JS-6

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 14-04526 RGK (AGRx)	Date	August 8, 2014
Title	***CARMELA VITALE 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 10); Defendants' Motion to Strike (DE 12)**

I. INTRODUCTION

On October 10, 2013, Carmela Vitale ("Plaintiff") 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. Plaintiff alleges the following nine 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) Punitive Damages; and (9) Loss of Consortium.

On June 12, 2014, Medtronic removed the action to federal court on the ground of diversity jurisdiction. On June 19, 2014, Medtronic filed the current Motion to Dismiss and Motion to Strike. For the following reasons, the Court grants Medtronic's Motion to Dismiss and denies as moot Medtronic's Motion to Strike.

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, Plaintiff underwent spinal surgery using the off-label INFUSE. Specifically, Plaintiff's surgery did not conform with either the method of implant approved by the FDA or the labeling specifications. Plaintiff has suffered post-operative injury in the form of severe pain as a result of uncontrolled bone growth. Plaintiff alleges 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 Plaintiff, had the risks associated with off-label INFUSE been known, she would not have undergone that particular course of treatment, which allegedly resulted in her 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

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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 Plaintiff's claims. Medtronic also challenges Plaintiff's claims on grounds independent of the preemption argument.

To date, Plaintiff has not filed an opposition to Medtronic's Motion to Dismiss. Pursuant to Local Rule 7-12, the failure by a party to file any required document, or the failure to file it within the deadline, may be deemed consent to the grant or denial of the motion. On this basis alone, the Court has authority to grant Medtronic's motion. *See Wystrach v. Ciachurski*, 267 Fed. App'x 606, 607 (9th Cir. 2009, unpub.)(holding that the trial court did not abuse its discretion in applying its local rule summarily to grant defendants' motion to dismiss because plaintiffs failed timely to respond).

However, even if the Court considered the merits of the motion, dismissal would be warranted. As this Court has found in a nearly identical case, the FDCA and MDA expressly and/or impliedly preempt all of Plaintiff's products liability claims. *See Kabina Dunbar, et al v. Medtronic, Inc., et al*, (CV-14-1529-RGK), Order Re: Defendants' Motion to Dismiss, Docket Entry 56. As a result, Plaintiff's negligence per se claim fails as well. As to the remaining claims, review of Plaintiff's allegations indicate insufficient pleading to sustain a claim for relief.

V. CONCLUSION

Based on the foregoing reasons, the Court **grants** Medtronic's Motion to Dismiss, and **denies as moot** Medtronic's Motion to Strike.

IT IS SO ORDERED.

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Initials of Preparer _____