

The Salcido Report: False Claims Act Public Disclosure Alert

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11th Circuit's Decision in AseraCare: Important in Determining When Clinical Judgment Regarding Medical Necessity Can Result in an Overpayment and How Evidence Regarding Corporate Knowledge Must be Tied to Claims to Establish False Claims Act Liability

October 10, 2019

Key Points:

- Reasonable disagreement among clinicians, by itself, does not result in a false claim.
- Clinical judgment must be objectively false to constitute an FCA violation.
- A clinical judgment may only be objectively false when there are verifiable facts at odds with the exercise of valid clinical judgment.
- A reckless truth cannot create FCA liability; thus courts should exercise care to ensure that alleged corporate knowledge is directly linked in time and place to discrete false claims so the analysis of whether claims are false in the first instance is not tainted.

Two common issues arise in False Claims Act (FCA) litigation, one specific to health care FCA litigation and one that cuts across all FCA actions involving corporate entities.

The first issue is when can clinical judgment be deemed “false” for purposes of the FCA. If the clinician reasonably believes the services or procedures are appropriate in light of the patient’s condition, when, if ever, can that opinion be a false opinion under the FCA, potentially subjecting the clinician to treble damages and substantial civil penalties? This issue is significant because it is relevant not only to FCA actions but also regarding internal reviews health care entities undertake to determine whether an overpayment is due to the government because a particular service or procedure potentially lacked medical necessity.

The second issue is when can the FCA plaintiff use scattered communications within a company regarding generalized alleged misconduct to establish that discrete claims are “knowingly” false. Historically, FCA plaintiffs—even when litigating against national

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companies or companies operating at multiple sites—have sought to identify a handful of purportedly provocative emails (e.g., we need to generate more revenue, profitability must be sustained, etc.) to seek to establish that the company acted with reckless disregard or deliberate ignorance of the truth or falsity of a particular claim. Generally, the FCA plaintiff will ask the court or jury to infer that the requisite intent existed from the emails or other communications without specifically linking the communication—in time and place—to the purported false claim.

The 11th Circuit’s decision in *United States v. AseraCare, Inc.*¹ addresses both of these issues.

First, as to clinical judgment, the decision sets forth the proper method to evaluate when disagreements regarding clinical judgment can result in a false claim. The 11th Circuit concurred with the district court that a mere reasonable disagreement among clinicians is insufficient to establish FCA falsity. The court concluded that absent a showing of an objective and knowing falsehood, the FCA is not an appropriate instrument to serve as the government’s primary line of defense against questionable claims for reimbursement.

This decision has significant ramifications both in defending FCA cases and in health care entities’ internal reviews and audits. As to the FCA, medical necessity cases have been a staple of FCA lawsuits since 1986 when the FCA’s scope was substantially expanded. The court’s ruling will significantly deter the government from bringing such lawsuits when all that exists is a mere battle of experts. Additionally, the court’s ruling may also result in health care entities transforming the manner in which they conduct medical reviews. Many entities evaluate clinical judgment as either being “right” or “wrong” in light of the medical documentation. If the judgment appears wrong, the entity may believe that there is a duty to remit an overpayment to the government. But, as the 11th Circuit correctly concluded, this approach is overly simplistic and wrong because at times there can be two or more reasonable opinions, with none of them being false or wrong.

Second, as to the link that must exist between FCA knowledge evidence and the actual claim for payment, the court found that the government must actually tie evidence of improper practices, by place and time, to the specific claims at issue to establish FCA liability. This is significant because the FCA plaintiff, at trial and the summary judgment stage, frequently will seek to take scattered emails and texts reflecting a corporate strategy to be profitable and regulatory lapses to assert that unrelated claims are “knowingly” false. Importantly, the court in *AseraCare*, joining a growing list of other courts, rejected this approach.

How to Assess Clinical Judgment Under the FCA

In *AseraCare*, the 11th Circuit considered the circumstances in which a certification can be considered “false” when the hospice provider certifies that the patient is “terminally ill” and clinicians can reasonably disagree regarding whether a patient is “terminally ill.”

Specifically, the government alleged that the defendant hospice submitted documentation that falsely represented that Medicare recipients were “terminally ill” when, in the government’s view, they were not.² For a hospice claim to be eligible for Medicare reimbursement, the patient’s attending physician, if there is one, and the hospice medical director must “each certify in writing at the beginning of [each] period,

that the individual is terminally ill ... based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness."³ "Terminally ill" means that the individual "has a medical prognosis that the individual's life expectancy is 6 months or less."⁴ The court noted that, importantly, none of the relevant language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact and that CMS has recognized in crafting the implementing regulations that "[p]redicting life expectancy is not an exact science."⁵ The statutory and regulatory framework also did not state or imply that the patient's medical records must unequivocally demonstrate to an unaffiliated physician, reviewing the records after-the-fact, that the patient was likely to die within six months of the time the certifying physician's clinical judgment was made.⁶ Rather, the court concluded, the framework asks a physician responsible for the patient's care to exercise his or her judgment as to the proper interpretation of the patient's medical records.⁷ And while there is no question that clinical judgments must be tethered to a patient's medical records, the court noted that it is equally clear that the law is designed to furnish physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.⁸

To establish its case, the government retained an expert physician to review a sample of claims to determine whether patients admitted to the hospice were terminally ill. Upon direct review of patients' medical records and clinical histories, the government's expert opined that 123 patients from a sample were ineligible for the hospice benefit at the time the defendant received reimbursement for their care.⁹ In rendering this opinion, the government's expert made clear that his testimony reflected only his own clinical judgment based on his after-the-fact review of the supporting documentation.¹⁰ He conceded that he was "not in a position to discuss whether another physician [was] wrong about a particular patient's eligibility. Nor could he say the defendant's medical expert, who disagreed with him concerning the accuracy of the prognoses at issue, was necessarily 'wrong'."¹¹ Moreover, the government's expert never testified that, in his opinion, no reasonable doctor could have concluded that the identified patients were terminally ill at the time of certification.¹²

At the conclusion of trial, after the jury had heard the government's and the hospice's expert clinicians' divergent opinions regarding whether the patients were terminally ill, the district court provided the following instruction to the jury on falsity to address the issue: "A claim is 'false' if it is an assertion that is untrue when made or used. Claims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable."¹³ Thus, under the court's instruction, the precise question before the jury was which doctor's interpretation of those medical records sounded more correct. In other words, in this battle of experts, the jury was to decide which expert it thought to be more persuasive, with the less persuasive opinion being deemed a "false" opinion.¹⁴

Under the court's falsity instruction, the jury ultimately found that the defendant had submitted false claims for 104 of the 123 patients at issue during the relevant time period.¹⁵

Following the partial verdict in this first phase of trial, the defendant moved for judgment as a matter of law, arguing that the court had articulated the wrong legal standard in its jury instructions.¹⁶ The district court agreed, noting that it "became convinced that it had committed reversible error in the instructions it provided to the

jury.”¹⁷ It ultimately concluded that proper jury instructions would have advised the jury of two “key points of law” that the court had not previously acknowledged: (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.¹⁸ The court ultimately concluded that the failure to instruct the jury on these points was reversible error and that the only way to cure the prejudice its instruction caused was to order a new trial.¹⁹

The 11th Circuit concurred with the district court that a mere reasonable disagreement among clinicians is insufficient to establish FCA falsity. The court concluded that absent a showing of an objective and knowing falsehood, the FCA is an inappropriate instrument to serve as the government’s primary line of defense against questionable claims for reimbursement of hospice benefits.²⁰ The court noted that such a jury charge would need to convey 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.²¹ Instead, the court ruled that 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 are circumstances are shown, the FCA claim fails as a matter of law.²²

The court noted that objective falsity could be demonstrated in a number of ways. For instance, an objective falsehood may exist when a certifying physician fails to review a patient’s medical records or otherwise familiarize herself with the patient’s condition before asserting that the patient is terminal because it fails to reflect clinical judgment.²³ Objective falsehood may exist when a plaintiff proves that a physician did not, in fact, subjectively believe that her patient was terminally ill at the time of certification.²⁴ A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records.²⁵ The court reasoned that in each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts.²⁶ But the court concluded, by contrast, 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.²⁷ A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong.²⁸ The court acknowledged that compelling the plaintiff to establish objective falsity “will likely prove more challenging for an FCA plaintiff” than “to find an expert witness willing to testify to a contrasting clinical judgment regarding cold medical records.” But that ultimately “if this is a problem, it is one for Congress or CMS to solve.”²⁹

The FCA's Plaintiff's Burden to Link Alleged Guilty FCA Knowledge to Discrete FCA Claims

In any entity with hundreds or thousands of employees, there will be typically frequent communications regarding the need to maintain a budget, enhance revenue and increase profits. There may also be other communications addressing an actual or perceived failure to adhere to internal policies or regulatory breaches. Today with rampant texting and email communications, a veritable treasure trove of such communications may be available to any FCA plaintiff in discovery.

In FCA lawsuits, the use of such evidence is problematic when there is no clear or logical linkage between the purported bad corporate “knowledge” communications and the submission of false claims. Indeed, in FCA trials and actions reaching the summary judgment stage involving a sample of claims, the plaintiff frequently makes the following two moves: first, identify and introduce as evidence documents that confirm that for-profit companies seek to be profitable, such as budgeting documents that take the form of managers reminding employees that revenue targets are important or budgets should be satisfied.³⁰ From these documents, the FCA plaintiff wants the Judge or the jury to infer that the company must have been willing to commit fraud to achieve revenue targets or budgets.³¹ And, in a trial setting, plaintiffs will seek to get these communications admitted into evidence and flash them, in rapid succession, before the jury during closing.

Second, aside from the general anecdotal evidence related to profitability and periodic regulatory lapses, the FCA plaintiff separately identifies and introduces claims for payment that are purportedly false and material to the government’s determination to pay. But the government and relator never connect the purported guilty knowledge with the discrete claims. Frequently the court is left with nothing more than that perhaps some employees at one site or division sought that a particular practice occur and that a stream of claims were submitted at a different site or by different individuals with a complete disregard for connecting FCA knowledge with FCA false claims.

Historically, courts have rejected this approach when the government has sought a jury instruction that jurors can pool together the knowledge possessed by all employees to determine whether a claim is knowingly false because this approach may inappropriately extend the FCA to reach honest mistakes or merely negligent conduct. For example, in *United States v. Sci. Applications Int’l Corp.*, the D.C. Circuit considered whether a defendant could possess the requisite knowledge under the FCA based upon the “collective knowledge” of its employees.³² In *Sci. Applications*, the government alleged that the defendant falsely represented that it did not have a conflict of interest regarding its government work.³³ Over the defendant’s objection, at trial, the district court instructed the jury that corporations are “liable for the collective knowledge of all employees and agents within the corporation so long as those individuals obtained their knowledge acting on behalf of the corporation.”³⁴ Additionally, the court instructed the jury:

Therefore, if a corporation has many employees or agents, you must consider the knowledge possessed by those employees and agents as if it was added together and combined into one collective pool of information. If that collective pool of information here gives a reasonably complete picture of ... false or fraudulent claims or false statements, you may find that [the defendant] itself possessed a reasonably complete picture of the false or fraudulent claims or false statements and acted knowingly.³⁵

The D.C. Circuit rejected the district court’s jury instruction. The court ruled that “under the FCA, ‘collective knowledge’ provides an inappropriate basis for proof of scienter because it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act’s language, structure, and purpose.”³⁶ The court noted that “Congress clearly had no intention to turn the FCA, a law designed to punish and deter fraud, into a vehicle for either punish[ing] honest mistakes or incorrect claims submitted through mere negligence or imposing a burdensome obligation on government contractors rather

than a limited duty to inquire.”³⁷ The court ruled that imposition of collective knowledge would undermine the statutory definition of what constitutes actionable knowledge because the “‘Collective knowledge’ theory allows a plaintiff to prove scienter by piecing together scraps of ‘innocent’ knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.”³⁸

Significantly, in *AseraCare*, the district court applied the same principle—ensuring that loose anecdotal knowledge evidence does not taint or prejudice the factfinder’s analysis regarding whether discrete claims are false—by bifurcating the trial into two stages.

In *AseraCare*, the government sought to bolster the testimony of its clinical expert by developing evidence that defendant’s broader business practices fostered and promoted improper certification procedures while deemphasizing clinical training on terminal-illness prognostication.³⁹ For example, the government’s proffered evidence regarding the defendant’s practices included a former Director of Clinical Services testifying that one physician she worked with was in a habit of signing certifications before reviewing any medical documentation whatsoever, stating that clinical staff typically “just gave him ... a stack of papers to sign, [and] he just signed the papers.”⁴⁰ Another former employee testified that signing certifications had become so rote for one physician that he “would nod off” while signing.⁴¹

The defendant, concerned that such evidence would distort the jury’s analysis regarding the falsity of the claim moved the district court to bifurcate the trial so that in Phase I the jury would consider whether any “false” claim was submitted and, if so, in Phase II the jury would consider whether any false claim was “knowingly” presented to the government.

The district court granted the defendant’s motion. The court ruled that the “falsity” of the claims “cannot be inferred by reference to [the defendant’s] general corporate practices unrelated to specific patients.”⁴² The court concluded that allowing the government to present knowledge evidence before falsity was determined would be unduly prejudicial to the defendant, thus warranting separation of the knowledge and falsity elements.⁴³ Significantly, the 11th Circuit manifested its concurrence with this approach, noting that “crucially, on remand the Government must be able to link this evidence of improper certification practices to the specific claims at issue in its case. Such linkage is necessary to demonstrate both falsehood and knowledge.”⁴⁴

In so ruling, the 11th Circuit has joined the chorus of several other courts ruling that if the FCA plaintiff asserts a corporatewide scheme, the plaintiff must furnish corporatewide proof demonstrating a top-down corporatewide scheme and not simply scattered, isolated, low-level email strings unrelated to the purported false claims.⁴⁵

Conclusion

AseraCare reaffirms important FCA principles. As to clinical judgment, the court established additional precedent that there is no basis to credit after-the-fact review of cold medical records over and above the clinical judgment of the treating or supervising physician. Indeed, if the treating or supervising physician’s judgment could be second-guessed in this way in the context of a liability proceeding with laymen as fact finders, it could chill sound medical decision-making.

AseraCare is important in not only deterring the government from bringing these lawsuits, but also in providing guidance to health care entities regarding how to conduct internal medical reviews. That is, under *AseraCare*'s reasoning, the fact that a particular medical reviewer believes that the service is not medically necessary is not enough, by itself, to conclude that an overpayment is due. Instead, an additional question needs to be asked regarding whether reasonable clinicians can disagree regarding whether the service is necessary in light of the patient's condition. If so, there is unlikely to be any known overpayment due to the government for purposes of the FCA.

Finally, a reckless truth does not create FCA liability. To preserve this principle, *AseraCare* is also very important in demonstrating how to construct a framework to ensure that loose anecdotal communications unrelated to the purported false claims are not introduced in a way that taints the fair consideration of whether false claims were presented in the first instance. In a world of massive repositories of emails and texts, courts should follow *AseraCare*'s guide and require that plaintiff only present such evidence when it can directly connect that evidence in place and time with the purported false claims.

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About the Author

Robert Salcido is a leading FCA practitioner.

Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions that the government or relator filed at trial or summary judgment. Some of those cases include:

- Mr. Salcido was lead counsel for Golden Living in an FCA action where the federal government had sued Golden Living's predecessor company, Beverly Enterprises, for \$895 million, alleging that Beverly had engaged in an unlawful kickback scheme with McKesson Corp. in violation of the Anti-Kickback Act and the FCA. After 14 days of trial, the court ruled that Beverly and McKesson did not violate the FCA or the Anti-Kickback Act because their business negotiations were fair, reasonable and conducted in good faith. See *United States of America ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683 (N.D. Miss. 2012).
- Mr. Salcido was lead counsel for Aegis Therapies and a Golden Living skilled nursing facility where the federal government had alleged that defendants provided medically unnecessary rehabilitation therapy. The district court granted defendants' summary judgment motion, ruling that the government had used the wrong standard to assess whether the services were medically necessary and failed to prove that defendants' certification regarding medical necessity was objectively false. See *United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2014 U.S. Dist. LEXIS 45221 (S.D. Ga. Mar. 31, 2015).
- Mr. Salcido was lead counsel for defendants, an operator of a chain of skilled nursing companies and a rehabilitation company, during a five-week FCA jury trial. Based upon the trial record, the district court entered judgment for the defendants ruling that the relator did not establish FCA materiality at trial as a matter of law. See *United States ex rel. Ruckh v. Salus Rehab., LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018).
- Mr. Salcido was lead counsel for a defendant physician and multispecialty group practice that the government accused of FCA violations. The district court dismissed all the government's claims on summary judgment. Ultimately, because the United States' action lacked "substantial justification," the United States was ordered to pay defendants more than \$400,000 in legal fees. In making the ruling, the court ruled that Medicare fraud law is an area of expertise and ruled that it was undisputed that Mr. Salcido possessed such expertise. See *United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006).
- Mr. Salcido was lead counsel for Golden Living in an action where the relator and the government sued multiple defendants alleging that they violated the FCA because they knowingly created and operated a supply company in violation of Medicare Supplier Standards. The district court granted defendants' FCA summary judgment motion regarding the Supplier Standards allegations, finding that the government's prior administrative proceedings demonstrated that the defendant supply company was entitled to payment. See *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664 (N.D. Miss. 2011).

Mr. Salcido has authored a number of books and chapters in leading publications (including the American Health Lawyers Association, BNA Books and Bloomberg BNA) regarding the application of the FCA, including:

- *False Claims Act & the Health Care Industry: Counseling & Litigation* (3d ed. American Health Lawyers Ass'n 2018).

- “The False Claims Act in Health Care Prosecutions: Application of the Substantive, Qui Tam and Voluntary Disclosure Provisions” in *Health Care Fraud and Abuse: Practical Perspectives*, Ch. 3 (3d ed. BNA Books 2013) (with annual supplements).
- “False Claims Act: Health Care Applications and Defenses” in *Bloomberg BNA Health Law and Bus. Series No. 2650* (2012).

Because of his work successfully defending a number of FCA lawsuits, Mr. Salcido has been recognized in:

- *The National Law Journal* in its 2019 inaugural list of Health Care Law Trailblazers recognizing those who have made an impact through new strategies or innovative court cases for several notable FCA wins.
- Recognized by *The National Law Journal* in its 2018 Winning Litigators chosen for their “great results for clients in high stakes matters” for obtaining a successful trial verdict in an FCA lawsuit.
- *The National Law Journal* in its 2014 Litigation Trailblazers & Pioneers as one of 50 “people who have made a difference in the fight for justice” for his outstanding work in defending FCA lawsuits.
- *Chambers USA: America’s Leading Lawyers for Business* (2006-2019), in the 2011-2019 editions of *Chambers USA*, listed under Health Care: Regulatory and Litigation, Leading Individuals (Nationwide) (Band 1) and as Health Care Leading Individuals (District of Columbia) (Band 1).
- *Law360*, which selected Robert as one of the four Health Care MVPs for 2012 based upon a successful trial verdict obtained in defense of a national skilled nursing facility chain in a \$895 million FCA lawsuit the government filed.

Before entering private practice, Mr. Salcido served as trial counsel for the U.S. Department of Justice Civil Fraud Section, which has nationwide jurisdiction over the FCA, where he led several successful prosecutions of the FCA on the United States’ behalf.

1 No. 16-13004, 2019 U.S. App. LEXIS 27074 (11th Cir. Sept. 9, 2019).

2 Id. at *11-12.

3 Id. at *5 (quoting 42 U.S.C. § 1395(7)(A)).

4 Id. (quoting 42 U.S.C. § 1395(dd)(3)(A)).

5 Id. at *36 (quoting 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010)). See also 79 Fed. Reg. at 50470 (“[W]e also have recognized the challenges in prognostication” and therefore expect “that the certifying physicians will use their best clinical judgment.”).

6 Id. at 36.

7 Id.

8 Id. at *39. The court also underscored that the government’s contentions did not include traditional fraud-like allegations such as that the defendant had billed for phantom patients, that certifications or medical documentation was forged, or that the defendant’s employees lied to certifying physicians or withheld critical information regarding patient conditions. Id. at *13. Moreover, the court noted that there was no doubt that the defendant possessed accurate and comprehensive documentation of each patient’s medical condition and that the appropriate medical personnel signed its certifications of terminal illness. Id.

9 Id. at *12. Specifically, in developing its case, the government began by identifying a universe of approximately 2,180 patients for whom defendant had billed Medicare for at least 365 continuous days of hospice care. Id. The government then focused its attention on a sample of 223 patients from within that

universe. Id. Through direct review of these patients' medical records and clinical histories, the government's primary expert witness, identified 123 patients from the sample pool who were, in his view, ineligible for the hospice benefit at the time the defendant received reimbursement for their care. Id. Should it prevail as to this group, the government intended to extrapolate from the sample to impose further liability on the defendant for a statistically valid set of additional claims within the broader universe of hospice patients for whom the defendant received Medicare payments. Id. at *12-13.

10 Id. at *19.

11 Id.

12 Id.

13 Id. at *23. Prior to trial, the defendant moved the district court to bifurcate trial into two phases: Phase One would address the FCA's falsity element and Phase Two would address the FCA's remaining elements and the government's common-law claims. Id. at *16. The district court granted the motion in light of its concern that evidence pertinent to the knowledge element of the FCA would confuse the jury's analysis of the threshold question of whether the claims at issue were "false" in the first instance. Id. at *17. The court did allow in Phase One general testimony regarding the defendant's business practices and claims submission process during the relevant time period, but only to contextualize the falsity analysis and "afford[] the jury an opportunity to more fully understand the hospice process within [the defendant]." Id., at *18. The court noted that such evidence was not, however, admissible to prove the falsity of the claims at issue. Id.

14 Id. at *22

15 Id. at *26.

16 Id.

17 Id.

18 Id.

19 Id.

20 Id. at *53.

21 Id.

22 Id. at *45.

23 Id. at *44.

24 Id.

25 Id.

26 Id.

27 Id.

28 Id. at *44-45.

29 Id. at *52. Historically, it has been easy to prevail against the government in FCA medical necessity cases because of the leeway courts have appropriately afforded for reasonable clinical judgment. Indeed, this law firm has won two medical necessity FCA cases against the government at the summary judgment stage, including one where the court was sufficiently offended by the government's theory that it awarded the defendant more than \$400,000 in attorneys' fees. See *United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006); id., Order Granting Supplement to Def.'s Application for Att'ys' Fees and Other Expenses, ECF No. 109; see also *United States ex rel. Lawson v. Aegis Therapies, Inc.*, No. 210-072, 2015 U.S. Dist. LEXIS 4522 (S.D. Ga., Mar. 31, 2015). In FCA cases in which the defendant does not prevail, the typical grounds is that there are published guidelines specifically indicating how clinical judgment should be exercised and the clinician, without basis, deviates from those standards. See, e.g., *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730 (10th Cir. Jul. 2018). In *St. Mark's Hosp.*, in reversing the district court's grant of defendants' motion to dismiss, the Tenth Circuit noted that the plaintiff had alleged that the applicable Medicare statute authorized reimbursement only when the relevant procedure (known as patent foramen ovale, "PFO") was reasonable and necessary for the treatment of an illness; that there is agreement in the medical community that a PFO closure is not medically necessary except where there is a confirmed diagnosis of a recurrent stroke; that the applicable guidelines allow for consideration of the procedure only when the patient has had two or more strokes and that the guidelines do not "contemplate the potential for PFO closures" if the patient has not had a prior stroke; that

the defendant claimed to believe that the procedure should be performed prophylactically to cure migraine headaches or to prevent strokes even if the patient had never before had a stroke; and, knowing that Medicare would not pay on that basis, the defendant falsely represented that the procedure was being performed based on the indications set forth in the guidelines. Id. at 736-737. The 11th Circuit noted that “[o]bviously the [St. Mark’s] facts are quite different from those alleged” in *AseraCare*. 2019 U.S. App. LEXIS 27074, at *52, n.15.

30 Cf. *United States ex rel. Lawson v. Aegis Therapies, Inc.*, No. 210-072, 2015 U.S. Dist. LEXIS 4522, at *35-37 (S.D. Ga., Mar. 31, 2015) (rejecting the government’s contention that the defendants had a “nefarious plan to defraud” when a manager testified that the company had a benchmark of billing therapy services at the highest level 75-80% of the time based upon historical utilization when there was “no evidence that these metrics were used to promote or demote therapists, determine bonuses, or provide any other type of incentives to the therapists” and use of benchmarks reflected nothing more than a “prudent” business practice because the “historical benchmark helped [the defendant] compare its current ‘hospital census’ to previous months and years. A deviation from past statistics could signal a change in one of several important variables to the SNF’s business climate, such as doctor referrals, changing patient demographics, and the relational dynamics between therapists, physicians, and nurses who work together to create patient plans of care” and hence did “not create a material issue of fact as to whether Defendants’ knew they or their therapists were submitting false claims to the Government”).

31 Based upon this logic – or lack thereof – countless courts have reminded the government and relators that simply seeking to be profitable, by itself, is not a violation of the FCA. See, e.g., *United States ex rel. Ruscher v. Omnicare*, No. 4:08-cv-3396, 2015 U.S. Dist. LEXIS at *81 (S.D. Tex. Sept. 3, 2015) (“evidence of a profit motive—which Relator certainly has—is not equivalent to evidence of a knowing intention to violate the FCA”) aff’d, 663 Fed. Appx. 368 (5th Cir. 2016); *United States ex rel. Gudur v. Deloitte Consulting, LLP*, No. H-00-1169, 2007 U.S. Dist. LEXIS 18297 at *103 (S.D. Tex. Mar. 15, 2007) (“evidence of profit motive alone is insufficient to demonstrate FCA liability”), aff’d, No. 07-20414, 2008 U.S. App. LEXIS 17038 at *4–*5 (5th Cir. Aug. 7, 2008) (the relator “essentially argues that evidence of a regulatory violation coupled with [defendant’s] profit motive is sufficient to create a fact issue as to knowledge and intent”). See also *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 520–21, 528–31 (6th Cir. 2012) (rejecting the government’s contention that when a provider restructured its operations to take advantage of “loopholes in the Medicare regulatory scheme that would permit it to increase profits” there was an FCA violation because the government did not establish that the provider violated any Medicare rules or regulations and pointing out, notwithstanding the government’s contention, that “[w]hy a business ought to be punished solely for seeking to maximize profits escapes us”); *United States ex rel. K&R P’ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 984 (D.C. Cir. 2008) (noting that defendant’s “eagerness” to bail itself out of financial trouble “does not mean [it] knew” it acted “unlawfully”).

32 626 F.3d 1257 (D.C. Cir. 2010).

33 Id. at 1262-63.

34 Id. at 1273.

35 Id.

36 Id. at 1274.

37 Id. (internal quotations and citations omitted).

38 Id. at 1275 (internal quotation and citation omitted).

39 Id. at *13.

40 Id. at *62.

41 Id.

42 Id. at *17.

43 Id. The court, however, did allow in the first phase of trial regarding the falsity element anecdotal testimony regarding improper clinical or corporate practices that “had a time and place nexus with the 123 allegedly ineligible patients at issue.” Id. at *18. Although the 11th Circuit agreed with the district court’s determination that an objective falsehood must be established, it vacated and remanded the district court’s post-verdict grant of summary judgment to *AseraCare*. Id. at *63. The district court, in ruling for *AseraCare*, had only considered the evidence developed at trial. The 11th Circuit disagreed with this approach and remanded so that the district court could reconsider the matter based on the entirety of the evidence, not just the evidence presented at trial. Id.

44 Id. at *63.

45 See, e.g., *U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258, 1268-69 (M.D. Fla. 2018) (finding that the relator must offer evidence of a top down directive and noting that the relator had failed to establish the existence of a scheme as against the “Management Entity”—an LLC that sat atop the specialized nursing facilities alleged to have submitted false claims—because the relator had set forth only “a scattering of claims in a smattering of facilities [which] is a wholly insufficient basis from which to infer the existence of a massive, authorized, cohesive, concerted, enduring, top-down, corporate scheme to defraud the government”); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-604, 2016 U.S. Dist. LEXIS 80160, at *64 (N.D. Tex. June 20, 2016) (“Relator seemingly suggests she is only required to prove Defendants operated with reckless disregard as to falsity, and not that the certifications or claims were actually false or fraudulent. This view reflects a misunderstanding of the FCA’s falsity element, confusing the FCA’s scienter requirement—which requires knowledge or reckless disregard—with the necessity to show that records or claims were false. The FCA’s knowledge element is an independent, additional hurdle for Relator, not a shortcut around proof of falsity. Without evidence linking Relator’s ‘scheme’ evidence to the 291 patients whose files Dr. Steinberg analyzed, there is no evidence that the certifying physicians for the 291 patients were not exercising their best clinical judgments nor that they did not believe the subject patients were terminally ill when they certified them as such, and thus there is no evidence of the falsity required to establish liability”); cf. *U.S. ex rel. Oberg v Pa. Higher Educ. Assistance Agency*, No. 18-1028, 2019 U.S. App. LEXIS 517, at *3-5 (4th Cir. Jan. 8, 2019) (noting that the district court did not error in excluding audit at trial when the audit found that the defendant had paid excessive salaries and bonuses to its executives and managers and the relator sought to show that the findings tended to establish FCA scienter—that is, that the desire for personal gain motivated defendant’s officers to submit false claims—because as “the district court correctly explained: ‘it doesn’t really make any difference whether they were operating well or not well or whatever. The only issue in this case is: Did they commit fraud and file a false claim?’”).

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