UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

№ 14-CV-351 (JFB)(ARL)

SARAH CORDOVA AND GLEN CORDOVA,

Plaintiffs,

VERSUS

SMITH & NEPHEW, INC.,

Defendant.

MEMORANDUM AND ORDER
July 30, 2014

JOSEPH F. BIANCO, District Judge:

This products liability case arises out of alleged defects in an artificial hip replacement manufactured and sold by defendant Smith & Nephew, Inc. ("defendant" or "Smith & Nephew"). Plaintiff Sarah Cordova ("Cordova") claims that Smith & Nephew's R3 Ceramic Acetabular System artificial hip joint (the "R3 Ceramic System") caused her great discomfort and deteriorated prematurely due to design and manufacturing defects. This lawsuit followed, in which Cordova and her husband Glen Cordova (collectively, "plaintiffs") allege the following causes of action under New York state tort law: (1) strict liability based on design defect, manufacturing defect, and failure to warn; (2) negligent failure to warn; (3) breach of express warranty; (4) breach of implied warranty; (5) negligence; and (6) loss of consortium.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), defendant moves to dismiss all claims except the strict liability, breach of implied warranty, negligence, and loss of consortium claims to the extent they are premised on an alleged manufacturing defect. For the reasons set forth *infra*, the Court grants the motion. In particular, 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.*, preempt the design defect and failure to warn claims because the R3 Ceramic System is a Class III medical device that received premarket approval by the U.S. Food and Drug Administration ("FDA"). The Court need not decide whether the MDA preempts the breach of express warranty claim because the Court concludes that the allegations supporting this claim are too conclusory to survive a motion made under Rule 12(b)(6). Finally, the negligence, breach of implied warranty, and loss of consortium claims are dismissed

to the extent they rely on an alleged design defect or failure to warn, but not insofar as they are premised upon an alleged manufacturing defect.

I. BACKGROUND

A. Federal Regulation of Medical Devices

The FDCA "has long required FDA approval for the introduction of new drugs into the market." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). In 1976, in light of the perceived "inability of the common-law tort system to manage risks associated with dangerous devices," Congress empowered the FDA to regulate medical devices by enacting the MDA. *See id.* at 315–16. As part of the new regulatory regime, the MDA created three categories of medical devices—Class I, Class II, and Class III—according to the risks a device presents. 21 U.S.C. § 360c(a); *see Riegel*, 552 U.S. at 316; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77 (1996). A device falls into Class III if it either "(I) 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 (II) presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

Before a Class III device can be brought to market, it is subject to a "rigorous regime of premarket approval," *Riegel*, 552 U.S. at 317, in order "to provide reasonable assurance of its safety and effectiveness," 21 U.S.C. § 360c(a)(1)(C)(ii). [1] The FDA's review of one application for premarket approval takes "an average of 1,200 hours," during which the FDA weighs "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use,'" and also considers the device's proposed labeling. *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)); *see also Lohr*, 518 U.S. at 477. After its review is complete, the FDA may either grant premarket approval, deny premarket approval, or condition premarket approval "on adherence to performance standards, restrictions upon sale or distribution, or compliance with other requirements." *Riegel*, 552 U.S. at 319 (internal citations omitted).

Once the FDA grants premarket approval to a device, the device is subject to various reporting requirements. *Id.* (citing 21 U.S.C. § 360i). Additionally, the manufacturer cannot make any changes "in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness," unless the FDA approves the manufacturer's application for supplemental approval to do so. *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

[1] A device may also enter the market through "the § 510(k) process." *Riegel*, 552 U.S. at 317. As the Supreme Court has explained,

> A new device need not undergo premarket approval if the FDA finds it is "substantially equivalent" to another device exempt from premarket approval. § 360c(f)(1)(A). The agency's review of devices for substantial equivalence is known as the § 510(k) process, named after the statutory provision describing the review. Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices. P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007).

Id.

B. Allegations in the Amended Complaint

The following facts are taken from the amended complaint and the exhibits attached thereto, and are not findings of fact by the Court. Instead, the Court will assume these facts to be true and, for purposes of the pending motion to dismiss, will construe them in the light most favorable to plaintiffs, the non-moving parties.

1. The R3 Ceramic System

The FDA classified the R3 Ceramic System as a Class III medical device. (Am. Compl. ¶ 19.) Accordingly, Smith & Nephew had to apply for premarket approval of the R3 Ceramic System before bringing it to market, and the FDA granted conditional premarket approval for the R3 Ceramic System on December 17, 2004. (*Id.* ¶ 20; *see* Am. Compl. Ex. A, Premarket Approval Letter, Dec. 17, 2004.) After receiving premarket approval to sell the R3 Ceramic System, Smith & Nephew submitted several applications for supplemental approval of proposed changes, which the FDA granted. (Am. Compl. ¶ 23.) On February 18, 2008, the FDA granted supplemental approval No. S008. (*Id.* ¶ 24.)

On December 21, 2010, the FDA issued Warning Letter No. 147052 (the "Warning Letter") to Smith & Nephew. (*Id.* ¶ 26.) The Warning Letter advised Smith & Nephew that the R3 Ceramic Systems manufactured at Smith & Nephew's plant in Tuttlingen, Germany were adulterated because they were not being produced in conformity with the Current Good Manufacturing Practice ("CGMP") requirements set forth in 21 C.F.R. Part 820. (*See* Am. Compl. Ex. C, Warning Letter, at 1.) Specifically, the FDA found that there was "no process validation study to support the minimum and maximum settings" used to press different sized titanium rings into the liners of the R3 Ceramic Systems. (*Id.*)

Four months later, on April 22, 2011, Smith & Nephew conducted an FDA Class II Recall of the R3 Ceramic Systems. (Am. Compl. ¶ 35.) The recall provided the following information: "Manufacturer Reason for Recall: During the manufacturing process for several batches of R3 Ceramic Liners, the titanium rings were pressed onto the ceramic component with a higher force than allowed by manufacturing specifications. This has the potential to result in lower than expected strength for the liners." (*Id.*)

On June 20, 2013, the FDA sent a "Close Out" Letter to Smith & Nephew, which indicated that Smith & Nephew had "addressed the violations contained in the Warning Letter." (*Id.* ¶ 37; Am. Compl. Ex. E, Close Out Letter, at 1.)

2. Cordova's Hip Implant

About six months before the FDA issued the Warning Letter, Cordova underwent right hip replacement surgery on June 11, 2010, during which defendant's R3 Ceramic System was used. (Am. Compl. ¶¶ 6–7, 25.) Following hip surgery, plaintiff experienced "continuous periods of grinding sensations, squeaking sounds and limited ranges in motion" in her hip. (*Id.* ¶ 41.) As a result, she became unable to carry out "her normal and ordinary household and vocational duties." (*Id.*) By July 18, 2013, plaintiff was experiencing "great discomforts" from her artificial hip, and on that date, she underwent another surgery to replace the R3 Ceramic System with a different artificial hip device. (*Id.* ¶¶ 31–32.) When the R3 Ceramic System was removed, inspection of it revealed cracks and strength failures to its ceramic liner and proximate component structures, indicating that it had deteriorated

prematurely. (*Id.* ¶ 33.) The deficiencies in plaintiff's artificial hip were the same deficiencies identified by the FDA in the Warning Letter. (*Id.* ¶ 34.)

C. Procedural History

Plaintiffs commenced this action in the Supreme Court of the State of New York, County of Suffolk, on December 4, 2013. Defendant timely removed the case to this Court on January 16, 2014.

By letter dated February 21, 2014, defendant requested a pre-motion conference in anticipation of moving to dismiss the complaint. The Court held a pre-motion conference on March 13, 2014, during which the parties agreed that plaintiffs would submit an amended complaint.

Plaintiffs filed the amended complaint on April 8, 2014. Defendant filed the present motion to dismiss on May 23, 2014. Plaintiffs filed their opposition to the motion on June 24, 2014, and defendant filed its reply on July 8, 2014. The Court heard oral argument on July 29, 2014. The Court has fully considered the submissions of the parties.

II. STANDARD OF REVIEW

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *See, e.g.*, *Cleveland v. Caplaw Enters.*, 448 F.3d 518, 521 (2d Cir. 2006); *Nechis v. Oxford Health Plans, Inc.*, 421 F.3d 96, 100 (2d Cir. 2005). "In order to survive a motion to dismiss under Rule 12(b)(6), a complaint must allege a plausible set of facts sufficient 'to raise a right to relief above the speculative level.'" *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 91 (2d Cir. 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). This standard does not require "heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570.

The Supreme Court clarified the appropriate pleading standard in *Ashcroft v. Iqbal*, setting forth two principles for a district court to follow in deciding a motion to dismiss. 556 U.S. 662 (2009). The Court instructed district courts first to "identify[ ] pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 679. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*. Second, if a complaint contains "well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.*

The Court notes that, in adjudicating a motion to dismiss under Rule 12(b)(6), it is entitled to consider: (1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents integral to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint, (4) public disclosure documents required by law to be, and that have been, filed with the Securities and Exchange Commission, and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence. *E.g. Jones v. Nickens*, 961 F. Supp. 2d 475, 483 (E.D.N.Y. 2013); *David*

Lerner Assocs., Inc. v. Phila. Indem. Ins. Co., 934 F. Supp. 2d 533, 539 (E.D.N.Y. 2013), *aff'd*, 542 F. App'x 89 (2d Cir. 2013); *SC Note Acquisitions, LLC v. Wells Fargo Bank, N.A.*, 934 F. Supp. 2d 516, 524 (E.D.N.Y. 2013), *aff'd*, 548 F. App'x 741 (2d Cir. 2014).

III. DISCUSSION

A. Legal Standard

Defendant's motion turns primarily on the following preemption provision in 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 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(a). In *Riegel*, the Supreme Court held that FDA premarket approval constitutes a federal "requirement" that activates this preemption provision. 522 U.S. at 322. Moreover, a state's common law may constitute a "requirement" for purposes of this statute. *Id.* at 323–24.

Accordingly, where a medical device has received premarket approval, a plaintiff's state common law claim is preempted if it relates to "the safety or effectiveness of the device" and is "different from, or in addition to," the federal requirements. *See* 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 323. "If a state common law, for instance, requires that a medical device manufacturer design a certain device in a manner that is safer than a model that the FDA has already approved," a design defect claim under that state law would be preempted because the state law "could 'disrupt the federal scheme.'" *Bertini v. Smith & Nephew, Inc.*, --- F. Supp. 2d ----, No. 13-CV-79 (BMC), 2014 WL 1028950, at *3 (E.D.N.Y. Mar. 17, 2014) (quoting *Riegel*, 552 U.S. at 325). To avoid preemption, therefore, a plaintiff must establish that the state's duties merely "parallel" the federal requirements. *Riegel*, 552 U.S. at 330 (noting 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"); *see also Bertini*, 2014 WL 1028950, at *3 (holding that, to avoid dismissal of a state law claim related to the safety or effectiveness of a device that has received FDA premarket approval, "a plaintiff must establish that the state and federal requirements are equivalent").

"To complicate the preemption doctrine further, however, a plaintiff's claim cannot be based *solely* on [a violation of federal law]." *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203 (JS)(WDW), 2014 WL 2863087, at *3 (E.D.N.Y. June 23, 2014) (emphasis added). This is because the Supreme Court has held that there is no private cause of action for noncompliance with the medical device provisions of the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); *see also Gale v. Smith & Nephew, Inc.*, --- F. Supp. 2d ----, No. 12-CV-3614 (VB), 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (noting that "a plaintiff would not have a private right of action under federal law to bring claim alleging the device did not

comply with the MDA"); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 153 (S.D.N.Y. 2011) ("Noncompliance with a MDA provision does not in and of itself provide a cause of action for a private litigant.").

Riegel and *Buckman* taken together thus "'create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" *Gale*, 2013 WL 563403, at *3 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). On the one hand, the plaintiff's claim must be based on conduct that violates federal law (*i.e.*, a parallel claim), or else it is preempted, but "'the plaintiff must not be suing *because* the conduct' violates federal law, because he has no private right to bring such a claim." *Id.* (quoting *Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1204). In other words, to state a plausible products liability claim that avoids federal preemption, a plaintiff must "set forth facts pointing to specific premarket approval requirements that have been violated, *and link those violations to his injuries*." *Id.* (emphasis added); *see also Franzese*, 2014 WL 2863087, at *3; *Burkett v. Smith & Nephew Gmbh*, No. 12-CV-4895 (LDW) (ARL), 2014 WL 1315315, at *4 (E.D.N.Y. Mar. 31, 2014); *Bertini*, 2014 WL 1028950, at *3; *Simon v. Smith & Nephew, Inc.*, --- F. Supp. 2d ----, No. 13-CV-1909 (PAE), 2013 WL 6244525, at *4 (S.D.N.Y. Dec. 3, 2013).

B. Application

1. Strict Liability

Cordova's first cause of action alleges strict products liability based on theories of manufacturing defect, design defect, and the failure to warn. (*See* Am. Compl. ¶¶ 45–52); *cf. McCarthy v. Olin Corp.*, 119 F.3d 148, 155–56 (2d Cir. 1997) ("In New York, there are three distinct claims for strict products liability: (1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm; and (3) a design defect, which results when the product as designed is unreasonably dangerous for its intended use." (internal citations omitted)).

At the outset, the Court notes that defendant does not move to dismiss the manufacturing defect claim. (*See* Def.'s Mem. at 5 n.3; Def.'s Reply at 2.) Accordingly, the Court does not address that component of the first cause of action, and the manufacturing defect claim remains.

a. Design Defect

To state a claim for defective design, a plaintiff must allege that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001) (citing *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108 (1983)); *see also Emslie v. Borg-Warner Auto., Inc.*, 655 F.3d 123, 125 (2d Cir. 2011).

Here, Cordova only vaguely alleges that Smith & Nephew's product design was "unreasonably dangerous" and "contrary to safer reasonable alternatives." (Am. Compl. ¶ 47.) Cordova does not claim that the design of the R3 Ceramic System deviated in any way from the design approved by the FDA; the Warning Letter and recalls cited in the amended complaint relate only to a *manufacturing* defect, not a *design* defect.

Because Cordova does not claim that the design of the R3 Ceramic System differed from the design approved by the FDA, Cordova's design defect claim boils down to a direct attack on the very design approved by the FDA. Accordingly, based on the allegations in this case, the imposition of liability on defendant for a design defect would constitute a state law requirement "in addition to" federal requirements, which the MDA expressly forbids. *See* 21 U.S.C. § 360k; *see also Franzese*, 2014 WL 2863087, at *6 ("Plaintiffs point to an FDA warning letter relating primarily to manufacturing issues, and have not alleged that Defendants strayed from the design approved by the FDA. Accordingly, this claim is preempted."); *Burkett*, 2014 WL 1315315, at *4 (holding design defect claim preempted where medical device at issue had received premarket approval, and plaintiffs did not claim any change from approved design); *Bertini*, 2014 WL 1028950, at *6 (same); *Simon*, 2013 WL 6244525, at *7 ("[D]esign defect claims regarding a PMA-approved device are squarely preempted by the MDA."). The Court thus grants defendant's motion to dismiss the design defect claim.

b. Failure to Warn

"Under New York law, a plaintiff may recover in strict products liability 'when a manufacturer fails to provide adequate warnings regarding the use of its product.'" *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 725 F.3d 65, 123 (2d Cir. 2013) (quoting *Rastelli v. Goodyear Tire & Rubber Co.*, 79 N.Y.2d 289, 297 (1992)).[2]

With respect to this claim, Cordova alleges that Smith & Nephew failed to warn the public that the R3 Ceramic System was defective (Am. Compl. ¶¶ 18, 49), and that "the instructions and warnings provided were inaccurate and/or inadequate" (*id.* ¶ 55). Cordova does not claim that Smith & Nephew modified or failed to include the labels and warnings that the FDA approved as part of the premarket approval process. Nor does Cordova allege that Smith & Nephew's alleged failure to warn violated any other federal requirement.

Based on the allegations in the amended complaint, Cordova's failure to warn claim is preempted. In particular, it is significant that Cordova does not base her claim upon the violation of any federal requirement. Absent the violation of a federal requirement, a failure to warn claim must be dismissed as preempted by the MDA. *See, e.g., Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1205 ("The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted."); *Bertini*, 2014 WL 1028950, at *8 ("Because plaintiffs fail to identify a federal requirement that defendant warn the public and health care professionals directly that its devices were defective, plaintiffs' 'failure to warn' theory

[2] The amended complaint appears to assert both strict liability and negligence claims based upon the alleged failure to warn. "'Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent.'" *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 439 (S.D.N.Y. 1999) (quoting *Martin v. Hacker*, 83 N.Y.2d 1, 8 n.1 (1993)). Accordingly, the Court considers plaintiff's failure to warn claims together.

of strict liability does not 'parallel' federal requirements."); *Burkett*, 2014 WL 1315315, at *6 (holding that plaintiff failed to plead parallel failure to warn claim where she did not "sufficiently reference federal requirements or regulations related to adequate warnings"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286–87 (E.D.N.Y. 2009) (holding that MDA preempted a failure to warn claim where plaintiff failed to allege that defendant's warnings violated federal requirements); *cf. Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (holding that MDA did not preempt claim that defendant failed to warn the FDA in violation of FDA reporting requirements); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769–71 (5th Cir. 2011) (holding that MDA did not preempt failure to warn claim "to the extent that this claim [was] predicated on Boston Scientific's failure to report 'serious injuries' and 'malfunctions' of the device *as required by the applicable FDA regulations*" (emphasis added)). Accordingly, the Court grants the motion to dismiss the failure to warn claim.

2. Breach of Express Warranty

"To state a claim for breach of express warranty under New York law, a plaintiff must allege (1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, --- F. Supp. 2d ----, No. 13-CV-3073 (NSR), 2014 WL 1285137, at *12 (S.D.N.Y. Mar. 27, 2014) (citing *Avola v. La.-Pac. Corp.*, --- F. Supp. 2d ----, No. 11-CV-4053 (PKC), 2013 WL 4647535, at *6 (E.D.N.Y. Aug. 28, 2013)); *see CBS Inc. v. Ziff-Davis Publ'g Co.*, 75 N.Y.2d 496, 502–504 (1990).

Courts are split as to whether an express warranty claim is subject to MDA preemption at all. "The Third and Seventh Circuits have held that such claims are not preempted because any 'requirements' imposed by the warranty are voluntarily assumed by the warrantor, not imposed by the state." *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008) (citing *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1327–28 (3rd Cir. 1995)). This position finds support in *Cipollone v. Liggett Group, Inc.*, in which the Supreme Court held that for purposes of the Federal Cigarette Labeling and Advertising Act's preemption provision,[3] "the 'requirement[s]' imposed by an express warranty claim are not 'imposed under State law,' but rather imposed by the warrantor." 505 U.S. 504, 525 (1992). Other decisions have found this reasoning to be persuasive. *See, e.g.*, *Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1207 ("Though *Cipollone* construed a different, narrower express preemption provision, the opinion suggests that breach of express warranty claims are not expressly preempted by § 360k."); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 165 (S.D.N.Y. 2011). However, other courts have held that an express warranty claim *is* preempted if it is based upon representations approved by the FDA. *See, e.g.*, *Parker*, 585 F. Supp. 2d at 1303 ("Plaintiff's express warranty claim would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in

[3] That statute states, in relevant part, that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. § 1334(b).

addition to the federal requirements. Therefore, that claim is preempted by section 360k."); *Burkett*, 2014 WL 1315315, at *8 ("To the extent that Burkett's [breach of express warranty] claim is based on FDA-approved representations, it is preempted."); *Horowitz*, 613 F. Supp. 2d at 285 ("Plaintiff's breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer."). The reasoning behind these decisions seems to be that an express warranty claim would require a factfinder to decide whether representations about a medical device were true, notwithstanding the FDA's initial approval of those representations. *See, e.g.*, *Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1208 ("To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement. . . . The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted."); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) ("A jury hearing Gomez's state-law breach of express warranty claim would have to decide whether Kendall's representations about the Angio-Seal were true. Because those representations—including the label, warnings, and IFU—were approved by the FDA through the PMA process, the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme. The claim is preempted."); *see also Leonard v. Medtronic, Inc.*, No. 10-CV-03787-JEC, 2011 WL 3652311, at *10 (N.D. Ga. Aug. 19, 2011).

In this Court's view, a breach of warranty claim is not preempted to the extent it relies on a manufacturing defect. For instance, if a plaintiff alleges (1) a defendant's express warranty of safety and compliance with certain manufacturing standards, (2) reliance on this warranty, (3) breach of the warranty due to a manufacturing defect in violation of federal requirements, and (4) resulting injury, the MDA would not preempt this claim. *See, e.g.*, *McConologue v. Smith & Nephew, Inc.*, --- F. Supp. 2d ----, Civil Action No. 3:13–CV–00880 (VLB), 2014 WL 1246834, at *16 (D. Conn. Mar. 24, 2014) (holding that breach of express warranty claim was not preempted where plaintiff had alleged that device was defective in violation of federal law); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) ("Howmedica has confused Hofts' express warranty claim with a defective labeling claim, which would be preempted under *Riegel*. Hofts does not allege that the Trident's FDA-approved label was defective. Hofts is perfectly happy with the label. He contends only that the device implanted in his hip should fit the description on that label. He claims that the Trident did not live up to the FDA-approved promises contained in its label and that he was harmed as a result."). By contrast, a breach of express warranty claim premised upon a defect in a design or label approved by the FDA would be preempted because such a claim would require a factfinder to reach a determination completely at odds with that of the FDA. *See, e.g.*, *Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1208; *Gomez*, 442 F.3d at 932.

In the instant case, the Court concludes that the allegations in the amended complaint do not suffice to state a breach of warranty parallel claim. Cordova alleges in a wholly conclusory fashion that Smith &

Nephew breached express warranties "regarding the performance of the [R3 Ceramic System]" (Am. Compl. ¶ 63), including warranties "that it would be safe to use" (*id.* ¶ 64), and that it was "inspected and accepted in accordance with this defendant's own and other recognized safety standards" (*id.* ¶ 66). The failure to set forth with any detail "the terms of the particular warranty" upon which the plaintiff allegedly relied is grounds for dismissal under Rule 12(b)(6). *Prue v. Fiber Composites, LLC*, No. 11-CV-3304 (ERK) (LB), 2012 WL 1314414, at *10 (E.D.N.Y. Apr. 17, 2012) (dismissing breach of warranty claim where plaintiff alleged "at a high order of abstraction" that defendants had expressly warranted their products to be free from defects, reasonably safe, and fit for their intended use); *see, e.g.*, *Bertini v. Smith & Nephew, Inc.*, No. 13-CV-0079 (BMC), 2013 WL 6332684, at *5 (E.D.N.Y. July 15, 2013) (dismissing breach of warranty claim as too conclusory, where plaintiff alleged only that defendant had warranted its device to be "safe and effective"); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 579 (E.D.N.Y. 2012) (dismissing breach of warranty claim where plaintiffs did not allege details of warranty's terms, such that they "alleged nothing which makes plausible that [the] various risks differ from what was warranted."). Moreover, Cordova has failed to specify whether the breach of the alleged warranty was a manufacturing defect or a design defect. The failure to allege how a breach of an express warranty violated federal requirements—for instance, by alleging that the breach was a manufacturing defect in violation of FDA regulations—is also grounds for dismissal under the MDA. *See, e.g.*, *Burkett*, 2014 WL 1315315, at *8. In other words, Cordova has not pleaded sufficient facts to allow this Court to determine whether the MDA preempts her breach of express warranty claim.

Nevertheless, because better pleading could cure the defects identified in this claim, the Court will give Cordova leave to replead her breach of express warranty claim. *See, e.g.*, *Oliver Sch., Inc. v. Foley*, 930 F.2d 248, 253 (2d Cir. 1991) ("Where the possibility exists that the defect can be cured and there is no prejudice to the defendant, leave to amend at least once should normally be granted as a matter of course."). If Cordova wishes to do so, plaintiffs' counsel shall file a second amended complaint amending Cordova's breach of express warranty claim no later than thirty days from the date of this Order.

3. Breach of Implied Warranty, Negligence, and Loss of Consortium

Finally, Smith & Nephew moves to dismiss the breach of implied warranty, negligence, and loss of consortium claims only to the extent they rely on any theory of liability *other than a manufacturing defect*. (*See* Def.'s Mem. at 17–20; Def.'s Reply at 10.) For the reasons discussed *supra*, the breach of implied warranty and negligence claims are preempted to the extent they rely on a design defect or failure to warn theory. *See, e.g.*, *Bertini*, 2014 WL 1028950, at *10–12. Glen Cordova's loss of consortium claim must also be dismissed to the extent it is derivative of those claims. *See, e.g.*, *Rodriguez v. Athenium House Corp.*, 557 F. App'x 37, 38 n.1 (2d Cir. 2014) (summary order) (noting that loss of consortium claim is a derivative claim); *Bertini*, 2014 WL 1028950, at *12 (dismissing husband's loss of consortium claim because wife's claims were dismissed). However, the breach of implied warranty, negligence, and loss of consortium claims may proceed to the extent they are premised on an alleged manufacturing defect. *See, e.g.*, *Gelber*, 788 F. Supp. 2d at 166–67 (holding that MDA did not preempt plaintiffs' implied warranty

and negligence claims to the extent they alleged a manufacturing defect claim).

IV. CONCLUSION

For the reasons set forth herein, the Court grants the motion to dismiss in its entirety. Cordova's design defect, failure to warn, and breach of express warranty claims are dismissed. Moreover, Cordova's breach of implied warranty and negligence claims are dismissed to the extent they rely on a theory of design defect or failure to warn; however, they are not dismissed to the extent they rely on a theory of manufacturing defect. Glen Cordova's loss of consortium claim may proceed to the extent it is derivative of Cordova's remaining claims. Finally, plaintiffs shall file a second amended complaint no later than thirty days from the date of this Order if Cordova wishes to amend her breach of express warranty claim.

SO ORDERED.

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JOSEPH F. BIANCO
United States District Judge

Dated: July 30, 2014
Central Islip, NY

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Plaintiffs are represented by David J. DeToffol of DeToffol & Associates, Attorneys at Law, 30 Broad Street, 35th Floor, New York, NY 10004. Defendant is represented by Glenn S. Kerner, Nilda Maria Isidro, and Carla Rose Karp of Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, NY 10018.