UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

LAURA BLANKENSHIP,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**Case No. 4:13-CV-1087 (CEJ)**
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on the motions, filed by defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., Medtronic Vertelink, Inc., Medtronic Sofamor Danek, Inc., and Warsaw Orthopedic, Inc. (collectively "Medtronic"), to dismiss plaintiff's third amended complaint and to strike exhibits 3 and 4, attached to plaintiff's response in opposition to the motion to dismiss. Plaintiff has responded to the motions and the issues are fully briefed.

I. Background

Medtronic is in the business of designing, manufacturing, and selling medical devices, including the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion device (Infuse). On July 2, 2002, Infuse was approved by the Food and Drug Administration (FDA) "for spinal fusion procedures in skeletally mature patients with degenerative disc disease (ddd) at one level from L4-S1 . . . to be implanted via an anterior open or an anterior laparoscopic approach." [Doc. ##57-1, 57-2].

On September 19, 2007, plaintiff underwent a cervical diskectomy and fusion at C4-5, C5-6 and C6-7, with instrumentation and placement of the Infuse bone graft at each level. Dr. Timothy Kuklo was plaintiff's surgeon. This surgery is considered to

be "off-label" because the FDA has not approved Infuse for cervical placement.[1] Plaintiff contends that she is permanently and totally disabled from the off-label surgery.

On March 11, 2013, plaintiff filed a second amended complaint asserting claims of manufacturing defect; failure to warn; design defect; negligence; strict liability; fraud; negligence per se; intentional misrepresentation; and violations of California's unfair competition law. Medtronic moved to dismiss all of plaintiff's claims. On March 25, 2014, the Court issued an order granting defendants' motion to dismiss. Blankenship v. Medtronic, Inc., 2014 WL 1226491 (E.D. Mo. Mar. 25, 2014). However, the order also granted plaintiff leave to amend her fraud and intentional misrepresentation claims. Id. at *9-11. The Court found that while these claims escaped both express and implied preemption, plaintiff failed to plead them with the particularity required by Federal Rule of Civil Procedure 9(b). Id.

On April 8, 2014, plaintiff filed a third amended complaint alleging fraud and intentional misrepresentation (Count I) and violation of the Missouri Merchandising Practices Act, Mo. Stat. §§ 407.010, *et seq.* (Count II). [Doc. #97]. On May 9, 2014, defendants filed the instant motion to dismiss, arguing that plaintiff again fails to satisfy Rule 9(b)'s particularity requirement. [Doc. #101]. On May 23, 2014, plaintiff filed a response in opposition to defendants' motion to dismiss, which included four exhibits. [Doc. #108, Ex. 1-4]. On June 13, 2014, defendants filed a motion to strike, arguing that the Court should strike plaintiff's exhibits 3 and 4.

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[1] **"Off-label" usage is defined as "use of a device for some other purpose than that for which it has been approved by the FDA." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001).**

II. Discussion

A. Motion to Strike

Exhibit 3, attached to plaintiff's response in opposition to defendants' motion to dismiss, is a "Staff Report on Medtronic's Influence on Infuse Clinical Studies" prepared by the staff of the United States Senate Finance Committee in October 2012 ("Staff Report"). Exhibit 4 includes (1) a letter from Senator Charles E. Grassley to Mark Stephen Wrighton, Chancellor, Washington University in St. Louis, dated May 15, 2009; (2) a letter from Senator Charles E. Grassley to Major General Carla G. Hawley-Bowland, United States Army, dated May 15, 2009; (3) a letter from Senator Charles E. Grassley to James D. Heckman, Editor of The Journal of Bone and Joint Surgery, dated May 15, 2009; and (4) a letter from Senator Charles E. Grassley and Senator Max Baucus to Major General Carla G. Hawley-Bowland, United States Army, dated December 17, 2012 (collectively "Senate Letters").

Defendants argue that the Staff Report and the Senate Letters "are not subject to judicial notice because they are subject to reasonable dispute and are irrelevant to the questions before this Court on [defendants'] motion to dismiss." [Doc. #112]. In response, plaintiff asserts that she never requested exhibits 3 or 4 to be judicially noticed. Instead, plaintiff argues that these exhibits should not be stricken because they are highly relevant to her fraud and intentional misrepresentation claims and aid in satisfying Rule 9(b)'s particularity requirement.[2]

The Eighth Circuit has held that when considering a motion to dismiss under

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[2] Because plaintiff makes clear in her response brief to defendants' motion to strike that she is not requesting that exhibits 3 or 4 be judicially noticed, the Court will not address whether judicial notice would be appropriate.

Fed.R.Civ.P. 12(b)(6), "the court generally must ignore materials outside the pleadings, but it may consider some materials that are part of the public record or do not contradict the complaint, as well as materials that are necessarily embraced by the pleadings." Porous Media Corp. v. Pall Corp., 186 F.3d 1077, 1079 (8th Cir. 1999) (internal citations omitted). Materials that are necessarily embraced by the pleadings may include documents that have been incorporated by reference in the complaint. Piper Jaffray Cos. v. National Union Fire Inc. Co., 967 F. Supp. 1148, 1152 (D. Minn. June 17, 1997).

Plaintiff's third amended complaint contains numerous references to the Senate Report and the Senate Letters in order to show that Medtronic's actions and practices were so blatantly fraudulent that the U.S. Senate was prompted to conduct a 16-month investigation into the company's conduct. See Pl.'s Comp. ¶¶ 34, 160, 216, 219, 229, 350-377, 389-418. Plaintiff further references the Senate Report and Senate Letters throughout the complaint in order to support her allegations that Medtronic manipulated medical literature in order to conceal the serious side effects and health risks related to the off-label use of Infuse and entered into consulting and royalty agreements with physicians, including Dr. Kuklo, for the purpose of perpetrating fraud on the medical community.

Thus, the Court finds that exhibits 3 and 4, which do not contradict plaintiff's allegations and are incorporated by reference, are "necessarily embraced" by the third amended complaint. Furthermore, exhibits 3 and 4 are relevant in supporting plaintiff's allegations and providing the requisite particularity required to show that Medtronic was engaged in a fraudulent scheme, which included the involvement of Dr. Timothy Kuklo. Therefore, the exhibits will not be stricken.

B. Motion to Dismiss

To satisfy Rule 9(b), the complaint must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 187 (2nd Cir. 2004). After review of plaintiff's third amended complaint, the Court finds that plaintiff has remedied the earlier deficiencies and has sufficiently pled fraud and intentional misrepresentation in satisfaction of Rule 9(b)'s particularity requirement.

Plaintiff alleges that Medtronic had knowledge of the serious adverse side effects and risks of the off-label use of Infuse, but that it intentionally downplayed these risks and falsely represented that patients were not harmed by the off-label use of Infuse. See Comp. ¶¶ 120, 146-149, 217-219, 469-470. Plaintiff points to published medical studies and articles showing that Medtronic had knowledge of the serious adverse effects. Id. ¶¶ 103, 113-120, 123. For example, plaintiff alleges that a 1999 trial "had to be terminated due to the high incidence of adverse events in participants," but that one of Medtronic's paid opinion leaders represented that the results were "encouraging." Id. at ¶¶ 261, 311.

Plaintiff further alleges that Medtronic used royalty and consulting agreements with physicians and opinion leaders in order to induce other surgeons to use Infuse in an off-label manner. Id. ¶¶ 198-199, 211, 224-229. The 142-page complaint is replete with instances of Medtronic agents downplaying the severe risks and side effects and promoting Infuse for off-label uses. In addition, plaintiff alleges that Medtronic actively authored and edited medical literature for the purpose of hiding the truth about the

safety of Infuse for off-label uses and overemphasizing its benefits. Id. ¶¶ 208, 214, 217, 220-248, 396, 398, 411.

Plaintiff alleges in great detail how Medtronic's representations were fraudulent, who was involved in the alleged scheme, and when the fraud allegedly occurred. For example, plaintiff alleges that Medtronic consultants were paid to author an article in 2009, in which they represented that the participants of a clinical trial did not suffer any adverse events, while an independent physician found a three-fold increase in the number of adverse events. Id. at ¶ 221. Plaintiff points to various third-party studies and articles, which reported concerns with Medtronic-sponsored authors who inaccurately related the safety and risks of Infuse to the medical community. Id. at ¶¶ 367-387. Plaintiff additionally cites to specific emails and statements made between Medtronic consultants and Medtronic employees discussing the ways in which they should downplay the side effects to the public and the medical community. Id. at ¶¶ 231-237, 246.

Plaintiff's allegations in this case are similar to those in Hornbeck v. Medtronic, Inc., 2014 WL 2510817 (N.D. Ill. June 2, 2014), which further supports that plaintiff has satisfied the particularity requirements of Rule 9(b). In Hornbeck, the plaintiff also alleged that Medtronic entered into royalty and consulting agreements with opinion leaders to influence other surgeons to use Infuse in an off-label manner and that these opinion leaders misrepresented and intentionally omitted the risks involved. Id. at *1-2. The plaintiff in Hornbeck alleged that Medtronic "deceived the medical community by manipulating the medical literature regarding Infuse Bone Graft component to misrepresent the product's safety and efficacy." Id. at *2. Regarding plaintiff's fraud claims, the court held that because the complaint detailed "an elaborate campaign to

manipulate the medical community as to the safety and efficacy of a use of the Infuse bone graft component that the FDA did not approve," the complaint sufficiently addressed "the who, what, when, where, why, and how of the Medtronic [d]efendants' alleged fraud." Id. at *5; see also Houston v. Medtronic, Inc., 2014 WL 1364455 (C.D. Cal. Apr. 2, 2014) (alleging similar fraud claims).

However, despite plaintiff's extensive allegations, Medtronic argues that the third amended complaint should be dismissed because plaintiff failed to identify a specific false statement made to her by her surgeon, Dr. Timothy Kuklo, and that plaintiff failed to sufficiently show that Dr. Kuklo was an agent of Medtronic. While it is true that the complaint does not identify a specific statement made to her by Dr. Kuklo, plaintiff did allege sufficient facts showing that Dr. Kuklo was a paid consultant of Medtronic (as evidenced by his receipt of nearly $850,000 from Medtronic over the past ten years); that Dr. Kuklo knew of the serious adverse side effects and risks regarding the off-label use of Infuse; that he was a major participant in Medtronic's scheme to improperly promote Infuse for off-label uses; that he deliberately falsified data in Medtronic reports by exaggerating the benefits of off-label use of Infuse; and that he intentionally and fraudulently concealed, downplayed, and misrepresented the health and safety hazards to plaintiff and the medical community. See Pl.'s Comp. ¶¶ 49, 51, 275-289, 295, 453. Plaintiff further alleges that she would not have consented to the off-label surgery had she known the truth about the dangers and risks of the off-label use of Infuse. Id. ¶¶ 10, 28, 50, 482.

The Court finds that plaintiff's detailed and numerous allegations involving Medtronic's widespread campaign to fraudulently misrepresent the health risks and safety of the off-label use of Infuse combined with Dr. Kuklo's lucrative ten year

involvement in the alleged scheme are sufficient, at this stage of the litigation, to support plaintiff's fraud claims. See Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 985 (citing Cooper v. Pickett, 137 F.3d 616, 625 (9th Cir. 1997)) ("Falsity may also be established through allegations of circumstantial evidence.").

Defendants further argue that the third amended complaint should be dismissed because plaintiff contradictorily alleges that Dr. Kuklo was deceived by Medtronic's fraudulent misrepresentations, while also arguing that he was part of the alleged scheme. The Court finds this argument to be insufficient to dismiss plaintiff's fraud claims. See Complaint in Hornbeck, 2014 WL 2510817, Case No. 1:13-CV-7816, Doc. #1, at ¶¶ 212-213, 334, 339, 341 (plaintiff alleged that her surgeon knowingly concealed the risks and dangers of off-label use, while simultaneously alleging that her surgeon was a victim of Medtronic's fraudulent misrepresentations).

Although the Court will allow plaintiff's fraud and intentional misrepresentation claim (Count I) to proceed, plaintiff's claim based on the Missouri Merchandising Practices Act (Count II) will be dismissed. The case management order entered in this case established May 3, 2013 as the deadline for amending pleadings. [Doc. # 23, p. 17]. The March 25, 2014 order granted plaintiff leave to amend her previously alleged fraud claim (Count VI of the second amended complaint) and intentional misrepresentation claim (Count VIII of the second amended complaint). See Blankenship, 2014 WL 1226491 ("Plaintiff is granted leave to amend, if possible, *these fraud-based claims* in order to satisfy the particularity requirement of Rule 9(b).") (emphasis added). The order was not intended as an open invitation for plaintiff to raise an additional claim. Plaintiff has not requested leave to assert a new claim and, hence, has not shown good cause. See Fed. R. Civ. P. 16(b)(4); Sherman v. Winco

Fireworks, Inc., 532 F.3d 709, 716 (8th Cir. 2008)(party seeking leave to amend a pleading outside deadline set forth in case management order must show "good cause").

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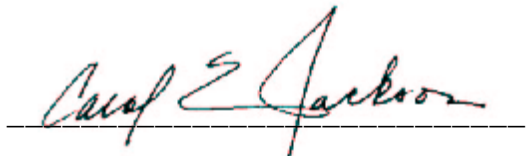
Accordingly,

IT IS HEREBY ORDERED that defendants' motion to strike plaintiff's exhibits 3 and 4, attached to plaintiff's response in opposition to the motion to dismiss [Doc. #111] is denied.

IT IS FURTHER ORDERED that defendants' motion to dismiss plaintiff's third amended complaint [Doc. #101] is denied.

IT IS FURTHER ORDERED that Count II of the third amended complaint is dismissed.



CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 4th day of August, 2014.