IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

GLORIA RHYNES, Individually and on behalf of the general public, and DARRELL JENKINS, Plaintiffs, v. STRYKER CORPORATION; STRYKER ORTHOPEDICS; AND DOES 1 through 30, inclusive, Defendants.	Case No. 10-5619 SC ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

I. INTRODUCTION

This matter comes before the Court on a Motion to Dismiss Plaintiffs' First Amended Complaint ("FAC") filed by Defendants Stryker Corporation and Howmedica Osteonics Corporation, sued herein under the name Stryker Orthopedics, (collectively, "Defendants") against Plaintiffs Gloria Rhynes ("Rhynes") and Darrell Jenkins ("Jenkins") (collectively, "Plaintiffs"). ECF No. 29 ("Mot."). The Motion is fully briefed. ECF Nos. 30 ("Opp'n"), 31 ("Reply"). For the reasons set forth below, the Court GRANTS Defendants' Motion and DISMISSES the FAC with leave to amend.

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II. BACKGROUND

Plaintiffs commenced this action in the Superior Court of California, County of San Francisco, on September 30, 2010. ECF No. 1 ("Not. Of Removal") Ex. A ("Compl."). Plaintiff Rhynes asserted four claims against Defendants arising from an allegedly defective artificial hip prosthesis[1] that she received during a hip replacement surgery on August 15, 2005: negligence, strict liability for defective product, violation of California's Unfair Competition Law ("UCL"), and wanton and reckless misconduct. Id. Plaintiff Jenkins asserted a derivative claim for loss of consortium. Id.

The Court granted Defendants' initial Motions to Dismiss and Strike Plaintiffs' Complaint on May 31, 2011. ECF No. 26 ("May 31, 2011 Order"). The Court dismissed Rhynes' claims for negligence and strict liability for two reasons. First, the Court held that Rhynes had failed to include sufficient well-pleaded factual allegations to state a claim because she had not explained how the allegedly defective implant injured her. Second, the Court held that Rhynes' attempt to avoid the statute of limitations for her claims by invoking the "discovery rule" failed because she had not adequately pled sufficient facts as to how she discovered the injury and why she could not have discovered it sooner. The Court granted Rhynes leave to amend these two claims.

The Court also dismissed Rhynes' UCL claim without leave to

[1] The prosthesis was approved by the U.S. Food and Drug Administration ("FDA") as a Class III medical device, the class of devices that "is purported or represented to be 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).

amend because it sought equitable relief where Plaintiffs had an adequate remedy at law. The Court dismissed Plaintiffs' claim for wanton and reckless misconduct with leave to amend. Lastly, the Court struck all strict liability design defect allegations from the Complaint under Hufft v. Horowitz, 4 Cal. App. 4th 8, 19-20 (Ct. App. 1992) (manufacturers of prescription implanted medical devices are not subject to strict liability for design defects).

On June 23, 2011, Plaintiffs filed a FAC in which Rhynes reasserted her claims for strict liability, negligence, and wanton misconduct, and Jenkins reasserted his claim for loss of consortium. ECF No. 27 ("FAC") ¶¶ 6-26. With respect to how Rhynes was injured, the FAC alleges Rhynes underwent surgery on August 15, 2005, at which time she was implanted with a Trident acetabular shell hip prosthesis ("the device"). Id. ¶ 5. The FAC explains that the device was defective because manufacturing discrepancies caused the loosening of the acetabular shell, causing "considerable inflammation and wear in the adjoining bone and joint including fragments from the component invading the nearby tissue and bone impairing [Rhynes'] mobility, causing intense pain and injury." Id.

With respect to the discovery rule, the FAC alleges Rhynes was unaware of the injury from the defect until February 2009, when surgery revealed the defective product. Id. Rhynes was allegedly unable to discover the defect earlier because "she was only able to discover the defective product by undergoing a serious and invasive surgery which she undertook at the time prescribed by her treating physicians and after other treatments failed." Id.

The FAC also includes allegations regarding defects discovered

by the FDA. Specifically, Plaintiffs allege that, prior to the surgery in which Rhynes was implanted with the device, the FDA conducted an investigation and advised Defendants in two separate warning letters that they had failed to conform to proper manufacturing and quality control standards. Id. ¶¶ 18d, 20. Plaintiffs also allege that, in spite of these warnings, Defendants failed to warn Rhynes of the possible defects in the device and the possible harms that it could cause. Id.

In their Motion, Defendants argue that (1) Plaintiffs' claims are time-barred because Plaintiffs have again failed to properly plead application of the discovery rule, and (2) Plaintiffs' claims are preempted by the Medical Device Amendments ("MDA"), 21 U.S.C. 360c et seq., to the Food, Drug and Cosmetics Act ("FDCA").

III. LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "tests the legal sufficiency of a claim." Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009). However, "the tenet that a court must accept as true all of the allegations contained in a [claim] is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory

statements, do not suffice." Id. (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). The allegations made in a complaint or counterclaim must be both "sufficiently detailed to give fair notice to the opposing party of the nature of the claim so that the party may effectively defend against it" and "sufficiently plausible" such that "it is not unfair to require the opposing party to be subjected to the expense of discovery." Starr v. Baca, 633 F.3d 1191, 1204 (9th Cir. 2011).

IV. DISCUSSION

A. Discovery Rule

Defendants contend that Plaintiffs' claims are barred by the applicable statute of limitations because they were not brought within two years of the date on which Rhynes was allegedly injured.[2] Mot. at 9. Defendants further argue that the "discovery rule" does not save Plaintiffs' time barred claims. Id.

California's discovery rule delays the accrual of a cause of action until a plaintiff either became aware of the injury and its cause or could have discovered the injury and cause through reasonable diligence. Fox v. Ethicon Endo-Surgery, Inc., 35 Cal. 4th 797, 808 (2005). In order to rely on the discovery rule, "[a] plaintiff whose complaint shows on its face that his claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." Id. (internal quotation omitted). Under the discovery

[2] The California Code of Civil Procedure provides that the applicable statute of limitations for a personal injury action is two years. Cal. Civ. Proc. Code § 335.1.

rule, the statute of limitations begins to run "when the plaintiff suspects or should suspect that her injury was caused by wrongdoing." Jolly v. Eli Lilly & Co., 44 Cal. 3d 1103, 1110 (Cal. 1988).[3] "A plaintiff need not be aware of the specific 'facts' necessary to establish the claim." Id. at 1111. "In assessing the sufficiency of the allegations of delayed discovery, the court places the burden on the plaintiff to show diligence; conclusory allegations will not withstand demurrer." Fox, 35 Cal. 4th at 808. (internal quotations omitted).

The Court finds that Plaintiffs have alleged sufficient facts to invoke the discovery rule. Plaintiffs pled that Rhynes did not discover the allegedly defective device until 2009 when she underwent surgery. See FAC ¶ 5. Plaintiffs also pled that Rhynes could not have learned of Defendants' wrongdoing any earlier because Rhynes "was only able to discover the defective product by undergoing a serious and invasive surgery which she undertook at the time prescribed by her treating physicians and after other treatments failed." Id.

Defendants contend that Plaintiffs' allegations are insufficient, arguing that Rhynes should have suspected wrongdoing when she experienced "intense physical pain" after the acetabular shell allegedly loosened in August 2005. Id. at 10 (citing FAC ¶ 5). However, nothing in the FAC suggests that Rhynes suspected or should have suspected that her pain was due to a defect in the device. Rhynes could have reasonably attributed her pain to a number of other factors, including side effects of the operation or a difficult recuperation. "The mere fact that an operation does

[3] See also Rivas v. Safety-Kleen Corp., 98 Cal. App. 4th, 218, 228 (Ct. App. 2002).

not produce hoped-for results does not signify negligence and will not cause commencement of the statutory period." Kitzig v. Nordquist, 81 Cal. App. 4th 1384, 1392 (Ct. App. 2000) (quoting Bristol-Myers Squibb Co. v. Super. Ct., 32 Cal. App. 4th 959, 964 (Ct. App. 1995)). The authority relied on by Defendants does not support their contention that pain alone should have caused Rhynes to suspect wrongdoing.[4]

Defendants also argue that Plaintiffs have not pled sufficient facts to establish that Rhynes was unable to discover the wrongdoing until her 2009 surgery. Mot. at 11-12. The Court disagrees. Plaintiffs pled that, despite engaging in other medical treatments recommended by her physicians, Rhynes was unable to discover the device was defective until she underwent "serious and invasive surgery." See FAC ¶ 5. "A plaintiff is not required to discover the negligent cause of her injuries at all costs to her own health and welfare. Rather, the plaintiff is only required to take all reasonable steps to protect her health." Hills v. Aronsohn, 152 Cal. App. 3d 753, 760 (Ct. App. 1984). The FAC alleges that Rhynes took reasonable steps to address the pain resulting from her 2005 procedure and those steps did not give rise to suspicion that the pain was caused by the allegedly defective device.

[4] See Jolly, 44 Cal. 3d at 1107-08 (claims were time-barred because plaintiff was aware that the defective product caused her injuries as early as 1972, but delayed filing her action until 1981 because she did not know the identity of its manufacturer); Knowles v. Super. Ct., 118 Cal. App. 4th 1290, 1298 (Ct. App. 2004) (claims time-barred because plaintiffs admitted that they suspected medical negligence shortly after their parent's death); Rivas, 98 Cal. App. 4th at 228-29 (claims time-barred because, seven years before plaintiff filed suit, he was diagnosed with kidney failure and told to stay away from the defective product, a solvent he was using at work).

The Court finds that the FAC alleges sufficient facts to invoke the discovery rule. Accordingly, the Court declines to dismiss Plaintiffs' claims as time-barred.

B. MDA Preemption

Defendants argue that Plaintiffs' entire action is barred by the preemption clause of the MDA, 21 U.S.C. § 360c et seq. Under the MDA:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this Act 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 Act.

21 U.S.C. § 360k(a). In Riegel v. Medtronic, Inc., 552 U.S. 312, 324-25 (2008), the Supreme Court held that this provision barred state law tort claims challenging the safety and effectiveness of a catheter that received FDA premarket approval. The Supreme Court reasoned, "[s]tate tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." Id. at 325.

The Supreme Court also noted that the MDA only preempts state laws to the extent that they are "different from, or in addition to" the requirements of federal law. Id. at 330. Accordingly, the statute does not bar states from "providing a damages remedy for claims premised on a violation of FDA regulations" since "state

duties in such cases 'parallel' rather than add to federal requirements." Id.

Defendants point out that at least fourteen district courts have dismissed actions brought against Defendants' hip replacement system based on the Supreme Court's holding in Riegel.[5] Mot. at 6. Defendants also cite to at least another thirteen cases in which courts applied Riegel in dismissing actions involving a number of other FDA approved Class III devices.[6] Id. at 7 n.6. Defendants contend that the instant action is also preempted by the MDA, as the device was approved by the FDA and Plaintiffs' claims are

[5] See Funk v. Stryker, 631 F.3d 777 (5th Cir. 2011), affirming Funk v. Stryker, 673 F. Supp. 2d 522 (S.D. Tex. 2009); Wilhite v. Howmedica Osteonics Corp., 10cv2471, 2011 WL 2530984 (N.D. Ohio June 20, 2011); White v. Stryker, 10–CV–544–H, 2011 WL 1131496 (W.D. Ky. Mar. 25, 2011);; Cornwell v. Stryker Corp., 10-cv-00066-EJL, 2010 WL 4641112 (D. Idaho, Nov. 1, 2010); Bass v. Stryker, 09–CV–632–Y, 2010 WL 3431637 (N.D. Tex. Aug. 31, 2010); Lewkut v. Stryker Corp., 724 F. Supp. 2d 648 (S.D. Tex. 2010); Anthony v. Stryker Corp., 09–cv–2343, 2010 WL 1387790 (N.D. Ohio March 31, 2010); Yost v. Stryker, 09-cv-28-FtM-29DNF, 2010 WL 1141586 (M.D. Fla. March 23, 2010); Lemelle v. Stryker Orthopaedics, 698 F.Supp.2d 668 (W.D. La. 2010); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271 (E.D.N.Y. 2009); Hayes v. Howmedica Osteonics Corp., 08-6104, 2009 WL 6841859 (D. N.J. Dec. 15, 2009); Covert v. Stryker Corp., 08CV447, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009) (decision recommending dismissal); Delaney v. Stryker Orthopaedics, 08-03210 (DMC), 2009 WL 564243 (D.N.J. Mar. 5, 2009); Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D. Colo. 2008).

[6] See Nimtz v. Cepin, 08cv1294 L(AJB), 2011 WL 831182 (S.D. Cal. Mar. 3, 2011); Cohen v. Guidant, CV-05-8070-R, 2011 WL 637472 (C.D. Cal. Feb. 15, 2011); Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011) (affirming district court's dismissal, 2009 WL 2190069 (M.D. Fla. July 22, 2009)); Steen v. Medtronic, Inc., 10-CV-936-L, 2010 WL 2573455 (N.D. Tex. June 25, 2010); Heisner v. Genzyme Corp., 08-C-593, 2010 WL 894054 (N.D. Ill. Mar. 8, 2010); Hughes v. Boston Scientific Corp., 08cv79KS-MTP, 2009 WL 3817586 (S.D. Miss. Nov. 12, 2009); Williams v. Allergan USA, Inc., CV–09–1160–PHX–GMS, 2009 WL 3294873 (D. Ariz. Oct. 14, 2009); Heisner v. Genzyme Corp., 08-C-593, 2009 WL 1210633 (N.D. Ill. Apr. 30, 2009); Dorsey v. Allergan, Inc., 08–0731, 2009 WL 703290 (M.D. Tenn. Mar. 11, 2009); In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009); Link v. Zimmer Holdings, Inc., 604 F. Supp. 2d 1174 (N.D. Ill. 2008); Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090 (D. Minn. 2008); Adkins v. Cytyc Corp., 07CV00053, 2008 WL 2680474 (W.D. Va. Jul. 3, 2008).

predicated on state law tort duties which constitute regulations that are "different from, or in addition to" established federal regulations. Id. at 7-8.

Plaintiffs respond that their claims are not preempted by the MDA because, unlike the cases cited by Defendants, Plaintiffs' claims impose "requirements that are parallel with, not in addition to, federal requirements." Opp'n at 2. Plaintiffs rely in part on Bausch v. Stryker Corp., 630 F.3d 546 (7th cir. 2010), where the Seventh Circuit reversed the district court's dismissal of state law tort claims involving an FDA approved Class III device. The court found that the plaintiff's claims were not preempted because the plaintiff alleged that "the FDA found that the defendants failed to comply with [21 C.F.R.] section 820.90 regarding nonconforming products, and that the product implanted in [the plaintiff] failed to comply with product specifications as approved by the FDA through the pre-market approval process." Id. at 556. Plaintiffs also point to Warren v. Howmedica Osteonics Corp., 10 CV 1346 DDN, 2011 WL 1226975 (E.D. Mo. Mar. 29, 2011). In that case, the plaintiffs' claims survived a motion to dismiss where they alleged "that defendants failed to manufacture the Trident System in conformity with the FDA's [pre-market approval application] specifications, which resulted in a defective device whose manufacture and design were not approved by the FDA." Id. at *4.

Further, Plaintiffs argue their case is distinguishable from cases cited by Defendants such as Funk, 631 F.3d at 782, where tort law claims were dismissed because the plaintiffs' allegations of FDA violations were impermissibly conclusory and vague. Opp'n at 5. In Funk, the Fifth Circuit affirmed dismissal because the

complaint relied on res ipsa loquitur and did not explain "how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." 631 F.3d at 782.

The Court finds that Plaintiffs' claims are preempted by the MDA because Plaintiffs have failed to allege violations of state law duties that parallel federal requirements. Under Reigel, a plaintiff may avoid preemption by stating a claim premised on a violation of FDA regulations. 552 U.S. at 330. In the cases cited by Plaintiff where state law tort claims survived MDA preemption, the plaintiffs alleged that the device at issue violated specific FDA regulations. See Bausch, 630 F.3d at 556; Warren, 2011 WL 1226975, at *4. In the instant action, Plaintiffs allege that the FDA warned Defendants about "bad manufacturing and quality control practices." FAC ¶ 20. However, Plaintiffs do not allege what FDA requirements were violated, much less how Defendants' manufacturing process deviated from those particular requirements. Plaintiffs' claims are closer to those rejected in Funk than those found to be sufficient in Bausch and Warren.[7]

Accordingly, the Court GRANTS Defendants' Motion to Dismiss. The Court grants Plaintiffs leave to amend because they have indicated they are prepared to set forth more specific allegations regarding Defendants' violations of particular FDA requirements. See Opp'n at 6. Additionally, although the Court has already granted leave to amend once, Defendants did not raise their MDA preemption arguments in the last round of pleading.

[7] Defendants argue that Bausch and Warren are not controlling since they ignore the Rule 8 pleading requirements set forth in Iqbal and Twombly. Reply at 5-6. The Court need not presently address this issue as it finds that, even under Bausch and Warren, Plaintiffs' allegations are inadequate.

V. CONCLUSION

The Court GRANTS Defendants Stryker Corporation and Howmedica Osteonics Corporation's Motion to Dismiss and DISMISSES Plaintiffs Gloria Rhynes and Darrell Jenkins' First Amended Complaint WITH LEAVE TO AMEND. If Plaintiffs choose to file an amended complaint, it shall be filed within thirty (30) days of this Order. Failure to do so will result in dismissal of the action with prejudice.

IT IS SO ORDERED.

Dated: October 27, 2011

UNITED STATES DISTRICT JUDGE