UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES - GENERAL

Case No.	CV 21-8889 PA (SKx)	Date	April 7, 2022
Title	Sherly Poozhikala, et al. v. Medtronic Inc., et al.		

Present: The Honorable	PERCY ANDERSON, UNITED STATES DISTRICT JUDGE	
Kamilla Sali-Suleyman	Not Reported	N/A
Deputy Clerk	Court Reporter	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	
None	None	

Proceedings: IN CHAMBERS COURT ORDER

Before the Court is a Motion to Dismiss Plaintiffs' Second Amended Complaint filed by defendant Medtronic, Inc. ("Defendant"). (Docket No. 32.) Plaintiffs Sherly Poozhikala and Pious Poozhikala ("Plaintiffs") filed an Opposition (Docket No. 33), and Defendant filed a Reply (Docket No. 35). Pursuant to Rule 78 of the Federal Rules of Civil Procedure and Local Rule 7-15, the Court finds that this matter is appropriate for decision without oral argument.

I. Background

In their Second Amended Complaint ("SAC"), Plaintiffs allege that on September 12, 2018, Sherly Poozhikala ("Sherly") received a defective pacemaker ("ICD") from Defendant, Model No. DDMB1D1.[1/] On or about July 7, 2019, Sherly's ICD began sounding a rapid depletion battery alarm. Sherly contacted Defendant's rhythm management office and spoke with an employee, who checked the home monitor system and assured Sherly that her ICD was working correctly. On July 8, 2019, the battery alarm sounded again but this time, Defendant advised Sherly that there was an issue with the ICD's battery. On July 9, 2019, Defendant advised Sherly that a physician would contact her but no physician ever did. Sherly visited her own physician, Dr. Duane Bridges, who confirmed the ICD was nearing the end of its battery. Plaintiff alleges the battery failed because Defendant failed to test and use adequate components, and Defendant later admitted the ICD contained a defective L303 Integrated Circuit. Dr. Bridges ordered that Sherly either be admitted to the emergency room for surgery preparations or wear a "Life Vest," an external defibrillator which can only be removed briefly for bathing and weighs approximately 15 pounds. Sherly elected to use the Life Vest until July 18, 2019, when she underwent surgery to replace her ICD.

Plaintiffs allege that Defendant knew the ICD had safety issues prior to its implant. Plaintiffs point to a December 2017 Class 1 device recall, which Defendants initiated for the

[1/] The SAC omits the serial number of her pacemaker, though it was provided in the First Amended Complaint ("FAC") as No. CWA218194H. (See FAC, Docket No. 13.)

same ICD model but identifying different serial numbers, that recommended "physicians strongly consider prophylactic device replacement for patients implanted with an affected device."[2/] (See RJN, Ex. A.) Plaintiffs also note that the December 2017 recall notice states a patient died, which Plaintiffs allege resulted from rapid battery depletion, although the recall notice itself states the death was unrelated. (See id.) In connection with that death, Plaintiffs allege that Defendants violated several federal regulations requiring PMA supplements, reporting, and corrective and preventive action procedures. Plaintiffs also point to two urgent medical device recalls for the same ICD model in January and March 2018, citing battery depletion issues and recommending physicians consider prophylactic device replacement. (See RJN, Ex. B.) Plaintiffs allege that despite these recall notices, Defendant placed the ICD on the market without adequately warning patients or physicians of potential dangers. Plaintiffs also allege that if Defendant had properly reported these defects and notified Plaintiffs or their physician of the battery depletion issues, Plaintiffs would not have suffered an injury.

According to the SAC, Defendant also breached warranties, both express and implied, in selling the faulty ICD. Plaintiffs allege that Defendant made several express warranty statements, which were misleading and deceptive, that were not FDA-approved. Those statements include that the ICD would be safe and effective for eight years, that there was a limited lifetime warranty that included reimbursement to patients of unreimbursed medical expenses, and a brochure statement that the ICD offered 25% greater longevity than Defendant's other devices. Plaintiff also alleges that the ICD was not fit for its intended use and was an adulterated good, being "defectively manufactured with a faulty L303 Integrated Circuit," thus failing to satisfy the implied warranty of merchantability.

Plaintiffs' SAC alleges eight causes of action against Defendant: (1) Fraudulent Misrepresentation and Fraud in the Inducement; (2) Strict Products Liability - Failure to Warn; (3) Strict Product Liability - Misrepresentation; (4) Product Liability - Negligence - Failure to Warn; (5) Product Liability - Negligence in Manufacturing; (6) Breach of Express Warranty; (7) Breach of Implied Warranty of Merchantability; and (8) Loss of Consortium. Defendant now moves to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a), and 9(b).

[2/] Plaintiff requests that the Court take judicial notice of FDA recall notices. (See Req. For Judicial Notice ("RJN") at 2, Docket No. 34.) The FDA documents are "judicially noticeable as a public document available on the FDA website and therefore 'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'" Funke v. Sorin Grp. USA, Inc., 147 F. Supp. 3d 1017, 1025 (C.D. Cal. 2015) (quoting Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1170 n.1 (C.D. Cal. 2013) (taking judicial notice of FDA Premarket Approval Letter finding "the document is judicially noticeable as a public document available on the FDA website")). Defendant does not oppose. Accordingly, the Court takes judicial notice of these FDA documents.

II. Legal Standard

For purposes of a Motion to Dismiss brought pursuant to Federal Rule of Civil Procedure 12(b)(6), plaintiffs in federal court are generally required to give only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). While the Federal Rules allow a court to dismiss a cause of action for "failure to state a claim upon which relief can be granted," they also require all pleadings to be "construed so as to do justice." Fed. R. Civ. P. 12(b)(6), 8(e). The purpose of Rule 8(a)(2) is to "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964, 167 L. Ed. 2d 929 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47, 78 S. Ct. 99, 103, 2 L. Ed. 2d 80 (1957)). The Ninth Circuit is particularly hostile to motions to dismiss under Rule 12(b)(6). See, e.g., Gilligan v. Jamco Dev. Corp., 108 F.3d 246, 248–49 (9th Cir. 1997) ("The Rule 8 standard contains a powerful presumption against rejecting pleadings for failure to state a claim.") (internal quotation omitted).

However, in Twombly, the Supreme Court rejected the notion that "a wholly conclusory statement of a claim would survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some set of undisclosed facts to support recovery." Twombly, 550 U.S. at 561, 127 S. Ct. at 1968 (internal quotation omitted). Instead, the Court adopted a "plausibility standard," in which the complaint must "raise a reasonable expectation that discovery will reveal evidence of [the alleged infraction]." Id. at 556, 127 S. Ct. at 1965. For a complaint to meet this standard, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id. at 555, 127 S. Ct. at 1965 (citing 5 C. Wright & A. Miller, Federal Practice and Procedure §1216, pp. 235-36 (3d ed. 2004) ("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action") (alteration in original)); Daniel v. Cnty. of Santa Barbara, 288 F.3d 375, 380 (9th Cir. 2002) ("'All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party.'") (quoting Burgert v. Lokelani Bernice Pauahi Bishop Tr., 200 F.3d 661, 663 (9th Cir. 2000)). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555, 127 S. Ct. at 1964-65 (internal quotations omitted). In construing the Twombly standard, the Supreme Court has advised that "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009).

III. Analysis

A. Preemption

Defendant first contends that Plaintiffs' claims are expressly and impliedly preempted by the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. Here, the ICD is classified as a Class III device by the FDA – that is, a device "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or [] presents a potential unreasonable risk of illness or injury," 21 U.S.C. § 360c(a)(1)(c) – and thus subject to rigorous pre-market approval requirements and post-approval standards and scrutiny. See Weber v. Allergan, Inc., 940 F.3d 1106, 1110 (9th Cir. 2019).

The pre-market approval ("PMA") process is the most rigorous review imposed by the FDA and is imposed on Class III devices. See id. The PMA process "imposes 'requirements' under the MDA." Riegel v. Medtronic, Inc., 552 U.S. 312, 322, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). PMA is specific to individual devices and "is federal safety review." Id. PMA is given only if the FDA determines the approved form of a device "provides a reasonable assurance of safety and effectiveness." Id. (citing 21 U.S.C. § 360e(d)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(I)). Here, the FDA approved the ICD on October 12, 2016 as part of a supplemental PMA application submitted by Defendant. (See RJN, Ex. B, Docket No. 20-1.)

The MDA expressly preempts state law regulation of medical devices, and provides that:

> [N]o 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 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 held that § 360k preempted state law claims challenging the safety and effectiveness of a Class III medical device that had received pre-market approval from the FDA." Weber, 940 F.3d at 1111 (citing Riegel, 552 U.S. at 321-25). Under the express preemption statute, "the MDA allows state law claims against a manufacturer of a Class III medical device only if they are 'premised on a violation of FDA regulations' relating to the device." Id. (quoting Riegel, 552 U.S. at 330). Therefore, "for a state law claim regarding a Class III medical device to survive express preemption by the MDA, a plaintiff must establish that the defendant violated an FDA requirement." Id.

Even if a plaintiff establishes an FDA violation occurred, thereby overcoming express preemption, there is also the possibility of implied preemption. "The FDCA provides that enforcement of its requirements (including the MDA) 'shall be by and in the name of the United States.'" De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1091 (N.D. Cal. 2016) (quoting 21 U.S.C. § 337(a)). "[T]he Federal Government rather than private litigants . . . [is] authorized to file suit for noncompliance with the medical device provisions." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). "Thus, a claim that 'exist[s] solely by virtue' of federal requirements (such as a claim for fraud in submissions to the FDA during the premarket approval process) is impliedly preempted by the MDA, while claims that rely on 'traditional state tort law' may proceed (to the extent they can overcome express preemption)." De La Paz, 159 F. Supp. 3d at 1091-92 (quoting Buckman, 531 U.S. at 349 n.4).

This leaves a "narrow gap" for state-law claims to survive preemption. See Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1120 (9th Cir. 2013). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)." Id. (emphasis in original) (quoting In re Medtronic, Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)). As a result of this preemptive structure, "[t]he overwhelming majority of state law tort claims, including claims based on negligence, design defect, manufacturing defect, failure to warn, fraud, negligent misrepresentation, breach of implied and express warranties, unfair competition, and false advertising, have been held preempted." De La Paz, 159 F. Supp. 3d at 1092 (collecting cases).

Here, Plaintiffs contend that they are asserting "parallel" claims that are not expressly preempted, because their claims are premised on Defendant's failure to follow federal standards, and are not impliedly preempted, because their claims are based on state law.[3/] Plaintiffs point to

[3/] Plaintiffs also repeat their argument that there is a strong presumption against preemption. (See Opp'n at 7, Docket No. 33.) As discussed in the prior order, that presumption does not apply here. (See

their general allegation that "Plaintiff is informed and believes Defendants violated applicable federal statutes and regulations relating to medical devices" and subsequent list of federal regulations. (See Opp'n at 11 (citing SAC ¶¶ 25-33).) However, Plaintiffs must allege facts plausibly showing Defendant violated federal standards, not merely conclusory assertions. Plaintiffs' list of possible violations provides no factual support. See Paturzo v. Bos. Sci. Corp., No. 8:16-cv-2174-JLS-KESx, 2017 WL 8220600, at *4-5 (C.D. Cal. Apr. 21, 2017) ("Although Plaintiffs list several federal regulations that Defendants purportedly violated, they fail to allege any facts relating the premature battery depletion to Defendants' manufacturing processes and, specifically, the FDA's requirements for manufacturing."); Simmons v. Bos. Sci. Corp., No. CV 12-7962 (FFMx), 2013 WL 1207421, at * (C.D. Cal. Mar. 25, 2013) ("Plaintiffs must do more than baldly assert that the device violated federal standards."); see also Lawrence v. Medtronic, 791 F. App'x 679, 680 (9th Cir. 2020), cert. denied, 141 S. Ct. 312, 208 L. Ed. 2d 60 (2020) ("Although such theories are not preempted if the claim is that Medtronic failed to comply with a federal requirement, [the Complaint] contains only conclusory allegations, which fail to identify any specific federal requirement that was violated or the specific nature of the . . . purported defects.").

Plaintiffs then contend that the SAC "specified factually how the Defendants violated the federal regulations." (Opp'n at 11.) While the SAC does include more targeted allegations of regulatory violations, closer examination reveals that these too lack factual support. Plaintiffs first allege that Defendant violated 21 C.F.R. § 814.39(a) after Defendant became aware of issues related to Model DDMB1D1 because Defendant was "required to submit a PMA supplement for review and approval . . . before making a change affecting the safety or effectiveness of the device." (SAC ¶¶ 38, 55, 82, 102.) Plaintiffs are correct that a PMA supplement is required after Defendant makes a change affecting safety or effectiveness, but nowhere does the SAC allege Defendant made a change. Nothing within the regulation requires Defendant to submit a PMA supplement based on their awareness of potential issues with Model DDMB1D1 as Plaintiffs contend. See 21 C.F.R. § 814.39(a) ("[A]n applicant shall submit a PMA supplement for review and approval . . . before making a change affecting the safety or effectiveness of the device" and can include new uses, labeling changes, use of different facilities, changes in sterilization procedure, packaging changes, changes in product design.). Plaintiffs fail to plausibly allege Defendant violated this regulation.

Plaintiffs next allege that Defendant violated 21 C.F.R. § 803.50 by failing to report and investigate an adverse event. (See SAC ¶¶ 40-41, 56, 58-59, 84-85, 103, 105.) Under that regulation, manufacturers are required to report to the FDA whenever their device "(1) [m]ay have caused or contributed to a death or serious injury or (2) [h]as malfunctioned and this device

Order at 5 n.2, Docket No. 30.)

or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a). Furthermore, a manufacturer is "responsible for conducting an investigation of each event [where a device caused or contributed to death or serious injury] and evaluating the cause of the event." 21 C.F.R. § 803.50(b)(3).

Plaintiffs allege Defendant failed to report an adverse event or investigate a death, based solely on the December 2017 recall notice's statement that a patient with a similar pacemaker passed away. (See SAC ¶¶ 39-41, 57-59, 83-84, 104-05.) Plaintiffs do not allege any relevant connection between the source of their injury, the defective L303 Integrated Circuit, and the product recall notices, which do not discuss that component. (See RJN, Ex. A.) Plaintiffs must "allege a factual basis for their claim that Defendants failed to alert the FDA of adverse events similar to" Plaintiffs'. Simmons, 2013 WL 12130261, at *4. Instead, Plaintiffs speculate that Defendant did not report or meaningfully investigate the death and that a faulty L303 Integrated Circuit was the cause. This is made even more implausible by the fact that Defendant issued the recall notices several months before Plaintiffs received their ICD. Therefore, Plaintiffs fail to plausibly allege Defendant did not comply with the federal reporting and investigating requirements.

Plaintiffs also allege that Defendant violated several regulations requiring Defendant to establish and maintain certain procedures. The first, 21 C.F.R. § 820.100, requires that "[e]ach manufacturer shall establish and maintain procedures for implementing corrective and protective action" and that the procedures must "include requirements" for analyzing, investigating, identifying, verifying, implementing, ensuring, and submitting quality data and problems for management review. 21 C.F.R. § 820.100. The second, 21 C.F.R. § 820.90, requires that "[e]ach manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements," including procedures that "address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." 21 C.F.R. § 820.90(a). In addition, the regulation requires "procedures that define the responsibility for review and the authority for the disposition of nonconforming product" and "procedures for rework, to include retesting and reevaluation . . . to ensure that the product meets its current approved specifications." 21 C.F.R. § 820.90(b). The third, 21 C.F.R. § 820.198(a), requires that "[e]ach manufacturer shall maintain complaint files" and "shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit," ensuring that complaints are processed in a uniform and timely manner, documented, and evaluated to determine if a report is necessary. 21 C.F.R. § 820.198(a). However, Plaintiffs allege these violations in wholly conclusory fashion that regurgitate near verbatim the regulations themselves. (See SAC ¶¶ 118-19 ("Defendant failed to establish and maintain procedures to control products that does not conform to specified requirements," "failed to establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product," and "failed to establish and maintain procedures for

rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications").) Such regurgitations, without factual support, are insufficient. See Paturzo, 2017 WL 8220600, at *4-5 (granting motion to dismiss where plaintiff alleged an ICD defect resulted from defective processes and violations of 21 C.F.R. §§ 820.90 & 820.100, because "they fail to allege any facts relating the premature battery depletion to Defendants' manufacturing processes and, specifically, the FDA's requirements for manufacturing" such that "the Court can draw no reasonable inference that the premature battery depletion was the result of a manufacturing defect, let alone that the manufacturing defect arises from Defendants' failure to comply with the FDA requirements"). Plaintiffs also allege that Defendant violated these regulations by failing to file an adverse event report and failing to submit a PMA supplement, but these unsupported allegations do not provide any support that Defendant did not establish required procedures. Therefore, Plaintiffs fail to adequately plead Defendant did not establish, maintain, or follow procedure in contravention of federal standards.

Plaintiffs' remaining allegations, though not targeted at specific regulations, also fail to establish that Defendant plausibly violated federal standards. One subset of these allegations concerns the manufacture of Plaintiffs' ICD and that it was adulterated due to the faulty L303 Integrated Circuit. (SAC ¶¶ 117, 136.) However, Plaintiffs' own experience, even taken together with the recall notices concerning Defendant's similar devices, is insufficient to plausibly establish that Defendant inadequately tested components or otherwise failed to comply with federal standards. See Weber, 940 F.3d at 1114 ("[M]ere evidence suggesting that her [device] was defective does not show that Allergan failed to comply with the FDA's Current Good Manufacturing Practices. Likewise, evidence that some other implants produced by [defendant] were defective does not demonstrate noncompliance." (citing Erickson v. Bos. Sci. Corp., 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011))). Similarly, Plaintiffs fail to show that their ICD was adulterated, as there are no factual allegations supporting that the device deviated from or did not meet relevant standards. See 21 U.S.C. § 351; see also Somerville v. Medtronic, Inc., No. 8:20-cv-02177-JLS-ADS, 2021 WL 5926029, at *6 (C.D. Cal. Aug. 19, 2021) (finding device was plausibly adulterated where it did not meet standards, was subject to recall, and the FDA issued a letter noting substandard conditions).

Another subset of allegations concern communications between Defendant and Plaintiffs or Plaintiffs' physician, but these too fail to plausibly establish that Defendant violated federal regulation. Plaintiffs allege in conclusory fashion that "Defendants made untrue representations of material facts and omitted material information" and "sponsored biased medical trials, reports, and articles." (SAC ¶ 78.) Similarly, Plaintiffs allege that, "in [Defendant's] sales materials, there is nothing related to rapid battery depletion stated in the 'Potential Complications' section on their website, the warranty, nor any of the materials provided." (Id. ¶ 103.) However, Plaintiffs fail to plead how these statements went beyond any FDA-approved statements. See De

La Paz, 159 F. Supp. 3d at 1094 ("[A] claim for breach of express warranty based on statements that went 'beyond the FDA approved statements,' even with regard to approved uses, could survive preemption, to the extent it did not rely on a contradiction of the FDA's conclusion in the premarket approval process." (quoting Suckow v. Medtronic, Inc., 971 F. Supp. 2d 1042, 1049 (D. Nev. 2013))). Likewise, the SAC's allegations concerning longevity and limited lifetime warranties fail to provide facts plausibly indicating Defendant breached a warranty, or that these warranties went beyond statements approved by the FDA. (See SAC ¶¶ 124-29; Frere v .Medtronic, Inc., No. EDCV 15-02338-BRO (DTBx), 2016 WL 1533524, at *8 (C.D. Cal. Apr. 6, 2016).)

Based on the foregoing, Plaintiffs have failed to plausibly allege Defendant violated federal regulations and Plaintiffs' claims are thus subject to express preemption and properly dismissed.[4/] When assessing whether leave to amend is proper, courts consider "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment." U.S. ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1052 (9th Cir. 2001) (internal citations and quotations omitted). However, "[f]utility of amendment can, by itself, justify the denial of a motion for leave to amend." Id. "Although leave to amend should be liberally granted, the amended complaint may only allege 'other facts consistent with the challenged pleading.'" Reddy v. Litton Indus., Inc., 912 F.2d 291, 296-97 (9th Cir. 1990) (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., Inc., 806 F.2d 1393, 1401 (9th Cir. 1986)). Here, Plaintiffs have amended their complaint twice, once as a matter of right after Defendant filed a motion to dismiss, and once after the Court gave Plaintiffs the opportunity to cure deficiencies. (See Docket Nos. 18, 30.) Despite attempts to specify which regulations Defendant purportedly violated, Plaintiffs have failed to allege new facts in support of their claims. Therefore, the Court dismisses Plaintiffs' claims without leave to amend.

B. Other Issues

Defendant also contends that Plaintiffs' claims fail for additional reasons, such as a lack of particularity in pleading fraud, preclusion from failure to warn based on the learned intermediary doctrine, a lack of pleading causation, a lack of pleading privity, and inadequate pleading of facts surrounding warranties. Because the Court dismisses the claims for being expressly preempted, the Court need not address those arguments.

[4/] Plaintiffs' claim for loss of consortium, which does not implicate preemption issues, is derivative of Plaintiffs' other claims. See Tucker v. CBS Radio Stations, Inc., 194 Cal. App. 4th 1246, 1256, 124 Cal. Rptr. 3d 245 (2011). As such, that claim is also properly dismissed.

Conclusion

Based on the foregoing, the Court grants Defendant's Motion to Dismiss. The Court will issue a Judgment consistent with this Order.

IT IS SO ORDERED.