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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

DEBRA and PATRICK MARTIN, Plaintiffs, vs. MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC., Defendants.	)	No. 2:14-cv-0385-HRH

O R D E R

Motion to Dismiss

Defendants move to dismiss plaintiffs' complaint.[1] This motion is opposed.[2] Oral argument was requested but is not deemed necessary.

Background

Plaintiffs are Debra and Patrick Martin. Defendants are Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.

[1]Docket No. 13.

[2]Docket No. 15.

Defendants are alleged to have "researched, developed, manufactured, marketed, promoted, advertised, sold and distributed" a medical device known as the Infuse® Bone Graft device.[3] The Infuse device "consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) the bone graft substitute which consists of liquid rhBMP-2 (derived from Chinese hamster cells);[4] and (3) an absorbable collagen sponge (ACS) which holds the protein and is then placed inside the cage."[5]

The Infuse device is considered a Class III medical device[6] and thus in order to market the device, defendants had to obtain Premarket Approval (PMA) from the Federal Drug Agency (FDA). "Premarket approval is a 'rigorous' process." Riegel, 552 U.S. at 317 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996)). "The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds

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[3]Complaint for Damages at 3, ¶ 1 & 6, ¶ 22, Docket No. 1.

[4]Plaintiffs refer to this component as the "bone protein" in their response to the instant motion.

[5]Complaint for Damages at 13, ¶ 57, Docket No. 1.

[6] "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or 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.'" Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008) (quoting 21 U.S. C. § 360c(a)(1)(C)(ii)). Examples of Class III devices are "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators[.]" Id.

there is a reasonable assurance of the device's safety and effectiveness." Id. at 318 (internal citations omitted). "The agency must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" Id. (quoting 21 U.S.C. § 360c(a)(2)(C)). As part of the PMA process, the manufacturer "must include copies of all proposed labeling for the device," which must include, among other things, "information for use...."[7] "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading[.]" Riegel, 552 U.S. at 318 (internal citations omitted).

"On July 2, 2002, the FDA approved Infuse® to treat degenerative disc disease, but only by means of one specific procedure, namely, anterior lumbar interbody fusion (ALIF) surgeries on a single level between L4 and S1."[8] Plaintiffs allege that "[t]here are numerous

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[7]Complaint for Damages at 16, ¶ 68, Docket No. 1.

[8]Id. at 17, ¶ 74. The initial PMA has been supplemented and the FDA has approved the use of the Infuse device at the L4-S1 to L2-S1 level, has approved alternative cage components, and has approved the use of the bone protein alone (without the cage component) for certain oral maxillofacial surgeries and to repair tibial fractures. Id. at 17, n.1; Exhibits B, D, E & F, Request for Judicial Notice, Docket No. 14. (Defendants have requested that the court take judicial notice of numerous PMA documents. Plaintiffs do not oppose this request and because these documents are publically available and/or official FDA documents, the court may take judicial notice of these documents without converting this Rule 12(b)(6) motion into a motion for summary judgment. Lee v. City of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001). "Once a device has received premarket approval," the manufacturer cannot "make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Riegel, 552 U.S. at 319.

lumbar and cervical spine procedures for which Infuse® was not initially approved and for which it has never subsequently been approved."[9] Use of a medical device in a manner not consistent with the FDA-approved label is known as "off-label" use.

Although physicians may independently decide to use a device off-label, plaintiffs allege that "medical device companies are prohibited by federal law from promoting off-label uses for their medical devices or from paying doctors inducements or kickbacks to promote off-label uses[.]"[10] Yet, according to plaintiffs' allegations, this is exactly what defendants did. Plaintiffs allege that defendants

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[9]Complaint for Damages at 18, ¶ 78, Docket No. 1. Defendants contend that the FDA does not approve "uses" of a medical device through the PMA process but rather that the FDA approves the device itself and the labeling for the device. See Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, Case No. 1:06-cv-1435-SEB-JMS, 2008 WL 4367554, at *6 (S.D. Ind. 2008) (quoting 21 U.S.C. § 396) ("The Food, Drug, and Cosmetic Act is clear that it does not '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.' Thus, the FDA does not approve or disapprove the use of medical devices for specific treatments.")). But, plaintiffs contend that "the FDA's detailed safety and effectiveness evaluation is strictly tied to the manufacturer's intended use of the device." Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 985 (D. Ariz. 2013). "The FDA looks only at the 'safety and effectiveness of a device ... with respect to the persons for whose use the device is represented or intended, with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" Id. (quoting 21 U.S.C. § 360c(a)(2)).

[10]Complaint for Damages at 19, ¶ 79, Docket No. 1. It has been estimated that by 2011, "at least 85% of InFuse use [was] off-label." Staff Report on Medtronic's Influence on Infuse Clinical Studies at 3, Exhibit B, Memorandum in Opposition to Defendants' Motion to Dismiss, Docket No. 15.

> [i]n order to drive sales of Infuse®, ... engaged in a multi-faceted campaign[11] to promote off-label uses of Infuse® that consisted of the following techniques:
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> a. Utilizing its sales representatives to promote off-label uses of Infuse® by having the representatives be present in operating rooms during surgery to assist physicians, distribute the false and misleading medical literature that was written and/or edited by [defendants], make recommendations concerning dosing, and refer physicians to [defendants'] paid physicians;
> b. Utilizing its distributors to purchase gifts for physicians and facilities with the aim of inducing those parties to use Infuse® off-label;
> c. Utilizing "Opinion Leaders" and other paid physician consultants to promote off-label uses of Infuse® at conferences, in VIP meetings, hands-on demonstrations, and by having these paid physicians serve as resources for other physicians seeking more information on off-label uses of Infuse®; and
> d. Playing an active role in the writing and editing of nearly all published medical literature on Infuse® from at least 2001 through 2006[.12]

Plaintiffs further allege that defendants engaged in this off-label promotion even though defendants knew that the off-label uses they were promoting were dangerous and

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[11]The editor-in-chief of The Spine Journal referred to this as a "carnival-like promotion" in that "[m]arket boosters adverted that the BMP-2 product went beyond all other medical innovations." Response to Long-Awaited YODA Report on Controversial Spinal Fusion Product, Exhibit A at 1, Memorandum in Opposition to Defendants' Motion to Dismiss, Docket No. 15.

[12]Complaint for Damages at 39-40, ¶ 158, Docket No. 1.

likely to cause side effects, "such as severe uncontrolled or ectopic bone growth, severe inflammatory reaction, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement."[13] Plaintiffs allege that defendants engaged in the off-label promotion of the Infuse device because it was profitable for them to do so.[14]

"On July 14, 2010," plaintiff Debra Martin "underwent a posterolateral lumbar interbody fusion at L4-5 and L5-S1. To achieve fusion, [Debra's] surgeon performed an off-label procedure by utilizing a posterolateral approach, as well as by failing to use the required LT-Cage™."[15] Plaintiffs allege that defendants, "through their sales representatives and paid Key Opinion Leaders,[16] directly and indirectly promoted, trained, and encouraged [Debra's] surgeon to engage in the off-label procedure of utilizing a posterolateral approach without the required LT-Cages™."[17] Plaintiffs allege that in August 2013, Debra "was diagnosed with bony overgrowth at L5-S1. A CT-scan also

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[13]Id. at 28-32, ¶¶ 112-123.

[14]Id. at 35-36, ¶¶ 136-140 (alleging, for example, that defendants sold $4 billion worth of Infuse devices between 2002 and 2011).

[15]Id. at 80, ¶ 299.

[16]Plaintiffs allege that Key Opinion Leaders "were paid physician promoters[.]" Id. at 4, ¶ 6.

[17]Id. at 80, ¶ 300.

revealed the formation of a cyst near the cage, which had become displaced.[18] As a result, [Debra] has required extensive medical treatment."[19]

On February 27, 2014, plaintiffs commenced this action. Plaintiff Debra Martin asserts the following state law claims against defendants: 1) fraudulent misrepresentation/fraud in the inducement, 2) strict products liability - failure to warn, 3) strict products liability - design defect, 4) strict products liability - misrepresentation, 5) product liability - negligence, 6) breach of express warranty, and 7) violation of Arizona's Consumer Protection statutes. Debra's claims are based on her contention that defendants "should not have violated federal law by falsely and misleadingly promoting and marketing new designs and uses for a product that were never considered or approved by the FDA."[20] Patrick Martin asserts a loss of consortium claim.

Defendants now move to dismiss plaintiffs' claims.

Discussion

Defendants move to dismiss pursuant to Rules 9(b) and 12(b)(6), Federal Rules of Civil Procedure. "Rule 12(b)(6) authorizes courts to dismiss a complaint for 'failure to state a claim upon which relief can be granted.'" In re Rigel Pharmaceuticals, Inc. Securities

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[18]This allegation is inconsistent with plaintiffs' allegation that Debra's surgeon did not use the LT-Cage™.

[19]Complaint for Damages at ¶ 301, Docket No. 1.

[20]Plaintiffs' Response at 3, Docket No. 15 (emphasis omitted).

Litig., 697 F.3d 869, 875 (9th Cir. 2012) (quoting Fed. R. Civ. P. 12(b)(6)). "To avoid dismissal, the complaint must provide 'more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "'[A] plaintiff must 'allege sufficient factual matter ... to state a claim to relief that is plausible on its face.'" OSU Student Alliance v. Ray, 699 F.3d 1053, 1061 (9th Cir. 2012) (quoting Pinnacle Armor, Inc. v. United States, 648 F.3d 708, 721 (9th Cir. 2011)). "In evaluating a Rule 12(b)(6) motion, the court accepts the complaint's well-pleaded factual allegations as true and draws all reasonable inferences in the light most favorable to the plaintiff." Adams v. U.S. Forest Srvc., 671 F.3d 1138, 1142-43 (9th Cir. 2012). "Rule 9(b) provides that '[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.'" United States ex rel. Cafasso v. General Dynamics C4 Systems, Inc., 637 F.3d 1047, 1054-55 (9th Cir. 2011) (quoting Fed. R. Civ. P. 9(b)). "To satisfy Rule 9(b), a pleading must identify 'the who, what, when, where, and how of the misconduct charged,'" as well as "'what is false or misleading about [the purportedly fraudulent] statement, and why it is false.'" Id. at 1055 (quoting Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)).

Defendants argue that plaintiffs' claims must be dismissed because they are preempted. The FDA regulates medical devices pursuant to the Medical Device

Amendments of 1976 (MDA). The MDA contains an express preemption clause that provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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). "A state law claim will be expressly preempted by Section 360k(a) when 1) there are federal requirements applicable to the medical device and 2) the state law claim seeks to impose requirements[[21]] that relate to safety and effectiveness of the device that are 'different from, or in addition to' those federal requirements." Hawkins v. Medtronic, Inc., Case No. 1:13–CV–00499 AWI SKO, 2014 WL 346622, at *3 (E.D. Cal. Jan. 30, 2014) (quoting Riegel, 552 U.S. at 321–22).

Plaintiffs' claims may also be impliedly preempted. "Implied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law." Kashani-Matts v. Medtronic, Inc., Case No. SACV 13-01161–CJC(RNBx), 2014 WL 819392, at *2 (C.D. Cal. Feb. 14, 2014) (citing Buckman Co. v.

[21]"State 'requirements' include the state's common law legal duties." Eidson v. Medtronic, Inc., 981 F. Supp. 2d 868, 880 (N.D. Cal. 2013) (Eidson I).

Plaintiffs' Legal Comm., 531 U.S. 341, 352–53 (2001)).[22] "A state law claim will be impliedly preempted when it is not based on a violation of state law tort duties." Hawkins, 2014 WL 346622, at *4. "Claims not tied to state law tort duties are essentially private actions to enforce the FDCA and are barred by Section 337(a)"[23] of the MDA. Id.

"Together, express preemption and implied preemption leave only a 'narrow gap' through which the plaintiff's claims must fit in order to survive." Kashani-Matts, 2014 WL 819392, at *2 (quoting Perez, 711 F.3d at 1120). A plaintiff can pass through this narrow gap by alleging "parallel" claims. As the Court explained in Riegel, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (quoting Lohr, 518 U.S. at 495). "'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.' 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.'" Wolicki-Gables

[22]Plaintiffs suggest that Buckman only applies to fraud-on-the-FDA claims because that was the claim at issue in that case, but Buckman cannot be read that narrowly. See e.g., Perez v. Nidek Co., 711 F.3d 1109, 1119-20 (applying Buckman to fraud by omission claim based on a failure to disclose information to patients).

[23]Section 337(a) states in relevant part that "all 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).

v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005)). "'To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation.'" Eidson v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1996024, at *7 (N.D. Cal. 2014) (Eidson II) (quoting Erickson v. Boston Scientific Corp., 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011)).

Defendants first argue that plaintiffs' claims are expressly preempted. To determine if state law claims are expressly preempted under § 360k(a), the court employs a two-part test. First, "[s]ince the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law, [the court] must determine whether the Federal Government has established requirements applicable to" the medical device in question. Riegel, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). "If so," the court "must then determine whether [plaintiffs'] common-law claims are based upon [Arizona] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." Id. at 321-322 (quoting 21 U.S.C. § 360k(a)). If both prongs are met, the claims are expressly preempted.

Defendants argue that the first prong of the express preemption test is met because Riegel establishes that the PMA process for a medical device imposes federal requirements that preempt state-law tort claims. The Court in Riegel found that the PMA process for a Class III catheter "impose[d] 'requirements'", in large part because the PMA process "is [the] federal safety review." Id. at 322-23. Because the Infuse device obtained PMA, defendants argue that the federal government has established requirements applicable to the Infuse device.

Plaintiffs acknowledge that the Infuse device went through the PMA process, but they argue that the PMA process only applied to the Infuse device that contained all three components and that the FDA only reviewed the safety and effectiveness of the device for one specific use. Thus, plaintiffs argue that the federal requirements were imposed only for that use. Plaintiffs insist that the PMA does not establish federal requirements applicable to the unreviewed, unapproved uses of the bone protein component by itself. Plaintiffs rely primarily on Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977 (D. Ariz. 2013), to support their argument.[24] There, Ramirez had a lumbar fusion operation, in which her surgeon "used only the rhBMP–2 bone graft component of the Infuse device and employed a posterior approach." Id. at 983. Ramirez asserted numerous state-law tort claims against

[24]In their opposition, plaintiffs cite to numerous state court decisions that they contend have also rejected defendants' preemption arguments. Plaintiffs' citation to these decisions was unhelpful because in large part the courts' reasoning was not clear as the decisions were made on the record or in conclusory written orders.

defendants, and defendants moved to dismiss those claims. The court held that Ramirez's claims were not expressly preempted under § 360k(a). The court explained that "[t]he fundamental purpose of § 360k's express preemption provision is to avoid having another entity (jury, state regulators, or state legislatures) arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process." Id. at 991. "That concern vanishes when the plaintiff brings a claim against a manufacturer that arises out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer." Id. "When the device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection." Id. "It is true that federal requirements are still applicable to the device, including requirements that Medtronic not alter the design or label of the device without FDA consent. But 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. (footnote omitted). "In the absence of federal approval of the new use, there is nothing to preempt state law requirements." Id. at 993.

The court in McDonald-Lerner v. Neurocare Assocs., P.A., Case No. 373859-V, slip op. (Md. Cir. Ct. Aug. 29, 2013), relying on Ramirez, reached a similar result. There, the

court explained that "[t]here is no legitimate federal concern with state judges or state juries meddling with the decisions of the FDA when the state law claims, as alleged in this case 'arise out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer.'" Id. at 12 (quoting Ramirez, 2013 WL 4446913, at *9). "In other words, preemption under § 360k is not even an issue because the PMA for 'the Infuse® Bone Graft/L-T Cage Device' does not establish device-specific requirements for the bone protein alone and without the LT-Cage, or the implantation of any or all of the device through a posterior approach." Id. "In short, there is no basis for preemption under § 360k(a) under the first prong of Riegel." Id.; see also, Hornbeck v. Medtronic, Inc., Case No. 13 C 7816, 2014 WL 2510817, at *3-4 (N.D. Ill. June 2, 2014).

Plaintiffs argue that similarly here, the court should find that the first prong of Riegel has not been met because the basis for their claims is defendants' "false and misleading promotion of misbranded uses of the Bone Protein...."[25] In short, plaintiffs argue that their claims are not expressly preempted because they are based on the off-label use of the Infuse device, a use that was not subject to the FDA's review during the PMA process.

[25]Memorandum in Opposition to Defendants' Motion to Dismiss at 6, Docket No. 15.

However, "Ramirez has been rejected—for good reason—by numerous courts." Beavers-Gabriel v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1396582, at *10 (D. Hawai'i 2014). Courts have concluded

> that Ramirez "is not consistent with the text of § 360(k), the scope of federal requirements imposed on Class III devices, or Ninth Circuit precedent." Houston II, 2014 WL 1364455, at *5. Houston II explains that off-label promotion is in fact regulated by the FDA—§ 360(k) applies broadly to "devices" as opposed to particular "uses" of such devices, and the MDA prohibits off-label promotion through its statutes and regulations prohibiting misbranded devices. Id. In other words, contrary to Ramirez' suggestion that manufacturers could "escape[] federal requirements by promoting an off-label use, a device manufacturer's off-label promotion [is] itself [] subject to specific MDA provisions." Id.
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> Houston II further explains that Ramirez is contrary to Perez, which "implicitly held that the MDA imposes requirements on devices that are used in off-label manners, even when the off-label uses are promoted by the device manufacturer." Id. (citing Perez, 711 F.3d at 1112–13, 1118–19). Houston II reasons that Perez, in addressing claims for off-label use and promotion, held that "the [medical device at issue] was subject to device-specific requirements" as a result of the MDA's premarket approval regulations. Id. (citing Perez, 711 F.3d at 1118).

Id. This court joins the majority of other courts which have rejected Ramirez to the extent that it holds that the preemption analysis does not apply to claims based on off-label promotion. The preemption analysis does apply to plaintiffs' claims which are based on defendants' off-label promotion of the Infuse device. It is possible that some or all of plaintiffs' claims are preempted.

Defendants first raise a general argument that plaintiffs' claims are preempted because plaintiffs have not and cannot identify a federal prohibition on off-label promotion. Plaintiffs contend that defendants' off-label promotion violated the Federal Drug and Cosmetic Act (FDCA) because the Infuse device was "misbranded." Plaintiffs allege that misbranding occurs "when the directions and indications for the unapproved uses that the manufacturer 'intends' the product to be used for have not been included on the label."[26] Plaintiffs allege that misbranding a product violates Section 352(f) of the FDCA and that under Section 331(b) of the FDCA, a manufacturer can be liable for misbranding.[27] Plaintiffs also contend that the FDCA prohibits the "adulteration" of a medical device introduced into interstate commerce. See 21 U.S.C. § 331(a)-(c). "Under the FDCA, 'a ... device shall be deemed to be adulterated' with respect to an intended use if it is a Class III device which has not received premarket approval or § 510(k) clearance with respect to that intended use." Taylor v. Danek Medical, Inc., Case No. Civ.A. 95–7232, 1998 WL 962062, at *9 (E.D. Pa. Dec. 29, 1998) (quoting 21 U.S.C. § 351(f)).

Defendants argue, however, that the Second Circuit recently rejected a similar argument in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012). There, Caronia "was found guilty of conspiracy to introduce a misbranded drug into interstate commerce, a

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[26] Complaint for Damages at 37, ¶ 144, Docket No. 1.

[27] Id. at ¶¶ 143, 145.

misdemeanor violation of 21 U.S.C. §§ 331(a) and 333(a)(1)." Id. at 152. "Specifically, Caronia, a pharmaceutical sales representative, promoted the drug Xyrem for 'off-label use,' that is, for a purpose not approved by the U.S. Food and Drug Administration...." Id. "On appeal, Caronia principally argue[d] that the misbranding provisions of the FDCA prohibit off-label promotion, and therefore, unconstitutionally restrict speech." Id. at 160. In its discussion, the Second Circuit observed that "promoting off-label drug use concerns lawful activity (off-label drug use), and the promotion of off-label drug use is not in and of itself false or misleading." Id. at 165. The court thus "construe[d] the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." Id. at 168. The court's "conclusion [was] limited to FDA-approved drugs for which off-label use is not prohibited[.]" Id. at 168-69. District courts have relied on Caronia to hold that claims based on off-label promotion are preempted and are not parallel claims because "federal law does not bar off-label promotion[.]" Shuler v. Medtronic, Inc., Case No. CV 14–00241–R, 2014 WL 988516, at *1 (C.D. Cal. Mar. 12, 2014).

Defendants' reliance on Caronia is misplaced because Caronia held that the misbranding provisions of the FDCA did not prohibit "truthful off-label promotion of FDA-approved prescription drugs." Caronia, 703 F.3d at 168 (emphasis added). Plaintiffs' claims are premised on allegations that defendants' off-label promotion of the Infuse device

was not truthful, but rather was misleading and false. The FDCA does prohibit untruthful off-label promotion. See Eidson II, 2014 WL 1996024, at *15 (N.D. Cal. 2014) (internal citations omitted) ("[e]ven assuming off-label promotion per se does not constitute a violation of federal law as Defendants argue, Defendants have advanced no authority suggesting that federal law permits false and misleading off-label marketing"); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) (Houston I) ("federal law ... certainly prohibits false or misleading off-label promotion"); Schouest v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 1213243, at *7 (S.D. Tex. 2014) ("federal law bars off-label promotion when it is false or misleading").

Defendants next make a general argument that plaintiffs have not alleged parallel state law claims because there is no state law duty to abstain from off-label promotion. See Hawkins, 2014 WL 346622, at *19 ("Off-label promotion itself exists only as a creation of the FDCA scheme. A state law cause of action cannot rest solely on the off-label promotion of INFUSE®"); 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"). Defendants also argue that this lack of a traditional state-law duty to refrain from off-label promotion means that plaintiffs' claims are impliedly preempted.

> "[T]o avoid being impliedly preempted under Buckman, a claim must rely[] on traditional state tort law which had

> predated the federal enactments in question[ ]. 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. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly pre-empted under Buckman."

Id. at 1214-15 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009)).

This general argument fails because there is a state law duty to refrain from making misrepresentations, and this duty or requirement predates the FDCA. See Jennings v. Lee, 461 P.2d 161, 164 (Ariz. 1969) (setting out the "well-settled" elements of a claim for fraudulent misrepresentation).

Because defendants' general preemption arguments fail, it is possible that all or some of plaintiffs' claims are parallel claims. In order to determine whether plaintiffs have stated any parallel claims that would survive defendants' motion to dismiss, the court must apply the preemption analysis to each of plaintiffs' claims.

Fraud claims

In the first cause of action in plaintiffs' complaint, Debra alleges that defendants fraudulently concealed and misrepresented 1) the health and safety problems associated with the off-label use of the Infuse device, 2) their practice of promoting the off-label use of the Infuse device, and 3) the "known comparative risks and benefits of the use of" the

Infuse device.[28] Similarly, in the fourth case of action, which is a strict liability claim based on misrepresentations, Debra alleges that "[i]n the course of marketing Infuse, [d]efendants made untrue representations of material facts and omitted material information" about the risks of using the Infuse device off-label.[29] And, in the seventh cause of action, Debra asserts a violation of the Arizona Consumer Fraud Act, based on allegations that defendants had a state statutory duty to refrain from unfair or deceptive acts or practices in the development, manufacture, promotion, and sale of the Infuse device[30] and that defendants violated this duty "by knowingly and falsely representing that Infuse® was fit to be used for the purpose for which it was advertised, when in fact Infuse® was defective and dangerous when used off-label[.]"[31]

To the extent that Debra's fraud claims are based on allegations that defendants made misrepresentations and omissions in the labeling of the Infuse device, "the court joins the majority of courts finding that such claims are expressly preempted." Beavers-Gabriel, 2014 WL 1396582, at *10. "As Caplinger ... explains: 'allowing [such a] claim to proceed would permit a finding that defendants were required to alter the Infuse Device's warning

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[28]Complaint for Damages at 82, ¶ 308, Docket No. 1.

[29]Id. at 88, ¶ 353.

[30]Id. at 93, ¶ 391.

[31]Id. at 94, ¶ 397.

and label and to provide additional warnings above and beyond those on the Infuse Device's label and accompanying the device—a label and warnings that were specifically approved by the FDA as part of the PMA process." Id. (quoting Caplinger, 921 F. Supp. 2d at 1219). "Such [a] claim is expressly preempted because it seeks to impose different and/or additional written warnings and labeling beyond those approved by the FDA through the PMA process." Id.

To the extent that Debra's fraud claims are based on allegations "that [d]efendants made misrepresentations and omissions in promoting off-label use of the Infuse Device—the court joins those courts determining that such claim is neither expressly preempted nor impliedly preempted." Id. at *11. As the Houston I 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. (quoting Houston I, 957 F. Supp. 2d at 1179-80); see also, Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069, 1098-99 (D. Or. 2013) (finding fraud claims based on off-label promotion not preempted); Eidson I, 981 F. Supp. 2d at 883 (finding that to the extent the fraudulent misrepresentation/fraud in the inducement "claim is based on alleged misrepresentations and omissions Defendants made while promoting the off-label use of the Infuse Device", the claim was neither expressly or impliedly preempted); Scovil v. Medtronic, Inc., --- F. Supp. 2d ---, 2014 WL 502923, at *10 (D. Ariz. 2014) (finding claims based on allegations "that Defendants knowingly made false statements to doctors while they were promoting the off-label use of the Infuse device ... not preempted because they parallel the federal prohibition of off-label promotion and are rooted in traditional state common law claims, not violations of the MDA"); Kashani–Matts, 2013 WL 6147032, at *5 ("[t]o the extent that Plaintiff's fraud claims are based on alleged misrepresentations and omissions Medtronic made while promoting and marketing the Infuse Device, such claims could survive preemption").

But Debra's fraud claims based on the off-label promotion allegations must still be dismissed as these claims have not been pled with the requisite particularity. Debra has certainly alleged who made misrepresentations about the Infuse device and when and where those misrepresentations were made. But, she has not alleged which misrepresentations were relied on by her and her surgeon. Instead she generally alleges that

"[d]efendants through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained, and encouraged [Debra's] surgeon to engage in the off-label procedure of utilizing a posterolateral approach without the required LT-Cages™."[32] As the court in Beavers-Gabriel explained when dismissing almost identical fraud claims for failure to comply with Rule 9(b),

> [t]he Complaint certainly details (in voluminous fashion) the numerous alleged omissions and misrepresentations made by Defendants, including, for example, that they (1) funded studies which failed to accurately describe the adverse side effects of off-label uses, (2) ensured that adverse side effects were under-reported by writing and editing the published medical literature, and (3) used "opinion leaders" and other paid physician consultants to promote off-label uses of the Infuse Device at conferences, VIP meetings, demonstrations, and to serve as resources for other physicians seeking information on off-label uses. The Complaint identifies the dates of many of these alleged bad acts, and describes as much as possible the individuals responsible for these actions.
>
> Missing from the Complaint, however, is the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians— i.e., that Plaintiff and Plaintiff's physicians relied on these misrepresentations. Although the Complaint generally asserts that "Plaintiff and Plaintiff's physicians ... [relied] on MEDTRONIC's concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to use Infuse® in an off-label manner," the Complaint fails to identify what particular misrepresentations and/or concealments were made to Plaintiff and Plaintiff's physicians (as opposed to the medical field generally), who made those particular representations and/or omissions, and when those events occurred.

[32]Complaint for Damages at 80, ¶ 300, Docket No. 1.

Beavers-Gabriel, 2014 WL 1396582, at *12 (internal citations omitted).

In sum, Debra's fraud claims (the first, fourth and seven causes of action) are dismissed. But, Debra is given leave to amend as to her fraud claims which are based on allegations that defendants made misrepresentations while promoting the off-label use of the Infuse device.

Strict liability - failure to warn

In the second cause of action in plaintiffs' complaint, Debra alleges that defendants had a duty to warn her and her physicians about the dangers of using the Infuse device for off-label uses.[33] She argues that this claim survives defendants' motion to dismiss because it could be considered a parallel claim under two cognizable theories.

First, Debra argues that this claim runs parallel to the federal prohibition on off-label promotion. She cites to Riley v. Cordis Corporation, 625 F. Supp. 2d 769 (D. Minn. 2009), to support this argument. There, the court stated that

> [i]t seems possible ... that Riley could plead a narrow failure-to-warn claim that would escape preemption. Specifically, if Riley pleaded that (1) Cordis affirmatively promoted the off-label use of the Cypher stent in a manner that violated federal law, and (2) that, while promoting the device in violation of federal law, Cordis failed to include adequate warnings and directions about the off-label use that it was promoting, then Riley's claim might survive.

[33]Complaint for Damages at 84-85, ¶¶ 320-327, Docket No. 1.

Id. at 783. Debra contends that she has alleged such a claim. She argues that when the FDA approved the Infuse device, that approval pertained only to the device if it contained all three parts and that defendants unilaterally changed the intended use of that device by actively promoting the use of the bone protein alone. Or in other words, Debra argues that defendants were manufacturing, marketing, selling, and promoting an unregulated application of the bone protein, which violates both federal law and state law. See 21 U.S.C. § 352(a) (prohibition on misbranding); A.R.S. §§ 12-681 - 12-689 (product liability statutes).

This court joins the majority of other courts which have held that failure-to-warn claims "based on off-label promotion of Infuse are expressly preempted." Eidson II, 2014 WL 1996024, at *19; Beavers-Gabriel, 2014 WL 1396582, at *13 (failure to warn claim based on off-label promotion preempted because it "seeks to impose on Defendants a duty to provide warnings beyond those already outlined by the FDA, which Riegel prohibits"); Houston II, 2014 WL 1364455, at *6 ("Houston's claim that Medtronic failed to warn Houston or her physician is expressly preempted"); Hawkins, 2014 WL 346622, at *14-15 (holding that claim based on failure to warn during off-label promotion was expressly preempted); Kashani-Matts, 2013 WL 6147032, at *4 (holding that failure to warn claim based on allegations "that Medtronic failed to warn Plaintiff and her physicians of the risks and dangers involved in the offlabel use of the Infuse Device and that the warnings

accompanying the Device did not adequately warn of the dangers of using the Device in cervical fusion surgery" is expressly preempted by the MDA). Thus, Debra's failure to warn claim premised on defendants' off-label promotion is dismissed.

Debra also contends that her failure to warn claim is cognizable under Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013). There, "Richard Stengel had a SynchroMed EL Pump and Catheter surgically implanted in his abdomen to deliver pain relief medication directly into his spine." Id. at 1227. This device led to Stengel being paralyzed. Id. "When it received FDA approval of its SynchroMed EL Pump and Catheter, Medtronic was not aware of certain risks associated with the device. Before Stengel was paralyzed, however, Medtronic had become well aware of those risks but had failed to inform the FDA, even though the MDA required Medtronic to do so." Id. The Stengels sued and Medtronic moved to dismiss their complaint. Id. at 1226. "The Stengels moved to amend their complaint to add a new state-law negligence claim. That claim alleged that Medtronic had violated a state-law duty of care by failing to report known risks associated with use of its medical device to the Food and Drug Administration ("FDA")." Id. More specifically,

> [t]he new claim in the Stengels' proposed amended complaint alleges that, under federal law, Medtronic had a "continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable

> to the product." It further alleges that Medtronic failed to perform its duty under federal law to warn the FDA. Finally, the complaint alleges that, because Medtronic failed to comply with its duty under federal law, it breached its "duty to use reasonable care" under Arizona negligence law.

Id. at 1232. The Ninth Circuit held that "[t]he Stengels' proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted." Id. at 1233. The court explained:

> Plaintiffs' claim is brought under settled Arizona law that protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers. The whole modern law of negligence, with its many developments, enforces the duty of fellow-citizens to observe in varying circumstances an appropriate measure of prudence to avoid causing harm to one another. Arizona tort law includes a cause of action for failure to warn. Under Arizona law, negligence standards impose a duty to produce products with appropriate warning instructions. A product may be unreasonably dangerous in the absence of adequate warnings. The manufacturer of a product must warn of dangers which he knows or should know are inherent in its use. This duty may be a continuing one applying to dangers the manufacturer discovers after sale.
>
> If a more precise parallel were necessary, the Stengels have alleged it and Arizona law provides it. The Stengels' new claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA. Arizona law contemplates a warning to a third party such as the FDA. Under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is reasonable assurance that the information will reach those whose safety depends on their having it.

Id. (internal citations and quotation marks omitted).

Debra argues that similarly here she has alleged a state-law failure to warn claim that runs parallel to defendants' violations of the FDCA's requirements to submit reports of adverse events and include those events in their labeling. Debra contends that her failure-to-warn allegations are similar to those in Stengel because after the 2002 PMA approval of the Infuse device, defendants failed to report certain adverse events to the FDA.[34]

Courts have held that failure-to-warn claims "based on failure to report adverse events to the FDA escape[] both express and implied preemption." Eidson II, 2014 WL 1996024, at *19; Houston II, 2014 WL 1364455, at *8 (C.D. Cal. 2014) (same); Poll v. Stryker Sustainability Solutions, Inc., Case No. CIV 13–440–TUC–CKJ, 2014 WL 199150, at *1 (D. Ariz. Jan. 17, 2014) ("Poll has alleged Howmedica's failure to advise the FDA of relevant adverse consequences of the Cormet System has resulted in Poll's injuries/damages"). But the problem here is that although plaintiffs have alleged that defendants failed to warn the FDA about adverse events, they have not alleged how that failure to warn caused or contributed to their damages or injuries. Plaintiffs allege that they were damaged because defendants failed to warn Debra and her doctors, but they do not allege that they were damaged because of defendants' failure to warn the FDA about adverse events. A failure

[34]Complaint for Damages at 38, ¶ 148, Docket No. 1 (alleging that defendants violated the FDCA "by failing to account for adverse events and update its labeling, directions for use, and advertising to address the adverse events resulting from ... off-label uses").

to warn claim based on a failure to warn doctors and patients would be preempted. Houston I, 957 F. Supp. 2d at 1175 (quoting Perez, 711 F.3d at 1118) ("'had the plaintiffs predicated their claim on a failure to warn doctors directly—an action not required by FDA regulations—that claim would have been preempted because it would have been an addition to the federal requirement'"). Here, "a causal connection between [plaintiffs'] injuries and the alleged failure to report is absent. Plaintiff[s] generally allege[] that Defendants failed to report adverse events to the FDA. [They] also generally allege[] that these failures caused or contributed to [their] injuries. What is not alleged is any factual content that would support the causal nexus." Hawkins, 2014 WL 346622, at *8; see also, Beavers-Gabriel, 2014 WL 1396582, at *14 (dismissing failure to warn claim because "Plaintiff asserts that Defendants failed to provide warnings to Plaintiff and her physicians, not the FDA, and Plaintiff provides no facts or argument tying the failure to submit reports of adverse events to the FDA to a failure to warn Plaintiff and her physicians"). Thus, Debra's failure to warn claim which is based on a failure to report adverse events to the FDA is dismissed. But, Debra is given leave to amend as to this claim.

Strict products liability – design defect

In the third cause of action in plaintiffs' complaint, Debra alleges that the Infuse device's design was defective because "the design was unsafe when used in the manner

promoted by [d]efendants...."[35] Debra argues that her design defect claim is not preempted and she cites to Ramirez for support. There, the court found that the plaintiff's design defect claim was not preempted because the

> fact that Medtronic is alleged to have actively promoted the use of Infuse outside of the prescribed federal approval process has opened up state law claims premised on the new, unapproved use of Infuse. Infuse may indeed be defectively designed for the off-label uses that Medtronic may have actively promoted. Certainly the FDA has not made a finding one way or the other. Because there are no applicable federal regulations that govern the product for this new use, there is no conflict for preemption purposes.

Ramirez, 961 F. Supp. 2d at 999. Similarly, Debra argues her design defect claim is not preempted because defendants were marketing a device that had never been considered or approved by the FDA.

The weight of authority is, however, to the contrary. See Dunbar v. Medtronic, Inc., Case No. CV 14-01529-RGK (AJWx), 2014 WL 3056026, at *4 (C.D. Cal. June 25, 2014) (holding that design defect claim is preempted because for the plaintiffs' "[t]o prevail on this claim, a jury would have to make findings that conflict with those of the FDA); Poll, 2014 WL 199150, at *6 (holding that a design defect claim was preempted because "a finding of Howmedica's liability on the defective design claim would constitute an imposition of additional requirements on the design of the device than those mandated by

[35]Complaint for Damages at 86, ¶ 339, Docket No. 1.

the FDA through PMA and supplemental approval"); Scovil, 2014 WL 502923, at *9 (holding that the plaintiffs' design defect claim was preempted); Caplinger, 921 F. Supp. 2d at 1222 (same); Houston I, 957 F. Supp. 2d at 1177 (quoting Bryant v. Medtronic, Inc., 623 F.3d 1200, 1206 (8th Cir. 2010) (finding a strict liability design defect claim preempted because it "attack[ed] 'the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device'"); Beavers-Gabriel, 2014 WL 1396582, at *15 ("The court joins the majority of courts finding that this claim is expressly preempted—to prevail on this claim, Plaintiffs would need to establish that the Infuse Device should have been designed in a manner different than that approved by the FDA"); Kashani-Matts, 2013 WL 6147032, at *4 ("Because Plaintiff's design defect claim is an 'attack' on the FDA review process rather than a parallel state claim, it is preempted by the MDA"); Alton, 970 F. Supp. 2d at 1102 ("Because recognition of the design defect claim would tend to undermine the federal medical device regulatory scheme, the claim is [expressly] preempted"). The court is persuaded by this authority and holds that Debra's design defect claim is preempted. Thus, her design defect claim is dismissed.

Negligence

In the fifth cause of action in plaintiffs' complaint, Debra alleges that defendants had a duty to fully and adequately warn others about the health and safety risks related to the off-label use of the Infuse device and to disclose their practice of improperly promoting off-

label uses of the Infuse device.[36] Debra alleges that defendants breached this duty by 1) unreasonably and improperly promoting the off-label use of the Infuse device, 2) by failing to warn physicians and plaintiffs about the dangers of off-label uses, 3) by failing to exercise reasonable care to prevent the Infuse device from creating a unreasonable risk of harm to consumers; and 4) by failing to exercise reasonable care in complying with federal regulations.[37]

To the extent that Debra's negligence claim "is based on a failure to provide warnings on the labeling of the Infuse Device, or based on any negligence in the design and manufacture of the Infuse Device," the claim is expressly preempted "because such claim would seek to impose labeling and design requirements different, or in addition to, the FDA requirements." Beavers-Gabriel, 2014 WL 1396582, at *15; see also Caplinger, 921 F. Supp. 2d at 1223 (dismissing negligence claim based on a failure to warn because it was expressly preempted); Hawkins, 2014 WL 346622, at *19 (same); Eidson I, 981 F. Supp. 2d at 890-91; (same) Ledet v. Medtronic, Inc., Case No. 1:13CV200–LG–JMR, 2013 WL 6858858, at *5 (S.D. Miss. Dec. 30, 2013) (same); Dawson v. Medtronic, Inc., Case No. 3:13–cv–663–JFA, 2013 WL 4048850, at *7 (D.S.C. Aug. 9, 2013) (same).

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[36]Complaint for Damages at 90, ¶ 368, Docket No. 1.

[37]Id. at 90-91, ¶ 371.

"To the extent" that Debra's negligence claim "is based on the theory that Defendants were negligent in promoting the Infuse Device for off-label uses, it is not expressly preempted, but is barred by implied preemption." Beavers-Gabriel, 2014 WL 1396582, at *16. It is impliedly preempted "pursuant to Buckman" because "Defendants' duty (as an element of the negligence claim) to abstain from off-label promotion exists solely by virtue of the federal prohibition of off-label promotion and finds no independent source from traditional state law." Id. "In other words, absent the FDCA's prohibition of off-label promotion, Defendants have no duty based on state law to abstain from promoting the Infuse Device for off-label purposes." Id.; see also, Eidson I, 981 F. Supp. 2d at 891 ("negligence claim based on off-label promotion is not based on any conduct that would give rise to a recovery under state law even in the absence of the FDCA" and thus is impliedly preempted); Houston I, 957 F. Supp. 2d at 1178 ("any negligence claim based solely on illegal off-label promotion is impliedly preempted under Buckman and § 337(a)"); Dunbar, 2014 WL 3056026, at *4-5 (negligence claim based on "improper promotion and marketing of INFUSE for off-label use" is impliedly preempted).

To the extent that Debra's negligence claim is based on a failure to comply with federal law, she has failed to state a plausible claim because she did "not specify what federal laws were violated" so the court cannot "determine whether [she] is asserting a parallel state law claim." Beavers-Gabriel, 2014 WL 1396582, at *15.

In sum, Debra's negligence claims are dismissed. Although Debra does not raise this argument, it is possible that she could amend her negligence claim to state a plausible parallel state law claim. Courts have held that "a negligence allegation predicated on Medtronic's failure to submit adverse-event reports to the FDA after the FDA granted the Infuse device premarket approval" survive preemption. Schouest, 2014 WL 1213243, at *10. Thus, Debra will be given leave to amend her negligence claim, but only to the extent that such a claim is based on allegations regarding defendants' failure to report adverse events to the FDA.

Breach of express warranty

In the sixth cause of action in plaintiffs' complaint, Debra alleges that defendants made express warranties regarding the safety and efficacy of off-label uses of the Infuse device.[38] While defendants concede that not every warranty claim would be preempted, they argue that those, like Debra has asserted here, that implicate the safety or effectiveness of a medical device which has been through the PMA process, are preempted.

However, in Beavers-Gabriel, 2014 WL 1396582, at *17, the court found that a similar breach of warranty claim "survives both express preemption and implied preemption." The court explained that express preemption does not apply because

> "[F]ederal law already prohibits false or misleading off-label promotion. Therefore, to the extent that Plaintiff seeks to

[38]Complaint for Damages at 92, ¶ 381, Docket No. 1.

> impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff 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, Defendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes."

Id. (quoting Houston I, 957 F. Supp. 2d at 1180–81). The court also determined that implied preemption does not apply because a "breach of warranty claim is well-recognized under Hawaii law and requires a plaintiff to establish 'that (1) Defendants made an affirmation of fact or promise regarding the product, (2) that statement became part of the basis of the bargain, and (3) the product failed to perform according to the statement.'" Id. (quoting Stoebner Motors, Inc. v. Automobili Lamborghini S.P.A., 459 F. Supp .2d 1028, 1035 (D. Haw. 2006)). "This liability for a breach of warranty exists independently of the FDCA—Plaintiff's breach of warranty claim would exist even absent federal law." Id.

But even if Debra's breach of express warranty claim is not preempted, it must still be dismissed because she has not

> allege[d] sufficient facts to assert a plausible breach of warranty claim. Although the Complaint details Medtronic's alleged representations regarding off-label use of the Infuse Device, it fails to include any facts suggesting that those representations became the 'basis of the bargain' for [Debra] and her physicians. Indeed, the Complaint fails to describe what specific warranties Medtronic made to [Debra] and/or her physicians.

Id.; see also, Houston I, 957 F. Supp. 2d at 1181 ("Plaintiff has alleged no facts demonstrating that Defendants made any affirmations specifically to Plaintiff or her physician so as to form the basis of the bargain"); 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"); Ramirez, 961 F. Supp. 2d at 1001 (dismissing breach of express warranty claim because "any affirmation that forms the basis of an express warranty must be between the seller and the buyer" and Ramirez "does not allege (in anything other than the most conclusory manner) that Medtronic targeted her with its guarantees of safety in off-label use of Infuse"). Thus, Debra's express warranty claim is dismissed, not because it is preempted, but because she has not alleged what specific warranties were made to her or to her physicians. However, Debra is given leave to amend as to this claim.

Loss of consortium claim

The parties do not expressly address Patrick Martin's loss of consortium claim which is asserted in the eighth cause of action in plaintiffs' complaint. "Loss of consortium is a derivative claim, so it cannot exist unless 'all elements of the underlying cause [are] proven.'" Tavilla v. City of Phoenix, Case No. 1 CA–CV 10–0429, 2011 WL 4794940, at *9 (Ariz. Ct. App. Oct. 11, 2011) (quoting Barnes v. Outlaw, 964 P.2d 484, 486–87 (Ariz. 1998)).

Thus, this claim would survive a motion to dismiss to the extent that Debra's claims survive. Because all of Debra's claims are being dismissed, Patrick's loss of consortium claim must also be dismissed. However, because Debra has been given leave to amend as to some of her claims, Patrick is also given leave to amend his claim.

Conclusion

Defendants' Motion for Leave to File Supplemental Briefing[39] is denied.

Defendants' motion to dismiss[40] is granted. Plaintiffs' claims are dismissed. Plaintiffs are given leave to amend 1) Debra's fraud claims based on defendants' misrepresentations in off-label promotion, 2) Debra's failure to warn claim based on a failure to report adverse events to the FDA, 3) Debra's negligence claim based on a failure to report adverse events to the FDA, 4) Debra's breach of express warranty claim, and 5) Patrick's loss of consortium claim. Plaintiffs' amended complaint, if they elect to file one, shall be filed on or before August 13, 2014.

DATED at Anchorage, Alaska, this 23rd day of July, 2014.

/s/ H. Russel Holland
United States District Judge

[39]Docket No. 24.

[40]Docket No. 13.