UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

LAURA BLANKENSHIP,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**Case No. 4:13-CV-1087 (CEJ)**
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on the motion to dismiss the second amended complaint for failure to state a claim filed by defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., Medtronic Vertelink, Inc., Medtronic Sofamor Danek, Inc., and Warsaw Orthopedic, Inc. (collectively, "Medtronic") pursuant to Fed. R. Civ. P. 12(b)(6). The defendants also move for a hearing and oral argument. Plaintiff has responded and the issues are fully briefed.

I. Background

Medtronic is in the business of designing, manufacturing, and selling medical devices, including the InFUSE™ Bone Graft/ LT-CAGE™ Lumbar Tapered Fusion device (Infuse). The bone graft component is inserted into the fusion cage component to form the complete device. On July 2, 2002, Infuse was approved by the Food and Drug Administration (FDA) through the required pre-market approval process and was "indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (ddd) at one level from L4-S1 . . . to be implanted via an anterior open or an anterior laparoscopic approach."[1] [Doc. ##57-1, 57-2]. On December 1, 2003,

[1] **Medtronic requests that the Court take judicial notice of nine exhibits. [Doc. #57]. "Generally, the Court must ignore materials that are outside of the**

the FDA approved the Infuse bone graft to be used with an INTERFIX Cage for identical surgical applications as the LT-Cage. [Doc. #57-4].

On September 19, 2007, plaintiff underwent a cervical diskectomy and fusion at C4-5, C5-6 and C6-7, with instrumentation and placement of the Infuse bone graft at each level. The cage used in plaintiff's surgery was neither an LT-Cage nor an INTERFIX Cage. Plaintiff claims that shortly after her surgery she experienced severe, chronic, and ongoing numbness and pain in her head, throat, neck, shoulders, and arms. Plaintiff alleges that she is permanently and totally disabled from the pain and numbness and is unable to maintain employment.

Plaintiff attributes her injuries to Medtronic's improper promotion of the Infuse device for "off-label uses."[2] Plaintiff alleges that despite the FDA's specific description of the use for which the device was indicated, Medtronic created "a marketing plan that explicitly included the improper overpromotion of off-label uses, by artificially lowering the price of the surgery and instructing their sales forces to visit physicians and other health care providers and mislead them into the false belief that Infuse Bone Graft was safe for all spinal surgeries, and safe for use with non-FDA metal cage devices." [Doc. 24, at 20]. Plaintiff asserts that she would not have consented to the cervical surgery if she had been aware of the off-label risks.

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pleadings, however, district courts 'may take judicial notice of public records and may thus consider them on a motion to dismiss.'" Stahl v. United States Dept. of Agric., 327 F.3d 697, 700 (8th Cir. 2003). Matters of public record may include records and reports of administrative bodies. Accordingly, the Court will take notice of Medtronic's Exhibits 1-6, which include the FDA's pre-market and supplemental approvals for the Infuse device. [Doc. #57, Ex. 1-6].

[2] "Off-label" usage is defined as "use of a device for some other purpose than that for which it has been approved by the FDA." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001).

In the second amended complaint, plaintiff asserts the following claims: (1) manufacturing defect; (2) failure to warn; (3) design defect; (4) negligence; (5) strict liability; (6) fraud; (7) negligence per se; (8) intentional misrepresentation; and (9) violations of California's unfair competition law. Medtronic has moved to dismiss all claims on the basis that they are expressly and impliedly preempted by the Medical Device Amendments of 1976, 21 U.S.C. §§ 360k(a), 337(a).

II. Legal Standard

A. Motion to Dismiss

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. Fraud

Fed.R.Civ.P. 9(b) establishes a heightened pleading standard for complaints alleging fraud. The Eighth Circuit has described Rule 9(b)'s particularity requirement:

> **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.

C. Express and Implied Preemption

In the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act (FDCA), Congress authorized the FDA to regulate the safety and effectiveness of medical devices. See 21 U.S.C. § 301, *et seq*. The devices receiving the most federal oversight are those in Class III,[3] which includes the Infuse device at issue here. A Class III device is subject to a rigorous pre-market approval process,

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[3] A Class III device is defined as one that cannot be classified 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)(i), (ii), (iii).

which includes FDA review of the device's benefits, effectiveness, risks of injury, and proposed labeling. § 360c(a)(1)(c). If a manufacturer wishes to make any changes in design specifications, manufacturing processes, labeling, or other feature that would affect the device's safety or effectiveness after receiving the pre-market approval, it must submit a supplemental application for additional FDA approval. § 360e(d)(6).

"To preserve federal regulatory authority over medical devices and thereby enable the FDA to balance various statutory objectives," the MDA contains an express preemption provision, which prevents states from imposing requirements on medical devices that are "different from, or in addition to" those imposed by the FDCA. See Gavin v. Medtronic, Inc., 2013 WL 3791612, *3 (E.D.La. July 19, 2013); § 360k(a). The Supreme Court has established a two-step inquiry for determining whether state law claims are expressly preempted. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). First, the court must determine whether the federal government established requirements applicable to the medical device. If yes, then the court must determine whether the state claims would impose requirements different from, or in addition to, the federal requirements. Id. at 321-23. The Eighth Circuit has explained that "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir. 2010).

However, the MDA does not prevent a state from providing a damages remedy for a violation of state law that parallels a federal requirement under the MDA. Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013) ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty[.]"). "In

order for a state requirement to be parallel to a federal requirement . . . the plaintiff must show that the requirements are 'genuinely equivalent.' 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." McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005). Additionally, "[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific [federal] requirements that have been violated." Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011); Otis-Wisher v. Fletcher Allen Health Care, Inc., 2013 WL 3214714, *4 (D.Vt. June 25, 2013) ("[A] plaintiff must do more than simply incant the magic words 'Medtronic violated FDA regulations' in order to avoid preemption.").

While it is established that parallel claims are not preempted under the MDA, "it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001). "Congress intended that the MDA be enforced exclusively by the Federal Government." Id. at 352; see § 337(a) ("enforcement, or to restrain violations of th[e] [FDCA] shall be by and in the name of the United States."). Therefore, in order for plaintiffs to maintain their parallel state claims, they must "rely[] on traditional state tort law which has 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., 2013 WL 453133, *6 (W.D. Okla. Feb. 6, 2013). Thus, a state law claim is impliedly preempted when it "exist[s] solely by virtue" of a federal requirement. Buckman, 531 U.S. at 353.

III. Discussion

Step one of the preemption inquiry is to determine whether the federal government has established requirements applicable to the Infuse device. Riegel, 552 U.S. at 321-323. This question is easily answered in the affirmative. The Supreme Court has recognized that specifications listed in a pre-market approval are federal requirements and deviations from those specifications are considered violations of the FDCA. Id. at 321. Because the Infuse device received pre-market approval from the FDA, as well as supplemental approvals, the federal government has established requirements in regards to the Infuse device. See Gavin, 2013 WL 3791612, at *12 ("[B]ecause the Infuse Bone Graft received premarket approval from the FDA . . . the first condition under the Riegel two-step analysis is satisfied.").

The second step of the preemption inquiry is to determine whether plaintiff's state law claims would impose requirements different from, or in addition to, the federal requirements. Id. at 321-323. However, in order to answer this inquiry, the court must first establish whether the plaintiff has alleged a *specific* federal violation. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996); Wolicki-Gables, 634 F.3d at 1301.

In the second amended complaint, plaintiff alleges that Medtronic violated the FDA's Current Good Manufacturing Practices (CGMP), but she does not point to any specific sections or practices. General allegations of failure to comply with the CGMP are not sufficient to plead a specific federal violation. See In re Medtronic, 623 F.3d at 1206. However, plaintiff also alleges that Medtronic violated requirements specific to the FDA's pre-market approval of the Infuse device. Claims premised on a violation of a pre-market approval requirement are sufficient to plead a specific federal violation.

See Riegel, 552 U.S. at 330; Williams v. Cyberonics, Inc., 2010 WL 2982839, *2 (3d Cir. 2010); Simmons v. Boston Scientific Corp., 2013 WL 1207421, *4 (C.D. Cal. Mar. 25, 2013).

Specifically, plaintiff argues that the FDA's pre-market and supplemental approvals of the Infuse device indicate that the device is to be used for spinal fusion procedures and for use with an LT or Interfix Cage. Plaintiff alleges that despite these indications, Medtronic encouraged doctors to use the Infuse device for non-approved procedures and cages. Plaintiff alleges that the FDA issued a letter to Medtronic on July 1, 2007 warning against the off-label use of the Infuse device in cervical spine placements. Plaintiff alleges that these actions caused the introduction of adulterated and misbranded medical devices into interstate commerce in violation of 21 U.S.C. § 351 *et seq*.

Medtronic argues that these allegations do not qualify as a specific federal violation because off-label promotion is not prohibited and, thus, cannot be the basis for a misbranding claim under § 351. In support of this argument, Medtronic cites to United States v. Caronia, 703 F.3d 149, 154 (2d Cir. 2012), which states that "[t]he FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use." However, what Medtronic fails to point out is that Caronia acknowledged that "the FDA [has] construed the FDCA's misbranding provisions to prohibit off-label promotion by pharmaceutical manufacturers[.]" Id. Furthermore, Caronia is distinguishable because it was an appeal of a *criminal* conviction in which a pharmaceutical sales representative was found guilty of conspiracy for introducing a misbranded drug into interstate commerce. Caronia addressed the limited issue of whether the government "can *prosecute* pharmaceutical

manufacturers and their representatives under the FDCA" for speech promoting off-label uses of an FDA-approved drug. Id. at 169 (emphasis added). In contrast, the plaintiff here is bringing a *civil* case against the manufacturer itself. Caronia does not apply in the instant case.

The Court is also aware of Dawson v. Medtronic Inc., 2013 WL 4048850 (D.S.C. Aug. 9, 2013), which held that off-label promotion is not a violation of federal regulations and does not constitute misbranding under 21 U.S.C. § 352. However, this Court cannot agree with Dawson and is not the only court to disagree. See Wolicki-Gables, Inc. 641 F.Supp. 2d at 1292 ("The Court recognizes that the FDCA and its regulations prohibit off-label promotion by manufacturers[.]"); Carson v. Depuy Spine Inc., 365 Fed. Appx. 812, 815 (9th Cir. 2010) ("[T]he marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA."). Furthermore, pursuant to 21 C.F.R. § 814.39(a)(1), the federal government requires manufacturers to file supplemental approvals with the FDA for any "new indications for use of the device." If medical device manufacturers were permitted to promote their products for non-approved off-label uses, the regulations promulgated by the FDA would be meaningless and manufacturers would have little reason to participate in the supplemental approval process. Accordingly, the Court finds that plaintiff's second amended complaint sufficiently alleges a specific federal violation.

The Court now moves on to determine whether plaintiff's state law claims are "different from, or in addition to" federal requirements and, if not, whether such claims would give rise to liability under state law even if the FDCA had never been enacted. Riegel, 552 U.S. at 321-23; Buckman, 531 U.S. at 353.

Count One: Manufacturing Defect

Count One alleges that the "use of Infuse Bone Graft via cervical disketcomy surgery and fusion was a reasonably foreseeable use, marketed, and promoted by Medtronic." [Doc. #24, ¶ 116]. Plaintiff alleges that the "Infuse Bone Graft implanted into [p]laintiff was defective, as evidenced by defendant's failure to comply with the manufacturing specifications required by Infuse Bone Graft's [pre-market approval]." [Doc. #24 at ¶ 118].

"An adequately pleaded claim that a specific device was not manufactured in accordance with its [pre-market approval] specifications can survive preemption." In re Medtronic, 592 F. Supp.2d at 1161, n. 17 (D. Minn. Jan. 5, 2009) (aff'd In re Medtronic, Inc., 623 F.3d 1200). In the instant case, plaintiff does not adequately plead a manufacturing defect in the second amended complaint. Plaintiff's claim is that the manufacturing process became defective as a result of Medtronic's promoting the Infuse device for off-label uses. This argument "purports to impose liability on the manufacturer despite the manufacturer's compliance with the applicable FDA design and manufacturing specification[s], as approved by the FDA during the pre-market approval process[.]" Warren v. Howmedica Osteonics Corp., 2011 WL 1226975, *4 (E.D.Mo. Mar. 29, 2011) (citing Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011)). Thus, plaintiff is attempting to impose responsibilities on Medtronic that are different from, or in addition to, the federal requirements. Accordingly, the Court finds Count One to be expressly preempted under § 360k(a).

Count Two: Failure to Warn

In Count Two, plaintiff alleges that "Medtronic had an established duty to plaintiff and to the FDA to warn of the dangers in using Infuse Bone Graft for off-label purposes

which makes Infuse Bone Graft unreasonably dangerous to use without such warning" and that Medtronic was "aware of the dangers generally known to the scientific community at the time they manufactured and distributed Infuse Bone Graft." [Doc. #24, ¶ 125].

"For [p]laintiff to prevail, a jury would have to find . . . that [d]efendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device[.]" Houston v. Medtronic, Inc., 2013 WL 3927839, *8 (C.D. Cal. July 30, 2013); Caplinger, 2013 WL 453133, at *13 (same); see also In re Medtronic Inc., 623 F.3d at 1205 (dismissed failure to warn claim on the basis that plaintiff "did not allege that Medtronic modified or failed to include FDA-approved warnings."). Plaintiff's failure to warn claim would "establish labeling and warning requirements different from, or in addition to, federal requirements for the Infuse Device." Id.

Furthermore, even if plaintiff based this claim on Medtronic's failure to file an adverse event report with the FDA, the Eighth Circuit has held that such a claim is preempted under Buckman. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d at 1205-06 ("Plaintiffs alleged that Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations . . . these claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by 337(a) as construed by Buckman."). Accordingly, Count Two is expressly preempted under § 360k(a).

Count Three: Design Defect

Count Three contains the allegation that the "Infuse Bone Graft, when used off-label, was designed in a materially defective manner." [Doc. #24 at ¶ 128]. Plaintiff claims that "had Medtronic [] complied with their duties to the FDA and as described

under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action." [Doc. #24 at ¶ 129]. Plaintiff further claims the "off-label usage of Infuse Bone Graft was not only reasonably foreseeable but explicitly intended by the promotion and marketing, by Medtronic[.]" [Doc. #24 at ¶ 132].

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]." In re Medtronic Inc., 623 F.3d at 1206. The Infuse device received pre-market approval from the FDA and plaintiff "does not allege the design of Infuse was anything other than the design approved by the FDA." See Otis-Wisher, 2013 WL 3214714, at *5. Allowing this 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. To permit a jury to second-guess the Infuse Device's design would risk interference with the federally-approved design standards and criteria." Caplinger, 2013 WL 453133, at *13. Plaintiff's design defect claim is attempting to establish design requirements different from, or in addition to, federal requirements. Accordingly, the Court finds Count Three expressly preempted under § 360k(a).

Count Four and Count Seven: Negligence and Negligence Per Se

Plaintiff alleges that Medtronic negligently engaged in "the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing of the Infuse device." [Doc. 24, ¶ 135]. Plaintiff alleges defendant negligently engaged in "the illegal off-label promotion of Infuse Bone Graft by recommending to physicians, and instructing them to use it in procedures for

which it had not been approved;" "promoting the off-label use of Infuse Bone Graft by instructing, promoting and directing the use of the product in cervical fusion procedures that had not been approved by the FDA;" "failing to disclose [] that the promoted off-label use of Infuse Bone Graft can result in serious side effects;" "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;" "representing that the off-label use of Infuse Bone Graft was safe when, in fact, it was unsafe;" "promoting Infuse Bone Graft beyond the narrow and limited uses for which it was approved;" "failing to adequately warn the medical community, the general public, and plaintiff of the dangers, contra-indications, and side effects from the off-label use of Infuse Bone Graft;" and "failing to act as a reasonably prudent drug manufacturer." [Doc. #24, ¶ 135].

Other district courts have dismissed nearly identical negligence claims. For instance, in Houston v. Medtronic Inc., 2013 WL 453133, plaintiff based her negligence claim on the improper promotion of the Infuse Device for off-label uses; failure to warn physicians and plaintiff of the dangers associated with off-label uses; failure to comply with federal law; and failure to use reasonable care to prevent unreasonable risk of harm to plaintiff. Id. at * 8. The court held that "to the extent [p]laintiff's negligence claim is premised on a failure to warn or dangerous design, the claim is expressly preempted . . . on the theory that state law required [d]efendants to issue warnings . . . 'different from' or 'in addition to' what applicable federal requirements demand." Id. at *9. Furthermore the Houston court stated that "*any* negligence claim based *solely* on illegal off-label promotion is impliedly preempted" because the "claim that [d]efendants engaged in illegal off-label marking of the Infuse Device 'exist[s] solely

by virtue' of federal regulations, and is not rooted in any traditional state tort law." Id. (emphasis added).

In Gavin v. Medtronic Inc., 2013 WL 3791612, the court dismissed plaintiff's negligence claim, which was also based on Medtronic's off-label promotion of the Infuse device. Id. at 11. Gavin cited to a Fifth Circuit opinion which held that "[n]o negligence claims can be maintained as to devices that complied with the FDA requirements because success on those claims requires a showing that the FDA requirements themselves were deficient." Id. at 14 (citing Gomez v. St. Jude Medical Daig Div. Inc., 442 F.3d 919, (5th Cir. 2006)). The court explained:

> **[T]o state a valid parallel claim that is not expressly preempted by § 360(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).**

Id.

This Court likewise concludes that plaintiff's negligence and negligence per se claims are impliedly preempted. "[P]laintiff's negligence claim based upon defendants' promotion and marketing of the Infuse Devise is not based on conduct that would give rise to a recovery under state law [] in the absence of the FDCA." Caplinger v. Medtronic, Inc., 2013 WL 453133, at *15. Although Missouri products liability law supports recovery under a negligence theory, the conduct plaintiff complains of 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." Linegar v. Armour of America, 909 F.2d 1150, 1152-53 (8th Cir. 1990); Caplinger, 2013 WL 453133, at *6; see also John Coleman v. Medtronic, Inc., Case No, B243609 (LA Super. Ct. Jan. 27, 2014), at 19 ("The only convincing reason to dismiss a cause of action based on 'negligence per se' is if such a claim is not cognizable under state law."). "To determine whether said conduct is improper would require reliance on the requirements of the FDCA. Further, even the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not part of [Missouri] substantive law. While plaintiff couches her claim as a state law negligence claim, this claim is, in substance, a claim for violating the FDCA." Id. at *15-16. Accordingly, Counts Four and Seven are impliedly preempted under § 337(a) .

Count Five: Strict Liability - Excluding Design Defect

Plaintiff alleges in Count Five that "the off-label use of Infuse Bone Graft in a cervical fusion procedure was defective, unsafe and ineffective, and Medtronic Defendants knew or should have known that it was unsafe and ineffective when used in an off-label manner as promoted, instructed and supplied by Medtronic Defendants, and as utilized in Plaintiff's September 19, 2007 surgery." [Doc. #24, ¶ 145]. Plaintiff alleges that Medtronic "promoted the off-label use of Infuse Bone Graft with the knowledge of its risk to patients." [Doc. #24, ¶ 151]. Plaintiff claims that the "risk attendant to the off-label use of Infuse Bone Graft greatly outweighed the benefit to be expected from said use as promoted by Medtronic[.]" [Doc. #24, ¶ 153].

Plaintiff's strict liability claim is also impliedly "preempted because promoting the off-label use of an FDA approved medical device is not unlawful under 'traditional state tort law which, had predated the federal enactments in question.'" Dawson, 2013 WL

4048850, at *6 (citing Buckman, 531 U.S. 341 at 353)); see also In re Medtronic Inc., 592 F. Supp.2d at 1161 ("Plaintiffs' claims are based only on 'generalized common law theories' such as strict liability, negligence, and breach of warranty. Such claims are preempted.").

Furthermore, plaintiff "cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of [pre-market] approval." Perez v. Nidek Co., Ltd., 711 F.3d 1109 (9th Cir. 2009). In the July 2007 warning letter, the FDA attempted to address Medtronic's off-label use of the Infuse device in cervical placements. However, the FDA chose not to take any official action against Medtronic. "Whether Defendants' use of the [device] was in violation of the FDCA depends on, among other things, the scope of the [pre-market approval]. . . whether Defendants were engaged in a permissible 'off-label use' . . . All of these matters rest within the enforcement authority of the FDA, not this Court." Id. at 1120. Accordingly, Count Five is impliedly preempted under § 337(a).

Count Six and Count Eight: Fraud and Intentional Misrepresentation

In Count Six, plaintiff alleges that Medtronic "concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' and patients decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment[.]" [Doc. #24, ¶ 160]. Plaintiff alleges five instances, as reported by the United States Senate Committee on Finance, where Medtronic employees or agents knowingly or recklessly provided inaccurate or misleading information: (1) "Dr. John Kenneth Burkus, a Medtronic consultant, admitted via email that he expected a Medtronic study to be endorsed by authors who did not author the article;" (2) "Julie Bearcraft, a Medtronic employee, asked that reports of adverse

events associated with Infuse Bone Graft be omitted;" (3) "Rick Treharne, a Medtronic employee, admitted via email that he helped author a spinal surgery study, even though he is not a medical doctor;" (4) "Bill Martin, a Medtronic employee, stated via email that off-label surgeries should not be discouraged;" and (5) "Dr. Kulko [plaintiff's surgeon] is believed to have fabricated and overstated data regarding Infuse Bone Graft." [Doc. #24, ¶ 161].

In Count Eight, plaintiff alleges that "[i]n connection with the marketing and sales of Infuse Bone Graft, Defendants made misrepresentations of material facts regarding the merchantability and safety of the Infuse Bone Graft for off-label use." [Doc. #24, ¶ 181]. Plaintiff alleges Medtronic "reported findings with significantly less incidences of complications than were reported in the data supporting the findings and misrepresented the independence of the authors of the reports on Infuse Bone Graft's off-label use" and "paid sham consulting fees" to physicians "for the agreement to perform unlawful promotional activities for on-label and off-label sales." [Doc. #24, ¶ 182, 184]. Although the word "fraud" is not specifically used in these allegations, the Court finds that they can be read only as averments that Medtronic committed fraud through its intentional misrepresentations. As such, plaintiffs' allegations are subject to analysis under Rule 9(b). See Crocker v. KV Pharmaceutical Co., Case No. 4:09-CV-198 (Mar. 24, 2010) (citing Urban v. Comcast Corp., 2008 WL 4739519, *9 (E.D.Pa. Oct. 28, 2008)).

The Court finds Houston v. Medtronic, Inc., 2013 WL 3927839, to be particularly instructive in regard to this claim. In concluding that plaintiff's fraud-based claims were not preempted, the Houston court explained:

> **Leaving aside Rule 9(b) for the moment, the Court concludes that Plaintiff's fraud-based claims could escape both express and implied preemption. As an initial matter. Plaintiff's fraudulent advertising claims are not impliedly preempted under Buckman because they are moored in traditional state common law that exists independently from the FDCA. With respect to express preemption, Plaintiff's claim that Defendants made fraudulent statements to promote off-label uses of the Infuse Device lies "parallel" to federal requirements. First, although federal law permits Defendants to engage in advertising beyond the subject device's label, it requires that such representations not be false or misleading. Second, federal regulations prohibit device manufacturers from promoting off-label uses of medical devices. Against this backdrop, Plaintiff's fraud claims are parallel or "genuinely equivalent" to federal law[.]**

Id. at *10 (internal citations omitted).

Section 407.020 of the Missouri Revised Code, provides that acts of "deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise . . . is declared to be unlawful." Mo. Rev. Stat. § 407.020. Therefore, "leaving aside Rule 9(b) for the moment" and following the Houston analysis, plaintiff's fraud and misrepresentation claims escape express and implied preemption.

However, the Court must dismiss plaintiff's fraud and intentional misrepresentation claims because plaintiff has failed to plead them 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." Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 187 (2nd Cir. 2004). Although plaintiff has alleged who made the representations and the general content of the statements, she has not alleged with specificity when and where these representations

were made, to whom the representations were made, and how some of these representations are fraudulent.

The Court will dismiss Counts Six and Eight without prejudice. Plaintiff is granted leave to amend, if possible, these fraud-based claims in order to satisfy the particularity requirement of Rule 9(b).

Count Nine: California Unfair Competition law

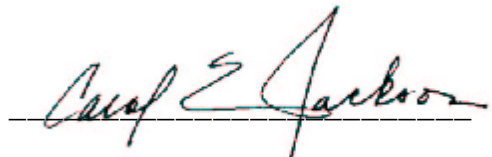
Plaintiff concedes that she cannot maintain a claim based on the California Unfair Competition Law because she is not a citizen of California. Accordingly, the Court will dismiss this claim with prejudice.

* * *

Accordingly,

IT IS HEREBY ORDERED that defendant's motion to dismiss the second amended complaint [Doc. #55] is granted.

IT IS FURTHER ORDERED that defendants' motion for oral argument [Doc. #58] is moot.



CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 25th day of March, 2014.