UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

MARTIN Z. GAVIN	**CIVIL ACTION**
VERSUS	**NO. 12-0851**
MEDTRONIC, INC., et al.	**SECTION: "G"(5)**

ORDER AND REASONS

Before the Court is Defendants Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA's (collectively, "Medtronic" or "Defendants") Amended Motion to Dismiss Plaintiff's Complaint,[1] wherein Defendants request dismissal of Plaintiff Marvin Z. Gavin's ("Plaintiff") complaint on the basis that Plaintiff's claims are expressly or impliedly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a), are prohibited by the "no private right of action" provision of the federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 337(a); and are barred under Louisiana law.[2] On April 24, 2013, the Court heard oral argument on the pending motion. Having considered those arguments, the complaint, the motion, the memorandum in support, the response, the reply, the parties' post-hearing memoranda, and the applicable law, the Court will grant in part and deny in part the motion to dismiss.

[1] Rec. Doc. 56.

[2] Rec. Doc. 56-1 at p. 7.

I. Background

A. Procedural Background

On March 30, 2012, Plaintiff filed this product liability action in the Eastern District of Louisiana to recover for personal injuries allegedly caused by Medtronic's illegal off-label promotion of the INFUSE Bone Graft.[3] On June 22, 2012, Medtronic, the manufacturer of the medical device, filed its first motion to dismiss.[4] In addition to extensively briefing the motion, Medtronic filed five notices of supplemental authority between June of 2012 and February of 2013, to which Plaintiff responded. Therefore, on March 6, 2013, the Court denied Medtronic's first motion to dismiss without prejudice and granted the parties "leave to refile their pleadings so that they may present the Court with cohesive arguments addressing all relevant supplemental authority."[5] The Court simultaneously ordered that oral argument would be held on the resubmitted motion to dismiss on April 24, 2013.[6]

In accordance with the Court's order, on April 9, 2013, Medtronic filed the instant Amended Motion to Dismiss Plaintiff's Complaint,[7] arguing that Plaintiff's claims are (1) expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a); (2) impliedly preempted by § 360k(a); prohibited by the "no private right of action" provision of the FDCA, 21 U.S.C. § 337(a); and (4) barred for independent state law reasons under the Louisiana Products Liability Act ("LPLA").[8] Defendants also filed a Request for Judicial Notice in

[3] Rec. Doc. 1 ¶¶ 1-2.

[4] Rec. Doc. 8.

[5] Rec. Doc. 55.

[6] *Id.*

[7] Rec. Doc. 56.

[8] Rec. Doc. 56-1 at p. 7.

Support of Defendants' Amended Motion to Dismiss,[9] which the Court granted on April 10, 2013.[10] Plaintiff timely opposed the pending motion to dismiss on April 16, 2013, arguing that Plaintiff has avoided preemption by alleging valid "parallel claims" under Louisiana state law based on Defendants illegal off-label promotion of the INFUSE Bone Graft.[11] After oral argument was heard on the pending motion, Plaintiff filed a Post-Hearing Memorandum[12] on April 30, 2013, and Defendants responded on May 3, 2013.[13] On July 3, 2013, with leave of Court, Defendants filed a Notice of Supplemental Authority Regarding Medtronic's Pending Amended Motion to Dismiss Plaintiff's Complaint.[14]

B. Factual Background

The current regulatory framework for medical device approval, established by the Medical Device Amendments of 1976 to the FDCA, contains a three-class classification system for medical devices. Class III devices, such as Medtronic's Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device, pose the greatest risk of complications or death and are therefore subject to a rigorous premarket approval process.[15] After the manufacturer submits a Premarket Approval Application ("PMA"), including the intended uses of the device and all proposed labeling, the FDA grants premarket approval once the manufacturer demonstrates the device's

[9] Rec. Doc. 57.

[10] Rec. Doc. 58.

[11] Rec. Doc. 59.

[12] Rec. Doc. 67.

[13] Rec. Doc. 70.

[14] Rec. Doc. 75.

[15] Rec. Doc. 1 ¶¶ 27-28; *see also* Rec. Doc. 56-1 at p. 10.

safety and effectiveness through an exhaustive process that analyzes clinical investigations and non-clinical laboratory studies.[16]

On July 2, 2011, the FDA granted premarket approval for Medtronic's Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device (the "Device"). The Device consists of (1) the recombinant human bone morphogenetic protein-2 ("rhBMP-2"); (2) an absorbable collagen sponge; and (3) an "interbody fusion device."[17] Plaintiff refers to the first two components—the collagen sponge carrying the active ingredient rhBMP-2—as the INFUSE Bone Graft.[18] The FDA approved the Device for use in an Anterior Lumbar Interbody Fusion ("ALIF"), fractures of the tibia, and certain oral and maxillofacial surgeries.[19] However, Plaintiff alleges that Medtronic promoted the INFUSE Bone Graft for at least three other "off label" uses[20] despite Medtronic's knowledge of the serious risks posed by these off-label uses.[21]

On February 7, 2011, Plaintiff underwent a spinal Transforaminal Lumbar Interbody Fusion ("TLIF") surgery to treat his chronic back pain, in which his surgeon used a mixture of Plaintiff's own bone fragments and INFUSE Bone Graft.[22] However, Plaintiff's surgeon used the INFUSE Bone Graft in an "off-label application," because the surgeon opted for a posterior spinal fusion procedure for which the device was not expressly approved.[23] As a result of the

[16] Rec. Doc. 1 ¶ 28.

[17] Rec. Doc. 56-1 at p. 10.

[18] Rec. Doc. 1 ¶ 35.

[19] *Id.* ¶ 32.

[20] An "off-label" use is the use of a device for some other purpose than that for which it has been approved by the FDA. The existence of off-label uses is a corollary of the fact that the FDA does not regulate the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

[21] Rec. Doc. 1 at ¶¶ 32-40.

[22] *Id.* ¶¶ 1, 56.

[23] *Id.* ¶ 57.

surgery, Plaintiff states that he "has seen three physical therapists/pain management specialists, endured numerous painful and unsuccessful epidural spinal injections, and will undergo surgery for the implantation of a TENS unit to help 'ease' his debilitating and now permanent pain."[24]

Plaintiff alleges that Medtronic, "through its sales representative and paid consultants directly and indirectly promoted, trained and encouraged Plaintiff's surgeon to use INFUSE Bone Graft in an off-label manner, including utilizing it in posterior approach spinal fusions."[25] Such promotion allegedly included undisclosed payments to doctors who published articles in medical journals, delivered presentations, and appeared at consulting engagements addressing off-label use of INFUSE Bone Graft.[26] In turn, Medtronic's sales force would allegedly direct other doctors to these consultants or their written work.[27] Plaintiff claims that he would have chosen a different treatment if he had been informed that the INFUSE Bone Graft was being used in an off-label manner and of the increased risks associated with such use.[28]

Accordingly, Plaintiff alleges seven causes of action. First, Plaintiff claims that the INFUSE Bone Graft contained inadequate warnings regarding the dangerous risks associated with off-label use in violation of Louisiana Revised Statute § 9:2800.57.[29] Second, Plaintiff claims that Defendants are strictly liable for their allegedly willful, wanton, and reckless conduct in promoting the INFUSE Bone Graft for off-label uses when Defendants knew or should have known that the product would be dangerous and defective when used in an off-label

[24] *Id.* ¶ 60.

[25] *Id.* ¶ 58.

[26] *Id.* ¶ 44.

[27] *Id.*

[28] *Id.* ¶¶ 55, 59.

[29] *Id.* ¶¶ 62-73.

application.[30] Third, Plaintiff alleges that Defendants expressly represented that the INFUSE Bone Graft was safe and fit for its intended purposes, was of merchantable quality, did not produce dangerous side effects, and had been adequately tested, and that Defendants breached those express warranties in violation of Louisiana Revised Statutes § 9:2800.58.[31] Plaintiffs' fourth and fifth causes of action allege that Defendants breached the warranty of fitness for ordinary use and the implied warranty of merchantability and fitness under Louisiana law, respectively, by promoting the product for off-label uses for which Defendants knew it was inherently dangerous.[32] Sixth, Plaintiff alleges that Defendants failed to exercise ordinary care in promoting INFUSE Bone Graft for off-label uses and without warning of the risk of dangerous and permanent adverse effects.[33] Plaintiff's seventh, and final, cause of action alleges numerous violations of the FDCA in Defendants' manufacture, promotion and sale of INFUSE Bone Graft.[34]

II. Applicable Law

A. Express Preemption and a Valid Parallel Claim

1. Express Preemption

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, which authorizes the U.S. Food and Drug Administration ("FDA") to regulate the safety and

[30] *Id.* ¶¶ 74-84.

[31] *Id.* ¶¶ 85-92.

[32] *Id.* ¶¶ 93-104.

[33] *Id.* ¶¶ 105-112.

[34] *Id.* ¶¶ 113-115.

effectiveness of medical devices.[35] Under the MDA, there are three classes of medical devices depending on the degree of risk the device presents. Class III medical devices are subject to the greatest level of FDA scrutiny and "must complete a thorough review process with the FDA before they may be marketed."[36] Premarket approval of Class III medical devices is a rigorous process, and once a PMA is granted, the MDA forbids the manufacturer to make "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness, without FDA permission," and any such permission requires an application for supplemental premarket approval that is evaluated under similar criteria as the initial application.[37]

After premarket approval is granted, a device is subject to reporting requirements,[38] including the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device and to report any incidents in which the device may have caused or contributed to death or serious injury.[39] Based on newly reported data or existing information, the FDA has the power to withdraw premarket approval, and it must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.[40]

To preserve federal regulatory authority over medical devices and thereby enable the FDA to balance various statutory objectives, 21 U.S.C. § 360k of the MDA sets forth an express preemption clause that states:

[35] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 336 (2008).

[36] *Buckman*, 531 U.S. at 344.

[37] *Riegel*, 552 U.S. at 319.

[38] *See* 21 U.S.C. § 360i.

[39] *See* 21 C.F.R. §§ 814.84(b)(2), 803.50(a).

[40] 21 U.S.C. §§ 360e(e)(1), 360h(e).

> 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.

In *Riegel v. Medtronic, Inc.*,[41] the United States Supreme Court developed a two-part analysis for determining whether state law claims are expressly preempted by § 360k(a) of the MDA.[42] First, a court determines whether "the Federal Government has established requirements applicable to" the particular medical device.[43] If federal requirements applicable to the particular device have been established, a court next evaluates whether the plaintiff raises state law claims that would impose requirements "different from or in addition to" the federal requirements and that relate to safety and effectiveness of the device.[44]

Claims involving a Class III medical device that has received premarket approval satisfy the first step of the analysis, because the PMA process establishes specific requirements applicable to particular devices.[45] Accordingly, state tort claims relating to Class III medical devices are necessarily preempted to the extent that they impose duties that are "different from or in addition to" the requirements set forth by the FDA.[46]

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[41] 552 U.S. 312.

[42] *Id.* at 321.

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.* at 329; *see also Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 929 (5th Cir. 2006).

However, the Supreme Court has made clear that "[s]tate requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."[47] Therefore, the express preemption provision in § 360k(a) 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."[48] Thus, a plaintiff may avoid express preemption of their claim by alleging a valid parallel claim based on violations of FDA regulations to recover state tort damages for injuries suffered from the use of a Class III medical device that has received premarket approval.[49]

B. Implied Preemption

Often referred to as the "no private cause of action" provision, § 337(a) of 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." The Supreme Court interpreted § 337(a) in *Buckman Co. v. Plaintiffs' Legal Committee*,[50] wherein the Court found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government."[51] The plaintiff in *Buckman* alleged that a regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market a medical device. In holding that the plaintiff's claims were impliedly preempted, the Supreme Court concluded that the federal

[47] *Riegel*, 552 U.S. at 330.

[48] *Id.* (quoting *Medtronic Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

[49] *Id.*

[50] 531 U.S. 341.

[51] *Id.* at 352.

statute empowers the FDA to deter and punish fraud and that the "balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under tort law."[52]

However, the *Buckman* court specifically distinguished claims not related to a field of law that states had traditionally occupied, such as "fraud-on-the-agency" claims, from claims based on traditional state tort principles, which implicate federalism concerns and the historic primacy of state regulation of matters of health and safety.[53] The Supreme Court found that while § 360k(a) "can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim."[54] Rather, a valid state law claim that avoids implied preemption must "rely[] on traditional state tort law which had predated the federal enactments in question."[55]

Thus, in order for a claim to fit through the narrow gap available between express and implied preemption, the plaintiff must allege that a well-recognized duty owed under state law was breached by a manufacturer's conduct that violates the FDCA. In other words, 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."[56]

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[52] *Id.* at 348.

[53] *Id.*

[54] *Id.* at 353.

[55] *Id.*

[56] *Caplinger v. Medtronic, Inc.*, No. CIV-12-630-M, 2013 WL 453133, at *6 (W.D. Okla. Feb. 6, 2013).

C. Louisiana Law and the LPLA

Under Louisiana law, the LPLA, La. Rev. Stat. § 9:2800.51, *et seq.*, establishes the "exclusive theories of liability for manufacturers for damage caused by their products."[57] The LPLA provides that a product is unreasonably dangerous only if: (1) the product is unreasonably dangerous in construction or composition; (2) the product is unreasonably dangerous in design; (3) the product is unreasonably dangerous because an adequate warning about the product has not been provided; or (4) the product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product.[58]

Although Plaintiff asserts seven causes of action, the only claims asserted under the LPLA involve inadequate warning and breach of express warranty. Under Louisiana Revised Statute § 9:2800.57, a claim for inadequate warning exists when:

> A. A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.
> B. A manufacturer is not required to provide an adequate warning about his product when:
>
> (1) The product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics; or
>
> (2) The user or handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic.
>
> C. A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

[57] La. Rev. Stat. § 9:2800.52.

[58] La. Rev. Stat. § 9:2800.54

Plaintiff also asserts a breach of express warranty claim pursuant to Louisiana Revised Statute § 9:2800.58, which provides:

> A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue.

III. Parties' Arguments

A. Defendants' Arguments

1. Device Specific Requirements

Medtronic argues that all of Plaintiff's claims are expressly preempted under *Riegel*'s interpretation of § 360k(a). Regarding the first step in the *Riegel* analysis, Medtronic contends that "[c]laims involving a device, such as the Infuse device, that has received Premarket Approval automatically satisfy this first condition[,]" because the FDA has established requirements applicable to the Device.[59] Medtronic notes that the Device and all of its components were granted premarket approval, which "Plaintiff even pled . . . in his complaint."[60] Further, Medtronic explains that off-label use of medical devices—an accepted corollary of the FDA regulatory system—includes the ability of physicians to use portions of a device even when labeling approved by the FDA indicates the components should be used together.[61] In support of its contention that the INFUSE Bone Graft, a component of the Device, has received premarket approval, Medtronic directs the Court to various district court cases and a decision from the Fifth

[59] Rec. Doc. 56-1 at p. 14.

[60] Rec. Doc. 60-1 at p. 7.

[61] *See* Rec. Doc. 70 at pp. 6-7.

Circuit where the court upheld a finding by the district court that a component part received premarket approval when the medical device system it was part of received premarket approval.[62]

2. Preemption and Sufficiency of Plaintiff's Claims

Medtronic asserts that the "manufacturing design, and warning defect claims, as well as negligence and fraud [claims]" that Plaintiff alleges are all expressly preempted, because "[e]ach of these claims would require a finding that the Infuse device should have been manufactured, designed or labeled differently from the manner approved by the FDA."[63] According to Medtronic, "[c]laims encompassing state common law tort theories, such as strict liability and negligence, automatically impose state law requirements within the meaning of 360k(a)," and such claims are expressly preempted "to the extent they assert state tort liability despite compliance with FDA requirements."[64] Medtronic notes that Plaintiff does not allege that Defendants failed to label or manufacture the Device as required by the FDA. Therefore, Medtronic argues that Plaintiff's claims based on inadequate warning and negligence are expressly preempted because they would require a finding, as a matter of Louisiana law, that

[62] *Id.* at pp. 7-8 (citing *Bass v. Stryker Corp.*, 669 F.3d 501, 508 (5th Cir. 2012) (component of PMA device is covered under that PMA); *see also Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471 (D. Mass. 2012) ("[O]nce premarket approval is granted, all claims relating to all components of the device are preempted."); *Wilhite v. Howmedica Corp.*, 833 F. Supp. 2d 753, 762 (N.D. Ohio 2011) ("[C]omponents of medical devices will not be separately considered when the device as a whole underwent the PMA process and received approval."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) (preemption applied because medical device had premarket approval, even though the allegedly defective component had previously been regulated through a different process); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (finding that components of a PMA-approved device work together as a single medical device, and that picking these components apart to apply different preemption analysis "makes no sense").

[63] Rec. Doc. 56-1 at p. 15.

[64] *Id.* at pp. 14, 16.

Medtronic failed to provide adequate warnings despite having labeled and manufactured the Device in compliance with FDA requirements. Similarly, Medtronic contends that Plaintiff's strict liability claim is preempted because it would require a finding that the Device was defective despite the fact that the design and label was approved by the FDA and manufactured in compliance with FDA requirements.[65]

Medtronic also argues that all of Plaintiff's breach of implied warranty and breach of warranty of fitness for ordinary use claims are preempted, because they are premised on the assertion that the device was not safe or effective or should have been labeled, manufactured, or designed differently. However, Medtronic claims that such a conclusion would contradict the FDA's determination via the PMA process that the Device is safe and effective.[66]

In addition, Medtronic explains that the Fifth Circuit has already determined that claims under the LPLA, which provide the exclusive theories of liability for manufacturers in Louisiana, amount to a state law challenge to federal law by creating requirements that are different from or in addition to the federal requirements, and are therefore preempted.[67] Thus, Medtronic contends that all claims premised on a violation of the LPLA, which includes Plaintiff's express warranty and inadequate warning claims, must be dismissed based on Fifth Circuit precedent.[68] Further, Medtronic claims that Plaintiff's third cause of action for breach of express warranty under the LPLA fails because Plaintiff "does not allege what these warranties state and does not show that he relied on these alleged express warranties."[69]

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[65] *Id.* at pp. 17-18.

[66] *Id.* at p. 18.

[67] *Id.* at 17 (citing *Gomez*, 442 F.3d at 930-32).

[68] *Id.* at pp. 17-18; Rec. Doc. 70 at p. 10.

[69] Rec. Doc. 70 at p. 11; Rec. Doc. 56-1 at p. 29.

Medtronic further argues that Plaintiff's allegations are insufficient to survive a motion to dismiss. Medtronic specifically relies on the Fifth Circuit's holding in *Funk v. Stryker Corp.*,[70] that "impermissibly conclusory and vague pleadings that fail to specify the alleged defect that deviated from the FDA's requirements are insufficient to survive a motion to dismiss."[71] Here, Defendants claim that Plaintiff's only attempt to allege a parallel claim by identifying a "genuinely equivalent" federal requirement occurs in Plaintiff's seventh cause of action alleging off-label promotion and various supposed reporting violations without any supporting factual allegations.[72] Medtronic argues that "Plaintiff does not explain how violations of a federal requirement relate to the plaintiff's alleged injuries," especially when "the FDA-required label for the Infuse Device *did* include warnings about risks from off-label approaches, among other things."[73] Medtronic maintains that absent a causal connection between an alleged federal violation and the injury at issue, Fifth Circuit precedent requires that Plaintiff's attempts to establish a parallel claim based on violations of federal law fail.[74] Thus, Medtronic argues that Plaintiff fails to allege a parallel claim that meets the basic pleading requirements necessary to avoid dismissal.[75]

[70] 631 F.3d 777 (5th Cir. 2011).

[71] Rec. Doc. 56-1 at p. 21 (citing *id.* at 782).

[72] *Id.* at pp. 20-21.

[73] *Id.* at p. 24.

[74] *Id.* (citing *Funk*, 631 F.3d at 782).

[75] *Id.*

3. Allegations of Off-Label Promotion and Implied Preemption

According to Medtronic, none of Plaintiff's claims are saved by his allegations of off-label promotion or failure to report adverse events. Medtronic explains that "there is no express federal prohibition against off-label promotion."[76] Further, Medtronic states that Plaintiff has not identified any state law claim based on off-label promotion to support a valid parallel claim.[77] Indeed, Medtronic claims that Plaintiff cannot identify a valid state law claim because "the very concepts of off-label promotion and FDA adverse event reporting exist only within, and by virtue of, the federal regulatory scheme."[78] Thus, Medtronic argues that Plaintiff's claims must be dismissed because he has failed to identify a federal requirement that Medtronic has violated and a parallel pre-existing state law duty.[79] Moreover, Medtronic notes that district courts have found claims expressly preempted even when, as here, the plaintiff alleges off-label promotion of a device.[80]

Medtronic reasons that even if claims based on off-label promotion and violations of federal regulations were not expressly preempted, Plaintiff's claims are impliedly preempted under the analysis set forth by the Supreme Court in *Buckman*, and barred by the no private right of action provision found in 21 U.S.C. § 337(a), insofar as Plaintiff seeks to enforce the FDCA's

[76] *Id.* at p. 21 (citing *United States v. Caronia*, 703 F.3d 149, 167-69 (2d Cir. 2012)).

[77] *Id.*

[78] *Id.* at p. 22 (citing *Buckman*, 531 U.S. at 350; *Sons v. Medtronic, Inc.*, No. CIV-12-630-M, 2013 WL 164007, at *6 (W.D. La. Jan. 14, 2013)).

[79] *Id.* at pp. 19-21.

[80] *Id.* at 15-16 (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1283-88 (M.D. Fla. 2009); *Pardo v. Medtronic, Inc.*, No. 10-1562, 2010 WL 5300847, at *2, 4 (E.D. La. Dec. 15, 2010) (Lemelle, J.)).

provisions governing the approval of medical devices or off-label promotion.[81] Medtronic reasons that:

> By seeking to impose liability for an alleged violation of the federal restrictions on off-label promotion, Plaintiff is either (1) trying to usurp the FDA's regulatory oversight role for policing violations of the agency's regulations; or (2) basing his 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.[82]

4. Louisiana Law and the LPLA

Finally, because the LPLA provides "the exclusive theories of liability [in Louisiana] for manufacturers for damage cause by their products,"[83] Medtronic argues that Plaintiff's asserted claims outside of the LPLA must be dismissed on independent state law grounds. According to Medtronic, the LPLA provides for theories upon which a device may be deemed "unreasonably dangerous": (1) defective construction or composition; (2) defective design; (3) inadequate warning; and (4) failure to comply with an express warranty.[84] Thus, Medtronic asserts that Plaintiff's claims raised outside of the LPLA, including the claims of strict liability, negligence, breach of implied warranty, breach of warranty of fitness for ordinary use, and violations of federal regulations, must be dismissed because Louisiana law no longer recognizes these independent theories of recovery against a manufacturer.[85]

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[81] *See id.* at pp. 22, 26-27.

[82] *Id.* at pp. 26-27.

[83] *Id.* at p. 28 (citing *Sons*, 2013 WL 164007, at *6 (citing La. Rev. Stat. § 9:2800.52)).

[84] *Id.*

[85] *Id.* at pp. 28-29 (citing *McQuiston v. Boston Scientific Corp.*, No. 07-1723, 2009 WL 4016120, at *6 (W.D. La. Nov. 19, 2009) (citing *Jefferson v. Leads Indust. Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir. 1997))).

B. Plaintiff's Arguments

1. Device Specific Requirements

In opposition to the motion to dismiss, Plaintiff argues that the Court need not even reach Medtronic's preemption defense, because the "PMA does not establish device-specific federal requirements for [INFUSE] Bone Graft when used separately and cannot provided a basis for express preemption under § 360k(a).[86] According to Plaintiff, the PMA granted by the FDA applied to the Device, but the FDA never approved the INFUSE Bone Graft component for use separately.[87] Therefore, Plaintiff contends that the first step of the *Riegel* analysis is not satisfied, because there are no federal requirements applicable to the INFUSE Bone Graft component of the Device.

2. Preemption and Sufficiency of Plaintiff's Claims

In opposition to the motion to dismiss, Plaintiff asserts that the Device was only approved for anterior procedures and the FDA specifically instructed Defendants "to take measures to prohibit the off-label use and promotion of posterior uses."[88] According to Plaintiff, Medtronic was required to obtain FDA approval if it sought to legally promote the Device for posterior use, and so, by promoting the Device for off-label uses, Medtronic violated federal law. Further, Plaintiff claims that Medtronic's failure to obtain approval for the posterior use or provide adequate warnings for the off-label uses for which it was promoting the Device resulted in state tort liability. Therefore, Plaintiff argues that he seeks "to impose liability on Medtronic for

[86] Rec. Doc. 59 at p. 16.

[87] *Id.* at p. 8.

[88] *Id.* at p. 13.

Medtronic's conduct in violation of both federal law and state law, and thus Plaintiff's state-law claims parallel Medtronic's federal law duties."[89]

Plaintiff claims that he "has expressly alleged that Medtronic violated federal law in its improper promotion of INFUSE Bone Graft for off-label uses and failure to report adverse events," thereby inducing Plaintiff's surgeon to engage in an off-label use of the product.[90] Although Plaintiff agrees that off-label use is permitted, Plaintiff argues that federal law prohibits device manufacturers from promoting such off-label uses.[91] Therefore, Plaintiff claims that he has asserted a parallel claim that avoids preemption under the *Riegel* analysis, because "[t]he purpose of these federal prohibitions of off-label promotion is identical to the purpose behind Louisiana's tort law: to protect its citizens from unreasonably dangerous products."[92]

Plaintiff disputes Medtronic's conclusion that claims under the LPLA are expressly preempted. Plaintiff explains that the cases Medtronic relies upon to support its position that the LPLA claims are preempted "either involved approved on-label uses of Class III medical devices and/or were not premised on violations of federal regulations."[93] In contrast, Plaintiff refers the Court to a decision from the United States District Court for the District of Minnesota, *Riley v. Cordis Corp.*,[94] where the court held that state-law claims for injuries resulting from unlawful promotion of a medical device would escape preemption under §§ 360k(a) and 337.[95]

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[89] *Id.* at p. 17.

[90] *Id.* at 20.

[91] *Id.* at p. 21.

[92] *Id.*

[93] *Id.* at p. 24.

[94] 625 F. Supp. 2d 769.

[95] *Id.* 783-84.

Further, Plaintiff argues that the complaint "meets and exceeds the pleading requirement of *Twombly* and the pleading requirements pertaining to the specificity of 'parallel' claims in post-*Riegel* medical device cases."[96] Plaintiff explains that the complaint contains the following specific allegations:

> numerous pages describing the history of this medical device and Medtronic's [improper conduct after receiving PMA approval] with respect to the illegal off-label promotion of the device for unapproved uses, Medtronic's failure to report adverse events, his surgeon relied upon the representations and instructions given by Medtronic concern[ing] use of the device and efforts to hide or downplay those adverse events, and that he suffered injury (ectopic bone growth) as a result of the off-label uses of the device.[97]

Plaintiff also claims that many of the district and state courts that have considered the off-label promotion of medical devices have concluded that "state-law claims based on injury caused by illegal off-label promotion of medical devices are not preempted under 360k(a)."[98]

Even if the Court finds some claims expressly preempted, Plaintiff asserts that the claims for breach of warranty are not preempted pursuant to 21 C.F.R. § 808.1(d), which provides that certain state requirements are not preempted, including "requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as . . . the Uniform Commercial Code ["UCC"] (warranty of fitness))."[99] Plaintiff explains that his breach of warranty claims specifically allege that "Medtronic, through its undisclosed paid agents/consultants and sales representatives, made assurances regarding the safety and efficacy of the INFUSE Bone Graft component which were false and

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[96] Rec. Doc. 59 at p. 23.

[97] *Id.*

[98] *Id.* at p. 24 (citing *Riley*, 625 F. Supp. 2d 790; *Cornett v. Johnson & Johnson*, 48 A.3d 1041 (N.J. 2012); *Cabna v. Stryker Biotech, LLC*, No. BC 46531, 2013 WL 3876245 (Cal. Super. Aug. 20, 2012)).

[99] *Id.* at p. 28.

unsubstantiated.[100] Plaintiff explains that the express warranty claim, a recognized state law cause of action, seeks to enforce the very language which the FDA had approved, therefore paralleling the requirement made by the FDA.[101] Plaintiff clarifies that Medtronic's reliance on the Fifth Circuit's decision in *Gomez* is misplaced, because "a proper reading of *Gomez* actually allows a claim to go forward regarding labeling if that labeling has not been done in compliance with the FDA process."[102]

3. Implied Preemption

Plaintiff asserts that implied preemption, as articulated in *Buckman*, is inapplicable here, because *Buckman* involved allegations the FDA would not have approved the device if the manufacturer had not made fraudulent representations to the FDA regarding its indented use.[103] In contrast, Plaintiff contends that his allegations support traditional state tort law claims based on Medtronic's conduct in violation of federal prohibition against off-label promotion and failure to report and warn about adverse events."[104]

4. Louisiana Law and the LPLA

Plaintiff also argues that his other claims of negligence, breach of implied warranty, breach of warranty of fitness for ordinary use are not subsumed by the LPLA as Medtronic

[100] *Id.*

[101] *Id.*

[102] *Id.*

[103] *Id.* at p. 26.

[104] *Id.* at p. 27.

contends, because the LPLA is only the exclusive remedy against a manufacturer.[105] Therefore, Plaintiff argues that his claims independent of the LPLA can proceed against Medtronic in its role as an active marketer, promoter, and trainer of sales representatives on the off-label uses of the INFUSE Bone Graft, which is separate and apart from Medtronic's role as the manufacturer.[106]

IV. Standard of Review on a Motion to Dismiss

"The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when all well-pleaded facts are assumed true and are viewed in the light most favorable to the plaintiff."[107] "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."[108] Plaintiff must put forth sufficient factual allegations "to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true."[109] The court must not evaluate the likelihood of the claim's success, but instead ascertain whether the plaintiff has stated a legally cognizable claim that is plausible.[110] In deciding a motion to dismiss, a court may consider documents attached to or incorporated in the complaint and matters of which judicial notice may be taken pursuant to Federal Rule of Evidence 201(b) without turning the motion to dismiss into

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[105] *Id.* at 29.

[106] *Id.* (citing *In re Kaiser Plant Explosion at Kaiser*, 2001-2555 (La. 9/26/01), 797 So.2d 678).

[107] *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007)).

[108] *Reyna v. Donley*, 479 F. App'x 609, 611 (5th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotations omitted)).

[109] *Robinson v. Coca–Cola Co.*, 477 F. App'x 232, 235 (5th Cir. 2012) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d at 205).

[110] *Lone Star Fund*, 594 F.3d at 387 (citing *Iqbal*, 556 U.S. 662).

a motion for summary judgment.[111]

"The pleading standards for a Rule 12(b)(6) motion to dismiss are derived from Rule 8 of the Federal Rules of Civil Procedure, which provides, in relevant part, that a pleading stating a claim for relief must contain 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" [112] Although the court must accept all allegations in a complaint as true, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."[113] Moreover, "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law."[114]

V. Analysis

A. Effect of Allegations of Off-Label Promotion on Preemption Analysis

According to Plaintiff, "the fundamental issue in this case is whether federal law preempts state-law claims against manufacturers and/or marketers of a Class III medical device, where the plaintiff claims harm as a result of the illegal promotion of the medical device for uses not approved by the [FDA]."[115] In essence, Plaintiff's position is that §360k(a) does not preempt any state law claim that arises out of the promotion of an off-label use of a device. But Plaintiff's position as to the effect of allegations of off-label promotion is inconsistent with the text of § 360k(a). As other district courts confronting similar allegations have recognized:

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[111] *Funk*, 631 F.3d at 783; *see also Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790, 805 (W.D. La. 2008) (stating that a court "may take judicial notice of and consider the public records of the FDA . . . without transforming a [motion to dismiss] into a motion for summary judgment.").

[112] *In re McCoy*, 666 F.3d 924, 926 (5th Cir. 2012) (quoting Fed. R. Civ. P. 8(a)(2)).

[113] *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

[114] *Neitzke v. Williams*, 490 U.S. 319, 326 (1989) (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

[115] Rec. Doc. 59 at p. 7.

> under § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular use of a device; the question is whether there are federal requirements applicable "to the *device*." If there are—and, as *Riegel* makes clear, the PMA process unquestionably imposes such requirements—then any state requirements that are different from, or in addition to, those federal requirements are preempted. Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used.[116]

Similarly, nothing in § 360k(a) or *Riegel* suggests that applicability of the preemption analysis depends on how the device is being promoted to be used. Therefore, regardless of the Plaintiff's allegations of off-label promotion, each of the asserted causes of action must be analyzed to determine whether the asserted state law claim is expressly or impliedly preempted under § 360k(a) or § 337(a), respectively.[117]

B. Device Specific Requirements

The first step of the *Riegel* analysis requires the Court to determine whether the FDA has established requirements applicable to the INFUSE Bone Graft. Here, the Device is a Class III medical device approved by the FDA through the rigorous PMA process. Plaintiff contends that the PMA was granted on the Device and does not apply to the INFUSE Bone Graft component of the Device. However, Plaintiff neglects to cite any authority for its proposition.

In *Bass v. Stryker Corp.*,[118] the Fifth Circuit held that the district court did not err in finding that premarket approval granted for a medical device also established specific federal requirements applicable to a component of the medical device.[119] Persuasive authority from

[116] *Caplinger*, 2013 WL 453133, at *10 (quoting *Riley*, 625 F. Supp. 2d at 779).

[117] *See id.* (Oklahoma district court reaching the same conclusion when evaluating nearly identical allegations of off-label promotion).

[118] 669 F.3d 501.

[119] *Id.* at 508.

other district courts also indicates that the preemption analysis is not applied differently to the component parts of a medical device and the medical device itself that has received premarket approval.[120] Although the Court has not located any authority in this circuit involving the off-label use of a component part of the device, such off-label use is a corollary of the FDA regulatory system, and an unconvincing basis for finding the preemption analysis inapplicable here.

As Plaintiff notes, the PMA that the FDA approved for the Device was expressly restricted to the use of both components together: "These components must be used as a system. The InFUSE® Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device component."[121] However, as the Supreme Court explained 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."[122] Therefore, Plaintiff's physician was free to use the INFUSE Bone Graft component without the LT-Cage component, and such use was, by definition, an off-label use. In fact, Plaintiff even gives the present circumstances as an example of an off-label use, stating:

> Any application of INFUSE Bone Graft outside of its FDA approved usage is considered off-label. Examples of off-label uses include: when the rhBMP-2 is applied without using the LT-CAGE or with a substitute cage; use of INFUSE

[120] *See, e.g.*, *Duggan*, 840 F. Supp. 2d at 471 ("[O]nce premarket approval is granted, all claims relating to all components of the device are preempted."); *Wilhite*, 833 F. Supp. 2d at 762 ("[C]omponents of medical devices will not be separately considered when the device as a whole underwent the PMA process and received approval."); *Lewkut*, 724 F. Supp. 2d at 656 (preemption applied because medical device had Premarket Approval, even though the allegedly defective component had previously been regulated through a different process); *Riley*, 625 F. Supp. 2d at 780 (finding components of a PMA-approved device work together as a single medical device, and that picking these components apart to apply different preemption analysis "makes no sense").

[121] Rec. Doc. 59 at p. 16.

[122] 531 U.S. at 350.

> Bone Graft in a PLIF, TLIF or any other procedure besides an ALIF procedure using the LT-CAGE; or use of INFUSE Bone Graft in an ALIF procedure that involved a multiple-level fusion.[123]

The Court agrees with Plaintiff that the above-listed examples of applications of the Device are, in fact, off-label uses, including the use of only part of the Device. Therefore, Plaintiff's arguments undercut his position against preemption, because Plaintiff is essentially arguing that preemption is inapplicable here because using the INFUSE Bone Graft component alone was an off-label use of the Device. This argument is clearly inconsistent with *Riegel* which also involved the off-label use of a medical device.[124] Moreover, the Plaintiff's complaint even states that "[t]he FDA has [] approved INFUSE Bone Graft."[125] Accordingly, because the INFUSE Bone Graft received premarket approval from the FDA through the PMA process as a component part of the medical device, the first condition under the *Riegel* two-step analysis is satisfied.[126]

C. Plaintiff's State Law Causes of Action

Having determined that requirements specific to the INFUSE Bone Graft have been imposed by the FDA, the Court must determine whether the state law causes of action Plaintiff alleges impose requirements different from or in addition to those established by the FDA. Plaintiff's first cause of action alleges that the INFUSE Bone Graft was unreasonably dangerous pursuant to the LPLA, because Medtronic gave inadequate warnings regarding the risks

[123] Rec. Doc. 1 ¶ 46.

[124] *See* 552 U.S. at 320.

[125] Rec. Doc. 1 ¶ 1.

[126] *See Riegel*, 552 U.S. at 321.

associated with off-label use of the device.[127] Plaintiff has not alleged that Medtronic failed to provide the warnings and labels required by the FDA, but rather contends that Medtronic should have added to, or changed, its warnings for the Device to account for risks created by alleged off-label promotion. Under Louisiana Revised Statute § 9:2800.57(A), a claim for inadequate warning exists when "[a] product is unreasonably dangerous because an adequate warning about the product has not been provided if . . . the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic." Therefore, in order for Plaintiff to succeed on this cause of action, the fact finder would have to find that the Device required additional warnings and labels beyond those approved by the FDA in the PMA process, but these additional warnings and labels are precisely the type of additional requirements which are expressly preempted by § 360k(a).[128]

However, a claim for inadequate warning also exists under Louisiana Revised Statute § 9:2800.57(C) when:

> [a] manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

Here, Plaintiff's inadequate warning claim alleges that:

> [t]he subject device manufactured and promoted by Defendants was also defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject device, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the device, and/or

[127] La. Rev. Stat. § 9:2800.57.

[128] *See Sons*, 2013 WL 164007, at *5; *see also Hinkel v. St. Jude Med., S.C.*, 569 F. Supp. 2d 739, 747-48 (E.D. La. 2012) (Barbier, J.) (inadequate warning claim preempted).

> alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the device could cause serious injury.[129]

In the complaint and in post-hearing briefing, Plaintiff identifies federal regulations which imposed reporting and supplementation obligations on Defendants after the PMA was granted,[130] and Plaintiff alleges that Medtronic failed to comply with those obligations. In particular, Plaintiff asserts that "Conditions of Approval" of the PMA granted for the Device specifically included the obligation under 21 C.F.R. § 803.50 to report incidents in which the device may have caused or contributed to serious injury and the obligation under 21 C.F.R. § 814.39 to submit a PMA supplement when unanticipated adverse effects or increases in incidences of anticipated adverse effects occur.[131]

In *Hughes v. Boston Scientific Corp.*,[132] the plaintiffs were also "proceeding on the theory that [the defendant] failed to comply with the FDA's [] regulations requiring a manufacturer of a Class III device to report incidents in which the device may have caused or contributed to a death or "serious injury."[133] Assuming that Mississippi law imposed a duty on manufacturers to provide adequate warnings or instructions, which included a duty to provide "reasonable warnings" of risks, the Fifth Circuit concluded that:

> [the plaintiff's] claim is not expressly preempted to the extent she asserts that [the manufacturer] violated the state duty to warn by failing to accurately report serious injuries and malfunctions of the [] device as required by the FDA's []

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[129] Rec. Doc. 1 ¶ 65.

[130] *See id.* ¶ 114 (citing 21 C.F.R. § 803.50 (requiring reporting of adverse events); 21 C.F.R. § 803.56 (requiring prompt investigation of all serious, adverse drug experiences); 21 C.F.R. § 814.39 (submission of a PMA Supplement); 21 C.F.R. § 814.84 (requiring periodic reporting).

[131] Rec. Doc. 67 at p. 4.

[132] 631 F.3d 762 (5th Cir. 2011).

[133] *Id.* at 766 (citing 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a)).

> regulations. The [] regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, and this information is disseminated to the public.
>
> A factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks. Thus, we are satisfied that [the plaintiff's] failure to warn claim is not expressly preempted to the extent that it is based on [the manufacturer's] violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the HTA device. This claim does not impose additional or different requirements to the federal regulations, but is parallel to the federal requirements.[134]

Defendants attempt to distinguish *Hughes* from this case by emphasizing that the survival of the plaintiff's failure to warn claim in *Hughes* was premised on Mississippi law, which permits such a claim, whereas, Defendant argues, Louisiana law recognizes no "analogous state-law duty."[135] This Court disagrees. The Fifth Circuit found in *Hughes* that the manufacturer's alleged failure to report serious injuries under the FDA regulations breached a duty under Mississippi law to provide reasonable warnings of risk. Similarly, the LPLA recognizes that the manufacturer has a duty to use reasonable care to provide an adequate warning to users and handlers of the device if it knows or should have known that the device presents a serious risk of harm even after the device has left the manufacturer's control,[136] and Plaintiff has alleged that Medtronic violated the analogous duties owed under the federal regulations to report adverse events. *Hughes* determines that the state law duty to provide adequate warnings and the federal reporting requirements imposed by 21 C.F.R. § 803.50 are parallel. Thus, insofar as Plaintiff inadequate warning claim is premised on a violation of FDA reporting requirements, he has adequately alleged a valid parallel claim, sufficient to withstand a motion to dismiss.

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[134] *Id*. at 770-771.

[135] Rec. Doc. 56-1 at p. 22.

[136] *See* La. Rev. Stat. § 9:2800.57(C).

Plaintiff's second cause of action, based on strict liability, alleges that Defendants acted in a willful, wanton, and reckless manner, because they "knew that INFUSE Bone Graft, when used in off-label procedures as promoted by Defendants, was unsafe, defective, and unreasonably dangerous."[137] In *Riegel* and *Lohr*, the Supreme Court concluded that "the common-law causes of action for negligence and strict liability . . . imposed 'requirements' that [are] preempted by federal requirements."[138] In *Gomez*, the Fifth Circuit found that a strict liability defective design cause of action under Louisiana law was expressly preempted. The Fifth Circuit elaborated that "[t]o permit a jury to second-guess the [device] design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria."[139]

Courts have drawn similar conclusions with respect to preemption of causes of action based on negligence.[140] Plaintiff's sixth cause of action alleges that "Defendants failed to exercise ordinary care in promoting, marketing and/or sale of INFUSE Bone Graft," because "they knew or should have known that using INFUSE Bone Graft in off-label procedures caused a risk of unreasonable, dangerous and permanent adverse effects."[141] The Fifth Circuit held in *Gomez* that "[n]o negligence claims can be maintained as to devices that complied with the FDA requiements because success on those claims requires a showing that the FDA requirements themselves were deficient." Therefore, in *Gomez*, the Fifth Circuit found that the district court

[137] Rec. Doc. 1 ¶ 84.

[138] *Riegel*, 552 U.S. at 332 (Stevens, J., concurring) (citing *Lohr*, 518 U.S. at 504-505).

[139] 442 F.3d at 930.

[140] *See, e.g.*, *Riegel*, 552 U.S. at 332-33 ("And although not all common-law rules qualify as 'requirements,' the Court correctly points out that five Justices in *Lohr* concluded that the common-law causes of action for negligence and strict liability at issue in that case imposed 'requirements' that were pre-empted by federal requirements specific to a medical device.").

[141] Rec. Doc. 1 ¶ 107.

properly limited the plaintiff's negligence claim, under the LPLA, to "a claim that the [device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications."[142]

Plaintiff's second and sixth causes of action, based on strict liability and negligence, must also be dismissed on independent state law grounds. Even if Plaintiff had adequately alleged FDA requirements that Medtronic did not comply with and identified the parallel requirements imposed by Plaintiff's Louisiana strict liability and negligence claims, it is well-established that the LPLA provides "the exclusive theories of liability for manufacturers for damages caused by their products."[143] In *Jefferson v. Lead Industries Association, Inc.*,[144] the Fifth Circuit explained that "[w]hile the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer."[145] In addition, "breach of implied warranty . . . is not available as a theory of recovery for personal injury."[146] District courts in Louisiana that have considered the application of the LPLA in medical device cases have also concluded that all causes of action asserted outside of the LPLA framework are not viable as independent theories of recovery, and must be dismissed.[147]

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[142] 442 F.3d at 933.

[143] La. Rev. Stat. § 9:2800.52.

[144] 106 F.3d 1245.

[145] *Id.* at 1251.

[146] *Id.*

[147] *Sons*, 2013 WL 134007 at *6; *see also King v. Bayer Pharm. Corp.*, No. 09-0465, 2009 WL 2135223, at *4 (W.D. La. July 13, 2009); *Doucet v. Danek Medical Inc.*, No. CIV. A. 6:96-2439, 1999 WL 1129648 (W.D. La. June 28, 1999).

Plaintiff relies on the opinion from the Supreme Court of Louisiana, in *In re Kaiser Plant Explosion at Kaiser*,[148] to argue that he may pursue claims outside of the LPLA against Medtronic in its role other than a manufacturer. *Kaiser* arose out of an explosion at an aluminum processing plant, and the Louisiana Supreme Court's summary opinion contained a one sentence explanation for the decision to reinstate the trial court's denial of summary judgment: that "genuine issues of material fact as to whether [the defendant] acted in a role other than manufacturer."[149] Therefore, the Court is unconvinced by Plaintiff's reliance on *In re Kaiser Plant Explosion at Kaiser* as authority supporting that Plaintiff may pursue an action against a medical device manufacturer independently of the LPLA. Further, The LPLA defines manufacturers to include "[a] seller of a product who exercises control over or influences a characteristic of the design, construction or quality of the product that causes damage."[150] Given the broad definition of "manufacturers" provided in the LPLA, it is unconvincing that the LPLA should be interpreted in contravention of the plain language of the statute that the exclusive remedy against manufacturers is under the LPLA. Accordingly, Plaintiff's claims against Medtronic for negligence and strict liability must be dismissed on independent grounds under Louisiana law, because the only remedies available to Plaintiff in this case are provided in the LPLA.

Regarding Plaintiff's third, fourth and fifth causes of action alleging breach of express warranty, breach of warranty of fitness for ordinary use, and breach of implied warranty of merchantability and fitness, Plaintiff would be required to persuade the fact finder that the

[148] 2001-2555 (La. 9/26/01); 797 So. 2d 678.

[149] *Id.*

[150] La. Rev. Stat. § 9:2800.53(1)(b).

Device was not safe and effective, a finding that would be contrary to the FDA's approval. In *Gomez*, the plaintiff also alleged an express warranty claim under the LPLA, and the U.S. Fifth Circuit found that Louisiana law "goes beyond merely enforcing the federal requirements," but "requires proof that 'the express warranty was untrue.'"[151] The Fifth Circuit went on:

> A jury hearing [the plaintiff's] state-law breach of express warranty claim would have to decide whether [the defendant's] representations about the [medical device] were true. Because those representations-including the label, warnings, and [Instructions For Use]-were approved by the FDA through the PMA process, the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme. The claim is preempted.[152]

Louisiana's federal district courts have consistently applied *Gomez* in finding that express warranty claims under the LPLA are preempted.[153] Moreover, Plaintiff has never managed to articulate the terms of any express warranty made to him by Medtronic or how the express warranty caused Plaintiff's injuries. Therefore, Plaintiff has failed to allege the necessary elements to support a breach of express warranty claim under the LPLA, even if an express warranty claim was not preempted.

In addition, Plaintiff's breach of implied warranty and breach of warranty of fitness for ordinary use claims set forth in the fourth and fifth causes of action must be dismissed. First, in *Gomez*, the Fifth Circuit considered the plaintiff's claim under a theory of redhibition, "which is

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[151] 442 F.3d at 932 (quoting La. Rev. Stat. § 9:2800.58).

[152] *Id.*

[153] *See Hinkel*, 869 F. Supp. 2d at 747-48 (citing *Gomez* and noting that a breach of express warranty claim preempted); *Cenac v. Hubbell*, No. 09-3686, 2010 WL 4174573, at *6 (E.D. La. Oct. 21, 2010) (Africk, J.); *Bencomo v. Guidant Corp.*, No. 06-2473, 2009 WL 1951821, at *5-6 (E.D. La. June 30, 2009) (Barbier, J.); *McQuiston*, 2009 WL 4016120, at *6-7; *Poole v. Hologic, Inc.*, No. 10-314, 2010 WL 3021528, at *5 (W.D. La. July 29, 2010).

Louisiana's equivalent to a breach of implied warranty claim."[154] The Fifth Circuit explained that the FDA approves the warnings, labels, and instructions and information for physicians and patients pertaining to the medical device, and once approved, the medical device manufactures have ongoing obligations to report experience with the device to the FDA.[155] Ultimately, "the FDA has the plenary authority to amend the regulations and requirements it imposed relating to the device, up to and including removing it from the market."[156] Therefore, the Fifth Circuit held that the implied warranty claim was preempted, because "[t]o permit a jury to decide [the plaintiff's implied warranty] claims . . . would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the plaintiff]."[157] Second, as discussed in greater detail above, Plaintiffs breach of implied warranty and breach of warranty of fitness for ordinary use claims are outside of the LPLA framework, and therefore no longer viable claims against a manufacturer in Louisiana. Accordingly, Plaintiffs express and implied warranty claims must be dismissed.

Plaintiff's seventh cause of action is entitled "Violations of Federal Regulations," and lists without any supporting factual allegations eight provisions of the FDCA and corresponding federal regulations which Plaintiff's allegedly violated.[158] To the extent that Plaintiff seeks to enforce the alleged violations of federal law, his claim must be dismissed because § 337(a) of the FDCA clearly states that an action for "enforcement, or to restrain violations, of the[e] [FDCA]

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[154] 442 F.3d at 931.

[155] *Id.*

[156] *Id.*

[157] *Id.*; *accord Riegel*, 552 U.S. at 327–28 (affirming dismissal of implied warranty claims on preemption grounds); *Hinkel*, 869 F. Supp. 2d at 747-48; *Cenac*, 2010 WL 4174573 at *6; *Bencomo*, 2009 WL 1951821 at *5-6; *McQuiston*, 2009 WL 4016120, at *5.

[158] Rec. Doc. 1 ¶114.

shall be by and in the name of the United States." Further, Plaintiff's seventh cause of action must cannot survive a motion to dismiss, because Louisiana does not recognize any claim for violations of FDA regulations. Other district courts in Louisiana have similarly concluded that these claims must be dismissed, because the "only remedies available to plaintiff[] in this case are provided in the LPLA."[159]

Alternatively, Plaintiff may be attempting to identify the federal requirements Defendants violated in order to assert a valid parallel claim. First, Plaintiff fails to identify the traditional state law duties that are "parallel" or "genuinely equivalent" to the eight FDA requirements Plaintiff alleges were violated.[160] Second, "to plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard."[161] In *Bass*, the Fifth Circuit permitted a defect manufacturing claim, noting that "[t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is . . . the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury."[162] In this case, Plaintiff has failed to identify violations of federal regulations and provide allegations connecting those violations to Plaintiff's specific injury.

[159] *Sons*, 2013 WL 164007, at *6.

[160] *Riegel*, 552 U.S. at 331; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011).

[161] *Bass*, 669 F.3d at 509.

[162] *Id.* at 511.

D. Implied Preemption and Bar on a Private Cause of Action under the FDCA

Plaintiff claims that his allegations of off-label promotion save his state law claims from preemption, because promoting a device for off-label use is deemed "misbranding" in violation of 21 U.S.C. § 351(f). However, to state a valid parallel claim that is not expressly preempted by § 360k(a), impliedly preempted by § 337(a), or barred by the "no private cause of action," Plaintiff must do more than demonstrate that Defendants violated FDA regulations and requirements; Plaintiff must also demonstrate how that conduct breaches a well-recognized state duty. The conduct complained of here—the promotion of the INFUSE Bone Graft in off-label procedures by Medtronic—is regulated by the FDCA. There is no Louisiana state law claim premised on off-label promotion. Indeed, the very concept of "off-label" use and promotion is derived from the regulatory system imposed by the MDA and the FDCA. Therefore, to the extent that Plaintiff's claims are premised on allegations of off-label promotion of the INFUSE Bone Graft, the claims are impliedly preempted under *Buckman* and § 337(a).[163]

V. Conclusion

For the foregoing reasons, Plaintiffs second through sixth causes of action must be dismissed because they are expressly or impliedly preempted by the MDA, prohibited by the § 337(a), and/or barred under Louisiana law. Plaintiff's seventh cause of action fails to allege with particularity sufficient allegations to survive a motion to dismiss. Further, it appears that claims premised on the alleged violations of federal law cited in Plaintiff's seventh cause of action may be impliedly preempted. Nevertheless, Plaintiff is granted leave to amend, if possible, his

[163] *Buckman*, 531 U.S. at 350.

seventh cause of action to state a valid parallel claim.[164] Finally, Plaintiff's claim for inadequate warning under the LPLA survives preemption insofar as Plaintiff's inadequate warning claim is premised on a violation of FDA reporting requirements, and therefore alleges a valid parallel claim sufficient to withstand a motion to dismiss. Accordingly,

IT IS HEREBY ORDERED that the Amended Motion to Dismiss Plaintiff's Complaint[165] is **GRANTED IN PART** and **DENIED IN PART**;

IT IS FURTHER ORDERED that Plaintiff's second through sixth causes of action based on strict liability, breach of warranty, and negligence are **DISMISSED WITH PREJUDICE**;

IT IS FURTHER ORDERED that Plaintiff is granted leave to amend his seventh cause of action to state a valid parallel claim by **August 19, 2013**.

NEW ORLEANS, LOUSIANA, this 19th day of July, 2013.

Nannette Jolivette Brown

NANNETTE JOLIVETTE BROWN
UNITED STATES DISTRICT JUDGE

[164] *See, e.g.*, *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) (instructing that when a district court dismisses the complaint, but does not terminate the action altogether, the plaintiff may amend under Rule 15(a) with permission of the district court); *Dowdy v. Procter & Gamble Mfg. Co.*, 267 F.2d 827, 828 (5th Cir. 1959) ("It is also equally true, under the settled law in this circuit, that, if [the complaint] did not state such a claim, the district judge was in error in dismissing it without granting leave to amend.").

[165] Rec. Doc. 56.