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

Case No. CV 12-7962 PA (FFMx) Date March 25, 2013

Title Diana Simmons, et al. v. Boston Scientific Corp., et al.

Honorable
NITED STATES DISTRICT

Present:
The

Paul Songco N/A N/A Deputy Clerk Court Reporter Tape No.

Attorneys Present for Plaintiffs: Attorneys Present for Defendants:

None None

Proceedings: IN CHAMBERS - ORDER

Before the Court is a Motion to Dismiss the Third Amended Complaint filed by defendants Boston Scientific Corporation and Guidant LLC ("Defendants"). [Docket No. 49.] Plaintiffs Diana Simmons and Emmett Simmons (collectively, "Plaintiffs"), have filed an Opposition. 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. Factual & Procedural Background

On April 23, 2007, Diana Simmons received a Guidant Vitality 2 DR Implantable Cardiverter Defibrillator ("ICD") Implant, Model No. T165 (the "T165" or "Subject Device"). ICDs are medical devices that are implanted into a patient's chest to monitor heart rhythms. Should these rhythms become abnormal, the device initiates an electric shock to the heart to reinstate the heart's natural rhythm. ICDs can function as both pacemakers and defibrillators.

On May 13, 2010, the Subject Device allegedly malfunctioned and shocked Diana Simmons six times, knocking her to the ground and causing her debilitating chest pain. She was

hospitalized in intensive care for several days. There is no indication that the Subject Device has been removed.

Plaintiffs assert that two distinct problems with the Subject Device's battery charge combined to produce the malfunction experienced by Diana Simmons. Specifically, Plaintiffs assert that in April 2007, Defendants and the Food and Drug Administration ("FDA") issued a recall of the Subject Device for a "faulty capacitor" issue that would lead to premature battery depletion. (See Third Amended Complaint ("TAC") ¶¶ 22-27.) This faulty capacity issue would allegedly would create "an electrostatic field" that "stores energy . . . [w]hen there is a difference in voltage across the conductors[.]" (Id. ¶ 23.) Plaintiffs then allege that "[t]he faulty capacitor at the center of the April 10, 2007 recall was a part of the Subject Device implanted into [Diana Simmons]. The faulty capacitor was part of the same analog to digital circuit that caused a lack of tachy therapy for the Vitality generators, as noted by the FDA on February 6, 2006 following an inspection of Guidant's manufacturing facilities." (Id. ¶ 24.) Plaintiffs explain that "[t]he analog to digital latching fault . . . was compounded by the faulty capacitor noted by the FDA at the time of the April 10, 2007 recall." (Id. ¶ 25.) These two known manufacturing defects

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

Case No. CV 12-7962 PA (FFMx) Date March 25, 2013

Title Diana Simmons, et al. v. Boston Scientific Corp., et al.

combined, Plaintiffs allege, to produce the shock suffered by Diana Simmons: "In the Subject Device, the defective capacitor stored an electrical charge that would not be handled by the capacitor correctly because the electrical charge would not travel back into the Subject Device, which caused [the] inappropriate and unintended shock [to Diana Simmons]." (Id. ¶ 26.)

On May 8, 2012, Plaintiffs filed this action in Los Angeles Superior Court. Defendants, for the second time, removed the action to this Court on September 14, 2012, on the basis of diversity jurisdiction. See 28 U.S.C. § 1332. Plaintiffs filed a First Amended Complaint on September 28, 2012. In response to Defendants' Motion to Dismiss the First Amended Complaint, Plaintiffs filed a Second Amended Complaint ("SAC") on November 5, 2012. Plaintiffs' SAC alleged the following five causes

of action against Defendants: (1) strict liability (manufacturing defect); (2) strict liability (failure to warn); (3) negligence per se; (4) strict liability (design defect); and (5) loss of consortium.

On January 14, 2013, the Court granted Defendants' motion to dismiss the SAC, finding that each of Plaintiffs' claims was preempted by the Medical Device Amendments, 21 U.S.C. §§ 360c et seq., to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. The Court thus dismissed with prejudice Plaintiffs' negligence per se claim, and dismissed with leave to amend the remainder of Plaintiffs' claims. The Court also ruled that because "publicly-noticeable documents submitted by both Plaintiffs and Defendants demonstrate that the Subject Device was not subject to a recall[,]" Plaintiffs' manufacturing defect and failure to warn claims were dismissed with prejudice to the extent they relied on allegations regarding recalls of Defendants' other devices that took place in February 2006 and April 2007. (See Order of January 14, 2013, at *6). Finally, the Court also dismissed with [prejudice Plaintiffs' design defect claim "to the extent this claim is not premised on a violation of mandatory federal regulations." (Id. at * 6.)

Plaintiff filed the TAC on February 5, 2013. Defendants now move to dismiss the TAC for failure to state a claim. Having considered the parties' submissions, and for the reasons that follow, the Court grants Defendants' Motion.

II. Legal Standard: Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) allows for dismissal of a complaint for "failure to state a claim upon which relief can be granted." In order to survive a Rule 12(b)(6) motion, typically a complaint need only give "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "All allegations of material fact are taken as true and construed in the light most favorable to the plaintiff." In re Stac Elecs. Sec. Litig., 89 F.3d 1399, 1403 (9th Cir. 1996) (quoting In re Wells Fargo Sec. Litig., 12 F.3d 922, 925 (9th Cir. 1993)). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Id. (citations omitted).

III. Analysis

A. Federal Preemption Under the Medical Device Amendments of 1976 and Riegel v. Medtronic, Inc.

Defendants first contend that Plaintiffs' state-law claims are 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. The MDA includes an express preemption provision that provides, with an exception not applicable here, that,

> 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. For a state law cause of action to be preempted, there must be "(1) a federal requirement imposed on the device under the FDCA, and (2) the challenged state or local rule must impose a requirement that is different from, or adds additional obligations to, the federal requirement." Degelmann v. Advanced Med. Optics Inc., 659 F.3d 835, 841 (9th Cir. 2011) (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 321-22, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)).

The Subject Device is classified as a Class III device by the Food and Drug Administration ("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. The Subject Device was approved by the FDA on March 8, 2004, as part of a supplemental pre-market approval ("PMA") application submitted by

Defendants. The supplemental PMA was based in part on a July 18, 1997 PMA for Defendants' VENTAK AV AICD System.

The PMA process is the most rigorous review imposed by the FDA and is imposed on Class III devices. The Supreme Court in Riegel, 552 U.S. at 322-23, determined that the PMA process "imposes 'requirements' under the MDA." 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)).

The Riegel Court determined that reference to a state's "requirements" includes the state's common-law legal duties. 552 U.S. at 324-25 ("State tort law ... disrupts the federal scheme no less than state regulatory law to the same effect."). Thus, following the Riegel decision, courts have applied section 360k(a) preemption provision broadly to preempt state claims such as strict products liability, negligence, negligence per se, manufacturing and design defect, breach of warranty, and failure to warn. See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litis., 592 F. Supp.2d 1147, 1152 (D. Minn. 2009), aff'd, 623 F.3d 1200 (8th Cir. 2010).

Whether Plaintiffs' claims are preempted in this case turn on whether their claims would impose a requirement different from or additional to requirements imposed by the FDCA/MDA. As explained by the Supreme Court, "§ 360k 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 (citation omitted). Accordingly, § 360k preempts a state-law claim where plaintiffs seek to enforce state-law requirements that would require a defendant to give warnings to patients or physicians different from or broader than those required by FDA regulations. See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d

1200, 1203 (8th Cir. 2010). However, as recently explained by the Ninth Circuit, where a state law failure to warn claim is premised on a defendant's failure to report to the FDA relevant adverse health consequences of its Class III device of which it became aware after obtaining PMA, such a claim would not be preempted, because FDA regulations *require* (rather than allow) recipients of PMA to file an adverse event report with the FDA if they learn of information "reasonably suggest[ing]" that one of its devices "[m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a); see Stengel v. Medtronic, Inc., 2013 U.S. App. LEXIS 621, at *24-25 (9th Cir. January 10, 2013).

The Court now addresses each of Plaintiffs' remaining claims in turn.

1. Count 1: Strict Liability – Manufacturing Defect

Plaintiffs first allege a strict liability claim for manufacturing defect under California law. Plaintiffs' claim now appears to be based solely on a violation of the Subject Device's PMA (rather than additionally on a violation of the FDCA's Current Good Manufacturing Practices ("CGMPs")).

Specifically, Plaintiffs allege that "the loss of tachy therapy and the faulty capacitor, which lead to the unintended shock in Plaintiff Diana Simmons's device on May 13, 2010, violated the Subject Device's [PMA] because it served no therapeutic benefit in the treatment of life-threatening ventricular arrhythmias." (TAC ¶ 39.) Such an allegation is, without more, insufficient to overcome § 360k preemption. In order to state a "parallel" claim successfully, Plaintiffs must do more than baldly assert that the device violated federal standards. Rather, "Plaintiff must provide some allegations regarding the nature of the alleged . . . defect as it relates to the FDA approval process." Heisner v. Genzyme Corp., 2008 U.S. Dist. LEXIS 60569, at *18 (N.D. Ill. July 25, 2008). Moreover, a plaintiff "cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption." Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011). Rather, a plaintiff must allege that the defendant "violated a particular federal specification referring to the device at issue," Ilarraza v.

Medtronic, Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009), or identify specific PMA requirements that have been violated. 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).

The TAC fails to meet this pleading standard. First, Plaintiffs' TAC – like the SAC – fails even to state what PMA specifications were imposed on the Subject Device, let alone which specifications the Subject Device failed to satisfy. The TAC discusses, as did the SAC, recalls of and FDA advisories regarding Defendants' other defibrillator models. But, as Defendants point out, none of those recalls or advisories involved Diana Simmons' T165. Moreover, as the Court explained in its prior Order, even if those recalls or advisories *had* involved the T165, the TAC would be found wanting. 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, e.g., Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1056, 70 Cal. Rptr. 3d 566 (2008) ("The fact that the FDA implemented a Class I recall of the [medical device] does not alter our conclusion [that plaintiff's claims are premempted]."); In re Medtronic, 592 F. Supp. 2d at 1155-56 (dismissing all claims as preempted despite the devices at issue being subject to FDA recall).

Accordingly, the Court dismisses Plaintiffs' claim for manufacturing defect.

2. Count 2: Strict Liability – Failure to Warn

In support of their state law failure to warn claim, Plaintiffs allege that Defendants "failed to adequately warn of the potential risks and side effects of employing th[e] [Subject Device]." (TAC ¶ 49.) Plaintiffs further allege that "Defendants' failure to warn included but was not limited to its failure to report adverse events to the FDA, and its failure to present accurate and truthful research regarding the extent of the problem over all 73,000 devices that were originally recalled, its failure to adequately inform the hospital where Plaintiff Diana Simmons had the device implanted 13 days after the [April 2007] recall, and failing to report adverse events to the FDA, including Plaintiff's May 13, 2010 incident even after Defendants were served with a lawsuit in this matter." (Id. ¶ 51.)

This allegation is identical to that contained in the SAC, which the Court determined was insifficient. Again, the Court notes that the April 2007 recall did not implicate the Subject Device, and thus Plaintiffs' claim in that regard is without merit.

Moreover, as discussed in the Court's Order of January 14, 2013, Defendants did have an obligation under federal law to file an adverse event report with the FDA if they learned of information

"reasonably suggest[ing]" that one of its devices "[m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a); see Stengel, 2013 U.S. App. LEXIS 621, at *24-25. However, Plaintiffs again provide no factual allegations sufficient to render plausible their claim that Defendants violated this federal obligation. Rather, the TAC merely baldly asserts that Defendants failed to report adverse events related to electric shocks to persons implanted with the Subject Device. (See id..) Such unsupported allegations, without more, are insufficient state a claim under Twombly. Cf. Stengel, 2013

U.S. App. LEXIS 621, at *6 (allowing possibility for such a claim where the FDA discovered in its inspections of the defendant-manufacturer's facility that the manufacturer had become aware of certain risks associated with the device at issue without alerting the FDA). Moreover, the bare allegation that Defendants did not report the malfunctioning of Diana Simmons' device to the FDA does not support an inference that Defendants violated their federal obligations prior to that time, and, finally, a failure to notify the FDA of Diana Simmons' injury could have no causal relationship to the injury she suffered.[1/] Thus, Plaintiffs fail to state a claim for failure to warn under this theory as well.

The Court thus dismisses this claim.

4. Count 3: Strict Liability – Design Defect

Plaintiffs next assert a claim for design defect against Defendants. Plaintiffs' allegations in the TAC are identical to those of the SAC that the Court found deficient. Accordingly, the Court dismisses this claim for the reasons set forth in detail in the Court's Order of January 14, 2013.

5. Count 5: Loss of Consortium

Plaintiffs' claim for loss of consortium is derivative of their other claims. See Tucker v. CBS Radio Stations, Inc., 194 Cal. App. 4th 1246, 1256, 124 Cal. Rptr. 3d 245 (2011). As such, the Court also dismisses this claim.

Conclusio
n

For all of the foregoing reasons, the Court grants Defendants' Motion to Dismiss the TAC.

Ordinarily, courts will dismiss a claim with leave to amend. However, "[i]t is not an abuse of discretion to deny leave to amend when any proposed amendment would be futile." Reddy v. Litton Industries, Inc., 912 F.2d 291, 296 (9th Cir. 1990). "Although leave to amend should be liberally granted, the amended complaint may only allege 'other facts consistent with the challenged pleading.'" Id. at 297 (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986).

The Court has given Plaintiffs numerous opportunities to state a claim. Nonetheless, Plaintiffs have – over the course of three complaints – failed to provide factual allegations sufficient to state any viable claims for relief. The Court thus determines that granting Plaintiffs leave to file a fourth complaint would be futile.

Accordingly, the Court dismisses this action with prejudice.

[1/] Defendants dispute this allegation, claiming that after the filing of the Complaint they did report to the FDA the adverse event experienced by Diana Simmons.

IT IS SO
ORDERED.