When Medical Opinions, Judgments, and Conclusions Are “False” Under the False Claims Act: Criminal and Civil Liability of Physicians Who Are Second-Guessed by the Government

“Contradiction is not a sign of falsity, nor the lack of contradiction the sign of truth.”

I. INTRODUCTION

Traditionally considered a Civil War relic, the False Claims Act (FCA) remains a widely-used tool for the United States government to punish wrongdoing, particularly in the healthcare industry. In a press release, the United States Department of Justice reported recovering $2.8 billion in FCA settlements and judgments for the 2018 fiscal year—$2.5 billion of which came from healthcare fraud claims related to federal healthcare programs such as Medicare and Medicaid. The significant amount of healthcare fraud recoveries

3. See Press Release, U.S. Dep’t of Justice, Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 [https://perma.cc/H8RZ-6W7K] (discussing breakdown of fraud contributions to overall recovered amount). The announcement noted that since the 1986 amendments to the FCA, the government has recovered more than $59 billion in total. See id. While outside the scope of this Note, the government collects large sums of money related to healthcare from the drug and medical device industry in particular. See id. Notably, the first case of healthcare fraud was brought under the FCA in 1996 involving a suit against a drug manufacturer for the off-label promotion of gabapentin, whereby parties submitted false claims to the federal government for reimbursement of the drug. See United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., 147 F. Supp. 2d 39, 43-45 (D. Mass. 2001) (discussing nature of claim and recovery sought). Additionally, hospice care fraud, within the particular context of medical necessity, has increasingly become an area of focus for FCA claims due to the “rapid growth of the industry, vague clinical standards around necessity, and dark incentives flowing from reimbursement policy.” See Isaac D. Buck, A Farewell to Falsity Shifting Standards in Medicare Fraud Enforcement, 49 SETON HALL L. REV. 1, 13 (2018) (describing new front of hospice fraud). According to Buck, “[w]ith an increasing emphasis on the hospice benefit, and a growing number of citizens reaching retirement age, both the Office of Inspector General (OIG) within the Department of Health and Human Services [[HHS]], and the DOJ, have turned attention to the problem of hospice fraud.” Id. at 14. The Medicare hospice benefit is overseen by the Centers for Medicare and
under the FCA is primarily due to the 1986 FCA amendments, with a continuing increase due to the 2010 Patient Protection and Affordable Care Act (ACA) amendments, which lowered the public disclosure hurdle. In particular, many of the burgeoning healthcare fraud claims under the FCA are brought by *qui tam* plaintiffs—that is, private individuals who bring suit on the government’s behalf—and based on alleged lack of medical necessity.

The FCA prohibits an individual from “knowingly” presenting a false or fraudulent claim to the United States government. A recent FCA suit questioned whether a physician’s medical opinion regarding the medical necessity of a treatment or procedure was “reasonable and necessary under the government’s definition of the phrase.” Until recently, courts had generally agreed that a mere difference in scientific or medical opinion could not constitute the basis of an FCA claim. Recent Sixth and Tenth Circuit decisions, however, have imposed both civil and criminal liability on healthcare providers based on a finding of objectively false medical opinions that caused the government to pay physicians for services provided to Medicare and Medicaid patients.

While there are bright lines at either end of the spectrum for false claims, these decisions show a troubling shift towards broadening the scope of when a medical opinion or judgment can be “false or fraudulent” under the FCA, which has substantially expanded the potential liability for healthcare providers and their employers. Although stating that a jury would not have acted unreasonably if

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5. See Michael W. Youtt et al., *False Claims Act Actions—The Developing Case Law Regarding If and When Opinions of Medical Necessity Can Be Fraudulent*, HEALTH LAW., Apr. 2015, at 36, 36 (describing FCA’s *qui tam* provision); *see also* Press Release, supra note 3 (attributing large portions of recoveries to *qui tam* plaintiffs).


7. See United States *ex rel.* Polakoff v. St. Mark’s Hosp., 895 F.3d 730, 743 (10th Cir. 2018); Youtt et al., supra note 5, at 36 (providing examples of claims submitted for knowingly unnecessary medical services).

8. See Youtt et al., *supra* note 5, at 37-38 (listing cases commonly holding mere differences in medical opinion not actionable under FCA).

9. See *Polakoff*, 895 F.3d at 742-43 (holding physician’s medical opinion sometimes objectively false); United States v. Paulus, 894 F.3d 267, 277 (6th Cir. 2018) (holding differences in expert testimony sufficient to prove services medically unnecessary, if jury so finds).

10. See *Polakoff*, 895 F.3d at 743 (underscoring broad definition concerns of “false or fraudulent”); W. Diversified Servs., Inc. v. Hyundai Motor Am., Inc., 427 F.3d 1269, 1276 (10th Cir. 2005) (discussing “managing agent” theory); *supra* note 9 (explaining bright lines); *see also* Polakoff, 895 F.3d at 745 n.9 (disagreeing with district court’s application of managing agent theory). Under the FCA, “a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority[,]” and may be held liable under
it found that the physician performed the procedure in good faith, the Sixth Circuit nevertheless reinstated a physician’s criminal conviction based on both another expert disagreeing with the treating physician’s opinion and the treating physician’s high billings and enormous salary. Similarly, in a civil case, the Tenth Circuit held that it is possible for a medical judgment to be false or fraudulent under the FCA in a matter involving a type of cardiac heart procedure known as patent foramen ovale (PFO) closures—despite the lack of national coverage guidelines for such procedures.

This Note examines the history of the FCA and common-law precedent regarding whether and when medical opinions or judgments can serve as the basis of an FCA claim. This Note then discusses how the recent decisions from the Sixth and Tenth Circuits have expanded healthcare providers’ potential liability, and further analyzes the impact that widening the liability net will have on the practice of medicine—including the unintended consequence of limiting Medicare and Medicaid patients’ access to treatment. This Note concludes with a brief discussion of necessary policy reforms, in light of the trend towards holding healthcare providers liable for their professional medical judgments, and encourages other courts not to follow the Sixth and Tenth Circuits’ reasonings.

II. HISTORY

A. Historical Background of the FCA

Congress passed the FCA, originally known as the Informer’s Act, in 1863 to combat the massive expenses incurred due to individuals committing fraud

the FCA for employees’ acts. See Hyundai Motor Am., Inc., 427 F.3d at 1276; see also Brief for Appellant at 31-32; United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019) (No. 16-13004), 2016 WL 4582600, at *18-19 (arguing ample evidence presented under FCA falsity standard).

11. See Paulus, 894 F.3d at 276-78.


15. See infra Part IV (describing impacts on healthcare industry at large).
Against the government. During the Civil War, defense contractors defrauded the government using various methods, including billing for nonexistent or worthless goods, charging extraordinarily high prices for delivered goods, and generally robbing the government when purchasing the “necessities of war.” The FCA is thus typically referred to as a “Civil War relic,” but Congress drafted it broadly enough to apply to all types of fraud committed against the government, and it has increasingly been used to combat and rectify Medicare and Medicaid fraud. A person who knowingly submits a “false or fraudulent claim” to the government for reimbursement may be liable for civil penalties of up to $10,000 for each false claim, as periodically adjusted, plus triple the amount of the government’s damages. In addition, the government may prosecute individuals for submitting false claims under the criminal FCA.

While the government may bring civil claims under the FCA, the Act also includes a qui tam provision. The phrase qui tam comes from a Latin phrase


18. See Meador & Warren, supra note 2, at 456, 459 (describing use of broadly-drafted FCA during New Deal and pre-World War II eras). But see Joan H. Krause, ‘Promises to Keep’: Health Care Providers and the Civil False Claims Act, 23 CARDOZO L. REV. 1363, 1369 (2002) (discussing law expanding “beyond its modest military origins”). Congress expanded the FCA “to encompass virtually any individual or entity that transacts business with the federal government.” Id. at 1369-70.

19. See 31 U.S.C. § 3729(a) (2018) (stating fines not to exceed $10,000 but adjusted for inflation). A civil penalty must not be less than $5,000 per claim. See id.

20. See 18 U.S.C. § 287 (2018) (declaring imprisonment not to exceed five years for anyone who makes false claim). The criminal FCA provides that “[w]hoever makes or presents to . . . the United States . . . any claim upon or against the United States . . . knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years.” Id.; see id. § 1035(a) (specifying imprisonment for no more than five years for any matter involving healthcare benefit programs). In contrast, under the criminal False Statements Act, courts have held that a statement is “false” by negating any reasonable interpretation of the facts, and furthermore, have held that the government may not introduce evidence that shows the defendant’s state of mind. See MARC A. VAN ALLEN, What Is “False” Under the False Claims Act? (laying out different standards between fraud statutes), in NAVIGATING THE GOVERNMENT CONTRACTS PROCESS (2010), 2010 WL 3650148, at *3.

21. See 31 U.S.C. § 3730(b)(1) (stating individual’s right to bring violation on government’s behalf); Pamela H. Bucy, Where to Turn in a Post-Punitive Damages World: The “Qui Tam” Provisions of the False Claims Act, 58 ALA. L. WR. 356, 356-57 (1997) (describing empowerment of “private attorneys general” to combat government fraud); Andrew M. Hyer, The Good, the Bad, and the Ugly: The Unnecessarily Broad Impact of Qui Tam Civil False Claims Act Cases on Rural Health Care Providers, 23 HEALTH MATRIX 459, 466 (2013) (explaining qui tam provision specifically intended to create financial incentives). It should be noted that a Texas court found the entire ACA unconstitutional, even deeming § 3730 unconstitutional, as it is not severable from
meaning “who as well for the king as for himself sues in this matter.”

The provision allows a private individual, known as a relator, to bring suit on behalf of the United States government and share any recovery with the government. Qui tam relators are entitled to a maximum of 30% of any recovery, as well as their costs and reasonable attorney’s fees. Due to the 1986 amendments to the FCA, which increased qui tam relators’ maximum recovery from 15% to 30%, there has been an escalating number of actions by relators who serve as private prosecutors. In addition to monetary incentives, amendments to the FCA in the ACA made it easier to overcome the public disclosure bar to qui tam claims.

When I lodged my initial complaint with the company, I believed what we were doing was unethical and only technically illegal. This ethical transgression drove my decision. My peers could live with the implications of “doing 60 in a 55 mph zone” because it did indeed seem trivial. However, my personal betrayal... so filled me with shame that I could not live with this seemingly trivial violation.

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further incentivizing *qui tam* litigation.\(^{26}\) In fact, healthcare fraud prosecution is the leading recovery area for FCA claims.\(^{27}\) Healthcare providers may find that disgruntled employees, coworkers, and competitors become relators under the FCA, even though they otherwise would have no standing to bring a claim for alleged Medicare or Medicaid fraud.\(^{28}\)

**B. Using the FCA to Bootstrap Medicare and Medicaid Fraud Claims on the Government**

The FCA is applicable to many statutes that include provisions for the

\(^{26}\) See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02 (2010) (codified as amended at 31 U.S.C. § 3730(c)(4)(A) (2018)) (amending FCA). Prior to the ACA, a relator could be barred from bringing an action if the case was based on a public disclosure of information; this was commonly known as the “public disclosure bar.” See False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 3, 100 Stat. 3153, 3157 (codified as amended at 31 U.S.C. § 3730(c)(4)(A) (2018)) (replacing “government knowledge bar” with public disclosure bar). In addition to creating the public disclosure bar, the 1986 amendments also created the “original source” exception. See id.; see also Thomas & DeSantis, supra note 4, at 164 (discussing intentionally replacing original source exception). Because the original source exception was foreclosing too many *qui tam* actions, Congress purposefully expanded the scope of the FCA by creating the public disclosure bar. See Thomas & DeSantis, supra note 4, at 168; see also Joel D. Hesch, Restating the “Original Source Exception” to the False Claims Act’s “Public Disclosure Bar” in Light of the 2010 Amendments, 51 U. Rich. L. Rev. 991, 997-1000 (2017) (outlining history of public disclosure bar and original source exception). While this expanded the scope of *qui tam* claims, the public disclosure bar nonetheless “still kept the door closed too tightly[,]” allowing defendants to use the public disclosure bar as grounds to have FCA complaints dismissed. See Hesch, supra, at 1000. The ACA, however, amended the FCA’s language to allow the government, not the court, to unilaterally have the final decision on whether a court may dismiss a case based on a public disclosure. See Patient Protection and Affordable Care Act § 10104(j)(2); Hesch, supra, at 1002. Other amendments to the FCA in 2009 increased its scope in civil actions, closed loopholes, including eliminating the scienter requirement to prove fraud involving indirect claims, extended the statute of limitations, expanded whistleblower protections, and eliminated certain other defenses. See Van Allen, supra note 20, at *1. These 2009 amendments also contributed to the increasing number of government and relator claims. See id. at *2.

\(^{27}\) See supra note 3 (describing collection of large sums of money from healthcare fraud claims); see also Matthew, supra note 25, at 532 (stating healthcare fraud prosecution fastest growing area of *qui tam* litigation). Notably, in 1988, only 15% of total *qui tam* cases involved HHS. See Fraud Statistics, U.S. Dep’t. Just., https://www.justice.gov/civil/page/file/1080696/download [https://perma.cc/FML2-Z5NA] (dividing total 1988 HHS *qui tam* by total 1988 *qui tam*). By late 2018, HHS was involved in 92% of total *qui tam* filings. See id. (dividing total 2018 HHS *qui tam* by 2018 total *qui tam*).

reimbursement of expenses to the federal government. The Medicare Act states that no payment may be made “for any expenses incurred for items or services” that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Healthcare providers seeking reimbursement under the Medicare Act must “certify the necessity of the services and, in some instances, recertify the continued need for those services.” Additionally, Medicaid regulations define fraud as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.”

The HHS Secretary decides whether a medical service is “reasonable and necessary.” For some items and services, the HHS Secretary issues a “national coverage determination” stating whether a particular item or service is covered nationally. If there is no national coverage determination, local Medicare contractors may issue a “local coverage determination.” In addition, contractors have the discretion to make individual claim determinations based on the particular facts of an individual’s case if there is no national or local coverage determination that applies. When deciding whether to reimburse a medical provider for a Medicare claim, contractors must consider a service to be “reasonable and necessary if the contractor determines that the service is: [s]afe and effective; [n]ot experimental or investigational . . . ; and [a]ppropriate.”


32. 26 C.F.R. § 455.2 (emphasis added).

33. See 42 U.S.C. § 1395ff(a)(1) (giving HHS Secretary power to promulgate regulations); Heckler v. Ringer, 466 U.S. 602, 617 (1984) (describing HHS Secretary’s power). As the Supreme Court stated, “[t]he Secretary’s decision as to whether a particular medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” Heckler, 466 U.S. at 617.

34. See 42 U.S.C. § 1395ff(f)(1)(B) (stating determination does not include determination of assigned codes). The determination also does not include a decision with respect to the amount of payment made for a particular covered item or service. See id.

35. See id. § 1395ff(f)(2)(B) (stating determination made by fiscal intermediary or carrier under part A or part B of subchapter XVIII).


37. See CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP’T HEALTH & HUMAN SERVS., PUB. NO. 100-
When examining whether a claim is appropriate, claims examiners assess whether the service was “furnished in accordance with accepted standards of medical practice for the diagnosis and treatment of the patient’s condition or to improve the function of a malformed body member.” When the provider submits a claim for payment, the provider must sign a form certifying that “the services on this form were medically necessary.” By signing such form for payment of services that are not on the national or local coverage list, a healthcare provider must rely on his or her medical opinion and judgment that the services were medically necessary. Under the FCA, such medical opinion may be challenged as a legally false claim for payment based on an expressly false certification.

The courts have established two doctrines—false certification, either express or implied, and promissory fraud—that attach potential FCA liability to claims for Medicare and Medicaid payment that are not explicitly or independently false. The false certification theory has been the foundation for complaints against healthcare providers alleging fraud under the FCA. Section 3729(a)(1)(A) of the FCA imposes liability on a person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” Section 3729(a)(1)(B) imposes the same liability on a person who “knowingly makes, uses, or causes to be made or used, a false record or statement.

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38. See id. (indicating other standards of appropriateness) (emphasis added).


40. See Polukoff, 895 F.3d at 741-44 (describing medical opinions’ falsity standards).

41. See id. at 741 (comparing express and implied false certification).

42. See United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166, 1171 (9th Cir. 2006) (describing construction of false or fraudulent claim). Under the false certification theory, the claim can be false under the FCA “where a party merely falsely certifies compliance with a statute or regulation as a condition to government payment.” See id. Under promissory fraud, “liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained through false statements or fraudulent conduct.” See id. at 1173.


material to a false or fraudulent claim.\textsuperscript{45} An FCA cause of action generally requires proving three elements: the defendant presented a claim for payment to the United States; the claim was false or fraudulent; and the defendant acted knowingly.\textsuperscript{46} The FCA does not define what makes a claim false or fraudulent, and thus the courts developed a federal common law.\textsuperscript{47} The FCA, however, does define the term “knowing” or “knowingly”—the scienter requirement—as follows:

(1) the terms “knowing” and “knowingly”–
   (A) mean that a person, with respect to information–
      (i) has actual knowledge of the information;
      (ii) acts in deliberate ignorance of the truth or falsity of the information; or
      (iii) acts in reckless disregard of the truth or falsity of the information; and
   (B) require no proof of specific intent to defraud.\textsuperscript{48}

Common actions under the FCA alleging that a Medicare or Medicaid claim is fraudulent raise two issues: when and whether medical opinions or judgments can be false or fraudulent, and whether the healthcare professional acted knowingly.\textsuperscript{49}

C. Whether and When Opinions Can Be “False” Under the FCA

With respect to the second element of an FCA claim—whether the statement

\textsuperscript{45} See id. § 3729(a)(1)(B) (emphasis added).
\textsuperscript{46} See United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) (applying three elements to specific facts of case). Proof of the first element typically involves applying the false certification theory, but further analysis of this element is outside the scope of this Note. See Escobar, 136 S. Ct. at 1995 (stating submission of claim impliedly certifies compliance with conditions of payment). If the submitted claim “fails to disclose the defendant’s violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim ‘false or fraudulent.’” Id. The Supreme Court, in this specific case, granted certiorari to resolve the disagreement among circuit courts regarding the validity and scope of the implied false certification theory. See id. at 1998. As the Court held, “liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement.” Id. at 1995. Further, FCA liability “does not turn upon whether those requirements were expressly designated as conditions of payment . . . . What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” Id. at 1996. While noting that not every undisclosed violation of an express condition of payment will trigger liability, the Court greatly expanded the scope of FCA liability. See id. at 2001. The Court assured, however, that such expansion will be moderated by the FCA’s “rigorous” materiality and scienter requirements. See id. at 2002.
\textsuperscript{47} See Escobar, 136 S. Ct. at 1999 (describing “settled principle” of common-law interpretation); Luckey, 2 F. Supp. 2d at 1047 (noting definition of “knowingly” in statute but lack thereof for “false” or “fraudulent”).
\textsuperscript{49} See infra Section II.C (discussing precedent of falsity and knowledge standards of medical opinions).
was false or fraudulent—courts generally agree that mere differences of scientific or medical opinion are not actionable under the FCA.\(^\text{50}\) In order for a record or statement to serve as the basis of an FCA claim, it must be based on an objectively verifiable fact.\(^\text{51}\) As such, mere “[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.”\(^\text{52}\) That is, courts acknowledge that, as a matter of law, mere disputes over scientific knowledge or methodology are insufficient to give rise to an FCA claim.\(^\text{53}\) For example, the court in *United States ex rel. Lamers*

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\item \(^\text{50}\) See Youtt et al., * supra* note 5, at 37 (describing actionable claims under various legal standards). An individual’s exercise of his scientific or professional judgment falls outside the scope of the FCA. See *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1047 (N.D. Ill. 1998) (declining to find claim false or fraudulent under FCA). In *Luckey*, the relator brought a claim under the FCA alleging that the laboratory she formerly worked for presented false claims to the federal government regarding the sales of its plasma-based therapies. See *id.* at 1036-37. Looking to prior case law, however, the court concluded that the plaintiff failed to present anything more than a scientific dispute, relying solely on an expert’s testimony. See *id.* at 1047. The court stated that “mere deviation from scientific norms is insufficient to support an FCA action.” *Id.* at 1048. In particular, the court in *Luckey* relied on language from *United States ex rel. Milam v. Regents of the University of California*, which stated:

> At most, the Court is presented with a legitimate scientific dispute, not a fraud case. Disagreements over scientific methodology do not give rise to False Claims Act liability. Furthermore, the legal process is not suited to resolving scientific disputes or identifying misconduct. As a recent law review article stated, “[t]he discord between the scientific and legal approaches to misconduct is well illustrated by the efforts of federal agencies to settle upon a proper definition of ‘misconduct.’ . . . The division between misconduct and legitimate science may be difficult to distinguish, and not even a mens rea requirement such as ‘deliberate falsification’ is sufficient to adequately distinguish the two.”


\item \(^\text{51}\) See *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App’x 980, 983 (10th Cir. 2005) (holding denial of coverage not false or fraudulent). The court noted, however, it was not going so far as to state that a fact that relies upon clinical medical judgments for verification could not form the basis of an FCA claim in all instances. See *id.* The court made sure to distinguish the nature of the facts at hand, which were not rendered capable of proof or falsity. See *id.* The court concluded that the therapeutic effects of treatment were necessarily ambiguous when administered to a premature infant. See *id.* Such a determination relies on the “resolution of two sets of inherently ambiguous determinations by defendants.” See *id.* at 984. Thus, there could not be a determination of fraud under the FCA. See *id*.; see also *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) (stating evidence only showed disputed legal issue). Alone, a disputed legal issue is not enough to support a reasonable inference of falsity under the FCA. See *Hagood*, 81 F.3d at 1477.

\item \(^\text{52}\) See *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) (denying plaintiffs’ partial summary judgment motion because faulty installation of gears not false under FCA).

\item \(^\text{53}\) See *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (declining to find fraud in defendant’s performance of government defense contracts). The court in *Wang* stated:

> Bad math is no fraud.

> . . . Proof of one’s mistakes or inabilities is not evidence that one is a cheat.

> . . . Without more, the common failings of engineers and other scientists are not culpable under the Act.

> . . . The phrase “known to be false” . . . does not mean “scientifically untrue”; it means “a lie.”

The Act is concerned with ferreting out “wrongdoing,” not scientific errors. What is false as a matter...
of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.

Id. at 1420-21 (citation omitted); see Hagood, 81 F.3d at 1477 (mere disputed legal issue not enough to state FCA claim). Mere differences in physicians’ opinions concerning whether a procedure was medically necessary require a different standard from other areas of law, such as medical malpractice, which requires a jury to hear issues as a matter of fact. See David B. Honig, The False Claims Act and Quality of Care, HALL RENDER: FALSE CLAIMS ACT DEF. (Feb. 13, 2013), https://www.hallrender.com/2013/02/13/the-false-claims-act-and-quality-of-care-2/ [https://perma.cc/MY79-X6SU] (describing different standards between FCA and malpractice cases); Nancy Reynolds, A Trend in 2017: Use of the False Claims Act for Malpractice Cases in Long Term Care, LONG TERM CARE COUNS.: DISP. RESOL. (Jan. 8, 2018), https://ltccounsel.com/a-trend-in-2017-use-of-the-false-claims-act-for-malpractice-cases-in-long-term-care/ [https://perma.cc/5XK8-2CLX] (describing concerning change of application of FCA from “fraud gatekeeper” to “malpractice regulator”).

54. See 168 F.3d at 1013 (7th Cir. 1999).
55. See id. at 1018 (drawing on rulings in Wang and Hagood) (citations omitted).
57. See id. at 873-74, 886 (describing evidence merely showed differences in scientific method to reach results).
58. Id. at 886.
59. See Lamers, 168 F.3d at 1018 (stating consideration of falsity question will incorporate knowledge discussion); United States v. Prabhu, 442 F. Supp. 2d 1008, 1028 (D. Nev. 2006) (claiming even if court found falsity, government gave no proof defendant knowingly submitted false claim); Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1048 (N.D. Ill. 1998) (assuming arguendo even if payment false or fraudulent, must still show third element of knowledge); Milam, 912 F. Supp. at 887 (arguing even if statement not scientifically true, must still present evidence of knowledge).
60. United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) (pointing out correctness of trial judge’s opinion).
under the FCA. Further, a defendant generally has not acted knowingly when the defendant’s “conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance.”

For example, in Prabhu, the government pursued an FCA claim, alleging that defendants knowingly submitted false claims by billing for simple pulmonary stress tests, claiming that the services were medically necessary. The court concluded that there was no evidence of the claims being false, and further, that the government presented no material disputed fact to show that Dr. Prabhu knowingly submitted a false claim. To support this ruling, the court noted that Dr. Prabhu’s billing practice conformed to a “reasonable interpretation of ambiguous regulations that he, and his staff, believed in good faith were proper.”

The court further noted that, at worst, the billing circumstances surrounding the pulmonary stress tests were disputed legal issues, which cannot serve as the basis of an FCA claim. The court reasoned that when a physician submits healthcare claim forms, that physician certifies that the services are medically necessary. Further, because Dr. Prabhu determined from his personal evaluation that further therapy was needed, and the government failed to show any proof that the services were medically unnecessary, Dr. Prabhu’s certification was therefore literally true, for which there can be no false claim as

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62. See Prabhu, 442 F. Supp. 2d at 1028-29 (pointing out Ninth Circuit language regarding inapplicability of honest mistakes to FCA claims); see also Hagood v. Sonoma Cty. Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996) (distinguishing knowing fraud from innocent mistake or mere negligence); Hindo v. Univ. of Health Sci/Cli. Med. Sch., 65 F.3d 608, 613 (7th Cir. 1995) (requiring lie to support claim or purposeful fraud scheme); United States ex rel. Anderson v. N. Telecom, Inc., 52 F.3d 810, 815, 817 (9th Cir. 1995) (stating evidence must support inference of knowing fraud and declining to find such knowing presentation); Wang ex rel. United States v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992) (failing to find wrongdoing where evidence merely showed negligence or innocent mistake). In Hagood, the Ninth Circuit heard the case twice—first on a motion to dismiss and second on a motion for summary judgment. See 81 F.3d at 1467 (holding plaintiff to higher standard upon second hearing). When the court addressed the knowledge requirement upon first hearing the case, it stated:

Innocent mistake is a defense to the criminal charge or civil complaint. So is mere negligence. The statutory definition of “knowingly” requires at least “deliberate ignorance” or “reckless disregard.” To take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful. . . .

. . . But what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either “fraudulent” or simply “false.” The requisite intent is the knowing presentation of what is known to be false.

63. See Prabhu, 442 F. Supp. 2d at 1029 (explaining ambiguity born of undefined terms).
64. See id. at 1010-11.
66. See id. at 1029.
67. See id. at 1031.
68. See id. at 1031-32.
a matter of law. A physician’s opinion about the medical necessity of a surgery, procedure, or any sort of medical intervention generally may not serve as the basis of an FCA claim under existing precedent. With that said, however, a statement of medical necessity is not completely isolated from scrutiny, and may be actionable under the FCA if it is precluded by known facts or lacks supporting facts. A statement of medical necessity also may be actionable under the FCA if it is not honestly held, such as when a physician has supplied false information regarding a patient’s medical condition.

III. ANALYZING DEVELOPING LAW: WHEN A MEDICAL OPINION IS “OBJECTIVELY FALSE” UNDER PAULUS AND POLUKOFF

A. The Circuit Courts’ Decisions Regarding Whether Medical Opinions Can Be False Under the FCA

Both the Sixth and the Tenth Circuits have recently expanded upon precedent regarding when a medical judgment or opinion can be false under the FCA, overturning decisions from district courts in Kentucky and Utah, respectively. In Paulus, a jury convicted the defendant for knowingly and systematically exaggerating the results of coronary artery blockages based on the interpretation of angiograms. The relator alleged that Dr. Paulus actually saw a 30% blockage, but intentionally noted it as an 80% blockage for the purposes of billing and performing unnecessary procedures. Additionally, several audits concluded that a large portion of the procedures Dr. Paulus performed were not.

69. See Prabhu, 442 F. Supp. 2d at 1032.
70. See id. at 1032-33 (declining to find statement of medical necessity false under FCA).
71. See United States ex rel. Morton v. A Plus Benefits, Inc., 139 F. App’x 980, 983 (10th Cir. 2005) (stating fact relying upon medical judgment may form basis of FCA claim in some instances); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 792 (4th Cir. 1999) (determining sufficient evidence to form basis of FCA claim). In Harrison, the Fourth Circuit stated: “[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.’” See Harrison, 176 F.3d at 792 (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 109, at 760 (5th ed. 1984)); see also United States ex rel. Loughren v. Unum Grp., 613 F.3d 300, 310 (1st Cir. 2010) (noting opinion may form basis of FCA claim where facts known would preclude opinion); United States ex rel. Wall v. Vista Hospice Care, Inc., 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011) (requiring physician’s medical judgment predicated on objectively verifiable fact).
74. See Paulus, 894 F.3d at 273-74 (deliberating for four days after twenty-three days of trial).
75. See id. at 270 (describing theory on which federal jury convicted Dr. Paulus).
The district court vacated his conviction, “reasoning that angiogram interpretations are not facts subject to proof or disproof.” Specifically, the district court reasoned that the percentage of blockage “is a subjective medical opinion, incapable of confirmation or contradiction.” On appeal, the Sixth Circuit stated that opinions are not “completely insulated from scrutiny[,]” and held that an opinion may form the basis of an FCA fraud allegation when it is not honestly held or when the speaker knows of facts that would preclude his opinion. The court held that, in rendering his medical opinion, Dr. Paulus was misrepresenting facts. In the appellate court’s view, based on the opposing expert’s opinion, Dr. Paulus’s large salary, and the number of procedures Dr. Paulus performed, a reasonable jury could find that he was seeing one thing on the angiogram while consciously writing down another result. The court held that these facts fulfilled the FCA’s scienter requirement and subsequently reinstated Dr. Paulus’s conviction.

Similarly, in Polukoff, a civil qui tam action, a relator sued Dr. Sorensen and

76. See id. at 273 (noting one audit showed at least half of stents not medically necessary).
77. Id. at 270 (finding truth in Paulus’s work because angiogram interpretations inherently not false).
78. See Paulus, 894 F.3d at 275 (reasoning government failed to prove falsity and fraudulent intent). The lower court based its reasoning on the evidence presented at trial, which it found legally insufficient to sustain the conviction. See id. at 274-75. The government rested its case primarily on nine testimonies—three of which were specifically called to offer expert testimony. See id. at 273. The experts acknowledged that “inter-observer variability” can exist between two cardiologists conducting an angiogram. See id. at 272. Specifically, two cardiologists’ interpretations could vary between 10% and 20%, with variations occurring most often in the “intermediate” stenosis range between a 50% to 70% blockage. See id. Dr. Paulus further offered studies as evidence that the inter-observer variability may be even larger. See id. Taking this evidence into account, the district court found that interpreting angiograms is a difficult task subject to frequent disagreement between cardiologists. See id. at 275. Therefore, the district court concluded that interpretations of angiograms cannot be “subject to proof or disproof,” and cannot serve as the basis of false or fraudulent claims under the FCA. See id.
79. See United States v. Paulus, 894 F.3d 267, 275 (6th Cir. 2018) (noting one may falsely represent own state of mind).
80. See id. at 276 (explaining defendant charged with lying about angiograms’ results). The Sixth Circuit relied on a previous decision, United States v. Persaud, holding that the degree of arterial blockage is a fact capable of proof or disproof. See id. A physician tells a lie when he deliberately inflates the degree of stenosis he actually sees, and if that lie is used to bill for a more expensive procedure, the physician has committed fraud. See id. To support the idea that the degree of stenosis is a fact, the court looked to the definition of “fact.” See id. Although noting that the blockage cannot be witnessed by the naked eye, the court stated that the blockage nonetheless “actually exists” as “an aspect of reality.” See id.; Fact, BLACK’S LAW DICTIONARY, supra note 22. The court further stated that “it would be an insult to common sense and the practice of medicine” to hold that the interpretation of an angiogram is not a fact. See Paulus, 894 F.3d at 276. Importantly, the court stated it would not fault a doctor for misreading an angiogram; Dr. Paulus, however, was allegedly observing one thing while consciously writing down the other in order to bill for unnecessary procedures. See id. Thus, although it may be difficult to prove, the court held that the decision should ultimately be left to the jury to decide based on whether the government’s proof—in this case, consisting mainly of expert testimonies—is worthy of belief. See id. at 277-78.
81. See Paulus, 894 F.3d at 276, 278.
82. See id. at 278.
two hospitals where he worked. The relator, Dr. Polukoff, alleged that Dr. Sorensen performed thousands of unnecessary heart surgeries, known as PFO closures. Specifically, Dr. Polukoff alleged that Dr. Sorensen performed PFO closures to cure migraines or prevent strokes, and further alleged that he saw Dr. Sorensen create a PFO by puncturing the intact atrial septum in patients that Dr. Sorensen found to have a normal septum during surgery. Guidelines on when a PFO closure is appropriate are vague and inconclusive. The district court granted Dr. Sorensen’s motion to dismiss based on precedent that medical opinions, judgments, and conclusions, about which reasonable minds may differ, generally cannot serve as the basis of an FCA claim. Reversing on appeal, the Tenth Circuit stated that there is no “bright-line rule” that a medical judgment cannot form the basis for an FCA claim and held that “a doctor’s certification to the government that a procedure is ‘reasonable and necessary’ is ‘false’ under the FCA if the procedure was not reasonable and necessary under the government’s definition of the phrase.” Notably, the court admitted that such a broad reading of the FCA might expose doctors to more liability.

83. See United States ex rel. Polukoff v. St. Mark’s Hosp., 895 F.3d 730, 734 (10th Cir. 2018) (describing suit brought by Dr. Polukoff after observing Dr. Sorensen’s medical practices).

84. See id. (stating Dr. Polukoff further alleged hospitals complicit and profited from fraud). PFO closures collectively refer to the procedure used to close either a PFO or an atrial septal defect (ASD). See id. at 736. Both PFOs and ASDs involve a hole between the left and right upper atria of the heart. See id. An ASD is typically an abnormality that forms as a result of tissue failing to form between the atria. See id.; Caswell, supra note 12, at 16. The foramen ovale, on the other hand, is present in all human fetuses—it allows blood to bypass the fetal lungs, which do not work until the first exposure to air once the baby is born. See Caswell, supra note 12, at 16. If the hole does not close upon the baby’s first breath, it is known as a PFO, which occurs in about 25% of the population. See id. Both conditions can lead to serious complications, including a stroke. See Polukoff, 895 F.3d at 736.

85. See Polukoff, 895 F.3d at 737-38 (discussing defendant’s alleged conduct).

86. See id. at 736-37 (referencing guidelines published by American Heart Association (AHA) and American Stroke Association (ASA)). The 2006 AHA/ASA Guidelines (Guidelines) advised that PFO closures may be considered for patients with two or more cryptogenic strokes, that there was insufficient data for patients with only one cryptogenic stroke, and for patients with no history of a cryptogenic stroke, the Guidelines did not contemplate PFO closures. See id. The inconclusive Guidelines were changed only five years later to similarly inconclusive guidelines that stated there was insufficient data regarding the use of PFO closures in patients with a stroke and PFO. See id. at 737. Dr. Polukoff relied on these Guidelines to show that the PFO closures Dr. Sorensen performed were medically unnecessary because they were performed on patients merely with an elevated risk of stroke, but who had not yet suffered a stroke. See id.

87. See id. at 739-40 (reviewing district court’s dismissal of complaint).

88. See id. at 742-43 (holding factual allegations sufficient to state legal claim). The court stated three reasons for holding a medical judgment false or fraudulent under the FCA: the FCA must be read broadly; an opinion in and of itself does not disqualify it from forming the basis of an FCA claim; and medically unnecessary procedures are actionable under the FCA. See id. at 742. The court held that Dr. Polukoff sufficiently pled enough to state a claim as a matter of law, including the allegations that Dr. Sorensen performed a large number of procedures, the procedures violated hospital and industry guidelines, other physicians objected to Dr. Sorensen’s practice, a hospital audit found that guidelines had been violated, and Dr. Sorensen represented that the procedures were performed to prevent strokes when he knew payment would not be given for the treatment of migraines. See id. at 743.

89. See United States ex rel. Polukoff v. St. Mark’s Hosp., 895 F.3d 730, 743 (10th Cir. 2018) (pointing to
In another case, *United States v. AseraCare Inc.*, the government alleged that AseraCare knowingly submitted false claims to Medicare by approving patients for hospice treatment who had a life expectancy longer than six months. Based on precedent, the lower court granted summary judgment for the defendant, finding that “mere difference of opinion between physicians, without more, is not enough to show falsity” and that “contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law.” On appeal to the Eleventh Circuit, the government challenged the court’s decision and, in its brief, sought to further expand the law making medical opinions false, arguing that “no additional evidence was required for the government to prove that AseraCare’s claims for payment under Medicare were false” if the government’s experts merely disagreed. After a much-anticipated wait, the Eleventh Circuit rejected the government’s argument and affirmed the district court’s determination that merely showing a disagreement between experts is not enough to prove falsity under the FCA.

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90. 176 F. Supp. 3d 1282 (N.D. Ala. 2016), aff’d in part, vacated in part, remanded, 938 F.3d 1278 (11th Cir. 2019).

91. See id. at 1283 (stating claims boiled down to physicians’ conflicting views). To be eligible for hospice, a patient must receive a Certification of Terminal Illness (COTI) from a physician, which states that the patient has a life expectancy of six months or less if the terminal illness runs its normal course. See id. at 1283-84. See generally Buck, supra note 3, at 17-32 (providing general overview on history of AseraCare case). AseraCare is owned by Golden Living, LLC, one of the largest private companies in the United States, which had 42,000 employees in 2016. See Buck, supra note 3, at 18. In 2015, Golden Living’s total revenue was $3 billion. See id. With so much at stake, AseraCare became the target of FCA fraud allegations submitted by relators and the federal government asserting that the company “engaged in hospice fraud to illegitimately boost its profits.” See id.

92. See AseraCare, 176 F. Supp. 3d at 1283, 1286 (describing objective falsehood standard under FCA). The government presented evidence of one physician’s testimony, who stated that the medical records at issue did not support the COTI. See id. at 1284. The defendant, in turn, presented expert testimony that different pages in the same medical records did in fact show that the patients were properly referred to hospice care. See id. at 1284-85. Therefore, the court stressed that all that existed was the difference in opinion among experts, which alone is not sufficient to prove objective evidence of falsity. See id. at 1285. The lower court’s decision was “a focal point for the health law industry, with many in the provider community celebrating the decision.” See Buck, supra note 3, at 32.

93. See Brief for Appellant, supra note 10, at *19 (claiming correct legal standard applied). Under the government’s argument, the jury should be left to decide between two competing expert testimonies as to whether a Medicare claim is reimbursable. See id. at *28.

94. See United States v. AseraCare, Inc., 938 F.3d 1278, 1281 (11th Cir. 2019) (affirming in part and remanding in part). Looking specifically at the Medicare hospice benefit, the Eleventh Circuit stated:

[A] reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA. A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong.

Id. at 1297. The Eleventh Circuit, however, vacated the district court’s post-verdict grant of summary judgment for AseraCare, reasoning that the district court should have “considered all the evidence, both in the trial record
B. Appellate Courts’ Expansive View of “False or Fraudulent”

The circuit courts’ analysis in Paulus and Polukoff substantially expands precedent on whether medical opinions may serve as the basis of an FCA claim.95 In Paulus, the court based its conclusion on the premise that an opinion may form the basis of an FCA claim when it is either not honestly held or when the speaker knows of facts that would preclude his or her opinion.96 While such premise is in accordance with precedent, reflecting the knowing fraud or falsity standard under the FCA, the court extrapolated from the evidence to conclude that if an expert disputed Dr. Paulus’s medical opinion, a jury could conclude that Dr. Paulus was seeing one thing from the angiograms while intentionally writing down another.97 The court attempted to justify the jury’s decision by describing an arterial blockage as a “fact” that Dr. Paulus deliberately inflated to bill for unnecessary procedures.98 Although the government’s primary evidence consisted only of three experts who testified they would have found lower percentages of blockages, the court was satisfied that the government met its burden and that the issue should be left to the jury to decide.99 This, however, erroneously turns disputes about scientific knowledge and medical judgments into matters of fact, which prior courts have acknowledged as insufficient to give rise to an FCA claim as a matter of law.100 Where evidence merely gives rise to a scientific dispute, and not fraud, it cannot give rise to FCA liability.101 It is therefore insufficient for the government to meet its burden on this essential element by merely presenting differences in opinion, because as prior case law holds, mere differences in opinion about which reasonable minds may differ cannot be false as a matter of law under the FCA.102 That is, sincerely held medical judgments cannot be false, even if other experts may disagree.103

and the summary judgment record, to determine whether a triable issue existed regarding falsity.” See id. at 1303.

95. See supra Section II.C (discussing case law on mere differences of scientific or medical opinions).


97. See id. at 276 (noting difficulty lies in proving assertion, but left to jury to decide); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 792 (4th Cir. 1999) (stating opinion contains applied assertion speaker knows no facts to preclude it); United States v. Gwinn, No. 5:06-cv-00267, 2008 WL 867927, at *15 (S.D. W. Va. Mar. 31, 2008) (finding opinion false where not honestly held).

98. See Paulus, 894 F.3d at 276 (concluding Dr. Paulus misrepresented facts when interpreting angiogram).

99. See id. at 273, 276-77 (stating court may not acquit merely because it doubts government’s expert testimony).

100. See supra notes 53-55 and accompanying text (explaining falsity under FCA more than mere disputed legal issue).

101. See supra notes 50-52 and accompanying text (describing precedent on mere differences of scientific or medical opinions).


103. See United States ex rel. Morton v. A Plus Benefits, Inc., 139 F. App’x 980, 984 (10th Cir. 2005) (concluding opinion based on resolving two ambiguous determinations not false under FCA).
Similarly, in reversing the lower court decision, the Tenth Circuit in \textit{Polukoff} admittedly took an “expansive view” of false or fraudulent conduct.\textsuperscript{104} Although the Tenth Circuit heard the case on an appeal of a motion to dismiss, the court made significant statements of law.\textsuperscript{105} The court’s broad definition of falsity—that a doctor’s certification of a procedure as reasonable and necessary is false if the procedure is not reasonable and necessary under the government’s definition of the phrase—misconstrues the precedent.\textsuperscript{106} As the Ninth Circuit stated in \textit{Wang ex rel. United States v. FMC Corp.},\textsuperscript{107} the phrase “known to be false” means that it is a lie.\textsuperscript{108} It is undisputed that an opinion may be false when it is not honestly held.\textsuperscript{109} To base falsity, however, simply on a certification that is contrary to the government’s definition of “reasonable and necessary,” particularly where there are inconclusive guidelines in place, drastically undermines a physician’s medical judgment.\textsuperscript{110} The government’s definition of the phrase does not take into account the physician’s honestly held belief.\textsuperscript{111} Thus, the court in \textit{Polukoff} unreasonably concluded that even when a physician honestly believes a procedure was medically necessary, that opinion may be false under the FCA as long as the government can show it is contrary to its own definition.\textsuperscript{112}

Further, although the District Court for the Northern District of Alabama properly followed precedent in \textit{AseraCare}, and the Eleventh Circuit ultimately affirmed the lower court’s reasoning on falsity, the government’s argument on

\begin{footnotes}
\item[104] See United States \textit{ex rel.} Polukoff \textit{v. St. Mark’s Hosp.}, 895 F.3d 730, 741 (10th Cir. 2018) (taking such expansive view because Congress did not define false or fraudulent).
\item[105] See id. at 734 (reversing lower court’s grant of defendants’ motions to dismiss).
\item[106] See id. at 743 (defining reasonable and necessary under Medicare Act).
\item[107] 975 F.2d 1412 (9th Cir. 1992).
\item[108] See id. at 1421 (stating mere common failings of scientists not culpable under FCA).
\item[109] See supra note 72 and accompanying text (describing rulings where physicians’ opinions found false under FCA).
\item[110] See United States \textit{ex rel.} Polukoff \textit{v. St. Mark’s Hosp.}, 895 F.3d 730, 741 (10th Cir. 2018) (concluding falsity based on government’s definition of “reasonable and necessary”); United States v. Prabhu, 442 F. Supp. 2d 1008, 1029 (D. Nev. 2006) (concluding physician’s actions conformed with ambiguous guidelines). As the court in \textit{Prabhu} stated, a defendant “does not ‘knowingly’ submit a ‘false’ claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance.” See 442 F. Supp. 2d at 1029. In \textit{Polukoff}, the Guidelines Dr. Polukoff relied on were vague and inconclusive. See 895 F.3d at 736-37; supra note 86 (describing standards for PFO closures according to Guidelines). Under the \textit{Prabhu} standard, it could be argued that Dr. Sorensen’s actions were consistent with a reasonable interpretation of ambiguous guidelines. See supra note 86 and accompanying text. Although the Guidelines stated that PFO closures were typically not considered for patients with no history of a cryptogenic stroke, the Guidelines also stated that there was insufficient data even for patients who had both a stroke and PFO. See supra note 86. The court in \textit{Polukoff}, however, did not consider such an argument. See 895 F.3d at 741.
\item[111] See supra notes 37-40 and accompanying text (describing standards under Medicare claim).
\item[112] See \textit{Polukoff}, 895 F.3d at 743 (stating such definition may expose physicians to more liability). If a physician believed in good faith that a service or procedure was medically necessary, the physician should not be held liable under the FCA when the government deems it to be an unnecessary treatment. See Yoott et al., \textit{supra} note 5, at 43. If the government can prove the procedure was not necessary, the appropriate remedy is denying or recouping payments, and not treble damages and civil or criminal penalties under the FCA. See id.
\end{footnotes}
appeal to the Eleventh Circuit similarly sought to lower the bar for finding a medical opinion false under the FCA. Like the court in *Paulus*, the government missed the point when it argued that the jury is “fully capable” of determining, with the aid of expert testimony, whether a Medicare claim is reimbursable. It is well established that mere differences of opinion, alone, are not enough to prove falsity under the FCA. To reiterate, such a lower standard argued by the government would present the issue as a matter of fact, which strays from precedent acknowledging medical opinions and disputes over scientific knowledge as insufficient to give rise to an FCA claim as a matter of law. The government sought to support its position by analogizing to medical malpractice cases, which allow a defendant to present expert testimony to support a negligence claim. Such an analogy, however, is misplaced because medical malpractice involves issues of negligence, whereas FCA cases involve fraud, which requires scienter. Thus, different standards must be applied to these two different areas of law: It is necessary for a medical malpractice claim to go to a jury to hear expert testimony on the standard of care, but it is unnecessary and improper for a jury to hear an issue on the credibility of a physician’s personal medical judgment.

**C. Impact of the Circuit Court Decisions on the Healthcare Industry**

The Sixth and Tenth Circuits’ broad readings of the FCA have the potential to chill physicians’ decisions to provide care to Medicare and Medicaid patients, which in turn, may cause a decline in the quality of and access to healthcare.

113. *See* Brief for Appellant, *supra* note 10, at *19* (stating merely presenting contrary expert testimony sufficient to prove falsity under FCA).

114. *See* id. at *28* (stating jury should make decision with expert’s aid).

115. *See* *supra* note 52 and accompanying text (outlining language from court decision).

116. *See* *supra* notes 53-55 and accompanying text (describing FCA liability more than disputed legal question).

117. *See* Brief for Appellant, *supra* note 10, at *29* (claiming to take AseraCare decision to “logical conclusion”).

118. *See* Reynolds, *supra* note 53 (distinguishing medical malpractice negligence claims from FCA violations).

119. *See* Honig, *supra* note 53 (discussing issues with blurring lines between malpractice and FCA cases). Because the medical standard of care is fluid, expert testimony is required to determine the appropriate standard. *See* id. As a result, fact-based determinations are required to be made by a jury. *See* id.

120. *See* Youtt et al., *supra* note 5, at 43 (discussing consequences of imposing FCA penalties on physicians who acted in good faith). As the lower court stated in *AseraCare*:

The court is concerned that allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians. . . . If the court were to find that all the Government needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician’s clinical judgment. The court refuses to go down
As the Eleventh Circuit stated in AseraCare, “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.”

121 The FCA is meant to ferret out wrongdoing, not punish mere scientific errors. 122 Existing precedent contained mechanisms to punish fraudfeasors who did not honestly hold their opinions or lacked facts to support their opinions; mechanisms were already in place to punish Dr. Paulus and Dr. Sorensen, assuming the egregious facts in each case were true. 123 Yet, the language set out in both the Paulus and Polukoff decisions unreasonably extends the precedent and casts too wide of a net, encompassing not only those physicians who engage in wrongdoing, but also those who exercise their medical judgment in accordance with their good faith medical opinion. 124

As a result of the risk of such harsh penalties, physicians may be reluctant to provide services for the already-underserved populations covered by Medicare and Medicaid, or may stop participating in Medicare and Medicaid plans altogether. 125 Physicians are already disincentivized to accept patients covered by Medicare or Medicaid due to lower payments compared to private health plans. 126 Adding the risk of treble damages or jail time based on a jury’s decision that another expert disagreed or because the procedure was not “necessary” under the government’s definition of the phrase may further disincentivize physicians.

121 See United States v. AseraCare, Inc., 938 F.3d 1278, 1295 (11th Cir. 2019) (requiring judgments tied to valid medical records).

122 See Wang ex rel. United States v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992) (stating purpose of FCA); supra note 53 (describing law on physicians’ opinions).

123 See supra notes 71-72 and accompanying text (describing precedent where statements of medical necessity false under FCA).

124 See supra Section III.B (describing inappropriate expansion of precedent under Paulus and Polukoff).

125 See Maxham, supra note 31, at 327 (stating CMS rule could cause providers to opt out of Medicare); Shaffer, supra note 14, at 1005-06 (warning state false claims enforcement may disincentivize physicians). As Maxham argues, “physicians already face cuts in their Medicare reimbursement” and an added administrative burden could cause physicians to opt out of participating in the Medicare program or reduce the number of Medicare patients they accept. See Maxham, supra note 31, at 327-28. Further, as Shaffer argues, state Medicaid liability reforms could cause physicians to simply refuse performing services for Medicaid patients in order to avoid false claims allegations and the potential of treble damages. See Shaffer, supra note 14, at 1021. Although Schaffer is concerned with state false claims statutes, expansion under the federal FCA would have similar implications. See id. at 995.

126 See Ubel, supra note 14 (describing low Medicaid reimbursement rate). Medicaid pays physicians about 61% of what Medicare pays. See id. Low reimbursement rates, combined with long waits to receive payment, complex paperwork, and sicker patients, cause many physicians to simply refuse to see Medicaid patients. See id.; see also Feke, supra note 14 (describing low Medicare reimbursement rate compared to private health insurance). Medicare also has a low reimbursement rate — 80% of what private health insurance pays. See Feke, supra note 14. As a result of this low reimbursement, coupled with delays and other hurdles, many physicians burn out or opt out of Medicare. See id.
from treating Medicare and Medicaid patients, which is too significant of a risk to place on the nation’s most vulnerable populations—the elderly and the poor.127 With the potential to have chilling effects on physicians’ decisions to provide treatment, such expansion of precedent should not be taken lightly, particularly with the possible negative impacts on the elderly and low-income.128

IV. CONCLUSION

Healthcare remains a major industry for the government in obtaining fraud recoveries under the FCA. The vast amount of recoveries, particularly in the context of medical necessity claims, coupled with the relaxed standards and incentives for relators to bring qui tam actions against hospitals and physicians, is concerning. If accepted by other courts, the Sixth and Tenth Circuit decisions will unreasonably expand physicians’ liability for good faith medical judgments and continue to incentivize qui tam actions. The low bar of evidence required by these decisions—that the government need only show a differing expert opinion and that a procedure was not reasonable and necessary if not reasonable and necessary under the government’s definition of the phrase—will make it easy for the government and relators to reach a jury and allow laypersons to second-guess a physician’s clinical judgment.

Such standards have the potential to chill access to and quality of healthcare, particularly for those covered under Medicare and Medicaid. The United States has fought for decades to obtain sufficient coverage for the low-income and the elderly—two of the nation’s most vulnerable and fragile populations. Should the decisions in Paulus and Polukoff become the new national standard for FCA medical necessity claims, physicians may become reluctant to diagnose and treat the elderly and the poor because even good faith medical opinions may become scrutinized and deemed false. Further, if these decisions are accepted, healthcare institutions may adopt more internal review practices of all physician judgments. Requiring each and every judgment to undergo a process of review will delay patient care and increase costs. Overall, courts should take available opportunities to reject the reasoning of these decisions because the risks posed—reduced care for the elderly and the poor, delayed access to healthcare, and increased costs for the healthcare industry at large—are not risks that courts should be willing to take.

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127. See Youtt et al., supra note 5, at 43 (describing consequences of broadly applying FCA); supra note 125 and accompanying text (explaining effect on healthcare providers of broadly applying FCA).
128. See supra Section III.C (describing potential to disincentivize physicians from treating Medicare and Medicaid patients).