UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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THERESA BURKETT,

Plaintiff,

-against-

SMITH & NEPHEW Gmbh, *et al.*,

Defendants.
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MEMORANDUM AND ORDER

CV 12-4895 (LDW) (ARL)

WEXLER, District Judge

Plaintiff Theresa Burkett ("Burkett") brings this products liability action against defendant Smith & Nephew, Inc. ("Smith & Nephew")[1] for personal injuries allegedly resulting from a defectively manufactured and designed medical device. Smith & Nephew moves to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Burkett opposes the motion.

I. BACKGROUND

A. Statutory Background and Preemption

1. The Medical Device Amendments

In 1976, the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, was amended by the Medical Device Amendments of 1976 ("MDA") to give the Food and Drug Administration ("FDA") the authority to regulate medical devices. *See generally* 21 U.S.C. § 360c *et seq.* The MDA's statutory scheme "imposed a regime of detailed federal oversight," *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1003 (2008), creating three levels of scrutiny to be

[1]In the complaint, Burkett also named non-U.S. companies Smith & Nephew GmbH and Smith & Nephew, PLC as defendants. However, she voluntarily dismissed these defendants.

applied to various medical devices before premarket approval ("PMA") may be granted, *see* 21 U.S.C. § 360c(a)(1). The highest level of scrutiny is applied to a device that is "purported or represented to be for a use in supporting 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. . . ." *Id.* § 360c(a)(1)(C)(ii). Such devices, deemed "Class III" medical devices, are subject to the MDA's PMA process, which is designed to "provide reasonable assurance" of the device's safety and efficacy. *See id.* The PMA process for a Class III medical device is a "rigorous" process that typically requires submission of a multivolume application that includes reports of safety and efficacy studies, an explanation of the device's components, and details regarding its manufacturing, packaging, and installation. *See id. generally* § 360e; *Riegel*, 128 S. Ct. at 1004. After the FDA grants PMA to a device, the manufacturer continues to have various reporting and post-approval obligations. For instance, the MDA prohibits the manufacturer from making changes in the design specifications, manufacturing processes or labeling of the medical device that would affect safety or effectiveness of the device, absent the FDA's further review and approval. *Riegel*, 128 S. Ct. at 1005 (citing § 360e(d)(6)(A)(i)). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing § 360e(d)(6); 21 C.F.R. § 814.39(c)). The reporting requirements include an obligation to inform the FDA of new clinical investigations or scientific studies, incidents of the device causing or contributing to death or serious injury, and malfunctions that would likely cause or contribute to death or serious injury. *Id.* (citing § 360i; 21 C.F.R. 830.50(a)). The FDA has the power to withdraw approval based on newly reported

data or existing information. *Id.* (citing § 360e(e)(1)).

2. Preemption

The MDA was passed in response to the introduction of sophisticated medical devices, the risks of which were not properly managed by state common-law tort systems. *See Riegel*, 128 S. Ct. at 1003. The MDA's comprehensive review process ensures the safety and efficacy of medical devices that were previously subject to a patchwork of state tort law. *See id.* To ensure uniformity in the safety and efficacy standards for such medical devices, the MDA includes an express preemption provision that provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to [medical devices covered by the MDA] any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device.

21 U.S.C. § 360k(a).

The Supreme Court in *Riegel* held that a plaintiff's state-law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of an FDA-approved medical device were preempted by the MDA. *Riegel*, 128 S. Ct. at 107-10. In its analysis, the Court focused on the MDA preemption provision barring the imposition of requirements that "are different from, or in addition to," requirements imposed by federal law. *See id.* at 1011. The Court observed that the MDA preemption provision does not bar a state from providing a damages remedy for claims premised on the violation of FDA regulations, because "the state duties in such a case 'parallel,'

rather than add to, federal requirements." *Id.* Thus, the Court left open a narrow class of state law claims, so-called "parallel" claims, for injuries alleged to have been caused by federally-regulated medical devices. *See In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (referring to narrow "back door" left open by *Riegel*), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

To determine whether a claim is preempted by the MDA, a court must first find that federal requirements are imposed on the particular medical device. *Riegel*, 128 S. Ct. at 1006. If so, the court must then determine whether the plaintiff's claim is based on a state requirement that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* Should that be case, the claim is preempted if the state requirement is "different from, or in addition to," the federal requirements. *Id.*

B. The Complaint

For purposes of this decision, the allegations of the complaint can be summarized as follows. On October 1, 2010, Burkett was implanted with an artificial hip containing an "R3 ceramic acetabular hip liner" ("R3 liner") manufactured by Smith & Nephew. Complaint ¶ 19. Three months earlier, the FDA determined that R3 liners manufactured at Smith & Nephew GmbH's plant in Tuttlingen, Germany were adulterated and were not being produced in conformity with Current Good Manufacturing Practices ("CGMPs") outlined in 21 C.F.R. § 820. *Id.* ¶ 24. The FDA specifically found that there was no process validation study to support the minimum and maximum settings being used to press titanium rings into the R3 liners. *Id.* ¶ 24. Smith & Nephew maintained that the R3 liners were suitable for use despite this shortcoming, and claimed that the problem had been corrected. *Id.* ¶ 26. On December 21, 2010, the FDA

issued a warning letter that rejected Smith & Nephew's response. *Id.* ¶ 28. Since then, Smith & Nephew has acknowledged that titanium rings in R3 liners were incorrectly installed due to inadequate quality controls, leading to increased risk of a liner fracture, and at a higher rate than expected. *Id.* ¶ 25. On March 10, 2011, Smith & Nephew issued a recall of R3 liners (including the liner implanted in Burkett) due to the risk of fracturing. *Id.* ¶ 29. On October 26 and November 30, 2011, Burkett underwent revision surgery to correct issues, including those involving the R3 liner and including "pistoning," difficulties in everyday activities, inability to engage in athletic activities, and/or pain. *Id.* ¶¶ 22, 30.

According to Smith & Nephew, Burkett mistakenly alleges that the R3 liner received approval as " 'substantially equivalent to legally marketed predicate devices' on March 3, 2009." Defendant Smith & Nephew Inc.'s Memorandum of Law in Support of Motion to Dismiss Plaintiff's Complaint and Jury Demand, at 3 n.2 (quoting Complaint ¶ 12). Burkett does not dispute, as Smith & Nephew asserts, that the R3 liner actually was granted FDA approval via the "supplemental" PMA process for use within one of Smith & Nephew's hip replacement systems, and was granted FDA approval on February 18, 2008. *Id.* at 2-3 & nn.2, 3; Declaration of Glenn S. Kerner in Support of Smith & Nephew Inc.'s Memorandum of Law in Support of Motion to Dismiss Plaintiff's Complaint and Jury Demand, Exh. A. As noted above, a manufacturer must receive supplemental PMA from the FDA for any changes, and the FDA evaluates the proposed changes "under largely the same criteria as an initial application." *Riegel*, 128 S. Ct. at 1005.

Burkett commenced this action, asserting nine state law claims: (1) strict liability – design defect; (2) strict liability – failure to warn; (3) strict liability – manufacturing defect; (4) negligence; (5) fraudulent misrepresentation; (6) breach of express warranty; (7) breach of

implied warranty; (8) violation of New York General Business Law ("GBL") §§ 349, 350-e; and (9) unjust enrichment.

Smith & Nephew moves to dismiss, arguing that Burkett's claims are preempted and inadequately pled. The parties have submitted the fully briefed motion as well as supplemental authorities.

II. DISCUSSION

A. Motion to Dismiss Standard

In *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544 (2007), the Supreme Court held that to avoid dismissal a plaintiff is required to plead enough facts "to state a claim for relief that is plausible on its face." *Id.* at 570; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678-80 (2009). While heightened factual pleading is not required, *Twombly* holds that a "formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555. On a motion to dismiss, the court must, as always, assume that all allegations in the complaint are true and draw all reasonable inferences in favor of the nonmoving party. *Plair v. City of New York*, 789 F. Supp. 2d 459, 463 (S.D.N.Y. 2011). However, the court must ensure that the complaint sets forth "enough facts to state a claim to relief that is plausible on its face." *Twombly,* 550 U.S. at 570; *see Ruston v. Town Bd. for Town of Skaneateles*, 610 F.3d 55, 57 (2d Cir. 2010). A pleading that does nothing more than recite the elements of a claim, supported by mere conclusory statements, is insufficient to "unlock the doors of discovery." *Iqbal,* 556 U.S. at 678. Rather, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679.

B. Disposition of the Motion

It is undisputed that the R3 liner is designated as a "Class III" medical device, and that it received PMA as safe and effective through the PMA process. The parties do not dispute that Burkett's claims are based on state requirements relating "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," making them subject to preemption. 21 U.S.C. § 360k(a)(2). Thus, the court must determine whether Burkett sufficiently pleads "parallel" claims.

Smith & Nephew argues that each claim is insufficiently pled under *Twombly* and *Iqbal* and that none of the claims state a parallel claim because each fails (1) to allege a violation of federal law that is specific to the device at issue, *i.e.*, the R3 liner; and/or (2) to tie the alleged violation to Burkett's purported injuries, *i.e.*, link the alleged injury to any purported manufacturing defect noted in the FDA's letter, or to any purported defect addressed by the voluntary recall. *See Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588-89 (E.D.N.Y. 2009) (to state parallel claim, complaint must allege violation of federal requirement that specifically refers to device at issue); *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *6 (N.D. Ga. Aug. 19, 2011) (to state parallel claim, complaint must causally link alleged violation to plaintiff's injury).

1. Strict Liability – Design Defect

Under New York law, "a design defect may be actionable under a strict products liability theory if the product is not reasonably safe." *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 256-57 (1995). "[A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in

its introduction into the stream of commerce." *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 479 (1980). Burkett argues that her design defect claim is based on Smith & Nephew's alleged failure to comply with federal laws *after* the FDA approved the design of the R3 liner. However, as Smith & Nephew argues, the complaint does not allege that Smith & Nephew altered the design of the device from the design approved by the FDA. Rather, Burkett's allegations regarding an FDA inspection and letter relate only to the *manufacture*, not to the FDA-approved *design*, of the R3 liner.[2] Moreover, Burkett does not link any purported violations of federal requirements to her alleged injury. Accordingly, Burkett's design defect claim is preempted by the MDA; therefore, it is dismissed.

2. Strict liability – Manufacturing Defect

Under New York law, "[t]o plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 129 (1981)). Burkett argues that her complaint sufficiently alleges a parallel claim for defective manufacture based on Smith & Nephew's post-PMA violation of federal law, namely, those laws applicable to post-approval surveillance and

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[2] *See* Complaint ¶ 23 ("'[T]he methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements . . . .'"); *id.* ¶ 25 ("[D]ue to inadequate quality controls, the titanium rings were pressed into the R3 liner with a higher force than specified for a number of batches."); *id.* ¶ 27 ("Smith & Nephew also said it returned the controls on the press used to manufacture the device to its proper settings . . . .").

manufacturing, specifically the CGMPs, leading to Burkett's injuries. Burkett maintains that her injuries were caused by the manufacturing defect noted in the FDA's letter and ultimately leading to Smith & Nephew's voluntary recall of the R3 liner.

Burkett's claim fails for at least two reasons. First, Burkett does not allege a violation of federal requirements specific to the R3 liner, the device at issue. Rather, she relies on violation of CGMPs, and argues that a parallel claim may be predicated on alleged violation of CGMPs, relying on cases such as *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436, 440-41 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 555-56 (7th Cir. 2010); *and Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156-60 (S.D.N.Y. 2011). However, this Court has rejected that reasoning, holding in *Ilarraza* that a parallel claim may not be predicated on alleged violation of CGMPs. *Ilarraza*, 677 F. Supp. 2d at 588. As this Court stated:

> Despite the sheer volume of the material upon which Plaintiff relies, he fails to state a parallel claim. This is because no regulation relied upon refers specifically to the medical device at issue here. Instead, each regulation cited is nothing more than a general statement of a CGMP's. It has been recognized that these standards "are intended to serve only as 'an umbrella quality system' providing 'general objectives' medical device manufacturers must seek to achieve." *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278-79 (E.D.N.Y.2009) (citations omitted); *accord In re Medtronic*, 592 F.Supp.2d at 1157 (referring to CGMP's as "simply too generic, standing alone, to serve as the basis for plaintiff's manufacturing defect claims"). These regulations are purposefully broad so as to apply to a broad range of medical devices. The regulations are to be tailored by each manufacturer of a device to apply to their particular safety and efficacy needs. *See id.* The intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim. Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various

> lawsuits. This would necessarily result in the imposition of standards that are "different from, or in addition to" those imposed by the MDA-precisely the result that the MDA preemption provision seeks to prevent. *Accord In re Medtronic*, 592 F. Supp. 2d at 1158; *see also Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 532, 2009 WL 4281389 *9 (S.D. Tex. 2009) (complaint dismissed on preemption ground where plaintiff set forth nothing more than conclusory allegations of wrongdoing). Accordingly, where, as here, a plaintiff relies on nothing more that [sic] CGMP's in support of a parallel cause of action, preemption bars the claim.

Ilarraza, 677 F. Supp. 2d at 588. Because Burkett's manufacturing defect claim is based on violation of generally applicable CGMPs, as opposed to federal requirements specific to the R3 liner, preemption bars the claim. *Id.*; *Horn v. Boston Scientific Neuromodulation Corp.*, 2011 WL 3893812, at *8-9 (S.D. Ga. Aug. 26, 2011); *Cenac v. Hubbell*, 2010 WL 4174573, at *4-5 (E.D. La. Oct. 21, 2010); *In re Medtronic*, 592 F. Supp. 2d at 1157-58; *see also Gale v. Smith & Nephew, Inc.*, 12 CV 3614 (VB), slip op. at 8-9 (Briccetti, J.) (S.D.N.Y. Sept. 13, 2013) ("[T]he Court finds plaintiff's allegations that [Smith & Nephew] violated generally applicable CGMPs, as opposed to requirements specific to the [medical device at issue], are insufficient to avoid federal pre-emption and thus plausibly state a claim.").

Moreover, Burkett fails to link the alleged violation to her purported injuries. As Smith & Nephew points out, Burkett's allegation of causation is not made in the *complaint*, but in her opposing brief, wherein she asserts that "[v]ery soon after the defective R3 liner was implanted in [her], it failed and fractured," and that the manufacturing defect noted in the FDA's letter and addressed by the voluntary recall is what "caused the device to fail." Plaintiff's Memorandum of Law in Opposition to Defendant Smith & Nephew, Inc.'s Motion to Dismiss Plaintiff's Complaint and Jury Demand ("Plaintiff's Mem."), at 10. The complaint alleges that Burkett

underwent revision surgery more than seven months after the alleged recall on March 10, 2011, "due to persistent difficulties with the R3 liner." Complaint ¶ 30. In this respect, Burkett allegedly experienced "problems" with the R3 liner "shortly after surgery," which problems included "pistoning"; "difficulties in everyday activities"; "inability to engage in athletic activities"; and/or "pain." Complaint ¶ 22. Burkett does not allege in the *complaint* that these "problems" resulted from the purported manufacturing defect that was the subject of the FDA's letter and ultimate recall. Because Burkett fails to tie the alleged violation to her purported injuries, her claim is preempted. *See Leonard*, 2011 WL 3652311, at *6.

Accordingly, Burkett's manufacturing defect claim is preempted by the MDA; therefore, it is dismissed.

3. Strict Liability – Failure to Warn

Under New York law, "[t]o prevail on a claim for negligent failure to warn, a plaintiff must demonstrate that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed. Appx. 8, 10 (2d Cir. 2011) (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998)). " 'A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.' " *Id.* (quoting *Liriano*, 92 N.Y.2d at 237). Smith & Nephew argues that Burkett's failure to warn claim is preempted because the claim seeks to hold it liable for failing to provide warnings above and beyond those specifically approved and required by the FDA as part of the PMA process. *See Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286-87 (E.D.N.Y. 2009). In response, Burkett argues that her complaint alleges a failure to warn claim

based on Smith & Nephew's post-PMA violation of federal law, namely, the PMA's specific monitoring and reporting requirements, leading to Burkett's injuries. To the extent that Burkett alleges that Smith & Nephew failed to warn of an unapproved alteration in the R3 liner occurring in the manufacturing process in violation of PMA requirements applicable to the R3 liner, such claim arguably would not be based on a state requirement that "is 'different from, or in addition to,' federal requirements," and would not be preempted; *See Messner v. Medtronic*, 975 N.Y.S.2d 367 (Table), 2013 WL 1688886, at *11 (N.Y Sup. Ct., Richmond County Apr. 9, 2013). However, Burkett does not sufficiently reference federal requirements or regulations related to adequate warnings, let alone specific to the R3 liner, and she fails to link the purported violation to her injury. Thus, the complaint does not sufficiently plead a parallel claim for failure to warn. Accordingly, Burkett's failure to warn claim is preempted by the MDA; therefore, it is dismissed.

4. Negligence

Under New York law, to state a claim for negligence, a plaintiff must show: "(1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d at 82 (citing *McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997)). Smith & Nephew argues that Burkett fails to allege a parallel claim of negligence. To the extent that Burkett's negligence claim sounds in defective design, it is preempted and dismissed, as the complaint does not allege that Smith & Nephew altered the design of the device from the design approved by the FDA. To the extent that

Burkett's negligence claim sounds in manufacturing defect, it is preempted and dismissed, as Burkett does not sufficiently allege that a particular violation of a federal requirement specific to the R3 liner led to her injuries. To the extent that Burkett's negligence claim sounds in failure to warn, she does not sufficiently reference federal requirements or regulations related to adequate warnings, let alone those specific to the R3 liner, and she fails to link the purported violation to her injury. Thus, the complaint does not sufficiently plead a parallel claim for negligent failure to warn and it is dismissed.

5. Fraudulent Misrepresentation

Under New York law, to state a claim for fraud, a plaintiff must establish "(1) a material misrepresentation or omission of fact (2) made by defendant with knowledge of its falsity (3) and intent to defraud; (4) reasonable reliance on the part of plaintiff; and (5) resulting damage to the plaintiff." *Crigger v. Fahnestock & Co.*, 443 F.3d 230, 234 (2d Cir. 2006). Burkett maintains that her fraud claim is based on Smith & Nephew's "failure to notify [her] and her physicians that the R3 liner implanted in her was adulterated because of [Smith & Nephew's] violations of federal law, despite knowing that the R3 liner was in fact adulterated and would fail and fracture at a higher rate." Plaintiff's Mem. at 20 (citing Complaint ¶¶19-37; 79-89). However, as Smith & Nephew argues, Burkett does not sufficiently reference federal requirements or regulations related to a device manufacturer's representations, let alone those specific to the R3 liner, and she fails to link the purported violation of federal law to her injury. Thus, the complaint does not sufficiently plead a parallel claim for fraudulent misrepresentation.

Moreover, as Smith & Nephew argues, Burkett has not provided enough factual support for her allegations under the heightened pleading standard in Fed. R. Civ. 9(b). As Burkett

acknowledges, where a claim is premised on fraudulent omission, so that the plaintiff cannot specify the time and place of the alleged fraudulent statements because no affirmative act occurred, the plaintiff must still allege " '(1) what the omissions were (2) the person responsible for the failure to disclose; (3) the context of the omissions and the manner in which they misled the plaintiff; and (4) what the defendant obtained through the fraud.' " *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011) (quoting *Manhattan Motorcars, Inc. v. Automobili Lamborghini, S.p.A.*, 244 F.R.D. 204, 213 (S.D.N.Y.2007)). Burkett's allegations of fraudulent omission "lack specifically plead[ed] events which give rise to a strong inference that the defendant[] had an intent to defraud, knowledge of falsity, or a reckless disregard of the truth," *Fagan v. Amerisource Bergen Corp.*, 356 F. Supp. 2d 198, 218 (E.D.N.Y. 2004) (internal quotation marks omitted), and fail to plead "when and how the omitted material information should or could have been revealed . . . as required under Rule 9(b)," *Kubicki ex rel. Kubicki v. Medtronic*, 2013 WL 1739580, at *12 (D.D.C. Mar. 21, 2013).

Accordingly, Burkett's fraudulent misrepresentation claim is preempted by the MDA and inadequately plead; therefore, it is dismissed.

6. Breach of Express Warranty

Under New York law, "[t]o state a claim for breach of express warranty, the plaintiff must show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon.' " *Gelber*, 788 F. Supp. 2d at 165 (quoting *Schimmenti v. Ply Gem Indus., Inc.*, 549 N.Y.S.2d 152, 154 (2d Dep't 1989)). Smith & Nephew argues that Burkett fails to state a parallel claim for breach of express warranty because the claim is not based on any violation of federal law concerning

advertisements, labeling, marketing, and promotion. As Smith & Nephew notes, the complaint merely alleges that Smith & Nephew "advertised, labeled, marketed and promoted" the R3 liner as "safe and effective," when, conversely, it was not safe and effective. Complaint ¶¶ 91, 93. To the extent that Burkett's claim is based on FDA-approved representations, it is preempted. *See Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 205-06 (W.D.N.Y. 2011); *Horowitz*, 613 F. Supp. 2d at 285. However, Burkett argues that the claim is premised on express warranties in Smith & Nephew's advertising and promotional materials that "may not have required or obtained FDA approval." Plaintiff's Mem. at 22. Notwithstanding Burkett's argument, the complaint fails to identify these alleged "advertising and promotional materials" or specific representations exceeding the scope of FDA-approved statements. *See Horowitz*, 613 F. Supp. 2d at 285. Thus, the complaint does not sufficiently plead a parallel claim for breach of express warranty.

Moreover, with no identification of the alleged "advertising and promotional materials," Burkett's claim is likewise insufficiently pled under the *Twombly* and *Iqbal* pleading standards. *See id.*; *Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, at *5 (S.D.N.Y. Apr. 24, 2013).

Accordingly, Burkett's breach of express warranty claim is preempted by the MDA and inadequately plead; therefore, it is dismissed.

7. Breach of Implied Warranty

Under New York law, "to recover under a breach of implied warranty of merchantability claim plaintiff must establish that the [product] was not 'reasonably fit for the ordinary purpose for which it was intended.' " *Horowitz*, 613 F. Supp. 2d at 284 (quoting *Denny*, 87 N.Y.2d at 265). Again, Burkett's claim does not sufficiently allege that a particular violation of federal law

applicable to the R3 liner led to her injuries. Accordingly, Burkett's claim is preempted by the MDA; therefore, it is dismissed.

8. Violation of New York General Business Law §§ 349, 350-e

"To make out a prima facie case under [GBL § 349], a plaintiff must demonstrate that (1) the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured as a result." *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000). Burkett's consumer protection claim is based on theories of failure to warn and false representations. Here again, Burkett's claim does not sufficiently allege that a particular violation of federal law applicable to the R3 liner led to her injuries. Accordingly, Burkett's claim for violation of GBL § 349 is preempted by the MDA; therefore, it is dismissed.

9. Unjust Enrichment

To state a claim for unjust enrichment under New York law, a plaintiff must allege "that (1) the other party was enriched, (2) at that party's expense, and (3) that it is against equity and good conscience to permit the other party to retain what is sought to be recovered." *Campione v. Campione*, 942 F. Supp. 2d 279, 283 (E.D.N.Y. 2013). Burkett's unjust enrichment claim alleges that she "expected that the R3 liner was safe and medically effective," and that the "failure of [Smith & Nephew] to provide [Burkett] with the remuneration expected enriched [Smith & Nephew] unjustly." Complaint ¶¶ 113-114. Once again, Burkett's claim does not sufficiently allege that a particular violation of federal law applicable to the R3 liner led to her injuries. Accordingly, Burkett's claim for unjust enrichment is preempted by the MDA; therefore, it is dismissed.

C. Leave to Amend

Burkett requests leave to amend should the Court find "that insufficient facts have been alleged to support any or all" of her claims. Plaintiff's Mem. at 25. Upon consideration, the Court grants leave to amend.

III. CONCLUSION

For the above reasons, Smith & Nephew's motion to dismiss is granted without prejudice to Burkett's right to file an amended complaint within 60 days from the date of this order.

SO ORDERED.

/s/
LEONARD D. WEXLER
UNITED STATES DISTRICT JUDGE

Dated: Central Islip, New York
March 31, 2014