UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDITH RINCON, Plaintiff, -v- COVIDIEN and MEDTRONIC, INC., Defendants.	16-CV-10033 (JMF) MEMORANDUM OPINION AND ORDER

JESSE M. FURMAN, United States District Judge:

Plaintiff Judith Rincon sues Defendant Medtronic, Inc., also denominated as Covidien (herein referred to as "Medtronic"), for injuries she allegedly sustained as a result of hernia repair surgery involving the use of Covidien Parietex Composite ("PCO") mesh on October 6, 2006. (Docket No. 15 ("Am. Compl.") ¶ 33). Over six years later, in August 2012, Rincon returned to the hospital and was diagnosed with an abdominal wall infection, which required further surgery. (*Id.* ¶ 35). More than a year after that, in November 2013, Rincon was diagnosed with another abdominal wall infection that required removal of the PCO mesh and another hernia repair. (*Id.* ¶ 36). Rincon asserts several causes of action against Medtronic: negligence (Am. Compl. ¶¶ 1-46), strict product liability (*id.* ¶¶ 47-58), and failure to warn. (*Id.* ¶¶ 59-71). Defendants now move, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss Rincon's Amended Complaint. (Docket No. 31).

When reviewing a motion to dismiss the Court "must accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." *LaFaro v. N.Y. Cardiothoracic Grp., PLLC,* 570 F.3d 471, 475 (2d Cir. 2009) (internal quotation marks omitted). The Court will not dismiss any claims pursuant to Rule 12(b)(6) unless the plaintiff

has failed to plead sufficient facts to state a facially plausible claim to relief. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To state a plausible claim, Plaintiff must provide "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" — a standard that requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. If Plaintiff has not "nudged [her] claims across the line from conceivable to plausible, [his claims] must be dismissed." *Id.* at 570.

Applying those standards here, Rincon's claims plainly fail as a matter of law. Under New York law, which the parties agree applies to this case (*compare, e.g.*, Docket No. 36 ("Rincon Opp'n"), at 5 *with* Docket No. 33 ("Medtronic Mem."), at 6), all of Rincon's claims require her to prove that the PCO mesh caused her injuries. *See Goldin v. Smith & Nephew, Inc.*, No. 12-CV-9217 (JPO), 2013 WL 1759575, at *2-6 (S.D.N.Y. Apr. 24, 2013) (reciting standards under New York law for all three of Rincon's theories of liability); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 574-80 & n.6 (E.D.N.Y. 2012) (same). Ignoring conclusory assertions and the recitation of legal standards, however, Rincon fails to allege any facts that plausibly establish such causation. In fact, only three allegations in Rincon's Complaint can be construed as facts: that she had a hernia repair surgery using PCO mesh on October 6, 2006; that six years later, in August 2012, she developed an abdominal wall infection; and that, in November 2013, she underwent a second hernia repair surgery due to an abdominal wall infection, during which the PCO mesh from her first surgery was removed. (Am. Compl. ¶¶ 33, 35, 36). Taken together, these facts — even liberally construed (not that there is a basis for liberal construction here) — fall far short of demonstrating that Medtronic's mesh was a "but for" cause of Rincon's later injuries. *See Goldin*, 2013 WL 1759575, at *2, *6, (requiring proof that a defendant's defective

product or failure to warn was "the proximate cause" of the plaintiff's injuries to sustain these theories of liability). Indeed, as Medtronic observes, there are several plausible explanations for Rincon's medical problems in 2012 and 2013: "(1) natural complications flowing from [Rincon's] hernia disease; (2) the development of a completely new hernia years after [her] October 6, 2006 hernia repair surgery that caused the abdominal wall infections . . .; (3) natural complications flowing from unrelated co-morbidities or adverse health conditions; or (4) alleged problems associated with Medtronic's mesh." (Medtronic Mem. 5). Nothing in the Amended Complaint even endeavors to explain why the mesh is a more likely, let alone proximate, cause of Rincon's alleged harms. In the final analysis, therefore, Rincon offers only the sort of "[t]hreadbare recital[] of the elements of a cause of action, supported by mere conclusory statements," that the Supreme Court has made clear is insufficient to survive a motion to dismiss. *Iqbal*, 556 U.S at 678; *see also Rodman v. Stryker Sales Corp.*, 14-CV-1102 (JMF), 2014 WL 5002095, at *1-3 (S.D.N.Y. Oct. 7, 2014) (granting a motion to dismiss under almost identical circumstances on the ground that the plaintiff's claims regarding an allegedly defective coating on his hip implant were wholly conclusory); *Bertini v. Smith & Nephew, Inc.*, No. 13-CV-0079 (BMC), 2013 WL 6332684, at *2 (E.D.N.Y. July 15, 2013) (similar); *Goldin*, 2013 WL 1759575, at *2-6 (similar).

In any event, Rincon's claims fail for another reason. Under New York law, Rincon must prove the existence of a defect (in either the product or, for her failure to warn theory, in Medtronic's warnings about the product) to prevail on all her claims. *See Goldin*, 2013 WL 1759575, at *2-6; *Reed*, 839 F. Supp. 2d at 574-80 & n.6. But Rincon fails to allege a defect except in the most conclusory terms: that Medtronic manufactured the PCO mesh (Am. Compl. ¶¶ 31-32), that the mesh was used during her hernia surgery in 2006 (*id.* ¶¶ 33-34), that she needed subsequent medical procedures in 2012 and 2013 (*id.* ¶¶ 35-36), and thus Medtronic must

not have "properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided [] the proper warnings" regarding the mesh. (*Id.* ¶ 39). In her opposition to Medtronic's motion, Rincon for the first time raises the specter of a defect — specifically, that the mesh was manufactured defectively because it used "an absorbable hydrophilic film (coating) intended to keep the mesh from adhering to the patient's bowel" and that this coating, upon information and belief, "makes infections much more likely" and is "nearly impossible to be fully removed." (Rincon Opp'n 5). It is well established, however, that a plaintiff may not amend his or her complaint "by asserting new facts or theories for the first time in opposition to . . . [a] motion to dismiss." *K.D. ex rel. Duncan v. White Plains Sch. Dist.*, 921 F. Supp. 2d 197, 209 n.8 (S.D.N.Y. 2013). If anything, therefore, Rincon's allegations with respect to the hydrophilic coating serve only to illustrate the deficiencies in her Amended Complaint — namely, that it does not identify any actual defect in the coating and says nothing about *how* the coating, even if defective, caused Rincon's specific injuries.

In short, Rincon's failure to allege the existence of a defect (in the product and in Medtronic's warnings about the product), much less support it with facts sufficient to "nudge[] [the] claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, is fatal to the Amended Complaint's ability to survive a motion to dismiss. *See, e.g.*, *Rodman*, 2014 WL 5002095, at *2-3 (granting a motion to dismiss for similar reasons); *Bertini*, 2013 WL 6332684, at *2-6 (same); *Goldin*, 2013 WL 1759575, at *2-7 (same); *Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-CV-8357 (BSJ) (HBP), 2010 WL 5480775, at *2 (S.D.N.Y. Dec. 30, 2010) ("Plaintiffs do not, however, specify the actual defective component or the nature of the defect. . . . In light of the lack of specificity, the Court may not draw a 'reasonable inference that the defendant is liable for the misconduct alleged' as required by *Twombly* and *Iqbal*.").

Accordingly, Defendants' motion to dismiss is GRANTED, and Plaintiff's Amended Complaint is dismissed in its entirety.

One question remains: whether Rincon should be permitted to amend her Amended Complaint again, as she suggests (albeit does not quite request) in her opposition brief. (*See* Rincon Opp'n 7 ("Whether the details of this particular claim is not [sic] articulated well enough in the amended complaint, . . . this court surely can permit plaintiff to amend her complaint . . . ."). Although courts "should freely give leave when justice so requires," Fed. R. Civ. P. 15(a)(2), a court need not grant leave to amend when further amendment would be futile, *see, e,g.*, *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) (stating that "[l]eave to amend may properly be denied if the amendment would be futile, as when the proposed new pleading fails to state a claim on which relief can be granted" (citation omitted)); *McBeth v. Porges*, 171 F. Supp. 3d 216, 235 (S.D.N.Y. 2016) (denying the plaintiff's request for leave to amended as futile because he had "already amended his complaint in an attempt to cure the deficiencies raised in [the d]efendants' initial motion to dismiss — a motion that, notably, was substantially identifical to" the second motion to dismiss). Here, even if Rincon were to add her new "facts" relating to the hydrophilic coating, her claims would all still fail for the reasons discussed above. Her request for leave to amend, to the extent one was made, is thus denied on futility grounds.

The Clerk of Court is directed to terminate Docket No. 31 and to close the case.

SO ORDERED.

Date: May 22, 2017
New York, New York

JESSE M. FURMAN
United States District Judge