FCA Ruling Eases Clinical Judgment Standard For Gov't

By **Derek Adams and Rosie Griffin** (March 12, 2020)

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Last Wednesday, the U.S. Court of Appeals for the Third Circuit held that a health care provider's clinical judgment can be false based on dueling expert testimony in a False Claims Act case.

The case — United States ex rel. Druding v. Care Alternatives[1] — was brought against New Jersey hospice care provider Care Alternatives. The relators, former employees of Care Alternatives, alleged that the defendant had admitted patients who were ineligible for hospice care because the accompanying physician certifications of terminal illness that ostensibly made the patients eligible for end-of-life care were false.

In Druding, the U.S. District Court for the District of New Jersey granted summary judgment for the defendant, finding that proof of an objective falsehood was required to establish falsity under the FCA, and that "a mere difference of opinion between experts" as to whether a patient's condition met the statutory definition of terminal illness — defined as six months or less to live — was insufficient.[2] The Third Circuit rejected that view and overturned the district court's decision.[3]

This fact pattern should sound familiar. It's the same one alleged in the closely watched AseraCare case decided last September by the U.S. Court of Appeals for the Eleventh Circuit.[4] In AseraCare, the court held that to establish the FCA element of falsity, the government and/or a relator must establish an objective falsehood.[5]

Those alleging False Claims Act liability premised on a defendant's clinical decision-making in the hospice context must "show something more than a mere difference of reasonable opinion concerning the prognosis of a patient's likely longevity."[6] Rather, they must "identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment."[7] In AseraCare, dueling expert testimony did not suffice.

Facing the same question in United States ex rel. Druding v. Care Alternatives, the Third Circuit squarely rejected not only the district court's holding, but also the U.S. Court of Appeals for the Eleventh Circuit's AseraCare holding.

Departing from its sister circuit, the court concluded that "a hospice-care provider's claim for reimbursement can be considered 'false' under the FCA on the basis of medical-expert testimony that opines that accompanying patient certifications did not support patients' prognoses of terminal illness."[8]

Because Congress did not define what makes a claim false or fraudulent under the FCA, the court turned to common law, noting that within that framework, an opinion can be false. The court thus concluded that the meaning of "false" under the statute was at odds with a position that a finding of falsity would not stand on a mere difference of opinion.[9]

The Third Circuit also took issue with the district court's holding that "a medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual

inaccuracy" and that a "differing medical conclusion regarding a patient's prognosis alone" could not establish factual inaccuracy.[10]

This, the court found, "improperly conflates the elements of falsity and scienter" and "reads the scienter element out of the text of the statute."[11] Rather than requiring a showing of factual inaccuracy, the element of "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."[12]

If those conditions were not met — for example because a certification that clinical information and other documentation support the patient's medical prognosis — the element of falsity is established. And, the court found, this may be proven by expert testimony establishing that a patient's prognosis was not supported.

The court's analysis and conclusion as to falsity distinguishes factual falsity from legal falsity. Guided by the U.S. Court of Appeals for the Tenth Circuit's rationale in United States ex rel. Polukoff v. St. Mark's Hospital,[13] the court explained that factual falsity — to which the Druding district court limited its analysis — is established through a showing that facts contained within the claim are untrue.

Legal falsity, the court explained, is based instead on the false assertion, either express or implied, of compliance with applicable statutory, regulatory or other core requirements.[14]

Applying this approach to determining falsity to the facts in Druding, the court determined that even though the original physician's honestly held opinion may not be factually false, it may be legally false if it fails to comply with statutory and regulatory requirements (i.e., a finding that the medical record did not support the physician's opinion).

The court went on, however, to note that its holding does not render objectivity irrelevant — rather, it "speaks to the element of scienter, not falsity."[15]

Thus, even if falsity is established based on expert testimony, the government and/or relator will still need to establish that the certifying physician acted with the requisite level of scienter to trigger FCA liability. A certifying physician's reasonable belief in his or her clinical opinion would negate a finding of scienter — and with it FCA liability — even if that clinical opinion was legally false.

Perspective

The Third Circuit's Druding opinion will come as welcome news to the government and relators after AseraCare's pro-defendant holding on clinical judgment and objective falsity. In the Third Circuit, the Druding decision eases the burden of establishing falsity in cases involving clinical judgment.

That said, the holding is not entirely relator and government-friendly. The court also cautioned that the FCA's scienter requirement is rigorous and "helps to limit the possibility that hospice providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis."[16]

Thus, while the court determined that expert testimony alone may support a finding of falsity, it is unlikely that such testimony — without additional scienter evidence — would ultimately support FCA liability.

Similar to AseraCare, this decision leaves open for debate a critical question for FCA liability — how tight must the nexus be between the defendant's scienter and the individual claim at issue? In that respect, the decisions are not incongruous. AseraCare requires that linkage to establish that a clinical judgment is false, whereas Druding will require that linkage to establish the defendant's scienter.

As a practical matter, however, answering this question at the point of falsity may lend itself to a tighter requirement than answering this question as to scienter. On the one hand, jurors may be more inclined to accept proof of scienter through emails or witness testimony that may not be linked to a specific false claim. On the other hand, if that evidence must be linked on a claim-by-claim basis to establish and move past the falsity element, that is a far greater lift for the plaintiff.

In addition, it will likely be easier for the government and/or relators to survive summary judgment if expert testimony alone can establish falsity. Issues of scienter, which often involve weighing of evidence and making credibility determinations, are more often decided at trial than at summary judgment.

Implications

Likely deflated by the AseraCare decision, and the case's culmination in a less than desired $1 million settlement, Druding offers the government and relators renewed hope in utilizing expert testimony to establish falsity in FCA cases premised on clinical judgment. Such evidence is often the only way a plaintiff can submit proof on a claim-by-claim basis, and therefore it weighs heavily in clinical judgment cases.

That said, the relators in Druding still have an uphill battle to climb at trial if they are to overcome the rigorous scienter standard recognized by the Druding court.

The question of whether Druding or AseraCare got it right will continue to be litigated in other cases. As reflected by the U.S. Department of Justice's recent announcement of a National Nursing Home Initiative, its commitment to bringing cases related to elder fraud — which often turn on clinical judgments — shows no signs of waning.[17]

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[1] United States ex rel. Druding v. Care Alternatives, Inc., No. 18-3298, 2020 BL 80203 (3d Cir. Mar. 4, 2020).

[2] Id. at *1.

[3] Id. at *11.

[4] United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019).

[5] Id. at 1296–97.

[6] Id. at 1297.

[7] Id.

[8] Druding, 2020 BL 80203 at *4–5.

[9] Id. at *5.

[10] Id. at *7.

[11] Id. at *5, 6.

[12] Id. at 7.

[13] United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730 (10th Cir. 2018).

[14] Druding, 2020 BL 80203 at *6–7.

[15] Id. at *10.

[16] Id. at *6.

[17] https://www.justice.gov/opa/pr/department-justice-launches-national-nursing-home-initiative.