NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEBORAH A. BECKER and RAYMOND BECKER, her husband, Plaintiffs, v. SMITH & NEPHEW, INC., ABC CORP. 1-X, JOHN DOE I-X, AND JANE DOE 1-X (said names being fictitious and unknown), Defendants.	**OPINION** Civ. No. 15-2538 (WHW)(CLW)

Walls, Senior District Judge

Plaintiffs Deborah Becker and Raymond Becker bring this products liability case, involving a hip implant, against Defendant Smith & Nephew, Inc. Defendant now moves to dismiss under Fed. R. Civ. P. 12(b)(6), arguing that the Medical Device Amendments of 1976 preempt Plaintiffs' claims, and that the complaint lacks the specificity required by federal pleading standards. Decided without oral argument under Fed. R. Civ. P. 78, Defendant's motion is granted. The complaint is dismissed without prejudice, and Plaintiffs are granted 90 days to file an amended complaint.

BACKGROUND

Plaintiffs filed a complaint in New Jersey Superior Court on May 20, 2014, which Defendant removed to this Court on August 29, 2014. *See* 2:14-cv-05452-WHW-CLW, ECF No. 1-1. On Defendant's motion, the Court dismissed the complaint without prejudice. *Id.* ECF Nos.

10-11. On April 9, 2015, Plaintiffs filed an amended complaint with the new docket number and caption listed above. ECF No. 1.

For purposes of this motion, the Court assumes the truth of the complaint's factual allegations. On August 16, 2007, Plaintiff Deborah Becker underwent total hip replacement surgery, during which her doctor inserted an implant in her left hip. Compl. ¶ 14. Defendant Smith & Nephew, Inc. manufactured, designed and sold all the components of the implant, which the complaint refers to as the "Acetabular System." *Id.* ¶¶ 15, 20. The "Acetabular System is a cobalt-chromium metal on metal implant that has been shown to release ions into the body." *Id.* ¶ 20. "Chromium and cobalt ions are carcinogens linked to blood poisoning and genotoxicity." *Id.* "The deterioration of bone and muscle around the implant can lead to loosening and device failure." *Id.* These complications may lead to metallosis, a condition that has afflicted patients who received the implant. *Id.* ¶¶ 20-21.

Defendant recalled the Acetabular System on or about June 2012. *Id.* ¶ 18. After the recall, Defendant sent out "hazard alert" letters to doctors who had implanted the system's metal liners, warning of reports of "infection, dislocation, metal sensitivity, loosening/lysis and fracture." *Id.* ¶ 19. Deborah Becker "suffered metallosis as a result of the Smith & Nephew Acetabular System implant," showing high levels of cobalt and chromium toxicity in her system. *Id.* ¶¶ 22, 24. She underwent surgery to remove the implant on September 6, 2013. *Id.* ¶ 25. She endured painful physical therapy after her discharge. *Id.* ¶ 26. By May 2014, her cobalt and chromium levels had decreased significantly. *Id.*, Ex. B.

The complaint lists five causes of action, which the Court interprets as sounding in strict liability in tort, breach of express warranty, violation of the New Jersey Consumer Fraud Act, and loss of consortium (on behalf of Deborah Becker's husband Raymond Becker), along with a

request for punitive damages. *See* Compl. Defendant moved to dismiss on May 13, 2015, arguing that Plaintiffs' causes of action are either preempted under the Medical Device Amendments or otherwise inadequately pled. ECF No. 5.

Attached to its motion, Defendant submits a notice from the U.S. Food and Drug Administration ("FDA") dated May 9, 2006, granting premarket approval for the Birmingham Hip Resurfacing ("BHR") System. Ex. A to Def.'s Mot. Plaintiffs do not contest that this is the device that was implanted into Deborah Becker; the interoperative record attached to the complaint confirms the device's identity. *See* Compl. Ex. A 3.

STANDARD OF REVIEW

A pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face "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.* "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Id.* (internal quotations and alterations omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—that the pleader is entitled to relief." *Id.* at 679.

DISCUSSION

I. Plaintiffs' Strict Liability Claim is Preempted under the Medical Device Amendments

a. The Product in Question Received Premarket Approval from the FDA

The Medical Devices Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Federal Food, Drug & Cosmetics Act, 21 U.S.C. § 301 *et seq.*, authorize the FDA to regulate the safety and effectiveness of medical devices. Under the MDA, medical devices are divided into three categories according to the risks that the devices present. Class III devices, which includes the device in this case, are those that are either too unproven to be rendered safe by general controls or that present a potential for unreasonable risk of illness or injury. 21 U.S.C. § 360(a)(1)(C). The MDA usually requires Class III devices to receive premarket approval ("PMA") before the FDA allows them to be sold. The FDA approves a device for distribution only if it is satisfied that the device is reasonably safe and effective for its intended purpose. 21 U.S.C. § 360(e)(d)(2).

This Court takes judicial notice of the FDA's website, and holds that it establishes premarket approval of the BHR Acetabular Cup. *See* http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040033A.pdf.

b. Absent Factual Allegations that Defendant's Product Deviated from FDA-Approved Design and Manufacturing Processes, the MDA Preempts Plaintiffs' Strict Liability Claim

The MDA contains the following preemption provision:

> 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. § 360(k)(a).

In *Riegel v. Medtronic,* the Supreme Court held that state laws are preempted by the MDA if: (1) the Federal Government has established "specific requirements applicable to a particular device," and (2) the plaintiff's claims are based on "state requirements" related to safety and effectiveness that are "different from, or in addition to" the federal requirements. 552 U.S. 312, 315 (2008) (citing 21 U.S.C. § 360c). The Supreme Court reasoned that a state law demanding a manufacturer's devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Id.* at 325. Included in the meaning of "state requirements" are common law causes of action, such as negligence, strict liability, and breach of implied warranty. *Id.* at 324–25, 327–28; *see also Smith v. Depuy Orthopaedics Inc.*, 552 F. App'x 192, 194 (3d Cir. 2014) (upholding finding of MDA preemption of New Jersey Products Liability Act claims).

State requirements are pre-empted under the MDA "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (citing § 360k(a)(1)). "Thus, § 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." *Id.* Such claims must be pled with particularity. *See Desai v. Sorin CRM USA, Inc.*, No. CIV. 12-2995, 2013 WL 163298, at *7 (D.N.J. Jan. 15, 2013) (citing cases).

Count I of Plaintiffs' complaint advances "[g]eneralized common law theories of liability"—in other words, "precisely the type of claims the MDA sought to preempt." *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010). "Success on [strict liability] claims would require them to show that the . . . device was unsafe or ineffective despite the PMA

process, thereby interfering with the requirements already established by the MDA, which has preempted safety and effectiveness determinations for a device." *Id.* No allegation in the complaint specifies how Defendant's product deviated from FDA-approved design and manufacturing processes. It follows that Plaintiffs' "allegations of strict products liability . . . are pre-empted by the MDA." *See Williams*, 388 F. App'x at 171.

Plaintiffs contend that they should be permitted to allege unspecified deviations from FDA requirements at the pleading stage, and fill in the blanks through discovery. Pl.'s Br. 8. But a plaintiff must successfully plead a claim before obtaining discovery, not the other way around. Such a premature request for discovery conflicts with Rules 8 and 11(b) of the Federal Rules of Civil Procedure. *See Desai*, 2013 WL 163298 at *7; *see also Hayes v. Howmedica Osteonics Corp.*, Civ. No. 08–6104, 2009 WL 6841859 (D.N.J. Dec.15, 2009) (dismissing a strict liability claim involving a hip prosthesis under *Twombly*, which "[does] not distinguish between and among different types of cases. It would be wrong for this Court to rule that this plaintiff because of her particular injury and theory of harm has a right to support [her claim] through discovery as opposed [to] allegations in the complaint"). As the Third Circuit recognized, "many PMA preemption motions are decided without any discovery." *Smith*, 552 F. App'x at 196. Plaintiffs' first cause of action for strict liability is dismissed.

II. Plaintiffs' Express Warranty Claim Is Insufficiently Pled

To succeed on a claim for breach of express warranty, a plaintiff must show: (1) that a defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description. *See* N.J. Stat. Ann. § 12A:2–313.

A cause of action for breach of express warranty may or may not be preempted under the MDA.[1] If a claim is "based on the information contained in FDA approved product labels and packaging inserts," it is barred. *See Cornett v. Johnson & Johnson*, 211 N.J. 362, 392 (2012). To avoid preemption, the plaintiff must show that the defendant-manufacturer made "voluntary statements" that were "not approved by the FDA or mandated by the FDA about the use or effectiveness" of a medical device. *Id.*; *see also Horn v. Thoratec Corp.*, 376 F.3d 163, 168 n.7 (3d Cir. 2004).

Count IIII of the complaint asserts that Defendant "represented that the Acetabular System was safe and effective for use by individuals such as Plaintiff." Compl. ¶ 51. It recites that these "affirmations of fact or promises made by the seller to the buyer . . . became part of the basis of the bargain," *id.* ¶ 52, and that the "Product did not conform to the representations made by Defendant in that the Product was not safe and effective for use by individuals such as Plaintiff." *Id.* ¶ 53. It alleges in boilerplate fashion that "breach of warranty was a substantial factor in bringing about Plaintiff's injuries and damages." *Id.* ¶ 56.

Count III asserts no supporting facts. The content of any such "warranty" is not given. Who said what to whom, where, when, and how, is unknown. There is no factual allegation in the complaint that Defendant ever made any identifiable, voluntary, unapproved statement to Deborah Becker or her physician regarding the safety, effectiveness or proper applications of the implant. In short, this is "a formulaic recitation of the elements of a cause of action," which *Twombly* tells us "will not do." 550 U.S. at 556; *see also Clements v. Sanofi-Aventis, U.S., Inc.*, No. 14-CV-1423 KM, 2015 WL 3648911, at *11 (D.N.J. June 11, 2015) (finding same).

[1] Unlike claims for breach of implied warranty, a claim for breach of express warranty is not subsumed by the New Jersey Products Liability Act ("PLA," N.J.S.A. § 2A:58C–1 *et seq.*). *See* N.J.S.A. § 2A:58C–1b(3).

Plaintiffs' cause of action for breach of express warranty is dismissed.

III. Plaintiffs' Consumer Fraud Claim Is Barred Under New Jersey Law

"Except for claims for breach of an express warranty, all claims for harm caused by a product under New Jersey law, regardless of the theory underlying the claim, are governed by the New Jersey Products Liability Act ('PLA')." *Calender v. NVR Inc.*, 548 F. App'x 761, 764 (3d Cir. 2013) (citing N.J.S.A. § 2A:58C1(b)(3)). The PLA encompasses "virtually all possible causes of action relating to harm caused by consumer and other products." *In re Lead Paint Litig.*, 191 N.J. 405, 436-37 (2007). As the New Jersey Supreme Court has held, "the PLA is the sole source of remedy for plaintiffs' defective product claim; therefore, the Consumer Fraud Act ('CFA'), N.J.S.A. §§ 56:8–1 to –106, does not provide an alternative remedy." *Sinclair v. Merck & Co.*, 195 N.J. 51, 54 (2008). Plaintiffs allege damage caused by a defective product. They may not maintain such an action under the Consumer Fraud Act. Count IV of the complaint is dismissed.

IV. The New Jersey Products Liability Act Bars Plaintiffs' Claim for Punitive Damages

The New Jersey Products Liability Act prohibits punitive damages when a device complies with FDA regulations. *See* N.J.S.A. § 2A:58C-5. Because Plaintiffs do not contest that the implant complies with FDA regulations, demonstrated by the device's receipt of premarket approval, Plaintiffs' claim for punitive damages is dismissed.

V. Raymond Becker's Derivative Claim for Loss of Consortium Is Dismissed

Raymond Becker brings a claim for loss of consortium resulting from his wife's alleged injuries. Compl. ¶¶ 64-66. This derivative claim is preempted because the underlying claims cannot stand. *See Riegel,* 522 U.S. at 321 (affirming dismissal of loss of consortium claim because "it was derivative of the pre-empted claims"). Count V of the complaint is dismissed.

VI. Plaintiffs Are Granted Leave to Amend within 90 Days

The Third Circuit has liberally permitted pleading amendments to ensure that "a particular claim will be decided on the merits rather than on technicalities." *Dole v. Arco Chem. Co.,* 921 F.2d 484, 487 (3d Cir. 1990). Where a complaint is dismissed under Rule 12(b)(6), "a District Court must permit a curative amendment, unless an amendment would be inequitable or futile." *Alston v. Parker,* 363 F.3d 229, 235 (3d Cir. 2004).

Considering the possibility that Plaintiffs could plead a parallel claim, and provide specific facts evidencing a breach of express warranty, it is not presently possible to say that any opportunity to amend would be "inequitable or futile." Plaintiffs are given 90 days to file an amended complaint.

CONCLUSION

Defendant's motion is granted. The complaint is dismissed without prejudice to file an amended complaint within 90 days of the date of the accompanying order.

DATE: 5 August 2015

Hon. William H. Walls
Senior United States District Judge