UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EBONIA ELLIOTT-LEWIS, et al.,	*	
	*	
Plaintiff/Relator,	*	
	*	
v.	*	Civil Action No. 14-cv-13155-IT
	*	
ABBOTT LABORATORIES, INC.,	*	
	*	
Defendant.	*	

MEMORANDUM & ORDER

May 5, 2017

TALWANI, D.J.

Currently pending before the court is Relator Ebonia Elliott-Lewis's Motion to Amend & File Her First Amended Complaint ("Motion for Leave to Amend") [#61]. For the reasons set forth below, that motion is GRANTED with respect to Counts 3 and 4, and DENIED with respect to Counts 1 and 2.

I. Background

On March 28, 2016, the court granted Defendant Abbott Laboratories, Inc.'s ("Abbott") Motion to Dismiss [#14], finding that Relator's Complaint [#1] failed to adequately allege that Abbott violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, or the retaliation provisions of the False Claims Act, 42 U.S.C. § 3730(h). Mem. & Order [#44]. Seventeen days later, the court issued an Order of Dismissal [#49] closing the case.

On April 26, 2016, Relator filed a Notice of Appeal [#50], and the next day, filed a Motion for Relief from Judgment Pursuant to Federal R. Civ. Proc. Rule 60(b)(6) ("Motion for Relief from Judgment") [#53].

On May 23, 2016, after this court stated that it was inclined to allow the motion for relief from judgment if the case was remanded, Mem. [#56], the First Circuit returned the case to allow this court to adjudicate Relator's motions, Order of Court [#59].

This court subsequently allowed the Motion for Relief from Judgment [#53], but denied the Motion to Amend Complaint [#54] without prejudice. Mem. & Order [#60]. The court noted that the Motion to Amend Complaint [#54] was not presented to Abbott prior to filing as required by the local rules, and that the proposed amended complaint was not a short and plain statement as required under Rule 8 of the Federal Rules of Civil Procedure. Mem. & Order [#60]. Relator thereafter filed the currently pending Motion to Amend [#61] which attached a revised proposed First Amended Complaint [#61-1].

II. Analysis

A. Relator's Motion May Be Considered Under Fed. R. Civ. P. Rule 15(a)

Abbott argues that Relator's Motion for Leave to Amend [#61] falls outside of the scope of Fed. Rule Civ. P. 15(a)'s permissive amendment policy because Relator originally requested leave to amend only in a footnote in her opposition to the motion to dismiss, and because a ruling on the motion to dismiss has already issued. Def.'s Opp'n Relator's Mot. Leave Am. ("Def.'s Opp'n") 4, 5 n.1 [#65]. Citing Fisher v. Kadant, Inc., 589 F.3d 505, 510 (1st Cir. 2009), Abbott argues that Relator is not entitled to "test the mettle of successive complaints," and may not file a motion to amend after dismissal was granted. Def.'s Opp'n 4 [#65].

As the Fisher court noted, however, the context within which the court addresses a request for leave to amend is important. While the district court in Fisher had no authority to

consider a motion to amend under Rule 15(a) filed after judgment had entered, the court only lacked such authority "until the judgment is set aside." Fisher, 589 F.3d at 508; Acevedo-Villalobos v. Hernandez, 22 F.3d 384, 389 (1st Cir. 1994) ("Unless postjudgment relief is granted, the district court lacks power to grant a motion to amend the complaint under Rule 15(a)."). Here, the court has set aside the judgment.

Relator had requested leave to amend in the opposition to the motion to dismiss and had reiterated that request during oral argument, and the court had indicated that such a motion could be filed after the court issued its order on the motion to dismiss. While Relator failed to file a motion for leave to amend before the case was closed, there was no date set by the court for Relator to file such a motion. Relator's counsel has explained that he failed to file a motion to amend the complaint in a timely fashion because he had not had the opportunity to speak with defense counsel and present a proposed amended complaint to defense counsel prior to final judgment being entered. Thus, given the totality of circumstances, the court reviews Relator's request for leave to amend pursuant to the standards governed by Rule 15(a). See United States ex rel. D'Agostino v. EV3, Inc., 802 F.3d 188, 195 (1st Cir. 2015) (leave can be granted even where party requested such leave after a motion to dismiss has been fully briefed); United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 734 (1st Cir. 2007), abrogated on other grounds by Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

B. Compliance with Rule 8

Abbott argues that the Motion for Leave to Amend [#61] should be denied because Relator has failed to comply with Rule 8's "short and plain" pleading standards. Def.'s Opp'n 6-9 [#65]. Although Relator's First Amended Complaint is ninety-one pages, wordiness alone would not warrant dismissal. "Dismissal [for noncompliance with Rule 8] is usually reserved for those cases in which the complaint is so confused, ambiguous, vague, or otherwise unintelligible

that its true substance, if any, is well disguised." Sayied v. White, 89 F. App'x 284 (1st Cir. Mar. 12, 2004) (unpublished) (per curiam) (quoting Salahuddin v. Cuomo, 861 F.2d 40, 42 (2d Cir. 1988)). The complaint, while unwieldy, is not so unintelligible as to warrant dismissal based on Rule 8.[1]

C. The Requirements of Rule 15(a)

Generally, Rule 15(a) provides that leave to amend shall be "freely given when justice so requires," and reflects a "liberal amendment policy." O'Connell v. Hyatt Hotels of P.R., 357 F.3d 152, 154 (1st Cir. 2004) (citing Fed. R. Civ. P. 15(a)) (internal quotation marks omitted). Grounds for denial include undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, futility of amendment, and undue prejudice to the opposing party. Foman v. Davis, 371 U.S. 178, 182 (1962). Relator has not filed multiple amendments, there has been no discovery, no scheduling order has issued, and while Relator failed to file the motion for leave to amend within seventeen days of the order of dismissal, the court does not find that delay to be unduly prejudicial.

Abbott argues that amendment of the complaint would be futile. A determination of futility is based on whether "the complaint, as amended, would fail to state a claim upon which relief could be granted." Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996); Giuffre v. Deutsche Bank Nat. Trust Co., 759 F.3d 134, 139 (1st Cir. 2014). The standard applied is the same as in a Rule 12(b)(6) motion to dismiss. Glassman, 90 F.3d at 623.

1. Count 1: Violations of 31 U.S.C. § 3729, False Claims Act

Relator posits two theories to support Count 1: fraud in the inducement, and off-label promotion.

[1] That said, the court will not require Abbott to answer the proposed First Amended Complaint's eighty-six endnotes.

a. Fraud in the Inducement

To plead her fraud in the inducement theory, Relator asserts that Abbott engaged in pre-approval promotion of ABSORB Bioresorbable Vascular Scaffold System ("ABSORB")[2] for use in treating coronary and peripheral vascular disease (*i.e.* for use in the heart and the leg). First Am. Compl. ¶¶ 38, 62-63. Relator contends that pre-approval promotion of ABSORB for use in the leg was tantamount to initiating an unapproved clinical trial, and the implantation of ABSORB in the leg would be tantamount to medical battery. Id. ¶¶ 11, 29, 31, 62, 65. She asserts that because the alleged unapproved clinical trial would involve medical battery, no patient could give valid informed consent to participation in that trial. Id. ¶¶ 28.2, 31, 90. And where patients could not give valid informed consent, the supposed trials would be in violation of human subject protection regulations requiring informed consent. Id. ¶¶ 29, 31, 63, 90. Moreover, according to Relator, pre-approval promotion of ABSORB for use both in the heart and the leg violated 21 CFR § 812 (specifically, 21 CFR § 812.5 and 21 CFR § 812.7), an additional human subject protection regulation. Id. ¶¶ 11, 31, 107-08. These violations of human subject protection regulations, stemming from pre-approval promotion of ABSORB, affected all supposed clinical trials for ABSORB. Id. ¶¶ 36, 65, 72, 108. Compliance with human subject protection regulations is a precondition for Medicare's payment of routine clinical trial costs. Id. ¶¶ 11, 32, 58, 76. Relator concludes that where all supposed clinical trials for ABSORB were in violation of human subject protection regulations, all claims for reimbursement of routine costs of those trials, certifying such compliance, were false. Id. ¶¶ 37, 66, 91, 108.

[2] ABSORB is an absorbable drug-eluting stent. Pl.'s Reply Br. Relating Futility Issues Raised by Def.'s Opp'n Pl.'s Mot. Amend Compl. & File First Am. Compl. 2 n.1 [#72].

Although the First Amended Complaint thus alleges a violation of a human subject protection regulation (*i.e.* the requirement of informed consent), based on implantation of ABSORB into the leg, which would in turn have rendered false the claims for reimbursement of routine costs that certify such compliance, a claim based on a fraud in the inducement theory is futile for two reasons. First, the First Amended Complaint does not allege that any physician who received such pre-approval promotion actually implanted ABSORB into a leg. Second, Relator does not allege any claim submitted for reimbursement to Medicare or Medicaid based on that hypothetical ABSORB implantation into a leg. Although the First Amended Complaint lists numerous claims submitted to Medicare for ABSORB implantation procedures, all of those claims were based on coronary catheterization, not implantation into a leg. See id. ¶¶ 111-13. Thus, the First Amended Complaint does not connect pre-approval promotion of ABSORB for use in the leg, and any false claims submitted.

With respect to pre-approval promotion of ABSORB for use in the heart, the First Amended Complaint is futile for different reasons. Relator's theory only succeeds if the regulatory violations she asserts are in fact human subject protection regulations.[3] But although the First Amended Complaint alleges that by conducting pre-approval promotion of ABSORB for use in the heart, Abbott violated 21 CFR § 812, specifically 21 CFR § 812.5 and 21 CFR § 812.7, and that these regulations are human subject protection regulations, 21 CFR § 812.5 and 21 CFR § 812.7 are not listed as one of the human subject protection regulations set forth in 45 CFR § 46 or 21 CFR § 50. Nor are they identified as an additional human subject protection regulation by their own language. Rather, 21 CFR § 812.5 relates to labeling of investigational

[3] The First Amended Complaint does not allege that the clinical trials studying implantation of ABSORB in the heart violated any informed consent requirements.

devices, and 21 CFR § 812.7 relates to prohibiting promotion and other practices. Neither of those provisions plausibly relates to human subject protection. Thus, while relator may have alleged regulatory compliance violations, those regulations were not human subject protection regulations, and therefore compliance with those regulations was not a precondition of payment by Medicare. Where there is no precondition that Abbott is alleged to have violated, the relator cannot show a causal link between the claim for reimbursement and the violation.

The First Amended Complaint also appears to assert that certification of compliance with 21 CFR § 812 is a requirement for a Premarket Approval Application, which is submitted to the FDA, and that because Abbott violated 21 CFR § 812, its Premarket Approval Application, which certified compliance with 21 CFR § 812, was a false statement to the FDA. First Am. Compl. ¶¶ 10, 91-93. Leaving aside the fact that the First Amended Complaint does not close the loop and allege a causal link between the Premarket Approval Application and any later claims for reimbursement, FCA liability would not attach even if it had. The First Circuit rejected such a theory in D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016). In D'Agostino, the relator alleged that false statements made to the FDA to obtain FDA approval tainted all future claims made to Medicare and Medicaid, where FDA approval was a precondition to those payments. Id. at 7. The First Circuit rejected this theory both on materiality and causation grounds. First, it stated that "[t]he fact that CMS has not denied reimbursement for [the device] in the wake of [relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [relator] alleges." Id. Second, it stated that "alleging that the fraudulent representations 'could have' influenced the FDA to approve [the device] falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS." Id. The court reasoned that "[i]f the representations did not actually cause the FDA to grant approval it otherwise would not

have granted, CMS would still have paid the claims." Id. Moreover, "[t]he FDA's failure actually to withdraw its approval of [the device] in the face of [relator's] allegations precludes [relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained." Id. at 8. Relator's substantially similar argument here is thus precluded by First Circuit precedent.

Accordingly, the First Amended Complaint is futile with respect to any FCA allegations supported by a fraud in the inducement theory.

b. Off-Label Promotion Theory

The First Amended Complaint also posits an off-label promotion theory of false claims, as follows: Abbott promoted off-label use of XIENCE stents for use in patients with diabetes mellitus, without FDA approval for that indication. First Am. Compl. ¶¶ 10, 14. According to Relator, statistical analysis shows that approximately 40,000 claims for reimbursement of XIENCE stents implanted in diabetic patients were submitted to the government for reimbursement. Id. ¶¶ 10, 17-20. A condition of payment by Medicare and Medicaid is that devices and related services be authorized for marketing by the FDA, and that the procedures be reasonable and necessary. Id. ¶ 20. Relator asserts that claims for XIENCE stents in patients with diabetes mellitus were not reasonable and necessary. Id. ¶ 20. Nor were XIENCE stents authorized for marketing by the FDA for use in patients with diabetes mellitus. Id. ¶¶ 10, 14, 25. Therefore, she concludes, submission of claims to Medicare and Medicaid for implantation of XIENCE stents in patients with diabetes mellitus were false (*i.e.* not reimbursable). Id. ¶¶ 20, 109.

Count 1 is also futile on this theory. Relator alleges that Abbott targeted 2500 physicians[4] with promotional materials touting the use of XIENCE in patients with diabetes mellitus, and those 2500 physicians accounted for 80% of implantation procedures during the relevant period. First Am. Compl. ¶¶ 15, 21. Relator then identifies claims submitted to the government in two ways. First, she engages in statistical calculation to arrive at an approximation of 40,000 claims submitted.[5] Second, she provides a list of XIENCE stent-related claims submitted to the government for reimbursement during the relevant period. Id. ¶ 109. Missing from all of relator's allegations is any causal link between the promotional materials sent to the 2500 physicians and any decisions by those or any other physicians to use an XIENCE stent to treat a diabetic patient. Without these links, she has not properly alleged a false claim.

Additionally, even assuming the 2500 targeted physicians submitted claims to Medicare for implantation of XIENCE stents in diabetic patients, Medicare claims for off-label uses are not categorically false under the FCA. See U.S. ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 345, 347-48 (D. Mass. 2011). Medicare does reimburse for an off-label use of a medical device, where the procedure is reasonable and necessary. Id. at 347-48. Relator provides only a bare allegation that the XIENCE stent implantation procedures were not reasonable or necessary,

[4] Relator states that these physicians can be identified by their National Provider Identifiers, a list of which is attached at Appendix A to the First Amended Complaint. First Am. Compl. ¶ 21.
[5] Relator states that 990,000 stents were implanted during the relevant period. From this, she calculates that because XIENCE stents make up 35% of the market for stents, and because 80% of those XIENCE stents were implanted by the 2500 targeted physicians, and 30% of the patients who received those stents were diabetic, and 45% of those patients had Medicare, the physicians submitted approximately 37,500 claims to Medicare. She also calculates that because XIENCE stents make up 35% of the market for stents, and because 80% of those XIENCE stents were implanted by the 2500 targeted physicians, and 30% of the patients who received those stents were diabetic, and 3.7% of those patients had Medicaid, the physicians submitted approximately 3,000 claims to Medicaid. This calculation is flawed, as Relator does not state that the 30% of patients who were diabetic received their treatment from the 2500 targeted physicians. First Am. Compl. ¶ 19.

First Am. Compl. ¶ 20, and this barebones conclusion is insufficient to attach FCA liability under Fed. R. Civ. P. 9.

Accordingly, the First Amended Complaint is futile with respect to FCA allegations supported by an off-label promotion theory, and the Motion for Leave to Amend [#61] is DENIED as to Count 1.

2. *Count 2: Violations of 42 U.S.C. § 1320a-7b, Anti-Kickback Statute*

The First Amended Complaint also contains a claim under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. Relator alleges that Abbott paid conference speakers and sent funding to hospitals or other research foundations who ran continuing medical education events. First Am. Compl. ¶¶ 39, 95, 98. She alleges further that these payments, totaling more than $1 million, id. ¶ 97, were kickbacks because they were payments made to induce the recipients to recommend purchasing ABSORB and XIENCE products, and to allow Abbott employees the opportunity to deliver promotional presentations at Continuing Medical Education events which items may be paid for under a Federal health care program, id. ¶¶ 13, 27, 60, 96-98, 100-01.

Relator's Anti-Kickback claim fails for the same reasons it was initially dismissed. First, although the First Amended Complaint now identifies a series of alleged kickback payments, it does not identify any false claims submitted for payment as a result of those payments. Moreover, the transactions alleged as the kickback payments from Abbott to the providers are represented by "CMS Open Payments transaction identification numbers." Id. ¶¶ 97, 109. The First Amended Complaint does not allege why or how Medicare payment transaction numbers are evidence of a kickback payment from Abbott to the treatment providers.

The remaining allegations regarding kickbacks state that Abbott hosted presentations or gave educational grants to Continuing Medical Education conferences. As discussed in this court's prior Memorandum & Order [#44] dismissing the complaint, these allegations are

insufficient to state a claim for a False Claims Act claim based on a violation of the Anti-Kickback statute. Id. at 8; see New York v. Amgen, Inc., 652 F.3d 103, 110 (1st Cir. 2011) (relators "must show that the defendants knowingly caused the submission of the false or fraudulent claims, the submission of false records or statements to get the false or fraudulent claims paid, or otherwise conspired to defraud the state by getting the false or fraudulent claims paid"). The First Amended Complaint fails to allege any form of remuneration upon which FCA liability could attach, and also fails to allege false claims that were submitted as a result of that remuneration. Accordingly, the Motion for Leave to Amend [#61] is DENIED as to Count 2.

3. Count 3: Retaliation in Violation of 31 U.S.C. § 3730(h)

In Count 3 of the First Amended Complaint, retaliation in violation of 31 U.S.C. § 3730(h), Relator alleges that she submitted complaints about, and refused to engage in, illegal activity, and that that refusal and those complaints constituted protected conduct under the FCA. First Am. Compl. ¶¶ 42, 100, 116-17, 120. She alleges that her employment was terminated as a result of this protected conduct, and that her termination therefore was an act of retaliation in violation of 31 U.S.C. § 3730(h). Id. ¶¶ 118, 120-23.

To adequately state a claim for retaliation, a relator "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."[6] United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 235 (1st Cir. 2004), abrogated on other grounds by Allison Engine, 553 U.S. 662. Protected conduct is that which "reasonably could lead to a viable FCA action," id. at 236 (stating further that "this standard is most consistent with the broad interpretation for protected

[6] Abbott does not argue that Relator has failed to adequately allege prong 3, the causation element. Accordingly, the court does not address it.

activity under § 3730(h) urged by the legislative history"), including "investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government," id. at 237. A relator claiming retaliation for her protected activity need not prove an actual FCA violation, and an employer, even if innocent of the FCA violation, may not retaliate against an employee for engaging in protected conduct. Graham Cty Soil & Water Conservation Dist. v. United States ex rel. Wilson, 545 U.S. 409, 416 & n.1 (2005) (noting that Karvelas and other decisions "properly recognized that proving a violation of [31 U.S.C.] § 3729 is not an element of a § 3730(h) cause of action"). Accordingly, the question before the court is whether Relator can establish an objectively reasonable basis for her belief that Abbott violated the FCA.

Relator alleges that she complained about regulatory violations of 21 CFR § 801 and 21 CFR § 812, which she "genuinely believed" to be criminal violations. First Am. Compl. ¶ 116. Without more, such allegations would be insufficient. Relator goes on to allege, however, that she identified her complaints as implicating possible violations of the FCA. Id. ¶¶ 120-23. Moreover, these allegations are supported by additional facts indicating that Relator had first-hand experience regarding the alleged activities that she asserts constituted regulatory violations. Id. ¶ 100. Thus, the First Amended Complaint contains sufficient support for the allegation that Relator had an objectively reasonable basis for her belief that Abbott's activities induced the submission of false claims, and thus amounted to a violation of the FCA.

Relator further alleges that Abbott knew that she was engaged in protected conduct. For example, she alleges that in the months leading up to her employment termination, she notified the company of her belief that those regulatory violations "implicate[d] the False Claims Act." Id. ¶¶ 120-23. She also alleges that she initiated several internal complaints, seeking an

investigation into the potentially problematic activities, and met with individuals in the company regarding those complaints. Id. ¶ 100, 116-23. These allegations, concerning Relator's complaints to Abbott about Abbott's "knowing submission of false or fraudulent claims for payment to the government," satisfy the requirement for Abbott to have knowledge of her protected conduct. See Nowak, 806 F. Supp. 2d at 340-41; see also Karvelas, 360 F.3d at 238 (stating that a defendant's requisite awareness "mirrors the kind of activity in which the plaintiff must be engaged").

Accordingly, Relator's Motion for Leave to Amend [#61] is GRANTED as to Count 3.

4. Count 4: Violation of Public Policy

The First Amended Complaint contains one new, state-based claim—wrongful discharge in violation of public policy. First Am. Compl. ¶¶ 135-38. Generally, under Massachusetts law, an at-will employee "can be fired for any reason or for no reason at all." Smith v. Mitre Corp., 949 F. Supp. 943, 948 (D. Mass. 1997). The exception to this rule, construed narrowly by the Massachusetts Supreme Judicial Court, operates "where the discharge is for reasons that violate public policy." Id. at 948-49. For example, "[r]edress is available for employees who are terminated for asserting a legally guaranteed right . . . for doing what the law requires . . . or for refusing to do that which the law forbids . . . ." Id. at 949. Similarly, the public policy exception "protects an at-will employee who, in good faith, reports criminal conduct in her place of employment" either to public authorities or her superiors. Shea v. Emmanuel College, 682 N.E.2d 1348, 1350 (Mass. 1997); Smith, 949 F. Supp. at 950-51 (concluding that whistleblowers "can qualify for the public policy exception").

Relator alleges that she voiced concerns about regulatory violations, which she believed in good faith to be criminal violations. First Am. Compl. ¶ 116. She also alleges that she reported to her superiors that these regulatory violations implicated the FCA, and that she initiated an

internal investigation into those alleged violations. Id. ¶¶ 100, 116-23. These complaints are "sufficiently important to command the invocation of the exception." Smith, 949 F. Supp. at 951-52 (citing Tighe v. Career Sys. Dev. Corp., 915 F. Supp. 476, 485 (D. Mass. 1996) (concluding that 31 U.S.C. § 3730(h) "clearly express[es] a legislative policy encouraging persons . . . to inform the [government] of possible contractual or statutory violations by their employers")). Accordingly, Relator has stated a claim for termination in violation of public policy, and the Motion for Leave to Amend [#61] is GRANTED as to Count 4.

III. Conclusion

For the foregoing reasons, Relator's Motion for Leave to Amend [#61] is GRANTED with respect to Counts 3 and 4 and DENIED with respect to Counts 1 and 2. Relator is hereby ordered to docket her First Amended Complaint [#61-1], and must include—Leave to file granted on (date of order)—in the caption of the document. Abbott must file a responsive pleading, except as to Counts 1 and 2 and the footnotes, to the First Amended Complaint [#61-1] within twenty-one days of the date of this order.

IT IS SO ORDERED.

Date: May 5, 2017

/s/ Indira Talwani
United States District Judge