UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* MELAYNA LOKOSKY, Plaintiffs, v. ACCLARENT, INC., ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	No. 11-CV-11217-DLC

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS (Dkt. No. 61)

CABELL, U.S.M.J.

Melayna Lokosky began working for Acclarent, Incorporated (Acclarent) in 2007 as a sales representative. One of the products Acclarent sold was a sinus related device known as the Relieva Stratus MicroFlow Spacer (the "Spacer"). The plaintiff alleges that Acclarent engaged in practices which ultimately induced third parties to file false claims for payment for the Spacer with government programs like Medicare and Medicaid, and eventually terminated her for complaining about it. Following the previous dismissal of certain claims, the complaint asserts a claim for retaliatory termination pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3730(h), and a common law claim for wrongful termination in violation of public policy. The defendants move to

dismiss the complaint for failure to state a claim. (Dkt. No. 61). The plaintiff opposes the motion. (Dkt. No. 74). For the reasons discussed below, I find that the complaint states valid claims against Acclarent but not against Ethicon, Inc. (Ethicon) or Johnson & Johnson. Accordingly, the motion to dismiss is granted in part and denied in part.

I. RELEVANT BACKGROUND[1]

According to the complaint, Acclarent, in order to receive clearance for the Spacer, misrepresented to the FDA its intended use and its similarity to previously cleared products. (Compl. ¶ 12). More specifically, the FDA cleared the Spacer as an inert, non-drug delivering spacer to be placed in a patient's sinuses for no more than 14 days as a healing aid, but Acclarent's intended use for the device was to deliver the steroid Kenalog-40 in an unproven and off-label manner for 30 days or longer. (Id.). Kenalog-40 was never approved for use in the paranasal sinuses or for topical delivery through a sinus spacer. (Compl. ¶ 34). In fact, Acclarent knew the Spacer provided no additional benefits when used with the steroid Kenalog-40, and consequently hid this data from the FDA. (Compl. ¶ 13). Had Acclarent been truthful with the FDA, the Spacer never would have been approved for the market. (Id.).

[1] The facts are taken from the plaintiff's complaint and accepted as true for purposes of the motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007).

But, because Acclarent was not truthful, the FDA approved the Spacer. (Compl. ¶ 14). Once it was cleared, Acclarent never marketed the Spacer for its intended use. Instead, Acclarent instructed doctors to use the Spacer with off-label Kenalog-40 for more than 14 days. (Id.). By concealing the intended combination of the Spacer and Kenalog-40, and then uniformly marketing that off-label combination to hospitals and physicians, Acclarent caused the Spacer to be misbranded, and thus ineligible for federal reimbursement. (Compl. ¶ 15).

In 2009, Johnson & Johnson announced that its subsidiary, Ethicon, was acquiring Acclarent. (Compl. ¶ 17). Johnson & Johnson immediately became concerned about the off-label marketing of the Spacer and announced two months later that it would cease all active marketing of the product due to regulatory concerns. (Id.). Johnson & Johnson also announced that they would destroy all promotional material for the Spacer. (Compl. ¶ 64). Despite this announcement, Johnson & Johnson still manufactured, sold, and distributed the product. (Compl. ¶ 17).

Furthermore, Acclarent trained its sales representatives to tell doctors that the Spacer was specifically designed for use with Kenalog-40. (Compl. ¶ 39). Acclarent employees knew that saline solution would leak out of the Spacer in a matter of hours or days, rendering pointless the insertion of the Spacer for 14 days. (Id.). This same problem applied to other drugs of similar

viscosity, including antibiotics and most forms of corticosteroids. (Id.). The exception was Kenalog-40, whose viscosity was intended to maximize the time the drug remained in the injection area. (Id.). Use of the Spacer with Kenalog-40 is the only use that Acclarent has ever investigated in living human beings, and is the only use described in articles published in medical journals. (Compl. ¶ 40-41). The Acclarent sales force sold the device to physicians by insisting that it be used with Kenalog-40. The plaintiff learned from other sales representatives that physicians did not use the device with saline and that this was representative of the way physicians used the device around the country. (Compl. ¶ 56).

The plaintiff joined Acclarent in June 2007 and was an experienced medical device sales representative. (Compl. ¶ 65). She was one of the first sales representatives trained to sell the Spacer, and was one of the top sellers of the Spacer before the defendants stopped promoting the product in March 2010. (Id.). When the defendants stopped promoting the Spacer, sales representatives were told that their sales quotas would be adjusted to account for the lack of these sales, but in reality this did not occur and sales representatives were unable to meet their sales goals. (Compl. ¶ 66). As a result, sales managers began to put pressure on sales representatives to promote the Spacer as they had done before. (Compl. ¶ 67).

After the defendants announced that they would no longer promote the Spacer, the plaintiff was uncomfortable with its off-label promotion and was relieved to no longer have to sell it. (Compl. ¶ 68). But, in July 2010, one of the plaintiff's supervisors told her that the company needed to return to selling the Spacer. (Compl. ¶ 69). The plaintiff informed her supervisor that she did not think it was right to sell the product off-label and that she did not want to do it. (Id.). The supervisor told her to sell it anyway. (Id.).

In August 2010 the plaintiff conspicuously posed questions at a conference in the presence of in-house regulatory personnel about how to handle inquiries from physicians about the Spacer. (Compl. ¶ 70). Due to the plaintiff's questions, the regulators decided to stay at the conference an additional day, which in turn prevented the sales group from realizing its plan to use the time to discuss in private their plans to renew promotion of the Spacer. (Id.). Acclarent subsequently put the plaintiff on an unrealistic performance plan within 30 days of the sales meeting, and terminated her on or about January 4, 2011. (Compl. ¶ 71).

II. LEGAL STANDARD

Under Rule 12(b)(6) courts must apply the notice pleading requirements of Rule 8(a)(2). *Educadores Puertorriquenos en Accion v. Hernandez*, 367 F.3d 61, 66-67 (1st Cir. 2004). Under Rule 8(a)(2), a complaint need only include a short and plain

statement of the claim showing that the pleader is entitled to relief and giving the defendant fair notice of the grounds for the plaintiff's claim. *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Therefore, "a Court confronted with a Rule 12(b)(6) motion 'may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *Educadores Puertorriquenos en Accion,* 367 F.3d at 66 (*citing Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

To show that one is entitled to relief, the plaintiff must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully," and is met when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (*quoting Twombly,* 550 U.S. at 556). A court must "accept as true all well-pleaded facts set forth in the complaint and draw all reasonable inferences therefrom in the pleader's favor." *Haley v. City of Boston*, 657 F.3d 39, 46 (1st Cir. 2011) (*quoting Artuso v. Vertex Pharmaceuticals, Inc.,* 637 F.3d 1, 5 (1st Cir. 2011)). However, the Court is "not bound to accept as true a legal conclusion

couched as a factual allegation." *Id*. at 678 (*quoting Twombly,* 550 U.S. at 555).

III. ANALYSIS

A. Claims Against Ethicon and Johnson & Johnson

The defendants argue that Ethicon and Johnson & Johnson should be dismissed from the lawsuit because the complaint focuses on Acclarent's conduct and by contrast does not allege that either Ethicon or Johnson & Johnson engaged in any conduct related to the plaintiff's termination. The plaintiff demurs and argues that a recent amendment to the FCA has broadened the scope of who can be held liable under § 3730(h) by removing the term "employer."

As originally enacted, the FCA's anti-retaliation provision provided that "[a]ny employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of his employment by his or her *employer* because of [a protected activity] shall be entitled to all relief necessary to make the employee whole." 31 U.S.C. § 3730(h); False Claim Amendments Act, Pub.L. 99–562, 100 Stat. 3153 (1986) (emphasis added). In 2009, section 3730(h) was amended to expand protection from "employees" to "employees, contractors and agents," and to eliminate the word "employer." Pub.L. No. 111-21, §4(d), 123 Stat. 1617, 1624-25 (2009). As amended, the statute now reads:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor,

> or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h).

As a threshold matter, the plaintiff does not contend that the 2009 amendment to the FCA's anti-retaliation provision acts to automatically impose liability on the corporate parent of an employer. Rather, and as the court understands it, she argues that the removal of the word "employer" means that section 3730(h) is no longer limited to just employers, and that corporate parents like Ethicon and Johnson & Johnson therefore cannot be dismissed simply because they were not the plaintiff's actual employer. Accepting this proposition as true, it is still "a general principle of corporate law deeply 'ingrained in our economic and legal systems' that a parent corporation … is not liable for the acts of its subsidiaries." *See U. S. v. Bestfoods*, 524 U.S. 51, 61 (1998). There are of course some circumstances where a parent company may be liable for the actions of a subsidiary but these circumstances arise "only when compelling reasons justify disregarding corporate structure and piercing the corporate veil." *Clinical Dynamics Corp. v. Dynatech Nevada, Inc.*, Civ. A. No. 93–10048–Z, 1994 WL 175026, at *1 (D. Mass. April 13, 1994). "Where a party seeks to hold a parent company liable for the actions of

a subsidiary, that party carries the burden of overcoming the presumption of separateness by clear evidence." *Carballo-Rodriguez v. Clark Equipment Co.*, 147 F. Supp. 2d 63, 65 (D.P.R. 2001) (*citing Escude Cruz v. Ortho Pharmaceutical Corp.,* 619 F.2d 902, 905 (1st Cir. 1980)).

Here, the plaintiff has not alleged any facts that would justify disregarding the corporate structure and holding Ethicon or Johnson & Johnson liable for Acclarent's actions. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (parent company dismissed from action where plaintiff "implie[d] that [it] might be liable under a "piercing the corporate veil" theory, [but] he has not pled facts to support such a theory"). As far as can be gleaned from the complaint, the theory for holding Ethicon and Johnson & Johnson liable is that they acquired Acclarent and generally took over its daily operations. (Compl. ¶ 63). By contrast, the complaint does not allege that either entity took any actions in relation to the plaintiff. Rather, the complaint avers that Ethicon, a division of Johnson & Johnson, acquired Acclarent, and that Johnson & Johnson subsequently took over the day to day responsibilities for selling Acclarent products, including the Spacer. (Id.). The complaint avers further that, although Johnson & Johnson and Ethicon management oversaw Acclarent operations, they kept Acclarent as a separate division, and the Acclarent sales force

continued to report to the same Acclarent managers as before. (Id.). Finally, the complaint alleges that two months after Acclarent was acquired, the defendants announced that Acclarent would no longer promote the Spacer. (Compl. ¶ 64). Even reading these allegations in a light most favorable to the plaintiff, and drawing all reasonable inferences in her favor, I find that the complaint still fails to allege any knowledge or action on the part of Ethicon or Johnson & Johnson regarding the plaintiff's engaging in protected conduct or her termination. Indeed, the complaint explicitly states that "Acclarent" fired the plaintiff. (Compl. ¶ 2).

To be sure, and as the plaintiff notes, one court in this district has denied a motion to dismiss a parent company from an FCA retaliation claim. *See U.S. ex rel. Gobble v. Forest Laboratories, Inc.*, 729 F. Supp. 2d 446 (D. Mass. 2010). *Gobble* is distinguishable from the present case, however. Among other things, the complaint in that case alleged that the parent company was on notice of and knew about the plaintiff's protected conduct, that the parent company was responsible for relevant ethics guidelines, and that two of its employees were involved in the plaintiff's firing. *Id*. at 451. As noted, the complaint here does not allege that Ethicon or Johnson & Johnson had notice or knew of the plaintiff's protected conduct, or played any role in her termination. As such, the plaintiff has presented no reason

to depart from the longstanding precedent that parent companies are not liable for the actions of their subsidiaries merely because they are parent companies. *See United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 2011 U.S. Dist. LEXIS 47725, at *5 (D. Mass. 2011). Accordingly, the motion to dismiss will be granted with respect to Ethicon and Johnson & Johnson.

B. The Complaint States a Valid FCA Retaliation Claim Against Acclarent

To establish a prima facie claim for retaliatory termination under the FCA, a plaintiff must show that (1) she engaged in conduct protected under the FCA, (2) the employer knew that she was engaged in such conduct, and (3) the employer discharged or discriminated against her because of her protected conduct. *U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 272 (D. Mass. 2015) (*citing Maturi v. McLaughlin Research Corp.,* 413 F.3d 166, 172 (1st Cir. 2005)). FCA protected conduct is limited to those activities which could reasonably lead to a viable FCA action. *Hagerty*, 95 F. Supp. 3d at 272. These activities include "investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *Id.* (*citing U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004)).

1. Protected Conduct

The seminal case in this circuit on protected conduct under the FCA is *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004). In *Karvelas,* the First Circuit analyzed the legislative history of the FCA and determined that protected activity should be interpreted broadly as conduct that reasonably could lead to a viable FCA action. *Id.* at 236. While a plaintiff need not know that his actions could lead to a qui tam suit under the FCA, or even that the FCA existed, protected conduct is nonetheless limited to activities which reasonably could lead to FCA action. *Id.* at 237.

The plaintiff in *Karvelas* reported the destruction of reports of medical errors which suggested regulatory failures. The Court noted that "correcting regulatory problems may be a laudable goal, [but] it is not actionable under the FCA in the absence of actual fraudulent conduct." *Id.* (internal quotations omitted). However, the plaintiff in *Karvelas* also alleged that he investigated and reported problems with improper billing when he complained about completing patient evaluations for patients who had been discharged or had died. *Id.* These evaluations were billed to Medicare even though they were not reimbursable, and thus implicated the possibility of fraud, which in turn rendered his complaints about the practice protected conduct under the FCA. *Id.* at 238.

Karvelas was decided prior to Congress's amendment of the FCA but the First Circuit noted in a recent decision that the 2009 amendment merely clarified that "protected conduct" under the FCA has always encompassed measures such as internal complaints or objections to an employer. *U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 60 n.8 (1st Cir. 2017) ("[c]ourts have understood the amendment as having clarified that the provision [regarding protected conduct] covers not only steps in the litigation process, such as investigating or testifying, but also measures, such as internal reporting or objecting to employer directives, which might not be taken in direct furtherance of an actual lawsuit;" "*Karevlas* construed the pre-amendment provision as covering such activities.")

Thus, *Booker* makes clear that *Karvelas* already interpreted the FCA to include internal reporting as protected conduct. Therefore, to the extent the plaintiff asserts that the amendment would allow the plaintiff's action based on internal reporting to go forward where it was not previously permitted, the court disagrees. Rather, *Karvelas* and the amendments (and *Booker*) show that such internal reporting has always come within the scope of protected conduct, and is indeed sufficient to form part of an FCA retaliation claim so long as that internal reporting is tied to false claims for reimbursement.

Here, the plaintiff argues that because Acclarent only promoted and sold the Spacer for an off-label use, any sale of the Spacer would have necessarily resulted in the submission of a false claim. Consequently, when the plaintiff complained internally about off-label promotion and sales, she necessarily complained about potentially fraudulent claims to the government, and accordingly engaged in protected conduct. The plaintiff relies on several cases from this district to support her argument. *See U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 280 (D. Mass. 2016) ("complaints … involv[ing] concerns about kickbacks and other fraudulent conduct directed at physicians to encourage off-label use" is protected conduct); *Hagerty*, 95 F. Supp. 3d at 252 (motion to dismiss denied where "[plaintiff] became concerned that he would not be able to meet his sales quotas without resorting to fraudulent practices [and h]e raised his concerns and the fraudulent practices of other Cyberonics employees with his regional manager"); *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 324 (D. Mass. 2011) (motion to dismiss denied where "[plaintiff] expressed concern and asked how the Endovascular Group could be asked to sell peripheral products off-label given the legal restrictions and potential personal liability for sales representatives"); *Gobble*, 729 F. Supp. 2d at 450 (motion to dismiss denied where "[plaintiff's] complaint does not explicitly tie his retaliation claim to fraud

on the government but the complaint does generally describe how his inquiries support an FCA claim"); *U.S. ex rel. Bierman v. Orthofix Intern., N.V.*, 748 F. Supp. 2d 117, 121 (D. Mass. 2010) (motion to dismiss denied where "[plaintiff] alleges that he asked questions of his supervisors regarding the legality of the various schemes allegedly perpetrated by the defendants").

The court finds this precedent compelling. The law does not require a plaintiff to connect all of the dots between alleged off-label promotions and fraud on the government. *Gobble,* 729 F. Supp. 2d at 450. When the plaintiff refused to sell a product she believed was misbranded and illegally promoted off-label, and attempted to expose and stop the illegal sales tactics by complaining to a supervisor and by conspicuously posing questions suggesting illegal off-label marketing in the presence of in-house regulatory personnel, she was engaged in protected activity "that reasonably could lead to FCA action." *Hagerty*, 95 F. Supp. 3d at 272. The court is persuaded that the complaint sufficiently alleges that the plaintiff was engaged in protected conduct.

2. Employer Knowledge of Protected Conduct

"To meet the knowledge element of an FCA retaliation claim ... the employer must be on notice that the employee is engaged in conduct that reasonably could lead to a False Claims Act case." *Hagerty*, 95 F. Supp. 3d at 272 (*quoting Karvelas*, 360 F.3d at 238) (internal alteration marks original). The court finds that the

plaintiff's complaints and inquiries to her superiors about off-label marketing were sufficient to put Acclarent on notice and to establish its knowledge. *See Forest Laboratories, Inc.*, 729 F. Supp. 2d at 451 (plaintiff "adequately pled that the defendants were on notice of and knew about his protected conduct [where] [h]is complaint contains several allegations of complaints and inquiries to his supervisors about the allegedly unlawful kickbacks and off-label promotions…"). The complaint alleges that the plaintiff informed one of her supervisors that she did not think it was right to sell the Spacer off-label, and later purposely asked questions in the presence of in-house regulatory personnel about how to handle inquiries about the Spacer in dealing with customers. Moreover, the complaint alleges that sales managers were reportedly furious with her for having raised such questions, suggesting they knew the effect of her questions would be to raise concerns regarding Acclarent's marketing and selling of the Spacer, and wanted to avoid that result.

3. Discharge or Discrimination based on Protected Conduct

Acclarent argues that the plaintiff cannot show a causal link between her protected conduct and her termination because she has not alleged that she was terminated for her protected conduct, but rather was terminated because of "friction" between her and her supervisor. Acclarent argues that even if this friction were not

enough to justify the plaintiff's termination, the temporal connection between her refusal to promote the Spacer and her subsequent termination is too attenuated to show a causal connection between the two.

The court does not find this argument persuasive. While the plaintiff's complaint does mention friction between her and her supervisor, it makes the mention in passing only, on the way to alleging that the plaintiff was terminated for her protected conduct (i.e., for refusing to promote and sell the Spacer off-label based on her concerns). (Compl. ¶ 71) ("[T]here was a history of friction between the Relator and her boss which was well known to sales management, [but] senior management had protected her . . . until the Relator refused to engage in off-label promotion of the Microwflow Spacer[.]"). The plaintiff alleges that she was placed on an unrealistic performance plan within 30 days of the August 2010 sales meeting at which she conspicuously posed questions about the Spacer, and then terminated by January 4, 2011. At this juncture, the court is just not prepared to declare as a matter of law that the time period between the sales meeting and the plaintiff's termination is too attenuated to be causally related, especially where the plaintiff was placed on an unrealistic performance plan in the interim, allegedly, as is implied, to set the stage for her termination, and the parties

regardless dispute the length of time that elapsed between the protected conduct and the plaintiff's termination.[2]

In short, the complaint states a valid FCA retaliation claim against Acclarent.

C. There is Presently no Basis to Dismiss the Wrongful Termination Claim

The defendants argue that Arizona law applies to the plaintiff's claim of wrongful termination, and that, if so, her wrongful termination claim fails because under Arizona law a plaintiff must plead an Arizona statute upon which her claim for wrongful termination is based, and the plaintiff does not do so. The plaintiff does not respond directly to this argument. Rather, she argues that the court does not have enough information at this stage to determine definitively whether Arizona law applies. Moreover, the plaintiff suggested at the hearing that California law rather than Arizona law may apply to her wrongful termination claim because Acclarent's principal place of business is in California. As neither party has briefed or addressed the issue further, the court simply does not have enough information at this juncture to squarely resolve the issue. It is therefore not appropriate to dismiss this claim at this time. Discovery and time will yield the answer.

[2] The parties dispute whether the time between the protected conduct and the plaintiff's termination was four or six months.

IV. CONCLUSION

For the foregoing reasons, the defendants' motion to dismiss the complaint is GRANTED with respect to Ethicon and Johnson & Johnson, but DENIED with respect to Acclarent.

SO ORDERED.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: September 20, 2017