UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ROXANNE LAFOUNTAIN,	**:**	**14cv1598 (WWE)**
Plaintiff,	**:**	
	:	
v.	**:**	
	:	
SMITH & NEPHEW, INC.,	**:**	
Defendants.	**:**	

MEMORANDUM OF DECISION ON DEFENDANT'S MOTION TO DISMISS

This case stems from two failed hip replacement surgeries that involved implant parts designed, constructed, manufactured and sold by Smith & Nephew, Inc. Plaintiff Roxanne LaFountain underwent two surgeries at St. Vincent's Medical Center in Bridgeport, Connecticut, on August 25 and November 10, 2009, respectively.

Plaintiff alleges that defendant Smith & Nephew is liable to her under the Connecticut Product Liability Act ("CPLA"). In her fourth amended complaint, plaintiff alleges theories of strict products liability; breach of express and implied warranty; negligence; and innocent and negligent misrepresentation. Plaintiff's product liability claims relate to the defendant's design, testing, warnings, marketing, distribution, and warranties associated with the hip replacement system and its component parts.

Defendant has filed a motion to dismiss on the basis of preemption pursuant to the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act ("FDCA"). Defendant also argues that plaintiff has failed to state a claim.

I. BACKGROUND

The following factual background is reflected in the allegations of the complaint that are considered to be true for purposes of ruling on this motion to dismiss. The Court also includes facts that are reflected in official public documents of which the Court takes judicial notice. See Apotex Inc. v. Acorda Therapeutics, Inc., – F.3d – , 2016 WL 2848911, at *5 (2d Cir. May 16, 2016).

Defendant was involved in the manufacture, design, and marketing of healthcare products, including the hip replacement system and component parts that were used for plaintiff's hip replacement.

Prior to plaintiff's surgeries, defendant had received Section 510(k) approval from the United States Food and Drug Administration ("FDA") for (1) the Class II Reflection Acetabular System ("R3 Acetabular System"), which is an implant used for total hip replacement procedures. The R3 Acetabular System consists of the Acetabular Cup ("R3 Acetabular Shell") and one of several possible liners used for primary and revision hip replacement surgery; it is used with defendant's Echelon Hip Stems, Modular Femoral Heads and Modular Head Sleeves manufactured from cobalt chrome materials.[1] Defendant had also received FDA Section 510(k) Class II approval for these components prior to plaintiff's hip replacements.

Prior to plaintiff's surgeries, defendant had received FDA premarket approval for marketing the Birmingham Hip Resurfacing System ("BHR"), a Class III "metal on metal resurfacing artificial hip replacement system." In 2008, the R3 Acetabular Liner became a Class III component to be used with the BHR System. As of February 2009, defendant marketed the R3 Acetabular Liner for use with the R3 Acetabular System.

[1]See Bertini v. Smith & Nephew, 8 F. Supp. 3d 246, 250 (E.D.N.Y. 2014).

On August 25 and November 10, 2009, plaintiff underwent left and right hip replacements, respectively. Plaintiff's doctor decided to use the R3 Acetabular Liner with a hip replacement system other than the BHR System for which it was approved (an off-label use of a Class III device).

Plaintiff's Claims

Plaintiff alleges that the implanted devices, the R3 Acetabular Liners, Modular Femoral Heads, Modular Head Sleeves and Echelon Hip Stems caused the accelerated release of metal debris and ions into her body and blood stream, which resulted in her having to endure pain, difficulty walking and additional surgeries.

In her strict liability count, plaintiff asserts, inter alia, that defendant defectively designed the R3 Acetabular Liner by using cobalt-chrome materials; sold it without adequate warnings about its associated risk of causing accelerated release of metal debris and ions and other complications such as pain and infection; improperly marketed it for use with the R3 Acetabular System; violated FDA standards for obtaining FDA approval; misrepresented information to the FDA; improperly misbranded its R3 Acetabular Liner to be used in applications other than the BHR System; and failed to comply with FDA monitoring and reporting requirements.

Plaintiff alleges, inter alia, that defendant defectively designed and manufactured the Echelon Hip Stem, Modular Femoral Head and Modular Head Sleeve by using cobalt-chrome materials; improperly marketed them without adequate warnings about their associated risks including the accelerated release of metal debris and pain and infection; misrepresented information to the FDA; and failed to comply with FDA post-marketing surveillance requirements.

In her breach of express and implied warranty claims, plaintiff alleges that defendant expressly warranted that the R3 Acetabular Liner, the Modular Femoral Head, Modular Head Sleeve, and Femoral Stem were safe for their intended uses despite having knowledge that these devices had a design flaw that could likely lead to plaintiff's injuries. Defendant allegedly violated the express warranties of these device by "underplaying" the negative results associated with the use of the medical devices. Defendant impliedly warranted that these devices were of merchantable quality, and it breached this warranty when it delivered them to be used in plaintiff's surgeries despite the inherent design flaw. Defendant knew that the devices had a likelihood of causing complications based on their intended uses and failed to disclose that information to plaintiff or her surgeon.

In her negligence claim, plaintiff asserts that defendant knew or should have known that the R3 Acetabular Liners had not been subjected to appropriate FDA approval due to defendant's manipulation of the premarket approval process; failed to test the Liner to determine whether it could be safely implanted into a patient's body when used with a metal femoral head; failed to focus its testing of the R3 Acetabular System or the BHR System with use of the R3 Acetabular Liner; failed to provide proper warnings; designed, manufactured and fabricated the Liner in such a manner that it was subject to corrosion and failure when used in combination with its Femoral Heads; failed to comply with certain FDA requirements; and failed to subject the Liner to proper testing.

Relevant to the Echelon Femoral Stem, Modular Femoral Head, and Modular Head Sleeve, plaintiff asserts that defendant failed to adequately test the devices; failed

to provide proper warnings; designed and manufactured the devices in such a manner to cause an accelerated release of metal debris and ions; underreported and withheld information about the flaws in the devices; misrepresented information about the devices to the FDA; and failed to update the FDA with new information about the complications associated with the devices.

Plaintiff also alleges that defendant delayed its voluntary recall of the Modular Femoral Head and Head Sleeve despite being aware of information demonstrating a decline in its performance.

In her final count of innocent and negligent misrepresentation, plaintiff asserts that defendant should have known that its representation of the R3 Acetabular Liner's safety and effectiveness was false because defendant could have discovered the inherent design defect; ignored test results demonstrating the inherent defect; failed to timely report the negative test results and adverse health events; failed to accurately report the increased risk of failure to plaintiff's surgeon; promoted the use of the R3 Acetabular Liner prior to gaining appropriate FDA approval; and marketed the R3 Acetabular Liner for use in applications other than the BHR System.

II. DISCUSSION

The function of a motion to dismiss is "merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." Ryder Energy Distrib. v. Merrill Lynch Commodities, Inc., 748 F.2d 774, 779 (2d Cir. 1984). When deciding a motion to dismiss, the Court must accept all well-pleaded allegations as true and draw all reasonable inferences in favor of the pleader. Hishon v. King, 467 U.S. 69, 73 (1984). The complaint must contain the grounds upon

which the claim rests through factual allegations sufficient "to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A plaintiff is obliged to amplify a claim with some factual allegations to allow the court to draw the reasonable inference that the defendant is liable for the alleged conduct. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

A. Preemption

The Supremacy Clause of the United States Constitution "invalidates state laws that interfere with or are contrary to federal law." Hillborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 712 (1985). "When addressing questions of express or implied pre-emption, we begin our analysis with the assumption that the historic police powers of the States are not be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Altria Group, Inc. v. Good, 555 U.S. 70, 77 (2008).

1. Express Preemption

"Express preemption arises when a federal statute expressly directs that state law be ousted." Air Transport Ass'n of America, Inc. v. Cuomo, 520 F.3d 218, 220 (2d Cir. 2008). The Medical Device Amendments represent federal legislation that clearly directs express preemption of claims relative to certain medical devices subject to FDA approval.

The Medical Device Amendments provide "various levels of oversight for medical devices, depending on the risks they present." Riegel, 552 U.S. 312, 316 (2008). Devices used for "supporting or sustaining life" or that present "potential unreasonable risk of illness or injury" are designated Class III devices subject to the highest level of

government oversight with required premarket approval from the FDA. 21 U.S.C.§ 360c(a)(1)(c).

Section 360k(a), provides an express preemption clause:

> 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 the requirement applicable to the device under this chapter.

Pursuant to this express preemption clause, state common law tort claims are expressly preempted to the extent that such claims impose a standard "different from, or in addition to" federal requirements, and to the extent that such claims relate to the safety and effectiveness of Class III device subject to premarket approval. Riegle v. Medtronic, Inc., 552 U.S. at 323-330.[2]

Due to the rigors required for premarket approval more devices are subjected to the Section 510(k) process, by which the FDA affords approval based on substantial equivalence to devices already on the market. Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 401 (S.D.N.Y. Dec. 3, 2013). Claims related to medical devices approved through the FDA's Section 510(k) process are not subject to preemption. Riegel, 552 U.S. at 322-323.

2. Implied Preemption

[2]As discussed further in this ruling, Section 360k does not prevent a state damages remedy for claims premised on a violation of FDA regulations, where the state-imposed duties parallel rather than add to the federal requirements. Id. at 330.

Implied preemption arises, despite the absence of an explicit statutory directive, when Congress intended the Federal Government to occupy a field exclusively, or when state law conflicts with federal law. English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990).

The Supreme Court has determined that the Medical Device Amendments impliedly preempt claims asserting fraud on the FDA that inevitably conflict with the FDA's mandate to enforce its requirements or restrain violations thereof.[3] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). Buckman recognized that state law causes of action that parallel federal safety requirements can withstand preemption; however, the Court indicated that such state law actions cannot derive solely by virtue of the federal violation. For example, in Buckman, plaintiff alleged that defendant, a consulting company employed to assist a manufacturer secure FDA approval, had made fraudulent representations to the FDA to obtain approval to market the product; since the misrepresentation would not have occurred in the absence of the FDCA disclosure requirements, the Supreme Court found such state law "fraud-on-the-FDA" claim failed to establish a parallel state law cause of action.

Thus, a state law parallel claim can exist where "[t]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009). Some courts have acknowledged that the parallel claim doctrine cannot exist if preemption applies to all state law claims that effectively enforce federal requirements. See Raab v. Smith & Nephew, Inc., 2015 WL 9026631, at *9 (S.D. W. Va. Dec. 15,

[3]Section 337(a) provides that all proceedings to enforce or to restrain violations of the FDCA "shall be by and in the name of the United States."

2015) (noting that parallel state law claims will, in effect, seek to enforce federal requirements). As Raab elaborated, to avoid implied preemption, a parallel claim must incorporate federal standards and also be grounded in state law causes of action that exist and impose duties outside of the FDCA's operation. Id.; see also Laverty v. Smith & Nephew, Inc., 2016 WL 3444191, at *7 (N.D. Ill. June 23, 2016) (state law failure to warn predicated on manufacturer's failure to disclose defects not preempted.). Further, to state a parallel state law claim, plaintiff must allege facts linking the violation of the federal regulations with the plaintiff's injury. Gale v. Smith & Nephew, 989 F. Supp. 2d 243, 249 (S.D.N.Y. 2013).

B. Preemption of Plaintiff's Claims

Defendant argues that plaintiff's state law product liability claims are preempted by the Medical Device Amendments in light of the R3 Acetabular Liner's Class III status. Plaintiff counters that she has alleged plausible product liability claims based on the combination of component parts comprising the hip replacement system, and in the alternative, that each component part alone was independently responsible for her injuries. Further, she asserts that she has sufficiently alleged parallel claims related to the R3 Acetabular Liner and the hip implant's component parts that withstand preemption analysis.

1. Strict Liability and Negligence: R3 Acetabular Liner

The Court agrees that express preemption applies to plaintiff's strict liability and negligence claims asserted on the basis of an alleged defect with the R3 Acetabular Liner (with the exception of the parallel negligent failure to warn claims as discussed further in this ruling) .

Plaintiff does not appear to contest that strict liability and negligence design defect claims "cast doubt on the FDA's findings concerning the safety of the device's design and, thus, are categorically preempted by the [Medical Device Amendments]." Simoneau v. Stryker Corp., 2014 WL 1289426, *9, 12 (D. Conn. March 31, 2014). However, plaintiff asserts that she has alleged parallel state law failure to warn claims based on violation of the FDA standards for approval, testing and reporting. Defendant counters that plaintiff's pleading is deficient because she neither established a parallel state duty nor linked her injury to violations of federal requirements.

State strict liability and negligence claims related to failure to warn or failure to report may give rise to potential viable parallel state law claims. See Rosen v. St. Jude Medical, Inc., 41 F. Supp. 3d 170 (N.D.N.Y. 2014) (state law duty to report adverse events to medical community and provide ongoing warnings to the FDA paralleled federal requirements).

District courts within the Second Circuit have differed with regard to the level of specification required to satisfy the plausibility standard in pleading a parallel state law claim. See, e.g., Simoneau, 2014 WL 1289426, at 6 n.6 (rejecting pleading standard requiring citation to device specific regulations and discussing cases); Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (requiring particular federal regulation violated). Additionally, Connecticut law has not clearly established a duty to report adverse events to the FDA; moreover, a continuing post-sale duty to warn exists in negligence, although not in strict liability. Simoneau, 2014 WL 1289426, at 11 n.9, 10.

Construing the allegations most liberally in favor of plaintiff, the Court finds plausible parallel claims sounding in negligence for failure to warn or failure to report in violation of the federal requirements. However, plaintiff's strict liability and negligence claims based solely upon the R3 Acetabular Liner will be dismissed as preempted with the exception of the claims of negligent failure to warn or report.

2. Breach of Implied Warranties, Express Warranties and Misrepresentation: R3 Acetabular Liner

Plaintiff's claims alleging breach of implied warranty based on the R3 Acetabular Liner and innocent and negligent misrepresentations are preempted because they implicate the FDA's review of the safety and effectiveness of the Class III Liner and impose standards that differ from the federal requirements. See Riegel, 552 U.S. at 322 (Premarket approval is federal safety review); Smith v. Depuy Orthopedics, Inc., 2013 WL 1108555, *11 (D.N.J. March 18, 2013) (claims concerning safety and effectiveness of device were preempted). Further, preemption is appropriate because these counts fail to allege any violation of federal requirements linked to her injury. See Desabio v. Howmedica Osteonics Corp., 817 F. Supp. 2d 197 (W.D.N.Y. 2011) (dismissing state tort law claims as preempted where plaintiff alleged no violation of federal law).

However, the Court will not dismiss the breach of express warranty claim on the basis of preemption. Breach of express warranty is not "categorically preempted" even in cases of Class III medical devices because the MDA do not prohibit a manufacturer from imposing upon itself contractual standards that differ from federal requirements. See Simoneau, 2014 WL 1289426, at *14.

3. Combination of Components

Defendant argues that plaintiff's claims asserting injuries based on the R3 Acetabular System should all be dismissed due to the System's inclusion of the R3 Acetabular Liner, a Class III device.

Generally, courts have determined preemption based on the medical device as a whole rather than applying the analysis to each component part. See Bertini v. Smith & Nephew, Inc., 8 F. Supp. 3d 236, 253 (E.D.N.Y. 2014); such courts have noted that distinguishing between different components within a single system would "add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010); see also Riley v. Cordis Corp., 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (separating components of Class III device to apply different preemption analyses "makes no sense.")

Defendant's argument relies upon Simon and Bertini, both of which involved an R3 Acetabular System utilizing the R3 Acetabular Liner. Simon and Bertini acknowledged case law directing that preemption analysis should be applied to the hip replacement system as a whole, but nevertheless determined that the state law claims were preempted on the basis of the System's use of the Class III component R3 Acetabular Liner. Simon, 990 F. Supp. 2d at 405; Bertini, 8 F. Supp. 3d at 253-54 (preemption analysis should apply to hip replacement system as one unit).

However, unlike Simon and Bertini, the instant action alleges injuries stemming from the combination of component parts. In Simon, plaintiff's counsel identified the R3 Acetabular Liner, rather than the interaction of the R3 Acetabular System, as the source of the injury. Simon, 990 F. Supp. at 405. In Bertini, the district court justified

preemption by characterizing plaintiffs' claims as being dependent upon the alleged defect of R3 Acetabular Liner; the court went on to reason that "if a claim involving the R3 metal liner's alleged defect is preempted, the entire claim should be dismissed because plaintiffs will be unable to sufficiently plead the remainder of the claim." Bertini, 8 F. Supp. 3d at 253-54 ; see also Shuker v. Smith & Nephew PLC, 2015 WL 1475368, at *8 (E.D. Pa. March 31, 2015) (following Simon and Bertini).

Further, at least one district court has criticized Simon and Bertini for ignoring the R3 Acetabular System's status as a Class II Section 510(k)-approved device and separating the device into its component parts to create express preemption based on a Class III component. Huskey v. Ethicon, Inc., 29 F. Supp. 3d 736, 751 (S.D. W. Va. 2014).

Relevant to plaintiff's claims based on the combination of component parts, the Court, adopting Huskey's analysis, declines to separate the device into its component parts to create express preemption. See id. (noting that FDA had not examined R3 Acetabular Liner's safety and efficacy with regard to other hip replacement systems). The Court will deny the motion to dismiss on the basis of express preemption of claims because the combination of component parts comprising the hip implant system had not undergone the premarket approval process.

4. Enforcement of FDA Requirements

Defendant argues that several of plaintiff's allegations in count one and three are claiming fraud on the FDA similar to those that Buckman dismissed due to implied preemption.

Plaintiff alleges that defendant improperly marketed and distributed the R3 Acetabular Liner for use with the R3 Acetabular System in the U.S. before obtaining proper approval from the FDA; that defendant violated FDA standards for obtaining approval of the R3 Acetabular Liner; that defendant "improperly promoted, marketed and sold" the R3 Acetabular Liner for use in applications other than the Birmingham Hip Resurfacing System for which it was approved; and that defendant "knowingly misrepresented to the FDA" that the component parts–stem, head and sleeve–were "similar to commercially available devices" in order to gain 510(k) clearance.

These allegations of misrepresentations and noncompliance with the federal regulations seek to use state law to enforce or restrain noncompliance with the federal requirements; however, only the federal government may bring actions to enforce or restrain violations of the FDCA. See 21 U.S.C.§ 337(a).[4] Plaintiff has not establish a plausible parallel state law claim based on these allegations because the asserted violations of federal law exist solely by virtue of the Medical Device Amendments's regulatory scheme similar to those alleged in Buckman. The Court will dismiss these claims as impliedly preempted. Plaintiff is instructed to omit such allegations when she amends her complaint.

C. Plausibility of Plaintiff's Claims

Defendant argues that plaintiff's claims should be dismissed for failure to state a plausible claim. As to the remaining strict liability and negligence claims, plaintiff has

[4]Section 337(a) provides that, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."

satisfied the requisite standard to withstand a motion to dismiss. However, plaintiff has not pled a plausible claim of breach of express warranty.[5]

1. Express Warranty

To prevail on a breach of express warranty theory, plaintiff must prove the existence of an express warranty. Web Press Servs. Corp. v. New London Motors, Inc., 203 Conn. 342, 351 (1987). Pursuant to Connecticut General Statute § 42a-2-313(1), a seller may create an express warranty by:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

However, the seller need not use specific words or even intend to make a warranty; further, some seller statements constitute puffing without creating express warranties. Web Press Servs, 203 Conn. at 351. Here, plaintiff has alleged that defendant "expressly warranted" that the liner, head, sleeve and stem were safe for their intended uses "on the dates of the plaintiff's primary hip replacement surgeries." This Court has previously found as deficient a similar pleading of a breach of express warranty that lacked any allegations concerning the underlying warranty of safety and that failed to identify the party to whom the warranty was made. Simoneau, 2014 WL 1289426, at *14 (plaintiff need not prove the existence of warranty but must indicate representation

[5]The CPLA incorporates breach of warranty theories. Conn. Gen. Stat.§ 52-572m(b). The elements of the breach of warranty claims stem from the Connecticut Uniform Commercial Code ("CUCC"). Walters v. Howmedica Osteonics Corp., 676 F. Supp. 2d 44, 55 (D. Conn. 2009).

of warranty allegedly made). Accordingly, the Court will dismiss this claim but will permit plaintiff to replead to state a plausible claim of breach of express warranty.

2. Breach of Implied Warranty

Under the CUCC, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Conn. Gen. Stat. § 42a–2–314(1). Merchantable goods must be "fit for the ordinary purposes for which such goods are used" and must "conform to the promises or affirmations of fact made on the container or label." Conn. Gen. Stat. § 42a–2–314(2). There is an implied warranty that goods shall be fit for a particular purpose "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods...." Conn. Gen. Stat. § 42a–2–315.

Plaintiff has alleged that defendant "impliedly warranted" that the hip implant's component parts were of merchantable quality and breached the warranty when it delivered the components containing inherent defects to St. Vincent's Hospital. Defendant maintains that plaintiff has failed to set forth facts to support her assertion of a product defect. The Court finds that plaintiff has adequately alleged that the hip implant system contained defects that caused complications, including the release of metal debris and ions into the plaintiff's bloodstream. However, as previously discussed, to the extent that plaintiff's claim is premised on the R3 Acetabular Liner's federally-approved design and use, such claim is preempted. See Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009).

III. CONCLUSION

For the foregoing reasons, the motion to dismiss is GRANTED in part and DENIED in part. Plaintiff's strict liability, implied breach of warranty, negligent design, and innocent and negligent misrepresentation claims based on the R3 Acetabular Liner are DISMISSED with prejudice on the basis of express preemption. Plaintiff's 'fraud-on-the-FDA" claims alleged in counts one and three are DISMISSED with prejudice on the basis of implied preemption. Plaintiff's breach of express warranty claims are DISMISSED without prejudice with leave to replead.

Within 21 days of this ruling's filing date, plaintiff should file her amended complaint consistent with this ruling.

Dated this _18__ day of July, 2015, at Bridgeport, Connecticut.

/s/Warren W. Eginton
Warren W. Eginton
Senior U.S. District Judge