

## STRATEGIC PERSPECTIVES: Second opinions not enough for FCA—will there be a ripple effect?

By [Cathleen Calhoun, J.D.](#)

The recent 11th Circuit *AseraCare* decision is analyzed and experts share thoughts on its meaning for future FCA cases.

Last month, the 11th Circuit found that a False Claims Act (FCA) violation needs something more than a difference of opinion between doctors on treatment in order to find liability. In the much-anticipated decision, [United States v. AseraCare, Inc.](#), on September 9, 2019, the court found that an "objective falsity" is needed under the FCA, not just a difference of opinion between doctors. What advice did the court give about FCA claims and do experts think that other medical necessity claims will be impacted by the decision? This Strategic Perspective analyzes the *AseraCare* decision (including its "objective falsehood" discussion), looks at how other appellate courts have decided similar issues differently, and reveals what some experts think it means going forward.

### Winding Road to the Appellate Court

The claims came to the 11th Circuit after years of litigation at the lower court level. *AseraCare* operates over 60 hospice facilities in the United States, admitting about 10,000 patients annually. Three former *AseraCare* employees alleged, in a whistleblower complaint, that *AseraCare* knowingly received reimbursement payments for patients who were not eligible for the Medicare hospice benefit.

In 2014, the government brought suit, claiming that *AseraCare* hospice centers engaged in a scheme to defraud Medicare by forcing employees to liberally construe medical records so that the patients could be put on hospice (see [Can a dispute over hospice certifications for patients be a false claim? Court says maybe](#), December 8, 2014). Specifically, the government claimed that *AseraCare* pressured staff to meet aggressive quotas for hospice patient intakes, discouraging meaningful review and physician involvement. In addition, the government alleged that *AseraCare* submitted false documentation that certain Medicare patients were terminally ill. The district court denied *AseraCare*'s motion for summary judgment, finding that genuine issues of material fact existed and the claims should be brought before a jury.

After a trial, a jury found *AseraCare* liable, but then the court immediately decided that its jury instructions were wrong. According to the court, it had incorrectly instructed the jury on the FCA's falsity element. The court found that the opinion of one medical expert alone stating that the patients should not have been certified as terminally ill could not prove falsity. The court granted summary judgment in favor of *AseraCare* (see [Differing physician opinions on illness status not enough for falsity](#), April 5, 2016). The appeal by the government to the 11th Circuit followed.

### 11th Circuit Ruling

In a detailed opinion on September 9, 2019, the 11th Circuit affirmed the trial court's holding that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false under the FCA, when only a reasonable difference of opinions between experts exists (see [Medicare FCA claim against hospice not proven through expert](#), September 10, 2019). The court said that an "objective falsehood" is also needed. The 11th circuit court stated:

"Can a medical provider's judgment that a patient is terminally ill be deemed false based merely on the existence of a reasonable difference of opinion between experts as to the accuracy of that prognosis? The district court ultimately answered this question in the negative.... [W]e concur with the district court's ultimate determination that a clinical judgment of terminal illness... cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts... with no other evidence to prove the falsity of the assessment."

The 11th Circuit court added, "We also note that, had Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet, 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."

However, the appellate court sided in part with the government when it added that the government should have been allowed to rely on the entire record, not just the trial record, in making its case that other facts showed falsity. The court remanded the case to the trial court for reconsideration. In doing so, the court explained, "it is only fair that the Government be allowed to have summary judgment considered based on all the evidence presented.... When the goalpost gets moved in the final seconds of the game, the team with the ball should, at the least, have one more opportunity to punch it into the endzone."

**Objective falsehood.** According to the 11th Circuit, an "objective falsehood" can be shown in a variety of ways. The court specifically described scenarios for the purpose of providing examples of where an objective falsehood could be found:

- If a certifying physician fails to review a medical record or familiarize himself or herself with the patient's condition before saying the patient is terminal, that would be an objective falsehood.
- If it is proven that the doctor did not, in fact, subjectively believe that his or her patient was terminally ill at the time of certification of terminal illness, that would be an objective falsehood.
- If evidence proves that no reasonable physician could have concluded that the patient was terminally ill, that would be an objective falsehood as well.

**Key takeaways.** For making an FCA claim in the context of hospice reimbursement, the court provided the following guidance:

1. An allegation that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient that are inconsistent with the proper exercise of a physician's clinical judgment. If no such facts exist, the FCA claim will fail as a matter of law.
2. The government must show more than the difference of reasonable opinion between doctors concerning the prognosis of a patient's longevity.

## What's Next?

What will happen now that the case is back at the lower court level? The answer is not crystal clear, since other courts have decided differently.

**10th Circuit.** In [\*United States ex rel. Polukoff v. St. Mark's Hospital\*](#), the 10th Circuit found that a physician's medical judgment about the medical necessity of heart procedures can be "false or fraudulent" under the FCA. In that case, a cardiologist in Utah owned and operated a cardiology group practice known for performing septal defect (ASD) and patent foramen ovale (PFO) closures—procedures that close holes in the heart through inserting a surgical tube into blood vessels to access the heart, rather than performing open heart surgery. A cardiologist who worked at the group practice filed a whistleblower action alleging that the owner performed medically unnecessary ASD and PFO closures, and fraudulently collected payment from the government for the closures, in violation of the FCA. The whistleblower claimed that the ASD and PFO closures were not based on the existence of recurrent cryptogenic strokes as required, but were done for the prevention of possible strokes (see [\*Doctor's judgment of necessity may be challenged when it conflicts with government definition\*](#), July 10, 2018).

**6th Circuit.** The 6th Circuit found that the degree of a patient's heart blockage was a fact capable of proof or disproof. A medical doctor was accused of committing health care fraud through his exaggeration of the amount of blockage of arteries in order to perform medical procedures. The jury convicted the doctor of health care fraud, but the court granted the doctor's motion for an acquittal. On appeal, the 6th Circuit reversed the acquittal, stating that "a court may not enter a judgment of acquittal merely because it doubts the persuasiveness of the government's expert testimony" (see [\*United States v. Paulus\*](#), June 25, 2018).

## Commentary and Reactions

Wolters Kluwer posed the following questions about the *AseraCare* decision to [Andrew H. Struve](#), partner at Hooper, Lundy & Bookman, PC, and [Michael Clark](#), of counsel attorney at Baker Donelson.

**Question: Do you agree with the 11th Circuit's decision in *AseraCare* on September 9, 2019, and why?**

**Michael Clark:** Yes, it is a welcome and key decision now that the DOJ has begun challenging, in civil False Claims Act actions and criminal prosecutions, the medical necessity of services provided and the medical judgment of physicians and

allied healthcare practitioners providing the services as being tantamount to fraudulent conduct. In these types of enforcement actions, the real battleground often is the intent or good faith of the target who provided the services in issue.... Most courts have been very reluctant to curtail the Government's efforts, as judges are not trained in medicine.... The real danger here, particularly when juries are asked to determine if such challenged conduct constitutes civil or criminal fraud, is that juries generally aren't trained or experienced in medicine, so they may accept such "expert" opinions, even if the underlying methodology isn't fully identified or properly applied. In other types of actions, notably medical malpractice cases, courts properly recognize there often are clear differences of opinion about what is appropriate medical judgment and provide leeway for "respectable minority" positions.

**Andrew Struve:** I absolutely agree with the Court of Appeals' conclusion. As the court put it, "[a] properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong." That goes to the essence of medical decision making—we don't call it "the healing arts" for nothing. Put another way, reasonable minds often can differ about the proper course of action, whether in medicine, law, or other similar fields. In the absence of clear proof of fraud, it seems inappropriate to second guess such decisions—particularly, to demand repayment of fees, at pain of treble damages, debarment, professional humiliation, and the like.

**Question: How could the 11th Circuit's decision in *AseraCare* affect criminal health care fraud cases or civil False Claims Act cases where liability turns on the medical necessity of the services?**

**Michael Clark:** Unfortunately, in the very few cases that have examined this issue on appeal, courts naturally apply the very deferential standard of review in light of the conviction, and they largely accept the outcome by looking at other evidence in the trial record that are identified as "badges of fraud." White collar practitioners should actively evaluate the underlying methodology of such government experts and make timely and well-reasoned *Daubert* challenges even though courts are generally reluctant to grant them in criminal cases.

**Question: What do you think will happen when the case returns to the lower court?**

**Michael Clark:** The lower court clearly was very thoughtful in considering how the case was structured for being presented to the jury and cognizant of the importance of "getting it right" given the likely impact of the verdict on the industry. Given the appellate court's instruction to allow the Government to further develop its factual record, I have no doubt that the judge will do just that. But unless the Government can overcome the core problem that, at best, its expert's opinion is in equipoise with the expert opinion of the defense, it has an uphill battle looming.

**Question: Do you think that a higher evidentiary burden to prove objective falsity is consistent with the language, structure, and purpose of the FCA? Or do you have any other thoughts on the decision you would like to share?**

**Andrew Struve:** The decision is important from an access to care perspective. If the law were to allow potential False Claims Act liability in situations where reasonable professional minds could differ as to whether a given patient was "terminal" within the meaning of the Medicare standard, such a rule could easily have a chilling effect on access to hospice care, resulting delays of entry into hospice, or worse. Palliative care is a crucial service, at a time of great stress for the patient and [his or] her family. It's the last thing we want to chill or deter.

**Michael Clark:** Absolutely. The intersection of law, medicine, and ethics is too often fuzzy, particularly when viewed through the additional prism of cost savings. Given the potentially ruinous penalties involved, along with the near-death penalty effects of exclusion from Medicare, the Government has a tremendous advantage to begin with in these cases, and the FCA can be too blunt an instrument, which makes it critically important that subjectivity not drive its use.

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