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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

John Arvizu, et al.,

Plaintiffs,

v.

Medtronic Incorporated, et al.,

Defendants.

No. CV-14-00792-PHX-DGC

ORDER

Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. have filed a motion to dismiss pursuant to Rule 12(b)(6). Doc. 20. The motion is fully briefed. The Court will grant the motion in part and deny it in part.[1]

I. Background.

Defendants produce the "Infuse Device," which is the Class III medical device at issue in this case. Doc. 20 at 4. The Infuse Device consists of a "metallic spinal fusion cage," known as the LT-Cage, a "bone graft substitute which consists of liquid rhBMP-2" ("Bone Protein"), and "an absorbable collagen sponge (ACS) which holds the protein and then is placed inside the cage."[2] Doc. 1, ¶ 57. The Infuse Device was initially approved by the Food and Drug Administration ("FDA") via its Premarket Approval ("PMA")

[1] The requests for oral argument are denied because the issues have been fully briefed and oral argument will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); *Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998).

[2] Defendants define "rhBMP-2" as "recombinant human bone morphogenetic protein-2." Doc. 20 at 4. This substance is used to help fuse vertebrae in the spine as part of a spinal fusion surgery as an alternative to grafting a piece of the patient's own bone harvested from another location. Doc. 1, ¶¶ 51-55.

process on July 2, 2002.[3] *Id.*, ¶ 64. The approval was "for one limited and very specific spinal fusion procedure with the LT-Cage." *Id.* Plaintiffs John and Josephine Arvizu allege that "[t]here are numerous lumbar and cervical spine procedures for which [the Infuse Device] was not initially approved and for which it has never subsequently been approved." Doc. 1, ¶ 78. Plaintiffs allege that, despite the limited purpose for which the Infuse Device was approved, Defendants "engaged in a multi-faceted campaign to promote off-label uses of [the Infuse Device]," which included having sales representatives present in operating rooms to assist physicians during surgery, distributing false or misleading medical literature, referring physicians to paid patients, using distributors to purchase gifts for physicians, using paid physician consultants to promote off-label uses at conferences and meetings, and "playing an active role in the writing and editing of nearly all published medical literature on [the Infuse Device] from at least 2001 through 2006." Doc. 1, ¶ 158.

Some of the off-label uses allegedly promoted by Defendants used only the bone protein component of the Infuse Device. Plaintiffs allege that Defendants sold the bone protein and the LT-Cage separately despite the fact that the FDA approval for the Infuse Device required them to be used together. *Id.*, ¶¶ 76. Plaintiffs contend that the FDA had concerns about off-label uses of the Infuse Device because some studies showed that "uncontrolled bone growth developed in a number of patients" (*id.*, ¶ 81), which resulted in these other uses not receiving FDA approval.

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[3] Defendants ask the Court to take judicial notice of documents related to the PMA process for the Infuse Device. *See* Doc. 21. Although courts generally may not consider evidence or documents beyond the complaint in considering a Rule 12(b)(6) motion, a court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading." *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). The Court may take judicial notice of facts that are "not subject to reasonable dispute" that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Because the documents presented by Defendants are publicly available on the FDA's website and Plaintiffs do not dispute their authenticity, the Court will take judicial notice of these documents. *See Daniels–Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (finding it appropriate to take judicial notice of information made publicly available on government websites where the authenticity of the information was not challenged) (citing Fed. R. Evid. 201).

Plaintiffs allege that Mr. Arvizu's physician used the Infuse Device in an "off-label" manner. They specifically allege that Mr. Arvizu "underwent a transforaminal lumber interbody fusion at L5-S1[.]" Doc. 1, ¶ 299. Plaintiffs further allege that Defendants, "through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained and encouraged Plaintiff's surgeon to engage in the off-label procedure of utilizing a transforaminal approach without the required LT Cage." *Id.*, ¶ 300.

Plaintiffs brought this action on April 15, 2014, asserting claims for fraudulent misrepresentation and fraud in the inducement, failure to warn, design defect, misrepresentation, negligence, breach of express warranty, violation of Arizona's Consumer Protection Statutes, loss of consortium, and punitive damages. *See* Doc. 1, ¶¶ 305 -420. Defendants argue that these claims are expressly preempted by section 360k of the Medical Devices Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Doc. 20 at 2. They also contend that Plaintiffs' claims are impliedly preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Doc. 20 at 2.

II. Legal Framework.

A. Rule 12(b)(6).

When analyzing a complaint for failure to state a claim to relief under Rule 12(b)(6), the well-pled factual allegations are taken as true and construed in the light most favorable to the nonmoving party. *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). Legal conclusions couched as factual allegations are not entitled to the assumption of truth, *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009), and therefore are insufficient to defeat a motion to dismiss for failure to state a claim, *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010). To avoid a Rule 12(b)(6) dismissal, the complaint must plead enough facts to state a claim to relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This plausibility standard "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a

defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

B. Rule 9(b).

Rule 9(b) requires that a plaintiff "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) has been interpreted by the Ninth Circuit to require the pleader to "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986). The plaintiff must also "set forth . . . an explanation as to why the disputed statement was untrue or misleading when made." *Yourish v. Cal. Amplifier*, 191 F.3d 983, 993 (9th Cir. 1999); *see also Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003) ("Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged.").

C. Federal Preemption.

1. Express and Implied Preemption.[4]

Section 360k of the MDA includes this preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or

[4] In recent years, many cases across the country have considered both the express and implied preemption of claims under the MDA. Several courts have thoroughly and ably summarized the legal background. *See, e.g., Scovil v. Medtronic, Inc.*, -- F. Supp. 2d --, 2014 WL 502923, at *4-8 (D. Ariz., Feb. 7, 2014); *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-0049AWISKO, 2014 WL 346622, at *3-5 (E.D. Cal., Jan. 30, 2014); *Kashani-Matts v. Medtronic, Inc.*, No. SACV 13-01161-CJC (RNBx), 2013 WL 6147032, at *3 (C.D. Cal., Nov. 22, 2013); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1173-76 (C.D. Cal. 2013) (*Houston I*); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 985-87 (D. Ariz. 2013).

> to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

In *Riegel*, the Supreme Court outlined a two-part test to determine whether state law claims are expressly preempted under § 360k: (1) whether the federal government established "requirements" applicable to the device in question, and, if so, (2) whether the state common law claims are based on state law requirements "that are different from, or in addition to the federal ones" and "relate to safety and effectiveness." 552 U.S. at 321-22 (citing § 360k(a)); *see also Hawkins*, 2014 WL 346622, at *3 (quoting *Riegel*).

In *Buckman*, the court held that claims that a device manufacturer had made fraudulent representations to the FDA were "inherently federal in nature" because the relationship between the manufacturer and the FDA "originates from, is governed by, and terminates according to federal law." 531 U.S. at 347-48. The court held that such "fraud-on-the-FDA" claims were impliedly preempted (*id.* at 348) because they "exist solely by virtue of the FDCA disclosure requirements" (*id.* at 353). *See also Kashani-Matts*, 2014 WL 819392, at *2 ("Implied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law."); *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 [21 U.S.C. § 337(a)][.]").

2. Parallel Claims.

The *Riegel* court also affirmed the Supreme Court's earlier holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that § 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." *Id.* at 330. The Ninth Circuit has confirmed that "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013) (quoting *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc), *cert. denied by Medtronic Inc. v. Stengel*, -- S. Ct. --, 2014 WL

2807193 (June 23, 2014)). The Ninth Circuit has also observed that state law claims must fit through a "narrow gap" to avoid preemption, meaning that the "plaintiff must be suing for conduct that *violates* the FDCA," but also "must not be suing *because* the conduct violates the FDCA." *Perez*, 711 F.3d at 1120.

Applying this framework, the Court must first consider whether Plaintiffs' claims are expressly preempted under the test outlined in *Riegel*. If not, it must consider whether they seek to enforce a federal law or state a parallel state law cause of action based on conduct that violates federal law.

3. Cases Involving Off-Label Promotion.

Plaintiffs argue that because the use of the Infuse Device here was "off-label," neither aspect of *Riegel* is satisfied. Doc. 23 at 8. They contend that there "are not federal requirements applicable to the use of the Bone Protein component without the LT-Cage," and that their claims are therefore not expressly preempted. *Id.* at 8-9. In the alternative, they argue that they have stated parallel claims. *Id.* at 9. More specifically, Plaintiffs ask the Court to adopt the reasoning advanced in *Ramirez v. Medtronic*, where the court concluded that there were no federal requirements applicable to the off-label uses of the Infuse Device and that the plaintiff's claims were accordingly not preempted. 961 F. Supp. 2d at 997-1001. Defendants point to cases that have rejected the reasoning of *Ramirez* and have found that claims based on off-label promotion are preempted. Doc. 20 at 2 n.2 (citing cases).

In *Ramirez*, the plaintiff underwent a lumbar fusion in which her surgeon used only the "rhBMP-2 bone graft" component of the Infuse Device and not the LT-Cage. 961 F. Supp. 2d at 983. The court observed that "[t]he fundamental purpose of § 360k's express preemption provision is to avoid having another entity . . . 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. The court went on to reason that this 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.* The court concluded that "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 bases on which to pre-empt the application of state law designed to provide that protection." *Id.* The court ultimately found that although there were federal requirements that were applicable to the Infuse Device, Medtronic "departed the realm of federal regulation and returned to the area of traditional state law remedies" when it "allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device[.]" *Id.* Plaintiffs cite two unreported state court cases that have reached the same result. Doc. 23 at 9 (citing cases).

The court in *Hornbeck v. Medtronic, Inc.*, 13 C 7816, 2014 WL 2510817 (N.D. Ill. June 2, 2014), also reached a similar result, noting that "[i]t is simply disingenuous for [Medtronic] to argue that the Plaintiffs seek to enforce safety requirements different from or in addition to those imposed by the FDA when the FDA imposed those requirements on the two components used together." *Id.* at *4. The Court concluded that "[t]o the extent that [Medtronic] failed to comply with federal requirements, the Plaintiffs may proceed with their claims." *Id.*

Sever courts have disagreed with *Ramirez*. *See Houston v. Medtronic, Inc.*, No. 2:13-cv-01679-SVW-SHx, 2014 WL 1364455, at *5-6 (C.D. Cal. Apr. 2, 2014) (*Houston II*); *Scovil*, 2014 WL 502923, at *8-9; *Beavers-Gabriel v. Medtronic Inc.*, -- F. Supp. 2d --, 2014 WL 1396582, at *9-10 (D. Haw. Apr. 10, 2014) ("*Ramirez* has been rejected – for good reason – by numerous courts."); *Martin v. Medtronic, Inc.*, -- F. Supp. 2d --, 2014 WL 3635292, at *6 (D. Ariz. July 23, 2014) (following *Beavers-Gabriel*).

The *Houston II* court expressly rejected the conclusion in *Ramirez* that § 360k does not apply where a manufacturer promotes off-label use. *Id.* at 5. The court observed that "§ 360k(a) applies when the FDA imposes requirements on a '*device*,'" and that its scope "is not limited to particular 'uses' of a device." *Id.* (emphasis in original). The court reasoned that if § 360k "does not distinguish between uses of a device, it surely does not distinguish between whether a particular use of the device was promoted by the

manufacturer." *Id.* The court also observed that "there are multiple MDA requirements that apply to devices, even when they are used in an off-label manner and the off-label use is promoted by the manufacturer." *Id.* As examples, the court noted that manufacturers are required to report to the FDA information that reasonably suggests the device may have caused or contributed to a death or serious injury, and that manufacturers are prohibited from making changes in design specifications, manufacturing processes, or labeling without FDA approval. *Id.* The court also observed that "[o]ff-label promotion amounts to misbranding . . . and misbranding is subject to an extensive FDA enforcement scheme[.]" *Id.* (citing *Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815 (9th Cir. 2010); 21 U.S.C. § 331). *Houston II* also concluded that "the Ninth Circuit in *Perez* 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).

Ramirez and similar cases make valid points. It does seem unfair for Defendants on one hand to promote the use of the Bone Protein component of the Infuse Device in a manner not approved or even considered by the FDA during the PMA process, and "with the other hand put forth as justification for preemption the federal regulations that admittedly govern [the Infuse Device], but were nonetheless premised on [Defendants'] initial representations that [the device] would only be used in certain procedures[.]" *Ramirez*, 961 F. Supp. 2d at 991. But the Court finds the reasoning of *Houston II* and related cases to be more persuasive. Section 360k applies when the FDA imposes requirements on a "device," not specific uses of the device, and off-label uses remain subject to federal regulation and therefore to preemption. *See Houston II,* 2014 WL 1364455, at *5-6; *Beavers-Gabriel,* 2014 WL 1396582, at *9-10.

In addition, the Court is bound by § 360k, which instructs that states and their political subdivisions may not establish any requirement "with respect to any device intended for human use" which is "different from, or in addition to, any requirement applicable under this chapter to the device[.]" 21 U.S.C. § 360k(a)(1). The FDCA's

definition of "device" includes "any component, part, or accessory," which would include components not used together as originally intended. 21 U.S.C. § 321(h). Thus, although it is true that the Infuse Device was approved as a system that included three components, the statutory definition makes clear that each of these components is a "device" for purposes of the FDCA. Therefore, even the Bone Protein used alone is a "device" with applicable federal requirements, and the first aspect of *Riegel* is satisfied if Plaintiffs' claims impose requirements different from or in addition to those imposed on the device by federal law.

III. Analysis.

A. Fraud Claims – First, Fourth, and Seventh Causes of Action.

Plaintiffs assert three claims based on fraud: (1) fraudulent misrepresentation and fraud in the inducement, (2) strict liability based on misrepresentations, and (3) violation of Arizona's Consumer Protection Statute. Plaintiffs' fraudulent misrepresentation claim alleges that Defendants fraudulently concealed and misrepresented the health and safety hazards of the Infuse Device, their practice of promoting and marketing off-label uses to physicians, and information about the risks of the Infuse Device. Doc 1, ¶ 308. Their strict liability claim alleges that while marketing the Infuse Device "Defendants made untrue representations of material facts and omitted material information" regarding off-label uses of the Infuse Device. *Id.*, ¶ 353. Plaintiffs' claim based on Arizona's Consumer Protection Statute alleges that Defendants violated their statutory duty to refrain from unfair or deceptive acts and engaged in fraudulent and unconscionable business practices "by knowingly and falsely representing that [the Infuse Device] was fit to be used for the purpose for which it was advertised, when in fact [the Infuse Device] was defective and dangerous when used off-label[.]" *Id.*, ¶¶ 391, 397.

Any claim based on misrepresentation or omission dealing with the FDA-approved label of the Infuse Device is expressly preempted. *See Beavers-Gabriel*, 2014 WL 1396582, at *10 ("[A]llowing such a claim to proceed would permit a finding that defendants were required to alter the Infuse Device's warning 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.") (quoting *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219 (W.D. Okla. 2013)) (internal quotation marks and brackets omitted). But Plaintiffs do not allege misrepresentations or omissions based on the FDA approved label. Rather, they allege that Defendants "fraudulently concealed and misrepresented information" about the off-label uses of the Infuse Device. *See* Doc. 1, ¶¶ 305-18. These claims lie parallel to federal requirements. *See Houston I*, 957 F. Supp. 2d at 1179-80 (noting that federal law prohibits manufacturers from making false or misleading representations in advertising "beyond the subject device's label," and from promoting off-label uses, and concluding that there was no risk that the defendants "could be held liable under state law without having violated the federal law").

Although Plaintiffs' fraud claims are not preempted, they must still be pleaded with the particularity required by Rule 9(b). Fraud claims under Arizona law require nine elements: (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted upon by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) his reliance on its truth and his right to rely thereon; and (9) his consequent and proximate injury. *See Jennings v. Lee*, 461 P.2d 161, 164 (Ariz. 1969). Defendants argue that Plaintiffs have failed to meet these pleading requirements (Doc. 20 at 16), but the Court does not agree. Plaintiffs have alleged who made representations about the Infuse Device as well as when and where the representations were made (*see* Doc. 1, ¶¶ 158, 161 -273), and they have alleged that, as a result of these representations, Mr. Arvizu's physician used the Infuse Device in an unsafe manner (*id.*, ¶¶ 159, 300), resulting in harm to Plaintiffs (*id.*, ¶ 301). These allegations are sufficient to "give defendants notice of the particular misconduct so that they can defend against the charge and not just deny that they have done anything wrong." *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009). *See also*

Scovil, 2014 WL 502923, at *11 (declining to dismiss fraud claims).

The Court disagrees with other cases cited by Defendants (Doc. 20 at 16) that have found fraud claims to be insufficiently pleaded. *See Beavers-Gabriel*, 2014 WL 1396582, at *12 ("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."); *Martin*, 2014 WL 3635292, at *9 (dismissing similar fraud claims because the plaintiff "has not alleged which misrepresentations were relied on by her and her surgeon."). Plaintiffs have alleged numerous misrepresentations made by Defendants and have alleged that they and Mr. Arvizu's physician relied upon those representations. Doc. 1, ¶¶, 158-59, 161 -273, 300. The Court will deny Defendants' motion to dismiss Plaintiffs' first, fourth, and seventh causes of action on this basis.

B. Failure to Warn – Second Cause of Action.

Plaintiffs argue that "§ 360k(a) does not preempt a state-law duty to warn that parallels the manufacturer's federal duty to monitor PMA products on the market and to report adverse events to the FDA." Doc. 23 at 18. The Ninth Circuit has held that claims for failure to warn the FDA are not preempted. *See Stengel*, 704 F.3d at 1233. But the majority of Plaintiffs' allegations are that Defendants failed to warn them and their physicians. Doc. 1, ¶¶ 320-31. Plaintiffs contend that the "acts that violated the state-law duty to warn also violated requirements imposed on [Defendants] by the FDA," such as "the prohibition against misbranding." Doc. 23 at 16-17.

These claims are preempted because they would require Defendants to take actions that are different from or in addition to the requirements imposed by federal law. *See Beavers-Gabriel*, 2014 WL 1396582, at *13 (finding a claim for failure to warn doctors preempted because it would seek "to impose on Defendants a duty to provide warnings beyond those already outlined by the FDA"); *Scovil*, 2014 WL 502923, at *10 (same); *Martin*, 2014 WL 3635292, at *11 (same). *See also Stengel*, 705 F.3d at 1234 (Watford, J., concurring, joined by six judges) ("[A]ny attempt to predicate the [claim] on

an alleged state law duty to warn doctors directly would have been expressly preempted under [§ 360k][.]").

Plaintiffs also contend that their "failure to warn allegations are consistent with those in *Stengel*," and that Defendants "failed to report certain adverse events to the FDA[.]" Doc. 23 at 18. Plaintiffs' complaint alleges that "the FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including submitting adverse event reports[.]" Doc. 1, ¶ 147. Plaintiffs allege that Defendants "violated these FDCA statutes and accompanying regulations . . . by failing to account for adverse events[.]" *Id.*, ¶ 148. Plaintiffs provide little factual detail concerning this alleged failure to warn, but little factual detail is necessary or available when a plaintiff is alleging that the defendant failed to act. It is the absence of action that gives rise to the claim. The Court finds Plaintiffs' failure-to-warn-the-FDA claim to be sufficiently pled to defeat preemption.[5] The Court will dismiss Plaintiffs' failure to warn cause of action except as to Plaintiffs' allegations that Defendants failed to warn the FDA of adverse events. *See Stengel*, 704 F.3d at 1233.

C. Design Defect – Third Cause of Action.

To prevail on their design defect claim, "Plaintiffs would need to establish that the Infuse Device should have been designed in a manner different than that approved by the FDA." *Beavers-Gabriel*, 2014 WL 1396582, at *15; *see also Scovil*, 2014 WL 502923, at *9; *Houston I*, 957 F. Supp. 2d at 1177. This would impose requirements that are different from or in addition to federal law. Although Plaintiffs argue that the use of the Bone Protein component without the LT-Cage component was never approved by the FDA (Doc. 23 at 19), this does not change the analysis. As discussed above, there are federal requirements applicable to the Infuse Device and its components, and § 360k and *Riegel* do not permit state law claims that impose requirements different from or in

[5] As Judge Watford noted, however, this claim could have difficulty at the causation stage because Plaintiff must show that had Defendants timely notified the FDA, the FDA would have passed the information along to Plaintiff's doctor in time to prevent his harm and Plaintiff's doctor would have timely heeded the FDA warning. *Stengel*, 705 F.3d at 1234 (Watford, J., concurring, joined by six judges).

addition to the federal requirements. This claim is preempted.

D. Negligence – Fifth Cause of Action.

For reasons stated in part III(B) above, the Court will dismiss Plaintiffs' negligence claim to the extent it relies on Defendants' alleged failure to warn Plaintiffs and their physician.

Defendants argue that Plaintiffs' negligence claim is preempted because it would require a finding that, as a matter of state law, the FDA-approved manufacturing, design, and label of the Infuse Device was defective. Doc. 20 at 13. The Court does not agree. Plaintiffs allege that "Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse without an LT Cage[.]" Doc. 1, ¶ 368.

Some courts have held that similar negligence claims are impliedly preempted because there is no state law duty to refrain from off-label promotion. *See Beavers-Gabriel*, 2014 WL 1396582, at *16 ("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."); *Martin*, 2014 WL 3635292, at *14 (following *Beavers-Gabriel*). Other courts that have found that negligence claims based on off-label promotion in violation of federal law are not preempted. *See Scovil*, 2014 WL 502923, at *10 ("[T]he Court finds that Plaintiffs' allegations concerning the marketing of the device . . . are not preempted."). The Court concludes that Plaintiffs' claims are impliedly preempted because they "exist solely by virtue" of FDCA requirements. *See Buckman*, 531 U.S. at 353. Allowing Plaintiffs' claims to go forward would be essentially authorizing an impermissible action to enforce the provisions of the FDCA that prohibit misbranding. *See Kashani-Matts*, 2014 WL 819392, at *2 ("Implied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law."); *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 [21 U.S.C. § 337(a)][.]").

E. Breach of Express Warranty – Sixth Cause of Action.

Several courts have found that claims for breach of express warranty are neither expressly nor impliedly preempted in the context of off-label promotion. *See Beavers-Gabriel*, 2014 WL 1396582, at *17 (noting that "federal law already prohibits false or misleading off-label promotion" and that in order to avoid state law liability "Defendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law imposes") (quoting *Houston I*, 957 F. Supp. 2d at 1180-81); *Martin*, 2014 WL 3635292, at *15 (quoting *Beavers-Gabriel*). The Court agrees. The Court also agrees that this claim is not impliedly preempted because it could exist even in the absence of federal law.

The claim is nonetheless defective. Under Arizona law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." *Dillon v. Zeneca Corp.*, 42 P.3d 598, 602 (Ariz. Ct. App. 2002) (quoting A.R.S. § 47-2313(A)). Of course, "any affirmation that forms the basis of an express warranty must be between the seller and the buyer." *Ramirez*, 961 F. Supp. 2d at 1001. Plaintiffs do not allege that Defendants made any affirmations about the off-label uses of the Infuse Device directly to them, and their allegations that their physician relied on misleading off-label promotion cannot support a claim for breach of express warranty by Plaintiffs. The Court will grant Defendants' motion to dismiss this claim.

F. Loss of Consortium and Punitive Damages.

Defendants argue that "Plaintiffs' loss of consortium claim is barred because it is dependent on other claims all of which are preempted," and that "Plaintiffs' punitive damages 'claim' fails because the predicate claims fail." Doc. 20 at 25. Because the Court has not dismissed all of Plaintiffs' claims, it will decline to dismiss these claims.

G. Other Arguments for Dismissal.

1. No Prohibition on Off-Label Promotion.

Late in their motion, Defendants advance the argument that "Plaintiffs do not –

and cannot—identify a federal prohibition on off-label promotion." Doc. 20 at 18. Defendants cite several cases where courts have concluded that federal law does not bar off-label promotion and found that claims based on off-label promotion are preempted. *Id.* (citing *United States v. Caronia*, 703 F.3d 149, 160 (2d Cir. 2012)). The Court is unconvinced. *Caronia* was an appeal of a criminal case and the court considered whether the FDCA criminalized off-label promotion of prescription drugs. 703 F.3d at 160. The court said that the misbranding provisions of the FDCA do not prohibit and criminalize "the truthful off-label promotion of FDA-approved prescription drugs," and then stated that its conclusion was "limited to FDA-approved drugs for which off-label use is not prohibited[.]" *Id.* at 168-69. This case involves allegations of misrepresentation in off-label promotion of a Class III medical device. *Caronia* is not relevant to this claim, nor are the district court cases cited by Defendants that have relied on it.

Defendants also argue that the *Perez* court "recognized that even if off-label promotion violates federal law, whether a particular example of off-label promotion 'was in violation of the FDCA' is a matter that 'rest[s] within the enforcement authority of the FDA, not [the] Court.'" Doc. 20 at 18 (citing *Perez*, 711 F.3d at 1120). The *Perez* court considered only a fraud by omission claim and specifically noted that "courts have acknowledged that some fraud and false advertising claims related to FDA status may go forward," but found that Perez had presented no authority wherein "a court has allowed a plaintiff to bring suit solely for failure to disclose lack of FDA approval." *Id.* at 1119-20. Plaintiffs' claims go beyond mere failure to disclose lack of FDA approval, and the Court will not read *Perez* so broadly as to preempt any claim based on off-label promotion.

Defendants further argue that the Ninth Circuit has dismissed claims based on off-label promotion, but again their cited authority has no purchase here because it involved a motion for summary judgment. Doc. 20 at 18 (citing *Carson*, F. App'x at 815). Defendants have filed a motion to dismiss. That the Ninth Circuit upheld a grant of summary judgment where there was no evidence in the record that the defendant had illegally promoted an off-label use of a medical device, *Carson*, F. App'x at 815, does

not mean that all claims premised on off-label promotion should be dismissed.

Defendants also contend that Plaintiffs fail to state a parallel claim because "there is no state-law duty to abstain from off-label promotion." Doc. 20 at 19. There may indeed be no such state law duty, but that does not bar Plaintiffs' claims. There is a duty under Arizona law to avoid making fraudulent misrepresentations. *See Jennings*, 461 P.2d at 164. As noted above, claims based on fraudulent misrepresentations are parallel to federal requirements.

2. Statute of Limitations.

Defendants also argue that all of Plaintiffs' claims are barred by the applicable statute of limitations. Doc. 20 at 21. Defendants contend that the relevant statutes of limitations are two years after the cause of action accrues for personal injury actions (A.R.S. §§ 12-542 and 12-551), three years for fraud claims (A.R.S. § 12-543(3)), four years for breach of warranty claims (A.R.S. § 47-2725(A) & (B)), and one year for violations of the Consumer Fraud Act (*Murry v. W. Am. Mortg. Co.*, 604 P.2d 651, 654 (Ariz. Ct. App. 1979)). Plaintiffs do not dispute the applicability of these statutes, but note correctly that when a statute of limitations defense is raised in a motion to dismiss, the "complaint cannot be dismissed unless it appears beyond doubt that the plaintiff can prove no set of facts that would establish the timeliness of the claim." *Hernandez v. City of El Monte*, 138 F.3d 393, 402 (9th Cir. 1998) (quoting *Supermail Cargo, Inc. v. United States*, 68 F.3d 1204, 1206 (9th Cir. 1995)).

Plaintiffs argue that "a cause of action accrues, and the statute of limitations commences, when one party is able to sue another." *Gust, Rosenfeld & Henderson v. Prudential Ins. Co. of Am.*, 898 P.2d 964, 967 (Ariz. 1995). "Under the 'discovery rule,' a plaintiff's cause of action does not accrue until the plaintiff knows or, in the exercise of reasonable diligence should know, the facts underlying the cause." *Id.* "[I]t is not enough that a plaintiff comprehends a 'what'; there must also be reason to connect the 'what' to a particular 'who' in such a way that a reasonable person would be on notice to investigate whether the injury might result from fault." *Walk v. Ring*, 44 P.3d 990, 996

(Ariz. 2002) (en banc).

Plaintiffs argue that "Mr. Arvizu was not aware that [the Infuse Device] *might* have caused his injuries until April 17, 2012, when he saw a television commercial regarding the side effects caused by [the device]." Doc. 23 at 25. They further contend that he did not "*know* that his injuries were caused by [the Infuse Device] or that he had a cause of action against [Defendants] until his medical records were reviewed by an orthopedist in on (sic) or around April 7, 2014." *Id.* Although Defendants argue that Plaintiffs "were on constructive notice of the precise claims at issue" based on the labels of the Infuse Device (Doc. 20 at 22), the Court cannot conclude that it is "beyond doubt" that Plaintiffs can prove no set of facts that would establish the timeliness of the claims, with the exception of Plaintiffs' claim under the Consumer Fraud Act. The limitations period for that claim is one year and Plaintiffs concede that Mr. Arvizu became aware that his injuries may have been caused by the Infuse Device on April 17, 2012. This action was filed on April 15, 2014, more than one year after Mr. Arvizu knew, or in the exercise of reasonable diligence, should have known of the claim. The Court will dismiss only Plaintiffs' seventh cause of action on timeliness grounds.[6]

H. Leave to Amend.

Plaintiffs seek leave to amend their complaint. Doc. 23 at 25. Rule 15 makes clear that the Court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). The Court will therefore grant Plaintiffs' request for leave to amend.

IT IS ORDERED:

1. Defendants' motion to dismiss (Doc. 20) is **granted in part** and **denied in part** as set forth above.

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[6] Defendants have also filed a motion requesting permission to file a supplemental brief (Doc. 33) in response to a notice of supplemental authority filed by Plaintiffs (Doc. 32). Defendants argue that Plaintiffs' notice impermissibly included supplemental briefing. Doc. 33 at 2. This supplemental briefing is essentially a sur-reply, which the Local Rules do not permit (*see* LRCiv 7.2), and Plaintiffs did not seek the Court's permission to file any additional memoranda. The Court will disregard Plaintiffs' supplemental briefing and deny Defendants' motion to file a supplemental brief as moot.

2. Plaintiffs shall file an amended complaint on or before **September 19, 2014**.

3. Defendants' motion to file a supplemental brief (Doc. 33) is **denied as moot**.

Dated this 25th day of August, 2014.

David G. Campbell
United States District Judge