

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION

UNITED STATES OF AMERICA  
and THE STATE OF FLORIDA ex  
rel. CHRISTINA PAUL

Plaintiffs/Relator,

v.

Case No: 8:18-cv-396-T-36JSS

BIOTRONIK, INC.,

Defendant.

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**ORDER**

This matter comes before the Court upon Defendant Biotronik Inc.'s Motion to Dismiss the Second Amended Complaint and Supporting Memorandum of Law [Doc. 50], Plaintiffs/ Relator's Response in Opposition [Doc. 53], and Defendant's Reply to Plaintiff's Opposition [Doc. 57]. The Court, having considered the motion, will GRANT Defendant's Motion to Dismiss for the reasons stated herein.

**I. BACKGROUND AND FACTS<sup>1</sup>**

Defendant, Biotronik, is a medical device company with products and services related to patients suffering from cardiovascular and endovascular diseases. [Doc. 49 ¶ 5]. Relator, Christina Paul, was an employee of Biotronik, from April 7, 2014 until

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<sup>1</sup> The following statement of facts is derived from Relator's Second Amended Complaint (Doc. 49), the allegations of which the Court must accept as true in ruling on the instant Motion to Dismiss. See *Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992); *Quality Foods de Centro Am., S.A. v. Latin Am. Agribusiness Dev. Corp. S.A.*, 711 F. 2d 989, 994 (11th Cir. 1983).

June 2019. *Id.* ¶ 4. During that time, she worked as a Field Clinical Specialist, then as a Diagnostic Specialist *Id.* In both of her positions, Relator provided technical and clinical support to some of Defendant's sales staff. *Id.* Since at least April of 2014, Defendant has allegedly generated consumer demand for its services and devices through a fraudulent scheme in which it induces medical professionals to use its products and services through illegal incentives it pays, in violation of the federal anti-kickback statute. *Id.* ¶ 18.

Relator specifically alleges that from 2014 through June 2019, Defendant's employee, Paul McLoughlin, with Defendant's knowledge, provided incentives—including vacations and trips, meals, payments for cell phone bills, entertainment, holiday gifts, grand opening expenses, parties, marketing events, and donations—to referral sources and to physicians in exchange for their use of its services and products. *Id.* ¶¶ 19, 21. Relator identifies eleven physicians who were involved in this scheme: Dr. Ketul Chauhan; Dr. Rajesh Lall; Dr. Aung Tun; Dr. Ramanath Rao; Dr. Phillip Owen; Dr. Osama Al-Suleiman; Dr. Binu Jacob; Dr. Oji Joseph; Dr. Luis Carillo; Dr. Siva Bhashyam; and Dr. Irfan Siddiqui. *Id.* ¶¶ 22-31. Relator alleges she witnessed the illegal procuring of these clients. *Id.* ¶ 32.

Through this fraudulent scheme, Defendant allegedly gained market share and increased its profits in the form of an average \$3,000 for each loop device, \$7,000 for each pacemaker, \$13,500 for each defibrillator, and \$26,000 for each biventricular defibrillator. *Id.* ¶ 33. Defendant charged Medicare, Medicaid, and other Government-funded healthcare programs an additional \$500-1,000 per implanted device under the

guise of a home monitoring program that was not ordered by the physicians, was not consented to by the patients, and never occurred. *Id.* ¶ 34. Relator provided a list of eighty-five patients who were improperly placed on home monitoring or implanted with Defendant's products as a result of Defendant's kickback scheme. *Id.* ¶ 44.

Relator specifically alleges that McLoughlin was authorized by Defendant to set up and bill to Medicare and Medicaid home monitoring services for patients without the approval of the attending physicians. *Id.* ¶ 35. For example, in June 2017 McLoughlin set up home monitoring services for several of Dr. Ahmed's patients, despite the doctor's refusal, and billed these services to Medicare and Medicaid. *Id.* ¶¶ 36-37. On August 23, 2017, Dr. Ahmed's nurse, Ursula Morrow, contacted Relator advising that Dr. Ahmed's patients were coming into the clinic with home monitoring devices and asking what needed to be done. *Id.* ¶ 38. Ms. Morrow told Relator that neither she nor Dr. Ahmed knew about or had access to the home monitoring accounts, and requested an explanation. *Id.* Relator reported this to Defendant's Home Monitoring Department Management Representative, John Fitzke, in August 2017.<sup>2</sup> *Id.* ¶¶ 40-41. Defendant never took any steps to remedy the Home Monitoring issue or address the misconduct reported by Relator, and its Vice President of Regulatory Affairs subsequently instructed all employees not to put conversations with physicians or among staff in writing, and warned employees written communications could be subject to subpoena. *Id.* at ¶¶ 42-43, 46.

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<sup>2</sup> Relator's August 25, 2017 letter to Defendant regarding the home monitoring practices taking place within Dr. Ahmed's practice is provided with the complaint.

On May 14, 2020, Relator filed a Second Amended Complaint<sup>3</sup> against Defendant, asserting claims under the federal False Claims Act, 31 U.S.C. § 3729, and Florida's False Claims Act, § 68.082(2)(a), Fla. Stat. [Doc. 49]. Defendant has again moved to dismiss for failure to state a claim and failure to meet the heightened pleading requirements for fraud claims. [Doc. 50]. Among other things, it argues that the complaint does not sufficiently plead a kickback scheme; does not provide particular facts about fraudulent submissions to the government; fails to state which federal programs received and paid the claims; fails to identify any payment obligation Defendant had to the government; and does not allege a causal connection between Defendant's action and the submission of any false claim. *Id.* at pp. 7-15. Relator contends that the Second Amended Complaint satisfies all of the requirements identified by the Court in the order dismissing the original complaint and is sufficient to meet the necessary pleading standard for causes of action under the False Claims Acts. [Doc. 53].

## II. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), a pleading must include a “short and plain statement of the claim showing that the pleader is entitled to relief.” *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). Labels,

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<sup>3</sup> This lawsuit was originally filed on February 15, 2018. [Doc. 1]. Both the United States and the State of Florida declined intervention. [Docs. 18, 27]. Defendant moved to dismiss the complaint for failure to state a claim and failure to meet the heightened pleading requirements for fraud claims and the motion was granted with leave to amend the complaint. [Docs. 26, 45].

conclusions and formulaic recitations of the elements of a cause of action are not sufficient. *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Furthermore, mere naked assertions are not sufficient. *Id.* A complaint must contain sufficient factual matter, which, if accepted as true, would “state a claim to relief that is plausible on its face.” *Id.* (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citation omitted). The court, however, is not bound to accept as true a legal conclusion stated as a “factual allegation” in the complaint. *Id.*

Additionally, Federal Rule of Civil Procedure 9(b) places more stringent pleading requirements on claims alleging fraud. Fed. R. Civ. P. 9(b). “[U]nder Rule 9(b) allegations of fraud must include facts as to time, place, and substance of the defendant’s alleged fraud.” *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308 (11th Cir. 2002) (citation and internal quotations omitted). Plaintiffs are thereby required to set forth “the details of the defendants’ allegedly fraudulent acts, when they occurred, and who engaged in them.” *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009) (internal quotation marks omitted) (citing *Clausen*, 290 F.3d at 1310). Failure to satisfy the particularity requirement under Rule 9(b) amounts to failure to state a claim until Rule 12(b)(6). *See, e.g., Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005).

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