IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

GERARD E. LEDET and
SHARONDA J. LEDET **PLAINTIFFS**

v. **CAUSE NO. 1:13CV200-LG-JMR**

MEDTRONIC, INC., and MEDTRONIC
SOFAMOR DANEK, USA, INC. **DEFENDANTS**

MEMORANDUM OPINION AND ORDER
GRANTING DEFENDANTS' MOTION TO DISMISS

BEFORE THE COURT is the Motion to Dismiss [14] filed by the defendants Medtronic, Inc., and Medtronic Sofamor Danek, Inc. (hereafter collectively referred to as "Medtronic"). Medtronic argues that the product liability claims filed by the plaintiffs Gerard and Sharonda Ledet are preempted by 21 U.S.C. § 360(a) and 21 U.S.C. § 337(a). In the alternative, Medtronic argues: (1) the Ledets' claims are barred by the statute of limitations; (2) the warnings provided on the medical device at issue were adequate under Mississippi law; (3) the Ledets' design defect and implied warning claims are barred; and (4) the Ledets' fraud and misrepresentation claims do not conform to federal pleading standards. The Ledets have filed a response in opposition to the Motion, and Medtronic filed a reply in support of its Motion. After reviewing the submissions of the parties and the applicable law, the Court finds that Medtronic's Motion to Dismiss should be granted.

FACTS

On April 18, 2007, Dr. Eric Graham performed an anterior lumbar interbody spinal fusion procedure on Gerard Ledet at levels L4-S1. (Am. Compl. at 76, ECF No. 3). Dr. Graham utilized the Infuse device manufactured by Medtronic to perform the surgery. (*Id.*) "Infuse is a bio-engineered liquid bone graft classified by the FDA as a medical device . . . ." (*Id.* at 1). The Ledets claim that Infuse "is only approved by the FDA for lumbar surgery that is performed through the abdomen (anterior approach) when it is used in combination with an LT-Cage, a hollow metal cylinder that is used to insert the Infuse into the spine." (*Id.*) Dr. Graham utilized a Cougar spacer cage for Gerard's surgery instead of the LT-Cage. (*Id.* at 76).

After the surgery, Gerard suffered from increasing back pain, a shooting and burning pain down his left leg, and numbness in his left foot. (*Id.* at 77). The Ledets allege that imaging studies performed after the surgery "ultimately revealed that [Gerard] had developed uncontrolled bone growth . . .and resulting radiculopathy related to bone overgrowth at or near where the Infuse was implanted in the April 18, 2007 surgery." (*Id.*) "A June 2, 2009 lumbar spine CT [scan] revealed ' . . . left posterior osteophyte(s) displacing the left . . . nerve root(s)' at levels L4-S1." (*Id.*) Revision surgeries were performed on Gerard on October 21, 2009, and July 18, 2012, to remove the bone overgrowth. (*Id.*)

Despite the two revision surgeries, Gerard claims that he continues to suffer from severe pain and other difficulties as a result of the fusion surgery, and

Gerard's wife Sharonda claims she has suffered a loss of consortium. (*Id.* at 78-79).

The Ledets filed this lawsuit against Medtronic on April 24, 2013. Since the LT-Cage was not used for Gerard's surgery, the Ledets claim that the manner in which Infuse was utilized was an off-label use. The Ledets believe that this off-label use caused the complications Gerard experienced, and they assert that Medtronic improperly promoted the off-label use of Infuse despite its knowledge of the risk of harmful bone overgrowth. They claim they could not have known that the off-label use of Infuse caused Gerard's complications until March 2012 at the earliest. (*Id.* at 78). The Ledets have asserted the following causes of action: (1) fraudulent concealment and fraud in the inducement, (2) strict liability – failure to warn, (3) constructive fraud, (4) strict liability – design defect, (5) negligence, (6) negligent misrepresentation, (7) breach of express warranty, (8) breach of implied warranties, and (9) loss of consortium. Medtronic has filed the present Motion to Dismiss.

DISCUSSION

In order to survive a motion to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Turner v. Pleasant*, 663 F.3d 770, 775 (5th Cir. 2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "This standard 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re S. Scrap Material Co., LLC*,

541 F.3d 584, 587 (5th Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). In *Twombly*, the Court held that "heightened fact pleading of specifics" is not required, but "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555, 570. "When matters outside the pleadings are presented to and not excluded by the district court, the district court must convert a motion to dismiss into a motion for summary judgment." *Burns v. Harris Cnty. Bail Bond Bd.*, 139 F.3d 513, 517 (5th Cir. 1998). In the present case, the Court has not relied on any evidence outside of the pleadings.

I. EXPRESS PREEMPTION

Medtronic first argues that the Ledets' claims are expressly preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act (FDCA). *See* 21 U.S.C. § 360c et seq. The MDA includes an express preemption provision that provides:

> [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 MDA divides medical devices into three categories: Class I, Class II, and Class III. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (citing 21 U.S.C. §

360c(a)(1)). The MDA has "established a rigorous regime of premarket approval for new Class III devices." *Id.* at 317.

> The FDA spends an average of 1,200 hours reviewing each application . . . and grants premarket approval only if it finds there is a "reasonable assurance" of the devices's "safety and effectiveness," § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives . . . .
>
> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).

Id. at 318.

After premarket approval, the manufacturer is not permitted to make any changes to the device or its labeling that would affect safety or effectiveness, unless the FDA permits the changes. *Id.* at 319. Furthermore, the manufacturer is required to notify the FDA of studies and problems related to the device, such as injuries and deaths that may have been caused by the device. *Id.*

When determining whether the MDA expressly preempts a plaintiff's claims related to a medical device, a court must first determine (1) whether the federal government has established requirements pertaining to the device, and (2) whether the plaintiff's common law claims are based on state requirements that are "different from, or in addition to" the federal requirements and relate to safety and effectiveness. *Id.* at 321-22. "[Section] 360k does not 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." *Id.* at 330.

In *Riegel*, the Supreme Court held that premarket approval imposes requirements under the MDA that are specific to an individual device. *Id.* at 323. Devices that have received premarket approval automatically satisfy the federal requirement prong of preemption analysis. *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012).

The Infuse device manufactured by Medtronic is a Class III device that received premarket approval from the FDA. The off-label use of the bone graft component of Infuse in the present case does not affect this determination. *See Gavin v. Medtronic, Inc.*, No. 12-0851, 2013 WL 3791612 at *11 (E.D. La. July 19, 2013) (citing *Bass*, 669 F.3d at 508); *see also Houston v. Medtronic, Inc.*, No. 2:13cv1679-SVW-SH, 2013 WL 3927839 at * (C.D. Cal. July 30, 2013) ("Section 360k(a) broadly preempts any state requirement 'with respect to' a particular device . . . ."). "[A]llegations of promotion of off-label use of a device in violation of federal law does not automatically immunize a plaintiff's claims from being subject to a preemption analysis under § 360k(a)." *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1218 (W.D. Okla. 2013). This is because "[n]othing in the statute suggests that the preemption analysis somehow depends on how the device is used." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009)); *see also Gavin*, 2013 WL 3791612 at *11 ("off-label use is a corollary of the FDA regulatory

system, and an unconvincing basis for finding the preemption analysis inapplicable here.") Therefore, the federal government has imposed regulations pertaining to the Infuse device, including the bone graft component utilized in Gerard's surgery.

The second prong of express preemption analysis requires a determination regarding whether the Ledets' common law claims are based on state requirements that are "different from, or in addition to" the federal requirements and relate to safety and effectiveness. State common law claims "are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements." *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 (5th Cir. 2011).

II. IMPLIED PREEMPTION

In *Buckman Co. v. Plaintiffs' Legal Committee*, the United States Supreme Court held that the MDA can only be enforced by the Federal Government. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (citing 21 U.S.C. § 337(a)).[1] Thus, in order to avoid implied preemption, a plaintiff must "rely on traditional state tort law that predated the federal enactments in question." *Id.* at 353. Therefore, "for a state law claim to survive both express and implied preemption, "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.'" *Gavin*, 2013 WL 3791612 at *5 (quoting *Caplinger*, 921 F. Supp. 2d at 1215). In other words, "[t]he plaintiff must be suing for conduct that *violates* the

[1] 21 U.S.C. § 337(a) provides that a lawsuit for "enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."

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*)." *Caplinger*, 921 F. Supp. 2d at 1215 (emphasis in original).

III. ANALYSIS OF THE LEDETS' CLAIMS

A. Fraudulent Concealment, Fraud in the Inducement, and Constructive Fraud

In support of their fraudulent concealment and fraud in the inducement claims, the Ledets allege that: (1) "Medtronic fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of Infuse"; (2) "Medtronic fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label practice of using Infuse without an LT-Cage and placing it in multiple levels of the lumbar spine"; and (3) "Medtronic fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse and the relative benefits and availability of alternate products, treatments and therapies." (Am. Compl. at 80-81, ECF No. 3). The Ledets allege that Medtronic committed constructive fraud by marketing the "Infuse product to and for the benefit of Plaintiff, and market[ing] it to Plaintiff's physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects in their Infuse product, and that Plaintiff and Plaintiff's physician would use the product." (Am.

Compl. at 85, ECF No. 3).

To the extent that the Ledets' fraud claims "may be based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device," these claims are expressly preempted. *See Caplinger*, 921 F. Supp. 2d at 1219, 1221.[2] "To permit a jury to second-guess the Infuse Device's design, manufacturing, labeling, warning, and marketing would risk interference with the federally-approved design, manufacturing, labeling, warning, and marketing requirements." *Id.* at 1221.

To the extent that a plaintiff's fraud claims are "based upon alleged misrepresentations and omissions regarding [Medtronic's] practice of promoting and marketing to physicians the off-label use of the Infuse Device . . . ," the claims are impliedly preempted, because "even the concept of 'off-label' use is a creature of the FDCA." *Id.* at 1219. Therefore, the Ledets' fraud claims related to off-label use arise solely out of the FDCA, not state substantive law, and are subject to implied preemption.

B. Strict Liability – Failure to Warn

The Ledets allege that Medtronic knew of the dangers of off-label use of Infuse but breached its duty to warn Gerard and his physicians of the dangers. (Am. Compl. at 84, ECF No. 3). This claim is expressly preempted by the MDA, since the Ledets are claiming that Medtronic should have provided warnings that

[2] The Ledets' claims are very similar to those asserted by the plaintiff in *Caplinger*. *See, e.g., Caplinger*, 921 F. Supp. 2d at 1219.

were different from or in addition to the warnings required by the FDA. *See Houston*, 2013 WL 3927839 at *8; *Caplinger*, 921 F. Supp. 2d at 1221.

C. Strict Liability – Design Defect

The Ledets assert that "the Infuse device was defectively designed because the design was unsafe when used in the manner promoted by [Medtronic] and/or in a manner reasonably foreseeable by [Medtronic]." (Am. Compl. at 87, ECF No. 3). They also argue that the risks of danger in the design of Infuse outweigh its benefits. (*Id.*) "In other words, this claim attacks 'the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by §360k.'" *Houston*, 2013 WL 3927839 at *8 (quoting *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010)); *see also Caplinger*, 921 F. Supp. 2d at 1222.

D. Negligence

The Ledets' negligence claim is based on the following alleged conduct by Medtronic: (1) "[u]nreasonable and improper promotion and marketing of Infuse to physicians, including but not limited to the promotion and marketing of Infuse for use off-label . . .; (2) "[f]ailure to warn physicians and [Gerard] of the dangers associated with Infuse when used off-label . . .; and (3) "[f]ailure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse." (Am. Compl. at 90, ECF No. 3).

The improper promotion aspect of this claim is impliedly preempted, because

such a claim does not exist under state law in the absence of the FDCA. *See Caplinger*, 921 F. Supp. 2d at 1223; *Houston*, 2013 WL 3927839 at *9. As explained previously, the Ledets' assertion that Medtronic failed to provide adequate warnings is expressly preempted. As for the claim that Medtronic failed to comply with federal law and regulations, this claim is vague and conclusory, and it is based on insufficient facts. *See Caplinger*, 921 F. Supp. 2d at 1224; *Houston*, 2013 WL 3927839 at *9 (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (explaining that a plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption")).

E. Negligent Misrepresentation

In support of their negligent misrepresentation claim, the Ledets claim:

> Medtronic marketed their Infuse product to and for the benefit of Plaintiff and marketed it to his physicians, to induce Plaintiff and his physicians to use the product.
>
> Defendants also made untrue representations to Plaintiff and his physicians by sponsoring biased medical trials, reports, and articles that concluded that the dangers inherent [in] off-label use of Infuse did not exist or were significantly less [than] the actual dangers.

(Am. Compl. at 91, ECF No. 3). As the Court in *Caplinger* held with regard to an identical negligent misrepresentation claim, "Plaintiff's negligent misrepresentation claim would . . . establish design, manufacturing, labeling, and warning requirements different from, or in addition to, federal requirements for the Infuse Device." *Caplinger*, 921 F. Supp. 2d at 1224. As a result, this claim is also expressly preempted.

F. Breach of Express and Implied Warranties

The Ledets assert:

> At all times herein mentioned, 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 Bone Graft and expressly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in lumbar fusion procedures, were safe and effective.
> . . . .
> Plaintiff is informed and believes and based thereon alleges that his treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of off-label use of Infuse, but such off-label uses . . . were not effective, safe and proper for the use as warranted in that Infuse was dangerous when put to these promoted uses.

(Am. Compl. at 93-94, ECF No. 3). As the court explained in *Caplinger*, allowing a plaintiff to proceed with a breach of warranties claim based on the alleged unsafe nature of a device would conflict with the FDA's prior approval of that device. See *Caplinger*, 921 F. Supp. 2d at 1222. The Ledets' breach of warranties claim is expressly preempted.

G. Loss of Consortium

Sharonda Ledet's loss of consortium claim is a derivative claim. *See J & J Timber Co. v. Broome*, 932 So. 2d 1, 6 (¶19) (Miss. 2006). As a result, a loss of consortium claim cannot be maintained in the absence of an underlying personal injury claim. *See id.* Sharonda's loss of consortium claim must be dismissed due to the dismissal of Gerard's claims.

IV. STATUTE OF LIMITATIONS

The Court further finds that the Ledets' request for permission to amend their complaint should be denied, because their claims are barred by the statute of limitations. This is an alternate ground for granting Medtronic's Motion to Dismiss.

Mississippi Code Annotated § 15-1-49 provides:

> (1) All actions for which no other period of limitation is prescribed shall be commenced within three (3) years next after the cause of such action accrued, and not after.
> (2) In actions for which no other period of limitation is prescribed and which involve latent injury or disease, the cause of action does not accrue until the plaintiff has discovered, or by reasonable diligence should have discovered the injury.

"No provision of Section 15-1-49 provides that a plaintiff must have knowledge of the cause of the injury before the cause of action accrues, initiating the running of the statute of limitations." *Angle v. Koppers. Inc.*, 42 So. 3d 1, 7 (¶18) (Miss. 2010). The date on which the plaintiff's injury is diagnosed is the date on which the cause of action accrues. *See id.* The Mississippi Supreme Court has held:

> The question of whether a statute of limitations is tolled by the discovery rule often turns on the factual determination of what the plaintiff knew and when. Thus, occasionally the question of whether the suit is barred by the statute of limitations is a question of fact for the jury; however, as with other putative fact questions, the question may be taken away from the jury if reasonable minds could not differ as to the conclusion.

Stringer v. Trapp, 30 So. 3d 339, 342 (¶12) (Miss. 2010) (internal citations and quotation marks omitted).

Gerard's surgery was performed at levels L4-S1 of his spine on April 18,

2007. The Ledets allege that imaging studies performed after the surgery "ultimately revealed that [Gerard] had developed uncontrolled bone growth . . .and resulting radiculopathy related to bone overgrowth at or near where the Infuse was implanted . . . surgery." (Am. Compl. at 77). "A June 2, 2009 lumbar spine CT [scan] revealed ' . . . left posterior osteophyte(s) displacing the left . . . nerve root(s)' at levels L4-S1." (*Id.*) Revision surgeries were performed on Gerard on October 21, 2009, and July 18, 2012, to remove the bone overgrowth. (*Id.*) The Ledets filed this lawsuit on April 24, 2013.

Gerard's injury was diagnosed, at the latest, when a June 2, 2009, lumbar CT scan revealed bone overgrowth at the very levels of his spine on which surgery was performed. In addition, he was placed on notice at that time that the problems occurred in the very area where the Infuse device was implanted. As a result, the Ledets were required to file this lawsuit on or before June 2, 2012. However, this lawsuit was filed over ten months later. Consequently, this lawsuit would be untimely.

CONCLUSION

For the foregoing reasons, the Court finds that all of the Ledets' claims must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). The Court further finds that the Ledets should not be granted leave to amend their complaint. An amendment would be futile inasmuch as the claims are time barred.

IT IS, THEREFORE, ORDERED AND ADJUDGED that the Motion to Dismiss [14] filed by the defendants Medtronic, Inc., and Medtronic Sofamor Danek,

Inc., is **GRANTED**. This lawsuit is hereby **DISMISSED WITH PREJUDICE**.

SO ORDERED AND ADJUDGED this the 30th day of December, 2013.

s/ *Louis Guirola, Jr.*
LOUIS GUIROLA, JR.
CHIEF U.S. DISTRICT JUDGE