecessary procedures in their facilities, but billed the government for costs associated with these procedures anyway." Op. 12-13 [Aplt. App. 2520-21]. The court stated that, because the hospitals "are corporations, this knowledge must be held by a managing agent of either of these corporate entities." Op. 13 [Aplt. App. 2521]. The court held that the relator had stated a claim against St. Mark's, but not against Intermountain. Op. 13-14 [Aplt. App. 2521-22].

The district court rejected all of the relator's claims, however, on the ground that he had not alleged that defendants submitted an "objective[ly] false[]" claim to the government. Op. 15-16 [Aplt. App. 2523-24]. In the court's view, defendants' certifications that the cardiac procedures were medically necessary could not support FCA liability because proof of their falsity would "necessarily rest on evidence of medical opinions and subjective standards of care." Op. 20-21 [Aplt. App. 2528-29]. The district court relied on this Court's statement, in an unpublished opinion, that "the FCA requires proof of an objective falsehood." Op. 16 [Aplt. App. 2524] (quoting *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005) (unpublished)). Although *Morton* expressly declined to hold that a fact

whose "verification . . . relies upon clinical medical judgments" can never "form the basis of an FCA claim," 139 F. App'x at 983, the district court rejected the relator's claims as a matter of law, Op. 18-19 [Aplt. App. 2526-27].

The district court acknowledged the relator's assertion that defendants had departed from industry standards in performing the procedures. Op. 19 [Aplt. App. 2527]. The court rejected the relator's reliance on those standards, however, stating that he wrongly "equate[d] [them] with the medical necessity standard imposed by Medicare." *Id.* The court suggested that defendants could be liable if the government "promulgate[d] a regulation that clarifies the conditions under which it will or will not pay for a PFO closure." Op. 20 [Aplt. App. 2528]. "But in the absence of an objective standard created by the government," the court reasoned, the relator "can only rely upon the subjective and ambiguous 'reasonable and necessary' standard," which the court held could not support liability. *Id.*

SUMMARY OF ARGUMENT

The FCA applies broadly to "false or fraudulent" claims, 31 U.S.C. § 3729(a)(1)(A), (B), and Congress intended for it to address "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). In an FCA case involving eligibility for payment under Medicare, a claim is "false" if it is not reimbursable, and a claim is not reimbursable if the services at issue were not medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A). The district court's contrary holding—that a claim premised

on a knowingly false medical-necessity certification is not "objectively false," and thus cannot be actionable—conflicts with the statute and with decisions of other courts. The ruling also undercuts an essential safeguard against fraud, waste, and abuse and effectively insulates from FCA liability unscrupulous providers who would subject their patients to unnecessary medical procedures for the sake of profit.

Even if FCA liability required an "objectively false" claim, the claims here could meet that standard. By evaluating medical records, witness testimony, and other potential evidence, a jury can make the objective determination whether a medical-necessity certification is true or false. Juries often perform similar exercises in criminal health care fraud cases and malpractice cases, where courts rightly defer to the jury's ability to "weigh the evidence and determine the credibility of witnesses." *Brown v. Presbyterian Healthcare Servs.*, 101 F.3d 1324, 1334 n.9 (10th Cir. 1996). There is no credible basis to treat FCA cases differently. While an FCA defendant might not be liable if he reasonably, but erroneously, believed a procedure was medically necessary, that would be only because he did not act "knowingly," *see* 31 U.S.C. § 3729(a)(1)(A), (B)—not because his claim was reimbursable (*i.e.*, not "false").

The district court also applied an erroneous standard for corporate knowledge, stating that a corporation can be liable only if its "managing agent" possessed the requisite scienter. Op. 13 [Aplt. App. 2521]. That standard departs from basic principles of agency law, and it undermines Congress's intent that the FCA hold responsible corporate officials who "insulate themselves from knowledge of false

claims submitted by lower-level subordinates." S. Rep. No. 99-345, at 7 (1986). A corporation should instead be charged with the knowledge of any of its agents or employees acting within the scope of their authority.

ARGUMENT

I. A Certification That A Procedure Was Medically Necessary Can Be "False" Within The Meaning Of The False Claims Act

A. The District Court Erroneously Rejected The Relator's Claims For Lack Of An "Objective Falsehood"

1. The FCA imposes civil liability where a defendant knowingly presents a "false or fraudulent claim" to the government. 31 U.S.C. § 3729(a)(1)(A); *see also id.* § 3729(a)(1)(B). A false claim can "take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345, at 9. Congress intended the FCA 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); *see also United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1171 (10th Cir. 2010) (recognizing the FCA's "broad application to all fraudulent attempts to cause the Government to pay out sums of money" (quotation marks omitted)).

"Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005). The federal government will not reimburse a Medicare claim unless the services at issue

were "reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A), and a provider must expressly certify that he or she is seeking reimbursement for "medically necessary" services, CMS, Form 1500, *supra*.

The relator's theory of liability in this case—that defendants sought federal reimbursement for services that they certified were medically necessary, despite knowledge to the contrary—is one that courts have regularly accepted.[3] Indeed, false certifications of medical necessity are of particular concern because they jeopardize patient health and safety. Potential FCA liability provides a critical deterrent to unscrupulous providers who, motivated by profit, might otherwise knowingly subject patients to procedures that would not improve their health and could instead harm them.

The district court nonetheless rejected the relator's claims, concluding that a certification of medical necessity could not support FCA liability because it could not

[3] *See, e.g.*, *Frazier ex rel. United States v. Iasis Healthcare Corp.*, 392 F. App'x 535, 537 (9th Cir. 2010) (unpublished) (dismissing a claim as inadequately pled but suggesting that the relator could have stated a claim by "provid[ing] reliable indicia that" the defendant "submitted claims for medically unnecessary procedures" (quotation marks omitted)); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (holding that "claims for medically unnecessary treatment are actionable under the FCA" and declining to dismiss a suit where the defendants allegedly "ordered . . . services knowing they were unnecessary"); *see also United States ex rel. Hayward v. SavaSeniorCare, LLC*, No. 11-821, 2016 WL 5395949, at *9-10 (M.D. Tenn. Sept. 27, 2016); *United States v. Robinson*, No. 13-cv-27, 2015 WL 1479396, at *5-6 (E.D. Ky. Mar. 31, 2015); *United States v. Caris Life Scis., Inc.*, No. 10-cv-2237, 2013 WL 11579021, at *3 (N.D. Tex. Oct. 23, 2013); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000).

be "objectively false." *See* Op. 21 [Aplt. App. 2529]. Citing this Court's opinion in *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980 (10th Cir. 2005) (unpublished), the court stated that, as a matter of law, "[o]pinions, medical judgments, and conclusions about which reasonable minds may differ" could not give rise to FCA liability. Op. 18 [Aplt. App. 2526] (quotation marks omitted). But the FCA applies to all "false or fraudulent" claims, 31 U.S.C. § 3729(a)(1)(A), (B); it does not suggest that only claims that are "objectively" false are actionable. Indeed, the Supreme Court recently rejected a similar effort to narrow the FCA beyond its text, holding that the statute's reference to "false or fraudulent claims" is not limited to claims that involve "misrepresentations about express conditions of payment." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016); *see also* Claire M. Sylvia, *The False Claims Act: Fraud Against the Government* § 4:34 (2016) ("The Supreme Court's decision in *Escobar* confirms that the statute should be read as written and that engrafting nonstatutory requirements onto the statute is unwarranted.").

Although the district court stated that "[o]pinions . . . cannot be false for the purposes of an FCA claim," Op. 18 [Aplt. App. 2526] (quotation marks omitted), it is well established that an opinion *can* be false if the speaker does not believe it or lacks facts to support it. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1330 (2015) (applying that principle in a securities case and noting that it is "not unique to" securities fraud). "In offering an opinion, . . . a speaker is

making the factual statement that *he believes* something." *MHC Mut. Conversion Fund, L.P. v. Sandler O'Neill & Partners, L.P.*, 761 F.3d 1109, 1113 (10th Cir. 2014); *see also* Restatement (Second) of Torts § 539(1) (1977) (a speaker who expresses an opinion implicitly represents that the facts known to him are "not incompatible with his opinion" and "that he knows facts sufficient to justify him in forming it").

That principle applies to FCA claims. Even if "an allegedly false statement constitutes the speaker's opinion," it still "may qualify as a false statement for purposes of the FCA where the speaker knows facts which would preclude such an opinion." *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010) (quotation marks omitted).[4] Here, even if a statement of medical necessity were to be characterized as an "opinion," a person who certified that a procedure was medically necessary while believing it to be unnecessary (or while lacking sufficient basis to make the determination) should be liable. In that circumstance, the district court's objective-falsity framework would suggest the wrong result.

"Judicially-created categories sometimes can help carry out a statute's requirements, but they can also create artificial barriers that obscure and distort those requirements." *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385

[4] *See also Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047-49 (9th Cir. 2012) (holding that a false estimate can be the basis of FCA liability even if an estimate is an opinion); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999) ("[A]n opinion or estimate carries with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it.").

(1st Cir. 2011) (declining to distinguish between "factually false" and "legally false" claims and "express" and "implied" certifications). The "objective falsity" paradigm does not illuminate the boundaries of FCA liability. A Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary. If defendants sought federal reimbursement for procedures that they knew or had reason to know were not medically necessary, they defrauded the government and should be liable, regardless of whether one might label the falsity of their claims "objective" or "subjective."

2. In any event, even if the FCA did impose liability only for "objectively false" claims, whether the procedures here were reimbursable is objectively verifiable. A Medicare claim is reimbursable only if the services at issue were medically necessary, and an express or implied statement that a procedure was medically necessary is an objective one that can be either true or false. It is also one that a factfinder is well equipped to evaluate, by potential reference to clinical information and other documentation in a medical record, relevant policies and guidance promulgated by the government or other entities, and expert and other witness testimony. *See Medicare Program Integrity Manual* § 13.5.1 (instructing Medicare contractors determining whether an item or service is reimbursable to evaluate, among other things, whether it was "[s]afe and effective," "[n]ot experimental or investigational," "[f]urnished in accordance with accepted standards of medical practice," "[o]ne that meets, but does not exceed, the patient's medical need," and "[a]t least as beneficial as an existing and

available medically appropriate alternative"). Far from being "subjective and ambiguous," Op. 20 [Aplt. App. 2528], Medicare's "reasonable and necessary" standard provides adequate notice of the federal government's expectations in a program that covers thousands of health care services and procedures.

That establishing falsity in a health care fraud case might "rest on evidence of medical opinions and subjective standards of care," Op. 20 [Aplt. App. 2528], does not render an FCA claim incapable of objective evaluation. To the contrary, a jury is fully capable of evaluating, with the aid of expert testimony, whether patient medical records support claims for federal reimbursement. That is true even where the parties might present conflicting medical evidence: "to remove a plaintiff's claims from the jury simply because a difference of opinion among experts [might] exist[] would abrogate the jury's responsibility to weigh the evidence and determine the credibility of witnesses." *Brown v. Presbyterian Healthcare Servs.*, 101 F.3d 1324, 1334 n.9 (10th Cir. 1996) (quotation marks omitted).

Indeed, the need for juries to evaluate competing claims made by medical experts is not limited to the FCA context. In criminal proceedings, this Court has rejected the notion that conflicting medical evidence "per se create[s] a reasonable doubt." *United States v. MacKay*, 715 F.3d 807, 827 (10th Cir. 2013). The Court instead defers to "the jury's resolution of conflicting evidence and its assessment of the credibility of witnesses" in evaluating whether a defendant prescribed a drug "outside the usual course of medical practice and not for a legitimate medical

purpose." *Id.* Similarly, in medical malpractice suits, this Court has recognized that a jury might need to determine which of two experts is more credible regarding the defendant's compliance with the standard of care. *See, e.g.*, *Weese v. Schukman*, 98 F.3d 542, 547-48 (10th Cir. 1996) (reinstating a verdict because it was "within the jury's role as the factfinder to decide that [the plaintiff's] witnesses were not credible and therefore reject their testimony").

Courts have reached similar conclusions in criminal health care fraud cases. The Sixth Circuit recently held that a jury permissibly credited the testimony of government experts to find that a physician had knowingly required his patients to undergo unnecessary cardiac tests and procedures, rejecting his claim that "he was simply an over-protective cardiologist who [was] guilty of nothing more than relying on outdated practice methods." *United States v. Persaud*, No. 16-3105, 2017 WL 2557823, at *7 (6th Cir. June 13, 2017) (motion to publish granted July 7, 2017). The court explained that the defendant had wrongly "ask[ed] th[e] court to re-weigh the expert testimony that was presented at trial"; "the reliability and believability of expert testimony" is instead "exclusively for the jury to decide." *Id.*; *see also United States v. Patel*, 485 F. App'x 702, 709 (5th Cir. 2012) (unpublished) (holding that a jury "was permitted to credit" the testimony of government experts regarding the lack of medical necessity and the existence of false statements over contrary testimony and evidence from the defendant).

This principle applies with full force in FCA cases. As in any other type of litigation, a finder of fact can weigh the evidence and apply the appropriate standard of proof to determine whether a claim was false. Questions involving medical evidence might sometimes be difficult, and there might be FCA cases in which the jury finds that the government or a relator has failed to meet its burden of proof to show that a claim was not reimbursable. That does not mean, however, that the medical-necessity standard gives a jury insufficient guidance to make the relevant determinations. The district court erred in holding that the potential need for "evidence of medical opinions and subjective standards of care," Op. 20 [Aplt. App. 2528], precluded FCA liability as a matter of law.

3. The potential for reasonable minds to disagree about whether a medical procedure was necessary could be relevant to FCA liability—but not because it would preclude a finding of falsity, as the district court believed it would. *See* Op. 16-17 [Aplt. App. 2524-25]. Instead, the potential for a reasonable but erroneous belief that a claim was eligible for payment would go to scienter: to "whether the defendant actually knew or should have known that its conduct violated a regulation." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017).

The FCA imposes liability for the "knowing[]" presentment of a false claim, which includes "actual knowledge," "deliberate ignorance," or "reckless disregard." 31 U.S.C. § 3729(a), (b)(1). If a defendant submitted a claim in good faith, the knowledge requirement would not be met and the defendant would not be liable, even

if the claim was not reimbursable. But that would not mean the claim was not false: as the Supreme Court recently explained, courts should address "concerns about fair notice and open-ended liability . . . through strict enforcement of the Act's materiality and scienter requirements," not by "adopting a circumscribed view of what it means for a claim to be false or fraudulent." *Escobar*, 136 S. Ct. at 2002 (quotation marks omitted); *see also United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir. 1999) ("A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.").

4. The cases on which the district court relied are not to the contrary. Although this Court's unpublished opinion in *Morton* stated that the FCA "requires proof of an objective falsehood," *Morton* expressly declined to hold that a "fact cannot form the basis of an FCA claim" "merely because [its] verification . . . relies upon clinical medical judgments." 139 F. App'x at 982-83; *see also id.* at 983 ("[N]ot all clinical diagnoses and characterizations of medical care are intrinsically ambiguous."). This Court explained that the question is instead whether "the allegedly 'false' statement is susceptible to proof of truth or falsity." *Id.* As this brief explains, a medical-necessity certification is susceptible to proof of truth or falsity. Particularly in light of the Supreme Court's recent decisions in *Escobar* and *Omnicare*, this Court should clarify that the potential for reasonable disagreement about a claim's eligibility

for payment might bear on scienter but does not preclude a finding of falsity, "objective" or otherwise.

Some of the other cases the district court cited are best read to turn on conclusions regarding scienter. *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999), dismissed a claim because the relator had offered "no reason to believe that the City of Green Bay was out to cheat the federal government." Judge Jones's concurring opinion in *United States v. Southland Management Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J., concurring), likewise reasoned that defendants had not "knowingly" presented a false claim because, among other things, there were "legitimate grounds for disagreement over the scope" of the relevant requirements and the defendants had acted "in good faith." Similarly, although *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676-77 (N.D. Miss. 2011), referred to objective falsity, it turned on a conclusion that the defendant had reasonably believed its conduct was permissible.

The district court's reliance on *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996), was also misplaced. As the Ninth Circuit has since made clear, that case addressed an unusual statute and did not broadly limit the types of claims that can be "false or fraudulent." *See Oliver*, 195 F.3d at 463. *Hagood* does not govern falsity in the ordinary case, where it is the defendant's compliance with applicable requirements, "as interpreted by th[e] court," that determines whether he submitted a false claim. *Oliver*, 195 F.3d at 463. Similarly, although *United States ex rel. Wilson v.*

Kellogg Brown & Root, Inc., 525 F.3d 370 (4th Cir. 2008), mentioned the concept of "objective falsehood," it turned on a holding that a relator cannot state a claim merely by alleging that he disagrees with the defendant's interpretation of a contractual provision. *See id.* at 377-78 (contrasting the case with one in which a defendant knowingly submitted inaccurate information to obtain a government contract).[5]

B. The Relator Adequately Alleged Falsity In This Case

The relator adequately alleged that the cardiac procedures here were medically unnecessary and that defendants' claims were therefore false. The relator alleged, among other things, that the procedures contravened industry and hospital-level guidelines, Am. Compl. ¶¶ 83-90 [Aplt. App. 524-26]; that Dr. Sorensen performed an exceptionally large number of procedures, *id.* ¶ 93 [Aplt. App. 527]; that other physicians expressed concern, *id.* ¶ 114 [Aplt. App. 533]; that one hospital suspended Dr. Sorensen's privileges because he performed "multiple, medically unnecessary PFO

[5] The other cases the district court cited likewise do not support its conclusions. In *United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006), after considering extensive evidence regarding the necessity of the services at issue, the district court determined that the defendant's practices were "within the range of reasonable medical and scientific judgment" and that there was no "objective gap . . . between what the [d]efendant represented and what the [d]efendant would have stated had the [d]efendant told the truth." *Id.* at 1026-28, 1032-33. The district court here undertook no such inquiry. In any event, *Prabhu* did not override dispositive precedent from its Circuit holding that questions of good faith go to scienter, rather than falsity. *See Oliver*, 195 F.3d at 464. The government has appealed *United States v. AseraCare, Inc.*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015), which acknowledged in any event that "a difference of opinions among treating physicians and medical experts" does not "always defeat falsity." *Id.* at 1381 n.6.

closures," *id.* ¶ 115 [Aplt. App. 533]; and that Dr. Sorensen falsified medical records to conceal his conduct, *id.* ¶ 137 [Aplt. App. 542-43]. Indeed, the district court held that the relator had "adequately [pled] the specifics of a purportedly fraudulent scheme" by Dr. Sorensen "to defraud the government in violation of the FCA." Op. 12 [Aplt. App. 2520]; *see also* Op. 14 [Aplt. App. 2522] (similar conclusion as to one of the hospitals). These allegations, taken together, suffice to state a claim, and the district court erred in rejecting them.

One error merits specific discussion. The relator referred to industry guidelines allegedly stating that, while PFO closure may be appropriate for patients who have suffered strokes, "closure of a PFO for the treatment of migraine headaches is not indicated." Am. Compl. ¶¶ 83-86 [Aplt. App. 524-25]. The district court rejected the relator's reliance on these guidelines, relying on *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011), to conclude that "Medicare does not require compliance with an industry standard as a prerequisite to payment." Op. 19 [Aplt. App. 2527]. In *Chesbrough*, however, the court understood the relators to allege that industry standards were themselves a prerequisite of payment. *See* 655 F.3d at 467-68. Here, the relator is citing industry standards as evidence that defendants violated the statutory and regulatory medical-necessity requirement. While departure from industry practices

might not itself render a claim false, it is evidence that might tend to suggest a procedure was not reasonable and necessary.[6]

In fact, one of the factors the government considers in determining whether a procedure was "reasonable and necessary" is whether it was "[f]urnished in accordance with accepted standards of medical practice." *Medicare Program Integrity Manual* § 13.5.1. Courts likewise refer to industry practices in evaluating FCA claims. *See, e.g.*, *United States ex rel. Todd v. Fidelity Nat'l Fin., Inc.*, No. 12-cv-666, 2015 WL 1297557, at *3 (D. Colo. Mar. 19, 2015) ("[T]he standards of the title industry are relevant to a determination of whether the investigation and FCA claims of [the plaintiff] had a reasonable basis."); *cf. Persaud*, 2017 WL 2557823, at *9 (crediting government witness testimony regarding "the generally accepted threshold" at which cardiac procedures became necessary). A jury evaluating whether procedures were medically necessary might find it probative that a defendant performed the procedures when other members of his profession generally would not do so.

In rejecting reliance on industry guidelines, the district court suggested that a claim for reimbursement could be "false" only if it contravened a federal regulation defining "the conditions under which [the government] will or will not pay for a PFO

[6] *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), *abrogated on other grounds by Escobar*, 136 S. Ct. 1989, on which the district court also relied in this section of its opinion, expressly acknowledged that a defendant may be liable under the FCA where "a party contends that a particular procedure was deleterious or performed solely for profit." *Id.* at 698.

closure." *See* Op. 19-21 [Aplt. App. 2527-29]. The Secretary of Health and Human Services has broad discretion, however, to make reimbursement decisions either "by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). That discretion would be meaningless if a generally applicable rule were the only way for the government to protect itself against fraud. Issuing national coverage determinations as to every conceivable medical service would also leave no room to consider individual circumstances that might bear on medical necessity (which a jury considering an FCA claim, by contrast, is well equipped to evaluate). Furthermore, it is not clear that forcing the government to issue thousands of national coverage determinations would "help would-be defendants anticipate and prioritize compliance obligations" in any meaningful way. *Escobar*, 136 S. Ct. at 2002. The medical-necessity requirement applies even where the government has not issued a national coverage determination, and a jury can weigh the evidence to decide whether it is knowingly violated.

II. A Corporation Is Liable For The Acts Of Its Agents

The district court also erroneously stated that a corporation could be liable under the FCA only if its "managing agent" possessed the requisite scienter. Op. 13 [Aplt. App. 2521]. The court cited no authority for that proposition, which disregards basic principles of agency law. "It is well established that a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority." *Western Diversified Servs., Inc. v. Hyundai Motor Am., Inc.*, 427 F.3d 1269, 1276

(10th Cir. 2005); *see also* 3 William Meade Fletcher et al., *Fletcher Cyclopedia of the Law of Corporations* § 790, at 16 (perm. ed., rev. vol. 1999) ("[A] corporation is charged with constructive knowledge . . . of all material facts of which its officer or agent receives notice or acquires knowledge while acting in the course of employment within the scope of his or her authority."); Restatement (Third) of Agency § 5.03 cmt. a (2006) (acknowledging "the general principle that a principal is charged with notice of facts that an agent knows or has reason to know").

There is no reason to depart from these principles in the FCA context. To the contrary, Congress specifically intended that the FCA "hold responsible those corporate officers" who engage in "'ostrich-like' conduct," "insulat[ing] themselves from knowledge of false claims submitted by lower-level subordinates." S. Rep. No. 99-345, at 7. Other courts of appeals have thus held that corporations "may be vicariously liable under the FCA for the misrepresentations of their employees" so long as the relevant employee "is acting within the scope of his or her employment." *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir 2012); *see also United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747-48 (7th Cir. 2013) ("Corporations . . . 'know' what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge."); *United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977) (rejecting the notion that a corporation is liable only if the

wrongdoing employee "has a position of substantial responsibility and broad authority").

The district court's error regarding corporate scienter was a fundamental one, but it is not clear whether it affected the outcome in this case. The court concluded that the relator had adequately pled knowledge on the part of one of the defendant hospitals but, as to the other, had failed to identify "who knew what and when they knew it." Op. 13-14 [Aplt. App. 2521-22]. It is not clear whether that conclusion turned on a distinction between the knowledge of "managing agents" and the knowledge of other employees, and the government takes no position as to whether the relator's allegations establish corporate knowledge under the proper standard. This Court should nonetheless correct the district court's misstatements of the falsity and scienter standards and remand the case for further proceedings.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rules of Appellate Procedure 29(a) and 32(a). This brief contains 6500 words and was prepared in 14-point Garamond, a proportionally spaced font.

s/ Sarah Carroll
Sarah Carroll

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that (1) all required privacy redactions have been made; (2) any paper copies of this document submitted to the Court are exact copies of the version filed electronically; and (3) the electronic submission was scanned for viruses and found to be virus-free.

s/ Sarah Carroll
Sarah Carroll

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Sarah Carroll
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