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** [Dkt. No. 26.]

Before the Court is Defendant Ethicon, Inc.'s motion to dismiss pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). (Dkt. No. 26.) Plaintiffs filed an opposition, and Defendant filed a reply. (Dkt. Nos. 34, 35.) For the reasons set forth below, this Court GRANTS Defendant's motion to dismiss and GRANTS Plaintiffs' request for leave to file a second amended complaint.

Background

Plaintiffs Kimberly Weaver and James Weaver filed a form 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.) 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 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.)

Then, Plaintiffs filed a first amended complaint ("FAC") against Ethicon for negligence, strict liability, and loss of consortium. (Dkt. No. 25.) Ethicon filed a motion to dismiss arguing Plaintiffs' state law claims are expressly preempted by the Medical Device Amendment ("MDA"). Plaintiffs oppose arguing it falls under a narrow exception announced in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

Factual Background

Ethicon manufactures, designs, constructs, assembles, distributes and inspects the Sugiflo Hemostatic Matrix Kit ("Surgiflo"). (Dkt. No. 25, FAC ¶ 2.) The Surgiflo is sold to hospitals for use by surgeons during surgeries similar to the one performed on Plaintiff Kimberly Weaver. (Id. ¶ 2.)

On or about November 25, 2014, Plaintiff Kimberly Weaver underwent sinus surgery in San Diego, CA. (Id. ¶ 4.) The doctor used Surgiflo as a self-absorbing packing in her sinus area during the sinus surgery. (Id.) The purpose of the packing was to control bleeding following the surgery, to treat potential chronic nosebleeds after surgery, and to provide support to the septum after surgery. (Id.) On December 5, 2014, Kimberly had a second sinus surgery and it was determined that the Surgiflo did not self-absorb as warranted and represented by the manufacturer. (Id. ¶ 5.)

Plaintiffs allege that Ethicon negligently and carelessly designed, manufactured, constructed, assembled, inspected and sold Surgiflo making it dangerous and unsafe for its intended use. (Id. ¶ 6.) Ethicon breached its duty to Plaintiff Kimberly as the product was used as it was intended but did not reabsorb as planned. (Id. ¶ 7.) Plaintiffs contend that Surgiflo and its components were defective as to their design, manufacture and warnings causing the kit and its components to be in a dangerous and defective condition, that being the inability to reabsorb as intended, that made them

unsafe for their intended use. (Id. ¶¶ 12, 13.) Kimberly's husband, James Weaver suffered significant emotional distress from witnessing his wife's injury and suffered loss of society and comfort, and loss of consortium in the relationship. (Id. ¶10.)

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. 26, D's RJN[1], Ex. 1 at 23[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 other conventional procedures is ineffective or impractical." (Id. at 29.) On September 30, 1999, the FDA found Surgifoam safe and effective as designed, manufactured and labeled and issued an Approval Order. (Id. at 23; Dkt. No. 26, D's RJN, Ex. 2.) Since then, the application of Surgifoam has been supplemented, re-evaluated, and re-approved 28 separate times, including most recently on February 5, 2016. (Dkt. No. 26, 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. (Id., Ex. 4.) Another supplement was approved on October 2, 2009 granting Ethicon approval to market the Surgiflo Hemostatic Matrix Kit, which consists of

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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. 27.) Plaintiffs do not oppose. In ruling on a motion to dismiss pursuant to Rule 12(b)(6), a Court may consider exhibits attached to the complaint, matters subject to judicial notice, or documents necessarily relied on by the complaint whose authenticity no party questions. See Swartz v. KPMG LLP, 476 F.3d 756, 763 (9th Cir. 2007); 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."). Here, Defendant requests judicial notice of public record documents on the FDA's website. (Dkt. No. 11-1.) The Court may take judicial notice of "matters of public record." Lee, 250 F.3d at 688-89. As such, the Court GRANTS Defendant's request for judicial notice.

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

Surgiflo Hemostatic Matrix and "evithrom lyophilized human thrombin." (Id., 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. Express Preemption

Defendant argues that the state law claims fail in light of the express preemption provision provided by the MDA.[3] Plaintiffs argue that their complaint falls within the narrow exception left open in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), holding that state law claims are not preempted if they 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 establishes different levels of oversight for medical devices which is dependent on the risks they present which range from Class I devices which is subject to the lowest level of oversight to Class III involving the most oversight. Riegel, 551 U.S. at 316-17. A Class III device is subject to a rigorous pre-market approval process of the FDA. Id. 317 (citing 21 U.S.C. § 360c(a)(1)(C)). The FDA conducts a risk-benefit analysis of the medical device to determine the adequacy of the manufacturer's proposed label, and then the FDA either denies, approves or approves with conditions on the distribution, marketing or sale. Stengel, 704 F.3d at 1226.

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

[3]In addition, Defendant argues that the FAC failed to allege facts with particularity to support their causes of action and leave to amend should be denied because Plaintiffs were already afforded leave to amend and failed to remedy the deficiencies. Since the Court GRANTS Defendant's motion to dismiss with leave to amend, the Court need not address whether the FAC failed to comply with Rule 8.

> 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).

As to step one, the Court is to determine "whether the Federal Government has established requirements applicable to [Surgifoam]." Id. at 321. In this case, step one has 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. See Herron v. Smith & Nephew, Inc., 7 F. Supp. 3d 1043, 1048 (E.D. Cal. 2014) (quoting Riegel, 552 U.S. at 322-23) (PMA "imposes 'requirements' under the MDA" and they are "specific to individual devices").

As to the second step, the question is whether Plaintiffs' state law claims are based on "any requirement" of California law with respect to the device that is "different from, or in addition to" federal requirements and "relate to safety or effectiveness." Riegel, 552 U.S. at 321-22.

In Riegel, the United States Supreme Court held that common law claims of strict liability, negligence and implied warranty claims impose requirements that are different from the federal requirements. Id. at 323-24. The Court explained that common law duties are based on state law obligations that are different from the requirements under the FDA. Id. at 324.

In Riegel, the plaintiff and his wife brought claims of strict liability, negligence and breach of implied warranty under New York common law against manufacturer of catheter that ruptured in the plaintiff's coronary artery during heart surgery causing severe and permanent injuries. Id. at 320. The district court held that the MDA preempted the plaintiff's claims of strict liability, breach of implied warranty and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the catheter. Id. The court also concluded that the MDA preempted plaintiff's wife's claim for "loss of consortium to the extent it was derivative of the pre-empted claims." Id. at 321. The Second Circuit and the United States Supreme Court affirmed. Id. at 321, 330.

Here, Plaintiffs' allegations of negligence, strict liability and loss of consortium are similar to the ones brought in Riegel and concern solely the safety and effectiveness of Surgiflo. The FAC alleges that Ethicon was negligent in designing, manufacturing, constructing, assembling, inspecting and selling Surgiflo as it was dangerous and unsafe to use because it did not reabsorb as planned. (Dkt. No. 25, FAC ¶¶ 6, 7.) As to strict liability, Plaintiffs allege Surgiflo was "defective as to their design, manufacture, and warnings, causing the matrix kit and its components to be in a dangerous and defective condition that made them unsafe for their intended use." (Id. ¶ 12.) The Surgiflo was dangerous because it did not reabsorb as intended. (Id. ¶ 13.) Based on the Riegel two part inquiry, the Court concludes the state law claims in the FAC are preempted by the MDA and subject to dismissal.

However, Riegel 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." Riegel, 552 U.S. 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.") 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.; 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).

Here, the amended complaint makes no allegations concerning any violations of federal law, including violations of the FDA or any requirements related to the Surgiflo and does not allege a causal nexus between the violation and the injury.[4] Plaintiffs' citation to Bausch, 630 F.3d at 560 is unavailing. Citing to Bausch, Plaintiffs assert that they are not required to plead the specific regulatory requirements violated. However, 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,

[4]Plaintiffs also seek discovery prior to the Court's ruling on preemption citing Bausch. Bausch held that because information concerning the PMA process is confidential and not public, a complaint should not be dismissed for failing to allege specific details concerning the precise defect or the specific federal regulatory requirements under Rule 8. Bausch, 630 F.3d at 560. Here, the ruling in Bausch is not applicable as Plaintiffs have failed to allege any violation of federal regulations or requirements.

559-60. Here, Plaintiffs has not asserted any violation of a regulatory requirement or standard.

In the event the Court grants Defendant's motion to dismiss, Plaintiffs seek leave to file a second amended complaint in order to plead their parallel claims with more specificity. While Defendant argues that dismissal should be with prejudice because Plaintiffs failed to cure the deficiencies from the original complaint, dismissal on the original complaint was as to J&J, not Ethicon and the preemption defense is being raised for the first time in the instant motion. The Court does not find Defendant's argument persuasive. Accordingly, the Court GRANTS Defendant's motion to dismiss with leave to amend as it would not be futile to allow amendment. See Desoto, 957 F.2d at 658.

Conclusion

Based on the above, the Court GRANTS Defendant's motion to dismiss as the claims are preempted as plead, and GRANTS Plaintiffs' request for leave to file a second amended complaint. This shall be Plaintiffs' final opportunity to amend. A second amended complaint shall be filed within 14 days of the filing of this order. The hearing date set for August 26, 2016 shall be **vacated**.

IT IS SO ORDERED.

DATED: August 22, 2016

HON. GONZALO P. CURIEL
United States District Judge