UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUSAN SIMON, Plaintiff,	:	13 Civ. 1909 (PAE)
-v-	:	OPINION & ORDER
SMITH & NEPHEW, INC., Defendant.	:	

PAUL A. ENGELMAYER, District Judge:

In her Amended Complaint, plaintiff Susan Simon alleges that defendant medical device manufacturer Smith & Nephew, Inc. ("Smith & Nephew") designed, manufactured, and distributed the REFLECTION 3 Acetabular System ("R3 Acetabular System") and the optional metal liner component used in her hip replacement surgery, that the devices were defective, and that they caused her injury. Dkt. 23 ("Am. Compl."). On December 3, 2013, this Court issued an Opinion & Order, granting Smith & Nephew's motion to dismiss the Amended Complaint in its entirety. *See* Dkt. 35 ("December 3 Opinion" or "Opinion"). The Court assumes familiarity with the Opinion. Relevant here, the Court dismissed Simon's negligence, strict products liability, and breach of implied warranty claims against Smith & Nephew on the grounds that they are preempted and otherwise fail to state a claim upon which relief can be granted. *See* Opinion 9–17. On December 19, 2013, Simon moved for reconsideration of that decision. *See* Dkt. 41. For the reasons that follow, Simon's motion for reconsideration is denied.

I. Background

For purposes of addressing this motion, the Court briefly reviews the relevant regulatory framework and history, subjects which the December 3 Opinion addresses in greater detail.

The Medical Devices Amendments of 1976 ("MDA"), 21 U.S.C. § 360c, *et seq*., establishes "various levels of oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008). Devices that are primarily used for "supporting or sustaining human life" or that "present[] a potential unreasonable risk of illness or injury" are designated Class III devices. 21 U.S.C. § 360c(a)(1)(C). Class III devices are subjected to the highest level of oversight, and must receive premarket approval ("PMA") from the Food & Drug Administration ("FDA") before being placed on the market. *See id*. Most devices are not submitted for PMA approval. Instead, most come to market through the § 510(k) process, by which the FDA grants approval based on "substantial[] equivalen[ce]" to devices that are already on the market. *See Riegel*, 552 U.S. at 317.

As the Supreme Court held in *Riegel*, PMA approval for a particular device triggers the MDA's express preemption clause[1]; thus, state common-law tort claims are expressly preempted to the extent that they (1) relate to the safety and effectiveness of a PMA-approved device; and (2) impose standards "different from, or in addition to" federal requirements. *See Riegel*, 552 U.S. at 321–30. However, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330; *see Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 153 (S.D.N.Y. 2011).

II. Legal Standards

The standard governing motions for reconsideration under S.D.N.Y. Local Civil Rule 6.3 "is strict, and reconsideration will generally be denied unless the moving party can point to

[1] *See* 21 U.S.C. § 360k(a) (preempting any state requirement "which is different from, or in addition to, any requirement applicable . . . to the device [under federal law]," and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device [under federal law]").

controlling decisions or data that the court overlooked—matters, in other words, that might reasonably be expected to alter the conclusion reached by the court." *Shrader v. CSX Transp. Inc.*, 70 F.3d 255, 257 (2d Cir. 1995). Such a motion is "neither an occasion for repeating old arguments previously rejected nor an opportunity for making new arguments that could have previously been made." *Associated Press v. U.S. Dep't of Def.*, 395 F. Supp. 2d 17, 19 (S.D.N.Y. 2005); *see also Goonan v. Fed. Reserve Bank of N.Y.*, No. 12 Civ. 3859 (JPO), 2013 WL 1386933, at *2 (S.D.N.Y. Apr. 5, 2013) ("Simply put, courts do not tolerate such efforts to obtain a second bite at the apple."). On a Local Rule 6.3 motion, "a party may not advance new facts, issues, or arguments, not previously presented to the Court." *Polsby v. St. Martin's Press*, No. 97 Civ. 690 (MBM), 2000 WL 98057, at *1 (S.D.N.Y. Jan. 18, 2000) (citation omitted). Generally, district courts will only amend or alter a judgment "to correct a clear error of law or prevent manifest injustice." *In re Assicurazioni Generali, S.P.A.*, 592 F.3d 113, 120 (2d Cir. 2010).

III. Motion for Reconsideration

In the Amended Complaint, Simon brings strict liability, negligence, and breach of implied warranty claims under New York law against Smith & Nephew based on injuries sustained following hip replacement surgery. In her surgery, Simon was implanted with the Smith & Nephew-designed R3 Acetabular System, which had received § 510(k) approval, and was also implanted with an optional metal liner that was not part of that system, but which had received supplemental PMA approval in connection with a separate PMA-approved device, the Birmingham Hip Resurfacing ("BHR") System. The Amended Complaint alleges that her hip prosthesis was defective, and caused her injuries.

Familiarity with the Opinion is assumed. There, the Court concluded that Simon's state-law causes of action are preempted because the metal liner implanted during her surgery had been PMA-approved, and the Amended Complaint "does not allege that Smith & Nephew took any act to design an R3 Acetabular System to contain an optional metal liner component," nor does it allege "that Smith & Nephew encouraged medical personnel to use the optional metal liner component from the BHR System in conjunction with the R3 Acetabular System." *Id.* at 10−11. Thus, the Amended Complaint "does not allege facts that plausibly indicate that a non-PMA approved device was defective and caused [Simon's] injuries." *Id.* at 14.

The Court further concluded that, to the extent Simon's claims are not preempted, they fail to state a claim. With respect to the strict products liability claim, the Court noted that the Amended Complaint fails to allege that Smith & Nephew designed or marketed the R3 Acetabular System to include the metal liner designed for the separate BHR System; thus, the "the Amended Complaint does not allege any facts that could plausibly indicate that a Smith & Nephew product, *as designed*, was defective and caused her injuries." *Id.* at 11. Specifically, the Court noted that, in describing the alleged defect—*i.e.* the "metal on metal" interaction between the metal liner and components of the R3 Acetabular System—the Amended Complaint "describes the R3 Acetabular System in a manner flatly inconsistent with that system as defined and approved by the FDA"; the FDA approval papers for that system nowhere mention the metal liner from the separate BHR system that Simon alleges was implanted during her surgery; and the Amended Complaint lacks concrete allegations tying Smith & Nephew with a later decision (presumably made by on-scene medical personnel) to use the metal liner in conjunction with the R3 Acetabular System. *Id.* at 10. The allegation of a feasible alternative design was similarly ill-pled, the Court held: "The Amended Complaint states that Smith & Nephew could have

designed a hip replacement system that did not create metal-on-metal interactions, and such a design would have been safer. . . . But, as explained, the R3 Acetabular System as designed did not create metal-on-metal interactions involving the optional metal liner." *Id.* at 11−12.

For substantially the same reasons, the Court concluded that Simon's negligence and breach of implied warranty claims fail to state a claim: The Amended Complaint did not allege facts plausibly indicating that the R3 Acetabular System, as designed by Smith & Nephew, was defective and caused her injuries. *Id.* at 14, 16, 17. The boilerplate allegations in the Amended Complaint were insufficient to tie Smith & Nephew to the decision to include the metal liner from the BHR System in the separate R3 Acetabular System implanted during Simon's surgery.

In seeking reconsideration, Simon simply repeats arguments already considered and rejected by the Court. Specifically, she argues that the Court overlooked allegations in the Amended Complaint that Smith & Nephew in fact designed the R3 Acetabular System to include the metal liner component. *See* Memorandum of Law in Support of Motion for Reconsideration (Dkt. 43) ("Pl. Br.") at 4−8. In the words of Judge Rakoff, however, "[t]he Court did not overlook this argument; it rejected it." *Associated Press*, 395 F. Supp. 2d at 19. As explained in the December 3 Opinion and recited above, the Amended Complaint does not make any specific, concrete allegation as to Smith & Nephew's ostensible role in causing the metal liner from the BHR System to be used in connection with the R3 Acetabular System during Simon's surgical procedure. Thus, Simon fails to plausibly allege that any non-PMA approved Smith & Nephew product, *as designed*, was defective and caused her injuries. *See* Opinion at 11. Simon fails to point to any facts the Court overlooked that would warrant reconsideration of this conclusion. *See Goonan*, 2013 WL 1386933, at *2 (denying motion for reconsideration on the ground that it

"appears to be little more than an effort to re-litigate an issue that the Court has already decided").

Even if reconsideration were warranted, however, Simon's argument is unconvincing on the merits, for several reasons. First, as already noted, the Amended Complaint lacks allegations concretely stating that Smith & Nephew designed or marketed the R3 Acetabular System so as to contemplate or encourage use of the metal liner. To be sure, the Amended Complaint states that Smith & Nephew "introduce[d]" the liner for use with the R3 Acetabular System, Am. Compl. ¶ 26; but the use of this one spare verb does not constitute an explicit allegation that Smith & Nephew marketed the metal liner component that had been approved in connection with the BHR System for use with the separate R3 Acetabular System. Nor does the allegation that Smith & Nephew "released an urgent field safety notice . . . for the optional metal liner components of the R3 Acetabular System," *id*. ¶ 44, demonstrate that Smith & Nephew designed the R3 Acetabular System to include the metal liner. At best, the Amended Complaint can be read to make the conclusory statement that, in some unknown and unexplained manner, Smith & Nephew caused the metal liner to be used with that separate system. Without additional factual amplification, these vague and conclusory allegations are insufficient to survive a motion to dismiss. *See Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 333−34 (S.D.N.Y. 2011) (on motion to dismiss, "the Court accepts all factual allegations as true, but it does not credit 'mere conclusory statements'") (citation omitted); *see also Goldin v. Smith & Nephew, Inc.*, No. 12 CV 9217 (JPO), 2013 WL 1759575, at *7 (S.D.N.Y. April 24, 2013) (dismissing strict products liability, negligence, and other claims "base[d] . . . primarily on Plaintiff's failure to allege non-conclusory facts in support of its claims").

Second, even assuming that the Amended Complaint plausibly alleged that Smith & Nephew had designed or marketed the metal liner component for use with the R3 Acetabular System, Simon's claims would still be dismissed as preempted. In determining whether claims relating to the safety and effectiveness of an FDA-approved device are preempted by the MDA, "the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable 'to the *device.*'" *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009); *accord Bertini v. Smith & Nephew, Inc.*, No. 13 Civ. 0079 (BMC), 2014 WL 1028950, at *6 (E.D.N.Y. March 17, 2014). Here, the Amended Complaint alleges that Simon's injuries were caused by the "metal-on-metal" interaction between the metal liner component and the R3 Acetabular System's femoral head component, *see* Am. Compl. ¶¶ 62, 63, 65. Thus, the gravamen of the Amended Complaint is that her injuries were caused by the metal liner. Indeed, when pressed at argument, Simon's counsel flatly stated that the optional metal liner *itself* was the source of Simon's injury:

> MS. POMERANTZ: Plaintiff's ultimate contention was that it was that optional metal liner component that [was] used [that caused] the injuries to plaintiff.
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> . . .
>
> THE COURT: Let me see if I have you right. . . . Plaintiff's contention in the amended complaint is that it is the optional metal liner that caused the injury[?]
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> MS. POMERANTZ: Correct.
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> THE COURT: Not its interplay with the femoral head?
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> MS. POMERANTZ: Correct.
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> THE COURT: To be clear, your theory of liability here flows from the optional metal liner, not from the interplay of the optional metal liner and the femoral metal head, is that correct?
>
> MS. POMERANTZ: Yes.

Transcript of November 8, 2013 Oral Argument 25−26 (Dkt. 37). Whether Simon's injuries are understood to have resulted from that liner alone (as counsel clarified at argument), or from use of that liner in combination with other components of the R3 Acetabular System (as the Amended Complaint appeared to allege), the metal liner is at the heart of each and every one of Simon's claims. Thus, Simon's claims are preempted.

In *Bertini v. Smith & Nephew, Inc.*, Judge Cogan faced the identical issue. During a hip replacement surgery, Bertini had been implanted with a Smith & Nephew-designed R3 Acetabular System that utilized the R3 metal liner approved for use with the BHR System. Plaintiffs brought, *inter alia*, strict liability, negligence, breach of warranty claims against Smith & Nephew, alleging that the interaction between the metal liner and other components of the R3 Acetabular System caused his injuries. *See* 2014 WL 1028950, at *4−*5. Smith & Nephew moved to dismiss on the ground that the MDA preempted plaintiffs' claims. In response, plaintiffs argued that their claims were not preempted because "although the R3 metal liner was approved through the PMA process, it was only approved for use with the BHR System," whereas Smith & Nephew had allegedly "marketed the R3 metal liner to be used with the R3 System," which had not been PMA-approved. *Id.* at *6. Judge Cogan rejected that argument: "[P]reemption analysis is not concerned with how a particular device is *used* or whether there are federal requirements imposed on a particular *use* of the device. Rather, preemption is focused on whether there are federal requirements applicable to the device itself." *Id.* (emphases added).

The court then proceeded to the preemption analysis, mindful that the inquiry focused on the device as a whole, rather than its individual components. Because the PMA-approved metal liner was "the main focus of plaintiffs' Complaint" and was necessary to each of their claims, however, the court determined 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 that claim." *Id.* at *5. Separately analyzing plaintiffs' strict liability, negligence, breach of warranty, and other state-law claims, the court held each was preempted, or that it otherwise failed to state a claim. *See id.* at *5−*12.

The same is true here. Simon's strict liability, negligence, and breach of implied warranty claims all allege that the metal liner, alone or in conjunction with other components of the R3 Acetabular System, caused her injuries. Simon does not allege that the R3 Acetabular System alone, *i.e.*, independent of the metal liner, caused her injuries. The Court thus reaffirms its prior holding that Simon's claims are preempted, or otherwise fail to state a claim on which relief can be granted. Simon has given no reason for the Court to alter this conclusion. The dismissal of the Amended Complaint stands.

IV. Request for Leave to Amend or Additional Discovery

Simon also requests leave to amend her pleadings to add additional facts regarding Smith & Nephew's role in introducing the metal liner component for use with the R3 Acetabular System, or in the alternative a stay to allow for limited discovery as to whether her physician independently chose to implant the metal liner during her surgery. *See* Pl. Br. 9−10.

Federal Rule of Civil Procedure 15(a)(2) provides that leave to amend a complaint shall be "freely" given when "justice so requires." However, "'[i]t is within the sound discretion of the district court to grant or deny leave to amend.'" *Barbata v. Latamie*, No. 11 Civ. 7381 (DLC), 2012 WL 1986981, at *2 (S.D.N.Y. June 4, 2012) (quoting *Green v. Mattingly*, 585 F.3d 97, 104 (2d Cir. 2009)). The Supreme Court has directed courts to grant leave to amend under Rule 15 in the absence of factors "such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue

prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200–01 (2d Cir. 2007). "An amendment to a pleading will be futile if a proposed claim could not withstand a motion to dismiss pursuant to Rule 12(b)(6)." *Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002).

Simon's proposed amendment would be futile. For the reasons explained above, even assuming Smith & Nephew is responsible for introducing the metal liner component for use with the R3 Acetabular System, state-law claims focusing on the PMA-approved metal liner are preempted. All of Simon's claims rely on the metal liner to establish causation; Simon's proposed amendment would not address this deficiency. Denial of leave to amend under such circumstances does not amount to a "manifest injustice."

For substantially the same reasons, Simon's dilatory request for additional discovery is also denied. Simon has not identified any information that could be obtained regarding her physician's decision to use the metal liner component, or Smith & Nephew's ostensible role in that decision, that would alter the Court's preemption analysis. Additional discovery on this score would not be fruitful.

CONCLUSION

For the foregoing reasons, the motion for reconsideration is denied, as are Simon's requests for leave to amend and additional discovery. The Clerk of Court is directed to terminate the motion pending at docket number 41. This case remains closed.

SO ORDERED.

Paul A. Engelmayer

Paul A. Engelmayer
United States District Judge

Dated: March 26, 2014
New York, New York