"OBJECTIVE FALSITY" IN HEALTHCARE FRAUD AND ABUSE

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Introduction

There is currently a circuit split on the meaning of "falsity" under the False Claims Act ("FCA").2 This paper aims to demonstrate why the Supreme Court should adopt the Eleventh Circuit's objective falsity standard in which "a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion."3 The Supreme Court should adopt this theory for several reasons: (1) the courts actually seem to agree on whether a medical opinion can be deemed untrue, (2) they mainly disagree on the purpose of the documentation requirements and its effect on a falsity determination, (3) the Eleventh Circuit's analysis is superior because the Supreme Court has explicitly held the FCA is not there to punish garden-variety regulatory infractions,4 and (4) the presence of uncertainty in medical sciences.5

I. FALSE CLAIMS ACT

The civil FCA is located at 31 U.S.C. § 3729 through §3733.6 This statute aims to protect the "Government from being overcharged or sold shoddy goods or services."7 "[N]o specific intent to defraud is required," thus "knowing" under the statute includes "not only actual knowledge" but also "deliberate ignorance or reckless disregard of the truth or falsity of the information."8 Additionally, there is a criminal FCA located at 18 U.S.C. § 287.9 Under this statute, criminal penalties for false claim submissions include fines and imprisonment for a period of up to five years.10

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² Foley Hoag LLP, 'Objective Falsity' and the FCA: An Ongoing Circuit Split, JD SUPRA (Mar. 15, 2021), https://www.jdsupra.com/legalnews/objective-falsity-and-the-fca-an-2164689/ [https://perma.cc/7CTM-DDKW].

³ Id.; United States v. AseraCare, Inc., 938 F.3d 1278, 1281 (11th Cir. 2019); United States v. AseraCare Inc., 176 F. Supp. 3d 1282, 1286 (N.D. Ala. 2016).

⁴ Universal Health Servs., Inc. v. United States, 579 U.S. 176, 194 (2016).

⁵ Mark A. Hall, David Orentlicher, Mary Anne Bobinski, Nicholas Bagley, & I. Glenn Cohen, Medical Liability and Treatment Relationships 363–64 (4th ed. 2018).

⁶ False Claims Act, 31 U.S.C. §§ 3729–3733.

⁷ Fraud & Abuse Laws, OFF. OF INSPECTOR GEN. U.S. DEP'T OF HEALTH AND HUM. SERVS. (last visited Feb. 15, 2022), https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/[https://perma.cc/BC5D-3A5N].

⁸ *Id*.

⁹ *Id.*; 18 U.S.C. § 287.

¹⁰ 18 U.S.C. § 287.

Violating the FCA can result in substantial consequences, as the statute permits treble damages, a penalty for each false claim, and exclusion from participation in both Medicaid and Medicare11—a possibility that can be ruinous to most medical practices.12 The aim is to deter these unsafe and abusive practices as much as possible.13

II. "OBJECTIVE FALSITY" UNDER THE FCA

The judicial "objective falsity" standard "requires a false claim to be based on objectively verifiable facts to establish liability under the FCA."14 Circuit courts, however, are split as to "whether a difference in expert medical opinion that certain health services are medically necessary"—and therefore payable by the government—is sufficient to establish that the claim for services provided is false or fraudulent under the statute.15

In February 2021, the Supreme Court rejected, without comment, two petitions presenting that exact issue of "whether an expert medical opinion that differs from the defendant's clinical judgment" is sufficient to establish liability under the FCA's falsity definition.16 These petitions are Care Alternatives v. United States et al. and RollinsNelson LTC Corp. v. United States ex rel. Winters.17

III. CIRCUIT SPLIT

For purposes of clarity throughout this paper, the Eleventh Circuit's theory will be termed the "objective standard," meaning there must be a flagrant abuse of the defendant's medical judgment in order for a plaintiff to prevail on a FCA claim, and reasonable disagreement between medical experts is insufficient.18 Alternatively, the opposing theory will be termed the "reasonable disagreement standard," meaning a reasonable disagreement between medical experts is sufficient to support a plaintiff's FCA claim.19

¹¹ False Claims Act Prevention, UNIV. OF ROCHESTER MED. CTR. (last visited Feb. 15, 2022), https://www.urmc.rochester.edu/compliance-office/education-tools/false-claims-act-prevention.aspx [https://perma.cc/A3UV-MRB3].

¹² See Robert L. Vogel, *The False Claims Act and its Impact on Medical Practices*, VOGEL, SLADE & GOLDSTEIN, LLP (last visited Feb. 15, 2022), https://www.vsg-law.com/blog/the-false-claims-act-and-its-impact-on-medical-practices/ [https://perma.cc/539Q-LDVW].

¹³ See THE FALSE CLAIMS ACT & WHY IT MATTERS TO HEALTHCARE PROVIDERS, LEWIS BRISBOIS (Oct. 23, 2019), https://lewisbrisbois.com/newsroom/legal-alerts/the-false-claims-act-why-it-matters-to-healthcare-providers [https://perma.cc/JL24-AXUF].

¹⁴ Foley Hoag LLP, *supra* note 2.

¹⁵ Id

¹⁶ *Id*.

¹⁷ Id.; Petition for Writ of Certiorari, Care Alts. v. United States, et al. ex rel. Druding, et al., No. 20-371 (Sep. 16, 2020); Petition for Writ of Certiorari, RollinsNelson LTC Corp., et al., Petitioners v. United States, ex rel. Jane Winters, No. 20-805 (Dec. 3, 2020).

¹⁸ See Foley Hoag LLP, supra note 2.

¹⁹ See Foley Hoag LLP, supra note 2.

A. Reasonable Disagreement Standard

The Third Circuit rejected the objective falsity standard last year in *United States ex rel. Druding v. Druding* (which became *Care Alternatives* on appeal).20 In that case, former employees sued Care Alternatives for allegedly "admit[ing] patients who were ineligible for hospice care and direct[ing] employees to alter patient records to allow for eligibility."21 The court focused on whether Care Alternatives's physicians correctly assessed that their patients were terminally ill (meaning expected to die within six months) and therefore eligible for Medicare and Medicaid to cover their hospice care.22 The issue presented was whether a physician's clinical judgment can be considered a legal falsity if it is later challenged by a medical expert with a different judgment.23 The Third Circuit found that the difference in opinion *did* create a "genuine dispute of material fact as to falsity" and ruled in favor of the former employees.24

B. Analysis of Care Alternatives Opinion

In *Druding*, the plaintiffs retained an expert who opined that, based on the forty-seven patient records he examined, the patients were inappropriately certified for hospice care thirty-five percent of the time.25 He also found "that the medical records were incomplete for at least three patients."26 However, Care Alternatives's expert disagreed and testified that a reasonable physician would have found all of those patients eligible for hospice.27

Care Alternatives is a hospice facility, and the Medicare provisions for hospice benefits provide payment for individuals considered terminally ill.28 The statute requires the individual to be certified accordingly by at least one physician,29 and regulations promulgated by the Secretary add another requirement for that certification to be accompanied by "clinical information and other documentation that support the medical prognosis" of terminal illness in the medical record.30

Care Alternatives sought summary judgment, arguing the plaintiffs could not prove the prima facie elements of an FCA claim: "falsity, causation, knowledge, and materiality."31 Namely, Care Alternatives contended the plaintiffs had failed to produce sufficient evidence of "falsity."32 The district court granted the motion for

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<sup>20</sup> Id.; see United States v. Care Alts., 952 F.3d 89, 89–90 (3d Cir. 2020).
<sup>21</sup> Foley Hoag LLP, supra note 2; see Care Alt., 952 F.3d at 92.
<sup>22</sup> Care Alts., 952 F.3d at 92.
<sup>23</sup> See id. at 95.
<sup>24</sup> Id. at 91, 95.
<sup>25</sup> Id. at 94.
<sup>26</sup> Id.
<sup>27</sup> See id.
<sup>28</sup> Id. at 91–92.
<sup>29</sup> Id. at 92; 42 U.S.C. § 1395f(a)(7)(A).
<sup>30</sup> Care Alts., 952 F.3d at 93; 42 C.F.R. § 418.22(b)(2) (2011).
<sup>31</sup> Care Alts., 952 F.3d at 94.
<sup>32</sup> Id.
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summary judgment, holding that "a mere difference of opinion" between experts regarding the accuracy of the prognosis was insufficient to create a triable dispute of fact as to the element of falsity, which reflected the Eleventh Circuit's standard.33 It instead required the plaintiffs to produce evidence of an "objective falsehood, that the physicians' prognosis of terminal illness was incorrect, in order to prevail on the element of falsity."34

On appeal to the Third Circuit, the main issue was "whether a hospice-care provider's claim for reimbursement can be considered 'false' under the FCA on the basis of medical-expert testimony that opines that accompanying patient certifications did not support patients' prognoses of terminal illness."35 The Third Circuit held the answer is yes, thereby rejecting the Eleventh Circuit's "objective falsity" standard from the previous year.36 Instead, the court found the plaintiffs' expert medical testimony created "a genuine dispute of material fact as to the element of falsity."37

The Third Circuit came to this conclusion for two reasons: (1) the district court's standard "is at odds with the meaning of 'false' under the" statute's text; and (2) the "objective' falsity standard improperly conflates the elements of falsity and scienter."38

First, because Congress did not define "false" under the FCA, the Supreme Court looked to common law for guidance in Escobar, stating that "[a]bsent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses."39 The Restatement (Second) of Torts suggests "an opinion may be false when the speaker makes an express statement contrary to the opinion he or she actually holds."40 Thus, the Third Circuit found that the lower court's premise—that an opinion is subjective, and a difference of opinion is therefore not enough to show falsity—is inconsistent with the meaning of "false" under the FCA.41

The Third Circuit explicitly disagreed with the Eleventh Circuit's determination that "clinical judgments cannot be untrue." 42 The Third Circuit reasoned that an "opinion... will be deemed untrue... if it is issued without reasonable genuine belief or if it has no basis." 43 Thus, the court found that "a physician's judgment may be scrutinized and considered false." 44 Therefore, a difference of medical opinion is enough evidence to create a triable issue of fact regarding FCA falsity. 45

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<sup>33</sup> Id.
<sup>34</sup> Id.
<sup>35</sup> Id. at 95.
<sup>36</sup> Id.
<sup>37</sup> Id.
<sup>38</sup> Id.
<sup>39</sup> Id. (citing United Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1999–2000 (2016)).
<sup>40</sup> Id.
<sup>41</sup> See id. at 97.
<sup>42</sup> Id. at 100.
<sup>43</sup> Id. at 95 (citing Herskowitz v. Nutri/Sys., Inc., (857 F.2d 179, 184) (3d Cir. 1988)).
<sup>44</sup> Id. at 100–101.
<sup>45</sup> Id. at 101.
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Second, the Third Circuit found that the lower court's "objective falsity" standard conflates the elements of scienter ("knowledge") and falsity under the statute.46 The court reasoned that scienter helps limit the possibility that providers would be exposed to FCA liability anytime the government found an expert who disagreed with the certifying physician's medical prognosis.47 The Third Circuit wrote, "By requiring 'factual evidence that Defendant's certifying doctor was making a *knowingly* false determination,' the District Court's 'objective' falsity standard conflates scienter and falsity."48

Thus, the Third Circuit stated that a claim can be proven "false" in two ways: (1) "factually, when the facts contained within the claim are untrue"; and (2) legally, "when the claimant...falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment."49 For legal falsity, the Medicare Health Benefit regulations state two requirements: "(1) that a physician certifies the patient as terminally ill and (2) that clinical information and documentation supporting the prognosis accompany the certification."50 The Circuit Court reasoned that the District Court's standard only found an expert medical opinion to be false when there is a showing proving a violation of factual falsity under avenue (1), while the Circuit Court advanced a standard that finds liability when there has been a violation of either factual falsity under avenue (1) or of legal falsity under avenue (2).51 Under avenue (2), legal falsity is found, meaning an FCA violation has been committed, when clinical information and other documentation that support the medical prognosis do not accompany the certification.52 Based on this theory, the Third Circuit held that "disagreement between experts as to a patient's prognosis may be evidence of [element (2)]; its relevance need not be limited to the accuracy of another physician's judgment."53

The Third Circuit found support in the Tenth Circuit's holding in *Polukoff*, where that court held that FCA falsity can be based on legal falsity, where "falsity is simply a question of whether the claim is reimbursable, that is, compliance with the Medicare reimbursement instructions."54 That circuit found the defendant cardiologist's procedures were "false" due to failure to follow Medicare procedures.55 Those procedures require certification of the necessity of services and, in some instances, recertification of the continued need for those services that are *reasonable and necessary*.56 However, it is worth noting that the facts in that case made the defendant's conduct appear to be more obviously egregious: the plaintiff physician alleged (1) the defendant performed an unusually large number of the

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<sup>46</sup> Id. at 96.
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⁴⁷ *Id*.

⁴⁸ Id. (citing Druding v. Care Alternatives, Inc., 346 F. Supp. 3d 669, 688 (D.N.J., Sept. 26, 2018)).

⁴⁹ Id. at 96.

⁵⁰ Id. at 100.

⁵¹ See id. at 97.

⁵² *Id*.

⁵³ *Id*.

⁵⁴ Id. (citing United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 742–43 (10th Cir. 2018)).

⁵⁵ Care Alts., 952 F.3d at 97–98.

⁵⁶ Polukoff, 895 F.3d at 735.

specific cardiac procedure at issue; (2) these procedures violated industry and hospital guidelines; (3) other physicians had objected to defendant's practice; (4) the medical center (Intermountain) eventually audited the defendant's practice and reached the conclusion that the guidelines were violated in many of the cases reviewed; and (5) the defendant knew that Medicare and Medicaid would not pay for this cardiac procedure to treat migraines, and he "chose to represent that the procedures had been performed based on indications set forth" in the American Heart Association and American Stroke Association guidelines.57

In summation, according to the Third Circuit, "[u]nder a legal falsity theory, a medical opinion that differs from the certifying physician's opinion is...relevant evidence of the latter requirement, whether there was documentation accompanying the certification that supported the medical prognosis."58 The court continued: "[A] difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity. This does not mean that objectivity is never relevant for FCA liability...[h]owever, we find that objectivity speaks to the element of *scienter*, not *falsity*."59 Thus, according to the Third Circuit, "scienter" pertains to factual falsity under avenue (1) while "falsity" pertains to legal falsity under avenue (2) when a defendant fails to comply with statutory and regulatory requirements.60

Hence, the Third Circuit reversed the District Court's grant of summary judgment, finding that the plaintiffs' expert report challenging the defendant's hospice certifications created a triable issue of material fact for a jury regarding falsity.61 Again, it is worth noting this does not seem to rise to the level of egregious conduct in the Tenth Circuit case, which the Third Circuit relied upon.

C. Objective Falsity Standard

In contrast, the Eleventh Circuit found the opposite in *United States v. AseraCare, Inc.*62 This court determined that a "difference of reasonable opinion" alone is insufficient to establish falsity under the FCA's objective falsity standard.63 *AseraCare* involved nearly identical facts to *Care Alternatives*, but this court instead adopted an objective standard of falsity, which was affirmed on appeal: "[A] clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion."64

⁵⁷ *Id.* at 743.

⁵⁸ Care Alts., 952 F.3d at 100.

⁵⁹ *Id*.

⁶⁰ *Id*.

⁶¹ Id at 101

^{62 938} F.3d 1278,1278 (11th Cir. 2019); see Foley Hoag LLP, supra note 2.

⁶³ AseraCare, 938 F.3d at 1278.

⁶⁴ Id. at 1281.

D. Analysis of AseraCare Opinion

Similar to *Care Alternatives*, in *AseraCare*, the government alleged the defendants certified patients as "eligible for Medicare's hospice benefit, and billed Medicare accordingly, on the basis of erroneous clinical judgments that those patients were terminally ill."65 The government's contention depended upon its expert witness's opinion that the patients at issue were not terminally ill at the time they were certified.66 The district court granted summary judgment to defendant AseraCare "on the issue of falsity."67

On appeal, the Eleventh Circuit agreed with the district court's determination "that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment [italics added]."68

After a review of the statute and implementing regulations, the Eleventh Circuit reasoned that certification for terminal illness "will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness."69 This subjective clinical judgment in light of the patient's complete medical picture lies at the center of the eligibility inquiry.70 In fact, the Centers for Medicate and Medicaid Services ("CMS") has recognized that "predicting life expectancy is not an exact science," so the prognosis does not have to be proven as a matter of medical fact.71 Thus, CMS expects "that the certifying physicians will use their best clinical judgment."72

The Government argued that their expert's testimony created a factual dispute as to whether clinical information and other supporting documentation supported the medical prognosis of the terminally ill.73 However, the Circuit Court explained that the statutory and regulatory requirements for supporting documentation to accompany the claim is meant to address the CMS mandate that "there must be a clinical basis for a certification."74 Therefore, "the physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records...[and] Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review [by plaintiff's

⁶⁵ Id.

⁶⁶ *Id*.

⁶⁷ Id.

⁶⁸ *Id.* ⁶⁹ *Id.* at 1293.

⁷⁰ See id.

⁷¹ *Id*.

⁷² *Id.* at 1294.

⁷³ *Id*.

⁷⁴ *Id*.

expert]."75 The Eleventh Circuit decided CMS's commentary indicates that well-founded clinical judgments be granted deference.76

To support this view further, CMS removed the term "criteria" from a proposed regulation which defined requirements for certification, wishing "to remove any implication that there are specific CMS clinical benchmarks" that must be met to constitute terminal illness.77 This law is designed to give physicians "meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding."78 This does not, as the Government suggests, allow a physician to disregard the patient's underlying medical condition when making a determination.79 In fact, CMS retains a "well-established right" to review claims and deny those "it does not consider reasonable and necessary under the statutory standard."80

This begs the question: When can a physician's clinical judgment regarding a patient's prognosis be deemed false?81 The Eleventh Circuit explained that falsehood "can be shown in a variety of ways."82 For instance when: (1) "a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before" determining he is terminally ill; (2) a plaintiff proves the physician did not subjectively believe his patient was terminally ill; and (3) expert evidence proves that "no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records."83 The reason for using this objective falsehood standard is because, "in each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."84

In contrast, a reasonable difference of opinion among physicians that review medical documents after the fact, alone, is insufficient to suggest that the certifying physician's judgments (or claims based on them) are false under the FCA.85 The court went on to say that "[a] properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong."86 Accordingly, the rule laid down by this circuit is that, in order to properly state a claim under the FCA in the hospice reimbursement context, a plaintiff alleging a patient was falsely certified must show facts and circumstances surrounding the certification "that are inconsistent with the proper exercise of a physician's clinical

⁷⁵ *Id*.

⁷⁶ *Id.* at 1295.

⁷⁷ Id.

⁷⁸ *Id*.

⁷⁹ Id.

⁸⁰ *Id*.

⁸¹ Id. at 1296.

⁸² *Id.* at 1297.

⁸³ *Id*.

⁸⁴ *Id*.

⁸⁵ Id.

⁸⁶ Id.

judgment."87 Where such facts are not shown, the FCA claim must fail as a matter of law.88

The court distinguished the hospice context here from *Paulus*, in which the physician-defendant was convicted of healthcare fraud based on his performance of allegedly unnecessary heart procedures.89 The difference in that case was that the Government was able to produce expert testimony that the physician blatantly lied.90 This testimony specifically disputed that the level of blockage displayed by the angiogram test was at the level the defendant claimed that it was.91 Therefore, opinions are not entirely insulated from scrutiny, as they can 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."92 The Eleventh Circuit reasoned that this instance was distinct from the situation presented in AseraCare, where the Government's experts reached differing conclusions merely by weighing certain medical benchmarks differently than the defendants did.93 In other words, a good-faith medical diagnosis cannot be false, whereas an assertion regarding the degree of a blockage can be "objectively true or false."94 Thus, the defendant in Paulus was convicted for a misrepresentation of fact, not for providing an opinion.95 Essentially, the Government's expert testimony in that case "suggest[ed] that no reasonable doctor could [have] interpret[ed] the scan" as the defendant-physician did, which indicated Paulus was actually lying.96 Therefore, it was up to the jury to decide the reliability of the cardiology expert's testimony attempting to prove his colleague was lying about the scans.97

Although the Government expressed concern in *AseraCare* that an objective falsehood standard would be too difficult for plaintiffs to meet, the court concluded if this is a problem, it is one for Congress or CMS to resolve—not the courts.98 CMS and Congress could have imposed criteria for eligibility determinations to minimize the role of clinical judgment, but they were instead careful to position the clinical judgment of the physician at the core of the inquiry.99 Thus, the Eleventh Court held, "absent a showing of an objective and knowing falsehood, the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits."100

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<sup>87</sup> Id.
<sup>88</sup> Id.
<sup>89</sup> United States v. Paulus, 894 F.3d 267, 270 (6th Cir. 2018).
<sup>90</sup> See AseraCare, 938 F.3d at 1299–1300.
<sup>91</sup> Id. at 1299.
<sup>92</sup> Id. at 1300.
<sup>93</sup> Id.
<sup>94</sup> Id.
<sup>95</sup> Id.
<sup>96</sup> Id.
<sup>97</sup> Id.
<sup>98</sup> Id. at 1301.
<sup>99</sup> Id.
<sup>100</sup> Id.
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However, because the Government was precluded from presenting evidence about some questionable certification practices that AseraCare utilized, the case was remanded.101 Nine witnesses testified AseraCare had an intentional practice of failing to give physicians accurate, relevant, and complete information regarding patient certifications for hospice when requesting doctors to sign the certifications.102 For example, one physician had a habit of signing off on certifications prior to reviewing any medical documentation at all.103 These facts and circumstances presented triable issues of fact regarding the falsity of the specific claims at issue.104

IV. SUPREME COURT GUIDANCE

One previous Supreme Court decision may offer some guidance for the lower courts, but there is still ambiguity since the Court rejected the two more recent petitions.105 In the 2016 Supreme Court case, *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Court held that an alleged false claim requires that the claim be "material" to the payment decision made by the government to establish liability under the FCA.106 It specifically noted that "materiality" is defined in the statute as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."107 It also held that the FCA is not "an all-purpose antifraud statute," nor is it a "vehicle for punishing garden-variety breaches of contract or regulatory violations."108

The Supreme Court's decisions to deny certiorari are, arguably, consistent with the *Escobar* decision—and likely with an explicit objective falsity standard—in order to avoid multitudes of "garden variety" claims jamming up the courts.109 Despite this, the circuits remain split as to their respective approaches to objective falsity, and it is not hard to see why, as the decision did not overtly address this particular question.110 Thus, it may be worth the Supreme Court hearing the issue.

V. RECONCILING THE THIRD AND ELEVENTH CIRCUITS

There are three notable points for reconciling the two circuits and in determining the Eleventh Circuit has the superior analysis: (1) the courts actually seem to agree on whether a medical opinion can be deemed untrue, (2) the courts mainly disagree on the purpose of the documentation requirements and its effect on

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    101 Id. at 1305.
    102 Id. at 1303.
    103 Id. at 1305.
    104 Id. at 1304.
    105 See Foley Hoag LLP, supra note 2.
    106 Id.; Universal Health Servs. v. United States ex rel. Escobar, 579 U.S. 176, 181 (2016).
    107 Universal Health Servs., 579 U.S. at 192–93 (emphasis added).
    108 Id. at 194.
    109 Foley Hoag LLP, supra note 2.
    110 Id.
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a falsity determination, and (3) the Eleventh Circuit's analysis is superior because the Supreme Court has explicitly held the FCA is not there to punish garden-variety regulatory infractions.

First, regarding what the Third Circuit refers to as "factual falsity," the two circuits seem to agree. Both courts determined medical opinions are not shielded from scrutiny, although the Third Circuit suggested the Eleventh Circuit thought otherwise.111 Specifically, both circuits determined that an opinion is "false" if it is not genuinely held by the speaker.112

Second, the courts seem to mainly disagree on the role the documentation requirements play in the Medicare Hospice Benefit. The Third Circuit found it is evidence of a violation of legal falsity, while the Eleventh Circuit held it is merely there to provide documentation of the doctor's rationale113 and address the requirement that a medical basis exist for certification.114

Finally, the Eleventh Circuit's analysis is superior to the Third Circuit's because it promotes the considerations addressed in the Supreme Court's *Escobar* decision. Akin Gump wrote:

In *Escobar*, the Court made clear that the FCA is not "an all-purpose antifraud statute..." [or] a "vehicle for punishing garden-variety breaches of contract or regulatory violations..." Instead, as one recent court summarized... "*Escobar* rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely–multiplied by three–because of some immaterial contractual or regulatory non-compliance."115

Reflecting this sentiment, according to the Eleventh Circuit, "absent a showing of an objective and knowing falsehood, the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits."116

This analysis could even be taken beyond the hospice context for FCA liability to the medical field at large regarding FCA claims. This would work in other contexts for the same reasons it works in the hospice realm. Furthermore, objective falsity is a superior standard because it offers safeguards against patient abuse but also allows

¹¹¹ United States v. Care Alts., 952 F.3d 89, 100 (3d Cir. 2020).

¹¹² Id. at 95; See United States v. AseraCare, Inc., 938 F.3d 1278, 1300 n.13, 1301 n.15 (11th Cir. 2019).

¹¹³ See AseraCare, 938 F.3d at 1296.

¹¹⁴ Care Alts., 952 F.3d at 99.

¹¹⁵ Strauss Hauer & Feld LLP, 9th Circuit Makes Mandatory Escobar's Implied False Certification Test, but Fails to Faithfully Follow Escobar's Directives, AKIN GUMP (Sept. 4, 2018),

 $https://www.akingump.com/en/news-insights/9 th-circuit-makes-mandatory-escobar-s-implied-false.html \ [https://perma.cc/P89F-28M3].$

¹¹⁶ AseraCare, 938 F.3d at 1301.

leeway for physician autonomy and good-faith clinical judgments, especially in light of medical uncertainties.

VI. UNCERTAINTY OF MEDICAL SCIENCES AND THE "TWO SCHOOLS OF THOUGHT" DOCTRINE

Another reason the objective standard of falsity is preferable is the uncertainty of medical sciences.117 In an ancillary legal field, medical negligence liability, some states have adopted the "two schools of thought" doctrine.118 In their article, "Medical Uncertainty, Diagnostic Testing, and Legal Liability," Eric E. Fortress and Marshall B. Kapp wrote: "Health care cost considerations exert[] increasing influence today over clinical decisionmaking. One way to help contain costs while maintaining the quality of health care may be to increase among both physicians and patients an acknowledgment of, and tolerance for, a reasonable degree of medical uncertainty."119 Due to the ubiquity of patient-initiated medical malpractice lawsuits, many physicians resort to "defensive medicine," which is the practice of over-testing and overtreating in order to avoid the threat of liability of this kind.120 One problem with this, however, is that it can obviously lead to another danger: billing for medically unnecessary tests, which is another type of FCA violation.

The two schools of thought doctrine was articulated in *Jones v. Chidester*.121 The main proposition of the doctrine is that if there are two bona fide schools of thought among physicians, then a physician cannot be held liable in negligence for choosing one school of thought over another.122 The rationale for this theory is if there are two legitimate schools of thought, then a jury of lay persons should not have to decide the better alternative.123 The jury simply determines whether it believes there are two legitimate schools of thought sufficient to insulate the defendant from liability.124 Although this is in the medical negligence field, its rationale is applicable to the objective falsity issue for the FCA as well: lay persons are not qualified to determine liability when there are differing opinions between trained medical experts.125 However, because this is a claim based on a federal statute as opposed to state tort law, the issue should be decided in the preliminary stages by the judge instead as a matter of law, as the Eleventh Circuit explained in *AseraCare*.

VII. UNIFORMITY CONSIDERATIONS

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117 See HALL, supra note 5, at 363–64.
118 Id. at 338–40.
119 Id. at 363–64.
120 Id. at 364.
121 610 A.2d 964, 965 (Pa. 1992); HALL, supra note 5, at 338.
122 HALL, supra note 5 at 338.
123 See id. at at 339–40.
124 Id. at 340.
125 See id.
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Third and finally, the Supreme Court should adopt the Eleventh Circuit's objective standard to promote simplicity and uniformity among the lower courts. The extent to which reasonable minds differ regarding medical opinions can be easily determined with medical experts. If the defendant can find a reputable medical provider who would have followed the defendant's course of action as well, then this standard allows a judge to resolve the issue before presenting it to a jury—a jury which, as mentioned above, is not qualified to determine which of two medical professionals is "correct." In contrast, in the egregious situations (such as those discussed above in *Polukoff*) when it is not possible to find reputable expert medical testimony or other evidence that the defendant's course of action was reasonable, this would become a triable issue that is better suited for a jury of laypersons. This is much simpler than trying to hash out which of two "reasonable minds" were *more* reasonable at trial. Furthermore, by decisively laying down this standard, the Supreme Court would provide clarity and uniformity among the lower courts. This would be beneficial for potential plaintiffs, potential defendants, and even the courts.

CONCLUSION

In conclusion, the Supreme Court should adopt the Eleventh Circuit's explicit objective falsity standard. This will finally resolve the confusion among lower courts in applying an important federal Act. Furthermore, it is the superior theory for several reasons: (1) the courts actually seem to agree on whether a medical opinion can be deemed untrue, (2) the courts mainly disagree on the purpose of the documentation requirements and its effect on a falsity determination, (3) the Eleventh Circuit's analysis is superior because the Supreme Court has explicitly held the FCA is not there to punish garden-variety regulatory infractions, 126 and (4) the presence of uncertainty in medical sciences. 127

¹²⁶ Universal Health Servs. v. United States ex rel. Escobar, 579 U.S. 176, 194 (2016)

¹²⁷ See HALL, supra note 5 at 363–64.