## UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

# UNITED STATES OF AMERICA and STATE OF FLORIDA, *ex. rel.* Meria Broadnax,

#### Plaintiffs/Relator,

vs.

Case No. 8:13-cv-2724-T-27MAP

# SAND LAKE CANCER CENTER, P.A. and VINICIO HERNANDEZ, M.D.,

Defendants.

/

#### ORDER

**BEFORE THE COURT** are Defendants' Motion for Summary Judgment (Dkt. 80), and Relator's response (Dkt. 87). Upon consideration, the Motion is DENIED.

#### I. BACKGROUND

Defendant Sand Lake Cancer Center, P.A. ("SLCC") is an oncology medical practice founded by Vinicio Hernandez, M.D. in 2005. (Dkt. 83-4, Deposition of Vinicio Hernandez, M.D. at 16:11-19, 65:6-19). Dr. Hernandez is the sole owner of SLCC and the primary oncologist. (Dkt. 80-9, Affidavit of Dr. Vinicio Hernandez at ¶ 1).

Relator Meria Broadnax was employed by SLCC from June 2012 through January 2014 as a pharmacy technician. (Dkt. 83-1, Dec. 9, 2017 Deposition of Meria Broadnax at 26:3-24, 31:20-24). Her job duties included mixing chemotherapy drugs for patient treatments. (Id. at 26:3-24). She did not administer medicine and was not involved in the billing process. (Id. at 28:2-8, 81:8-12, 118:5-6, 130:10-23). Relator alleges that Defendants violated the False Claims Act, 31 U.S.C. § 3729(a)(1) ("FCA"), and the Florida False Claims Act ("FFCA"), Fla. Stat. §§ 68.081, *et seq.*, by billing government insurers for medication that was never provided to patients or was provided to patients in violation of safety regulations governing the use of vial medications. Specifically, Relator alleges that Defendants utilized single-dose vials of chemotherapy drugs on more than one patient and that physician ordered doses of chemotherapy were rounded down to avoid using additional medication vials. And, in violation of the False Claims Act, government sponsored insurance programs, including Medicare, Medicaid, and Tricare, were billed for medications that were purportedly wasted but in reality were used on other patients, and for medications that patients did not receive.<sup>1</sup>

Defendants move for summary judgment contending that the undisputed facts prove that there is no evidence they had the requisite knowledge to establish liability under the FCA and that Relator cannot establish materiality of a false statement.

#### II. STANDARD

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine factual dispute exists only if a reasonable fact-finder 'could find by a preponderance of the evidence that the [non-movant] is entitled to a verdict." *Kernel Records Oy v. Mosley*, 694 F.3d 1294, 1300 (11th Cir. 2012) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)). A fact is material

<sup>&</sup>lt;sup>1</sup> See Amended Complaint, Dkt. 15 at ¶ 77 ("Defendants deliberately shorted cancer medication to patients and used single use vials on multiple patients in an effort to increase profits and bonuses. The fraudulent billing occurred when patients were shorted medication yet billed like they had received the full amount. Defendants utilized single-use vials on multiple patients which allowed them to bill for waste even when there was no waste created. When waste was created, Defendants would use the wasted amount as a new dose to patients and re-bill the government.").

This is not a qui tam action in which the relator has actual knowledge of alleged violations. Rather, Relator relies on the testimony of Dr. Hernandez, nurses in the practice, and her experts.

if it may affect the outcome of the suit under governing law. *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997). All facts are viewed and all reasonable inferences are drawn in the light most favorable to the non-moving party. *See Scott v. Harris*, 550 U.S. 372, 380 (2007).

The moving party bears the initial burden of showing that there are no genuine disputes of material fact. *Hickson Corp. v. Northern Crossarm Co., Inc.*, 357 F.3d 1256, 1260 (11th Cir. 2004) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Once the moving party demonstrates the absence of a genuine issue of material fact, the nonmoving party must go beyond the pleadings through the use of affidavits, depositions, answers to interrogatories, and admissions on file to designate facts showing a genuine issue for trial. *See Celotex Corp.*, 477 U.S. at 324. The Court will not weigh the evidence or make findings of fact. *Morrison v. Amway Corp.*, 323 F.3d 920, 924 (11th Cir. 2003). Rather, the Court's role is limited to deciding whether there is sufficient evidence upon which a reasonable juror could find for the non-moving party. *See id*.

#### **III. DISCUSSION**

To succeed on her claims under 31 U.S.C. § 3729(a)(1)(A), Relator must prove that Defendants "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval." And under 31 U.S.C. § 3729(a)(1)(B), she must prove that Defendants "knowingly [made] use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim." Finally, under 31 U.S.C. § 3729(a)(1)(G), she must prove that Defendants "knowingly [made], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim." Finally, under 31 U.S.C. § 3729(a)(1)(G), she must prove that Defendants "knowingly [made], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money or property to the Government." Relator's claims brought under Florida law require proof of

the same elements. *See* Fla. Stat. § 68.082 (2) (a), (b), and (g).<sup>2</sup> "Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States v. R&F Properties of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005). But improper practices alone, without the submission of a false claim, are insufficient to state a claim under § 3729(a)(1)(A) or (B). *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009).

#### A. Knowledge

In their motion, Defendants argue that Relator cannot show that they acted knowingly and cannot show a material false statement in the billing claims submitted to the government. Under 31 U.S.C. § 3729, "the terms 'knowing' and 'knowingly' mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). While specific intent to defraud need not be proven, liability does not attach to innocent mistakes or simple negligence. *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015). Under the reckless disregard prong, "[1]iability attaches to only those who act in gross negligence—those who fail to make such inquiry as would be reasonable and prudent to conduct under the circumstances." *Id.* (quotation omitted). Proving deliberate ignorance requires an even higher showing and "plainly demands even more culpability than that needed to constitute reckless disregard." *Id.* at 1058 n.15. "In cases brought under the False Claims Act... the knowledge of an employee is imputed to the corporation when the employee acts for the benefit of the corporation and within the scope of his employment." *Grand Union Co. v. United States*, 696

<sup>&</sup>lt;sup>2</sup> All of Relator's claims require common proof and have overlapping elements. For each claim, Relator must prove that Defendants <u>knowingly</u> made a <u>material</u> false representation to the federal and state governments.

F.2d 888, 891 (11th Cir. 1983).

Defendants contend that "[n]o nurse and no one in the billing department knew of any of the wrongdoing alleged by Broadnax." (Dkt. 80 at 12). Relator counters that the record evidence shows that Dr. Hernandez knew that medication dosages were routinely rounded down.<sup>3</sup> Nurse Manager Bastani confirmed that the practice "always" rounded down medication. Nurses Redman and Calderon testified that Bastani instructed them to round down dosages rather than open a new vial and create waste. And there is evidence that single-use vials were used twice for two different patients. Bastani described that the practice utilized single dose vials on more than one patient by saving the waste left in the vial. She admitted to retaining single dose vials, excluding them from inventory, and accessing single dose vials two times on two different patients. Based on this testimony, material factual issues exist as to Defendants' knowledge of these practices and whether Dr. Hernandez knew of these practices but failed to reasonably investigate them, all questions for the trier of fact.

Relator alleges the practice engaged in "improper charting."<sup>4</sup> She complained to Dr.

1 money.

<sup>&</sup>lt;sup>3</sup> Dr. Hernandez explained the practice of rounding down as follows:

<sup>19</sup> If a patient needed to have 1,050

<sup>20</sup> milligrams, I would tell the nurses to give a

<sup>21</sup> thousand milligrams and -- and -- and not give the

<sup>22 50</sup> if -- because given that 50 we were required to

<sup>23</sup> open another vial, give 50 milligrams and waste

<sup>24 950.</sup> That's -- some practices do that. I think

<sup>25</sup> that was a -- that was a waste of government's

<sup>(</sup>Hernandez Dep. at 226:17-227:1).

<sup>&</sup>lt;sup>4</sup> This includes, for example, recording withdrawal of medication when it was not actually withdrawn from the Nucleus cabinet, and recording the dosage that was ordered rather than the dosage that was administered. (See Dkt. 87 at 10-13). The Nucleus cabinet is a computerized storage unit in which medication was stored, with restricted access. An electronic log was maintained of the medication placed in and removed from the cabinet. (Affidavit of Dr. Vinicio Hernandez, Dkt. 80-9  $\P$  6).

Hernandez about this, and Nurse Redman complained to Nurse Bastani. Dr. Hernandez admitted that he received complaints about falsification and misrepresentation on patient documentation, including chemotherapy charts. That is sufficient to demonstrate the existence of material factual issues as to whether Defendants had knowledge of misrepresentations on patient charts.

Finally, and most significantly, the record evidence demonstrates material issues of fact as to whether Dr. Hernandez or any other employee had knowledge that the federal and state governments were billed for the amount of medication ordered rather than the amount of medication actually administered. Although Dr. Hernandez adamantly denied improper billing, as noted, there were complaints of misrepresentative entries in patient charts which were brought to his attention. Nurse Redman testified that she charted what dosage had been ordered, rather than what was administered, as instructed, and when she complained to Batani, was told that Dr. Hernandez instructed to chart the medications that way and approved of the practice.

In sum, the record evidence demonstrates factual disputes regarding Defendants' knowledge of the practice of rounding down, using single-use vials twice, improper charting of medications administered, and whether these practices resulted in over billing, all of which must be resolved by the trier of fact.<sup>5</sup> And while the issue of whether Defendants knowingly over-billed the government may be close, that issue should nonetheless be decided by the jury. A pertinent question is whether Dr. Hernandez or any other employee of SLCC acted with deliberate indifference or reckless

<sup>&</sup>lt;sup>5</sup> (Compare Hernandez Dep. 226:8-226:13 (testifying that he instructed Relator and other employees to round down when calculating dosages) and 226:17-227:1 (testifying that if a dosage of 1,050 mg was ordered, the nurses would administer 1,000 mg if using the additional 50mg would result in waste) with (88:8-24 (testifying that every patient got the dose that was ordered and that they unknowingly accessed a single-dose vial for two patients)). And, Nurse Manager Bastani testified that the practice "always" rounded down medications. (Bastani Dep. 81:5-82:9).

While these practices alone might not constitute a violation of the FCA, and may or may not be medically acceptable, if false or fraudulent claims are submitted because of these practices, the FCA could be implicated.

disregard with respect to the way medication dosages were recorded and billed. More specifically, the question is whether Defendants failed to make a reasonable and prudent inquiry. *See Urquilla-Diaz*, 780 F.3d at 1058. For example:

- Dr. Hernandez testified that he overheard nurses discussing documentation mistakes pertaining to the amount of medication coming out of the Nucleus cabinet which did not match the medication administered. (Hernandez Dep. at 140:17-141:5). As noted, he received complaints from Relator and Nurse Redman that documentation of the administration of medication was not done properly. (Id. at 165:16-166:7).
- As noted, according to Redman, the dosage recorded on the charts was the dosage ordered and "not necessarily what was given." (Redman Dep. at 92:22-93:8).
- Relator testified that she complained about improper charting of a different dosage than what was administered and that she was instructed by the Billing Manager to record the use of an additional vial of medication when it was not actually used. (Broadnax Dep. at 89:25-90:13, 165-3-12, 200:25-201:5).

The evidence of routine rounding down, use of overfill, and improper charting are sufficient

to raise an inference which could be drawn by a jury that Defendants knowingly over-billed the

government. Drawing all reasonable inferences in favor of Relator, as the non-moving party,<sup>6</sup>

material issues of disputed fact exist as to whether Defendants acted with reckless disregard in

billing the government for medication not actually administered to patients in violation of the Act.

# B. Materiality

Relator's theory is straightforward. She alleges that Defendants submitted claims for payment

to the government for dosages of medication that were not actually administered and/or double-billed

<sup>&</sup>lt;sup>6</sup> All the evidence and factual inferences reasonably drawn from the evidence must be viewed in the light most favorable to the nonmoving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1280 (11th Cir. 2004).

for single-use vials of medication, making their claims factually false.<sup>7</sup> And she contends that although Defendants certified that the medical care or services provided and submitted were medically indicated and necessary and supported by documentation and treatment records, they were not. (See Dkt. 15 ¶¶ 94-100).

Under 31 U.S.C. § 3729, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Defendants contend that Relator cannot demonstrate materiality because the Government continued to pay the claims they submitted, even after this lawsuit was filed. However, in the case they rely on, the Fifth Circuit acknowledged that continued payment is not necessarily dispositive. *See United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 663 (5th Cir. 2017), *cert. denied sub nom. U.S. ex rel. Harman v. Trinity Indus., Inc.*, No. 17-1149, 2019 WL 113076 (U.S. Jan. 7, 2019) ("The lesson we draw from these well-considered opinions is that, though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality."). And courts have required proof that the government paid a claim "in full despite its actual knowledge that certain requirements were violated." *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003, 195 L. Ed. 2d 348 (2016); *Trinity*, 872 F.3d at 664; *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 907 (9th Cir. 2017), *cert. denied sub nom. Gilead Scis., Inc. v. U.S. ex rel. Campie*,

<sup>&</sup>lt;sup>7</sup> False or fraudulent claims brought under the presentment or make-or-use provisions of the False Claims Act may be factually false or legally false. *United States ex rel Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1344 (S.D. Fla. 2015), aff'*d as modified sub nom. United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148 (11th Cir. 2017). "A factually false claim occurs, for example, when a supplier submits a claim that misidentifies the goods supplied or requests reimbursement for goods that it never provided." *Id.* In other words, "the supplier falsely bills the government for something not received." *Id.* "A legally false claim is actionable when the supplier has falsely certified compliance with the applicable statutes and regulations, but nevertheless has submitted a claim." *Id.* 

No. 17-936, 2019 WL 113075 (U.S. Jan. 7, 2019).

To begin with, *Trinity* is factually distinguishable. Unlike this case, the evidence at trial demonstrated that the government agency had actual knowledge of the violations, thoroughly investigated them, expressly approved the traffic guardrail system despite the violations, and approved reimbursement. *Id.* at 647, 663-664. Here, although the government declined to intervene and there is testimony from Dr. Hernandez that claims were paid, that is the extent of the evidence provided.<sup>8</sup> As such, I find that although the evidence of governmental approval relied on by Relator is not overwhelming, there exists a disputed issue of material fact with respect to materiality.

The parties disagree on whether the so-called more "demanding" standard of materiality discussed in *Universal Health Servs., Inc. v. United States ex rel Escobar*, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016) applies in this case.<sup>9</sup> Notwithstanding, "a False Claims Act violation typically involves billing for services not provided or not medically necessary." *United States v. HPC Healthcare, Inc.*, 723 F. App'x 783, 788 (11th Cir.), *cert. denied sub nom. U.S. ex rel. Chase v. Chapters Health Sys., Inc.*, 139 S. Ct. 69, 202 L. Ed. 2d 23 (2018). That is precisely what Relator alleges occurred in this case. As Relator succinctly suggests, "it can be reasonably inferred that in

<sup>&</sup>lt;sup>8</sup> In other words, it is unclear what and when the government knew about the alleged violations, which calls into question its actual knowledge. *See Campie*, 862 F.3d at 907 ("Although it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us.").

<sup>&</sup>lt;sup>9</sup> It is not entirely clear, however, that *Escobar* changed the standard for materiality. As the Fifth Circuit explained:

Our approach to materiality, as stated in *Longhi*, is that "the FCA requires proof only that the defendant's false statements 'could have' influenced the government's pay decision or had the 'potential' to influence the government's decision, not that the false statements actually did so," the so-called "natural tendency test." The Supreme Court approved this standard in *Escobar*, writing that "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," and "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."

Trinity Indus. Inc., 872 F.3d at 661. And, Escobar involved an implied false certification claim.

each situation where the government was overbilled, the overbilling would have been capable of influencing the government's payment decision." And the examples in this record on which Relator relies on pages 18-19 of her response must be considered by the trier of fact to resolve this case.

Accordingly, Defendants' Motion for Summary Judgment (Dkt. 80) is DENIED.

**DONE AND ORDERED** this 4<sup>th</sup> day of February, 2019.

Is/ James D. Whittemore

JAMES D. WHITTEMORE United States District Judge

Copies to: Counsel of record