UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

AUTUMN ZETZ and ERIC ZETZ,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

CASE NO. 1:19-cv-00451-AWI-SAB

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS

(Doc. No. 6)

I. Background[1]

Autumn Zetz suffered from stress urinary incontinence. To treat her condition, Ms. Zetz was surgically implanted in 2008 with a pelvic mesh device called the Obtryx Sling. The Obtryx Sling ("Product") is a surgical mesh device that was manufactured, packaged, labeled, marketed, sold, and distributed by Boston Scientific Corporation ("Boston Scientific") as a treatment for stress urinary incontinence. The Product contains monofilament polypropylene mesh.

After Ms. Zetz was implanted with the Product, Ms. Zetz experienced serious adverse health effects, including pudendal neuralgia, catastrophic pain syndrome, bladder dysfunction, dyspareunia, and loss of mobility. These adverse effects occurred because, at least in part, the polypropylene in the Product is biologically incompatible with human tissue, thereby making the Product defective. In addition to Ms. Zetz, many other women who were implanted with the Product experienced serious adverse effects, including chronic pain and functional disabilities.

Prior to Ms. Zetz and many other women being implanted with the Product, Boston Scientific knew about but ignored and downplayed the Product's health risks and defects. Yet, to this day, Boston Scientific continues to falsely market and sell the Product as a safe, effective, and

[1] The facts in the background come from the factual allegations in Plaintiffs' complaint, see Doc. No. 1-1, which the Court construes as true. See Rio Props., Inc. v. Rio Int'l Interlink, 284 F.3d 1007, 1019 (9th Cir. 2002).

reliable medical product that is safer and more effective than available feasible alternative treatments for stress urinary incontinence.

Ms. Zetz and her husband, Eric Zetz (collectively "Plaintiffs"), sued Boston Scientific, pleading ten causes of action: (1) strict liability for failure to warn; (2) strict liability for manufacturing defect; (3) strict liability for design defect; (4) negligence; (5) breach of implied warranty; (6) breach of express warranty; (7) fraudulent misrepresentation; (8) negligent misrepresentation; (9) fraudulent concealment; and (10) loss of consortium. Then, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Boston Scientific moved to dismiss Plaintiffs' following causes of action: failure to warn under the strict liability and negligence theories; manufacturing defect under the strict liability and negligence theories; design defect under the strict liability theory; breach of implied warranty; fraudulent misrepresentation; negligent misrepresentation; and fraudulent concealment. Plaintiffs filed an opposition to the motion, and Boston Scientific filed a reply.

II. Legal Standard

Under Rule 12(b)(6), a cause of action may be dismissed because of the plaintiff's "failure to state a claim upon which relief can be granted." Fed. Rule Civ. Proc. 12(b)(6). A dismissal under Rule 12(b)(6) may be based on the lack of a cognizable legal theory or on the absence of sufficient facts alleged under a cognizable legal theory. Conservation Force v. Salazar, 646 F.3d 1240, 1242 (9th Cir. 2011); Johnson v. Riverside Healthcare Sys., 534 F.3d 1116, 1121 (9th Cir. 2008). In reviewing a complaint under Rule 12(b)(6), all allegations of material fact are taken as true and construed in the light most favorable to the non-moving party. Faulkner v. ADT Sec. Servs., 706 F.3d 1017, 1019 (9th Cir. 2013). However, complaints that offer no more than "labels and conclusions" or "a formulaic recitation of the elements of action will not do." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The Court is not required "to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." Wilson v. Hewlett-Packard Co., 668 F.3d 1136, 1145 n.4 (9th Cir. 2012); Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001). To avoid a dismissal under Rule 12(b)(6), "a complaint must

contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 570 (2007). The Ninth Circuit has distilled the following principles from Iqbal and Twombly: (1) to be entitled to the presumption of truth, allegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively; (2) the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation. Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011). In assessing a motion to dismiss, courts may consider documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice. Dichter-Mad Family Partners, LLP v. United States, 709 F.3d 749, 761 (9th Cir. 2013). If a motion to dismiss is granted, then the "district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." Henry A. v. Willden, 678 F.3d 991, 1005 (9th Cir. 2012).

III. Discussion

1. Failure to warn under strict liability and negligence theories

Boston Scientific argues that Plaintiffs failed to state a claim for failure to warn under the strict liability and negligence theories in light of California's learned intermediary doctrine "[t]o the extent such claims rely on a duty to warn anyone other [than] Ms. Zetz's prescribing physician." Doc. No. 6-1. California's learned intermediary doctrine holds that a manufacturer of prescription drugs or medical devices satisfies its duty to warn when it provides adequate warnings to the prescribing physician, as opposed to the patient. See Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996) ("[I]n the case of prescription drugs, the duty to warn runs to the

physician, not to the patient."); Brown v. Superior Court, 44 Cal. 3d 1049, 1061 n.9 (1988) ("It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician."). The rationale for the learned intermediary doctrine goes as follows:

> (1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

Carmichael v. Reitz, 17 Cal. App. 3d 958, 989 (1971). The learned intermediary doctrine applies to implanted medical devices, Bigler-Engler v. Breg, Inc., 7 Cal. App. 5th 276, 320 (2017), and it covers failure to warn claims under both the strict liability theory and the negligence theory. Saavedra v. Eli Lily & Co., 2013 U.S. Dist. LEXIS 173055, *8 (C.D. Cal. Feb. 26, 2013).

Here, Plaintiffs sufficiently alleged that Boston Scientific failed to provide adequate warnings to the learned intermediaries, which would include Ms. Zetz's physicians. The following allegations from the complaint illustrate this point:

> 31. The Obtryx sling was unreasonably susceptible to shrinkage and contraction inside the body. Defendant should have known of this serious risk and warned physicians and patients.
>
> 35. Further, while some of the problems associated with the Obtryx sling were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.
>
> 36. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Obtryx sling has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damages to a significant number of women, including Plaintiff, making them defective under the law.
>
> 44. Defendants knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Obtryx and the aftercare of patients implanted with the Obtryx.
>
> 63. The risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants

> deliberately concealed these risks and, instead, represented that the product was safe and effective and continued to market the Obtryx to physicians and patients, including Plaintiffs, without adequate warnings.

Doc. 1-1 (emphasis added).

It is true, as Boston Scientific points out, that the complaint also alleges that Boston Scientific failed to provide adequate warnings to Plaintiffs. To be clear, Plaintiffs' failure to warn claims can only be based on the information provided or not provided to Ms. Zetz's physicians, not Plaintiffs themselves.

Accordingly, Plaintiffs' failure to warn claims will not be dismissed.

2. Manufacturing defect under strict liability and negligence theories

Boston Scientific argues that Plaintiffs failed to state a claim for manufacturing defect under the strict liability and negligence theories because Plaintiffs failed to identify the specific manufacturing defect in the Product that was implanted in Ms. Zetz. Generally, a "manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." Barker v. Lull Engineering Co., 20 Cal. 3d 413, 429 (1978). Generally, a manufacturing defect claim posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." In re Coordinated Latex Glove Litigation, 99 Cal. App. 4th 594, 613 (2002). That is, "the product does not conform to the manufacturer's design." Garrett v. Howmedica Osteonics Corp., 214 Cal. App. 4th 173, 190 (2013). A plaintiff pursuing a manufacturing defect claim must identify/explain how the product either deviated from the manufacturer's intended result/design or how the product deviated from other seemingly identical models; therefore, a bare allegation that the product had "a manufacturing defect" is an insufficient legal conclusion. Lucas v. City of Visalia, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010).

According to Boston Scientific, Plaintiffs failed to allege "factual allegations as to how Ms. Zetz's particular device purportedly deviated from Boston Scientific's intended result or from other identical units of the same product line." Doc. No. 6-1. In response to this argument,

Plaintiffs argue that the following allegations in the complaint sufficiently alleged a manufacturing defect:

> 10. Defendant's pelvic mesh products, including the Product, contain monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with pelvic mesh products, including the Product. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.
>
> 30. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "issue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "issue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Obtryx sling was unreasonably susceptible to degradation and fragmentation inside the body.
>
> 45. The Obtryx implanted in Plaintiff was in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendant.
>
> 60. The Obtryx was designed to be permanently implanted into a woman's body yet the product changes: it contracts over time which can pull or compress nerves key for sexual function, mobility, bowel and bladder function. These changes occurred and the Obtryx implanted in Autumn Zetz degraded on explant.

Doc. No. 1-1 (complaint) (cited by Plaintiffs' opposition, Doc. No. 9).

According to Plaintiffs, these allegations support their manufacturing defect claim because the allegations identify how the Product failed to perform in Ms. Zetz's body as intended and designed by Boston Scientific. According to Plaintiffs, the Product's deviation from Boston Scientific's intended performance and design "gives rise to the inference that [the Product] was not properly manufactured." Doc. No. 9.

The Court rejects Plaintiffs' argument. In another recent manufacturing defect lawsuit before the Court concerning a pelvic mesh implant, the plaintiff likewise alleged that the pelvic mesh product deviated from its intended design and performance by degrading and fragmenting

after being implanted in the body. Garcia v. Bos. Sci. Corp., 2019 U.S. Dist. LEXIS 106378, at *6 (E.D. Cal. June 25, 2019) (Ishii, J.). The Court ruled that the complaint's allegations were insufficient to support a manufacturing defect claim because the allegations failed to explain how the alleged deviation related to the manufacture. Id. Similarly, in another manufacturing defect lawsuit concerning a mesh implant, the plaintiff alleged that there was a "defect in [the product's] manufacture that caused [the product] to shrink, harden, scarify, oxidize, migrate and had adhesion formation issues thereby causing debilitating and permanent pain to plaintiff's groin and abdominal area." Dilley v. C.R. Bard, Inc., 2014 U.S. Dist. LEXIS 70060, *8 (C.D. Cal. May 21, 2014). The district court ruled that these allegations were insufficient to support a manufacturing defect claim because the allegations failed to establish "what manufacturing defect the [implant] allegedly suffered from." Id. Here, Plaintiffs' allegations are similar to those in the two foregoing lawsuits: the allegations identify a defect but fail to identify or explain how the defect relates to the manufacture. This is to say, Plaintiffs' allegations that the Product degraded and fragmented and failed to perform as designed and intended after being implanted into Ms. Zetz do not demonstrate, let alone plead, a manufacturing defect.

Accordingly, Plaintiffs' manufacturing defect claims under the strict liability and negligence theories will be dismissed with leave to amend.

3. Design defect under strict liability theory

Boston Scientific argues that Plaintiffs' claim for design defect under the strict liability theory fails as a matter of law because California precludes liability for design defect under a strict liability theory for manufacturers of prescription medical devices. This is true. See Garrett v. Howmedica Osteonics Corp., 214 Cal. App. 4th 173, 182 (2013) ("The California Supreme Court in [Brown v. Superior Court, 44 Cal. 3d 1049 (1988)] held that a manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary negligence standard."). A pelvic mesh implant is a prescription medical device. Garcia, 2019 U.S. Dist. LEXIS 106378, at *10 (citing Mullins v. Ethicon, Inc., 117 F. Supp. 3d 810, 820 n.12 (S.D. W. Va. 2015)).

Accordingly, Plaintiffs' claim for design defect under the strict liability theory will be dismissed with prejudice.

4. Breach of implied warranty

Boston Scientific argues that Plaintiffs failed to state a claim for breach of implied warranty because Plaintiffs failed to demonstrate privity with Boston Scientific. According to Boston Scientific, Plaintiffs' allegations do not explain how Plaintiffs relied on Boston Scientific's implied warranties when deciding to implant Ms. Zetz with the Product. Boston Scientific also argues that Plaintiffs' implied warranty claim fails as a matter of law because a patient of an implantable medical product, such as Ms. Zetz, can never be in privity with the manufacturer, such as Boston Scientific, because the patient always and only relies on the physician's skill and judgment when deciding to be implanted with the particular product.

"Under California law, privity between parties is required for either claim of implied warranty." Coleman v. Bos. Sci. Corp., 2011 U.S. Dist. LEXIS 42826, *16 (E.D. Cal. Apr. 20, 2011) (discussing merchantability and fitness). "The general rule is that . . . there is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1058-59 (2008) (citations omitted). In the context of implantable medical products, privity does not exist between the patient and the manufacturer if the patient did not rely on the manufacturer's judgment to select the product but, instead, did rely on the skill or judgment of the physician. Id. at 1059; Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 788 (1994). Consequently, where the product at issue is an implantable medical product and the patient relied on the physician's skill or judgment in selecting the implantable product, various courts have dismissed breach of warranty claims for a lack of privity. See, e.g., Currier v. Stryker Corp., 2011 U.S. Dist. LEXIS 118408, at *10-11 (E.D. Cal. Oct. 12, 2011) (dismissing claims for breach of express and implied warranty because the court could not plausibly infer that the plaintiff "relied on anything other than his physician's skill and judgment in selecting the [product], nor that any purchase of the product was based on a warranty from the manufacturer to [p]laintiff"); Adams v. I-Flow Corp., 2010 U.S. Dist. LEXIS 33066, at *11-12 (C.D. Cal. Mar. 30, 2010) (dismissing breach of warranty claims

because the complaint was "devoid of any facts suggesting that plaintiffs relied upon anything other than their physicians skill and judgment in selecting and prescribing" the devices and "[t]here was simply no relationship between the defendant manufacturers and the plaintiffs"); Evraets, 29 Cal. App. 4th at 788 (dismissing implied warranty claim for lack of privity because the plaintiff "relied upon his physician's skill or judgment to select or furnish a suitable product").

With respect to Boston Scientific's argument that a patient of an implantable medical product can never be in privity with the manufacturer, Boston Scientific did not provide the Court with sufficient legal support to accept this argument. Boston Scientific cited to Evraets and Blanco from the California Courts of Appeal, but those opinions did not hold that a patient of an implantable medical product can never be in privity with the manufacturer. Rather, those opinions stated that in the context of implantable medical products, privity does not exist between the patient and the manufacturer if the patient did not rely on the manufacturer's judgment but did rely on the physician's skill and judgment. For example, the implied warranty claim in Evraets failed because the patient "did not rely on [the manufacturers'] judgment that an intraocular device was appropriate for him" but did rely "upon his physician's skill or judgment to select or furnish a suitable product." Id. And in Blanco, the implied warranty claim failed because "there is no evidence that [the patient] relied on [the manufacturer's] judgment that the valve was appropriate for her" but, "[r]ather, [the patient] relied on her physician's skill and judgment to select the Valve." Blanco, 158 Cal. App. 4th at 1059 (emphasis added).

Boston Scientific also cited in its reply to Currier, 2011 U.S. Dist. LEXIS 118408, at *10, wherein the district court stated that "[i]n the implantable medical product context, a patient lacks the privity required to establish a claim for breach of implied warranty." The district court based this statement on its interpretation of Evraets and Blanco. Id. Boston Scientific also cited in its reply to Schwartz v. Wright Med. Tech., Inc., 2014 U.S. Dist. LEXIS 192248, at *13-14 (C.D. Cal. Sep. 11, 2014), wherein the district court stated that "[a]s California law now stands, in the implantable medical context a patient lacks the privity required to establish a claim for breach of implied warranty." Like the district court in Currier, the district court in Schwartz based this statement on its interpretation of Evraets and Blanco. Id. at *14. Boston Scientific also cited in

its reply to Coleman v. Bos. Sci. Corp., 2011 U.S. Dist. LEXIS 42826, at *16 (E.D. Cal. Apr. 20, 2011), but in Coleman the district court recognized a rule that is undisputed here; namely, that "[u]nder California law, privity between parties is required for either claim of implied warranty." Id. Boston Scientific also cited in its reply to Quatela v. Stryker Corp., 820 F. Supp. 2d 1045, 1047-48 (N.D. Cal. 2010), wherein the district court dismissed with prejudice the plaintiff's implied warranty claim because the plaintiff, who was implanted with a medical pain pump, lacked privity with the manufacturer of the implant. The district court in Quatela dismissed the implied warranty claim with prejudice because "there is no indication that [the plaintiff] could allege additional or different facts that would demonstrate privity or some exception thereto." Id. at 1048.

In the Court's view, the foregoing case law is insufficient to lead to the conclusion urged by Boston Scientific, which is that a patient of an implantable medical product can never be in privity with the manufacturer. While some federal district courts appear to have reached this conclusion based on their interpretation of Evraets and Blanco, other federal district courts have not. For example, in Jager v. Davol Inc., 2016 U.S. Dist. LEXIS 188821, at *13 (C.D. Cal. Oct. 20, 2016), the district court indicated that an implied warranty claim could be brought if the plaintiff was capable of pleading sufficient facts to show privity between the plaintiff and the manufacturer. In light of the foregoing case law and the parties' limited briefing on the issue, the Court will not conclude at this time that a patient of an implantable medical product can never be in privity with the manufacturer.[2]

That brings us to Boston Scientific's second argument, which is that Plaintiffs' allegations failed to sufficiently explain the underlying facts of the implied warranty claim, such as explaining how Plaintiffs are in privity with Boston Scientific. In response to this argument, Plaintiffs argue

/ / /

[2] In the event that Plaintiffs refile an amended implied warranty claim, the claim will be subject to additional Rule 12(b)(6) scrutiny, and at that phase the Court may consider any additional briefing submitted by the parties on the question of whether a patient of an implantable medical product can be in privity with the manufacturer.

that the following allegations in the complaint sufficiently allege that Plaintiffs are in privity with Boston Scientific:

> 64. Plaintiff reasonably relied upon the representations of Defendants and had the Obtryx sling implanted in her body.
>
> 101. Plaintiffs and their physicians and healthcare providers were, and remain, unskilled in the research, design and manufacture of the Product and reasonably relied on the skill, judgment and implied warranty of Defendants in using the aforementioned Product.

Doc. No. 1-1 complaint) (cited by Plaintiffs' opposition, Doc. No. 9).

Here, the Court agrees with Boston Scientific. Plaintiffs' allegations fail to identify any specific representations made by Boston Scientific or any other specific facts that would suggest that Plaintiffs personally relied on Boston Scientific's representations when selecting and using the Product. See Jager, 2016 U.S. Dist. LEXIS 188821, at *13-14 (finding the plaintiff's privity allegations to too vague because they failed to identify any specific representations made by the medical implant product manufacturer and they failed to assert any facts that would suggest that the plaintiff personally relied on the manufacturer's representations when selecting the product); Currier, 2011 U.S. Dist. LEXIS 118408, at *10 ("Here, Plaintiff's vague allegations that unidentified 'Defendants' made unspecified 'representations' to Plaintiff, Plaintiff's parents and Plaintiff's physician are insufficient to state a claim for breach of warranty."). Instead, Plaintiffs' allegations only vaguely state that Plaintiffs relied in some unspecified way on some unspecified representations and unspecified "skill, judgment and implied warranty" of Boston Scientific when selecting and using the Product. Doc. No. 1-1. This is insufficient under Rule 8 and Iqbal to plead the requisite privity, especially since this is a medical implant lawsuit where there is a strong presumption that Plaintiffs relied on the skill and judgment of the physician, not the manufacturer, to select and use the Product.

Accordingly, Plaintiffs' breach of implied warranty claim will be dismissed with leave to amend. See, e.g., Jager, 2016 U.S. Dist. LEXIS 188821, at *13 (dismissing the implied warranty claim with leave to amend so the plaintiff could, if possible, "identify any specific representations made by [the manufacturers] and . . . assert any facts that would suggest that [the plaintiff] personally relied on these representations in selecting the [the product]").

5. Fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation

Plaintiffs pleaded claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. "The elements of a cause of action for intentional misrepresentation are (1) a misrepresentation, (2) with knowledge of its falsity, (3) with the intent to induce another's reliance on the misrepresentation, (4) actual and justifiable reliance, and (5) resulting damage." Daniels v. Select Portfolio Servicing, Inc., 246 Cal. App. 4th 1150, 1166 (2016). The elements of fraudulent concealment are: "(1) concealment or suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing or suppressing the fact; (4) the plaintiff was unaware of the fact and would not have acted as he or she did if he or she had known of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of the concealment or suppression of the fact." Hambrick v. Healthcare Partners Med. Grp., Inc., 238 Cal. App. 4th 124, 162 (2015). The elements of negligent misrepresentation are: "(1) a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the truth and justifiable reliance thereon by the party to whom the misrepresentation was directed, and (5) damages." Fox v. Pollack, 181 Cal. App. 3d 954, 962 (1986); see also Daniels, 246 Cal. App. 4th at 1166.

Because each of these causes of action sound in fraud, the plaintiff must meet the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. See Monreal v. GMAC Mortg., LLC, 948 F. Supp. 2d 1069, 1077-78 (S.D. Cal. 2013); United States ex rel. Ruhe v. Masimo Corp., 929 F. Supp. 2d 1033, 1036 (C.D. Cal. 2012); Das v. WMC Mortg. Corp., 831 F. Supp. 2d 1147, 1166 (N.D. Cal. 2011).[3] To plead fraud with the particularity required by Rule 9(b), a complaint "must identify the who, what, when, where, and how of the misconduct charged,

[3] Some courts within the Ninth Circuit are not applying Rule 9(b) to negligent misrepresentation claims. See, e.g., Petersen v. Allstate Indem. Co., 281 F.R.D. 413, 416 (C.D. Cal. 2012). The Court respectfully disagrees with these rulings. The Ninth Circuit has held that all claims sounding in fraud or grounded in fraud must meet Rule 9(b)'s heightened pleading requirement. See Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009). California courts have expressly held that "[c]auses of action for intentional and negligent misrepresentation sound in fraud . . . ." Daniels, 246 Cal. App. 4th at 1166. Therefore, this Court will continue to apply Rule 9(b) to negligent misrepresentation claims. See Marroquin v. Pfizer, Inc., 367 F. Supp. 3d 1152, 1166 (E.D. Cal. 2019); Oushana v. Lowe's Home Ctrs., LLC, 2017 U.S. Dist. LEXIS 86042, *8-*9 (E.D. Cal. June 5, 2017).

as well as what is false or misleading about the purportedly fraudulent statement, and why it is false." Davidson v. Kimberly-Clark Corp., 889 F.3d 956, 964 (9th Cir. 2018). "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1184 (9th Cir. 2016). Additionally, when the defendant is an entity, a complaint generally must also identify the person who made the false representations on behalf of the entity. See United States ex. Lee v. SmithKline Beecham, 245 F.3d 1048, 1051 (9th Cir. 2001); White v. J.P. Morgan Chase, Inc., 167 F.Supp.3d 1108, 1115 (E.D. Cal. 2018); Griffin v. Lending Tree Servicing, LLC, 166 F.Supp.3d 1030, 1057-58 (C.D. Cal. 2015).

Here, Plaintiffs argue that the complaint sufficiently alleges the "who," "what," "when," "where," and "how" of the alleged misconduct. The Court disagrees. For the "what" and the "how," the complaint only generally alleges that Boston Scientific made misrepresentations and concealments about the safety and efficacy of the Product to the medical community and the public, including Plaintiff, through sales and marketing materials. These generalized allegations of misrepresentation, concealment, and unspecified sales and marketing materials lack sufficient particularity under Rule 9(b). See Garcia v. Bos. Sci. Corp., 2019 U.S. Dist. LEXIS 106378, at *14 (E.D. Cal. June 25, 2019) (ruling in a pelvic mesh implant lawsuit that the plaintiff failed to provide sufficient detail under Rule 9(b) where the complaint alleged that "Defendant's written product descriptions, product labels, promotional materials and other materials did not disclose that the Product had a high rate of failure and did not correct the issues for which it was utilized[,] Defendant failed to conduct adequate studies, failed to provide post-marketing or post-sale warnings, and continued to make material misrepresentations to Plaintiff, her physicians, the medical community, the public, and the FDA concerning the design, manufacture, safety, and efficacy of the Product"); Hill v. Davol Inc., 2016 U.S. Dist. LEXIS 188812, *26 (C.D. Cal. Nov. 16, 2016) ("[A]lthough Plaintiff has indicated broadly that he and his physician viewed packaging and written advertisements representing the Ventralex Patch as safe for its intended use, Plaintiff

has neither identified a specific advertisement that either he or his physician viewed nor provided even a vague outline of the specific language used to make these representations."); Jager, 2016 U.S. Dist. LEXIS 188821, *18 ("Nothing in the Complaint points to specific content in Defendants' marketing materials, or statements made to Ms. Jager's physician — if any — that were allegedly false").

For the "who," the complaint fails to identify the particular individuals who made the misrepresentations and concealments. Rather, the complaint only generally refers to Boston Scientific. This is insufficient. See SmithKline Beecham, 245 F.3d at 1051; White, 167 F. Supp. 3d 1108 at 1115; Griffin, 166 F. Supp. 3d at 1057-58.[4]

For the "when" and the "where," the complaint alleges, according to Plaintiffs, that the misrepresentations and concealments occurred sometime "before" Plaintiff was implanted with the Product (which was November 12, 2008) and occurred where Plaintiffs lived, which is somewhere in California. Such allegations fail to provide the requisite particularity.[5]

Accordingly, Plaintiffs' fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims will be dismissed with leave to amend.

/ / /

[4] Plaintiffs suggest that the federal pleading standard for fraud is relaxed when the "who" behind the fraud is a corporate entity. States Plaintiffs, "The omission of the names of corporate personnel and their authority to speak is not fatal to a fraud claim where defendants had more knowledge of the facts than did the plaintiffs." Doc. No. 9. Plaintiffs cited no controlling authority for this argument, and the Court is not persuaded. "Where fraud is alleged against a corporate entity, the complaint must contain: (1) the name of the person who made the misrepresentation; (2) the person's authority to speak for the corporation; (3) with whom the person communicated; (4) what was said or written; and (5) when the communication occurred." Oster v. Onewest Bank, 2012 U.S. Dist. LEXIS 200661, at *11 (C.D. Cal. July 5, 2012); Tarmann v. State Farm Mut. Auto. Ins. Co., 2 Cal. App. 4th 153, 157 (1991) ("The requirement of specificity in a fraud action against a corporation requires the plaintiff to allege the names of the persons who made the allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written.") (cited with approval by Lopez v. Wells Fargo Bank, N.A., 727 F. App'x 425, 426 (9th Cir. 2018)).

[5] While it is true that some courts have recognized that the plaintiff may not be able to plead a specific time and place with respect to concealment, see Stewart v. Electrolux Home Prods., 304 F. Supp. 3d 894, 906-07 (N.D. Cal. 2018), Rule 9(b) still applies in such cases. See id. If alleging a precise time and location is not possible, then a plausible concealment claim should at least allege a time frame for the concealment and a description of the circumstances surrounding the concealment. Cf. id.

ORDER

Accordingly, IT IS HEREBY ORDERED that:

1. Boston Scientific's motion to dismiss (Doc. No. 6) is GRANTED in part and DENIED in part, as follows:
    a. The causes of action for failure to warn under the strict liability theory (first cause of action) and negligence theory (fourth cause of action) are not dismissed;
    b. The following causes of action are dismissed with leave to amend: manufacturing defect under the strict liability theory (second cause of action) and negligence theory (fourth cause of action); breach of implied warranty (fifth cause of action); fraudulent misrepresentation (seventh cause of action); negligent misrepresentation (eighth cause of action); fraudulent concealment (ninth cause of action); and
    c. The strict liability design defect cause of action (third cause of action) is dismissed with prejudice.
2. If Plaintiffs wish to amend the second, fourth, fifth, seventh, eighth, or ninth causes of action, then Plaintiffs must file an amended complaint by August 12, 2019. If an amended complaint is not filed by that time, then Boston Scientific must file an answer by September 3, 2019.

IT IS SO ORDERED.

Dated: July 18, 2019

SENIOR DISTRICT JUDGE