THE TRUTH ABOUT FALSITY: "DUELING EXPERTS" AND WHY THE FALSE CLAIMS ACT REQUIRES PROOF OF AN OBJECTIVE FALSITY

*Rachel L. Leung**

I. INTRODUCTION

Considering that the U.S. government pays out over one trillion dollars every year for federal health insurance programs,[1] it comes as no surprise that health care is a hot market for fraud.[2] In 2020 alone, national Medicaid and Medicare spending totaled $671.2 billion and $829.5 billion respectively.[3] These eye-bulging numbers have been sure to attract thieves and a whole slew of fraudulent activity to health care and government health programs specifically.[4] Estimates place the cost of fraud anywhere between 3 and 10 percent of total health care expenditures,[5] but the true extent of health care fraud—and its

*J.D. Candidate, 2023, Seton Hall University School of Law; B.A., 2020, University of Michigan. Many thanks to the members of the *Seton Hall Law Review* for their excellent editing. I would also like to thank my incredible parents and Isabella Leung for their constant love, support, and encouragement.

[1] CONG. BUDGET OFF., THE BUDGET AND ECONOMIC OUTLOOK: 2020 TO 2030 (2020), https://www.cbo.gov/publication/56073.

[2] *The $272 Billion Swindle: Why Thieves Love America's Health-Care System*, ECONOMIST (May 31, 2014), https://www.economist.com/united-states/2014/05/31/the-272-billion-swindle.

[3] *National Health Expenditures Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (last visited Oct. 29, 2022).

[4] *See* Nicole Forbes Stowell et al., *Investigating Healthcare Fraud: Its Scope, Applicable Laws, and Regulations*, 11 WM. & MARY BUS. L. REV. 479, 481 (2020).

[5] *The Challenge of Health Care Fraud*, NAT'L HEALTH CARE ANTI-FRAUD ASS'N, https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud (last visited Nov. 14, 2022) (estimating that the total cost of health care fraud is 3 percent of total health care expenditures); *Financial Crimes Report 2010-2011, Fiscal Years 2010-2011*, FED. BUREAU INVESTIGATIONS (Oct. 2011), https://www.fbi.gov/stats-services/publications/financial-crimes-report-2010-2011/financial-crimes-report-2010-2011 (estimating that the total cost of health care fraud is 10 percent of total health care expenditures).

cost to taxpayers—is largely unknown.[6] To both prevent and counteract the impact of fraud, the federal government has developed methods of its own for dealing with scammers seeking to take advantage of government health programs. The federal False Claims Act (FCA)[7]—a statute once used to prosecute corrupt government contractors for delivering "dying donkeys" and damaged muskets to the Union Army[8]—has become the Department of Justice's (DOJ) best tool for combatting health care fraud and abuse.[9] In Fiscal Year 2021, for example, the DOJ recovered over $5.6 billion in FCA settlements and judgments—the second largest annual FCA recovery to date.[10]

Despite the FCA's role as one of the government's most prized tools in its anti-fraud arsenal, the FCA has been inconsistently applied in the area of health care. As its title might indicate, the False Claims Act requires a false claim for liability; the FCA statute, however, does not define "falsity."[11] One way that the government may demonstrate the element of falsity is by proving that a doctor submitted a claim to Medicare for services that were "medically unnecessary."[12] The Centers for Medicare and Medicaid Services (CMS)—the federal agency charged with administering the Medicare and Medicaid programs—establishes certain conditions of payment, including medical necessity.[13] If a doctor provides medical services that a patient does not need, CMS would consider these services to be medically unnecessary, and if submitted to the government for reimbursement, these claims would constitute false claims under the FCA.[14] But a

---

[6] David A. Anderson, *The Aggregate Cost of Crime in the United States*, 64 J.L. & ECONS. 857, 872 (2021) ("With $3.8 trillion in annual health care expenditures . . . the 3–10 percent estimate corresponds with a cost range of $114.8–$379.5 billion.").

[7] False Claims Act, 31 U.S.C. §§ 3729–3733.

[8] United States *ex rel.* Newsham v. Lockheed Missiles & Space Co., 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting Tomes, *Fortunes of War*, 29 HARPER'S MONTHLY MAG. 228 (1864)).

[9] James F. Barger, Jr., *Life, Death, and Medicare Fraud: The Corruption of Hospice and What the Private Public Partnership Under the Federal False Claims Act Is Doing About It*, 53 AM. CRIM. L. REV. 1, 20 (2016).

[10] Press Release, U.S. Dep't of Just., Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021 (Feb. 1, 2022), https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.

[11] § 3729.

[12] United States *ex rel.* Polukoff v. St. Mark's Hosp., 895 F.3d 730, 742 (10th Cir. 2018).

[13] *Id.*

[14] *Id.*

problem arises when two doctors disagree as to whether medical services were in fact needed by the patient.[15] In FCA cases based on an allegation that health care services were medically unnecessary and thus fraudulent, a battle of the experts may emerge, as each side attempts to prove or disprove medical necessity with the use of expert witnesses.[16] At issue is whether an expert's contradictory opinion as to medical necessity alone is sufficient to demonstrate the falsity element of an FCA claim or whether a plaintiff must demonstrate that a claim is "objectively false."[17] Under a theory of "objective falsity," a claim for reimbursement cannot be false merely because a subsequent physician, reviewing medical records ex post, holds a differing opinion.[18] Rather, to prove falsity under the FCA, the government must demonstrate objectively verifiable facts that are at odds with the proper exercise of clinical judgment.[19]

In 2019, in *United States v. AseraCare*, the Eleventh Circuit held that the FCA requires proof of an objective falsehood.[20] According to the Eleventh Circuit, "[a] properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong" and that therefore, "a mere difference of opinion between physicians, *without more*, is not enough to show falsity."[21] Six months later, two other appellate courts issued opinions directly challenging the Eleventh Circuit's decision and the objective falsity standard.[22]

The Third Circuit, encountering a case on similar facts as *AseraCare*, firmly rejected the objective falsehood standard in *United States ex rel. Druding v. Care Alternatives*, holding that "medical opinions may be 'false' and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider

---

[15] Isaac D. Buck, *A Farewell to Falsity: Shifting Standards in Medicare Fraud Enforcement*, 49 SETON HALL L. REV. 1, 40–41 (2018) (arguing that the confusion within FCA enforcement centered around falsity is an enduring problem of medical necessity-based fraud).

[16] *Id.*

[17] United States v. AseraCare, Inc., 938 F.3d 1278, 1281 (11th Cir. 2019); United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 89–90 (3d Cir. 2020); Winter *ex rel.* United States v. Garden Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1109 (9th Cir. 2020).

[18] *AseraCare*, 938 F.3d at 1297.

[19] *Id.* at n.10.

[20] *Id.* at 1290.

[21] *Id.* at 1290, 1297 (emphasis in original).

[22] *Care Alts.*, 952 F.3d at 101; *Winter*, 953 F.3d at 1119.

on the question of falsity."[23] The Ninth Circuit, in *Winter ex rel. United States v. Garden Regional Hospital & Medical Center*, entered the fray shortly after and similarly rejected the objective falsity standard, concluding that "[a] physician's certification . . . can be false or fraudulent for the same reasons any opinion can be false or fraudulent."[24] And most recently, the Fifth Circuit, in *United States v. Mesquias*, offered strong criticism of the objective falsity standard.[25] Despite the fact that the correct falsity standard under the FCA remains such an important but unsettled area of law, the Supreme Court has declined to resolve the circuit split.[26]

This Comment urges courts to adopt the objective falsity standard because a reasonable difference in medical opinion between experts is insufficient by itself to prove falsity under the FCA.[27] The FCA simply was not meant to punish doctors for having a reasonable difference in medical opinion. Although this Comment argues in support of the objective falsity standard, it departs from the Eleventh Circuit and *AseraCare* in its definition of falsity. In recognizing that dueling expert testimony alone is insufficient to demonstrate falsity, the Eleventh Circuit properly adopted the objective falsity standard in *AseraCare*; however, the court impermissibly conflated falsity and scienter. Since the FCA requires the separate elements of falsity and scienter, this Comment encourages the adoption of the objective falsity standard, but one that recognizes the independent FCA elements of falsity and knowledge.

Part II of this Comment will provide background on the False Claims Act and CMS's "medically necessary" condition of payment. Part III will discuss the problem with dueling expert testimony and the interrelated yet independent nature of the FCA elements of falsity and scienter. Part IV will summarize the current circuit split, focusing on the holdings in *United States v. AseraCare*; *United States ex rel. Druding v. Care Alternatives*; *Winter ex rel. United States v. Garden Regional Hospital & Medical Center*; and *United States v. Mesquias*. Part V will discuss the falsity of medical opinions in the context of the 2015 Supreme Court case *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*. Part VI explains how the Eleventh Circuit conflated the

---

[23] *Care Alts.*, 952 F.3d at 98, 101.

[24] *Winter*, 953 F.3d at 1119.

[25] United States v. Mesquias, 29 F.4th 276, 282–83 (5th Cir. 2022).

[26] Care Alts. v. United States, 141 S. Ct. 1371 (2021); RollinsNelson LTC Corp. v. United States *ex rel.* Winter, 141 S. Ct. 1380 (2021).

[27] *AseraCare*, 938 F.3d at 1297.

FCA scienter and falsity elements and proposes an objective falsity standard that respects a separation of the elements. Finally, Part VII will conclude that an objective falsehood standard, which recognizes the essential distinction between the falsity and knowledge elements, is the correct standard for determining falsity under the FCA.

II. BACKGROUND

This Part provides a brief history of the FCA and an overview of its most relevant provisions, as well as an explanation of the "medically necessary" condition for Medicare and Medicaid payment.

A. *Overview of the FCA*

The FCA was originally enacted in response to widespread fraud against the government during the Civil War.[28] Tired of suppliers delivering defective goods to the Union Army, Congress responded by passing the FCA, which President Lincoln signed into law in 1863.[29] Since then, however, the statute has become a way for the federal government to recoup payment from, and punish, a variety of government contractors for filing false claims.[30] As a result, the FCA has been become the government's "primary civil enforcement tool to combat fraud."[31] In its modern use, the FCA is predominantly utilized to target health care fraud and has been described as "an essential tool to protect the integrity of the Medicare program."[32]

---

[28] James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1264–67 (2013) (listing some of the reports Congress received during the Civil War, which included "[t]he same mules being sold over and over again to Army quartermasters[;] Rotted ship hulls freshly painted to appear new then sold as new vessels to the NAVY[;] Infantry boots made of cardboard which wore out after a mile of marching[;] Uniform cloth made from recycled rags, which disintegrated when it became wet[;] Gunpowder barrels that when opened contained sawdust").

[29] *Id.* at 1266.

[30] James F. Barger, Jr., *States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts*, 80 TUL. L. REV. 465, 470 (2005) (explaining how the FCA has been used against health care providers, defense contractors, and oil and gas companies).

[31] *Hearing Before the Subcomm. on Immigration & Claims of the H. Comm. on the Judiciary: Health Care Initiatives Under the False Claims Act that Impact Hospitals*, 105th Cong. 14 (1998) (prepared statement of Donald K. Stern, U.S. Att'y for the District of Mass. and Chair, Att'y Gen.'s Advisory Comm., Dept. of Just.).

[32] *Id.* (statement of Lewis Morris, Assistant Inspector Gen. for Legal Affs., Off. of Inspector Gen., U.S. Dep't of Health and Hum. Servs.); *see* Press Release, U.S. Dep't of Just., *supra* note 10 ("Health care fraud was once again the leading source of the department's False Claims Act settlements and judgments this past year.").

The FCA imposes civil liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the government.[33] Under the FCA, a plaintiff must establish that the defendant made a false statement, with scienter, that was material, and which caused the government to make a payment.[34] Although the FCA does not define what a false claim is, the statute has an explicit knowledge requirement.[35] The FCA defines "knowing" and "knowingly" as having actual knowledge or acting in deliberate ignorance or in reckless disregard as to the truth or falsity of a claim.[36] Under the statute, specific intent to defraud is not required.[37]

The FCA has been amended several times since its enactment, most notably in 1986 when damages were increased from double damages to treble damages.[38] In addition to treble damages, those found guilty of violating the FCA face penalties for each false claim.[39] Penalties accrue for each separate violation; thus, a single fraudulent plot can involve thousands of violations, with the total penalties costing millions or tens of millions of dollars.[40] These per-claim penalties can be especially significant for health care providers, who might submit thousands of claims to federal health programs.[41]

The FCA permits private citizens, called *qui tam* relators, to file suits on behalf of the government against those who have submitted fraudulent claims to the government.[42] As an incentive for private

---

[33] 31 U.S.C. § 3729(a)(1)(A) & (B).

[34] Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1045 (11th Cir. 2015).

[35] § 3729(a)(1)(A) & (B).

[36] § 3729(b)(1)(A)(i)–(iii).

[37] § 3729(b)(1)(B).

[38] U.S. DEP'T OF JUST., THE FALSE CLAIMS ACT: A PRIMER, https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[39] 28 C.F.R. § 85.5 (2016). In 2021, the DOJ increased the minimum penalty for a single false claim to $11,803 and the maximum penalty to $23,607. *Id.*; *see also* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 182 (2016) (quoting Vermont Agency of Nat. Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 784 (2000)) ("Congress also has increased the Act's civil penalties so that liability is 'essentially punitive in nature.'").

[40] *See* U.S. DEP'T OF JUST., THE FALSE CLAIMS ACT: A PRIMER, *supra* note 38.

[41] Joan H. Krause, "*Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1370 (2002).

[42] 31 U.S.C. § 3730(b). The government may choose to intervene in a *qui tam* suit; the government then assumes the responsibility of litigating the case, but the relator remains as plaintiff. *Id.*

citizens to bring *qui tam* suits, relators can collect a percentage of the government's recovery if the suit is successful.[43] These whistleblower actions comprise a significant amount of all FCA claims filed and can result in large payouts to relators.[44]

B. *"Medically Necessary" as a Condition of CMS Payment*

Under the Social Security Act, the Medicare and Medicaid programs may only reimburse providers for services that are "reasonable and necessary."[45] Specifically, the statute establishes 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."[46] In addition, CMS requires physicians to certify directly on CMS claim forms that all services submitted for payment were in fact medically necessary.[47]

Within the Medicare program requirements, CMS explicitly defines "reasonable and necessary" as items or services that are (1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients.[48] Recently, CMS has issued additional guidance, defining "appropriate for Medicare patients" as:

> Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; Furnished in a setting appropriate to the patient's medical needs and condition; Ordered and furnished by qualified personnel; One that meets, but does not exceed,

---

[43] If the government chooses to intervene and a suit is successful, a relator can receive up to 25 percent of the government's recovery. 31 U.S.C. § 3730(d)(1)–(2). If the government declines to intervene and the case succeeds, a relator could potentially receive up to 30 percent of the settlement. *Id.*

[44] Press Release, U.S. Dep't of Just., *supra* note 10. In Fiscal Year 2021, for example, whistleblowers received a combined total of $237 million for filing *qui tam* actions under the FCA. *Id.*

[45] 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 440.230(d) (2011).

[46] § 1395y(a)(1)(A).

[47] CTRS. FOR MEDICARE & MEDICAID SERVS., HEALTH INSURANCE CLAIM FORM (OMB-0938-1197 Form 1500 (02-12)), https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf ("In submitting this claim for payment from federal funds, I certify that . . . the services on this form were medically necessary.").

[48] CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PROGRAM INTEGRITY MANUAL (CMS Pub. 100-08), § 13.5.4 (Reasonable and Necessary Provisions in LCDs).

> the patient's medical need; and [a]t least as beneficial as an existing and available medically appropriate alternative.[49]

Given these guidelines, claims for items or services that are not medically necessary are not reimbursable by CMS and will be denied.

III. THE PROBLEM WITH FALSITY IN THE FCA

The FCA requires a false claim, but conflicting medical testimony can completely frustrate the task of determining falsity. At the same time, proving a false claim under the FCA involves the analysis of several interconnected components. Scienter has a unique relationship to falsity; but while this element relates to falsity, it is a wholly independent element under the FCA. This Part explains how dueling expert testimony and falsity's relationship to scienter complicate the search for falsity.

A. *Identifying a False Claim*

The issue with conflicting medical testimony materializes itself predominantly in FCA cases based on allegations of medical necessity-based fraud.[50] As discussed in the previous Part, medical necessity is a condition of payment;[51] thus, every claim submitted to Medicare and Medicaid contains an express or implied certification that the services rendered were medically necessary.[52] Consequently, claims for medically *unnecessary* services are false claims under the FCA, and the providers who submitted those false claims are subject to FCA liability.[53] In these types of cases, notions of falsity are premised on medical necessity, but what may or may not be medically necessary is

---

[49] 86 Fed. Reg. 2987, 2988 (Mar. 15, 2021) (to be codified at 42 C.F.R. pt. 405).

[50] Buck, *supra* note 15, at 9 (arguing that the confusion within FCA enforcement centered around falsity is an enduring problem of medical necessity-based fraud).

[51] *See supra* Part II.B.

[52] By submitting claims to Medicare and Medicaid, providers are certifying, whether expressly or implicitly, that they have complied with all material program requirements that are "condition[s] of payment." United States *ex rel.* Polukoff v. St. Mark's Hosp., 895 F.3d 730, 741 (10th Cir. 2018); *see* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 181 (2016) (holding that although providers must comply with CMS requirements, not every requirement that is expressly designated as a condition of payment may provide a basis for liability); United States *ex rel.* Steury v. Cardinal Health Inc., 735 F.3d 202, 207 (5th Cir. 2013) (concluding that the plaintiff failed to sufficiently allege that merchantability was a condition of payment, either express or implied, without which the government would not have paid for the medical device).

[53] Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1114 (9th Cir. 2020).

based on a doctor's clinical judgment.[54] The problem with falsity is that courts cannot agree as to whether FCA liability may hinge entirely on another physician's contradictory medical opinion or whether something more is needed.[55]

The process for determining falsity tends to be more straightforward when a plaintiff alleges a factual falsity,[56] such as when a defendant submits a claim for services that were never provided.[57] On the other hand, when a plaintiff alleges that the services rendered were not medically necessary, the falsity, or truth, of the claim can be less apparent because in these types of FCA cases, a plaintiff is essentially attacking the underlying clinical judgment of the physician who certified the claim.[58] If a doctor bills for a knee replacement, and it is objectively clear that the patient never needed a knee replacement, then it is quite evident that these services were not medically necessary. When, however, two doctors disagree as to medical necessity, proving falsity becomes a battle of the experts.[59] In *Care Alternatives*, for example, the government asserted that the defendant submitted false claims by falsely certifying that hospice care was medically necessary

---

[54] Buck, *supra* note 15, at 7.

[55] *Compare* United States v. AseraCare, 938 F.3d 1278, 1296 (11th Cir. 2019) (holding that a physician's contradicting opinion is not sufficient to demonstrate falsity), *with* United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 101 (3d Cir. 2020) (holding that a physician's contradicting opinion "creates a triable issue of fact for the jury regarding falsity").

[56] Courts have developed a framework that recognizes two types of false claims: factually false and legally false claims. *Polukoff*, 895 F.3d at 741. Claims are factually false when a physician or entity bills for services in a higher reimbursement category than the services actually provided or bills for services that were never provided in the first place. *Id.* Meanwhile, a claim is legally false if a defendant falsely asserts or implies it has complied with a material statutory or regulatory requirement. *Id.* This factually false versus legally false distinction, however, does not provide any guidance on whether a claim is false merely because two doctors cannot agree as to whether the provided and reimbursed services were medically necessary. A claim may be legally false based on either an express or implied false certification. *Id.*

[57] *See* United States v. Krizek, 859 F. Supp. 5, 12 (D.D.C. 1994). In *Krizek*, the government alleged that Dr. Krizek submitted false claims by billing Medicare and Medicaid for numerous occasions in which he supposedly provided almost twenty-four hours of patient care in a single day. *Id.*

[58] *See Polukoff*, 895 F.3d at 741.

[59] *See AseraCare*, 938 F.3d at 1291 ("Where the parties present competing expert views on a patient's prognosis, the 'falsity' of the defendant's prognosis is put to a jury."); *see generally* Elizabeth A. Caruso, Comment, *Hospice Care's Adventures in Fraudland: "Battle of the Experts" & Proving Falsity Under the False Claims Act*, 62 B.C. L. REV. E. SUPP. II. 21, 23–24 (2021).

for certain patients.[60] The government's expert, Dr. Jayes, testified that the patients were ineligible for the Medicare hospice benefit.[61] Reviewing the same medical records, Care Alternatives' expert, Dr. Hughes, disagreed and concluded that hospice care was medically necessary for the patients.[62]

Some courts have concluded that a mere difference in opinion, as illustrated in the example above, is adequate to demonstrate falsity.[63] Meanwhile, other courts have recognized that dueling expert testimony alone is not a sufficient showing of falsity.[64]

B. *The Relationship Between Falsity and Scienter*

To prevail on an FCA claim, the government or plaintiff must prove four elements: falsity, scienter, causation, and materiality.[65] As the statutory language of the FCA confirms, a plaintiff must satisfy each element to have a valid FCA claim.[66] As a result, an FCA claim cannot succeed unless each element can be demonstrated independently. Additionally, the language of the text clearly indicates that falsity is an element separate from scienter.[67] Accordingly, there is no liability

---

[60] *See* United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 93 (3d Cir. 2020).

[61] *Id.* at 94.

[62] *Id.*

[63] *Id.* at 101.

[64] *AseraCare*, 938 F.3d at 1297 ("[T]he Government must show something more than the mere difference of reasonable opinion.").

[65] United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 487 (3d Cir. 2017) (stating that an FCA violation includes four elements: falsity, causation, knowledge, and materiality). *See also* United States *ex rel.* Longhi v. United States, 575 F.3d 458, 467–71 (5th Cir. 2009) (recognizing that an FCA claim has four requirements: a false or fraudulent statement, requisite scienter, materiality, and a payment of money); Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1045 (11th Cir. 2015) (quoting United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1166, 1174 (9th Cir. 2006)) (stating that a relator must prove "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due").

[66] 31 U.S.C. § 3729(a)(1) (stating that the FCA imposes liability on "any person who . . . (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim").

[67] *See id.*; *Care Alts.*, 952 F.3d at 96 ("[T]he plain language of the FCA denotes scienter as an element independent of falsity.").

under the FCA if a defendant had insufficient knowledge or if there is a lack of falsity.[68]

In the process of determining whether an FCA violation has occurred, however, the falsity and scienter elements may naturally overlap.[69] For example, knowledge may be relevant in proving falsity because a doctor did not subjectively believe that a patient needed certain medical services but nevertheless treated the patient and submitted a claim for reimbursement.[70] The fact that a physician does not actually hold the opinion she asserts is strong evidence showing that the physician had the requisite scienter but is also highly suggestive of the opinion's falsity.[71] The FCA, however, demands that knowledge be demonstrated separately from a false claim.[72] Furthermore, the falsity and scienter inquiries are fully capable of being distinguished for the purposes of determining FCA liability.[73]

Since the FCA demands, at a minimum, that a defendant act in deliberate ignorance or reckless disregard as to the truth of a claim,

---

[68] *See* Richard Hughes, *With a Worthless Services Hammer, Everything Looks Like a Nail: Litigating Quality of Care Under the False Claims Act*, 37 J. LEG. MED. 65, 83 (2017); Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1118 (9th Cir. 2020) (holding that "falsity is a necessary, but not sufficient, requirement for FCA liability. . . a plaintiff must still establish scienter").

[69] *See* United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[I]t is impossible to meaningfully discuss falsity without implicating the knowledge requirement."); United States *ex rel.* Phalp v. Lincare Holdings, Inc., 116 F. Supp. 3d 1326, 1360 (S.D. Fla. 2015) ("As a practical matter, the falsity analysis is intertwined with the scienter analysis.").

[70] *See Care Alts.*, 952 F.3d at 96 (concluding that evidence indicating a doctor knowingly made a false determination applies to scienter).

[71] An opinion expressly affirms that "the speaker actually holds the stated belief." Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 184 (2015). An opinion is both a statement of "the fact of the belief [and] the existing state of mind . . . of the one who asserts it." *Id.* (quoting W. KEETON, D. DOBBS. R. KEETON, & D. OWEN, PROSSER AND KEETON ON THE LAW OR TORTS § 109 (5th ed. 1984)).

[72] *Care Alts.*, 952 F.3d at 96 ("Combining the two elements into 'falsity' reads the scienter element out of the text of the statute.").

[73] In *United States ex rel. Jones v. Brigham and Women's Hospital*, a relator brought a *qui tam* FCA action against the defendants for submitting a grant application based on allegedly falsified data. 678 F.3d 72, 75 (1st Cir. 2012). The court analyzed the issue of whether the scientific methods used to produce the data were reliable under falsity. *Id.* at 85–92. Meanwhile, the court analyzed the issue of whether the defendant "knowingly created falsified data" under scienter. *Id.* at 95–96; *see also* United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 659–60 (5th Cir. 2017) (reviewing evidence of the accuracy of an engineering judgment under falsity and evidence of whether that judgment was honestly held under scienter).

the scienter element is often viewed as a limit to liability.[74] Congress intentionally drafted the FCA with a knowledge requirement to exclude "[i]nnocent mistakes, mere negligent misrepresentations and differences in interpretation."[75] As the Third Circuit in *Care Alternatives* explained, "[s]cienter helps to limit the possibility that hospice providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis."[76] Consequently, physicians would be subject to an unreasonable, increased risk of liability should the two requirements become indistinguishable and knowledge were folded into falsity.[77]

IV. DIFFERENT DIRECTIONS AND VARYING FALSITY STANDARDS

Part IV proceeds in five sections: Section A will discuss the Eleventh Circuit's holding in *United States v. AseraCare* and its articulation of the objective falsehood standard; Section B will summarize the Third Circuit's rejection of the objective falsehood standard in *United States ex rel. Druding v. Care Alternatives* and the court's grounds for departing from the Eleventh Circuit; Section C will discuss the Ninth Circuit's holding in *Winter ex rel. United States v. Gardens Regional Hospital & Medical Center* where the court joined the Third Circuit in rejecting the objective falsity standard; and finally, Section D will discuss *United States v. Mesquias* where the Fifth Circuit—

---

[74] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 192 (2016) ("[C]oncerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the [FCA's] materiality and scienter requirements.'") (quoting United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1270 (D.C. Cir. 2010)); *Care Alts.*, 952 F.3d at 100 (holding that falsity and scienter must be separate findings and describing the distinction between the two as "[m]ore than a formality").

[75] United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1267 (9th Cir. 1996); *see also* CONG. GLOBE, 37th CONG., 3d Sess. 955 (1863) (statement of Sen. Howard) (In explaining the motivation for enacting the FCA, Senator Howard stated, "our Treasury is plundered from day to day by bands of conspirators, who are knotted together in this city and other large cities for the purpose of defrauding and plundering the Government").

[76] *Care Alts.*, 952 F.3d at 96. A knowledge requirement also aligns with the purpose of the FCA in targeting fraud, which implies some degree of conscious wrongdoing. *See* United States *ex rel.* Lamers v. City of Green Bay, 998 F. Supp. 971, 986 (E.D. Wis. 1998) ("[T]he whole purpose behind the FCA . . . is to combat fraud on the government, not scrutinize statements for facial inaccuracies.").

[77] *See Lamers*, 998 F. Supp. at 986–87 ("[S]tatements or claims which are 'false' within the meaning of the FCA must be more than objectively untrue—they must betray or suggest intentional deceit.").

the most recent appellate court to address the issue—criticized the objective falsity standard.

A. *The Eleventh Circuit Holds that the FCA's Falsity Element Requires Objective Falsity*

In *United States v. AseraCare*, three former employees filed a *qui tam* action against AseraCare, alleging that the hospice care provider had a practice of knowingly submitting false claims to Medicare in violation of the FCA.[78] The government chose to intervene in the case and argued that AseraCare submitted claims falsely representing that patients qualified for hospice care when, in the government's view, they were not eligible.[79] The government's expert took a sample of 123 AseraCare patients and testified that the patients' medical records did not support terminal illness certifications.[80] The government claimed that since the patients were not terminally ill, AseraCare falsely certified them as eligible for the Medicare hospice benefit.[81] In a true battle of the experts, AseraCare's expert—upon examining the same medical documentation and considering the same medical standards for end-of-life determinations—determined that the patients were terminally ill, meaning that the hospice certifications were proper.[82] Notably, however, the government's expert conceded that he could not say that AseraCare's expert, in reaching the opposite conclusion, "was necessarily wrong."[83]

Concluding that the falsity element cannot be satisfied based solely on a difference in clinical opinion, the Eleventh Circuit held that the FCA requires proof of an objective falsehood.[84] In holding that a mere difference of reasonable opinion between experts reviewing medical records ex post is insufficient for proof of falsity, the court

---

[78] 938 F.3d 1278, 1284 (11th Cir. 2019).

[79] *Id.* For a hospice claim to be eligible for Medicare reimbursement, a patient's physician and the medical director of the hospice provider must "each certify in writing at the beginning of the period, that the individual is terminally ill . . . based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." 42 U.S.C. § 1395f(a)(7)(A)(i)(II).

[80] *AseraCare*, 938 F.3d at 1287.

[81] *Id.* at 1284.

[82] *Id.* at 1289.

[83] *Id.* at 1287 (internal quotations omitted).

[84] *Id.* at 1296–97. Additionally, the Eleventh Circuit affirmed the district court's grant of a new trial but vacated the district court's post-verdict grant of summary judgment to AseraCare because the district court failed to consider the matter based on the entirety of the evidence. *Id.* at 1305.

stated that "[a] properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong."[85] Instead, a plaintiff must prove an objective falsehood or "identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment."[86] In addition, the court listed three ways in which an objective falsehood could be shown in a case involving the hospice benefit:

> Where, for instance, a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal, his ill-formed "clinical judgment" reflects an objective falsehood. The same is true where a plaintiff proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification. A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records.[87]

The Eleventh Circuit explained that these examples represent an objective falsity because in each, "the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."[88]

In holding that the FCA's falsity element requires proof of an objective falsehood, the Eleventh Circuit aligned itself with earlier Fourth and Seventh Circuit holdings recognizing the objective falsity standard[89] and renewed the debate on the correct FCA falsity standard.

B. *The Third Circuit Rejects the Objective Falsity Standard*

Shortly after the Eleventh Circuit decided *AseraCare*, the Third Circuit considered a case on similar facts as *AseraCare* and rejected the objective falsity standard in *United States ex rel. Druding v. Care*

---

[85] *Id.* at 1297.

[86] *AseraCare*, 938 F.3d at 1297.

[87] *Id.*

[88] *Id.*

[89] United States *ex rel.* Yannacopoulos v. Gen. Dynamics, 652 F.3d 818, 836 (7th Cir. 2011) (holding that "[a] statement may be deemed 'false' for purposes of the False Claims Act only if the statement represents 'an objective falsehood.'"); United States *ex rel.* Wilson v. Kellogg Brown & Roots, Inc., 525 F.3d 370, 376–77 (4th Cir. 2008) (holding that "[t]o satisfy this first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood").

Alternatives.[90] In *Care Alternatives*, former Care Alternatives employees brought suit under the *qui tam* provision of the FCA against the hospice provider for submitting false Medicare and Medicaid hospice-reimbursement claims.[91] As in *AseraCare*, the relators' expert testified that the accompanying medical documentation did not support hospice certification for a majority of the patients sampled, while Care Alternatives' expert, in reviewing the same sample of forty-seven patients, arrived at the opposite conclusion.[92] Care Alternatives' expert determined that the patients were correctly diagnosed as terminally ill and that therefore, each hospice certification was appropriate.[93] Unlike the government's expert in *AseraCare*, the relators' expert here did not concede that the other expert could be correct; instead, the relators' expert testified that "any reasonable physician would have reached the conclusion he reached."[94] Relying on *AseraCare*, the district court granted summary judgment to Care Alternatives on the basis that the relators failed to identify sufficient evidence of an objective falsity.[95]

Finding that the objective falsity standard is at odds with the court's interpretation of falsity, the Third Circuit explicitly denounced the district court's reliance on *AseraCare*.[96] In rejecting the objective falsity standard, the Third Circuit held that a "mere difference of opinion" is sufficient to demonstrate falsity.[97] The court concluded that a physician's expert testimony contradicting a hospice certification is enough to create a triable issue concerning falsity.[98]

The court disagreed with the Eleventh Circuit and rejected the objective falsity standard for three main reasons.[99] First, according to the Third Circuit, the objective falsity standard improperly conflates the FCA's falsity and scienter elements.[100] Second, the Third Circuit determined that the objective falsity standard creates a bright-line rule

---

[90] 952 F.3d 89, 89, 100 (3d Cir. 2020).

[91] *Id.* at 93. In *Care Alternatives*, the government declined to intervene, so the relators proceeded to trial. *Id.*

[92] *Id.* at 94.

[93] *Id.*

[94] *Id.*

[95] Druding v. Care Alts., Inc., 346 F. Supp. 3d 669, 687–89 (D.N.J. 2018).

[96] *Care Alts.*, 952 F.3d at 96.

[97] *Id.* at 95.

[98] *Id.*

[99] *Id.* at 96–100.

[100] *Id.* at 96.

that medical opinions can never be false, which the court reasoned could not be true because a physician's opinion may be false and, in any case, the reliability of expert testimony is "exclusively for the jury to decide."[101] And third, the Third Circuit concluded that the objective falsity standard limits FCA liability to factual falsities, in contradiction with the Third Circuit's interpretation of falsity, which includes non-compliance with regulatory instructions.[102] Concluding that the testimony of the relators' expert created a triable issue of fact for a jury, the Third Circuit reversed the district court's grant of summary judgment to Care Alternatives and remanded the case.[103]

C. *The Ninth Circuit Seemingly Sides with the Third in Rejecting the Objective Falsity Standard*

In the same month as the Third Circuit decided *Care Alternatives*, the Ninth Circuit rejected the objective falsity standard in *Winter ex rel. United States v. Gardens Regional Hospital & Medical Center*.[104] Unlike *AseraCare* and *Care Alternatives*, *Winter* did not involve an alleged false claim submitted for hospice care.[105] In *Winter*, a former hospital director brought a *qui tam* action against Gardens Regional Hospital for, *inter alia*, filing false claims certifying that inpatient hospitalizations were medically necessary.[106] Winter's complaint alleged in extensive detail how sixty-five patient admissions were fraudulently billed to Medicare.[107]

Following the Third Circuit, the court held that a plaintiff asserting an FCA claim does not need to plead an objective falsehood because a physician's judgment "can be false or fraudulent for the same reasons as any other opinion."[108] The court ultimately found that Winter pleaded sufficient allegations of falsity to survive a motion to dismiss.[109] According to the court, Winter was able to demonstrate "more than just a reasonable difference of opinion."[110] In addition to her contention that the hospital admissions were false because they

---

[101] *Id.* at 98.

[102] *Care Alts.*, 952 F.3d at 99–100.

[103] *Id.* at 101.

[104] 953 F.3d 1108, 1119 (9th Cir. 2020).

[105] *Id.* at 1112.

[106] *Id.*

[107] *Id.* at 1120.

[108] *Id.* at 1119.

[109] *Id.* at 1121.

[110] *Winter*, 953 F.3d at 1120.

were not medically necessary, Winter also alleged that "a number of the hospital admissions were for diagnoses that had been disproven by laboratory tests, and that several admissions were for psychiatric treatment, even though Gardens Regional was not a psychiatric hospital—and one of those patients never even saw a psychiatrist."[111] The court also found it relevant that the hospital admissions in question failed to satisfy even the hospital's own admissions criteria and that it was Winter's job to review patients' medical records and apply the admissions criteria to evaluate medical necessity.[112] Intriguingly, although the court rejected the objective falsehood standard, like the Third Circuit in *Care Alternatives*, the Ninth Circuit concluded that its decision did not conflict with the Eleventh Circuit's holding in *AseraCare*.[113]

The parties in *Care Alternatives* and *Winter* petitioned for certiorari.[114] In February 2021, the Supreme Court declined the opportunity to review the falsity standard under the FCA by denying certiorari in both cases.[115]

D. *The Fifth Circuit Provides Criticism of the Objective Falsity Standard*

In March 2022, the Fifth Circuit added its weight to the circuit split and criticized the objective falsity standard in *United States v. Mesquias*.[116] In yet another case involving the Medicare hospice benefit, the Fifth Circuit discussed the merits of the objective falsity theory.[117] In *Mesquias*, the Fifth Circuit affirmed the jury's convictions of the defendants based on the court's finding that the jury had sufficient evidence on which to base their guilty verdicts.[118] The court found that there was "[o]verwhelming evidence" that the defendants, who owned and operated the Merida Group, had facilitated a scheme that falsely certified patients for home health and hospice services.[119]

---

[111] *Id.* at 1120–21.

[112] *Id.* at 1115, 1120.

[113] *Id.* at 1119.

[114] Petition for Writ of Certiorari, Care Alts. v. United States *ex rel.* Druding, No. 20-371 (Sept. 16, 2020); Petition for Writ of Certiorari, RollinsNelson LTC Corp. v. United States *ex rel.* Winter, No. 20-805 (Dec. 3, 2020).

[115] Care Alts. v. United States, 141 S. Ct. 1371 (2021); RollinsNelson LTC Corp. v. United States *ex rel.* Winter, 141 S. Ct. 1380 (2021).

[116] 29 F.4th 276, 282 (5th Cir. 2022).

[117] *Id.* 282–83.

[118] *Id.* at 283.

[119] *Id.* at 280.

The court found that part of their scheme involved building a roster of in-house medical physicians who would routinely lie that they had seen patients face-to-face, exaggerate their patients' diagnoses, and even fabricate diagnoses or medical records in order to certify them for hospice care.[120] The court found that the Merida Group certified "all patients who came to their facilities, regardless of eligibility" and that, as a result, approximately 70 to 85 percent of their patients were ineligible for hospice care despite being certified for those services.[121]

Although the Fifth Circuit did not outright reject the objective falsity standard, the court provided several reasons as to why, in its view, the objective falsity standard runs contrary to "[c]ommon sense."[122] In rejecting the defendants' argument that the court should adopt the objective falsity standard, the court stated, "health care providers cannot immunize themselves from prosecution by cloaking fraud with a doctor's note."[123] The court also criticized the objective falsity standard for being a categorical evidentiary requirement that is at odds with a "jury's ability to consider a broad array of direct and circumstantial evidence."[124]

Interestingly, the court distinguished *AseraCare*, finding that in that case, "there was no evidence of fraud beyond (1) after-the-fact expert testimony that the initial determinations of hospice eligibility were inaccurate, and (2) unrelated anecdotes of lax business practices."[125] The court stated that the Eleventh Circuit "recognized that stronger evidence, like facts inconsistent with doctors' proper exercise of their clinical judgment, could change the outcome."[126] And that here, according to the Fifth Circuit, there was that "stronger evidence," namely proof of "lies, kickbacks, and fabrication."[127] Filed on June 17, 2022, Mesquias petitioned the Supreme Court for a writ of

---

[120] *Id.* According to the court, the defendants would also intimidate employees and physicians who questioned their scheme. *Id.* For example, one medical director was fired for refusing to refer patients to hospice. *Id.*

[121] *Id.* at 280.

[122] *Mesquias*, 29 F.4th at 282–83.

[123] *Id.*

[124] *Id.*

[125] *Id.* at 282.

[126] *Id.*

[127] *Id.*

certiorari.[128] The high court denied Mesquias's petition on October 3, 2022.[129]

V. THE SUBJECTIVITY OF MEDICAL OPINIONS REQUIRES AN OBJECTIVE STANDARD

Some circuits have inaccurately framed the falsity dispute as a debate over whether medical opinions can be false, with those courts claiming that the objective falsity standard proposes a prohibition on any scrutiny of medical opinions.[130] Rather, the objective falsity standard, in conformance with the Supreme Court precedent laid out in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*,[131] instructs that a subjective medical opinion can be false if it is unreasonable, either because it is not a fair presentation of the facts on which the opinion was formed or no reasonable physician would have arrived at the same conclusion. The objective falsity standard recognizes that a subsequent, conflicting medical opinion does not necessarily render the original clinical judgment false if the inconsistency reflects a reasonable difference in opinion. This Part discusses how the objective falsity standard properly affords medical opinions deference when they involve subjective clinical judgments and how this standard properly corresponds with Supreme Court precedent and CMS guidance recognizing the subjectivity of medical opinions.

A. *The Falsity of Medical Opinions Post-Omnicare*

To set the stage, *Omnicare* was not a case addressing medical opinions.[132] It was not even a case in which the FCA was implicated.[133] Yet the courts in *AseraCare*, *Care Alternatives*, and *Winter* each attempted to apply the Supreme Court's reasoning in *Omnicare* in reaching their

---

[128] Petition for Writ of Certiorari, Mesquias v. United States, No. 22-5168 (June 17, 2022).

[129] *See* Mesquias v. United States, No. 22-5168, 2022 WL 4656410 (Oct. 3, 2022).

[130] *See* Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1113 (9th Cir. 2020) ("[T]he Eleventh Circuit was not asked whether a medical opinion could ever be false or fraudulent, but whether a reasonable disagreement between physicians, *without more*, was sufficient to prove falsity" (emphasis in original)); *see, e.g.*, United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 98 (3d Cir. 2020) (rejecting the objective falsehood standard for creating a "bright-line rule that a doctor's clinical judgment cannot be 'false'").

[131] 575 U.S. 175, 180 (2015).

[132] *Id.* at 178–79.

[133] *Id.*

respective, conflicting holdings.[134] In *Omnicare*, pension funds that had purchased Omnicare stock alleged that Omnicare violated Section 11 of the Securities Act of 1933 by making materially false representations in their company's registration statements.[135] Determining that the opinions Omnicare expressed in its registration statements were based on subjective assessments, the Supreme Court held that an "opinion is not an 'untrue statement of material fact,'" even if that opinion can ultimately be proven wrong.[136] The Supreme Court found that, in accordance with other common law sources,[137] an opinion could only be false if the holder of the opinion does not truly hold the stated opinion, knows facts that would make the opinion false, or omits material facts that would not "fairly align[] with the information in the issuer's possession at the time."[138]

Based on *Omnicare*, the Eleventh Circuit in *AseraCare* developed a similar rule, holding that medical opinions could not be false if "properly formed and sincerely held."[139] Under the *AseraCare* test, a medical opinion is "properly formed" as long as a physician, in forming an opinion, was informed as to a patient's medical records;[140] and an opinion is "sincerely held" if the physician subjectively believed in that

---

[134] United States v. AseraCare, Inc., 938 F.3d 1278, 1287, 1302 (11th Cir. 2019); United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 95 (3d Cir. 2020); Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1117 (9th Cir. 2020). In *Universal Health Servs., Inc. v. United States ex rel. Escobar*, the Supreme Court held that since Congress did not define a "false claim" in the FCA, Congress intended to incorporate common-law meanings of falsity. 579 U.S. 176, 187 (2016) (quoting Sekhar v. United States, 570 U.S. 729, 732 (2013) ("[I]t is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses.").

[135] *Omnicare*, 575 U.S. at 180. The Securities Act of 1933 requires companies offering securities to file registration statements containing specific disclosures about the company and the security. *Id.* at 178.

[136] *Id.* at 186.

[137] *Id.* at 191 n.10 (quoting RESTATEMENT (SECOND) OF CONTRACTS § 168 (AM. L. INST. 1979)) ("'[A] statement of opinion as to facts not disclosed and not otherwise known to the recipient may . . . be interpreted by him as an implied statement . . . (a) that the facts known to that person are not incompatible with his opinion; or (b) that he knows facts sufficient to justify him in forming it.'"). An opinion "is reasonably understood as implying that there are facts that justify the opinion or at least that there are no facts that are incompatible with it." RESTATEMENT (SECOND) OF TORTS § 539 cmt.a (AM. L. INST. 1976).

[138] *Omnicare*, 575 U.S. at 188–89.

[139] *AseraCare*, 938 F.3d at 1296–97.

[140] *See id.* at 1297.

opinion.[141] To a great extent, how a doctor arrived at a medical opinion matters in the falsity inquiry, but process alone does not determine the falsity of an opinion. A doctor can follow the correct process in developing a medical opinion and still arrive at an unreasonable conclusion.[142]

In spite of the Third Circuit's criticism, the objective falsity standard does not create a bright-line rule that a physician's opinion can never be false.[143] Medical opinions are subject to the "properly formed and sincerely held" requirement, but the Eleventh Circuit also explained that a physician's opinion could be false "when expert evidence proves that no reasonable physician" could have reached the same conclusion.[144] Therefore, the objective falsity standard does not blindly shield medical opinions from scrutiny by virtue of their classification as opinions. As the Supreme Court in *Omnicare* explained, opinions must still be based on verifiable facts.[145]

---

[141] *Id.*

[142] In *United States v. Prabhu*, the government alleged, *inter alia*, that the defendant failed to properly document the medical necessity of services he provided to some patients. 442 F. Supp. 2d 1008, 1011 (D. Nev. 2006). The court held that the documentation of the claims was not false "because his documentation practices would fall within the range of reasonable medical and scientific judgment regarding how to document medical necessity of pulmonary rehabilitation services." *Id.* at 1032. The court continued:

> To establish falsity under the FCA, it is not sufficient to demonstrate that the person's practices could have or should have been better. Instead, plaintiff must demonstrate that an objective gap exists between what the Defendant represented and what the Defendant would have stated had the Defendant told the truth.

Id. at 1032–33.

[143] *AseraCare*, 938 F.3d at 1297 (holding that medical judgments are not safe from scrutiny when there are "facts and circumstances . . . that are inconsistent with the proper exercise of a physician's clinical judgment"). *But see* United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 98 (3d Cir. 2020) (concluding that the district court, in applying the objective falsity standard, decided that medical judgments cannot be false).

[144] *AseraCare*, 938 F.3d at 1297.

[145] Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 186, 188 ("In the context of the securities market, an investor, though recognizing that legal opinions can prove wrong in the end, still likely expects such an assertion to rest on some meaningful legal inquiry—rather than, say, on mere intuition, however sincere."); *see also* United States v. Paulus, 894 F.3d 267, 275 (6th Cir. 2018) ("[O]pinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion.").

The objective falsity standard in *AseraCare* recognizes that opinions are often reached through a weighing of facts.[146] In *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Supreme Court held that certain misrepresentations could be actionable under the FCA if they are half-truths or representations that only state a fraction of the truth, "while omitting critical qualifying information."[147] Thus, different interpretations are not necessarily false so long as an opinion is a fair presentation of the facts on which the opinion is formed.[148] Like the Court in *Omnicare*, the Eleventh Circuit in *AseraCare* also noted that it would be unreasonable to base falsity on an expert with a mere difference of opinion reviewing a claim ex post.[149] At the time FCA litigation occurs, experts are often reviewing medical records months—or more likely years—after the fact.

To reiterate again, the *Omnicare* rule was formulated in the context of securities.[150] Admittedly, securities statements and medical opinions are not a perfect analogy. The Supreme Court in *Omnicare* characterized securities statements as "inherently subjective and uncertain assessments."[151] On the contrary, some medical opinions may simply not be up for debate.[152] Some medical opinions may be more objective than others, that it would be unreasonable for another doctor to disagree.[153] For example, in *United States v. Paulus*, a cardiologist was criminally convicted for health care fraud for performing unnecessary coronary stent procedures.[154] In *Paulus*, the government produced substantial expert testimony demonstrating

---

[146] *Omnicare*, 575 U.S. at 189–90.

[147] 579 U.S. 176, 188 (2016).

[148] *Omnicare*, 575 U.S. at 189–90; *see also* United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[E]rrors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA.").

[149] *See AseraCare*, 938 F.3d at 1297. In holding that a statement of genuine opinion is not false, even if the opinion can ultimately be proven wrong, the Supreme Court in *Omnicare* concluded that enforcement of the Securities Act is not "an invitation to Monday morning quarterback an issuer's opinions." *Omnicare*, 575 U.S. at 186.

[150] *Omnicare*, 575 U.S. at 186.

[151] *Id.*

[152] *See* United States v. Paulus, 894 F.3d 267, 274 (6th Cir. 2018) (concluding that although there is some subjectivity in reading x-ray results, a doctor's interpretation of x-ray results was unreasonable).

[153] *See id.*

[154] *Id.* at 272.

that Dr. Paulus "systematically exaggerated" the level of coronary blockage in his interpretation of angiograms in order to perform unnecessary stent procedures.[155] Instead of challenging the accuracy of the experts' angiogram interpretations, Dr. Paulus argued that there was a large range of accepted interpretations of angiograms.[156] The court disagreed, finding that "coronary artery blockage exists as 'an aspect of reality,'" meaning that a physician's opinion as to the level of coronary blockage could be objectively true or false.[157] Although it cannot be said that all medical opinions will involve "inherently subjective" assessments like securities may, the *Omnicare* principle is completely relevant when clinical decisions call for opinions that fall short of objective.[158]

The Third Circuit in *Care Alternatives* also rejected the objective falsity standard on the ground that it limited FCA falsity to factual falsity.[159] According to the Third Circuit, under the objective falsity standard, a medical expert's opinion is only false for purposes of FCA liability if it can be shown that the opinion is factually inaccurate.[160] By requiring something more than just a reasonable difference in medical

---

[155] *Id.* at 273–74.

[156] At trial, the government acknowledged that there could be some variation between accepted angiogram interpretations. *Id.* at 272. For example, an accepted "inter-observer variability," or the variation between two cardiologists' angiogram interpretations, might be where one doctor records a 60 percent blockage and another, an 80 percent blockage. *Id.* The government's experts, however, certified that the accepted inter-observer variability for angiograms generally only ranged between 10 percent and 20 percent. *Id.* The government asserted that, in any case, it is rare for cardiologists to commit such a large error, as Paulus did, by recording a 40 percent blockage as a 70 percent blockage. *Id.*

[157] *Id.* at 276.

[158] *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*, 27 HEALTH L. 36, 37 (2015) ("[W]hether a specific service or treatment for a particular patient falls within accepted or community standards of medical practice is often debatable."); United States *ex rel.* Wall v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 U.S. Dist. LEXIS 80160, at *55 (N.D. Tex. Jun. 20, 2016) ("[A]n FCA claim about the exercise of [clinical] judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis.").

[159] United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 96 (3d Cir. 2020).

[160] *Id.* at 97. Under legal falsity, medical necessity is a material regulatory requirement in certifying Medicare and Medicaid claims. It would, however, be an arduous task to prove a procedure was not medically necessary without necessarily involving some factual findings. The Third Circuit acknowledges that "legal falsity necessarily encompasses situations of factual falsity." *Id.* at 96.

opinion to demonstrate falsity, the objective falsity standard does not limit falsity to the accuracy of a physician's judgment; rather, the objective falsity standard seeks to avoid having courts decide the accuracy of medical opinions.

In *AseraCare*, the government's own expert conceded that he could not testify that AseraCare's expert was "necessarily wrong."[161] The government's expert also testified that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong."[162] Given the admission of the government's expert that two doctors in this context could disagree and neither would be false, it is clear that the hospice determination in *AseraCare* falls under the degree of subjectivity that *Omnicare* would directly apply to. Even if an expert cannot make the concession that the other expert may be correct, an opinion would not be wrong merely because another expert disagrees. When an expert testifies that any reasonable physician would have arrived at the same conclusion as he did, as was the case in *Care Alternatives*, this would be nothing more than a bare assertion of falsity and, without more, is insufficient to demonstrate that the original medical opinion was wrong.

Especially in an area as subjective as end-of-life determinations, where the only evidence of falsity is a contradictory after-the-fact opinion, this discrepancy is more indicative of a reasonable difference in medical opinion. A reasonable disagreement between two experts does not by itself prove that an opinion is untrue.[163] Thus, in a subjective area of medicine, an opinion is not false if two physicians can reasonably disagree. Furthermore, the FCA is not an opportunity for courts and other doctors to second-guess or "Monday morning quarterback" the reasonable clinical judgments of physicians after the fact, when some patients may have died or litigation has been drawn out over the course of years.[164] The objective falsity standard is cognizant of the subjectivity permitted in some clinical judgments and

---

[161] United States v. AseraCare, 938 F.3d 1278, 1287 (11th Cir. 2019).

[162] *Id.* at 1296.

[163] *See id.*; United States *ex rel.* Jones v. Brigham & Women's Hosp., 678 F.3d 72, 87 (1st Cir. 2012) (citing United States *ex rel.* Roby v. Boeing Co., 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000)) ("[E]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.").

[164] *See* Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 186 (2015)

recognizes that ex post scrutiny may come with the benefit of hindsight.

B. *More Than "Just a Reasonable Difference" in Opinion*

Like the Third Circuit in *Care Alternatives*, the Ninth Circuit similarly rejected the objective falsity standard in *Winter*.[165] Despite this, the Ninth Circuit inexplicably found that its decision did not conflict with *AseraCare*.[166] The Ninth Circuit, unlike the Third, recognized that the Eleventh Circuit did not conclude that all medical opinions were incapable of falsity.[167] Then, however, the Ninth Circuit reasoned that the Eleventh Circuit excluded cases of medical necessity from its objective falsity requirement and, thus, concluded that *AseraCare* did not apply to *Winter*—a medical necessity case.[168] In *AseraCare*, the Eleventh Circuit distinguished a medical necessity case, but it did not imply that its holding was limited to hospice cases.[169]

Although the Ninth Circuit purported to reject the objective falsity standard, the court could not find that its holding conflicted with *AseraCare*, likely because the court decided *Winter* based on many of the same reasons as the Eleventh Circuit articulated in support of the objective falsity standard. The facts in *Winter* differed from *AseraCare* in several significant ways. Unlike *AseraCare*, the relator in *Winter* was able to "allege[] more than just a reasonable difference of opinion" between experts to demonstrate falsity.[170] First, Winter's job was to review hospital admissions using the hospital's admissions

---

[165] Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1119 (9th Cir. 2020).

[166] *Id.* at 1118–19.

[167] *Id.* at 1119.

[168] *Id.*

[169] United States v. AseraCare, Inc., 938 F.3d 1278, 1300–01 n.15 (11th Cir. 2019) (distinguishing United States *ex rel.* Polukoff v. St. Mark's Hosp., 895 F.3d 730 (10th Cir. 2018)). Finding *Polukoff* distinguishable on the facts, the Eleventh Circuit explained that its present case differed because the hospice-benefit provision at issue "looks to whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion as to a patient's likely longevity." *Id.* The court concluded that the Tenth Circuit in *Polukoff* found a plausible allegation of falsity concerning whether a procedure was medically necessary because "there is agreement in the medical community that a PFO closure is not medically necessary" except in certain circumstances that were not invoked in the case. *Id.* The Eleventh Circuit distinguished *Polukoff* because *Polukoff* indicated that the reasonableness and necessity of a PFO closure could be objectively true or false, unlike the more subjective determination of hospice care certification. *See id.*

[170] *See Winter*, 953 F.3d at 1120.

criteria, and not only did she allege that the hospital admissions were not medically necessary, but she contended that they could not even satisfy the hospital's own qualifications for admission.[171] In addition, the relator identified patients who were admitted for supposed diagnoses that had been disproven by laboratory tests and patients who were admitted for psychiatric treatment when the hospital did not provide psychiatric services.[172] It was these additional facts, aside from Winter's competing opinion that the hospital admissions were medically unnecessary, that led the Ninth Circuit to conclude that she alleged a sufficient inference of falsity at the pleading stage.[173]

Although the Fifth Circuit criticized the objective falsity standard, like the Third Circuit, it seemed to decide *Mesquias* based on many of the reasons that the Eleventh Circuit used to adopt the objective falsity standard. Like the relator in *Winter*, the government in *Mesquias* was able to point to a significant amount of evidence demonstrating that the claims were objectively false.[174] As the Fifth Circuit pointed out, the government was able to bolster its case with "stronger evidence" than just a conflicting medical opinion to prove falsity.[175] The defendants had developed a scheme whereby they would falsely certify patients for hospice services reimbursable by Medicare.[176] Medicare requires that patients must be suffering from a terminable illness and expected to die within six months to be eligible; not only was this not the case for the patients that the defendants certified for hospice, but patients "were walking, driving, working, and even coaching athletic sporting events in some instances."[177]

By contrast, the outcome in *Care Alternatives* was the exact result the Eleventh Circuit in *AseraCare* attempted to avoid by adopting the objective falsehood standard: a finding of falsity based solely on the

---

[171] *Id.* at 1114–16. The fact that the inpatient admissions did not satisfy the hospital's criteria does not by itself demonstrate that the claims were false, but the court considered this information because it was relevant to whether the admissions were reasonable and necessary. *Id.*

[172] *Id.* at 1120–21.

[173] *Id.*

[174] United States v. Mesquias, 29 F.4th 276, 281–83 (5th Cir. 2022).

[175] *Id.* at 282.

[176] *Id.* at 280.

[177] Press Release, U.S. Dep't of Just., Owner of Texas Chain of Hospice Companies Sentenced for $150 Million Health Care Fraud and Money Laundering Scheme (Dec. 16, 2020), https://www.justice.gov/usao-sdtx/pr/owner-texas-chain-hospice-companies-sentenced-150-million-health-care-fraud-and-money.

conflicting opinion of a plaintiff's expert.[178] To be clear, the Third Circuit precisely held that a conflicting expert opinion "creates a triable issue of fact for the jury regarding falsity," but in doing so, the court rejected the objective falsity standard completely.[179] When falsity is lacking because a plaintiff has claimed nothing more than the existence of a reasonable disagreement between medical experts, a case should not proceed past summary judgment. In *Omnicare*, the Supreme Court recognized that some opinions should be afforded deference to avoid creating excessive liability in areas of unpredictable circumstances and events. In the context of medicine, this effect is only intensified when some subjective medical opinions cannot be neatly judged as correct or incorrect.

C. *CMS Anticipates Subjectivity in Medical Judgments*

Although clinical judgments are based in medical science, it is not reasonable to conclude that a medical opinion is false merely because one physician is willing to contradict another. CMS has acknowledged that "making a prognosis is not an exact science."[180] Specifically, CMS recognizes that certain medical judgments are more subjective than others, like determining life expectancy for the Medicare hospice benefit.[181] As a result, CMS entrusts that certifying physicians—and not experts reviewing medical records ex post—are the most qualified when it comes to determining whether patients should have been certified for hospice care: "We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill."[182] When submitting a claim, CMS asks only that medical records support, as opposed to conclusively prove, the certifying physician's opinion.[183] Like CMS, the Supreme Court's holding in *Omnicare* recognizes, and allows for, the subjectivity that physicians should be afforded in

---

[178] United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 101 (3d Cir. 2020).

[179] *Id.*

[180] 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014).

[181] *Id.* ("[M]aking medical prognostications regarding life expectancy is not exact.").

[182] 78 Fed. Reg. at 48,234, 48,247 (Aug. 7, 2013).

[183] 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014) ("A hospice is required to make certain that the physician's clinical judgment can be supported by clinical information and other documentation"); *see also* 42 C.F.R. § 418.22 (2011). (The regulations only require that "[c]linical information and other documentation that support the medical prognosis . . . accompany the certification" and "be filed in the medical record").

forming clinical judgments. After all, the FCA "is concerned with ferreting out 'wrongdoing,' not scientific errors."[184]

D. *Implications of Establishing an Objective Falsity Standard for FCA Claims*

Courts should adopt the objective falsity standard so that physicians, in the course of treating patients and having to adapt to their patients' changing circumstances in real-time, do not have to be concerned that their reasonable clinical judgments in a highly unpredictable and subjective area of medicine will later be deemed false. As CMS recognizes, medicine is not always "an exact science."[185] For certain areas of medicine, like hospice and end-of-life determinations, the validity of a medical opinion may be judged on a spectrum of reasonableness: "[t]he decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients."[186] There will, however, be some medical judgments that are completely outside the realm of reasonableness, and those opinions would be objectively false.[187] Likewise, there may be medical opinions which differ and contradict one another but are not necessarily false or unreasonable—these reasonable differences in subjective medical opinions cannot be objectively false.[188] Especially in medical-necessity based fraud cases, where liability turns on the ex post "correctness" of a physician's opinion, the impreciseness of medical science should be accounted for in defining a falsity standard that respects the role of physicians.

---

[184] Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992); *see also* United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[E]rrors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA.").

[185] 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014).

[186] United States *ex rel.* Bennett v. Medtronic, Inc., 747 F. Supp. 2d 745, 777 (S.D. Tex. 2010).

[187] *See supra* note 142 and accompanying text.

[188] *See* Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 189–90 (2015).

VI. NAVIGATING THE INTERSECTION OF KNOWLEDGE AND FALSITY

Under the FCA, a plaintiff must demonstrate not only that the claims were false but that the defendant knew they were false. The falsity and knowledge elements of an FCA claim may be interrelated, but for the purposes of determining FCA liability, they are independent obligations a plaintiff must meet. Some courts have permitted the lines between these two elements to blur, but this relaxed interpretation defies the statutory language and purpose of the FCA. Although the Eleventh Circuit in *AseraCare* correctly adopted the objective falsity standard, the court impermissibly combined the separate FCA elements of falsity and scienter in its definition of falsity. This Part discusses how the FCA elements were improperly conflated in *AseraCare* and proposes an objective falsity standard that respects the distinction between falsity and scienter.

A. *Whether a Medical Opinion was "Honestly Held" Applies to Scienter*

Despite the language of the FCA indicating that the elements are separate,[189] some courts have combined the falsity and scienter inquiries.[190] Whether an opinion was "honestly held" is a relevant question in the analysis of scienter,[191] but some courts have improperly attributed this issue to falsity.[192] In *Care Alternatives*, the Third Circuit held that the FCA requires the knowledge and falsity elements to be demonstrated independently.[193] In stating its reasons for its disapproval of the Eleventh Circuit's objective falsity standard, the

---

[189] *See supra* Part II.B.

[190] *See, e.g.*, United States *ex rel.* Morton v. A Plus Benefits, Inc., 139 F. App'x 980, 982 (10th Cir. 2005) (describing the falsity and knowledge elements as "inseparable"); United States *ex rel.* Modglin v. DJO Glob. Inc., 48 F. Supp. 3d 1362, 1405 (C.D. Cal. 2014) (ruling that relators failed to plead allegations of scienter for the same reasons they failed to satisfy falsity); Winter *ex rel.* United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1120 (9th Cir. 2020) ("[W]e note that many of the allegations supporting an inference of scienter also support an inference of falsity.").

[191] *See supra* note 71 and accompanying text.

[192] *See, e.g.*, United States v. Paulus, 894 F.3d 267, 275 (6th Cir. 2018) ("[O]pinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion."); *Winter*, 953 F.3d at 1119 (holding that an opinion can be false "if the opinion is not honestly held, or if it implies the existence of facts . . . that do not exist").

[193] United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 100 (3d Cir. 2020) ("[W]e make clear that in our Court, findings of falsity and scienter must be independent from one another for purposes of FCA liability.").

Third Circuit asserted that by demanding knowledge evidence when considering falsity, the Eleventh Circuit failed to allow for full consideration of knowledge evidence and impermissibly conflated the separate elements.[194] Specifically, the Third Circuit concluded that by requiring "factual evidence that Defendant's certifying doctor was making a *knowingly* false determination" in its falsity analysis, the district court improperly attributed the issue of whether an opinion was "honestly held" to the falsity element.[195]

An FCA violation cannot exist without a false claim: "[a]n actual false claim is the *sine qua non* of an FCA violation."[196] A falsity standard, however, that combines the elements of falsity and scienter "reads the scienter element out of the text of the statute."[197] This impermissible act of conflating the separate elements can have critical and unjustified consequences for physicians. Under the FCA's scienter requirement, a defendant must act "knowingly" as to the falsity of the claims.[198] A provider acts "knowingly" if they had actual knowledge, were deliberately ignorant, or recklessly disregarded the claims' falsity.[199]

Given that a plaintiff must satisfy falsity and scienter, "there may be clinical decisions that could meet the FCA's falsity standard . . . but that would not constitute false *claims* because the clinical decisions could be negligent or even reasonable."[200] Ordinary negligence will not suffice for knowledge under the FCA.[201] Thus, the scienter element statutorily "protect[s] reasonable, and even *some unreasonable*, beliefs and submissions."[202] As a result, incorporating knowledge elements into any FCA falsity standard violates the statutory text of the Act and thwarts Congress's intent in imposing a heightened knowledge requirement.

---

[194] *Id.*

[195] *Id.* at 96 (quoting Druding v. Care Alts., Inc., 346 F. Supp. 3d 669, 688 (D.N.J. 2018)). The Third Circuit further concluded that by requiring the plaintiff to produce evidence that a physician lied to prove falsity, the district court "incorporated a scienter element into its analysis regarding falsity that was inconsistent with the text and application of the statute." *Id.*

[196] Cafasso v. Gen. Dynamics C4 Sys., 637 F.3d 1047, 1055 (9th Cir. 2011).

[197] *Care Alts.*, 952 F.3d at 96.

[198] 31 U.S.C. § 3729.

[199] § 3729(b)(1)(A)(i)–(iii).

[200] Buck, *supra* note 15, at 43 (emphasis in original).

[201] *Id.*

[202] *Id.* at 44 (emphasis added).

Although the FCA's knowledge requirement is seen as a limit to liability, since the Act does not require specific intent to defraud, and the government need not prove that a defendant had actual knowledge of a violation,[203] deliberate ignorance or reckless disregard may not be such a high threshold for prosecutors to overcome.[204] A defendant may act knowingly by intentionally falsifying claims in order to bill for services she knows were never provided—this would be a case in which falsity is more readily capable of determination. In another case, however, falsity may assume a more significant role in determining liability if, for example, the government asserts that a defendant acted in reckless disregard as to the falsity of the claims by introducing evidence of sloppy billing or general corporate practices.[205] As the Fifth Circuit in *Mesquias* noted, "stronger evidence" is needed when the only evidence of fraud is "(1) after-the-fact expert testimony . . . and (2) unrelated anecdotes of lax business practices."[206] These improper practices may subject a physician to other liability,[207] but if the claims themselves are not false, there is no actionable FCA claim.[208]

---

[203] § 3729.

[204] Buck, *supra* note 15, at 43.

[205] In *United States v. Krizek*, the government alleged that Dr. Krizek, a psychiatrist, and his wife had a billing practice whereby Mrs. Krizek would assume a fifty-minute psychotherapy session took place, unless specifically instructed otherwise by Dr. Krizek, and bill for the full fifty-minute session even if a shorter session took place. 859 F. Supp. 5, 11–12 (D.D.C. 1994). In the trial against AseraCare, the district court judge bifurcated the trial into two phases—a falsity phase and a knowledge phase—because of concerns that if the government presented knowledge evidence before falsity, it would be "unduly prejudicial" to AseraCare. United States v. AseraCare, Inc., 938 F.3d 1278, 1287 (11th Cir. 2019). The government had wanted to produce evidence against AseraCare that "some hospice patients are recruited by staffers who troll public hospitals, tour public housing complexes or ride along with Meals-on-Wheels food deliveries" to scout for patients. Bernice Yeung, *AseraCare Hospice, San Francisco-Owned Company, Accused of Medicare Fraud*, HUFFINGTON POST (Mar. 7, 2012), https://www.huffpost.com/entry/aseracare-hospice-medicare-fraud_n_1190658.

[206] United States v. Mesquias, 29 F.4th 276, 282 (5th Cir. 2022).

[207] *See False Claims Act*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., at 00:53 (Dec. 19, 2011), https://oig.hhs.gov/newsroom/oig-podcasts/false-claims-act ("When the government pursues violations of the False Claims Act, it does not target innocent billing mistakes . . . even if a provider makes an innocent billing mistake, that provider still has a duty to repay the money to the government.").

[208] *See Mesquias*, 29 F.4th at 282; *see* Corsello v. Lincare, Inc., 428 F.3d 1008, 1014 (11th Cir. 2005) ("Underlying improper practices alone are insufficient to state a claim under the False Claims Act absent allegations that a specific fraudulent claim was in fact submitted to the government."); *AseraCare*, 938 F.3d at 1287 (summarizing the district court's conclusion that "while 'pattern and practice' evidence showing

A definition of falsity then that includes the issue of whether an opinion was honestly held is problematic because it potentially allows the government to satisfy its burden of proving falsity based on the separate issue of scienter. Although falsity and scienter have a special relationship, and "common law cases involving false opinions are often accompanied by a finding related to scienter," a falsity standard must clearly define falsity as a separate element from scienter.[209] Under the FCA, evidence to support whether a medical opinion was genuinely held has no place with falsity. Since falsity and scienter are separate elements, a physician's opinion is false under the FCA only if there is an objective falsehood, meaning that a physician's subjective, clinical judgment either conflicts with "clearly known facts" or is otherwise "completely unsupportable."[210] Any falsity standard under the FCA should recognize that—for the purposes of FCA liability—falsity and scienter may be related, but they are certainly not interchangeable.

B. *Limiting AseraCare's Objective Falsity Standard to Falsity*

The *AseraCare* standard is problematic due in large part to the way in which the Eleventh Circuit defined falsity. The Eleventh Circuit defined a false opinion as one that is not "properly formed and sincerely held," but in doing so, the court impermissibly incorporated a knowledge element into the falsity inquiry.[211] As the Third Circuit in *Care Alternatives* recognized, by defining falsity as an opinion that is not "sincerely held," the Eleventh Circuit conflated the separate elements of falsity and scienter.[212] In *AseraCare*, the Eleventh Circuit also provided three examples as to how an objective falsity could be demonstrated:

> [1] Where, for instance, a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal, his ill-formed "clinical judgment" reflects an objective falsehood. [2] The same is true where a plaintiff

deficiencies in AseraCare's admission and certification procedures could help establish AseraCare's knowledge of the alleged scheme to submit false claims—the second element of the Government's case—the falsity of the claims 'cannot be inferred by reference to AseraCare's general corporate practices unrelated to specific patients'") (emphasis omitted).

[209] United States *ex rel.* Druding v. Care Alts., 952 F.3d 89, 96 (3d Cir. 2020).

[210] Buck, *supra* note 15, at 41.

[211] *AseraCare*, 938 F.3d at 1297 (holding that an opinion is not untrue if it was "properly formed and sincerely held").

[212] *Care Alts.*, 952 F.3d at 96.

> proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification. [3] A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records.[213]

The first and the third examples that the court provided appropriately address falsity. Although the first example seemingly involves indicia of knowledge, it is proper to inquire into the basis for a physician's opinion under falsity because it examines whether facts can support a physician's clinical judgment.[214] The court's second example, however, would be directly applicable to the knowledge element and should therefore not be permitted to establish the separate issue of falsity.

What a physician "subjectively believes" speaks directly to the knowledge element because it asks what a physician knew, whereas the first and third examples are aimed at falsity because they examine whether a physician's medical opinion was properly formed and reasonable. While the issue of whether a physician subjectively believed in her opinion applies to the scienter element, the falsity of a medical opinion turns on whether an opinion was properly formed and objectively reasonable for a physician to have.

A falsity standard that integrates questions pertaining to knowledge into an analysis of falsity may lead to a reckless commingling of the separate FCA elements and undermines the statutory language of the FCA, in which Congress explicitly included a knowledge element.[215] If the scienter element is supposed to operate as a defense against FCA liability,[216] then an analysis into the falsity of a reimbursement claim should not be muddled together with overt inquiries into knowledge. Permitting the analyses of falsity and scienter to collapse into one another significantly diminishes a plaintiff's evidentiary burden to prove all elements of an FCA claim.[217] And although a jury does have the ability to hear a "broad array of direct and circumstantial evidence,"[218] limited judicial resources must

---

[213] *AseraCare*, 938 F.3d at 1297.

[214] Buck, *supra* note 15, at 41.

[215] 31 U.S.C. § 3729(a)(1)(A).

[216] *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 192 (2016).

[217] *Care Alts.*, 952 F.3d at 96.

[218] United States v. Mesquias, 29 F.4th 276, 282 (5th Cir. 2022).

be properly conserved for genuinely fraudulent claims that are able to satisfy all elements of an FCA claim.[219] A falsity standard that allows one element to completely envelop the other is fundamentally flawed because it contradicts the statutory text of the Act and does not require a plaintiff to satisfy all mandatory elements of an FCA claim. Therefore, the objective falsity standard should be adopted to the extent it does not impermissibly combine the falsity and scienter inquiries.

VII. CONCLUSION

The FCA was not intended to encourage courts to scrutinize the ex post correctness of clinical judgments with a level of mathematical accuracy that even CMS rejects. The objective falsity standard recognizes that a physician's reasonable clinical judgment is not false simply because another physician can offer a contradictory opinion after the fact. Not only is the objective falsity standard aligned with Supreme Court precedent, but it would reduce physicians' concerns that their reasonable medical opinions, in highly unpredictable and subjective areas of medicine, will be second-guessed at a later point in time. Finally, although knowledge evidence has some relevance to falsity, unless a falsity standard recognizes falsity and scienter as separate elements, findings of scienter may be substituted for the obligation to demonstrate falsity. Thus, courts should take care to ensure that the four elements of an FCA claim are recognized as separate elements. Health care fraud is a serious and growing problem in the United States, and the False Claims Act has proven itself to be the government's most useful tool against this form of theft. Most men and women, however, who enter the health care field do so because they want to help others. Given the sheer power of the FCA and the government's limited resources, the FCA should be reserved for genuinely fraudulent claims. It was never the intention of Congress or the purpose of the FCA to fault physicians for expressing an honest and justifiable difference in medical opinion.

---

[219] *See* Bell Atl. Corp. v. Twombly, 550 U.S. 544, 562 (2007) (quoting Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984)) ("[A] complaint . . . must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory.") (emphasis omitted); *see also* Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").