FCA FALSITY INVOLVING MEDICAL NECESSITY POST-*ASERACARE*

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In late 2019, the 11th Circuit issued an opinion in *United States v. AseraCare, Inc.*, 938 F. 3d 1278 (11th Cir. 2019) that was heralded as a significant victory for hospice and other healthcare providers that face after-the-fact scrutiny in FCA litigation of subjective clinical judgments. However, two petitions for writ of certiorari are currently pending with the United States Supreme Court on the question of what can constitutes "falsity" in FCA cases based on medical necessity.[1] The Supreme Court's action on these petitions may again shift the landscape for healthcare providers whose services involve subjective clinical judgment. This paper will provide background of the *AseraCare* decision and will highlight the cases pending before the Supreme Court.

I. *AseraCare* Decision

In *AseraCare*, the court considered how Medicare's requirements for hospice eligibility — which are centered on a physician's subjective "clinical judgment" as to a patient's life expectancy — intersect with the FCA's falsity element. The case began when three former employees alleged that AseraCare had routinely submitted unsubstantiated Medicare claims. The government later intervened, alleging that AseraCare had submitted documentation falsely representing that certain Medicare patients were terminally ill — that is, had a life expectancy of six months or less. The initial phase of trial on the issue of falsity boiled down to a classic "battle of the experts" as to whether the patients' medical records supported AseraCare's certifications of terminal illness for approximately 100 patients at issue. Significantly, the government's expert conceded that he could not say whether AseraCare's medical expert was wrong and that he himself had changed his own opinion concerning the eligibility of certain patients over the course of the proceedings. Nonetheless, the jury found that AseraCare had submitted false claims for roughly 85 percent of the patients at issue. Following the jury's findings, the district court ordered a new trial and *sua sponte* reconsidered and granted summary judgment based on the principle that a mere difference of opinion between physicians, without more, was not enough to show falsity.

In its decision, the 11th Circuit framed the relevant question as "When can a physician's clinical judgment regarding a patient's prognosis be deemed "false?"[2] The Court went on to note that "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [ ] be wrong."[3] The 11th Circuit concluded that a subjective but honest disagreement on medical prognosis could not be the basis for falsity under the FCA.[4]

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[1] *Care Alternative v. United States of America, et al. Case No.* ____ (Filed September 16, 2020); and *RollinsNelson LTC Corp. et al. v. United States of America ex rel. Jane Winter Case No.* ____ (Filed December 3, 2020).

[2] *AseraCare*, 938 F.3d at 1296.

[3] *Id.*

[4] *Id.* at 1297.

Instead something more "objective" must be demonstrated to show falsity. The Court stated that objective falsity could be met where a plaintiff identifies "facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment."[5] The Court noted some examples that might support objective falsity, such as 1) that the certifying physician failed to familiarize himself with the medical record; 2) that the physician did not in fact subjectively believe the prognosis to be true; or 3) proof by expert testimony that no reasonable physician could have concluded that a patient was terminally ill.[6]

It was important to the Court's decision that the regulatory framework required only that physicians exercise their clinical judgment considering the facts at hand and document their rationale. The court took the government to task for reading requirements into the regulations that were not present — namely, that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment.[7] According to the court, a physician's clinical judgment dictates eligibility. Pointing to CMS's own recognition that "predicting life expectancy is not an exact science," the court concluded that "the law [was] designed to give physicians meaningful latitude to make informed judgments without fear that those judgments [would] be second-guessed after the fact by laymen in a liability proceeding." [8]

II. Pending Writs of Certiorari

Two petitions for a writ of certiorari are currently pending with the United States Supreme Court on the question of what constitutes "falsity" in FCA cases based on medical necessity.[9] At issue are three decisions from the United States Courts of Appeals that tackled the question of whether a difference of opinion between medical professionals can be the basis for "falsity" under the FCA. Two of these cases involve the specific requirements of the Medicare hospice benefit program—namely that a physician certify that a patient is terminally ill with a life expectancy of six months or less. The other involves the requirements for certifying a patient for in-patient hospital treatment as opposed to less expensive out-patient care.

The first, a decision from the Third Circuit, stands in sharp contrast to the 11th Circuit's reasoning in *AseraCare*. In *United States ex rel. Druding v. Care Alternatives,* 952 F.3d 89, 100 (3rd Cir. 2020), the Third Circuit found that "medical opinions can be false" even if honestly held and reasonable. Thus, an after-the-fact expert opinion that the prognosis was incorrect presents a triable issue of fact for the jury for whether the claim may be "false."[10] The Third Circuit stated directly that it disagreed with the reasoning in *AseraCare* in the 11th Circuit.

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[5] *Id.*

[6] *Id.*

[7] *Id.* at 1294.

[8] *Id.* at 1295.

[9] *Care Alternative v. United States of America, et al. Case No.* ____ (Filed September 16, 2020); and *RollinsNelson LTC Corp. et al. v. United States of America ex rel. Jane Winter Case No.* ____ (Filed December 3, 2020).

[10] *Care Alternatives*, 952 F.3d at 101.

Shortly thereafter the Ninth Circuit also weighed in on this question in *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108 (9th Cir. 2020). Unlike the Third Circuit, however, the Ninth Circuit took pains to reconcile its decision with *AseraCare,* stating that the 11th Circuit "identified circumstances in which a medical opinion would be false" and any "objective falsehood" requirement embraced by the 11th Circuit was limited to the hospice-benefit provision at issue in *AseraCare*—and not at issue in *Winters,* which involved the physician certification of need for in-patient hospital treatment.[11] The Ninth Circuit concluded that a medical opinion can be false or fraudulent for the same reasons that other opinions could be false or fraudulent including that "the opinion is not honestly held, or if it implies the existence of facts that do not exist."[12]

Against this backdrop both Care Alternatives and affiliates of Gardens Regional Hospital filed motions for certiorari with the United States Supreme Court. The Gardens Regional petition broadly frames the question presented to the court as "Whether the False Claims Act requires pleading and proof of an objectively false statement?" Care Alternatives, perhaps because it is a hospice case like *AseraCare* frames a narrower question for the Court: "Whether a physician's honestly held clinical judgment regarding hospice certification can be "false" under the False Claims Act based on solely on a reasonable difference of opinion among physicians." In *Care Alternatives*, the Supreme Court directed relators to respond to the petition, and their opposition was filed January 8, 2020. In its opposition, relators encouraged the Court to deny the petition characterizing the difference between the circuits as being "minor" because both the Third and Eleventh Circuit agree that opinions can be false, noting the circumstances set out by the Eleventh Circuit that might show an opinion to be false. In addition, the opposition argued that even if the standard for falsity in these two hospice cases was somewhat different, the overall standard for FCA liability in both circuits was the same. Relators also rejected the idea that circuits are in "disarray" on the standard for FCA falsity.

Whether the Supreme Court grants certiorari on either or both of these cases could have profound consequence for future FCA cases based on medical necessity. Granting certiorari and adopting the petitioners' position in the *Gardens Regional* petition would eliminate the government's or a relator's ability to get to the jury on the question of falsity based solely on an expert opinion that treatment provided was not medically necessary. Instead, additional evidence of "objective falsity" of the type cited by the 11th Circuit in AseraCare would likely be necessary. On the other hand, adoption of the Third Circuit's position in *Care Alternatives* case would mean hospice and other medical necessity cases would move on to a jury with a triable issue of fact anytime the government or whistleblower's counsel could find any qualified expert willing to disagree with the medical judgment of physicians who ordered medical services. A more gradual, and careful, approach by the Court would be to grant certiorari on the *Care Alternatives* case to address the narrower question related to medical necessity in the context of the Medicare hospice benefit in which the Third Circuit has plainly stated that it has split with the *AseraCare* decision out of the 11th Circuit. In any event, a grant of certiorari in either case is likely to have as

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[11] *Winter*, 953 F.3d at 1108.

[12] *Winter*, 953 F.3d at 1119.

momentous an impact on FCA jurisprudence for the health care industry as the *Escobar* decision in 2016.