**UNITED STATES DISTRICT COURT**

**SOUTHERN DISTRICT OF CALIFORNIA**

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| KIMBERLY WEAVER AND JAMES WEAVER,<br><br>Plaintiffs,<br><br>v.<br><br>ETHICON, INC.; and DOES 1 through 20, inclusive,<br><br>Defendants. | CASE NO. 16cv257-GPC(BGS)<br><br>**ORDER GRANTING DEFENDANT'S MOTION TO DISMISS WITH LEAVE TO AMEND**<br><br>[Dkt. No. 38.] |

Before the Court is Defendant Ethicon, Inc.'s motion to dismiss pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). (Dkt. No. 38.) Plaintiffs filed an opposition, and Defendant filed a reply. (Dkt. Nos. 41, 42.) A hearing was held on December 2, 2016. (Dkt. No. 43.) Elliott Kanter, Esq. appeared on behalf of Plaintiffs and Aggie Lee, Esq. appeared on behalf of Defendant. (Id.) After a review of the second amended complaint, the parties' briefs, the applicable legal authority, and hearing arguments by the parties, the Court GRANTS Defendant's motion to dismiss with leave to amend.

**Procedural Background**

Plaintiffs Kimberly Weaver and James Weaver (collectively "Plaintiffs") filed a complaint in state court which was removed to this Court on February 1, 2016 against Defendants Johnson & Johnson ("J&J"), and its subsidiary, Ethicon, Inc. ("Ethicon").

(Dkt. No. 1.) On February 8, 2016, J&J filed a motion to dismiss for lack of personal jurisdiction pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(2) and failure to state a claim pursuant to Rule 12(b)(6). (Dkt. No. 3.) The Court denied J&J's Rule 12(b)(2) motion to dismiss without prejudice and granted Plaintiffs' request for jurisdictional discovery, denied J&J's Rule 12(b)(6) motion as premature, and granted Plaintiffs' leave of court to file an amended complaint once jurisdictional discovery is completed. (Dkt. No. 22.) Subsequently, the parties filed a joint motion to dismiss J&J. (Dkt. No. 23.)

Plaintiffs then filed a first amended complaint ("FAC") against Ethicon for negligence, strict liability, and loss of consortium. (Dkt. No. 25.) On May 26, 2016, Ethicon filed a motion to dismiss arguing Plaintiffs' state law claims are expressly preempted by the Medical Device Amendment ("MDA"). (Dkt. No. 26.) On August 22, 2016, the Court granted Defendant's motion to dismiss and granted Plaintiffs' request for leave to file a second amended complaint. (Dkt. No. 36.) On September 2, 2016, Plaintiffs filed a second amended complaint ("SAC") alleging manufacturing defect-strict liability, manufacturing defect-negligence, failure to warn-strict liability, failure to warn-negligence and loss of consortium. (Dkt. No. 37.) Defendant again moves to dismiss the SAC for failing to state a claim arguing that the state law claims are expressly preempted by the MDA and Plaintiffs have failed to allege state law claims that are parallel to violations of federal law.

**Factual Background**

Ethicon manufactures a variety of medical devices and distributes them to doctors, hospitals, and facilities in California which includes manufacturing the Sugiflo Hemostatic Matrix Kit ("Surgiflo"). (Dkt. No. 37, SAC ¶ 2.) Ethicon introduced Surgiflo in the United States in 1999. (Id. ¶ 3.)

On or about November 24, 2014, Plaintiff Kimberly Weaver underwent sinus surgery in San Diego, CA for chronic sinusitis. (Id. ¶ 6.) During the procedure, her surgeon used Surgiflo to control the bleeding. (Id.) Surgiflo's purpose is to act as

packing in order to control bleeding. (Id.) Her surgeon believed that the packing would self-absorb in her body within a couple of days. (Id.) On December 4, 2014, Kimberly underwent a second surgery due to complications from the first surgery consisting of migraine headaches, occipital neuralgia, nasal pain, pressure and other injuries which are detailed in her medical records. (Id. ¶ 7.) After the surgery, it was determined that her complaints were due to the failure of the Surgiflo to absorb into her body. (Id.) These complications and adverse effects were not detailed or reported to the Federal Drug Administration ("FDA") when Ethicon applied for premarket approval ("PMA") in 1999 and in subsequent re-evaluations and re-approvals. (Id.)

Plaintiffs allege that Surgiflo was not designed, manufactured and labeled in accordance with specifications approved by the FDA through the PMA process. (Id. ¶ 9.) As a result of the defects, Plaintiff Kimberly has suffered pain, mental anguish, loss of income and continues to suffer pain and suffering. (Id. ¶ 11.) Plaintiff James Weaver was present with his wife, Kimberly Weaver, except during the surgery, and has suffered loss of society, comfort, consortium, services, and income. (Id. ¶ 13.)

The Surgiflo is a Class III medical device and requires premarket approval ("PMA"). See 21 C.F.R. § 878.4490. On January 22, 2009, Ethicon submitted a PMA application for its Surgifoam Absorbable Gelatin Sponge ("Surgifoam"). (Dkt. No. 39-1, D's RJN[1], Ex. 1 at 2[2].) Surgifoam is used in "surgical procedures (other than neurological, urological and ophthalmological surgery) as an adjunct to hemostatis when control of capillary, venous and arteriolar bleeding by pressure, litgature and

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[1]Defendant filed a request for judicial notice of documents concerning the FDA's premarket approval of the Sugiflo which are available on the FDA's website. (Dkt. No. 39.) Plaintiffs do not oppose. The Court previously granted Defendant's request for judicial notice on the same documents. (Dkt. No. 36 at 3 n.1.) For the same reasons noted in the Court's prior order, the Court GRANTS Defendant's request for judicial notice. See Lee v. City of Los Angeles, 250 F.3d 668, 688-89 (9th Cir. 2001); United States v. Ritchie, 342 F.3d 903, 908 (9th Cir.2003) ("A court may, however, consider certain materials-documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice-without converting the motion to dismiss into a motion for summary judgment.").

[2]Page numbers are based on the CM/ECF pagination.

other conventional procedures is ineffective or impractical." (Id.) On September 30, 1999, the FDA found Surgifoam safe and effective as designed, manufactured and labeled and issued an Approval Order. (Id. at 2-17.) Since then, the application of Surgifoam has been supplemented, re-evaluated, and re-approved 29 separate times, including most recently on May 16, 2016. (Dkt. No. 39-3, D's RJN, Ex. 3.)

On May 5, 2005, the FDA approved a supplement and allowed Ethicon to market the Surgiform as a pre-filled paste from the powdered form as the Surgiflo Hemostatic Matrix. (Dkt. No. 39-4, D' RJN, Ex. 4.) Another supplement was approved on October 2, 2009 granting Ethicon approval to market the Surgiflo Hemostatic Matrix Kit, which consists of Surgiflo Hemostatic Matrix and "evithrom lyophilized human thrombin." (Dkt. No. 39-5, D's RJN, Ex. 5.)

## Discussion

### A. Legal Standard on Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) permits dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. See Balistreri v. Pacifica Police Dep't., 901 F.2d 696, 699 (9th Cir. 1990). Under Rule 8(a)(2), the plaintiff is required only to set forth a "short and plain statement of the claim showing that the pleader is entitled to relief," and "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint may survive a motion to dismiss only if, taking all well-pleaded factual allegations as true, it contains enough facts to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Threadbare recitals of the elements of a cause

of action, supported by mere conclusory statements, do not suffice." Id. "In sum, for a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009) (quotations omitted). In reviewing a Rule 12(b)(6) motion, the Court accepts as true all facts alleged in the complaint, and draws all reasonable inferences in favor of the plaintiff. al-Kidd v. Ashcroft, 580 F.3d 949, 956 (9th Cir. 2009). The court evaluates lack of statutory standing under the Rule 12(b)(6) standard. Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th Cir. 2011).

Where a motion to dismiss is granted, "leave to amend should be granted 'unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.'" DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992) (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986)). In other words, where leave to amend would be futile, the Court may deny leave to amend. See Desoto, 957 F.2d at 658; Schreiber, 806 F.2d at 1401.

**B. Analysis**

In the Court's prior order on Defendant's motion to dismiss, it held that the state law claims of strict liability, negligence, and loss of consortium were expressly preempted by the MDA and Plaintiffs did not allege facts to fall within the narrow exception to the express preemption doctrine announced in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). (Dkt. No. 36 at 7-9.) In its current motion, Defendant again argues that the state law claims are expressly preempted, and Plaintiffs fail to allege facts to fall within the narrow exception left open in Riegel. Plaintiffs argue that they have sufficiently alleged facts to support state law causes of action that are parallel with federal law.

The Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") was enacted to "extend the coverage of the FDCA to medical devices."

Stengel v. Medtronic Inc., 704 F.3d 1224, 1226 (9th Cir. 2013) (en banc). The MDA's preemption provision provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (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. Riegel established a two step analysis to determine whether a claim is expressly preempted under the MDA. Riegel, 552 U.S. at 321-22. First, the court must decide whether the FDA has established requirements specific to the device at issue. Id. at 321. Second, the court must determine whether the state-law claim would impose any requirements that are "different from or in addition" to the federal ones, and relate to safety or effectiveness. Id. at 321-22. State "requirements" include common law duties. Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013) (citing Riegel, 552 U.S. at 324-25). Riegel held that while common law claims of strict liability, negligence and implied warranty claims impose requirements that are different from the federal requirements, 522 U.S. at 323-24, it left open a narrow exception asserting that the MDA "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; Stengel, 704 F.3d at 1228 ("the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."); In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. Jan. 5, 2009) ("Riegel left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted.")

The Court previously held that step one had been met as the Surgifoam underwent a rigorous review process and obtained premarket approval on September 30, 1999 and underwent supplemental, re-evaluation and re-approval twenty eight times and include Surgiflo. (Dkt. No. 36 at 6.) The Court also held that the second

step had been met and concluded that the state law claims were preempted by the MDA. (Id. at 6.) The Court granted Plaintiffs leave to file an amended complaint in order to allege specific facts that would fall under the narrow exception pronounced by Riegel. (Id. at 7.)

In this motion, the parties dispute whether Plaintiffs have alleged facts to support state law claims that parallel federal requirements. State law claims asserting a violation of FDA regulations or requirements "parallel" federal requirements and are not preempted. In re Medtronic, Inc., 592 F. Supp. 2d at 1152. "To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013) (quoting Erickson v. Boston Scientific Corp., 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011). In Erickson, the court noted that a plaintiff cannot simply allege that the defendant violated FDA regulations in order to avoid preemption. Erickson, 846 F. Supp. 3d at 1092. Instead, "a plaintiff must allege that the defendant 'violated a particular federal specification referring to the device at issue,' . . . or identify specific PMA requirements that have been violated." Id. (plaintiff failed to state a claim by failing to allege how defendants deviated from any specific FDA requirements or how these violations affected the device); but see Bausch v. Stryker Corp., 630 F.3d 546, 553, 560 (7th Cir. 2010) (if plaintiffs can prove harm due to a violation of federal law, plaintiffs are not required to plead a violation of a specific regulatory requirement since much of the critical information for Class III medical devices are kept confidential as a matter of federal law).

**i. Manufacturing Defect**

Plaintiffs bring claims for manufacturing defect under the theories of negligence and strict liability. Defendant contends that Plaintiffs assert no causal nexus between the alleged defect and Plaintiffs' injuries. Plaintiffs respond that they have adequately

met the pleading requirements because they specifically alleged seventeen federal regulatory violations.

A manufacturing defect is "one that differs from the manufacturer's intended result or from other ostensibly identical units of the same line of products." Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 429 (1978). A "manufacturing defect" theory 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, 99 Cal. App. 4th 594, 613 (2002). "A manufacturing defect [is] a legal cause of injury only if the defect [is] a substantial factor in producing the injury." Garrett v. Howmedica Osteonics Corp., 214 Cal. App. 4th 173, 190 (2013) (citation omitted).

In order to survive MDA preemption on a manufacturing defect claim, courts have required specific allegations "that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and - based on the same deficiency - was defectively manufactured under California law." De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1092 (N.D. Cal. 2016) (quoting Funke v. Sorin Group USA, Inc., 147 F. Supp. 3d 1017, 1026 (C.D. Cal. 2015)). A plaintiff cannot merely assert that the device violated federal standards but must provide some allegation regarding "the nature of the alleged . . . defect as it relates to the FDA approval process." Simmons, 2013 WL 1207421, at *4 (plaintiff must allege that the defendant "violated a particular federal specification referring to the device at issue" or a specific PMA requirement); Parker v. Stryker Corp., 584 F.Supp.2d 1298, 1301 (D. Colo. 2008) (granting defendant's Rule 12(b)(6) motion because "nowhere does plaintiff's complaint provide any factual detail to substantiate th[e] crucial allegation" that the devices violated FDA requirements). Moreover, Plaintiffs "'cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption.'" Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) (quoting Wolicki–Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011)).

Here, the SAC generally alleges that Defendant "failed to inspect the product

assembly, product components, and product quality during manufacturing assembly without proper documentation of said inspections"; "there was inadequate lack of control of design of its product in the manufacturing process"; "there was inadequate training of personnel in the manufacturing process quality control, assembly, procedures, protocols, checking of assemblies, inspection of the simplest, final inspection of assemblies, final testing of assemblies, and packaging"; "there was inadequate failure to report previous problems"; "failure to follow good manufacturing procedures as required by the PMA", "packaging and container are not manufactures (sic) and constructed to protect the device alteration or damage during processing, storage, handling, distribution, and use"; "failed to perform a complete risk analysis violation of 21 CFR 820 et seq. . . . did not perform a complete risk analysis concerning the effect of the product when it did not fully absorb the human body"; and "failed to establish procedures for the validation of verification review especially in light of the instances where the product does not fully absorb." (Id. ¶¶ 19-28.)

These general allegations merely allege violations of the regulations but do not provide facts as to how Defendant violated these provisions. They are conclusory and do not support manufacturing defect claims based on the Surgiflo's failure to absorb. Thus, the claims fail to survive preemption.

Plaintiff's citation to Bausch is unavailing. In Bausch, the plaintiff alleged state law claims of negligence and strict liability alleging violations of federal regulatory" standards. Bausch, 630 F.3d at 549, 559-60. The court stated that the federal standard of notice pleading applies and there is no need for a plaintiff to identify specific federal regulatory requirements violated. Id. at 558. However, in Bausch, the plaintiff alleged facts that provided defendants with fair notice of the nature of the claims against them. Id. The complaint alleged that defendants knew or should have known before Plaintiff's surgery that the ceramic-on-ceramic hip replacement systems that was implanted was defective because they had received complaints that the device failed after it was implanted, Defendants recalled the device due to "dimensional anomalies",

and the FDA issued a letter warning that the device was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards." Id. at 559. In this case, Plaintiffs present no facts as to the Surgiflo's alleged failure to absorb to support a manufacturing defect claim.

Moreover, Plaintiffs allege that there was a Class 1 recall on the Surgiflo in 2010 and 2012 because the packaging was compromised causing problems with the product's sterilization. (Dkt. No. 37, SAC ¶ 4.) Later, the SAC alleges the "product recall was not complete, and that the product utilized on plaintiff was a recalled product that was not accounted." (Id. ¶ 16.) However, Plaintiffs do not allege whether the recall concerning the packaging relates to the non-absorption issue. See Simmons, 2013 WL 1207421 at *5 ("Plaintiff fails to link the recalls or advisories to the malfunction at issue here in any more than a conclusory manner, and courts have recognized that product recalls do not create a presumption that FDA requirements have been violated."); see also Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1056 (2008) ("The fact the FDA has implemented a Class I recall does not necessarily mean the FDA has completely removed the device from the marketplace.")

Accordingly, the Court GRANTS Defendant's motion to dismiss the causes of action for manufacturing defect/strict liability and manufacturing defect/negligence as preempted.

**ii. Failure to Warn**

Plaintiffs also assert a strict liability failure to warn claim and a negligent failure to warn claim. Defendant argues that the failure to warn causes of action are conclusory and merely present a laundry list of alleged violations of the FDA regulations without supporting facts. Plaintiffs disagree.

The SAC alleges that Defendant failed to warn the FDA of the injuries suffered and potential problems that would arise if Surgiflo failed to absorb which is in violation of numerous federal reporting regulations. (Dkt. No. 37, SAC ¶¶ 16, 29-37.) According to Plaintiffs, Defendant violated "21 CFR 803.10; 21 CFR

803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70." (Id. ¶ 49.) Plaintiffs also allege that Defendant was aware of the adverse events of a failure to absorb and failed to comply with federal regulations by not reporting the adverse effects of non-absorption. (Id. ¶ 16.) Defendant "had reports of non-absorption of its product from various sources and with that knowledge continued to not report the occurrences to the federal reporting agencies that it was required to do so." (Id.) Further, the SAC alleges that in 2010 it was reported that the product did not absorb and Defendant did not submit this information to the FDA. (Id. ¶ 31.)

A failure to report adverse events to the FDA can form the basis of a parallel negligence claim that survives preemption. Stengel, 704 F.3d at 1233 (holding that a failure to warn claim under Arizona law based on a failure to warn the FDA was not preempted); Anderson v. Medtronic, Inc., No. 14cv615-BAS(RBB), 2015 WL 2115342, at *7 (S.D. Cal. May 6, 2015) (indicating that the plaintiffs might be able to amend their complaint to allege negligence and strict product liability based on a failure to report to the FDA). California law creates a duty to warn parallel to 21 C.F.R. § 803.50(a), as a "device manufacturer can be found liable if it 'did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.'" Coleman v. Medtronic, Inc., 223 Cal. App. 4th 413, 428 (2014) (quoting Anderson v. Owens–Corning Fiberglass Corp., 53 Cal. 3d 987, 1002 (1991)). The California duty to warn can also run to the FDA and a failure to warn based on the defendant's failure to file adverse event reports with the FDA is not subject to preemption. Id. at 428-29.

To survive a motion to dismiss on a state law negligence failure to warn claim that is parallel to federal regulations the complaint "must include allegations of actual adverse events that Defendants did not report." Grant v. Corin Group PLC, 15cv169-CAB-BLM, 2016 WL 4447523, at *7 (S.D. Cal. Jan. 15, 2016). In Grant, the court

granted Defendants' motion to dismiss because the complaint summarily alleged that Defendants violated federal regulations requiring them to report adverse events without any specific allegations of actual adverse events. Id. A general allegation that Defendant failed to report adverse events to the FDA is not sufficient to demonstrate causation. See Hawkins v. Medtronic, Inc., No. 13cv499, 2014 WL 346622, at *8 (E.D. Cal. Jan. 20, 2014) ("Plaintiff generally alleges that Defendants failed to report adverse events to the FDA. He also generally alleges that these failures caused or contributed to his injuries. What is not alleged is any factual content that would support the causal nexus."). In Eidson, the district court denied defendant's motion to dismiss after the plaintiff amended the complaint to add specific facts as to the nature of the failure to report which included a study to allege that defendants under reported adverse events and plaintiff's surgeon would have had access to the adverse events if it was reported properly. Eidson v. Medtronic, Inc., 40 F. Supp. 3d 1202, 1234 (N.D. Cal. 2014); see also Michajlun v. Bausch & Lomb, Inc., No. 14-1365, 2015 WL 1119733, at *8 (S.D. Cal. Mar. 11, 2015) (complaint alleged articles discussing specific instances of the alleged adverse effects that were not reported); Simmons v. Boston Scientific Corp., No. 12-7962, 2013 WL 1207421, at *5 (C.D. Cal. Mar. 25, 2013) (mere allegation that defendants failed to report adverse events related to electric shocks to persons implanted with the medical device failed to state a claim).

In this case, Plaintiffs allege that Ethicon "had reports of non-absorption of its product from various sources and with that knowledge continued to not report the occurrences to the federal reporting agencies that it was required to do so." (Id. ¶ 16.) In addition, the SAC alleges that in 2010, it was reported that the product did not absorb as intended. (Id. ¶ 31.) These facts present only conclusory allegations that Defendant failed to report adverse events without specific instances of actual adverse events. While Plaintiffs attempt to provide specific facts by asserting that reports from "various sources" and in "2010, it was reported", there is no factual bases to support these allegations. Therefore, Plaintiffs have failed to allege failure to warn causes of action

that are parallel to federal regulations and cannot avoid preemption.

The SAC also alleges a failure to warn physicians and the general public which is in violation of the PMA. (Dkt. No. 27, SAC ¶ 56.) Defendant argues that these allegations are expressly preempted by the MDA. Plaintiffs do not address this issue in their opposition. "[A]ny attempt to predicate the [plaintiffs'] claim on an alleged state law duty to warn doctors directly would have been expressly preempted under 21 U.S.C. § 360k, which forbids state-imposed requirements that are 'different from, or in addition to' the requirements imposed by federal law." Stengel, 704 F.3d at 1234 (Watford, J., concurring); Anderson, 2015 WL 2115342 at *6 (failure to warn doctors and general public preempted); Funke, 147 F. Supp. 3d at 1024 (claim of failing to warn plaintiff and his medical provided were expressly preempted). Thus, Plaintiffs' failure to warn physician and the general public are preempted by the MDA. In sum, the Court GRANTS Defendant's motion to dismiss the failure to warn causes of action as preempted.

**iii. Loss of Consortium**

The SAC also alleges loss of consortium as to Plaintiff James Weaver. (Dkt. No. 37, SAC ¶ 13.) Defendant argues that because Plaintiffs' substantive claims are without merit, the loss of consortium claim, which is derivative in nature, also fails. Plaintiffs do not address this argument.

A loss of consortium claim is derivative of and dependent on the spouse's negligence action. Calatayud v. State of California, 18 Cal. 4th 1057, 1060 n. 4 (1998). In medical device cases, courts have held that loss of consortium is derivative of other causes of action. See Riegel, 552 U.S. at 321 (since the loss of consortium is derivative of the other causes of action, the Court dismissed it as preempted); Anderson, 2015 WL 2115342 at *9 (dismissing loss of consortium as it derivative of the other causes of action); Simmons, 2013 WL 1207421, at *6 (granting motion to dismiss as claim for loss of consortium is derivative of the other claims). Here, since the Court dismisses all causes of action, the loss of consortium based on these claims also fail, and the Court

GRANTS Defendant's motion to dismiss this claim as preempted.

**C. Leave to Amend**

Defendant asks the Court to grant its motion to dismiss with prejudice since Plaintiffs have previously been granted leave to amend the complaint and the Court warned Plaintiffs that the filing the SAC would be their final opportunity to amend. In their opposition, Plaintiffs ask the Court for leave to amend their complaint.

In the Court's prior order on Defendant's motion to dismiss, the Court granted Plaintiffs leave to file a second amended complaint in order to plead their parallel claims with more specificity and noted that it would be Plaintiffs' last opportunity to amend the complaint. (Dkt. No. 36 at 9.) Despite the Court's prior admonishment, it recognizes the difficulties of pleading parallel claims with factual support. See Bausch, 630 F.3d at 558; Cline v. Advanced Neuromodulation Sys., Inc., 921 F. Supp. 2d 1374, 1380 (N.D. Ga. 2012) (noting that meeting the pleading requirements for parallel claims is not easy). Therefore, the Court will allow Plaintiffs one final opportunity to plead parallel claims in compliance with the applicable caselaw and GRANTS Plaintiffs' request for leave to file a third amended complaint.

**Conclusion**

Based on the above, the Court GRANTS Defendant's motion to dismiss with leave to amend. Plaintiffs shall file a third amended complaint within 20 days of the filing of this Order.

IT IS SO ORDERED.

DATED: December 6, 2016

HON. GONZALO P. CURIEL
United States District Judge