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11th Circuit: Difference in Opinion Not Enough for FCA Liability

The 11th Circuit's long-awaited* AseraCare *opinion requires more than mere disagreement regarding clinical judgment to prove falsity under the False Claims Act.

The 11th Circuit rejected the government's theory of falsity in its long-running False Claims Act (FCA) case against long-term care provider AseraCare Inc. The 11th Circuit affirmed the lower court's ruling that mere clinical disagreement was insufficient to establish falsity under the FCA. The court kept the case alive, however, by remanding to provide the government an opportunity to present additional evidence of falsity. The 57-page opinion persuasively explains why a disagreement regarding "clinical judgment does not reflect an objective falsehood" and should help FCA defendants prevail in cases premised on a post hoc review of a provider's clinical judgment.

11th Circuit Rejects Government's Theory That Disagreements Regarding Medical Judgment Can Establish Falsity

The 11th Circuit's opinion represents the latest chapter in *United States v. AseraCare, Inc.*, a case replete with unexpected turns.[1] Some of the more unique aspects include (1) the unprecedented bifurcation of the trial into separate falsity and knowledge phases and (2) the declaration of a mistrial and *sua sponte* grant of AseraCare's earlier summary judgment motion because the government failed to prove falsity. The district court held that an FCA plaintiff must "direct the court to admissible, objective evidence ... other than [a medical expert's] testimony, that would prove falsity and show that the Government presented more evidence than merely a different of opinion to which reasonable minds could differ."[2] The government appealed the grant of a new trial and the grant of summary judgment.

The 11th Circuit, the first US Court of Appeals to address FCA liability in the hospice context, issued a lengthy opinion affirming the district court's well-reasoned holding on falsity: "We agree with the district court's conclusion 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."[3] Thus, in the context of hospice reimbursement, the plaintiff must "identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment."[4] Pointing to a reasonable disagreement regarding whether a provider — in exercising clinical judgment — should have characterized a patient as terminally ill at the time of hospice certification is not enough.[5]

The 11th Circuit rejected the government's reliance on a recent 6th Circuit appellate opinion adopting the government's theory that doctors' medical judgment can be "false or fraudulent" under the FCA. The 11th Circuit distinguished *United States v. Paulus*, which held that opinions "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,"[6] reasoning that there was no allegation that AseraCare's physicians had lied in their exercise of medical judgment or that their medical judgment was otherwise unreasonable.[7]

District Court Must Consider Additional Evidence of Falsity

The 11th Circuit then remanded the case for consideration of additional evidence the government planned to present at phase two of the trial on the knowledge element of the FCA.[8] The 11th Circuit determined that "the Government should have been allowed to rely on the entire record, not just the trial record, in making its case that disputed issues of fact, beyond just the difference of opinion between experts, existed sufficient to warrant denial of the district court's post-verdict *sua sponte* reconsideration of summary judgment on the falsity question."[9]

Yet in remanding the opinion, the court identified a key issue the government will have to address in order to prevail: "on remand, the Government must be able to link 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."[10] This framing of the issue may well doom the ability of the government to escape summary judgment, at least as to some of the claims at issue, on remand.

Regarding the type of additional evidence that should be allowed to introduce to show falsity in clinical judgment cases, the court suggested:

- The statements of nine witnesses who testified that AseraCare had a "deliberate practice of not giving physicians relevant, accurate, and complete information about patients whose certifications for hospice the doctors were being asked to sign[,]"
- The statement of a former director of clinical services that she "typically did not provide the certifying physician with any clinical information, but usually just gave him a stack of papers to sign[,]"
- "[E]vidence from AseraCare's internal and external auditors criticizing the company because the certifying medical directors were not adequately involved in making initial eligibility determinations and did not consistently receive medical information prior to the initial certification[,]" and
- "[T]estimony from a former AseraCare physician that employees did not defer to his clinical judgment that certain patients were unentitled to hospice benefits, but instead proceeded to file the claims."[11]

Somewhat surprisingly — given that most courts treat knowledge and falsity as separate and distinct elements under the FCA — the court additionally suggested that evidence of the certifying physician's *knowledge* when making the certification *might* also be relevant to *falsity* because "an opinion can enter falsifiable territory when it is based on information that the physician knew, or had reason to know, was incorrect."[12] The use of the term "knowledge" on this point will likely be over-read by relators and the government. Here, the certification at issue, unlike most certifications at issue in FCA cases, had a specific clinical representation embedded within it. The certification read in pertinent part that a physician or medical director must certify that an "individual is terminally ill ... *based on the physician's or medical director's clinical judgment* regarding the normal course of the individual's illness."[13] The court's use of the term "knowledge" is best read as merely ruling that the certification that the physician exercised clinical judgment can be false where a physician subjectively does not believe he or she is relying on accurate

information — not that subjective intent can make an opinion objectively false. Indeed, the court emphasized that "[o]bjective falsehood can be shown" only when "the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."[14]

Key Takeaways for FCA Defendants

AseraCare should prove to be a key case for FCA defendants on a variety of grounds, including:

1. **An FCA plaintiff cannot rely on reasonable disagreement regarding the exercise of clinical judgment alone to prove falsity.** *AseraCare* makes clear that FCA liability fails as a matter of law where a plaintiff's expert merely disagrees with a provider's exercise of clinical judgment.[15]

2. **The court's conclusion that "something more" is needed to demonstrate falsity is consistent with district court opinions.** As the 11th Circuit noted, numerous district courts "have embraced comparable reasoning" in cases that premise FCA liability on clinical judgments of terminal illness.[16]

3. **Providers' subjective knowledge is relevant to falsity only when it goes directly to the certification process and whether medical judgment was exercised at all.** The 11th Circuit's discussion of what evidence the government should be allowed to rely on to demonstrate falsity supports this interpretation, as the evidence the 11th Circuit discussed relates to whether AseraCare's hospice certification process writ large was flawed or false.[17] For example, the evidence to be considered relates to whether providers were exercising clinical judgment *at all* by examining the clinical record before certifying a patient for hospice.

4. **Even in sampling cases, the government must be able to link evidence of falsity to the claims at issue.** The court's warning that the government must link evidence of improper certification processes to the specific claims indicates that even in instances in which sampling is permitted, the government cannot rely on general allegations about a false certification process and must instead link this evidence to individual claims.

5. **Disputes about the exercise of clinical judgments should be addressed by regulatory agencies rather than FCA plaintiffs.** The court emphasized that CMS and Congress "were careful to place the physician's clinical judgment at the center of the [hospice certification] inquiry."[18] Rejecting the government's argument that requiring more to prove falsity would permit "providers with sloppy or improper admission practices [to] evade FCA liability so long as they can argue after the fact that their physicians' clinical judgments were justifiable," the court stated that "if this is a problem, it is one for Congress or CMS to solve."[19]

6. **This opinion has implications beyond the hospice context.** This holding will reverberate far beyond the hospice context. The government and relators frequently bring FCA cases questioning a provider's exercise of medical judgment, often based on a retroactive clinical review many years after the fact. The court makes clear that reasoned clinical assessment and perspective is a key factor in assessing potential liability and defenses under the FCA.

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Endnotes

[1] For an in-depth overview of the procedural history, please see two prior articles by Latham & Watkins discussing the district court rulings: https://www.lw.com/thoughtLeadership/aseracare-ruling-fca-is-not-for-differing-medical-opinions; https://www.lw.com/thoughtLeadership/aseracare-key-case-for-fca-defendants.

[2] *United States v. AseraCare Inc*, 176 F. Supp. 3d 1282, 1284 (N.D. Ala. 2016), *vacated and remanded sub nom. United States v. AseraCare*, Inc., No. 16-13004, 2019 WL 4251875 (11th Cir. Sept. 9, 2019).

[3] *United States v. AseraCare, Inc.*, No. 16-13004, 2019 WL 4251875, at *15 (11th Cir. Sept. 9, 2019).

[4] *Id.*

[5] *See id.* at *1 ("Upon careful review of the record and the relevant law, and with the benefit of oral argument, we concur with the district court's ultimate 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.").

[6] *Id.* at *17.

[7] The 11th Circuit emphasized that "there is no dispute that each patient certification was supported by a meaningful set of medical records evidencing various serious and chronic ailments for which the patient was entitled to some level of treatment." *Id.* at *7.

[8] *See id.* at *1 ("We do, however, think that the Government should have been allowed to rely on the entire record, not just the trial record, in making its case that disputed issues of fact, beyond just the difference of opinion between experts, existed sufficient to warrant denial of the district court's post-verdict sua sponte reconsideration of summary judgment on the falsity question. We therefore affirm in part and remand in part.").

[9] *Id.*

[10] *Id.* at *21.

[11] *Id.* at *19.

[12] *Id.* at *18.

[13] 42 U.S.C. § 1395f(7)(A) (emphasis added). "Terminally ill" means "a medical prognosis that the individual's life expectancy is 6 months or less." 42 U.S.C. § 1395x(dd)(3)(A).

[14] *AseraCare,* 2019 WL 4251875, at *15.

[15] The district court notably refused to go down this road, stating: "If the court were to find that all the Government needed to prove falsity in hospice provider cases was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment. The court refuses to go down that road." *AseraCare,* 176 F. Supp. 3d at 1285.

[16] *AseraCare,* 2019 WL 4251875, *at* *15 n.10. Many of these cases are included in the two articles in Endnote 1. Furthermore, in mid-2016 the Northern District of Texas issued an opinion holding that "[b]ecause a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that 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." *United States ex rel. Wall v. Vista Hospice Care, Inc.*, *No*. 3:07-CV-00604-M, 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016).

[17] The court recognized this in stating that "to the extent that a reasonable jury might credit the Government's proffered evidence regarding AseraCare's practices, that evidence suggests that AseraCare's certification procedures were seriously flawed" and that the government's proffered testimony "certainly raises questions regarding AseraCare's certification process writ large." *AseraCare,* 2019 WL 4251875, at *21 (further stating that it leaves it up to the district court and the parties to determine what "more" the government needs to show to prove falsity).

[18] *Id.* at *18.

[19] *Id.*