

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA
ex rel. JEFFREY J. BIERMAN,

Plaintiff,

v.

CIVIL ACTION NO.:
05-10557-EFH

ORTHOFIX INTERNATIONAL, N.V., ET AL.,

Defendants.

UNITED STATES OF AMERICA
ex rel. MARCUS LAUGHLIN,

Plaintiff,

v.

(Formerly CIVIL ACTION
NO.: 08-11336-JLT)

ORTHOFIX INTERNATIONAL, N.V., ET AL.,

Defendants.

MEMORANDUM AND ORDER

November 4, 2010

HARRINGTON, S.D.J.

Qui tam relator, Marcus Laughlin, brings this suit on behalf of the United States of America, against his former employer, Orthofix, Inc. and its parent company, Orthofix

International, N.V. alleging violations of the federal False Claims Act (FCA), 31 U.S.C. § 3729-3733, and analogous state statutes. Defendants move to dismiss Laughlin's Second Amended Complaint, contending that, among other things, the allegations contained therein have not been pled with sufficient particularity pursuant to Rule 9(b) of the Federal Rules of Civil Procedure. The Court grants the defendants' motion as to all claims with the exception of the wrongful termination claim, alleging a violation of 31 U.S.C. § 3730(h) against Orthofix International, N.V. (Count Six).

The United States Court of Appeals for the First Circuit has held that the heightened pleading requirements of Fed. R. Civ. P. 9(b) apply to claims brought under 31 U.S.C. §§ 3729(a)(1) (presenting false claims for payment), 3729(a)(2) (making false records or statements to get false claims paid), and 3729(a)(3) (conspiring to defraud the government by getting false claims paid). See United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009). Rule 9(b) requires a party, alleging fraud or mistake, to state with particularity the circumstances constituting the fraud or mistake. Fed. R. Civ. P. 9(b). To be sufficiently pled, the complaint must include "the time, place, and content of an alleged false representation." Gagne, 565 F.3d at 45 (internal quotations omitted); see United States ex rel. Karvelas v. Melrose-Wakefield Hospital, 360 F.3d 220 (1st Cir. 2004). While conclusory allegations are not sufficient, the rule may be satisfied "'where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA.'" Gagne, 565 F.3d at 45 (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007)).

Laughlin alleges in his complaint five schemes perpetrated by defendants, medical device manufacturers, to defraud medicare, medicaid and other government health programs in violation

of sections 3729(a)(1)-(3) and analogous state statutes.¹ Those schemes include: (1) charging the full purchase price of devices that should have been rented; (2) providing free devices to doctors but not accounting for the free devices when calculating the per unit price charged to the government health programs; (3) billing devices that were not covered by government health programs; (4) submitting so-called “fitting fees” for payment in which doctors did not perform the fittings; and (5) giving doctors illegal kickbacks to induce them to prescribe the defendants’ devices.

None of the alleged schemes are set forth with particularity. The scheme for which the most detail is provided is the so-called fitting fee scheme. For that scheme, the complaint states that, in September of 2005 Laughlin’s supervisor went to Laughlin’s office and “diagramed in detail on a white board the ‘physician’ fitting fee billing code process that territory managers used with their assigned physicians regarding the fitting fee bill to Medicare. Orthofix was able to offer this billing code to the physicians to obtain an additional fee from Medicare.” Other parts of the complaint allege that “Orthofix was encouraging and assisting doctors to charge fitting fees when in reality Orthofix employees performed the fittings,” that “[t]hese fitting fees are \$200-\$300 per occurrence,” and that “each patient must be fitted.”

¹ The first five counts of the Second Amended Complaint set forth allegations as to each scheme, but do not specify the section of the FCA under which relief is requested. The five schemes appear to be the basis for Count Seven, alleging a general violation of 3729(a)(3) (conspiracy); Count Eight, alleging a general violation of 3729(a)(1) (false claims); and Count Nine, alleging a general violation of 3729(a)(2) (false records or statements). The five schemes also appear to be the basis for Counts Ten through Fifty Six, which allege violations of various state statutes which are analogous to the FCA. "The heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court." Rost, 507 F.3d at 731 n.8. Accordingly, the Court determines whether the five schemes have been sufficiently pled as violations of sections 3729(a)(1)-(3) and analogous state statutes.

These allegations provide no detail concerning the submission of fitting fee claims for payment. They set forth that the fittings were performed by Orthofix employees and that the claims for payment were billed by doctors; they do not, however, claim that the billings were in any way fraudulent or improper. For instance, there is no allegation that a false statement, such as a verification that a doctor had performed the fitting, was ever made. The complaint further fails to set forth any detail with respect to the circumstances of the alleged fraud. There is no detail as to which Orthofix employees or doctors were involved in the scheme or the time period during which the scheme was perpetrated. There is also no detail as to how Orthofix was allegedly “encouraging and assisting” doctors to commit the fraud.

The allegations of the other four schemes provide substantially less detail. With respect to the rental scheme, the complaint simply states that “Medicare rules and regulations require patients be allowed the opportunity to rent any medical device which has been prescribed by the patient's doctor,” but that “Orthofix had a policy to only sell the devices to the patient.” With respect to the free devices scheme, the complaint alleges that devices were “given out for free to . . . physicians” thereby lowering the net price. The lower price, however was allegedly not charged to the government health programs. With respect to the non-covered device scheme, the complaint alleges that Laughlin was told by his supervisor that the “Insurance Adjuster staff w[as] billing TriCare for Cervical-Stim orders,” which were not approved for use by TriCare. With respect to the kickback scheme, the complaint alleges that Orthofix was paying referral fees to doctors’ staff.

These statements are nothing more than general or conclusory allegations, which fail to provide specifics as to the time, place, persons involved or the content of any alleged false

representation. Even reviewing the complaint as a whole, under the more relaxed standard set forth above, the Court concludes that the allegations relating to the five schemes to defraud medicare, medicaid and other government health programs have not been pled with sufficient particularity under Fed. R. Civ. P. 9(b) to pass muster. Those claims, namely counts 1-5 and 7-56, are, therefore, dismissed.

The remaining count, Count Six, alleges wrongful termination pursuant to 31 U.S.C. § 3730(h).² To prevail under 31 U.S.C. § 3730(h), a plaintiff must show that “1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct.” Karvelas, 360 F.3d at 235. “[A] retaliation claim does not require the [relator] to have filed an FCA lawsuit or to have developed a winning claim at the time of the alleged retaliation.” Id. at 236. Rather, the claim requires the relator only to have engaged in conduct, such as investigations or inquiries, that “reasonably could lead” to an FCA action. Id. at 238. “A retaliation claim under 31 U.S.C. § 3730(h) does not require a showing of fraud and therefore need not meet the heightened pleading requirements of Rule 9(b).” Id. at 236 n.23.

As to the first and second element, Laughlin alleges that he asked questions of his supervisors regarding the legality of the various schemes allegedly perpetrated by the defendants. These questions constitute inquiries that concern a potential knowing submission of false claims

² Section 3730(h) of the FCA provides that:

Any employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged . . . because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

on the part of the defendants and, therefore, are protected conduct under the FCA. The second element is met because Laughlin's questions regarding the schemes were posed to his supervisors and, in turn, put the supervisors on notice that he was engaged in protected conduct. As to the final element, Laughlin alleges that, following praise from his supervisors for his excellent job performance, he was abruptly fired after and because he engaged in protected conduct. He also alleges that he was presented with a severance agreement and release. Laughlin alleges that "[t]he release provided, in part, that Laughlin would not assist in any administrative or legal action brought by any state or federal agency and would not share in any settlement or recovery of any type." These allegations constitute a sufficient basis to conclude that Laughlin was fired because of the protected conduct. The wrongful termination claim, therefore, survives.

The complaint as against Orthofix, Inc. is dismissed. The docket indicates that Laughlin has failed to serve the complaint. Therefore, the sole remaining claim is the wrongful termination claim against Orthofix International, N.V.

The Court denies Laughlin's motion to again amend the complaint. Laughlin was recently given the opportunity to file an amended complaint that conformed to pleading standards and failed to do so. Allowing an amendment would reward undue delay. Furthermore, Laughlin does not indicate in his motion any information that he would add to the complaint. The Court, therefore, concludes that any amendment would be futile.

Defendants' Motion to Dismiss Relator Marcus Laughlin's Second Amended Complaint (Docket No. 126) is hereby **ALLOWED IN PART** and **DENIED IN PART**. Relator Marcus

Laughlin's Motion for Leave to Amend (Docket No. 141) is hereby DENIED.

SO ORDERED.

/s/ Edward F. Harrington
EDWARD F. HARRINGTON
United States Senior District Judge