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Falsity Under the False Claims Act—The Need for an Objective Standard of Proof

by Stephen A. Wood

In September of 2019, the United States Court of Appeals for the Eleventh Circuit issued an important decision in a False Claims Act case concerning the standard for proof of falsity. In *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), the court held that falsity under the False Claims Act required proof that a claim or statement was *objectively* false and not dependent upon individual judgments that could readily vary from one person to the next based on one's perspective or interpretation of the circumstances underlying the claim or statement. I discussed *AseraCare* this past March in a *WLF Legal Pulse* post.

In *AseraCare*, the government charged that a medical opinion underlying a treatment recommendation and subsequent request for federal Medicare reimbursement was false. The government's principal proof consisted of an expert's opinion that the defendant's doctor was wrong, despite conceding that the defendant's opinion was honestly and reasonably held. The case reaffirmed the requirement of objective proof of falsity in FCA cases and rejected the notion that a reasonable disagreement between experts on matters of opinion presents a jury question.

Since the Eleventh Circuit decided *AseraCare*, two appellate opinions, one issuing from the Ninth Circuit, one from the Third Circuit, have rejected the Eleventh Circuit's holding and rationale. In both *United States ex rel. Winter v. Gardens Regional Hosp. and Med. Ctr., Inc.*, 953 F.3d 1108 (9th Cir. 2020) and *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3rd Cir. 2020), the latter involving a fact pattern nearly identical to *AseraCare*, the courts held that medical opinions offered to satisfy certification requirements for treatment could give rise to liability under the FCA. Both cases rejected the *AseraCare* requirement of objective proof of falsity.

Both courts attempted to distinguish *AseraCare* and in the process misread or mischaracterized parts of the Eleventh Circuit's holding and rationale. The result in *Winter* is less troubling because it involved a pleading-stage dismissal and facts suggesting the possibility of objective falsity. *Druding*, on the other hand, is far more concerning. The case sets a bad precedent for its conclusion that regulatory noncompliance *per se* establishes falsity and that a disagreement among experts without more is sufficient to warrant a jury trial. Neither case offers a convincing argument for rejecting *AseraCare*'s sound requirement for objective proof of falsity, a requirement that ensures that a FCA defendant is not wrongly accused of fraud where, despite government disavowal, its actions are a product of rational decision-making.

United States v. AseraCare

The defendants in this case provided end-of-life hospice care services to patients. Federal law requires a patient's attending physician, if any, as well as the medical director of the hospice provider

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to certify in writing upon admission to hospice that an individual patient was terminal "based on the physician's clinical judgment regarding the normal course of the individual's illness." 42 USC § 1395f(7)(A). A patient is considered terminal if the patient's life expectancy is determined to be six months or less. The certification must be accompanied by medical documentation that supports the prognosis. An initial certification is valid for 90 days. To qualify for continued reimbursement beyond this period, providers must recertify every 90 days as long as the patient remains in hospice. Importantly, the regulations acknowledge that determining how long a terminal individual may live is difficult and prognoses are often imprecise. Thus, the regulations permit reimbursement beyond six months as long as medical professionals periodically recertify. *AseraCare*, 938 F.3d at 1282-83.

In 2008, three former employees of the defendants filed a *qui tam* suit in U.S. District Court for the Eastern District of Wisconsin. These relators alleged that defendants submitted hospice-care claims for Medicare reimbursement for patients who were in fact ineligible. The government intervened. Defendants argued that unless the government could show that no reasonable physician would have concluded that a given patient was terminally ill, its claims were not false.

During the trial, the government presented expert medical evidence contesting the defendants' patient certifications. This expert did not claim that no reasonable doctor could have concluded that the patients at issue were terminally ill. Rather, he testified that in his professional opinion the patients were not terminally ill. The defendants offered expert medical testimony of their own supporting the accuracy of the diagnoses made in the patient certifications. After approximately eight weeks of trial, the jury found that defendants had submitted false claims for 104 of the 123 patients.

In considering post-trial submissions, the district court, under F.R.C.P. 56(f)(3), *sua sponte* reconsidered its denial of the defendants' motion for summary judgment, and after briefing and additional post-verdict argument, granted summary judgment to the defendants. With the opinions of its experts on patient prognosis as the only admissible evidence of falsity, the government had failed to meet its burden.

On appeal, the government argued that falsity is established where an expert opines that a patient's medical records do not support a terminal illness prognosis. Where the parties present competing expert views on prognosis, falsity becomes a question for the jury, the government claimed. In opposition, the defendants argued that where certifying physicians exercise their reasoned clinical judgment, falsity cannot be established as a matter of fact, and there can be no consequent FCA liability.

The appellate court noted that the regulations themselves recognize that predicting life expectancy "is not an exact science" and that certifying physicians are expected to "use their best clinical judgment." *Id.* at 1294. "It follows that when a hospice provider submits a claim that certifies that a patient is terminally ill 'based on the physician's or medical director's clinical judgment . . . the claim cannot be 'false' . . . if the underlying clinical judgment does not reflect an objective falsehood." *Id.* at 1296-97.

United States ex rel. Winter v. Gardens Regional Hosp. and Med. Ctr., Inc.

In this *qui tam* case, the plaintiff claimed that defendants wrongly certified compliance with requirements for Medicare reimbursement of the cost of hospital admission. The regulations at issue provided that reimbursement is available for inpatient hospitalization only if "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose . . . ." 42 U.S.C. § 1395f(a)(3).

The relator, the defendant's former director of care management, was responsible for secondary review of hospital admissions. She questioned many of the admissions decisions by hospital doctors as not supported by established criteria. She noted that a large percentage of patients admitted to the hospital had been housed at a nursing-care facility owned by the company that co-owned the hospital.

She alleged further that patients were admitted for routine conditions, such as urinary tract infections, which were typically treated on an outpatient basis. She also alleged that patients were admitted for treatment of conditions such as septicemia, pneumonia, and bronchitis where the underlying medical records failed to mention such conditions. When she brought her concerns to the attention of hospital management, she was initially ignored, later counseled, and ultimately fired. The government declined to intervene in the action. The district court granted the defendants' motions to dismiss on grounds that, among others, a determination of "medical necessity" is a subjective medical opinion that cannot be proven to be objectively false. *Winter*, 953 F.3d at 1116.

The Ninth Circuit began its analysis noting that opinions are not entirely insulated from scrutiny under the FCA. "Under the common law, a subjective opinion is fraudulent if it implies the existence of facts that do not exist, or if it is not honestly held." *Id.* at 1117. The court cited decisions in other cases involving the same regulations holding that statements of opinion could be considered false. The court of appeals furthermore rejected the defendants' arguments that the FCA requires proof of an objective falsehood, noting that nothing in the text of the law supports the proposed restriction. The *Winter* court attempted to reconcile the Eleventh Circuit's *AseraCare* holding by first characterizing it as limited to the scenario where reasonable experts differed, *without more*. Second, the *Winter* court noted that the hospice regulation at issue in *AseraCare* mandated deference to the judgments of clinicians, whereas the statute at issue in *Winter* did not.

Having rejected a requirement for objective proof of falsity, the Ninth Circuit proceeded to analyze the relator's complaint regarding falsity, noting that the relator alleged that a number of the hospital admissions were for conditions historically treated on an outpatient basis, that a number of admissions were based on diagnoses that had been disproven by laboratory tests, and that several admissions were for psychiatric treatment, even though the defendant hospital was not a psychiatric hospital. Because the district court held in the alternative that the relator's allegations were not material, the Ninth Circuit analyzed that issue as well, concluding that materiality had been adequately pled, since the complaint contained allegations that reimbursement depended upon a finding of medical necessity.

United States ex rel. Druding v. Care Alternatives

Recently, the Third Circuit had the opportunity to consider a *qui tam* action involving hospice care services that was virtually on all fours with *AseraCare*, at least factually. Several former employees of the defendant alleged that the defendant had certified persons as eligible for hospice when they were not. Relators alleged that defendant directed its employees to alter patient Medicare certifications from ineligible to eligible, although the appellate court's opinion contains no discussion of evidence to support these allegations.[1] As in *AseraCare*, the litigation boiled down to a battle of the experts, with the relators' expert opining that 35% of patient records he had reviewed failed to support a finding of terminality. The defendant's expert disagreed. In the face of this, the district court granted the defendant's motion for summary judgment because the relators had failed to establish a genuine issue of fact on the element of falsity by proving an objective falsehood.

The court of appeals repudiated the objective standard of proof as "inconsistent with the statute and contrary to this Court's interpretations of what is required for legal falsity." *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95 (3rd Cir. 2020). Like some other federal district and courts, the Third

[1] The government declined to intervene in the case *seven years after it was filed,* a detail that must have seemed almost trivial to this Third Circuit panel in light of its bare mention in reciting the procedural history of the case. *See United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 93 (3rd Cir. 2020). Yet this delay represents a gross and outrageous abuse of the government's sealing prerogative that is regrettably all too common in False Claims Act cases brought by *qui tam* relators. The statute grants the government 60 days to review and investigate a complaint filed under seal, which may be extended upon a showing of good cause. 31 U.S.C. § 3730(b). Courts routinely rubber stamp serial *ex parte* requests for extension of the seal period. The implications for due process and other ramifications of this abuse have been the subject of other writings by the author. *See, e.g.*, https://www.wlf.org/2019/01/03/wlf-legal-pulse/end-the-endless-extensions-of-the-seal-period-in-false-claims-act-qui-tam-cases/.

Circuit has embraced an analysis that characterizes falsity as either factual or legal, the latter occurring when a defendant's claim falsely certifies compliance, expressly or impliedly, with some regulatory or contractual requirement. The district court, the Third Circuit noted, omitted consideration of legal falsity which required only evidence that defendant failed to meet regulatory certification requirements. *Id.* at 97. A disagreement between experts on a patient's certification of terminality was, contrary to the district court's ruling, sufficient to deny summary judgment.

The Third Circuit furthermore criticized the district court's analysis as "improperly conflat[ing] the elements of falsity and scienter," an approach that in the appellate court's judgment "reads the scienter element out of the text of the statute." *Id.* at 95-96. In granting summary judgment, the district court noted that despite extensive discovery the relators had no evidence that any physician had lied, taken money, or otherwise knowingly and falsely certified an ineligible hospice patient as eligible. The dispute between relators and defendant over falsity, like *AseraCare*, turned on a difference of expert clinical opinions. Yet, granting summary judgment on this record, in the Third Circuit's view, improperly incorporated scienter into the falsity analysis, an approach "inconsistent with the text and application of the statute." Furthermore, "[t]he 'reliability and believability of expert testimony . . . is *exclusively* for the jury to decide.'" *Id.* at 98 (emphasis added).[2]

Having decided the appeal, the Third Circuit closed with a discussion of the Eleventh Circuit's decision in *AseraCare* to explain its reasons for rejecting the holding of its sister circuit. First, the Third Circuit saw *AseraCare* as limited to the issue of "factual falsity," to the exclusion of "legal falsity," contrary to Third Circuit precedent. Without considering legal falsity, *AseraCare* was analytically incomplete. Next, the Third Circuit characterized *AseraCare* as concluding that clinical judgments cannot be false (an incorrect characterization that, at a minimum, overlooks contrary dicta in the *AseraCare* decision; indeed, the *AseraCare* court acknowledged that statements of opinion *per se* are not insulated from a claim of falsity). Finally, conceding that objectivity may be a relevant consideration, the Third Circuit panel opined that it is so only with respect to scienter, not falsity. *Id.* at 100.

Reconciling (or not) *Winter* and *Druding* with *AseraCare*

The Ninth Circuit claimed that *AseraCare* was concerned with a regulation that mandated deference to clinicians, unlike the regulation at issue in *Winter*. True, the hospice regulation at issue in *AseraCare* differed principally insofar as it expressly stated that clinical judgments are not precise. *See AseraCare*, 938 F.3d at 1282-83. Such a statement was absent from the regulation at issue in *Winter*. Yet, we are talking about medical judgments regarding treatment and prognosis. That such judgments are often imprecise and involve discretion based on experience, training, and other factors would seem obvious. After all, "medicine is an inexact science." *United States v. Brown*, 737 Fed. Appx. 777, 781 (7th Cir. 2018). Surely, these judgments in some instances may be beyond any reasonable debate, but just as often they are not.

What the regulations required in both *Winter* and *AseraCare* is that the diagnosis be tethered to and rationally supported by the underlying medical facts—symptoms, patient health history, prior treatments, etc. More likely, rather than regulatory deference, the principal distinction between the two cases is that the disposition in *Winter* came at the pleading stage. Not only that, relators alleged that the defendants were in effect manipulating these hospital admission decisions. Put differently, relators brought forth facts showing that admissions decisions turned on more than mere exercise of professional medical judgment. These alleged facts regarding the falsity of the medical necessity of

[2] The statement that the reliability of expert testimony is "exclusively for the jury to decide" flies in the face of nearly every pronouncement on the admissibility of expert testimony since the U.S. Supreme Court handed down its decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). The ellipsis appears in the *Druding* opinion and reference to the case cited by *Druding* reveals that the omitted phrase was "once properly admitted," an important qualification indeed. But the casual invocation of such a phrase in support of the Third Circuit's *Druding* opinion could be seen as a further example of an overall lack of analytical rigor.

hospital admission, if true, would seem capable of objective proof. Thus, it was completely unnecessary for the Ninth Circuit to reject the Eleventh Circuit's rule. In other words, had this case been brought in the Eleventh Circuit, the result likely would have been the same.

The Third Circuit's opinion in *Druding* is much more troublesome and difficult to reconcile with *AseraCare*. To begin with, the Third Circuit criticized the Eleventh Circuit's objective falsity standard of proof because the standard is extratextual, suggesting *AseraCare* was imposing requirements Congress had not intended. In fact, the *Druding* court's stilted application of its legal/factual falsity construct, equally absent from the text of the statute, was ironically responsible for an outcome that disserves Congressional objectives underlying the False Claims Act and creates precedent that will lead to confusion, promotion of meritless litigation, and FCA liability where none should exist.

The Supreme Court took up the question of proof of falsity under the FCA in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). There, the Court considered liability for implied certification of compliance with regulatory requirements, what would be considered "legal falsity" in the Third Circuit, although the Supreme Court avoided both the use of that term or any similar dichotomy. In *Escobar*, the High Court was concerned with defendant's omission of its failure to comply with certain licensing and treatment reimbursement regulations, and whether that rendered its claims for payment false:

> Congress did not define what makes a claim 'false' or 'fraudulent.' But '[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.' And the term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.

Id. at 1999 (citations omitted).

The court concluded that "'false or fraudulent claims' include more than just claims containing express falsehoods . . . misrepresentations by omission can give rise to liability." *Id.* Furthermore, "half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations." *Id.* at 2000. Given this characterization of falsity grounded in the common law, it seems fair to question whether the legal/factual falsity distinction retains analytical utility after *Escobar*. *Cf. United States v. Universal Health Serv., Inc.*, 780 F.3d 504, 512 (1st Cir. 2015) ("This circuit recently has eschewed distinctions between factually and legally false claims . . . reasoning that they 'create artificial barriers that obscure and distort [the statute's] requirements.'"), *rev'd on other grounds,* 136 S. Ct. 1989 (2016).

The *Druding* court's view of legal falsity seems to be that falsity is established where a claim is made that is not payable or reimbursable because of a failure to comply with regulatory requirements: "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *Druding*, 952 F.3d at 97. In *Druding*, relators were required to show that defendant failed to meet either of two regulatory requirements: (1) certifying a patient's prognosis, or (2) that the certification was supported by the clinical information. *Id.* Disagreement between experts regarding the latter requirement was all that was necessary to establish a triable issue on the element of falsity.

In this respect, *Druding* leads to the precise outcome *AseraCare* rightly sought to avoid, a jury trial where the only evidence of falsity or fraud is the opinion of a plaintiff's expert that—purely as a matter of reasoned medical judgment—she would not have made the certification that the defendant made. This does not rise to the level of fraud. If, as the district court determined, there was no other objective evidence to show that the patient certifications were incorrect or wrong in the sense that no objective physician would so certify or that the certifications were knowingly falsified, summary judgment should have been granted and affirmed on appeal. The Third Circuit finds as false a rational opinion or judgment

that does not rest on an objectively false foundation. This is not the sort of fiscal thievery that the False Claims Act was enacted to prevent and punish:

> The False Claims Act was originally adopted following a series of sensational congressional investigations into the sale of provisions and munitions to the War Department. Testimony before the Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war. Congress wanted to stop this plundering of the public treasury. At the same time it is equally clear that the False Claims Act was not designed to reach every kind of fraud practiced on the Government.

United States v. McNinch, 356 U.S. 595, 599 (1958). Through its blinkered approach to "legal" falsity and proof thereof, the Third Circuit in fact undermines the intent behind the law.

It makes no more sense to put such questions before the jury than it does a disagreement over the interpretation of an ambiguous contract. In such cases, courts have usually held that falsity is not established. *See, e.g., United States ex rel. K & R Ltd. P'ship v. Massachusetts Housing. Fin. Agency*, 530 F.3d 980, 983-84 (D.C. Cir. 2008) (falsity lacking where defendant's interpretation of ambiguous terms was not unreasonable). The procedural difference in those cases is that matters of contract or statutory interpretation are typically for the court. But because the believability of expert testimony is "exclusively for the jury to decide," the Third Circuit would hold that removing a case from the jury when two experts disagree to be legal error. Yet, this is precisely where courts must intervene to prevent such cases from proceeding to trial, to spare a defendant from the punitive effects of a FCA judgment imposing treble damages, statutory penalties, fees, and costs.

Finally, the Third Circuit's opinion that the district court conflated falsity and scienter, which had the effect of "read[ing] the scienter element out of the text of the statute," is equally indefensible. While it may be appropriate where possible to consider the element of falsity separate from the element of scienter, nothing in the statute expressly commands that approach. And in some cases it may be difficult to separate the two, for example, as discussed in *Escobar*, in the case of misrepresentations by omission or half-truths "that state the truth only so far as it goes." These falsities may not lend themselves to distinct proof on each element. If in fact consideration of evidence of scienter should be necessary to establish falsity where other evidence was lacking, that hardly removes scienter from the analysis or reads it out of the statute's text.

Conclusion

In fact, the element of falsity will rarely present a significant jury question. Where falsity is essentially uncontested (for example, where the government has been overcharged or received defective goods), the litigation will turn instead on proof of other elements, such as scienter or materiality or a defense such as public disclosure. Where falsity is lacking, the case should not proceed past summary judgment.

The False Claims Act has been recognized as a punitive statutory scheme whose effects often transcend the financial leading to reputationally ruinous consequences. Falsity under the FCA, unlike other ordinary civil cases, must therefore require objective, provable facts to prevent the possibility of a jury finding of fraud that depended solely on the government's judgment or interpretation or opinion of the defendant's conduct.

