UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

KATHLEEN A. ARTHUR,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:14-CV-52 (CEJ)
	)	
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on defendants' motion to dismiss plaintiff's complaint pursuant to Fed.R.Civ.P. 12(b)(6). Plaintiff has filed a response in opposition and the issues are fully briefed.

I. Background

A. Plaintiff's Surgery

On December 1, 2008, plaintiff Kathleen Arthur underwent an anterior cervical discectomy and fusion surgery in which her surgeon implanted the Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse"), manufactured by defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc., (collectively, "Medtronic"). Plaintiff alleges the surgery did not resolve her cervical pain and that she later developed numbness in her arm and fingers. Despite pain management treatment and additional surgical procedures, she continues to experience severe pain and numbness. She alleges that Medtronic knew before 2008 that the Infuse device causes excessive bone growth that compresses nerves around the spinal cord and causes severe pain. She further alleges that Medtronic promoted off-label use of Infuse in the cervical region. She brings claims for strict liability, failure to warn, negligence, negligent and

fraudulent misrepresentation, and breach of express and implied warranties. Defendants move for dismissal, arguing that her state-law claims are pre-empted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq*.

B. FDA Approval of the Infuse Device

On July 2, 2002, the FDA granted premarket approval for the Infuse device, as relevant here, for "spinal fusion procedures in skeletally mature patients with degenerative disc disease . . . at one level from L4-S1."[1] Def. Ex. 2 [Doc. # 12-2]. The Infuse device consists of two components: a metallic spinal fusion cage (the LT-CAGE™) and a bone-graft component consisting of a collagen sponge containing a protein used to induce new bone tissue at the site of implantation. InFuse™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device Important Medical Information (FDA warning label), Def. Ex. 3 at p.1. "The safety and effectiveness of the InFuse Bone Graft Component . . . implanted at locations other than the lower lumbar spine . . . ha[s] not been established." Id. at p.4. In this case, the Infuse device was implanted in plaintiff's cervical spine and thus was used in an "off-label" manner.

II. Legal Standards

A. Rule 12(b)(6)

[1]Medtronic asks the court to take judicial notice of the FDA's premarket approval documents and approved labeling, which are available on the FDA's public website. Plaintiff does not object. While courts generally cannot consider materials outside the pleadings when addressing a motion to dismiss, courts may take judicial notice of public records. Blankenship v. Medtronic, --- F. Supp. 2d ---, 2014 WL 1226491, at *1 n.1 (E.D. Mo. 2014). Courts have taken judicial notice of the FDA's documents regarding the Infuse device. See, e.g., id.; Beavers-Gabriel v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1396582, at *1 n.1.

The purpose of a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure is to test the legal sufficiency of the complaint. The factual allegations of a complaint are assumed true and construed in favor of the plaintiff, "even if it strikes a savvy judge that actual proof of those facts is improbable." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007) (citing Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002)); Neitzke v. Williams, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations"); Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) (a well-pleaded complaint may proceed even if it appears "that a recovery is very remote and unlikely"). The issue is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of his claim. Id. A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp., 550 U.S. at 570. See also id. at 563 ("no set of facts" language in Conley v. Gibson, 355 U.S. 41, 45-46 (1957), "has earned its retirement.") "Factual allegations must be enough to raise a right to relief above the speculative level." Id. at 555.

B. Rule 9(b)

Plaintiff's fraudulent misrepresentation claim is subject to Rule 9(b) of the Federal Rules of Civil Procedure, which provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting the fraud or mistake."

> Rule 9(b)'s particularity requirement demands a higher degree of notice than that required for other claims, and is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations. To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of defendant's false representations, as well as the details of the defendant's

> fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result. Put another way, the complaint must identify the "who, what, where, when and how" of the alleged fraud.

United States *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) (internal citations omitted). A plaintiff must state an underlying basis for its assertions sufficient to provide an indicia of reliability. Id. at 557 (citation omitted). While a plaintiff need not allege specific details of every alleged fraud, the plaintiff must provide some representative examples of the alleged misconduct. Id.

III. Discussion

Defendants argue that all of plaintiff's claims are expressly or impliedly preempted by federal law, and that her fraud claim additionally fails to comply with Rule 9(b).

A. The Medical Device Amendments

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act (FDCA) and authorized the FDA to regulate the safety and effectiveness of medical devices. 21 U.S.C. §§ 301 *et seq*. The MDA establishes different levels of oversight for medical devices, depending on the risks they present. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Class III devices[2] like the Infuse device at issue here receive the most federal oversight, and are subject to a rigorous pre-market approval process, in which the FDA reviews the device's benefits, effectiveness, and risks of injury. Id. at 317-18. The FDA will grant

[2]A Class III device is one that cannot be defined as a Class I or II device "because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device" and it is "represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

premarket approval "only if it finds that there is a 'reasonable assurance' of the device's 'safety and effectiveness'" after weighing "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" Id. at 318 (quoting §§ 360e(d) & 360c(a)(2)(C)). The FDA also reviews the proposed labeling, evaluating the safety and effectiveness of the device under the conditions specified on the label and determining that the labeling is not false or misleading. Id.; § 360c(a)(2)(B) and § 360e(d)(1)(A).

Once a device receives pre-market approval, the manufacturer must obtain FDA approval before making any changes in design specification, manufacturing processes, labeling, or other feature that would affect the device's safety or effectiveness. Riegel, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." Id. (citing § 360e(d)(6); 21 CFR § 814.39(c)). After premarket approval, the manufacturer is required to inform the FDA of any new studies of the device or incidents causing adverse effects. Id. (citing § 360i and 21 C.F.R. §§ 814.84(b)(2) & 803.50(a)). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Id. at 319-20 (citing §§ 360e(e)(1) & 360h(e)).

B. Express and Implied Preemption

The MDA provides for both express and implied preemption of state law claims. Beavers-Gabriel v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1396582, at * 5 (D. Haw. 2014); see also Mendez v. Shah, --- F. Supp. 2d ---, 2014 WL 2921023, at *4

(D.N.J. 2014) ("Given the extensive regulation by the FDA . . ., certain state law claims are preempted.") The MDA's express preemption provision states, in relevant part:

> [N]o State . . . may establish or continue in effect with respect to a device . . . any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Riegel sets forth a two-step analysis for determining whether a state-law claim is expressly pre-empted under § 360k(a). First, the court determines whether the FDA has established requirements applicable to the device at issue. Riegel, 552 U.S. at 322. Second, the court determines whether the plaintiff's state-law claims seek to impose requirements with respect to the device that are "different from, or in addition to" the federal requirements, and that relate to the safety or effectiveness of the device. Id.; see also *In re* Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig. (Sprint Fidelis), 623 F.3d 1200, 1204 (8th Cir. 2010) (common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by pre-market approval). A claim that a medical device "violated state tort law notwithstanding compliance with the relevant federal requirements" is expressly preempted. Beavers-Gabriel, 2014 WL 1396582, at *6 (quoting Riegel, 552 U.S. at 330); see also Eidson v. Medtronic, Inc. (Eidson II), --- F. Supp. 2d ---, 2014 WL 1996024, at *7 (N.D. Cal. 2014) (claims that impose state

requirements that are different from or in addition to the federal requirements are expressly preempted under § 306k(a)).

However, § 360k does not prevent a state from providing a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996). "In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are 'genuinely equivalent.'" McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005) (quoting Bates v. Dow Agrosciences LLC, 554 U.S. 431, 454 (2005)). State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law. Id.

Implied preemption arises under § 337(a), which provides, in relevant part: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). In Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), the Supreme Court construed § 337(a) as barring suits by private litigants for noncompliance with the FDCA or MDA because "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." Id. at 348. In order to avoid implied preemption, a cause of action must "rely[] on traditional state tort law which had predated the federal enactments in question." Id. at 353. "In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law – and that would give rise to liability under state law even if the FDCA had never been enacted." Caplinger v. Medtronic,

Inc., 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013). A state law claim is impliedly preempted when it "exist[s] solely by virtue" of the FDCA requirements. Buckman, 531 U.S. at 353. Read together—

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (emphasis in original).

C. Application of Preemption Principles, Generally

1. First Step of *Riegel*

The first step in the Riegel express-preemption analysis is to determine whether the FDA has established requirements applicable to the Infusion Device. Beavers-Gabriel, 2014 WL 1396582, at *8. The Supreme Court has held that the FDA pre-market approval process imposes device-specific "requirements" under the MDA. Riegel, 552 U.S. at 322. There is no dispute that the Infuse device obtained premarket approval and thus the first prong of the Riegel analysis is satisfied. Eidson v. Medtronic, Inc. (Eidson I), 981 F. Supp. 2d 868, 881-82 (N.D. Cal. 2013); see also Mendez, --- F. Supp. 2d ---, 2014 WL 2921023, at *5; Smith v. Medtronic, Inc., No. 13-451, 2014 WL 2547813, at *3 (W.D. La. 2014); Schouest v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1213243, at * 5 (S.D. Tex. 2014) (noting that courts "uniformly agree that the PMA process imposes requirements on the Infuse device").

2. Second Step of *Riegel* and Off-Label Promotion

The second step of the Riegel analysis requires the court to determine whether the plaintiff's state law claims seek to impose requirements that are "different from, or in addition to" the federal requirements. "In theory, the federal 'requirements'

should be easy enough to determine – they are defined by the MDA, the FDCA, and the implementing regulations." Beavers-Gabriel, 2014 WL 1396582, at * 8. However, courts have struggled to apply the second step of Riegel to claims asserting injuries arising from off-label promotion of the Infuse Device. Id.; Schouest, 2014 WL 1213243, at *5.

Federal law does not expressly define or ban off-label promotion. Id. at *6. However, the FDCA prohibits "[t]he alteration 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 "representation made or suggested by statement, word, device, or any combination thereof." § 321(n). In addition, FDCA regulations restrict a manufacturer's ability to engage in off-label promotion: 21 C.F.R. § 814.80 states: "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). Together, the FDCA's misbranding provisions and 21 C.F.R. § 814.80 constitute federal "requirements" for the purposes of Riegel's second step. Beavers-Gabriel, 2014 WL 1396582, at *9; Eidson I, 981 F. Supp. 2d at 884; Houston v. Medtronic, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) (Houston I); see also Schouest, 2014 WL 1213243, at *7 ("[F]ederal law bars off-label promotion when it is false or misleading.") (citing cases).

Plaintiff argues that the Court should apply Ramirez v. Medtronic, Inc., 961 F. Supp. 2d 977 (D. Ariz. 2013), in which the court held that the FDA's express preemption provision does not apply when a manufacturer engages in off-label promotion. The Ramirez court stated:

> By sidestepping the FDA-approved channel, Medtronic opened itself to state law claims based on its off-label promotion. The absence of federal approval of the specific use and the absence of federal regulations that govern how a manufacturer promotes the off-label use of its device means that traditional state-law standards of conduct remain and govern manufacturers' conduct. Section 360k does not apply by its terms to those claims.

Id. at 997 (D. Ariz. 2013), clarified on denial of reconsideration (Oct. 24, 2013). This reasoning has been rejected by several courts. See, e.g., Beavers-Gabriel, 2014 WL 1396582, at **9-10 and n.8 (listing cases); Schouest, 2014 WL 1213243, at *5 (Ramirez reads Riegel and Buckman too narrowly). First, the preemption statute, § 360k(a), applies to devices, not specific uses of devices. Houston v. Medtronic, Inc., No. 2:13-CV-1679, 2014 WL 1364455, at *5 (C.D. Cal. April 2, 2014) (Houston II). In addition, as discussed above, off-label promotion is itself subject to specific MDA provisions prohibiting misbranding. Id. "Thus, 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. And like premarket approval, these requirements govern the safety of Class III." Id. Thus, plaintiff's state-law claims based on off-label promotion cannot avoid preemption if they impose requirements that are "different from, or in addition to" the federal requirements. See also Riley, 625 F. Supp. 2d at 778-80 (rejecting argument that manufacturer's off-label use renders § 360k(a) inapplicable).

D. Plaintiff's Claims

1. Strict Product Liability – Design Defect[3] and Failure to Warn

In Count I, plaintiff alleges that her surgeon used the Infuse device "in a manner reasonably anticipated" and that the device was "in a defective condition unreasonably dangerous when put to said reasonably anticipated use." Compl. ¶¶ 18-19. "In order to properly allege a design defect claim, a plaintiff must plead 'concrete allegations that the product sold by Medtronic was not the product design approved in the [pre-market approval].'" Blankenship, 2014 WL 1226491, at *6 (quoting Sprint Fidelis, 623 F.3d at 1206) (alteration in original). As most courts have found, a design defect claim is expressly preempted because in order to prevail, plaintiff would need to establish that the Infuse device should have been designed in a manner different than that approved by the FDA. Id.; Beavers-Gabriel, 2014 WL 1396582, at * 15; Schouest, 2014 WL 1213243, at *11; Houston I, 957 F. Supp. 2d at 1177; see also Sprint Fidelis, 623 F.3d at 1206 (design defect claims are not "parallel claims. Rather, they are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k."). Plaintiff's design defect claim is expressly preempted under § 360k(a) and Count I will be dismissed.

In Count II, plaintiff asserts a claim for strict products liability based on a failure to warn, alleging that defendants failed to provide adequate warning of the dangers of using the device in an off-label manner. Compl. ¶ 26. This claim is also expressly pre-empted. "For [p]laintiff to prevail, a jury would have to find that [d]efendants were

[3]Plaintiff does not allege that the Infuse device she received was not manufactured in accordance with the design approved by the FDA, so the Court will construe Count I as asserting a design-defect claim. See Smith v. Brown & Williamson Tobacco Corp., 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) ("Manufacturing defect refers to the improper assembly of an individual product whereas design defect refers to a product, by nature of its design, being unreasonably dangerous.") (citation omitted) (emphasis added).

required to include warnings beyond those in the FDA-approved label for the Infuse Device." Blankenship, 2104 WL 1226491, at *6 (quoting Houston I, 957 F. Supp. 2d at 1177 (alterations in original). Count II will be dismissed.

2. Negligence

In Count III, plaintiff alleges that defendants negligently engaged in "unreasonable and improper promoting, marketing and selling of Infuse to . . . physicians for off-label use in the cervical area;" "fail[ed] to warn physicians . . . and [p]laintiff of the dangers associated with Infuse when used off-label in said cervical area;" and "fail[ed] to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse." Compl. ¶ 35.

Plaintiff's negligence claims based on failure to warn are expressly preempted because "these claims proceed on the theory that state law required [d]efendants to issue warnings about the risks of off-label uses . . . 'different from' or 'in addition to' what applicable federal requirements demand." Houston I, 957 F. Supp. 2d at 1178. Plaintiff's claims based on off-label promotion and failure to follow federal law are impliedly pre-empted under Buckman and § 337(a) because a claim that defendants "engaged in illegal off-label marketing of the Infuse Device 'exist[s] solely by virtue' of federal regulations, and is not rooted in any traditional state tort law. Permitting this claim to proceed would essentially allow a private litigant to attempt to enforce the FDCA." Id. (quotation and alteration in original). Plaintiff's negligence claims are expressly and impliedly preempted and Count III will be dismissed.

3. Negligent Misrepresentation

Plaintiff alleges in Count IV that "Medtronic supplied to [p]laintiff, through [her surgeon], information in the course of its business that Infuse was appropriate for use

in cervical operations." Compl. ¶ 40. The gravamen of this claim is a challenge to Medtronic's off-label promotion of the Infuse Device. As such, the claim is impliedly pre-empted because a claim that Medtronic engaged in off-label marketing "exists solely by virtue of federal regulations and is not rooted in any traditional state tort law." Blankenship, 2014 WL 1226491, at *7 (quoting Houston I, 957 F. Supp. 2d at 1178) (alterations and internal quotations omitted); see also Gavin v. Medtronic, Inc., No. 12-0851, 2013 WL 3791612, at *14 (E.D. La. July 19, 2013) ("[T]he 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 [p]laintiff'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)."). Count IV will be dismissed.

4. Fraudulent Misrepresentation

Plaintiff alleges in Count V that Medtronic made material, false representations. The court has previously determined that, as a general matter, fraudulent misrepresentation claims "escape both express and implied preemption." Blankenship, 2014 WL 1226491, at * 10 (quoting Houston I, 957 F. Supp. 2d at 1179). Such claims are not impliedly preempted under Buckman because "they are moored in traditional state common law that exists independently of the FDCA." Id. And, claims that Medtronic made fraudulent statements to promote off-label use are not expressly preempted because they parallel the federal prohibitions on false or misleading statements and off-label promotion. Id.

Nonetheless, plaintiff fails to plead her fraudulent misrepresentation claim with particularity as required by Rule 9(b). To satisfy Rule 9(b), the complaint must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2)

identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Id. (citation omitted). Plaintiff has satisfied none of these elements. However, in lieu of dismissal, the court will give plaintiff the opportunity to amend this claim to satisfy Rule 9(b)'s particularity requirement.

5. Breach of Implied and Express Warranties

Plaintiff alleges in Counts VI that Medtronic "actively promoted and marketed" off-label use of Infuse in the manner in which her surgeon used the product. She claims that Medtronic breached an implied warranty of fitness for the purpose as used by her surgeon. Compl. ¶¶ 58, 61-62. This claim is expressly preempted because it is "based on statements that Medtronic did not actually make." Schouest, 2014 WL 1213243, at *11. "Federal law governs all statements that Medtronic is obligated to make concerning the Infuse device, and therefore preempts [plaintiff's] breach of implied warrant claim." Id. See also Caplinger, 921 F. Supp. 2d at 1222 (to succeed on warranty claims, plaintiff had to prove Infuse device was not safe and effective, which would be contrary to FDA's approval). Count VI will be dismissed.

Plaintiff alleges in Count VII that, by actively promoting and marketing off-label use of Infuse, Medtronic created an "express warranty that Infuse shall conform to the foregoing description when used in the [off-label] manner in which it was used by" her surgeon. Compl. ¶ 68. She further alleges that Medtronic supplied her surgeon with samples of Infuse and made unspecified representations to induce her and her surgeon to purchase the device for use in plaintiff's surgery. ¶¶ 69-70. The court agrees with those that have found that claims for breach of express warranty are not expressly preempted by § 360k(a).

> [F]ederal law already prohibits false or misleading off-label promotion. Therefore, to the extent that [p]laintiff seeks to impose liability on [d]efendants for voluntarily making misleading warranties outside the label, [p]laintiff is not imposing any requirement different from or additional to what federal law already requires. In other words, to avoid state law liability on this claim, [d]efendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes.

Houston I, 957 F. Supp. 2d at 1180-81; see also Schouest, 2014 WL 1213243, at *11 (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"); Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069, 1104 (D. Or. 2013) (warranty claim premised solely on alleged voluntary statements to public and medical community regarding the safety and efficacy of off-label applications not preempted).

An adequately pleaded express-warranty claim also survives implied preemption because Missouri recognizes claims for breach of express warranty. The elements of such a claim are: (1) the defendant sold goods to the plaintiff; (2) the seller made a statement of fact about the kind or quality of those goods; (3) the statement of fact was a material factor inducing the buyer to purchase the goods; (4) the goods did not conform to that statement of fact; (5) the nonconformity injured the buyer; and (6) the buyer notified the seller of the nonconformity in a timely fashion. Renaissance Leasing, LLC v. Vermeer Mfg. Co., 322 S.W.3d 112, 122 (Mo. 2010) (*en banc*).

Plaintiff alleges that Medtronic promoted Infuse as a product suitable and appropriate for off-label use. This is not sufficient to state a claim for breach of express warranty as it fails to convey specific information regarding the warranty. See Pfitzer v. Smith & Wesson Corp., 4:13-CV-676-JAR, 2014 WL 636381 at *3 (E.D. Mo. Feb. 18, 2014) (citing Heisner *ex rel*. Heisner Genzyme Corp., 2008 WL 2940811, at

*8 (N.D. Ill. July 25, 2008) (allegation that defendant expressly warranted to plaintiff orally and in publications, package inserts and other written materials, that the product was "safe, effective, fit, and proper for its intended use," failed to adequately identify the affirmation, promise, description or sample that formed the basis of his bargain with defendant, thus failing to put defendant on notice as to the substance of this claim); see also Schouest, 2014 WL 1213243, at *11 ("While conceptually an express warranty claim could avoid express preemption, what is missing from Schouest's complaint, in its current form, is a description of what specific warranties Medtronic made to Schouest or her physicians.") Plaintiff will be given the opportunity to amend her claim in Count VII.

IV. Conclusion

For the foregoing reasons, the Court will grant defendants' motion to dismiss as to Counts I, II, III, IV, and VI. Plaintiff will be given the opportunity to amend Count V to plead fraudulent misrepresentation with particularity and to amend Count VII to assert a breach of express warranty claim based on alleged false warranties beyond the federally-approved labeling of the Infuse Device.

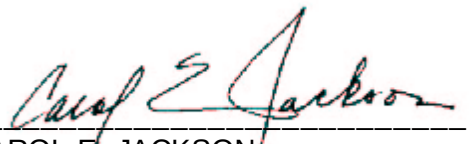
Accordingly,

IT IS HEREBY ORDERED that defendants' motion to dismiss [Doc. #10] is **granted in part.** Counts I, II, III, IV, and VI of the complaint are **dismissed for failure to state a claim**.

IT IS FURTHER ORDERED that the defendants' motion to dismiss is **denied without prejudice** as to Counts V and VII.

IT IS FURTHER ORDERED that plaintiff shall have 30 days in which to file a motion for leave to amend her complaint with respect to the claims asserted in Counts

V and VII only. A copy of the proposed amended complaint must be attached to the motion as an exhibit. Defendants will have 14 days to file a response to any motion to amend.



CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 11th day of August, 2014.