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CLIENT ALERT

The Eleventh Circuit's Recent *AseraCare* Decision Raises the Bar for Establishing Falsity in False Claims Act Cases Involving a Medical Provider's Clinical Judgment

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In a noteworthy decision issued last week, the Eleventh Circuit Court of Appeals held that a claim cannot be deemed "false" under the False Claims Act (the "FCA") based solely on a reasonable difference of opinion between experts as to a medical provider's clinical judgment. The Eleventh Circuit held that for a claim to be false and thus trigger FCA liability, the underlying clinical judgment must reflect an "objective falsehood." Addressing the Government's claims that AseraCare falsely certified patients for hospice care, the Court explained that a plaintiff making such claims "must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law." Although the Eleventh Circuit also vacated the grant of summary judgment in favor of AseraCare and remanded to the district court for consideration of the entirety of the Government's evidence, the decision is a welcome one for AseraCare and also for non-hospice healthcare provider defendants in FCA actions as the Court's decision on falsity will likely be applied more broadly to cases involving medical necessity, holding the Government and *qui tam* relators to a higher standard in order to proceed with FCA claims.

Background

The AseraCare defendants are operators of approximately 60 hospice facilities in the United States. The litigation commenced in 2008 when three former employees of AseraCare, acting as whistleblowers (*qui tam* relators), filed a complaint alleging that AseraCare submitted unsubstantiated hospice claims in violation of the FCA. Specifically, the complaint alleged that AseraCare certified patients for Medicare's hospice benefit on erroneous clinical judgments that those patients were terminally ill in order to receive "lucrative" Medicare hospice benefits. The Government intervened and filed an amended complaint alleging that AseraCare's actions were part of a "corporate climate that pressured sales and clinical staff to meet aggressive monthly quotas for patient intake and, in so doing, discouraged meaningful physician involvement in eligibility determinations."

The Government argued that hospice treatment for those patients who were represented as "terminally ill" when they were not, was "false" for the purposes of the federal False Claims Act. As such, the Government proceeded under the "false certification" theory of FCA liability—pursuant to which liability arises where "a defendant falsely asserts or implies that it has complied with a statutory or regulatory requirement when, in actuality, it has not so complied." The Government's case was largely based upon a sample of patients who had received at least 365

continuous days of hospice care. The Government's primary expert witness identified 123 patients from a sample of 223 patients who were, in his view, ineligible for the Medicare hospice benefit. To supplement its expert's testimony, the Government also sought to develop evidence that "AseraCare's broader business practices fostered and promoted improper certification procedures while deemphasizing clinical training on terminal-illness prognostication."

After extensive discovery, the district court denied AseraCare's motion for summary judgment. In an unprecedented move, the district court then granted AseraCare's request—over the Government's "vehement[]" objection—to bifurcate the trial into two phases. This bifurcation did not involve a traditional bifurcation between liability and damages, but rather a first phase trial on the falsity element of FCA liability followed by a second phase addressing the remaining FCA elements—including knowledge or scienter—and the Government's common-law claims. Following a trial on the first phase on the falsity element, the jury found, based primarily on competing expert testimony, that AseraCare had submitted false claims for 104 of the 123 patients at issue.

Before the trial could proceed to the second phase, the district court granted AseraCare a new trial after the district court determined that it had articulated the wrong legal standard in its jury instructions. Specifically, the district court concluded that it failed to instruct the jury "(1) that the FCA's falsity element requires proof of an objective falsehood; and (2) that a mere difference of opinion between physicians, *without more*, is not enough to show falsity." The district court then went even further, deciding *sua sponte* to consider summary judgment on the issue of falsity—specifically, "whether the Government, under the correct legal standard, ha[d] sufficient admissible evidence of more than just a difference of opinion to show that the claims at issue are objectively false as a matter of law."

Following briefing and argument, the district court applied its "newly adopted legal standard" and granted summary judgment in AseraCare's favor. The district court explained that the Government failed to offer any admissible evidence of falsity other than the opinion of its expert witness and, thus, "presented no evidence of an objective falsehood for any of the patients at issue." As such, the district court concluded that the Government could not prove the falsity element of its FCA claim as a matter of law.

The Government appealed the district court's summary judgment order and grant of a new trial, arguing that the legal standard the court applied reflected a "deeply flawed" understanding of the falsity element of an FCA claim.

The Eleventh Circuit's Decision

On September 9, 2019, the Eleventh Circuit issued its opinion affirming the district court's grant of a new trial, vacating the post-verdict grant of summary judgment to AseraCare, and remanding the case to the district court.

After reviewing the statutory and regulatory framework, the underlying record, and certain case law from other circuits, the Eleventh Circuit agreed with the district court that "the instruction given to the jury was inadequate and agree[d] with the general legal standard embraced by the district court after the verdict." Specifically, the Court of Appeals found that when a hospice provider submits a claim that certifies that a patient is terminally ill based on a physician's clinical judgment, the claim cannot be false—and thus cannot be actionable under the FCA—unless the underlying clinical judgment reflects an "objective falsehood." The Court explained that an "objective falsehood" is a "flaw that can be demonstrated through verifiable facts," and it provided examples of how an objective falsehood can be shown: (i) "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;" (ii) "a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification;" or (iii) "expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records." In reaching its decision, the Eleventh Circuit agreed with the district court's conclusion that "physicians applying their clinical judgments about a patient's projected life expectancy could disagree, and neither physician [could] be wrong," and that, "in order to show objective falsity as to a claim for hospice benefits, the Government must show something more than the mere difference of reasonable opinion concerning the prognosis of a patient's likely longevity." As such, the Eleventh Circuit explained that "a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA." Rather, the Court held that:

> in order to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law.

The Court of Appeals acknowledged the Government's concern that a requirement of objective falsehood would "produce a troubling under-inclusive problem"—allowing plaintiffs to evade FCA liability by showing nothing more than a reasonable difference of physician opinions. However, the Court found that this problem is one for Congress or CMS to solve. The Court noted that Congress and CMS "could have imposed a more rigid set of criteria for eligibility determinations that would have minimized the role of clinical judgment," but instead "they were careful to place the physician's clinical judgment at the center of the inquiry." As such, the Court concluded that "the mere difference of reasonable opinion between physicians, without more, as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood."

The Eleventh Circuit also addressed the district court's *sua sponte* grant of summary judgment in favor of AseraCare. Although emphasizing that it was not criticizing the district court for changing its mind on the appropriate standard for proving falsity under the FCA—and, indeed, commended the district court for its diligence, conscientiousness and thoughtfulness—the Eleventh Circuit agreed with the Government that the district court "took too constricted a view of the evidence upon which a determination of falsity could be made." In so concluding, the Court pointed to the district court's refusal to consider (i) other evidence from the first phase of the trial that the Government claimed showed knowledge of falsity and (ii) evidence that the Government planned to offer in the second phase of the trial to show AseraCare's claimed awareness that it was submitting claims that did not reflect a physician's good faith clinical judgment for each patient. Although the Government had offered evidence from a number of fact witnesses beyond its expert witness, the lower court refused to consider the evidence during its post-verdict consideration of summary judgment because the Government had not designated those witnesses as providing evidence of falsity—the subject of the first phase of the trial—during discovery. The Eleventh Circuit explained that:

> the Government had no idea that the district court would later order the bifurcation of trial between falsity and knowledge phases, and it clearly assumed that all of its evidence would be heard by the jury in one proceeding, with no need to so starkly pigeon-hole the category into which a given piece of evidence might fit.

The Eleventh Circuit concluded that "under all these unusual circumstances, it is only fair that the Government be allowed to have summary judgment considered based on all the evidence presented at both the summary judgment and trial stages." As such, the Court vacated the district court's grant of summary judgment and remanded the case for the district court to reconsider the matter based on the entirety of the evidence.

Takeaways

Evaluating the decision solely on the basis of its outcome—in particular, vacating the grant of summary judgment in favor of AseraCare and remanding the case to the district court for consideration of the full extent of the Government's evidence—may suggest that the case is a victory for the Government. However, at least two considerations call such a conclusion into question.

First, the Eleventh Circuit agreed with the district court that in the context of hospice reimbursement, disagreements in professional clinical judgment, without objective falsity, cannot trigger FCA liability. As such, it rejected the Government's articulation of the standard for falsity that would make it much easier for the Government and *qui tam* relators to prove this element in FCA cases.

Second, although the Eleventh Circuit remanded to allow the Government an opportunity to "try to persuade the district court that a triable issue exists on both falsity and knowledge," the Court emphasized that it did "not know that this effort will succeed." While the Eleventh Circuit noted that the Government proffered evidence regarding AseraCare's practices that suggests that its "certification procedures were seriously flawed," the Court stressed that the "Government must be able to link this evidence of improper certification practices to the specific 123 claims at issue in its case. Such linkage is necessary to demonstrate both falsehood and knowledge."

Although the case deals specifically with hospice services, the standards and requirements announced by the Eleventh Circuit are likely to be applied in similar contexts, such as in FCA cases involving issues of medical necessity where clinical judgment is similarly at the center of the inquiry as to eligibility for reimbursement. In such cases, relators and the Government will need to rely on more than mere differences in medical opinion to prove falsity and will need to demonstrate a specific link between alleged unlawful business practices and specific allegedly false claims.

Finally, given some of the veiled criticisms present in the Eleventh Circuit's opinion regarding the district court's decision to bifurcate the issues of falsity and the other requisite FCA elements, including knowledge, it may be unlikely that other district courts adopt this similar unusual procedural approach in the rare FCA cases that proceed to trial.

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