IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

Dianne Dawson, Plaintiff, vs. Medtronic, Inc.; Medtronic Sofamor Danek USA, Inc.; Medtronic Vertelink, Inc.; Does 1-10, inclusive; Medtronic Sofamor Danek, Inc.; and Warsaw Orthopedic, Inc., Defendants.	C/A No.: 3:13-cv-663-JFA ORDER GRANTING MOTION TO DISMISS

This case was originally filed in the Central District of California but was transferred to this court pursuant to 28 U.S.C. § 1404(a) in March 2013. This matter comes before the court on a motion to dismiss filed by Defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., and Medtronic Vertelink, Inc. (collectively, "Medtronic"). According to Medtronic, Plaintiff's claims should be dismissed because all are expressly preempted under 21 U.S.C. § 360k(a) pursuant to the Supreme Court's holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) or are impliedly preempted in accordance with the Supreme Court's holding in *Buckman v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001).

I. Factual and Procedural History

Plaintiff's Third Amended Complaint (hereinafter "Complaint," ECF No. 20) alleges that Plaintiff was injured by a Class III medical device—Medtronic's Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse Device"). The Infuse Device is a Class III medical device approved by the Federal Drug Administration ("FDA") through the rigorous Premarket Approval ("PMA") process. As initially approved, the Infuse Device is a medical device

generally consisting of three parts: (1) recombinant human bone morphogenetic protein-2 ("rhBMP-2"), (2) an absorbable collagen sponge, and (3) an "interbody fusion device" (either LT-Cage or INTERFIX Cage). It appears that the Infuse Device received PMA from the FDA for use in Anterior Lumbar Interbody Fusion procedures, which involve a single level fusion in the L4-S1 region of the lumbar spine.[1]

In 2005, Plaintiff underwent a cervical discectomy at C5-6 and C-7, with a C6 corptectomy with fusion and instrumentation wherein her surgeon implanted Infuse Bone Graft without the LT-Cage or INTERFIX Cage to facilitate spinal fusion, via an off-label[2] spinal fusion surgery. Soon after her surgery, Plaintiff began to experience severe, chronic, and ongoing numbness and pain in her right leg, her back, and her hands. Plaintiff also began to experience acute pressure from inside her head, blurred vision, discomfort in her neck area, and headaches that would last as long as six weeks. Since then, her pain has escalated and has spread to other parts of her body. Plaintiff also experiences poor balance, which requires her to use a walker. Plaintiff complains that her injuries were caused by severe bone growth, which she attributes to the off-label use of the Infuse Device.

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[1] According to Plaintiff's Complaint,

> While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1 and later granted approval for uses in certain oral maxillofacial surgeries.

ECF No. 20 at 13.

[2] "Off-label" use of a medical device is defined as the "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).

Plaintiff's Complaint lists the following causes of action against all of the named Defendants: (1) manufacturing defect, (2) failure to warn, (3) design defect, (4) negligence, (5) strict liability, (6) breach of express warranty, (7) fraud, (8) negligence per se, (9) intentional misrepresentation, and (10) California Unfair Competition Law. The Complaint contains various allegations that the use of the Infuse Device in Plaintiff's surgery was "off-label," but off-label uses of medical devices are an "accepted and necessary corollary" of the fact that the FDA does not regulate the practice of medicine.[3] Because Plaintiff cannot fault Defendants for the off-label use of her device, she instead bases her claims on Medtronic's alleged active promotion of the Infuse Device for this off-label use, which she claims they did without adequately disclosing its alleged risks.

Medtronic has filed the instant motion to dismiss, asserting that all of Plaintiff's claims are expressly preempted by 21 U.S.C. § 360k(a) pursuant to the Supreme Court's holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, which is explained in more detail below. Medtronic also asserts that Plaintiff's claims are impliedly preempted. According to Defendants, Plaintiff's allegations of off-label use and promotion do not save her claims from preemption because (1) the claims still would require that Medtronic add to or change the FDA-mandated warning label of the Infuse Device when it is prohibited from doing so by federal law; and (2) the claims are an attempt to pursue a private right of action and thus are barred by *Buckman* and § 337(a). Plaintiff disagrees with Defendants and submits that her claims fall into the narrow category of claims that are not preempted under either *Riegel* or *Buckman*.

[3] As the Supreme Court explained in *Buckman*, physicians are free to prescribe prescription products and devices for whatever purpose they judge their patients to need—regardless of whether that use has been assessed to be "safe or effective" by the FDA. *See Buckman*, 531 U.S. 341, 350.

II. Legal Standard

A. Dismissal Under 12(b)(6)

When considering a 12(b)(6) motion to dismiss, the court must accept as true the facts alleged in the complaint and view them in a light most favorable to the plaintiff. *Ostrzenski v. Seigel*, 177 F.3d 245, 251 (4th Cir. 1999). The United States Supreme Court has stated, however, that "[t]o 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*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "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.* Although "a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," a pleading that merely offers "labels and conclusions," or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Likewise, "a complaint [will not] suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancements.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 557). Accordingly, Plaintiffs must put forth claims that cross "the line from conceivable to plausible." *Id.* at 1950–51 (internal quotation omitted).

B. Medical Devices Act and Preemption

The Federal Food, Drug, and Cosmetic Act ("FDCA") has long required FDA approval for the introduction of new drugs into the market. However, the introduction of new medical devices was left largely for the states to supervise as they saw fit until 1976 when Congress passed the Medical Device Amendments of 1976 ("MDA"). Through the MDA, Congress established a detailed regime of federal oversight for medical devices, which consequently

limited some state control over the area. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 313 (2008). In fact, the MDA includes an express preemption provision that states:

> Except as provided in subsection (b) of this section, 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.

21 U.S.C. § 360k(a). The United States Supreme Court has interpreted that language to preempt state common law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device *if* such state law claims impose requirements "different from, or in addition to" the requirement imposed by the PMA process. *Riegel*, 552 U.S. at 323. The Supreme Court has made it clear that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations[, as long as] the state duties 'parallel,' rather than add to, federal requirements." *Id.* at 330. "To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). "Plaintiffs must also allege a link between the failure to comply and the alleged injury." *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp.2d 197, 204 (W.D.N.Y. 2011).

The FDCA states 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). According to the Supreme Court, that language is "clear evidence that Congress intended that the MDA be

enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

> Thus, a private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state law claim against a defendant when the state law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist. So, for example, a state-law claim that the defendant made a misrepresentation to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA.
>
> This does not mean that a plaintiff can never bring a state-law claim based on conduct that violates the FDCA. Indeed, the conduct on which the plaintiff's claim is premised must violate the FDCA if the claim is to escape express preemption by § 360k(a). Instead, to avoid being impliedly preempted under *Buckman*, a claim must rely on traditional state tort law, which [ ] predate[s] the federal enactments in question. In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*.

Caplinger v. Medtronic, Inc., 2013 WL 453133, at *6 (W.D. Okla. Feb. 6, 2013) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009)).

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). Thus, for a state law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

Id. (internal quotations and citations omitted).

III. Parties' Arguments

A. Express Preemption

According to Defendants, all of Plaintiff's claims are expressly preempted because all would require a finding that the Infuse Device should have been manufactured, designed, or labeled differently from the manner approved by the FDA. Many of Plaintiff's claims rely on Defendants alleged off-label promotion of the Infuse Device, but Plaintiff has failed to specify any federal laws or regulations that Defendants violated and further has failed to identify any state law authority imposing liability for off-label promotion. Thus, Defendants contend that Plaintiff has failed to properly allege a parallel claim, and, in the absence of any cognizable parallel state law claim, Defendants argue that Plaintiff's claims are preempted and must be dismissed.

Plaintiff responds to Defendants' arguments by stating that her "arguments are clear and succinct: the Defendants breached their duty to the FDA by promoting Infuse for uses not dictated in their PMA, thereby violating federal laws that directly inflicted harm upon" herself.

ECF No. 57-1 at 1. Plaintiff believes that she has properly alleged parallel claims by asserting that Defendants must abide by the FDA's rules and regulations and promoted their product in accordance with the uses delineated in their PMA and corresponding supplemental applications.[4] In support of her position, Plaintiff cites federal laws that prohibit adulterated or misbranded devices from being introduced into commerce and South Carolina laws that prohibit the same; thus, Plaintiff's arguments necessarily rely on this court finding that off-label promotion qualifies as misbranding. According to Plaintiff, "[t]he FDCA prohibits medical device companies from promoting devices for off-label uses, deeming them misbranded in violation of 21 U.S.C. § 352(f)." ECF No. 57-1 at 9. In support of that proposition, Plaintiff cites a case from the Northern District of Illinois, where a judge concluded that "the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses." *U.S. v. Caputo*, 288 F. Supp. 2d 912, 920 (2003).

Defendants submit that Plaintiff's reliance on *Caputo* is misplaced. *Caputo* was decided in 2003 before regulations regarding off-label promotion ceased effect through a sunset provision. *See* 21 U.S.C. § 360aaa, note. Though Plaintiff presumes that all communications about off-label uses are "illegal" off-label promotion, Defendants point out that the Second Circuit has recognized that "[w]hile the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion." *U.S. v. Caronia*, 703 F.3d 149, 160 (2d Cir. 2012). If this court were to agree that off-label promotion is not equivalent to misbranding, Defendants urge

[4] Though Plaintiff claims that Defendants' off-label promotion effectively concealed the potential adverse effects of the Infuse Device, Defendants point out that the labeling for the Infuse Device states "[t]he safety and effectiveness of the InFUSE Bone Graft component with other surgical implants, implanted at locations other than the lower lumbar spine, or used in surgical techniques other than anterior open or anterior laparoscopic approaches have not been established." ECF No. 59 at 3 (citing Request for Judicial Notice, ECF No. 50-9 at 4).

that any claim based on a state law proscribing off-label promotion would not be a parallel claim as the claim would require that Medtronic add to or change the FDA-mandated warning label of the Infuse Device when it is prohibited from doing so by federal law. Moreover, Defendants also point out that there is no South Carolina law proscribing off-label promotion of medical devices. Thus, even if federal law prohibited off-label promotion, there could be no parallel state claim, and any claim based on off-label promotion would be preempted. Defendants demonstrate further that the duties of the supposed parallel claim are not equivalent by distinguishing Plaintiff's proffered federal requirement—that Defendants not falsely promote off-label uses of an approved device—from Plaintiff's proffered state requirement—that defendants provide adequate warnings for the potential uses of its device. Finally, Defendants argue that Plaintiff has failed to establish a causal link between the alleged off-label promotion and her alleged injury.

B. Implied Preemption

Defendants further assert that Plaintiff's claims are impliedly preempted. According to Defendants,

> Plaintiff is either (1) trying to usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations; or (2) basing her various tort claims solely on a violation of federal law. Either way, Plaintiff's claims run headlong into *Buckman*'s implied preemption principles and the statutory bar against private actions based on a violation of FDA regulations.

ECF No. 50-1 at 20. Plaintiff disagrees that any of her causes of action are impliedly preempted. She contends that the "present case does not involve state law 'fraud on the FDA' claims, [and that] *Buckman*, therefore, is not even applicable." ECF No. 57-1 at 15. Additionally, she denies

that she is trying to usurp the authority of the FDA through her Complaint. However, Defendants point out that many of Plaintiff's claims based on federal regulations (which are not specified in the Complaint but are raised in Plaintiff's Response) are impliedly preempted because claims based on those regulations contend that Defendants failed to adequately update the FDA, which are, in fact, "fraud on the FDA" claims.

C. Failure to Plead Fraud-Based Claims with Particularity

Defendants submit that Plaintiff's fraud-based claims must be dismissed for additional reasons besides preemption. Specifically, the fraud and intentional misrepresentation claims have not been pled with particularity as required by Fed. R. Civ. P. 9(b); they lack details about the time, place, and contents of the false representations. On the other hand, Plaintiff believes that the information from U.S. Senate Committee Finance Reports gives sufficient details about the fraud that Medtronic allegedly perpetrated to meet the requirements of Fed. R. Civ. P. 9(b). Plaintiff additionally offers that "[a] Medtronic sales representative was in Plaintiff's operating room, promoted the off-label use of Infuse, all while concealing its adverse effects." ECF No. 57-1 at 17. In reply. Defendants stress to this court that Plaintiff has yet to plead her fraud-based claims with requisite particularity because she cannot point to the who, what, when, and where of the fraudulent statements made to her surgeon.

IV. Court's Analysis

First, the court must address Plaintiff's claims based on Defendants' alleged off-label promotion. The following claims in Plaintiff's Complaint refer to Defendants' alleged promotion: failure to warn, design defect, negligence, strict liability, breach of express warranty, fraud, and intentional misrepresentation. Unfortunately for Plaintiff, for any of these claims to survive the instant motion to dismiss, the court must accept Plaintiff's premise that off-label

promotion is illegal under the FDCA, and this court cannot do so. The court cannot adopt Plaintiff's position that Defendant's off-label promotion of the Infuse Device violated federal law because Plaintiff has failed to identify exactly which laws such conduct violates. Federal law clearly prohibits misbranding (21 U.S.C. § 352), but Plaintiff's only support for the contention that off-label promotion constitutes misbranding is a case from the Northern District of Illinois in 2003. Since that case was decided, the law in this area has changed—regulations that once controlled off-label promotion have lapsed, and the MDA does not otherwise mention off-label promotion. This court is not convinced that off-label promotion violates the FDCA. Consequently, any state laws proscribing off-label promotion would establish requirements "different from[] or in addition to[] any requirement" under the MDA and would be expressly preempted. *See* 21 U.S.C. § 360k(a). Additionally, to the extent that off-label promotion does violate the FDCA, claims based on such conduct would still be preempted because promoting the off-label use of an FDA-approved medical device is not unlawful under "traditional state tort law which, had predated the federal enactments in question[]." *Buckman*, 531 U.S. 341, 353. Any such claim would be in substance a claim for violating the FDCA and, thus, would be clearly preempted under *Buckman* and § 337(a). Other courts have similarly found claims based on off-label promotion to be impliedly preempted. *See Caplinger v. Medtronic*, --- F. Supp. 2d ---, 2013 WL 453133 at *11 (W.D. Okla. Feb. 6, 2013); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 783 (D. Minn. 2009).

Though, for the most part, Plaintiff's claims rely on Medtronic's alleged off-label promotion to show conduct that violated federal law, the court could also construe various claims in Plaintiff's more broadly to include other conduct. Plaintiff has not specifically pled such conduct, but, if she did, her claims would still be preempted as discussed below.

As currently pled, many of Plaintiff's claims are expressly preempted. Though Plaintiff's Complaint contains much information about alleged misconduct by Defendants, this court agrees with Defendants that Plaintiff has failed to set forth parallel claims because she has failed to identify conduct by the Defendants that violated federal statutes or regulations and that gives rise to a claim under state law. Additionally, many of Plaintiff's state law causes of action would require labeling and warning requirements different from or in addition to the federal requirements for the Infuse Device set through the PMA process. For those reasons, the court finds that the following claims are expressly preempted: failure to warn; design defect; negligence (to the extent based on failure to warn); strict liability; breach of express warranty; fraud; negligence per se; and intentional misrepresentation.

Though not specifically pled in her Complaint, Plaintiff offers (in her Response) some federal regulations that Defendant has allegedly violated, including 21 C.F.R. §§ 814.20(e), 803.50, 803.50(b)(3), 807.81, 814.39(a). However, upon inspection, all of these regulations relate to information that manufacturers are required to provide to the FDA, and Plaintiff cannot usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations. As such, this court finds that any claims based on Defendants' violations of these regulations would clearly be impliedly preempted.

As conceded by Defendants at the hearing, there are claims that Plaintiff could raise that would survive preemption—for instance, a claim that the Infuse Device that was used in her surgery contained a manufacturing defect and did not meet the specifications set for the Infuse Device during PMA. Plaintiff vaguely mentions such a claim in her Response. However, her Complaint, specifically her manufacturing defect claim, lacks the specificity required to properly allege that kind of claim. As currently pled, Plaintiff's manufacturing defect claim (and, indeed,

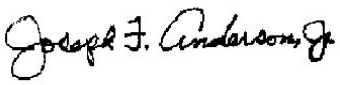
many of her other claims) merely contains a formulaic recitation of the elements, which is insufficient to survive a motion to dismiss under *Twombly*.

As final matter, Plaintiff concedes that her California Unfair Competition Law claim should be dismissed. Accordingly, the court hereby dismisses, with prejudice, Plaintiff's claim based on the California Unfair Competition Law. Despite this court's dismissal of Plaintiff's claim based on the California Unfair Competition Law, should Plaintiff choose to amend her Complaint based on the findings of this order Plaintiff is free to assert a claim that Defendants violated the South Carolina Unfair Trade Practices Act.

IV. Conclusion

For the reasons stated above, the court dismisses all of Plaintiff's claims, without prejudice, except her California Unfair Competition Law claim, which is dismissed with prejudice.

IT IS SO ORDERED.



August 9, 2013
Columbia, South Carolina

Joseph F. Anderson, Jr.
United States District Judge