UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KIMBERLY WEAVER AND JAMES WEAVER, Plaintiffs, v. ETHICON, INC.; and DOES 1 through 20, inclusive, Defendants.	CASE NO. 16cv257-GPC(BGS) **ORDER GRANTING DEFENDANT'S MOTION TO DISMISS WITH PREJUDICE** [Dkt. No. 47.]

Before the Court is Defendant Ethicon, Inc.'s motion to dismiss the third amended complaint pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). (Dkt. No. 47.) Plaintiffs filed an opposition, and Defendant filed a reply. (Dkt. Nos. 49, 51.) After a review of the parties' briefs and the applicable legal authority, the Court GRANTS Defendant's motion to dismiss the third amended complaint.

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 the complaint as expressly preempted 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 moved to dismiss the SAC 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. (Dkt. No. 38.) On December 6, 2016, the Court granted Defendant's motion to dismiss as expressly preempted with leave to amend one final time. (Dkt. No. 44.) On December 27, 2016, in an attempt to cure the deficiencies in the SAC, Plaintiff filed a third amended complaint ("TAC") alleging the same causes of action as the second amended complaint and adding a claim for punitive damages. (Dkt. No. 45.) Defendant filed the instant motion to dismiss on January 10, 2017 which is fully briefed. (Dkt. Nos. 47, 49, 51.)

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. 45, TAC ¶ 3.) Ethicon introduced

Surgiflo in the United States in 1999. (Id.)

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 with Thrombin 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 Court previously granted Defendant's 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. 36 at 3 n.1.) According to those documents, 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, Ex. 1 at 2[1].) Surgifoam is used in "surgical procedures (other than neurological, urological and ophthalmological surgery) as an adjunct to hemostatis when control of capillary,

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

venous and arteriolar bleeding by pressure, litgature and 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 Surgifoam 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).

B. Analysis

In the Court's prior orders on Defendant's two previous motions to dismiss on preemption, 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; Dkt. No. 44 at 10, 13, 14.) In its current motion, Defendant again argues that Plaintiffs have not cured the allegations to fall within the narrow exception left open in Riegel and the Court should dismiss the TAC with prejudice. 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; Dkt. No. 44 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. (Dkt. No. 36 at 6; Dkt. No. 44 at 10, 13, 14.) In allowing Plaintiffs leave to file a third amended complaint, they were granted one final opportunity to allege specific facts to support their state law causes under the narrow exception pronounced by Riegel. (Dkt. No. 44 at 14.)

In the 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, 957 F. Supp. 2d at 1174 (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 still fail to assert a causal nexus between the alleged defect and Plaintiffs' injuries. In response, Plaintiffs argue that there was a product recall for non-sterility due to faulty packaging, that the product recall was not complete, that Kimberly received a recalled product that was not accounted for, and the lack of sterility in the product caused it to not absorb and caused her injuries.

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 v. Boston Scientific Corp., No. 12-7962, 2013 WL 1207421, at *4 (C.D. Cal. Mar. 25, 2013) (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, though not entirely clear, it appears the TAC now alleges that Kimberly Weaver's injuries were caused by faulty packaging causing the product to become non-sterile, as evidenced by the recalls, which caused the Surgiflo to not absorb, and subsequently caused her infection.[2] She claims that her treating physician used a recalled product that was not accounted for and thus, she suffered injuries.

[2]In their prior complaints, Plaintiffs alleged that the manufacturing defect was the Surgiflo's failure to absorb, which caused her infection. (Dkt. No. 25, FAC ¶ 14; Dkt. No. 37, SAC ¶¶ 2, 11.)

Plaintiffs generally allege 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/or shipping container were not manufactured 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.) The Court previously found these allegations not sufficient to allege a manufacturing defect claim.

The TAC also added additional allegations that two recalls in 2012 were directly related to sterilization of the Surgiflo. (Id. ¶¶ 21, 39.) One recall dated August 21, 2012 was a Class 1 voluntary device recall of Surgiflo with Thrombin concerning an issue with the packing process where "a cut could potentially breach the double Tyvek pouch of the packaging." (Dkt. No. 45-1, TAC, Ex. 3[3] at 20.) The recall concerned lot/batch numbers that expired between January 2013 and June 2013 and the recall was

[3]The Court may "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." United States v. Ritchie, 342 F.3d 903, 908 (9th Cir. 2003). "Materials submitted as part of the complaint are not considered 'outside' the complaint and may be considered" on a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Butler v. Los Angeles County, 617 F. Supp. 2d 994, 999 (C.D. Cal. 2008) (citing Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001); and Hal Roach Studios, Inc. v. Richard Feiner & Co., 896 F.2d 1542, 1555 n. 19 (9th Cir. 1990) (material properly submitted as part of the complaint may be considered)). Here, both parties rely on the documents attached to the TAC to support their arguments.

terminated on September 11, 2014. (Id. at 19-20.) Another voluntary recall was a Class 2 recall which was initiated on April 3, 2012 and terminated on April 16, 2014. (Id., Ex. 3 at 21.) It concerned the packaging process control where the "lyophilized thrombin component of the Surgiflo Hemostatic Matrix kit with Thrombin has the potential to be non-sterile due to an undetected air leak which occurred during the manufacturing process." (Id. at 22.) The lot expiration dates ranged from June 2012 to March 2013. (Id. at 21.) The TAC further alleges that the "product recall was not complete, and that the product utilized on plaintiff was a recalled product that was not accounted." (Id., TAC ¶ 16.)

The Court concludes that Plaintiffs have failed to allege sufficient facts to support a state law manufacturing defect claim that is parallel to federal regulations. Plaintiffs' theory requires the Court to make inferences and assumptions that are not reasonable and not supported by the facts. First, the new allegation that non-sterility can cause the product to not absorb is speculative and not supported by any additional facts. Next, the argument that Plaintiff's physician used a recalled product is also conjecture and not factually supported. The 2012 recalls, terminated on April 16, 2014 and November 2014, create a reasonable inference that if the recalls were not complete, as alleged by Plaintiffs, Kimberly's physician could have used the defective product on her. However, both recalls had product code expiration dates with the latest expiration date of June 2013, over a year before Kimberly had her surgery in November 2014. Plaintiffs have not alleged that her physician used an expired recalled product during Kimberly's surgery. These speculative and unsupported allegations do not support the allegation that the Surgiflo used in Kimberly's surgery was a recalled product.

The TAC further adds allegations that Defendant failed to perform a complete risk analysis in violation of 21 C.F.R. § 820 *et seq*. by failing to include use of the product in sinus cavity surgery. (Dkt. No. 45, TAC ¶ 27.) The PMA contains no research, studies, risk analysis of the product when used in the nasal cavity. (Id.)

Furthermore, in 2005, Surgiflo's name changed from Surgifoam because Thrombin was added to the manufacturing process. (Id. ¶ 37.) Ethicon failed to submit a special supplement report when the product changed and invalidates the PMA approval process. (Id.) The change also required Ethicon to conduct new quality control testing procedures which it failed to do. (Id.) Again, these are conclusory allegations of Defendants' violations of alleged federal regulations; however, there are no facts that these alleged violations caused her injuries.

As noted in its prior order, Plaintiff's citation to Bausch that a plaintiff need not allege a specific federal regulation is not supportive. In Bausch, the plaintiff alleged state law claims of negligence and strict liability alleging violations of federal regulatory standards. Bausch v Stryker Corp., 630 F.3d 546, 549, 559-60 (7th Cir. 2010). In Bausch, the plaintiff alleged facts that provided defendants with fair notice of the nature of the claims against them because the plaintiff specifically alleged that the device implanted in her had the same catalogue number as the device subject to an FDA warning letter and inspections concerning manufacturing issues. Id. at 559. Moreover, the device in the plaintiff's body failed and the same device was later recalled. Id. In this case, Plaintiffs have not alleged facts that the Surgiflo used in her sinus surgery was subject to the 2012 recalls or that the conclusory alleged violations of federal regulations caused her injuries. Thus, 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 Report and Warn

Plaintiffs also assert claims for failure to warn and report adverse events to the FDA under strict liability and negligence. Defendant contends that Plaintiffs still have not demonstrated a causal connection between a failure to report adverse events and Kimberly's injuries.

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.

FDA regulations require the filing of adverse event reports and provide,

> (a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
>
> (1) May have caused or contributed to a death or serious injury or
>
> (2) Has malfunctioned and this device 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). To plead a failure to warn parallel claim, a plaintiff must allege the defendant failed to report adverse events and that the failure to warn caused the plaintiff's injuries. See Houston, 957 F. Supp. 2d at 1174. 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 the 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 on a large scale 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, 2013 WL 1207421, at *5 (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).

Here, Plaintiffs allege that Defendant was aware of the failure to absorb and failed to comply with federal regulations by not reporting the adverse effects of non-absorption. (Dkt. No. 45, TAC ¶ 16.) Ethicon knew that if the product did not absorb, it would lead to an infection especially in the area of the sinus cavity. (Id.) 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.) In May 2010, the FDA's MAUDE[4] Adverse Event Report contains a report that a risk manager at a user facility reported that the thrombin

[4]The Manufacturer and User Facility Device Experience ("MAUDE") is a public database maintained by the FDA and details adverse events involving medical devices. Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005); Horrillo v. Cook Inc., No. 08-60931-CIV, 2014 WL 2708544, at *4, n. 4 (S.D. Fla. June 6, 2014).

in the Surgiflo would not reconstitute; "it congealed into a solid material when mixed." (Dkt. No. 45-1, TAC, Ex. 1.) Plaintiffs complain that Ethicon violated 21 C.F.R. § 803.50 by failing to submit medical device reporting ("MDR") reports concerning the adverse effects of the Surgiflo when it does not fully absorb in a timely manner. (Id. ¶ 29.) According to Plaintiffs, because there was no adverse report regarding the failure to absorb, the FDA could not evaluate the significance of the adverse events. (Id. ¶ 31.) Moreover, had the adverse event been reported, the information would have reached Plaintiffs and her treating physician prior to her surgery and a reasonable surgeon would not have used the product. (Id. ¶ 52.)

The TAC has not presented specific instances of actual adverse events that Defendant failed to report regarding a failure to absorb. In correcting the deficiencies the Court noted in its prior order, Plaintiffs cite to a May 2010 MAUDE adverse event report as a specific instance of an adverse event that Defendant did not report. However, MAUDE is a public database maintained by the FDA containing adverse event report and is accessible to physicians and the public. See Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005); see generally Eidson, 40 F. Supp. 3d at 1233 (complaint alleged that MAUDE is public database known to and discussed in the medical community). In this case, while a utility user reported the adverse event concerning a failure to reconstitute, and not Defendant, the adverse event was public and accessible to the FDA and physicians. Without citing to a federal regulation, Plaintiff summarily allege that it was a direct violation of the PMA when Defendant did not follow up on the May 2010 adverse event. Even if there was a requirement that Defendant should have followed up on an adverse event reported by a utility user, the causation element, that had the adverse event been reported, the information would have reached her treating physician and he would not have used the product, has not been alleged because the adverse report was accessible to her treating physician. (See Dkt. No. 45, TAC ¶ 52.)

Moreover, Defendant argues that this adverse event report is unrelated and

concerns a failure to congeal, not a failure to absorb as alleged by Plaintiffs. While this report does not directly concern a failure to absorb, there is a reasonable inference that a failure to reconstitute could relate to the inability of the Surgiflo to reabsorb. However, one instance of an adverse event that plausibly could support a failure to absorb theory is not sufficient to have put Ethicon on notice about Surgiflo's failure to absorb. See Cline v. Advanced Neuromodulation Sys., Inc., 17 F. Supp. 3d 1275, 1287 (N.D. Ga. 2014) ("it is implausible that the failure of a single implanted device due to battery weld issues over a six-month period would prompt action from the FDA, Plaintiff, or Plaintiffs medical providers.")

Plaintiffs also allege that because Defendant has not reported Kimberly Weaver's own adverse event because it does not appear on the FDA's searchable database, Defendant has violated the federal regulations requirement to report adverse events. (Dkt. No. 45, TAC ¶ 22.) Defendant argues that Plaintiffs' argument is fatally flawed because they will not be able to demonstrate that the failure to report Kimberly's injuries caused her injuries.

The Court agrees with Defendant that a failure to report Kimberly's injuries would not satisfy the causation factor to demonstrate a failure to warn. An allegation that a defendant failed to report the adverse event giving rise the plaintiff's injuries to the FDA fails to demonstrate a causation connection between the failure to report and her injuries. See Johnson v. Hologic, Inc., No. 14cv794-JAM-KJN-PS, 2015 WL 75240, at *4 (E.D. Cal. Jan. 6, 2015); Malonzo v. Mentor Worldwide, LLC, No. C. 14-1144 JSW, 2014 WL 2212235, at *3 (N.D. Cal. May 28, 2014) (granting motion to dismiss failure to warn claim because the only failure to report was the plaintiff's injuries which would not have caused her injury).

Therefore, Plaintiffs have failed to allege failure to warn causes of action that

are parallel to federal regulations and cannot avoid preemption.[5] The Court GRANTS Defendant's motion to dismiss the failure to warn causes of action as preempted.

iii. Loss of Consortium and Punitive Damages

The TAC also alleges loss of consortium as to Plaintiff James Weaver, (Dkt. No. 45, TAC ¶ 13), and seeks punitive damages, (id. at p. 23). Defendant argues that because Plaintiffs' substantive claims are without merit, the loss of consortium and punitive damages claim, which are derivative in nature, also fail. Plaintiffs do not address this argument as they assert they have stated claims under state law.

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). In addition, punitive damages are also derivative of the substantive claims. See Knoppel v. St. Jude Medical Inc., No. SACV 13-383 JVS(ANx), 2013 WL 3803612, at *3 (C.D. Cal. May 7, 2013) ("because Plaintiffs' claims for punitive damages and loss of consortium are derivative of the preempted claims, those claims must be dismissed as well."). Here, since the Court dismisses all causes of action, the loss of consortium claim and punitive damages based on these claims also fail.

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[5]The TAC also alleges a failure to warn physicians and the general public. (Dkt. No. 45, TAC ¶¶ 51, 56.) In the prior order on Defendant's motion to dismiss, the Court concluded that failure to warn physicians and the general public based on state law are expressly preempted. (Dkt. No. 44 at 13.) The Court similarly concludes the same. See Stengel, 704 F.3d at 1234 (Watford, J., concurring) ("[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."); 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).

Conclusion

Based on the above, the Court GRANTS Defendant's motion to dismiss the third amended complaint with prejudice. The hearing set for February 24, 2017 shall be **vacated**.

IT IS SO ORDERED.

DATED: February 21, 2017

HON. GONZALO P. CURIEL
United States District Judge