UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	**CV 14-01529-RGK (AJWx)**	Date	June 25, 2014
Title	***KABINA DUNBAR, et al v. MEDTRONIC, INC., et al***		

Present: The Honorable	R. GARY KLAUSNER, U.S. DISTRICT JUDGE

Sharon L. Williams (Not Present)	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **(IN CHAMBERS) Order re: Defendants' Motion to Dismiss (DE 32)**

I. INTRODUCTION

On January 30, 2014, Kabina Dunbar and 28 other individuals ("Plaintiffs") filed a state court action against Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., and Medtronic Vertelink, Inc. (collectively, "Medtronic"). The action arises from alleged injuries caused by a medical product manufactured and sold by Medtronic. Plaintiffs allege the following eight claims: (1) Fraudulent Misrepresentation and Fraud in the Inducement; (2) Strict Products Liability - Failure to Warn; (3) Strict Products Liability - Design Defect; (4) Strict Products Liability - Misrepresentation; (5) Products Liability - Negligence; (6) Negligence Per Se; (7) Breach of Express Warranty; and (8) Loss of Consortium.

On February 28, 2014, Medtronic removed the action to federal court on the ground of diversity jurisdiction. On March 7, 2014, Medtronic filed the current Motion to Dismiss. For the following reasons, the Court **grants in part** Medtronic's motion.

II. FACTUAL BACKGROUND

Medtronic is the manufacturer and seller of the INFUSE Bone Graft and LT-Cage (collectively known as "INFUSE"), a prescription medical device used in spinal fusion surgeries. The purpose of the device is to accomplish the same outcome as implanting a patient's own bone or cadaver bone between the vertebrae in the spine, obviating the need for bone harvesting. The two components of the device are

(1) a metallic cylindrical cage (LT-Cage), and (2) a liquid protein and collagen sponge carrier for the protein (INFUSE Bone Graft), both of which are placed inside the cage. The LT-Cage maintains the spacing between the vertebrae and temporarily stabilizes the diseased region of the spine, and the liquid protein binds with the sponge to stimulate bone growth.

INFUSE is a Class III device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). Class III is a classification reserved for devices that pose the greatest risk of death or complications. For this reason, Medtronic was required to obtain pre-market approval ("PMA") from the FDA before it could sell or distribute INFUSE.

In 2001, Medtronic filed a PMA application, and in 2002, the FDA granted approval for use of INFUSE to treat degenerative disc disease. In its approval letter, the FDA stated that INFUSE may only be implanted (1) from the anterior (front) abdomen, and (2) placed within lumbar spine levels L4 through S1. Additionally, the FDA approved label states that the INFUSE bone graft must be used within the LT-Cage. Therefore, any variation of its use (e.g., posterior implant or use without the LT-Cage) constitutes "off-label" use of the device.

According to the Complaint, each of the plaintiffs underwent spinal surgery using the off-label INFUSE. Specifically, the plaintiffs' surgeries either did not conform with the method of implant approved by the FDA and/or did not conform with the labeling specifications. Each of the plaintiffs have suffered post-operative injury in the form of severe pain as a result of uncontrolled bone growth. Plaintiffs allege that Medtronic actively promoted the off-label use of INFUSE, failed to warn about the risks of off-label use, failed to report adverse events, and misrepresented material health and safety product risk information. According to Plaintiffs, had the risks associated with off-label INFUSE been known, they would not have undergone that particular course of treatment, which allegedly resulted in their injuries.

III. JUDICIAL STANDARD

The federal pleading standard states in relevant part that "a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a party may move to dismiss for failure to state a claim upon which relief can be granted. In deciding a Rule 12(b)(6) motion, the court must assume allegations in the challenged complaint are true, and construe the complaint in the light most favorable to the non-moving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). However, a court need not accept as true unreasonable inferences, unwarranted deductions of fact, or conclusory legal allegations cast in the form of factual allegations. *See W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981). Furthermore, a pleading must contain sufficient factual matter that, if accepted as true, states a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is facially plausible when there are sufficient factual allegations to draw a reasonable inference that the defendant is liable for the misconduct alleged. *Id.*

IV. DISCUSSION

Medtronic seeks dismissal on the ground that the FDCA and MDA expressly or impliedly preempt all of Plaintiffs' claims. Medtronic also challenges Plaintiffs' claims on grounds independent of the preemption argument. The Court agrees in part with Medtronics arguments as follows.

A. Federal Preemption Pursuant to the FDCA and MDA

1. *Express Preemption Under § 360k(a)*

§ 360k(a) of the MDA provides for express preemption, and states in pertinent part:

> [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 U.S. Supreme Court has set forth a two-step analysis for courts to determine whether the MDA expressly preempts a state law claim within the meaning of §360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). If the first step is answered in the affirmative, the court must proceed to the second step. The second step requires a court to determine whether the state law claims are based on state requirements that are different from, or in addition to, the federal requirements.[1] *Id*. at 321-322. "State requirements" include a state's common law legal duties. *Reigel*, 552 U.S. at 324-25. If the state requirements stemming from the claim differ from, or add to, the federal requirements, the state claim is expressly preempted by operation of § 360k(a). However, state claims that are premised on a violation of FDA regulations escape express preemption, as they are considered "parallel," rather than different from, or in addition to, the federal requirements. *Id*.

Even if a state claim runs parallel to federal requirements and escapes express preemption, it may still be subject to implied preemption under § 337(a) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

2. *Implied Preemption Under § 337(a) and* Buckman

§ 337(a) of the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Comm.*, the U.S. Supreme Court interpreted this provision to mean that even state claims that run parallel to federal requirements are preempted unless they are grounded in traditional state tort law, and do not depend exclusively on a federal requirement. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001). As pointed out by other courts, this does not mean that a plaintiff can never bring a state law claim based on conduct that violates the FDCA. In fact, the conduct that gives rise to the claim *must* violate the FDCA to escape express preemption. Instead, to avoid implied preemption, the conduct giving rise to the state claim must also be the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted. *See Houston v. Medtronic, Inc.*, 957 F. Supp.2d 1166, 1175 (C.D. Cal. 2013).

---

[1] As stated in the statute, the court must also determine whether the state requirements relate to the safety and effectiveness of the device. Here, there is no dispute that the state requirements asserted by Plaintiffs relate to the safety and effectiveness of the INFUSE.

B. Plaintiffs' Claims

Medtronic argues at the outset that the MDA expressly preempts all of Plaintiffs' claims. As stated above, determination of express preemption involves a two-step process. First, a court determines whether the FDA has established requirements applicable to the device at issue. If the court determines that requirements on the device have been established, the court must then determine whether the state claims are based on requirements different from, or in addition to, the federal requirements. The Court begins its analysis of Plaintiffs' claims by addressing step one - whether the FDA has established requirements - since this issue is device-specific (as opposed to claim-specific), and the Court's determination of this issue applies to all claims asserted by Plaintiffs.

Riegel v. Medtronic involved a Class III catheter that had received premarket approval. 552 U.S. 312 (2008). The U.S. Supreme Court in *Riegel* noted that, unlike general labeling duties, premarket approval is specific to individual devices. *Riegel*, 552 U.S. at 323. The Court further stated that, with respect to such devices, the FDA allows almost no deviation from the specifications contained in the approved applications, as adherence to the specifications allows reasonable assurance of safety and effectiveness. *Id*. Based on this, the Court reasoned that obtaining premarket approval for the catheter was akin to the establishment of federal requirements on the device. *Id*.

Similarly, INFUSE is also a Class III device that obtained premarket approval. It was subject to the same rigorous review process and post-approval manufacturing requirements. Therefore, the Court finds that the first prong of the *Riegel* test - whether the FDA has established requirements for the device - has been met.

Having made the above finding with respect to the INFUSE device, the Court will determine step two of the express preemption analysis and other the claim-specific issues, addressing each claim in turn.

1. *Strict Products Liability - Failure to Warn*

Plaintiffs allege that Medtronic knew of the dangers relating to off-label use of INFUSE, and had a duty to warn Plaintiffs and their physicians of these dangers. (Compl., ¶¶ 358-361.) Nonetheless, Medtronic failed to provide adequate warning, even though the off-label use was reasonably foreseeable and the dangers from such use were not readily recognizable to an ordinary consumer or physician. (Compl., ¶¶ 362-365.)

By way of their allegations, Plaintiffs base their claim on a theory that either (1) Medtronic was required to include warnings beyond those in the FDA-approved label of INFUSE, or (2) Medtronic was obligated to issue post-sale warnings about potential adverse effects from off-label use of INFUSE. As to post-sale warnings, while the FDA permits such warnings, it does not require them. *See Stengel*, 704 F.3d at 1234. In either case, Plaintiffs' claim seeks to impose on Medtronic labeling or warning requirements that go beyond what federal law requires. As there is no dispute that the issue of labeling and warning relate to the safety and effectiveness of the device, this claim is expressly preempted by the MDA.

Plaintiffs' Strict Products Liability - Failure of Warn claim is dismissed.

2. *Strict Products Liability - Design Defect*

This claim alleges that INFUSE was defectively designed because it was unsafe when used in the manner that was either promoted by Medtronic or reasonably foreseen by Medtronic. (Compl., ¶ 378.) Plaintiffs further allege that the device was defectively designed because the risks of danger outweigh its benefits. (Compl., ¶ 379.)

By way of their claim, Plaintiffs attack the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. To prevail on this claim, a jury would have to making findings that conflict with those of the FDA. Circuit courts have found that such claims are expressly preempted by § 360k. *See Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998)(holding that strict liability claim that product was "unreasonably dangerous" was expressly preempted because it conflicted with FDA premarket approval of the product).

Plaintiffs' Strict Products Liability - Design Defect claim is dismissed.

3. *Products Liability - Negligence*

Plaintiffs allege that Medtronic breached its duties to Plaintiffs by performing the following acts or omissions: (1) improper promotion and marketing of INFUSE for off-label use; (2) failure to warn Plaintiffs and physicians of the dangers associated with off-label INFUSE; (3) failure to exercise reasonable care in complying with federal law and regulations applicable to the sale and marketing of INFUSE; and (4) failure to exercise reasonable care in preventing INFUSE from creating an unreasonable risk of harm to Plaintiffs when used in a reasonably foreseeable manner. (Compl., ¶ 407.)

As to the first alleged act of negligence, the Court finds the claim not expressly preempted, but rather, impliedly preempted. In *Carson v. Depuy Spine, Inc.*, the Ninth Circuit considered whether off-label promotion by a drug manufacturer is prohibited by the FDCA, and determined that it is. *See Carson*, 365 Fed.Appx. 812, 815 (9th Cir. 2010)(unpublished)("[T]he marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA."). Although *Carson* is not binding, this Court finds the Ninth Circuit's reasoning persuasive and follows its holding. As such, Plaintiffs' claim based on off-label promotion runs parallel to the FDCA and survives express preemption. However, there is no claim for illegal off-label promotion rooted in traditional state tort law. Therefore, any common law claim arising from such an action exists only by virtue of the FDCA. Permitting this claim to proceed would essentially allow a private litigant to attempt enforcement of the FDCA. *Buckman* bars such an action under §337(a). Therefore, Plaintiffs' negligence claim based on off-label promotion is impliedly preempted.

As to Plaintiffs' negligence claim based on a failure to warn or dangerous design (2 and 4), the claim is expressly preempted for the same reasons stated in the preceding sections, IV.B. 1. and 2. Specifically, the claim fails because it is premised on the theory that state law required Medtronic to warn about the risks of off-label use, or make cost-benefit decisions about the design. These requirements are different from, or in addition to, those imposed by the federal requirements. Therefore, Plaintiffs' claim based on failure to warn and dangerous design is expressly preempted

Finally, to the extent Plaintiffs base their claim on failing to comply with other federal laws or regulations applicable to the sale or marketing of INFUSE, Plaintiffs fail to allege sufficient facts. Specifically, Plaintiffs fail to allege facts substantiating a violation of any particular federal requirement applicable to the device. Therefore, the Court cannot reasonably infer that these other "federal law of regulations" run parallel to the FDCA. Nor can the Court determine whether the claim can exist

independently from the FDCA. Plaintiffs' conclusory allegation that Medtronic failed to comply with federal law and regulations is insufficient to overcome either express or implied preemption.

Plaintiffs' Products Liability - Negligence claim is dismissed.

4. *Negligence Per Se*

Under the theory of negligence per se, as long as other requirements are met,[2] a presumption of negligence arises from the violation of a statute. *Padilla v. Pomona College*, 166 Cal.App.4th 661, 675 (2008).

Here, Plaintiffs' claim for negligence per se is "based on [Medtronic's] violations of FDCA regulations."[3] (Compl. ¶ 417.) As such, the standard of care for this negligence claim relies exclusively on the FDCA, and adjudication of this claim relies on the existence of the federal requirements. While courts have generally allowed a negligence per se claim based on violation of a federal statute, the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails.

§ 337(a) expressly states that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). As *Buckman* concluded, this provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4. Allowing a litigant to assert a negligence per se claim based on violation of the FDCA would frustrate congressional intent regarding the regulation of medical devices, and interfere "with the federal statutory scheme, which 'amply empowers the FDA to punish and deter fraud against the Administration.'" *Id*. at 348. Stated differently, a negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well.

Plaintiffs' Negligence Per Se claim is dismissed.

5. *Fraud Claims: Fraudulent Misrepresentation, Fraud in the Inducement and Strict Products Liability – Misrepresentation*

Plaintiffs' claim for Fraudulent Misrepresentation and Fraud in the Inducement alleges that Medtronic "fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff's physicians." (Compl., ¶ 343.) Specifically, Plaintiffs allege that Medtronic fraudulently concealed and misrepresented (1) the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of INFUSE; (2) the practice of promoting and marketing to physicians the off-label practice of using INFUSE without an LT-Cage and placing it posteriorly or laterally; and (3) information about the known comparative risks and benefits of the use of INFUSE, and the relative benefits and availability of alternate products, treatments and/or therapies. (Compl, ¶ 345.)

---

[2] The other requirements are: the statute at issue must have been enacted to protect a class of persons, of which the plaintiff is a member, against the type of harm the plaintiff suffered as a result of the statutory violation. *Padilla v. Pomona College*, 166 Cal.App.4th 661, 675 (2008).

[3] Plaintiffs specifically refer to regulations involving, among other things, compliance with PMA approval standard orders, promotion of devices for off-label uses, approval by the FDA for any product changes, and reporting adverse events. (Compl., ¶418.)

Similarly, Plaintiffs' claim for Strict Products Liability – Misrepresentation alleges that in the course of marketing INFUSE, Medtronic made untrue representations of material facts and omitted material information to Plaintiffs, Plaintiffs' physicians, and the public at large. (Compl., ¶ 388.) Plaintiffs further allege that Medtronic sponsored biased medical trials, reports, and articles that wrongfully and inaccurately claim that the dangers inherent to off-label use of INFUSE did not exist, or were significantly less than the actual dangers. *Id*. Finally, Plaintiffs allege that Plaintiffs and their physicians would not have proceeded with the off-label use of INFUSE had they known the material facts that Medtronic misrepresented or omitted. *Id*.

As to the issue of preemption, federal law that prohibits promotion of off-label uses of approved devices certainly prohibits *false or misleading* promotion. As such, Plaintiffs' fraud claims are not expressly preempted, because they run parallel to requirements and prohibitions imposed by the FDCA. Additionally, Plaintiffs' claims also escape implied preemption under § 337(a) and *Buckman* because claims of fraud are moored in traditional state common law and exist independently from the FDCA. Therefore, Plaintiffs' fraud claims are not preempted.

Because these claims sound in fraud, Federal Rule of Civil Procedure ("Rule") 9(b) applies. Under Rule 9(b), a plaintiff who asserts a fraud claim must plead the specific circumstances surrounding the alleged fraud. Here, Plaintiffs allege separate paragraphs for each of the named plaintiffs who underwent bone graft surgery. For each plaintiff, Plaintiffs uniformly allege "representatives of Medtronic . . . intentionally and/or carelessly, informed plaintiff's surgeon of the safety and efficacy of [INFUSE] as applied to [that] procedure." (Compl., ¶¶ 269-324.) Plaintiffs also allege a series of allegations involving Medtronic's off-label promotion. Such allegations primarily involve general statements that Medtronic manipulated medical literature and paid opinion leader consultants to misrepresent the safety and efficacy of INFUSE's off-label use. These boilerplate and general allegations fail to meet the heightened pleading requirements, as they fail to allege "the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392-93 (9th Cir. 1988) .

However, Plaintiffs also allege that Dr. Burkus and Dr. Haid received large sums of money from Medtronic to create fraudulent research. (Compl., ¶¶ 132-134.) Such research led to publications and presentations that promoted the use of off-label INFUSE, one of which was a 2004 article published in *The Spine Journal*. *Id*. These publications and presentations allegedly concealed the risk and danger of the off-label INFUSE. (Compl., ¶ 133.) Plaintiffs allege that prior to the surgeries, Plaintiffs' surgeons "believe that he/she read articles by Drs. Burkus and Haid endorsing the use of [INFUSE] as safe and effective, while failing to warn of the true risks of bone overgrowth and inflammatory reactions." (Compl., ¶ 327.) The Court finds that these allegations provide sufficient factual basis that meet the heightened pleading requirements of Rule 9(b).

Plaintiffs' claims for Fraudulent Misrepresentation/Fraud in the Inducement and Strict Products Liability – Misrepresentation are not preempted and adequately state a claim for relief.

6. *Breach of Express Warranty*

Plaintiffs allege that Medtronic "utilized journal articles, advertising media, sales representatives/consultants and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of [INFUSE] and expressly warranted to physicians and other members of the general public and medical community that such off-label uses . . . were safe and effective." (Compl., ¶ 427.) Plaintiffs further allege that their treating surgeon relied on Medtronic's express warranties regarding the safety and efficacy of off-label use of INFUSE, but such uses, in fact, were not effective, safe and proper for the uses as warranted. (Compl., ¶ 429.)

As an initial matter, the Court finds that this claim is neither expressly or impliedly preempted. As discussed in the preceding section, federal law prohibits false or misleading off-label promotion. To the extent Plaintiffs base their claim on Medtronic's alleged misleading warranties of off-label INFUSE, Plaintiff does not seek to impose any requirement different from, or additional to, existing federal requirements. Nor is the claim preempted under § 337(a) and *Buckman*, as a claim for breach of express warranty originates from traditional state law that predates, and exists independently from, the FDCA.

However, under California law, a breach of express warranty requires that (1) the seller made an affirmation of fact or promise, or provided a description of its goods; (2) the promise or description formed the basis of the bargain; (3) the seller breached the express warranty; and (4) the breach caused injury to the plaintiff. Cal. Comm.Code § 2313(1)(a); *Williams v. Beechnut Nutrition Corp.*, 185 Cal.App.3d 135, 142 (1986). Here, Plaintiffs have alleged no facts demonstrating that Medtronic made any affirmations specifically to Plaintiffs or their surgeons, so as to form the basis of the bargain.

Moreover, to adequately state a claim for breach of express warranty, a plaintiff must plead that notice of the alleged breach was provided to the seller within a reasonable time after discovery of the breach. *Alvarez v. Chevron Corp.*, 656 F.3d 926, 932 (9th Cir. 2011) (internal citations omitted). Here, Plaintiffs make no such allegation. Therefore, Plaintiffs' claim fails for this additional reason.

Plaintiffs' claim for Breach of Express Warranty is dismissed.

7. *Loss of Consortium*

As pointed out by Medtronic, Plaintiffs' loss of consortium claim alleges injuries suffered by Plaintiffs' spouses. However, none of the plaintiffs are named as spouses of an individual allegedly injured by INFUSE, nor does any plaintiff claim to be married. Plaintiffs fail to raise any argument in response to Medtronic's challenge to this claim.

Plaintiffs' claim for Loss of Consortium is dismissed.

V. CONCLUSION

Based on the foregoing reasons, the Court **grants in part** Medtronic's Motion to Dismiss. Specifically, the Court dismisses all claims except for Plaintiffs' claims for (1) Fraudulent Misrepresentation and Fraudulent Inducement; and (2) Strict Products Liability - Misrepresentation.

IT IS SO ORDERED.

_____ : _____

Initials of Preparer _____