UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

PEGGY JO SMITH	CIVIL ACTION NO. 13-451
VERSUS	JUDGE ELIZABETH FOOTE
MEDTRONIC, INC.	MAGISTRATE JUDGE MARK HORNSBY

MEMORANDUM RULING

Before the Court is a motion to dismiss the Plaintiff's first supplemental and amended complaint, filed by the Defendant, Medtronic, Inc. [Record Document 28]. In this motion, Medtronic seeks to dismiss the complaint filed by the Plaintiff, Peggy Smith ("Smith"), pursuant to Federal Rule of Civil Procedure 12(b)(6), on the basis that Smith's claim for off-label promotion and marketing: (1) is expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a); (2) is impliedly preempted under Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012 (2001); and (3) fails to state a cognizable claim under the Louisiana Products Liability Act and therefore fails under Rule 8 pleading standards. The Plaintiff has filed no opposition to the motion to dismiss. For the reasons that follow, Medtronic's motion to dismiss shall be **GRANTED**, and Smith's claims against Medtronic are **DISMISSED WITH PREJUDICE**.

I. FACTUAL BACKGROUND.

According to the complaint, in August of 2011, Smith underwent two spinal surgeries. In one or both of those surgeries, the doctors implanted the Infuse™ Bone Graft Device ("Infuse Device"), which was manufactured by the Defendant, Medtronic.

The Infuse Device is used to treat degenerative disc disease in a spinal fusion surgical procedure. It is a medical device consisting of three parts: (1) a metallic spinal fusion cage (the "LT-Cage"), (2) a recombinant human bone morphogenetic protein, and (3) a carrier/ scaffold for the bone morphogenetic and resulting bone. See Record Document 8-8, p. 1. According to the FDA's approved labeling, the Infuse Device is to be "implanted via an anterior open or an anterior laparoscopic approach" in a single level fusion in the L4-S1 level of spine. See id. at p. 3.

Smith's first surgery was an anterior lumbar interbody fusion at the L5-S1 area, including implantation of the LT-Cage. See Record Document 24, p. 3. This surgery had to be aborted when it was discovered Smith had an aortic aneurysm. See id. at p. 3, ¶ 6a. Her second surgery, just days later, used a posterior approach to perform a laminectomy, osteotomy, and multilevel interbody fusion without implantation of the LT Cage. See id. at p. 4 After the surgery, Smith began to experience pain, decreased mobility, incomplete paraplegia, and several other problems. Smith claims she suffers from injury to her spinal cord, which she attributes to the off-label use of the Infuse Device.[1] She thereafter filed the instant products liability suit against Medtronic, which will be discussed in greater detail below.

[1] Smith asserts that the Infuse Device was implanted at multiple levels and in increased dosages, both of which are off-label uses of the device. Strangely, presumably in error, Smith avers that "[u]se of the Infuse product *with* the LT Cage is an off label use of the product," even though the product is designed to be used with the LT Cage. Record Document 24, p. 6, ¶ 8b (emphasis added).

II. 12(b)(6) STANDARD.

Federal Rule of Civil Procedure 8 requires a short and plain statement of the claim showing the pleader is entitled to relief. A complaint is not required to contain detailed factual allegations, however, "a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007)(internal marks and citations omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2008) (internal marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. This plausibility requirement "asks for more than a sheer possibility that a defendant has acted unlawfully." Id. However, the complaint cannot be simply "unadorned, the-defendant-unlawfully-harmed-me accusation[s]." Id.

As the Fifth Circuit has explained, in order to survive a 12(b)(6) motion, "the complaint must contain either direct allegations on every material point necessary to sustain a recovery or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial." Rios v. City of Del Rio, 444 F.3d 417, 420–21 (5th Cir. 2006) (internal marks and citation omitted). Moreover,

> a statement of facts that merely creates a suspicion that the pleader might have a right of action is insufficient. Dismissal is proper if the complaint lacks

> an allegation regarding a required element necessary to obtain relief. The court is not required to conjure up unpled allegations or construe elaborately arcane scripts to save a complaint. Further, conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.

Id. at 421 (internal marks and citations omitted).

When reviewing a motion to dismiss, the Court may consider "matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322, 127 S. Ct. 2499 (2007). In the instant case, the Court has taken judicial notice of various FDA documents concerning the Infuse Device, all of which are found in Record Document 8.

III. PREMARKET APPROVAL.

Pursuant to the Medical Device Amendments of 1976 ("MDA"), there are three classifications of medical devices: Class I, Class II, and Class III. Class III devices, such as the Infuse Device, receive the greatest level of oversight.[2] A device is assigned to Class III if it cannot be established that a less stringent classification would provide a reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). Class III medical devices, which "receive the most federal oversight," Riegel v. Medtronic, Inc., 552 U.S. 312, 317, 128 S. Ct. 999 (2008), are subject to a rigorous premarket approval ("PMA")

[2] It is not disputed that the Infuse Device is a Class III device.

process. The PMA process requires a manufacturer to submit a comprehensive application to the FDA. On average, the FDA spends 1,200 hours reviewing a manufacturer's submission. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 479, 116 S. Ct. 2240, 2247 (1996). The FDA must weigh "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 18 U.S.C. § 360c(a)(2)(C). If there is reasonable assurance of the device's safety and effectiveness, the FDA will grant PMA.

Once PMA has been given, the MDA prohibits a manufacturer from making, without permission, any "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." Riegel, 552 U.S. at 319, 128 S. Ct. at 1005. After a device receives PMA, it remains subject to reporting requirements, including the obligation to inform the FDA of new information concerning the device and the duty to report incidents which resulted in death or serious injury, or incidents in which the device malfunctioned in a way that would likely cause or contribute to death or serious injury. See 18 U.S.C. § 360i(a)(1). The FDA retains the power to withdraw PMA after it is granted. See 18 U.S.C. § 360e(e)(1).

A. Express Preemption.

To ensure that the FDA's authority and oversight are not imperiled by contrary or differing state regulatory measures, Congress included an express preemption provision in the MDA, which provides in pertinent part:

> no 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.

Id. at 360k(a). In Riegel, the Supreme Court established a two-part test to determine if state law claims are preempted under § 360k(a). First, the court determines whether the Federal Government has established requirements applicable to the particular medical device. See Riegel, 552 U.S. at 321, 128 S. Ct. at 1006. Class III medical devices that have received PMA automatically satisfy this first prong of the inquiry. See id. at 322-23. There is no dispute that the Infuse Device has received PMA. Accordingly, the Infuse Device automatically satisfies prong one of the inquiry.

Next, the court determines whether the state-law claims impose requirements "different from, or in addition to" the requirements imposed by the PMA process and that relate to safety and effectiveness. See id. If a state-law claim is based upon a state requirement that is different from or in addition to the federal requirement, the plaintiff's claim is preempted by the MDA.

The Fifth Circuit has held that "the PMA process preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements if the state-law claims impose substantive requirements different from or inconsistent with the federal law." Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 929 (5th Cir. 2006)(internal marks omitted). In order to ascertain whether a claim is preempted, district courts must analyze the duties imposed under the state-law causes of action and consider whether a successful lawsuit based on those causes of action would impact or threaten the federal PMA process requirements. See id. at 930. The Court notes that the Fifth Circuit has found that state product liability tort claims, such as defective design, failure to warn, and inadequate labeling, are preempted because those claims relate to areas specifically covered in the PMA process and the state law sought to impose requirements that were different from and conflicted with the PMA process. See Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); see also Gomez, 442 F.3d at 931-32 (affirming dismissal of plaintiff's products liability and redhibition claims based on preemption); Lemelle v. Striker Orthopaedics, 2010 WL 996523 (W.D. La. Mar. 15, 2010) (holding that plaintiff's redhibition claim was preempted under the MDA); McQuiston v. Boston Scientific Corp., 2009 WL 4016120 (W.D. La. Nov. 19, 2009) (holding that plaintiff's state-law claims for design defect, inadequate testing, inadequate warnings, breach of express and implied warranties, manufacturing defect, negligence, fraud, and loss of consortium were preempted under the MDA).

Express preemption does not, however, "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330, 128 S. Ct. at 1011. That is because express preemption is aimed at avoiding inconsistent regulations at the state and federal level; therefore, if the state regulation is not inconsistent with, but rather parallels the federal requirements, the claim is not preempted.

B. Implied Preemption.

Section 337(a) of the Food, Drug and Cosmetics Act ("FDCA") provides that an action for "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). This is often called the "no private cause of action" provision. In Buckman, the Supreme Court found that Congress intended the MDA to be enforced exclusively by the Federal Government. Although certain state-law causes of action that parallel federal requirements are permissible, the Supreme Court clarified that not just "any violation of the FDCA will support a state-law claim." Buckman, 531 U.S. at 353, 121 S. Ct. 1012, 1020. Rather, the claim must be premised on a violation of the FDCA and rely on traditional state tort law which predated the federal enactments at issue and would give rise to liability under state law even in the absence of the FDCA. See Caplinger v. Medtronic, 921 F. Supp. 2d 1206, 1214 (W.D. Ok Feb. 6, 2013).

IV. PROCEDURAL HISTORY.

Smith filed the instant suit against Medtronic, claiming the Infuse Device was defective in a variety of ways. Medtronic filed its first motion to dismiss [Record Document

7], which was opposed by Smith [Record Document 18]. The Court held oral argument on the motion on May 14, 2013. At the hearing, Smith's counsel conceded that all of her state-law claims were preempted, and therefore abandoned, with the exception of a claim that Medtronic promoted or marketed the Infuse Device for off-label use. See Record Document 21. Accordingly, the Court granted Medtronic's motion to dismiss, yet allowed Smith the opportunity to amend her complaint to allege a cause of action for the promotion or marketing of off-label use of the Infuse Device. See Record Document 22. Smith thereafter filed an amended complaint on July 17, 2013 [Record Document 24], which prompted Medtronic to file the instant motion to dismiss. To date, the motion to dismiss is unopposed.

V. ANALYSIS.

In this case, all of Smith's primary allegations were dismissed based on preemption, a legal conclusion conceded by Smith's counsel. Thereafter, Smith was permitted to amend her complaint to allege promotion and marketing of off-label use. Although Smith did, indeed, file an amended complaint, a review of the pleading confirms that true substantive amendments were not incorporated in the pleading. Rather, existing sentences were supplemented or altered to include the words "off-label," but the mere addition of these words fails to substantively save the Plaintiff's case. Smith's amended complaint asserts the following off-label allegations: (1) the Infuse Device was "used off-label at multiple levels and in increased dosages" [Record Document 24, p. 8, ¶ 9e];[3] (2)

[3] Smith's amended complaint contains allegations pertaining to the off-label use of the Infuse Device by her physician. However, the Supreme Court clearly foreclosed

Medtronic "encouraged" off-label use, despite the fact that "the product was not to be used in the off-label procedures as were used in Ms. Smith" [Id. at p. 9, ¶ 12]; (3) Medtronic paid doctors to write articles in which the dangers of the Infuse Device were downplayed, and the United States Senate investigated these activities and "found that there were unreported complications and financial bias in the research done" [Id. at ¶ 13]; (4) Medtronic "failed to provide the FDA with available information regarding the off label use of the Defective Product [and] failed to abide by the requirements of the FDA by promoting the Infuse product for off-label use" [Id. at ¶ 17]; (5) that Medtronic knew or should have known of the foreseeable harm caused by the off-label uses "knowingly promoted by the company" and that Medtronic "downplayed the possibility and extent of complications associated with off-label use" [Id. at ¶ 21]; (6) Medtronic falsely and fraudulently misrepresented a number of facts relating to the Infuse Device's off-label use [Id. at p. 12, ¶ 22]; (7) the Infuse Device was placed into the stream of commerce in a

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this line of argument in Buckman:

> "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. . . . Indeed, a recent amendment to the FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.

Buckman, 531 U.S. at 351, 121 S. Ct. 1012, 1018 (internal citations omitted).

defective and unreasonably dangerous condition which failed to take into account the risk involved "in its use as promoted for off labeluse [sic]" [Id. at ¶23]; (8) because of inadequate testing, failure to comply with the manufacturing specifications of the FDA, and failure to provide information to the FDA that would have resulted in an alternative design, the Infuse Device was "defective for the off label use promoted" [Id. at ¶ 24]; and (9) Medtronic knew or should have known of the dangerous side effects caused by the Infuse Device's off-label use [Id. at ¶ 27]. The aforementioned allegations encapsulate all of the information presented by Smith in support of her complaint. That is, there is no additional factual information provided to elucidate or enhance those allegations.

Medtronic seeks dismissal of this case based on express preemption, implied preemption, and insufficiency of the complaint under Rule 8. The Court's own research leads to the conclusion that while it may be possible to state a non-preempted claim for off-label promotion and marketing, see Schouest v. Medtronic, Inc., --F. Supp. 2d --, 2014 WL 1213243 (Mar. 24, 2014) and Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977 (D.Ariz. Aug. 21, 2013), such a claim is not stated in the complaint currently before the Court. Smith has not pled a state-law LPLA or redhibitory claim with sufficient factual information or clarity to determine whether those state-law claims impose requirements that are in addition to or different from the PMA. Because of the dearth of information currently before the Court, the Court declines to engage in a preemption analysis. Nonetheless, dismissal is independently appropriate under Rule 8.

The first deficiency in Smith's complaint is that she has insufficiently pled the legal basis supporting her claims. That is, in a wholly conclusory fashion, she alleges simply that Medtronic is liable under Louisiana Civil Code Articles 2525 and 1953 and the Louisiana Products Liability Act ("LPLA"). However, Article 2525 is a reserved article, which contains no substantive content; thus, this article fails to support Smith's claim. Article 1953 provides: "Fraud is a misrepresentation or a suppression of the truth made with the intention either to obtain an unjust advantage for one party or to cause a loss or inconvenience to the other. Fraud may also result from silence or inaction." La. Civ. Code art. 1953. Reliance on this Article regarding fraud is misplaced, namely because it is in direct conflict with Smith's counsel's representations at oral argument, wherein she repeatedly told the Court that Smith was not alleging any type of fraud by Medtronic: "Plaintiffs . . . are not alleging the fraudulent conduct on the part of the defendant" [Record Document 23, p. 34]; "we're not saying that it was the fraudulent conduct of the defendant" [Id.]; "We're not saying the promotion is illegal . . . and it's not fraudulent" [Id. at p. 35]; "We are not alleging fraud" [Id. at p. 36]; "When you go and promote it knowingly for off-label uses, you're not committing something illegal and you're not fraudulent")[Id.]. Based upon counsel's direct representations to the Court, as well as the lack of specific allegations provided to sufficiently allege fraud, the Court will disregard any claims invoking Article 1953.

Although Smith's complaint cited to Article 2525, as previously mentioned, the Court will presume that Smith is attempting to invoke Article 2524 of the Redhibition Chapter entitled "Thing Fit for Ordinary Use," which provides:

> The thing sold must be reasonably fit for its ordinary use.
>
> When the seller has reason to know the particular use the buyer intends for the thing, or the buyer's particular purpose for buying the thing, and that the buyer is relying on the seller's skill or judgment in selecting it, the thing sold must be fit for the buyer's intended use or for his particular purpose.
>
> If the thing is not so fit, the buyer's rights are governed by the general rules of conventional obligations.

La. Civ. Code art. 2524.

In addition to her redhibition claim, Smith has also attempted to assert a claim under the LPLA, although she has failed to specify which particular category of the LPLA governs her claim. The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter." La. R.S. § 2800.52. The LPLA sets forth only four causes of action under which a product may be deemed unreasonably dangerous: (1) defect in construction or composition; (2) defect in design; (3) inadequate warning; or (4) failure to comply with an express warranty. Smith has not acknowledged these four categories, nor has she aligned her claims within one or more of them.

From the scant complaint, which is void of sufficient factual detail, the Court can only presume that Smith believes Medtronic represented to one or both of her physicians

that the Infuse Device could be used safely in an off-label manner.[4] However, therein lies the difficulty faced by the Court: the Court can only presume to know what Smith believes, a problem created by an inartfully drafted complaint and/or the Plaintiff's true lack of knowledge of the facts crucial to supporting her allegations.

Although all "well-pleaded" facts must be taken as true and viewed in the light most favorable to the Plaintiff, the Court is entitled to demand "well-pleaded facts." The Court is not required to fill in the gaps, speculate as to what cause of action the plaintiff may have, or create out of whole cloth the facts necessary to support that cause of action. In other words, the Court's review of the sufficiency of the complaint cannot be comprised of conjecture, making a best guess at what the Plaintiff's case may be. Further, as the Supreme Court has explained, a complaint is insufficient "if it tenders naked assertion[s] devoid of further factual enhancement." Iqbal, 556 U.S. at 678, 129 S. Ct. at 1950 (internal marks omitted). "Gone are the days when a plaintiff could assert 'a wholly conclusory statement of claim' and survive a motion to dismiss simply because his 'pleadings left open the possibility that [he] might later establish some set of undisclosed

[4] This supposition appears consistent with the wave of lawsuits against Medtronic, stemming from complaints of plaintiffs injured by, amongst other things, Medtronic's alleged promotion of off-label uses of the Infuse Device. See, e.g., Schouest v. Medtronic, Inc., -- F. Supp. 2d --, *2 (S.D. Tx. Mar. 24, 2014)(citing The Spine Journal article devoted to the risks of the Infuse Device and a 16-month investigation by the Senate Committee on Finance regarding Medtronic's payment to physicians who authored medical journal articles about the Infuse Device); Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977 (D.Ariz. Aug. 21, 2013)(discussing complaints of promotion of off-label use).

facts to support recovery.'" Callaway v. Am. Med. Sys., Inc., 2011 WL 7724268, *4 (W.D. La. Dec. 8, 2011) (citing Twombly, 550 U.S. at 561–62).

Here, to prevail on her claim against Medtronic, Smith's complaint must contain facts plausibly showing that Medtronic took some action or actions to market or promote the off-label use of the Infuse Device.[5] However, the complaint fails to do this. Though the complaint alleges that Medtronic promoted the off-label use of the Infuse Device, the only "fact" alleged in support of that claim accuses Medtronic of paying doctors to write articles downplaying the dangers of the Infuse Device. Accepting the truth of that factual allegation, as the Court must, there is still an utter lack of factual content to "nudge" Smith's claim "across the line from conceivable to plausible." Iqbal, 556 U.S. at 683, 129 S. Ct. at 1952. Smith's complaint is wholly void of a description of the actions Medtronic took to promote or market the Infuse Device in an off-label manner to her doctor, as well as information linking those actions to her injuries. In short, Smith's complaint contains insufficient factual allegations to raise a right to relief above a speculative level. As the Supreme Court has instructed, "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of 'entitlement to relief." Iqbal, 556 U.S. at 678, 129 S. Ct. at 1950 (quoting Twombly, 550 U.S. 544, 557, 127 S. Ct. 1955 (2007)(internal marks omitted)). Because Smith has

[5] Of course, during the course of this lawsuit, Smith would also have to be able to demonstrate that the off-label use of the Infuse Device is causally connected to the damages she suffered. See Bass v. Stryker Corp., 669 F.3d 501, 511-12 (5th Cir. 2012)(explaining that, in a products liability case, a sufficient complaint is one which identifies a manufacturing defect and links that defect to the plaintiff's specific injury).

already been given one opportunity to amend and has provided nothing more than conclusory allegations and has now failed to respond to the instant motion to dismiss, her complaint must be dismissed with prejudice.

VI. CONCLUSION.

For the foregoing reasons,

IT IS ORDERED that Medtronic's motion to dismiss [Record Document 28] be and is hereby **GRANTED**.

IT IS FURTHER ORDERED that the claims of Peggy Smith against Defendant Medtronic shall be **DISMISSED WITH PREJUDICE**. A judgment consistent with the instant memorandum ruling shall issue herewith.

THUS DONE AND SIGNED on this 4th day of June, 2014.

ELIZABETH ERNY FOOTE
UNITED STATES DISTRICT JUDGE