UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ANGIE L. WRIGHT,

Plaintiff,

Case No. 1:13-cv-716

v.

HON. JANET T. NEFF

MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK, USA, INC., and MEDTRONIC VERTELINK, INC.,

Defendants.

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OPINION

Pending before the Court in this diversity-products liability action is Defendants' Motion to Dismiss (Dkt 113). Plaintiff filed a response in opposition to Defendants' motion (Dkt 115), and Defendants filed a reply (Dkt 116). Defendants have also since filed numerous supplemental authorities for the Court's consideration (Dkts 123-26, 131-33). Having conducted a Pre-Motion Conference in this matter and having fully considered the parties' written briefs and accompanying exhibits, the Court finds that the relevant facts and arguments are adequately presented in these materials and that oral argument would not aid the decisional process. *See* W.D. Mich. LCivR 7.2(d). For the reasons that follow, the Court determines that Defendants' motion is properly granted in part and denied in part.

I. BACKGROUND

Defendants, whom Plaintiff sometimes collectively references as "Medtronic," design, manufacture, construct, assemble, inspect and sell various types of medical drugs and devices,

including spinal surgery drugs and devices, and specifically the Infuse Bone Graft and LT-Cage, collectively known as "Infuse," which is the medical device at issue in this case (Dkt 95, First Amend. Compl. ¶ 5).[1] Infuse, the trade name for rhBMP-2, a bone morphogenetic protein, is used as an alternative to procuring bone graft material from another part of a patient's body or from a cadaver (*id.* ¶¶ 79-82).

On July 2, 2002, the Food and Drug Administration (FDA) approved Infuse for use in an Anterior Lumbar Interbody Fusion (ALIF) procedure involving a single-level fusion in the L4-S1 region of the lumbar spine (Dkt 95, First Amend. Compl. ¶¶ 57-58, 84, 88). ALIF is performed by approaching the spine from the front through an incision in the abdomen and is primarily used to treat pain resulting from disc collapse (*id.* ¶¶ 58, 88). Infuse's FDA-approved label indicates the following:

> The InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device consists of two components containing three parts—a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. The InFUSE™ Bone Graft is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. **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.**

(Defs.' Ex. 3, Dkt 114-3 at 2) (emphases in original). The label further indicates that the device "is to be implanted via an anterior . . . approach," warning that "[t]he safety and effectiveness of the InFUSE Bone Graft component . . . used in surgical techniques other than anterior . . . approaches

[1]This Court has another case on its docket, *Thorn v. Medtronic*, No. 1:13-cv-239, involving the same device also implanted in an off-label manner.

have not been established" (*id.* at 4-5). The label expressly cautions that "the potential for ectopic . . . or undesirable exuberant bone formation exists" (*id.* at 6).

Plaintiff indicates that 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 (Dkt 95, First Amended Compl. at 22 n.1). 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 (*id.*). Similarly, Plaintiff represents that while Infuse was initially approved in 2002 for use with the LT-CAGE component, the FDA later approved it for use with an INTER FIX Cage component in 2003 (*id.* at 34 n.2).

On March 11, 2010, Plaintiff, a Michigan resident, had a spinal surgery using Defendants' Infuse device in an off-label manner (Dkt 95, First Amend. Compl. ¶¶ 1, 105). "Instead of performing an anterior procedure, Plaintiff's surgeon opted for a posterior procedure with an unapproved cage/spacer product" (*id.* ¶ 106). Plaintiff alleges that Defendants, through their sales representatives and paid "Key Opinion Leaders," directly and indirectly promoted, trained and encouraged Plaintiff's surgeon to use the Infuse Bone Graft in an off-label manner, including using it in posterior procedures and using the rh-BMP2 component of Infuse with an unapproved cage or spacer (*id.* ¶ 107). Plaintiff alleges that she "never recovered from her surgery and continues to have daily severe disabling back and nerve pain, and has had to have two spinal cord stimulators implanted into her back on two separate occasions" (*id.* ¶¶ 53, 108).

In her five-count First Amended Complaint filed on November 21, 2013, Plaintiff alleges "Failure to Warn" (Count I); "Design Defect" (Count II); "Negligence" (Count III); "Fraud" (Count IV); and "Breach of Express and Implied Warranties" (Count V) (Dkt 95). In lieu of answering the

First Amended Complaint, Defendants filed a Pre-Motion Conference request, proposing to file a motion to dismiss Plaintiff's First Amended Complaint (Dkt 97). Following a Pre-Motion Conference in December 2013, this Court issued a briefing schedule on the proposed motion (Dkt 102). The parties filed their motion papers in March 2014 (Dkts 113-22).

II. MOTION STANDARD

Defendants filed their motion to dismiss under FED. R. CIV. P. 12(b)(6), arguing, in pertinent part, that Plaintiff's claims are preempted. *See Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 608 (6th Cir. 2004) (explaining that preemption does not normally concern the subject-matter jurisdiction of a court to hear a claim, but "the merits of the claim itself—namely, whether it is viable and which sovereign's law will govern its resolution").

Defendants also assert under Rule 12(b)(6) that Plaintiff's claims fail on independent federal and state-law grounds. Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A complaint will survive a motion to dismiss if the plaintiff alleges facts that "state a claim to relief that is plausible on its face" and that, if accepted as true, are sufficient to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007). The plausibility standard "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility . . . .'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Specifically, the Sixth Circuit Court of Appeals

has held that "[i]n complying with Rule 9(b), a plaintiff, at a minimum, must allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993) (internal quotation marks omitted)). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b).

In deciding a motion to dismiss for failure to state a claim under FED. R. CIV. P. 12(b)(6), the court must treat all well-pleaded allegations in the complaint as true and draw all reasonable inferences from those allegations in favor of the nonmoving party. *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield,* 552 F.3d 430, 434 (6th Cir. 2008). "[W]hen a document is referred to in the pleadings and is integral to the claims, it may be considered without converting a motion to dismiss into one for summary judgment." *Commercial Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 335-36 (6th Cir. 2007). Also, "[a] court may consider public records without converting a Rule 12(b)(6) motion into a Rule 56 motion." *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008). *See, e.g., Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (taking judicial notice of the FDA-approved label and the statements contained therein because the label "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (granting request for judicial notice of drug labels publicly available on FDA website in connection with motion to dismiss).

"[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action,

supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Further, "the court need not accept as true a legal conclusion couched as a factual allegation, or an unwarranted factual inference." *Handy-Clay v. City of Memphis, Tenn.*, 695 F.3d 531, 539 (6th Cir. 2012) (citation and internal quotation marks omitted). The parties do not dispute for purposes of this motion that the substantive law of Michigan, the forum state, applies to the issues presented. *See generally Hardy v. Reynolds & Reynolds Co.*, 311 F. App'x 759, 761 (6th Cir. 2009) (discussing choice of law rules in a diversity case).

III. ANALYSIS

A. Overview of the Parties' Arguments

The federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, 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. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). With the passage of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq.*, Congress swept back some state obligations and imposed a regime of detailed federal oversight of medical devices. *Id.* "The federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and [] this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (indicating that the FDA is empowered to investigate suspected fraud, *see* 21 U.S.C. § 372; 21 C.F.R. § 5.35, and citizens may report wrongdoing and petition the agency to take action, § 10.30).

"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." *Buckman*, 531 U.S. at 350. The FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Thus, "the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman*, 531 U.S. at 350. Defendants argue that Plaintiff's state-law claims against them encroach upon the federal enforcement scheme and are preempted by the MDA, either expressly or impliedly. Defendants further argue that Plaintiff's claims fail on several independent federal and state-law grounds.

1. *Express Preemption*

Congress included an express pre-emption provision in the MDA, which provides in pertinent part that "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, (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 set forth a two-step analysis for courts to determine whether the MDA expressly preempts a state-law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321. If the first step is answered in the affirmative, then the court must proceed to the second step. The second step requires a court to determine

whether the state law claims are based on state requirements that are "different from, or in addition to," the federal requirements. *Id.* at 321-22. "State requirements" include a state's common law legal duties. *Id.* at 324-25. If the state requirements stemming from the claim differ from, or add to, the federal requirements, then the state claim is expressly preempted by operation of § 360k(a).

However, state claims that are premised on a violation of FDA regulations escape express preemption, as they are considered "parallel," rather than different from, or in addition to, the federal requirements. *Riegel*, 552 U.S. at 324-25. *See generally Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *2 (C.D. Cal. June 25, 2014) (discussing two-step analysis). "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*)." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (emphases in original).

Defendants argue that Plaintiff's claims are expressly preempted in their entirety by the MDA, as interpreted by the Supreme Court in *Riegel*, because the claims seek to impose state-law requirements on the design, manufacture or labeling of the medical device at issue in this case that are different from or in addition to the federal requirements imposed by the FDA (Dkt 114 at 17-20). Defendants argue that Plaintiff's allegations of off-label use or promotion do not negate premarket approval or its preemptive effect (*id.* at 23-24). Defendants emphasize that federal preemption under § 360k(a) does not turn on how a device is promoted (*id.* at 24).

In response, Plaintiff argues that this case does not present a preemption issue because the FDA has not set requirements applicable to the bone protein without the LT-CAGE or in posterior

approaches (Dkt 117 at 9-11). Plaintiff also asserts that she has stated parallel claims under Michigan's tort law and its products liability statute, MICH. COMP. LAWS § 600.2945 (*id.* at 11-23).

2. *Implied Preemption*

Section 337(a) of the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Citing § 337(a), the United States Supreme Court opined that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349, n.4. Indeed, the Supreme Court interpreted this provision to mean that even state claims that run parallel to federal requirements are impliedly preempted unless they are grounded in traditional state tort law and do not depend exclusively on a federal requirement. *Id.* at 353.

As pointed out by other courts, this does not mean that a plaintiff can never bring a state law claim based on conduct that violates the FDCA. *Dunbar,* 2014 WL 3056026, at *3. In fact, the conduct that gives rise to the claim must violate the FDCA to escape express preemption. *Id.* Instead, to avoid implied preemption, the conduct giving rise to the state claim must also be the type of conduct that would traditionally give rise to liability under state law "even if the FDCA had never been enacted." *Id.* (citing *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1175 (C.D. Cal. 2013) (*Houston I*)).

Defendants argue that there is no traditional state-law duty to abstain from off-label promotion and that, even if Plaintiff had stated such a parallel claim, any claim predicated on off-label promotion must be dismissed as impliedly preempted under *Buckman* and § 337(a) (Dkt 114 at 29-31). Defendants emphasize that the distinction between on-label and off-label use is a creation

of federal law and exists only by virtue of the federal regulatory scheme (*id.* at 31). In response, Plaintiff argues that the Supreme Court's decision in *Buckman* does not fit the facts here, where Plaintiff's claims arise "entirely under Michigan law" and where Defendants' violations of federal prohibitions against off-label promotion and failure to report adverse events "are not an element of any of Ms. Wright's claims" (Dkt 117 at 27).

3. *Independent Federal & State Law Grounds*

Last, Defendants argue that in addition to being expressly and impliedly preempted, Plaintiff's claims fail on independent federal and state-law grounds (Dkt 114 at 32). Specifically, Defendants argue that Plaintiff's failure to warn and negligence claims must both be dismissed because, pursuant to the learned intermediary doctrine and Michigan's codification of the sophisticated user doctrine, Defendants had no duty to provide Plaintiff's surgeons warnings beyond those required by the FDA through the premarket approval process, to wit: the FDA-approved labeling for the Infuse device (*id.* at 32-33). Defendants argue that Plaintiff's warranty claim fails because Defendants unambiguously disclaimed all warranties and there is no privity of contract between the parties (*id.* at 33-34). Last, Defendants argue that Plaintiff's fraud claim is fatally flawed where the allegations (1) are based upon "information and belief," (2) are "confusing and contradictory," (3) are inadequate for alleging that (a) her surgeon was an agent of Medtronic, (b) treating patients was within the scope of any purported agency, or (c) her surgeon made a false representation of fact upon which she relied; and (4) do not include an actual representation or omission that was made by Medtronic and relied on by her surgeon (*id.* at 34-39).

Relative to her negligence and failure-to-warn claims, Plaintiff responds that Defendants' reliance on the learned intermediary and sophisticated user doctrines is misplaced (Dkt 117 at 29-

30). Plaintiff argues that her warranty claims also prevail because (1) the claims are based on Defendants' "express warranties made to the medical community," (2) it is sufficient that privity of contract existed between Plaintiff's physician and Medtronic; (3) Plaintiff's First Amended Complaint is "replete with representations made by Medtronic to the medical community;" and (4) Defendants are not exempt from strict liability where they improperly marketed the device for dangerous off-label uses (*id.* at 31). Last, Plaintiff argues that her fraud claim is pleaded with sufficient particularity (*id.* at 32-37).

B. Plaintiff's Claims

1. *Failure to Warn*

In Count I ("Failure to Warn"), Plaintiff alleges that Defendants "illegally promoted the Infuse Bone Graft for off-label uses in violation of federal law—thereby forfeiting U.S.C. § 360k protection" (Dkt 95, First Amend. Compl. ¶ 110). Plaintiff alleges that Defendants had (1) "a parallel common law duty to fully and adequately warn Plaintiff and Plaintiff's physicians of the true health and safety risks related to the off-label use of Infuse;" (2) "a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse without an LT-Cage or INTER FIX Cage and the placement of Infuse posteriorly for lumbar spine surgeries;" (3) "a duty not to conceal the dangers of the off-label use of Infuse to Plaintiff and her physicians;" and (4) a duty to "fully and accurately disclose [to] the Plaintiff and her physicians the true health and safety risks related to Infuse and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices" (*id.* ¶¶ 110-11). Plaintiff alleges that through their described conduct, Defendants "breached their duties to Plaintiff and to Plaintiff's physicians" (*id.* ¶ 112). According to Plaintiff's First Amended Complaint, Defendants "negligently, carelessly and

recklessly failed to adequately warn the medical community, the general public, Plaintiff's surgeon and Plaintiff of the dangers, contra-indications, and side effects from the off-label use of Infuse Bone Graft" and "negated its own warnings by promoting the Infuse Bone Graft for off-label uses, such as the off-label procedures used in Plaintiff's surgeries" (*id.* ¶ 113).

The first step of the express preemption analysis, whether the FDA has established requirements applicable to the particular medical device at issue, *Riegel*, 552 U.S. at 321, is automatically satisfied where, as here, the device has received premarket approval (PMA). The second step of the express preemption analysis, the only step at issue here, requires this Court to determine whether the state requirements upon which Plaintiff's claim is based are "different from, or in addition to," the federal requirements. *See id.* at 321-22. The parties do not dispute that Michigan law requires manufacturers to provide adequate warnings, and, like the parties, the Court assumes for purposes of the motion that Defendants' conduct allegedly violates state law.

Federal law does not expressly define or ban off-label promotion. Courts have held that the FDCA's misbranding provisions and 21 C.F.R. § 814.80 together constitute "the federal requirements" for purposes of *Riegel's* second step. *Arthur v. Medtronic, Inc.*, No. 4:14-CV-52 CEJ, 2014 WL 3894365, at *5 (E.D. Mo. Aug. 11, 2014) (citing *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1034-35 (D. Hawaii 2014); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 884-85 (N.D. Cal. 2013) (*Eidson I*); and *Houston I*, 957 F. Supp. 2d at 1179). Specifically, the FDCA prohibits "[t]he adulteration or misbranding of any food, drug, [or] device ... in interstate commerce" and "[t]he introduction or delivery for introduction onto interstate commerce of any food, drug, [or] device ... that is adulterated or misbranded." 21 U.S.C. §§ 331(a) and (b). A device is misbranded if its labeling, or advertising, is "false or misleading." § 352(a) (labeling), § 352(q) (advertising).

Whether the labeling or advertising is misleading is determined by considering the "representation made or suggested by statement, word, device, or any combination thereof." § 321(n). Last, FDCA regulations restrict a manufacturer's ability to engage in off-label promotion: 21 C.F.R. § 814.80 states that "[a] device may not be manufactured, packaged, stored, labeled, distributed, or *advertised* in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device" (emphasis added). Out of this "muddy statutory and regulatory framework," courts have determined that "federal law bars off-label promotion when it is false or misleading." *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 702 (S.D. Tex. Mar. 24, 2014).

Defendants argue that the "gravamen" of Plaintiff's failure-to-warn claim is that Defendants should have made "different" or "additional" statements about Infuse, i.e., warnings beyond those specified by the FDA (Dkt 114 at 20). As other courts have determined, a jury finding that Defendants' labeling was inadequate "would be tantamount to a requirement that Medtronic do something 'different from, or in addition to,' what the FDA already approved." *Schouest,* 13 F. Supp. 3d at 703. Specifically, "a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in an off-label manner." *Houston I*, 957 F. Supp. 2d at 1177. Under this line of cases, Plaintiff's failure-to-warn claim here would be expressly preempted.

Plaintiff argues that this Court should instead follow *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013), clarified on denial of reconsideration (Oct. 24, 2013), where the district court held that the FDA's express preemption provision does not apply when a manufacturer engages in off-label promotion (Dkt 117 at 25, 28, 36). The Court is not persuaded. In *Ramirez*,

the "core" of the plaintiff's claim was that she was injured due to an off-label use of Infuse that resulted from Medtronic's practice of promoting such uses. *Id.* at 990. Citing 21 U.S.C. § 331(a), the district court decided that "when Medtronic allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device, it departed the realm of federal regulation and returned to the area of traditional state law remedies." *Id.* at 990-91 (footnote omitted). Thus, according to *Ramirez*, the plaintiff's claims were not preempted because "[s]ection 360k protects manufacturers who adhere to the federal regulatory program, but it does not expand federal law into heretofore unregulated areas," which *Ramirez* determined included the area of off-label promotion. *Id.* at 996.

As evidenced by the plethora of supplemental authorities provided by Defendants, the reasoning of the *Ramirez* district court has been rejected by numerous district courts, although no appellate court has yet considered the precise issue. *See, e.g., Arthur*, 2014 WL 3894365, at *5; *Martin v. Medtronic*, No. 2:14-cv-0385, 2014 WL 3635292 (D. Ariz. 2014) (joining the "majority of other courts" that have held that failure-to-warn claims based on off-label promotion of Infuse are expressly preempted) (citing cases therein); *Beavers-Gabriel*, 15 F. Supp. 3d at 1035 ("*Ramirez* has been rejected—for good reason—by numerous courts."); *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 486 (Md. Ct. App. 2014) (indicating that "*Ramirez* has been almost universally rejected").

The reasoning of *Ramirez* has been rejected as inconsistent with the text of § 360(k), which applies if federal requirements are applicable "to the *device*," not merely to specific uses of devices. The premarket approval application presented to the FDA includes "[a]n identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any

source, foreign or domestic, including information derived from investigations *other than those proposed in the application* and from commercial marketing experience." 21 C.F.R. § 814.20(b)(8)(*ii*) (emphasis added). "Once the FDA has cleared a device for introduction into the stream of commerce, physicians may use the device in any manner they determine to be best for the patient, regardless of whether the FDA has approved the device for this usage." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 197 (4th Cir. 2001). "'[O]ff-label' usage of medical devices ... is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350.

A second related reason courts have therefore determined the reasoning in *Ramirez* is not sound is that the *Ramirez* court presumed that the state-law claims before it were premised on off-label promotion that violated the FDCA. *See, e.g., Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1096 (D. Or. 2013) ("[T]he reasoning of *Ramirez*, although largely persuasive, ... depend[s] in part on a flawed premise ... in connection with the court's finding that Medtronic violated federal law specifically by promoting off-label applications of the Infuse device.").

Section 331(a), the provision the *Ramirez* court cited in support of the proposition that "[a] manufacturer is ... prohibited from promoting a use of the product that is not the specified use," does not expressly prohibit such promotion; rather, as recounted above, § 331 prohibits manufacturers only from the "introduction or delivery for introduction into interstate commerce of any ... device ... that is ... misbranded," 21 U.S.C. § 1331(a). *Alton*, 970 F. Supp. 2d at 1096. Misbranding is defined in part as labeling a device without including "adequate directions for use," 21 U.S.C. § 352(f)(1), and directions for use "may be inadequate because ... of omission, in whole or in part, or incorrect specification of ... [s]tatements of all conditions, purposes, or uses for which such device

is intended," 21 C.F.R. § 801.5(a), and whether a particular use is intended may be inferred from, inter alia, the manufacturer's statements in promotion of the device and its applications, 21 C.F.R. § 801.4. *Id.* Hence, contrary to the conclusion of the *Ramirez* court, "the promotion itself did not violate any provision of the FDCA, but rather constituted evidence material to the question whether the Infuse device was misbranded." *Id.*

In other words, "rather than escaping federal requirements by promoting an off-label use, a device manufacturer's off-label promotion itself is subject to specific MDA provisions." *Arthur*, 2014 WL 3894365, at *5 (quoting *Houston II,* 2014 WL 1364455, at *5). *See also McCormick*, 101 A.3d at 486 (indicating that "*Ramirez* has been almost universally rejected" because "federal law does impose requirements regarding off-label use and promotion of devices"). Therefore, after careful consideration of the parties' arguments and review of the legal authorities, the Court agrees that off-label promotion is governed by federal law, which sets the parameters and occupies the field for deciding whether a representation is false or misleading. Accordingly, Plaintiff's Count I, seeking reimbursement for the injuries she suffered due to the alleged inadequacy of the warnings for an off-label use, is a claim that falls within § 360k protection.

Further, Plaintiff's Count I does not state a parallel state-law claim because there is no state law duty to abstain from off-label promotion. "Off-label promotion itself exists only as a creation of the FDCA scheme." *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SK, 2014 WL 346622, at *19 (E.D. Cal. Jan. 30, 2014) (*Hawkins I*) ("A state law cause of action cannot rest solely on the off-label promotion of INFUSE."); *see also Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013) ("even the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law"). "A successful

failure-to-warn claim premised on inadequate labeling would therefore disturb the FDA's policy with respect to the regulation of these devices." *Schouest*, 13 F. Supp. 3d at 703-04 (citing *Buckman*, 531 U.S. at 350). Defendants correctly argue that this lack of a traditional state-law duty to refrain from off-label promotion means that Plaintiff's failure-to-warn claim in Count I is also impliedly preempted. In sum, Count I, in its entirety, is both expressly and impliedly preempted and will be dismissed.

2. *Design Defect*

In Count II of her First Amended Complaint, Plaintiff alleges that a manufacturer has a duty to use reasonable care in designing its product and guard against a foreseeable and unreasonable risk of injury (Dkt 95, First Amend. Compl. ¶ 127). Plaintiff alleges that the Infuse device was defectively designed at the time that it left Defendants' control and was placed into the stream of commerce (*id.* ¶ 121). Specifically, Plaintiff alleges that the device was defectively designed because (1) "the design was unsafe when used in the off-label manner promoted by Medtronic and/or in a manner reasonably foreseeable by Medtronic;" (2) "the risks of danger in the design outweigh the benefits of the design;" and (3) the Infuse device "caused users to suffer injuries, including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than equally-effective, alternative designs and treatments" (*id.* ¶¶ 122-24). Plaintiff alleges that as a legal and proximate result of the aforementioned defects of Infuse, she has sustained injuries and damages (*id.* ¶ 130).

The Court agrees with Defendants that under *Riegel*, Plaintiff's claim is foreclosed (Dkt 114 at 21). The Supreme Court held that "[s]tate tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme."

Riegel, 552 U.S. at 325 (ultimately affirming the district court's decision that the MDA preempts "claims of strict liability ... and negligence in the design" of a device). Hence, the Eighth Circuit Court of Appeals has held that "attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device ... are expressly preempted by § 360k." *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (Sprint Fidelis Lead medical device).

More specifically, in *Caplinger*, where the plaintiff who underwent a posterior-approach lumbar spine surgery utilizing the Infuse device alleged nearly an identical design-defect claim to Plaintiff's claim here, the district court held that allowing the design-defect claim to proceed "would permit a finding that a design defect rendered the Infuse Device unreasonably dangerous, even if defendants complied with all FDA regulations addressed to design." 921 F. Supp. 2d at 1222. "To permit a jury to second-guess the Infuse Device's design would risk interference with the federally-approved design standards and criteria. Plaintiff's strict products liability design defect claim would, therefore, establish design requirements different from, or in addition to, federal requirements for the Infuse Device." *Id.* In short, the Court finds that the design defect claim is expressly preempted under § 360k(a), and Count II will therefore be dismissed.

3. *Negligence*

In Count III of her First Amended Complaint, Plaintiff alleges "Negligence" based on Defendants' "duty to comply with federal law by promoting Infuse only for purposes approved by the FDA" (Dkt 95, First Amend. Compl. ¶ 136). Plaintiff alleges that Defendants were

> A. Negligently and carelessly engaging in the illegal off-label promotion of Infuse Bone Graft by recommending to physicians, including Plaintiff's physicians, and instructing them to use it in procedures for which it had not been approved;

B. Negligently, carelessly and recklessly promoting the off-label use of Infuse Bone Graft by instructing, promoting and directing the use of the product without an approved cage device;

C. Negligently, carelessly and recklessly failing to disclose that usage of Infuse® Bone Graft in non-ALIF procedures had not been approved by the FDA;

D. Negligently, carelessly and recklessly failing to disclose to physicians that the promoted off-label use of Infuse Bone Graft can result in serious side effects;

E. Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of Infuse Bone Graft;

F. Negligently, carelessly and recklessly representing that the off-label use of Infuse Bone Graft was safe when, in fact, it was unsafe;

G. Negligently, carelessly and recklessly promoting Infuse® Bone Graft beyond the narrow and limited uses for which it was approved;

H. Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, Plaintiff's surgeon and Plaintiff of the dangers, contra-indications, and side effects from the off-label use of Infuse Bone Graft; and

I. Negligently, carelessly and recklessly failing to act as a reasonably prudent device manufacturer.

(Dkt 95, First Amend. Compl. ¶ 139) (footnote omitted).

The Court agrees with Defendants that the "gravamen" of these allegations, like those in Plaintiff's failure-to-warn claim in Count I, is that Medtronic should have made "different" or "additional" statements about Infuse, i.e., warnings beyond those specified by the FDA (Dkt 114 at 20). The Court's prior analysis and conclusion is therefore applicable here, too, and the Court concludes that Plaintiff's negligence claim is expressly preempted. *See Scanlon v. Medtronic*, No. 13-224, 2014 WL 3737501, at *6 (D. Del. 2014) (the plaintiff's negligence cause of action is

preempted because it would "impose requirements on Medtronic—to perform and report additional studies—which are different from and in addition to those imposed by the FDA"); *Martin*, 2014 WL 3635292, at *14 (same).

Moreover, Plaintiff's negligence allegations based solely on illegal off-label promotion are impliedly preempted because any claim that Defendants engaged in illegal off-label marketing of the Infuse device "'exists solely by virtue' of federal regulations, and is not rooted in any traditional state tort law." *See Houston I*, 957 F. Supp. 2d at 1178 (quoting *Buckman*, 531 U.S. at 353); *see also Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 990 (E.D. Mo. 2014) (determining that although Missouri products liability law supported recovery, the conduct the plaintiff alleged relates to Medtronic's promotion of the Infuse device for the off-label uses, "which is a negligence claim that would not exist if the FDCA did not exist"). Therefore, Count III will be dismissed.

4. *Fraud*

In Count IV ("Fraud") of her First Amended Complaint, Plaintiff alleges that Defendants paid illegal kickbacks to physicians in connection with promoting the off-label use of Infuse, kickbacks that included "lucrative consulting and royalty agreements" and "lavish all-expense paid trips" (Dkt 95, First Amend. Compl. ¶¶ 146-51). Plaintiff alleges that her surgeon, Dr. Michael Kasten, took "part in Medtronic's fraudulent scheme" and received "sham consulting fees" and "therefore acted as an agent of Medtronic" (*id.* ¶¶ 152-54). Plaintiff alleges that Dr. Kasten "represent[ed] to Ms. Wright that her specific surgery, which utilized Infuse in an unapproved and unsafe manner, was 'safe'—when, in fact, Plaintiff's [sic] off label procedures using Infuse in a posterior approach or without the use of an approved cage were unsafe and known by Medtronic to be unsafe" (*id.* ¶ 155).

Plaintiff delineates, at length, how Medtronic continues to drive sales through off-label indications, despite entering into a "Corporate Integrity Agreement" and the "material risk of further regulatory action or other liability, and in conscious disregard for the health and welfare of spine patients such as Ms. Wright" (*id.* ¶¶ 162-86). Plaintiff alleges that "the Medtronic Defendants fraudulently and intentionally misrepresented material and important health and safety product risk information to Plaintiff and Plaintiff's physicians" and that "Plaintiff and her physicians would not have decided to use Infuse without an LT-Cage or INTER FIX Cage had they known of the safety risks related to Infuse" (*id.* ¶¶ 187-91).

Last, Plaintiff alleges that "Medtronic intended to cause Plaintiff and her physicians to rely on their concealment of information and misrepresentations about the safety risks related to Infuse to induce them to make off-label use of Infuse for Plaintiff's lumbar spine fusion surgery" (Dkt 95, First Amend. Compl. ¶ 192). Plaintiff alleges that she and her physicians were "justified in relying, and did rely, on Medtronic's fraudulent concealment of information and misrepresentations about the safety risks related to Infuse in deciding to use Infuse in an off-label manner for Plaintiff's fusion surgery" (*id.* ¶ 193). Plaintiff alleges that she was injured and incurred damages as the direct, proximate and legal cause of Defendants' fraudulent concealment and misrepresentations and suppression (*id.* ¶¶ 194-99).

In contrast to Plaintiff's failure-to-warn claim in Count I, a claim that this Court determined is expressly preempted because the claim would require warnings beyond those specified by the FDA, Plaintiff's fraud claim is not expressly preempted. The state tort law duties underlying Plaintiff's fraud claim are not "different from, or in addition to" federal requirements, which prohibit fraudulent promotion or advertising. *See Belle Isle Grill Corp. v. Detroit*, 666 N.W.2d 271, 280

(Mich. Ct. App. 2003) (setting forth the elements a plaintiff must show to establish fraud based on misrepresentation). Indeed, mere off-label promotion, divorced from any negligent or fraudulent misrepresentations, is not prohibited by federal law. Rather, to reiterate this Court's conclusion in analyzing Plaintiff's Count I, off-label promotion is itself governed by federal law.

Because Plaintiff's allegations of affirmative misrepresentations are based on independent state law duties, neither is the fraud claim impliedly preempted. "[T]hese claims would apply to a seller of a product not subject to any federal regulations who engaged in similar alleged misconduct." *Schouest, supra* (citing *Houston I*, 957 F. Supp. 2d at 1179 (holding that state fraud-based claims that include off-label promotion allegations are not impliedly preempted under *Buckman* "because they are moored in traditional state common law that exists independently from the FDCA"); *Eidson I*, 981 F. Supp. 2d at 885 (finding that fraud claims based on off-label promotion escape preemption because such claims "are based on state common law tort duties that exist independently from the FDCA and not solely by virtue of the FDCA"); *see also Hawkins v. Medtronic, Inc.*, ___ F. Supp. 3d ___, 2014 WL 6611876, at *7 (E.D. Cal. 2014) (*Hawkins II*) (explaining that a state tort duty exists independent of the FDCA for the plaintiff's allegation that the defendants were negligent by making misrepresentations during the course of off-label promotion and "removes it from the grasp of implied preemption because he [did not merely allege] they engaged in off-label promotion").

Defendants argue that even if this Court determines Plaintiff's fraud claim is not preempted, the claim must nonetheless be dismissed. The Court agrees with Defendants that Plaintiff's fraud claim, in its currently filed version, is internally inconsistent. As Defendants point out, the contradiction in the claim is that Plaintiff alleges "both that her surgeon defrauded her—which

requires that he had knowledge of the true facts—and that her surgeon was defrauded by Medtronic—which requires that he did *not* have knowledge of the true facts" (Dkt 116 at 20). However, in responding to Defendants' motion to dismiss, Plaintiff "withdrew" from her First Amended Complaint the references to her surgeon acting as Medtronic's "agent" and attached to her response a proposed Second Amended Complaint, which omits the references to her surgeon acting as Medtronic's "agent" as well as references to her surgeon's representations to her that her off-label surgery was "safe" (Dkt 117 at 35; Pl.'s Ex. 2, Dkt 117-2). The Court determines that these changes cure the internal inconsistency in Plaintiff's fraud claim and that placing this case in proper posture for resolution is in the interest of justice; therefore, the Court will grant Plaintiff leave to file the Second Amended Complaint. *See, e.g., Crabbs v. Copperweld Tubing Prods. Co.*, 114 F.3d 85, 91 (6th Cir. 1997) (affirming the district court's decision to permit the plaintiff to amend his complaint to conform to his position).

The Court is not convinced by Defendants' argument that Plaintiff's fraud claim should nonetheless be dismissed because Plaintiff failed to plead it with the particularity required by Rule 9(b). Plaintiff details how Defendants, from 1998 to the present, sponsored medical literature, conferences, and statements by sales representatives to persuade physicians to use Infuse in dangerous off-label uses, while misrepresenting, downplaying and/or falsifying the seriousness of adverse events resulting from such uses. As another district court observed of a substantially similar complaint, Plaintiff alleged "who" the Medtronic-sponsored authors were, "when" the articles were published, the "content" of the allegedly false articles promoting off-label procedures, and "why"

that content was false. *Hawkins II*, ___ F. Supp. 3d at ___; 2014 WL 6611876, at *11.[2] In other words, the allegations serve to "state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b).

Further, the Court rejects Defendants' argument that the fraud claim must be dismissed because Plaintiff failed to allege "an actual representation or omission that was made by Medtronic and relied on by her surgeon" (Dkt 114 at 39). Given the landscape Plaintiff describes, "a course of conduct that promotes Infuse as safe in spite of Medtronic's knowledge that such procedures are 'high risk and experimental,'" *Hawkins II*, ___ F. Supp. 3d at ___; 2014 WL 6611876, at *12, the Court finds sufficient for purposes of *Iqbal/Twombly* Plaintiff's additional allegation that Defendants "fraudulently and intentionally misrepresented material and important health and safety product risk information to Plaintiff and Plaintiff's physicians" and that "Plaintiff and her physicians would not have decided to use Infuse without an LT-Cage or INTER FIX Cage had they known of the safety risks related to Infuse" (Dkt 95, First Amended Compl. ¶ 187). *Compare Hawkins I*, 2014 WL 346622, at *13 (dismissing the plaintiff's original fraud claims where the plaintiff failed to allege "not only the content of the off-label promotion directed at his spine surgeon and on which the surgeon relied, but he also fails to allege who made those representations to his surgeon and when the representations were made") *with Hawkins II*, ___ F. Supp. 3d. at ___, 2014 WL 6611876, at *13-14 (considering the plaintiff's amended fraud claim and agreeing with the cited decisions of other courts that "the general allegation that a plaintiff's doctor relied upon misrepresentations made

[2]The district court also accurately observed that the extensive pleading extends well beyond what is necessary to state a claim for fraud based on off-label misrepresentation and extends into allegations of on-label misrepresentation, which falls within the FDA's premarket approval purview. *Hawkins II*, ___ F. Supp. 3d at ___; 2014 WL 6611876, at *12.

by Medtronic sponsored medical literature, conferences, and statements by sales representatives—despite the failure to plead what statements were relied upon, who made the misstatements, when they were made—were sufficient to plead reliance"). The Court will therefore deny Defendants' motion as to Count IV.

5. *Breach of Express and Implied Warranties*

Last, in Count V ("Breach of Warranty") of her First Amended Complaint, Plaintiff alleges that Defendants "utilized journal articles, advertising media, sales representatives and paid Key Opinion Leaders and other physicians to urge the use, purchase, and utilization of the off-label use of the Infuse Bone Graft and expressly and impliedly warranted to physicians and other members of the general public and medical community that such off-label uses, including the type of off-label procedure that Plaintiff underwent, was safe and effective" (Dkt 95, First Amend. Compl. ¶ 201). Plaintiff alleges that "Medtronic knew or, in the exercise of reasonable diligence, should have known that such off-label uses had the serious side effects set forth herein" (*id.* ¶ 202). Plaintiff alleges that "Ms. Wright's treating surgeon and his [sic] other physicians and medical professionals, relied on Medtronic's express and implied warranty representations" (*id.* ¶ 203).

Plaintiff alleges that "Medtronic breached the implied warranties of merchantability and fitness because the Infuse Bone Graft is unsafe for the promoted uses, is not merchantable, is unfit for its promoted use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact made by Medtronic" (Dkt 95, First Amend. Compl. ¶ 204). Plaintiff alleges that she was injured and incurred damages as the direct and proximate cause of Defendants' acts and conduct (*id.*

¶ 205). Plaintiff alleges that Medtronic's acts also constitute "misbranding" under the FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2), for which Defendants are subject to civil liability (*id.* ¶ 206).

The Court agrees with those courts that have found that an adequately pleaded claim for breach of express warranty is not expressly preempted by § 360k(a). Federal law "already requires [Medtronic] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Riley*, 625 F. Supp. 2d at 788; 21 U.S.C. § 331(b). *See also Arthur*, 2014 WL 3894365, at *8; *Houston I*, 957 F. Supp. 2d at 1180-81.

An adequately pleaded express-warranty claim also survives implied preemption because Michigan recognizes claims for breach of express warranty. *See infra.* In other words, Plaintiff's theory is not wholly dependent on federal law—her breach of express warranty claim would exist absent the FDCA and MDA. *See, e.g., Arvizu v. Medtronic, Inc.*, No. CV-14-00792, 2014 WL 4204933, at *9 (D. Ariz. Aug. 25, 2014); *Schouest*, 13 F. Supp. 3d at 707 (the plaintiff's "express warranty claim can survive to the extent she seeks to recover based on false warranties that Medtronic voluntarily and falsely made beyond the federally approved warning").

The remaining question is whether Count V is adequately pleaded, and the threshold issue is whether Plaintiff adequately pleaded that Defendants made an express warranty. The Uniform Commercial Code, as adopted by Michigan, defines an express warranty as "[a]n affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." MICH. COMP. LAWS § 440.2313(1)(a).

Here, the FDA label for the Infuse device states that "[n]o warranties, express or implied, are made" and that "[i]mplied warranties of merchantability and fitness for a particular purpose or

use are specifically excluded" (Defs.' Ex. 3, Dkt 114-3 at 4). Defendants argue that this unambiguous declaration defeats any warranty claim based on alleged statements outside the Infuse device's labeling (Dkt 114 at 33, citing *Bailey Farms, Inc. v. NOR-AM Chem. Co.*, 27 F.3d 188, 193 (6th Cir. 1994) (applying Michigan law and holding that "both the UCC and common law allow defendant to disclaim implied warranties")).

Plaintiff does not dispute that a seller may disclaim implied warranties under Michigan law as long as the disclaimer is conspicuous. *See* MICH. COMP. LAWS § 440.2316(2); *see also* MICH. COMP. LAWS § 440.1201(10) (providing that a term or clause is conspicuous "when it is so written that a reasonable person against whom it is to operate ought to have noticed it"). Rather, Plaintiff clarifies that her claim is not premised on any warranty set forth in the Infuse labeling but on "alleged express warranties made to the medical community" (Dkt 117 at 31). To that end, Plaintiff emphasizes that her complaint is "replete" with representations made by Medtronic to the medical community (*id.*).

Under Michigan law, however, Plaintiff is bound by what she signed. *See Pitts v. Monaco Coach Corp.*, 330 F. Supp. 2d 918, 923 (W.D. Mich. 2004) (rejecting the plaintiff's argument that his reliance on the salesperson's "various assurances" could save his warranty claim from dismissal where the defendant had notified the plaintiff of his disclaimer of warranties). Thus, Defendants have demonstrated that Plaintiff's Count V fails to state a claim for relief, and Count V will be dismissed.

IV. CONCLUSION

For the foregoing reasons, the Court determines that Plaintiff's failure-to-warn, design defect and negligence claims in Counts I, II and III do not survive preemption. Plaintiff's fraud and

warranty claims in Counts IV and V survive preemption, but Plaintiff's Count V fails to state a claim under Michigan law. Therefore, Defendants' Motion to Dismiss (Dkt 113) is granted in part and denied in part, with the end result being that only Plaintiff's fraud claim in Count IV will proceed. An Order will be entered consistent with this Opinion.

Dated: January 23, 2015

/s/ Janet T. Neff
JANET T. NEFF
United States District Judge