UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

SARVANAZ KASHANI-MATTS, **Plaintiff,** **vs.** **MEDTRONIC, INC.; AND MEDTRONIC SOFAMOR DANEK USA, INC.,** **Defendants.**	**Case No.: SACV 13-01161-CJC(RNBx)** **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT**

I. INTRODUCTION

In this action, Plaintiff Sarvanaz Kashani-Matts ("Plaintiff") asserts various state tort claims against Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic"), based on complications from a 2008 operation in which a Medtronic medical device was implanted in her spine. Plaintiff's First Amended

Complaint ("FAC") pleads causes of action for fraudulent misrepresentation and fraud in the inducement, strict products liability — failure to warn, strict products liability — design defect, and strict products liability — misrepresentation. (Dkt. No. 6 ["FAC"].) Medtronic moves to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) on grounds of federal preemption.[1] For the reasons stated below, Medtronic's motion is GRANTED.[2]

II. BACKGROUND

Medtronic manufactures and sells the Infuse Bone Graft / LT-Cage prescription medical device (the "Infuse Device"). (FAC ¶¶ 1–2.) The Infuse Device is used to join together vertebrae of the spine in spinal fusion surgery. (FAC ¶ 56.) Spinal fusion surgery is a procedure used to treat a number of back conditions, such as degenerative disc disease, by stabilizing the spine. (FAC ¶ 57.) The Infuse Device consists of a bone graft component and a metallic cage. The active ingredient of the bone graft component is a genetically engineered, bone morphogenetic protein. The protein stimulates bone growth, thereby helping to fuse the vertebrae together. (FAC ¶¶ 62–63.)

The Infuse Device is a Class III medical device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") as amended by the Medical Device Amendments of

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[1] As an initial matter, Plaintiff filed her opposition to Medtronic's motion to dismiss four days past the deadline. Local Rule 7-12 addresses a party's failure to timely file required papers. It states:

> The Court may decline to consider any memorandum or other paper not filed within the deadline set by order or local rule. The failure to file any required paper, or the failure to file it within the deadline, may be deemed consent to the granting or denial of the motion.

Accordingly, Medtronic's motion could be granted solely on the ground of Plaintiff's failure to timely file an opposition. Nevertheless, the Court finds that dismissal is appropriate on the merits as well.

[2] Having read and considered the papers presented by the parties, the Court finds this matter appropriate for disposition without a hearing. *See* Fed. R. Civ. P. 78; Local Rule 7-15. Accordingly, the hearing set for November 25, 2013 at 1:30 p.m. is hereby vacated and off calendar.

1976 ("MDA"). (FAC ¶ 71.) Manufacturers seeking to market Class III devices are required to obtain premarket approval from the Food & Drug Administration ("FDA"). (FAC ¶ 72.) Premarket approval is a "rigorous" process in which the manufacturer submits to the FDA extensive study reports, design specifications and descriptions, samples of the device, and proposed labeling, and the FDA conducts a comprehensive review and evaluation of all the submitted documents and materials, spending an average of 1,200 hours on each application. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008). The FDA then "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.' " *Id.* (quoting 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)). Medtronic's premarket approval application for the Infuse Device was submitted on January 12, 2001, and approved by the FDA on July 2, 2002. (FAC ¶ 78.) The FDA approved the Infuse Device with an indication for use in anterior lumbar interbody fusions.[3] (FAC ¶ 80.) In other words, it was approved for use in procedures in which the Device is implanted from the anterior (front) abdomen and placed in the lumbar region of the spine. (*See* FAC ¶ 79.) Plaintiff contends that any procedure implanting the Infuse Device from a different posture, for example, from the posterior (back), or any procedure placing the device in a region of the spine other than the lumbar region, such as the cervical region, constitutes an "off-label" use of the device. (FAC ¶¶ 83–84.) Approximately 85% to 90% of all spine surgeries employing the Infuse Device fall into the category of off-label use.[4] (FAC ¶ 133.)

On July 2, 2008, Plaintiff saw a physician for neck pain and was diagnosed with

[3] The Infuse Device has also been approved for procedures not relevant here; namely certain tibia fractures and dental surgeries. (*See* FAC ¶ 3.)

[4] The FDA does not prohibit or regulate off-label use of medical devices by medical professionals, and the Supreme Court has emphasized that off-label use is not merely legitimate but important in the practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

degenerative disc disease in the cervical spine region. (FAC ¶ 22.) On October 16, 2008, Plaintiff underwent an anterior-approach cervical fusion in which the Infuse Device was implanted at levels C4–C7 of her spine. (FAC ¶ 23.) Thirteen months later, Plaintiff experienced symptoms of back pain and saw a different physician, who subsequently performed an operation to remove the Infuse Device on September 18, 2012. (FAC ¶¶ 24–26.) Plaintiff alleges that the Infuse Device caused uncontrolled bone growth, damaged her spine at the C2-C3 levels, and migrated from the implant location resulting in spinal nerve compression. (FAC ¶ 26.)

The FAC alleges that Medtronic was aware that off-label use of the Infuse Device carried greater risk of danger but nevertheless promoted off-label use of the device to spine surgeons. (*See* FAC ¶ 9.) Plaintiff alleges that she underwent surgery without knowing the full extent of risks associated with the off-label procedure and would not have proceeded with the operation had she been aware of the true risks. (FAC ¶¶ 10–13.)

III. LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the claims asserted in the complaint. In considering whether to dismiss a case for failure to state a claim, the issue before the court is not whether the claimant will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims asserted. *Gilligan v. Jamco Dev. Corp.*, 108 F.3d 246, 249 (9th Cir. 1997). When evaluating a Rule 12(b)(6) motion, the district court must accept all material allegations in the complaint as true and construe them in the light most favorable to the non-moving party. *Moyo v. Gomez*, 32 F.3d 1382, 1384 (9th Cir. 1994). Rule 12(b)(6) is read in conjunction with Rule 8(a), which requires only a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2). Dismissal of a complaint for failure to state a claim is not proper where a plaintiff has alleged "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).

A plaintiff alleging fraud or mistake must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The heightened pleading standard of Rule 9(b) requires the plaintiff to allege the "who, what, when, where, and how" of the alleged fraud. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). The allegations of fraud must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993).

IV. ANALYSIS

Medtronic moves to dismiss the FAC on the ground that Plaintiff's state law claims are preempted by the MDA. The MDA contains an express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court set the framework for analyzing express

preemption under the MDA in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). Under the *Riegel* framework, the court must first determine whether the FDA has established requirements applicable to the device at issue. The court must then determine whether the plaintiff's claims are based on state requirements regarding the device that are "different from, or in addition to" the federal requirements, and that relate to safety and effectiveness. *Id.* at 321–22. If so, the plaintiff's claims are expressly preempted by the MDA.

The MDA does not, however, prohibit states from providing damage remedies for claims premised on violations of FDA regulations. *Id.* at 330. The state duties in that situation are "parallel" to the federal duties, and claims based on the parallel state duties are not preempted. *Id.*; *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

The MDA also impliedly preempts certain claims based on violations of federal requirements. Section 337(a) prohibits suits by private litigants to enforce the provisions of the Act, instead requiring that all such actions "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001), interpreted this provision as impliedly preempting claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law. *Id.* at 352–53; *see Stengel*, 704 F.3d at 1235. Together, express preemption and implied preemption provide only a "narrow gap" through which the plaintiff's claims must fit in order to survive. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

As to the threshold prong of *Riegel* — whether the FDA has established requirements for the device in question — the Infuse Device went through the rigorous

premarket approval process through which the FDA imposed specific requirements regarding the Device's safety and effectiveness. In addition, the Device is subject to continuing regulation by the FDA in areas such as its manufacturing process. This is sufficient to establish *Riegel*'s threshold prong. *Riegel*, 552 U.S. at 322 ("Premarket approval . . . imposes 'requirements' under the MDA."). The second prong of *Riegel*, whether Plaintiff's claims are based on any requirement of state law that is "different from, or in addition to" federal requirements and relate to safety and effectiveness, must be addressed separately for each of Plaintiff's claims.

a. Strict Products Liability – Failure to Warn

Plaintiff asserts a claim for strict products liability on the basis that Medtronic failed to warn Plaintiff and her physicians of the risks and dangers involved in the off-label use of the Infuse Device and that the warnings accompanying the Device did not adequately warn of the dangers of using the Device in cervical fusion surgery. (FAC ¶¶ 284–94.)

Plaintiff's failure to warn claim is expressly preempted by the MDA. Plaintiff does not allege that the product labeling accompanying the Infuse Device deviated from the labeling approved by the FDA. Requiring additional warnings in the Infuse Device labeling would impose requirements "different from, or in addition to" the FDA-approved labeling requirements specific to the Infuse Device. Requiring warnings to Plaintiff's physicians through other means would also be subject to express preemption. FDA regulations permit manufacturers to issue post-sale warnings, but the regulations do not require such warnings. *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (citing 21 C.F.R. § 814.39(d)). Therefore, requiring warnings to doctors would be in addition to FDA requirements and thus expressly preempted by the MDA. *See id.* ("[A]ny attempt to predicate the [plaintiffs'] claim on an alleged state law duty to warn doctors directly

would have been expressly preempted under 21 U.S.C. § 360k.").

b. Strict Products Liability – Design Defect

Plaintiff claims that the Infuse Device was defectively designed because "the design was unsafe when used in the manner promoted by [Medtronic] . . . [and] because the risks of danger in the design outweigh the benefits of the design." (FAC ¶¶ 304–05.) The safety and effectiveness of the Infuse Device was evaluated and approved by the FDA during the premarket approval process. Plaintiff does not allege that Medtronic sells Infuse Devices manufactured with a different product design then that approved by the FDA. Because Plaintiff's design defect claim is an "attack" on the FDA review process rather than a parallel state claim, it is preempted by the MDA. *See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) ("[Design defect claims] are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k."); *Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [medical devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme.").

c. Fraudulent Misrepresentation, Fraud in the Inducement, and Strict Products Liability – Misrepresentation

Plaintiff asserts that Medtronic "fraudulently and intentionally misrepresented material and important health and safety product risk information," and, had Plaintiff and her physician known of these risks, they would not have proceeded with the operation to implant the Infuse Device in her cervical spine. (FAC ¶ 270.) Plaintiff's cause of action captioned "strict liability — misrepresentation" is based on substantively the same allegations. (*See* FAC ¶¶ 318–22.)

To the extent that Plaintiff's fraud claims are premised on alleged misrepresentations or omissions in the labeling and warnings accompanying the Infuse Device, the claims would impose requirements "different from, or in addition to" FDA requirements and would therefore be preempted under § 360k(a). To the extent that Plaintiff's fraud claims are based on alleged misrepresentations and omissions Medtronic made while promoting and marketing the Infuse Device, such claims could survive preemption. As discussed below, however, the FAC fails to identify what specific misrepresentations or omissions form the basis for Plaintiff's claims. Without knowing the specific misrepresentations or omissions at issue, the Court cannot determine whether allowing Plaintiff's fraud claims to proceed would impose different or additional requirements for the purpose of determining express preemption.

Plaintiff's fraud claims nonetheless must be dismissed because they are not pled with the requisite particularity under Federal Rule of Civil Procedure 9(b). Although the FAC is over 80 pages and 300 paragraphs long, it is lacking in substantive, non-conclusory facts. The FAC alleges generally that Medtronic paid spine surgeon "opinion leaders" to promote off-label use of the Infuse Device. (*See* FAC ¶ 141.) The specific "who, what, when, where, and how" of the alleged fraud, however, is not alleged. Although the FAC acknowledge that there are many different uses that can constitute off-label use, it alleges only that the Infuse Device was promoted "for off-label use" without specifying what the off-label use was. (*See* FAC ¶ 177.) This is important because, where Plaintiff does allege the specific use, it often has little relevance to her claims. For example, Plaintiff alleges that one specific physician who was paid consulting fees by Medtronic falsified a study to make the Infuse Device appear more effective in off-label use. (FAC ¶ 186.) This study, however concerned the use of the Infuse Device to treat shin bone fractures in injured soldiers. (FAC ¶ 186.) The FAC is also significantly lacking in important "when" allegations. For example, in one of the few allegations specific to off-label use of the Infuse Device in spine surgery, Plaintiff alleges that

Medtronic paid an orthopedic surgeon named Dr. Paul Anderson $150,000 in consulting fees, and that Dr. Anderson co-authored a 2007 article favorably reporting on the use of the Infuse Device in an off-label posterolateral fusion procedure. (FAC ¶ 206.) The FAC does not, however, allege when the fees were paid — a fact which would be essential to the implication that Medtronic paid Dr. Anderson to promote an off-label use of the Device and to give Medtronic notice of the allegedly fraudulent conduct in order that it may prepare a defense. Without the particular details of the alleged fraud, Plaintiff's fraudulent misrepresentation/fraud in the inducement and "strict liability — misrepresentation" claims fail. *See Vess*, 317 F.3d at 1106.

V. CONCLUSION

For the foregoing reasons, Medtronic's motion to dismiss the FAC is GRANTED. The FAC is DISMISSED WITH LEAVE TO AMEND. Plaintiff shall file a second amended complaint consistent with this Order within twenty (20) days of the date hereof.

DATED: November 22, 2013

CORMAC J. CARNEY
UNITED STATES DISTRICT JUDGE