UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KAREN GREEN,

Plaintiff,

- against -

COVIDIEN LP,

Defendant.

ORDER

18 Civ. 2939 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

In this action, Plaintiff Karen Green asserts claims for strict products liability, negligence, breach of warranty, fraudulent misrepresentation, negligent misrepresentation, unjust enrichment, and consumer fraud against Defendant Covidien LP. Green alleges that she suffered injuries after her physician used Defendant's Symbotex Composite Mesh (hereinafter, "Symbotex Mesh") to repair a hernia. Defendant has moved to dismiss the Second Amended Complaint ("SAC") pursuant to Fed. R. Civ. P. 12(b)(6). (Dkt. No. 28) For the reasons stated below, Defendant's motion will be granted.

BACKGROUND

I. FACTS

On March 4, 2016, Plaintiff underwent a laparoscopic hernia repair procedure. (SAC (Dkt. No. 25) ¶ 58) "A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle [or] connective tissue." (Id. ¶ 21) Hernias can be treated surgically, and hernia repair surgeries are common in the United States. (Id. ¶¶ 24-25) Surgical mesh is surgically "introduced to the hernia site to strengthen the repair, in hopes of reducing the likelihood of recurrence." (Id. ¶¶ 26-27)

During Plaintiff's March 4, 2016 hernia repair procedure, her surgeon used Symbotex Mesh – which is "designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed" by Defendant – to repair the hernia. (Id. ¶¶ 35, 58-59) On March 13, 2016, Plaintiff underwent a second surgery to investigate "complaints of abdominal pain, possible adhesions, partial small bowel obstruction[,] and infected abdominal wall mesh." (Id. ¶ 60) During this second procedure, the mesh product that had been implanted in Plaintiff "was revised and adhesions[1] were taken down." (Id. ¶ 61)

Plaintiff alleges that the implantation of Symbotex Mesh in her body has resulted in "the risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries, and other complications." (Id. ¶ 63)

II. PROCEDURAL HISTORY

The Complaint was filed on March 8, 2018, in Supreme Court of the State of New York, New York County. (Notice of Removal (Dkt. No. 1); Cmplt. (Dkt. No. 1-1)) On April 3, 2018, Defendant removed the case to this District on the basis of diversity jurisdiction. (Id.)

The Amended Complaint was filed on July 26, 2018, and asserts claims for (1) strict products liability premised on defective design, defective manufacturing, and failure to warn; (2) negligence; (3) breach of implied warranty; (4) fraudulent and negligent misrepresentation; (5) unjust enrichment; and (6) violations of New York General Business Law ("GBL"), Sections 349 and 350. (Am. Cmplt. (Dkt. No. 14)) On August 17, 2018, Defendant moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). (Dkt. Nos. 18-19) This Court granted

[1] An adhesion is "scar-like tissue that sticks tissues together." Hernia Surgical Mesh Implants, FDA, https://www.fda.gov/medical-devices/implants-and-prosthetics/hernia-surgical-mesh-implants (last visited March 29, 2021).

Defendant's motion on August 30, 2019, but gave Plaintiff leave to amend. (August 30, 2019 Order (Dkt. No. 22))

The SAC was filed on September 23, 2019. (Dkt. No. 25) In the SAC, Plaintiff asserts the same causes of action pled in the Amended Complaint. Compare Am. Cmplt. (Dkt. No. 14) with SAC (Dkt. No. 25). Defendant has once again moved to dismiss pursuant to Rule 12(b)(6). (Def. Br. (Dkt. No. 29))

III. THE COURT'S AUGUST 30, 2019 ORDER GRANTING DEFENDANT'S RULE 12(b)(6) MOTION TO DISMISS

In an August 30, 2019 order (the "August 30, 2019 Order"), this Court granted Defendant's Rule 12(b)(6) motion to dismiss, finding that none of Plaintiff's claims were sufficiently pled. (August 30, 2019 Order (Dkt. No. 22))

As to Plaintiff's strict liability design defect claim, the Court found that the Amended Complaint mistakenly pled that the Symbotex Mesh is defective because of its "microporous" design. In her opposition brief, Plaintiff conceded that the Symbotex Mesh is a macroporous product. (Id. at 4 (citing Pltf. Opp. Br. (Dkt. No. 17) at 11)) This Court further found that Plaintiff's conclusory assertion "that a feasible alternative design exists – without pleading any supporting facts – [was] not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be." (Id. at 5) While Plaintiff alleged that "'safer and more effective alternatives to hernia mesh exist'" – citing the "Shouldice Repair, McVay Repair, Bassini Repair, and Dessarda Repair [products]" – this Court found that Plaintiff's allegations amounted merely to a claim that "'the product should not be used at all[, which] is insufficient to satisfy the feasible alternative design element.'" (Id. (quoting Am. Cmplt. (Dkt. No. 14) ¶ 29); Kennedy v. Covidien, LP, No. 1:18-cv-01907-LTS-KNF, 2019 WL 1429979, at *4 (S.D.N.Y. Mar. 29, 2019))

As to Plaintiff's strict liability manufacturing defect claim, this Court found that the Amended Complaint "d[id] not plead facts showing how Defendant's manufacturing process was flawed, or in what way the mesh in question deviated from Defendant's design." (Id. at 7) Moreover, Plaintiff's argument that the Amended Complaint "provides circumstantial evidence of a manufacturing defect" – because the Symbotex Mesh caused her injury, which "'was [not what it was] intended to do'" – was mere speculation. (Id. at 7 (quoting Pltf. Opp. Br. (Dkt. No. 17) at 13))

Plaintiff's strict liability failure to warn claim was deficient because the injuries Plaintiff allegedly suffered were warned of in the Symbotex Mesh's warnings. (Id. at 9) The Amended Complaint also failed to adequately allege "'how the provided warnings and information failed to []accurately reflect[] reality,'" and did not "'provide a plausible basis to support an inference that [Defendant] misrepresented anything.'" (Id. (quoting Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 576 (E.D.N.Y. 2012)) (alterations in August 30, 2019 Order)

Because the same "standard . . . applies to both strict products liability and negligence claims[,]" Plaintiff's negligence claim failed for the same reasons that her strict products liability claims failed. (Id. at 9-10 (citing Adams v. Genie Indus., Inc. 14 N.Y.3d 535, 542-43 (2010); Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102 (1983))

As to Plaintiff's breach of implied warranty claim, this Court found that the claim could not survive because, as Plaintiff conceded, the Amended Complaint "describe[d] the wrong product." (Id. at 12)

This Court likewise dismissed the Amended Complaint's negligent and fraudulent misrepresentation claims, finding that both claims sounded in fraud and were therefore subject to Fed. Rule Civ. P. 9(b)'s heightened pleading requirements. (Id. at 12-14) These claims failed

because the Amended Complaint did not identify any specific fraudulent statements. (Id. at 14-15) While the Amended Complaint alleged that "a number of misrepresentations appeared on Defendant's website, and in product brochures and videos," and that "Defendant misrepresented the Symbotex Mesh in, inter alia, 'reports, press releases, advertising campaigns, print advertisements, commercial media[,] . . . Dear Doctor letters, and Medical Information Letters, as well as during events hosted for medical professionals[,]' . . . Plaintiff [did] not quote these misrepresentations or otherwise identify them." (Id. at 15-16 (quoting Am. Cmplt. (Dkt. No. 14) ¶¶ 103, 108-09)) The Amended Complaint also did not explain why the alleged misrepresentations that were quoted in the Amended Complaint were false and misleading. (Id. at 16) Plaintiff's allegation that Defendant's warning in its promotional brochure was "'poorly provided[,]'" was "'very limited and inadequate'" and "omit[ted] known risks of using the Symbotex Mesh[,]" was insufficient to state a misrepresentation claim, because the Amended Complaint "[did] not explain why Defendant's warning is inadequate[.]" (Id. (quoting Am. Cmplt. (Dkt. No. 14) ¶¶ 79, 97(d), 98, 100, 103)) Moreover, most of the risks Plaintiff claimed were omitted were, "in fact, listed in Defendant's warning – including the injuries that Plaintiff actually suffered." (Id. (citing Kennedy, 2019 WL 1429979, at *7)) Finally, Plaintiff's allegation "that Defendant misrepresented that the Symbotex Mesh 'had been adequately tested in clinical trials and [was] found to be safe and effective'" was inadequate because Plaintiff "d[id] not identify any statement containing this alleged misrepresentation[.]'" (Id. at 17 (quoting Am. Cmplt. (Dkt. No. 14) ¶ 101))

In dismissing Plaintiff's unjust enrichment claim, this Court noted that such claims "'cannot survive "where [they] simply duplicate[], or replace[], a conventional contract or tort claim."'" (Id. at 17 (quoting Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274, 290

(S.D.N.Y. 2014) (quoting Corsello v. Verizon N.Y., Inc., 18 N.Y.3d 777, 790-91 (2012)))

Plaintiff's unjust enrichment claim was "'based on the same allegations as those set forth in support of [her] other claims.'" (Id. at 18 (quoting Greene v. Gerber Prod. Co., 262 F. Supp. 3d 38, 77 (E.D.N.Y. 2017)) (alteration in August 30, 2019 Order)

As to Plaintiff's claims under New York General Business Law ("GBL") Sections 349 and 350, this Court found that because the Amended Complaint "d[id] not quote or attach any consumer-oriented marketing material . . . [or] explain how that material misrepresented the risks of using the Symbotex Mesh[,]" those claims were inadequately pled. (Id. at 19)

Finally, this Court dismissed Plaintiff's cause of action for punitive damages, because "'a claim for punitive damages may not be maintained as a separate cause of action.'" (Id. at 19-20) (quoting La Porta v. Alacra, Inc., 142 A.D.3d 851, 853 (1st Dept. 2016) (citing Rocanova v. Equitable Life Assurance Soc'y of U.S., 83 N.Y.2d 603, 616–17 (1994)))

Although the Court dismissed each of Plaintiff's claims, it granted Plaintiff leave to amend, noting that "'[l]eave to amend should be freely granted,'" and that Defendant "ha[d] not pointed to any compelling reason why leave to amend should be denied." (Id. at 20 (quoting Jin v. Metro. Life Ins. Co., 310 F.3d 84, 101 (2d Cir. 2002))

DISCUSSION

I. MOTION TO DISMISS STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "In considering a motion to dismiss . . . the court is to accept as true all facts alleged in the complaint[,]" Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007) (citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 87 (2d Cir. 2002)),

and must "draw all reasonable inferences in favor of the plaintiff." Id. (citing Fernandez v. Chertoff, 471 F.3d 45, 51 (2d Cir. 2006)).

A complaint is inadequately pled "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement[,]'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557), and does not provide factual allegations sufficient "to give the defendant fair notice of what the claim is and the grounds upon which it rests." Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 121 (2d Cir. 2007) (citing Twombly, 550 U.S. at 555 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957))).

Fed. R. Civ. P. 9(b) sets standards for pleading fraud claims and requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) requires a plaintiff to "'(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" Kottler v. Deutsche Bank AG, 607 F. Supp. 2d 447, 462 (S.D.N.Y. 2009) (quoting Stevelman v. Alias Research, Inc., 174 F.3d 79, 84 (2d Cir. 1999); citing Anatian v. Coutts Bank (Switz.) Ltd., 193 F.3d 85, 88 (2d Cir. 1999)).

II. STRICT PRODUCTS LIABILITY

The SAC asserts claims for strict products liability premised on defective design, defective manufacturing, and a failure to warn.

A. Defective Design

To state a claim for defective design, 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 the plaintiff's injury."" Cowan v. Costco Wholesale Corp., No. 15 Civ. 5552 (PKC), 2017 WL 59080, at *2

(E.D.N.Y. Jan. 5, 2017) (quoting Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) (quoting Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001))).

As discussed above, in the August 30, 2019 Order, this Court dismissed Plaintiff's design defect claim on the grounds that the Amended Complaint (1) erroneously alleged that the Symbotex Mesh is defective because of its microporous – rather than macroporous – design; and (2) failed to adequately allege an alternative design. (August 30, 2019 Order (Dkt. No 22) at 4-6)

In moving to dismiss the SAC's design defect claim, Defendant argues that Plaintiff has again failed to adequately allege an alternative design. Defendant further contends that Plaintiff has not adequately alleged causation. (Def. Br. (Dkt. No. 29) at 14-15)

The SAC alleges that the Symbotex Mesh's design is defective for two reasons. First, the Symbotex Mesh is made from polyester, which is "a synthetic fiber derived from coal, air[,] water, and petroleum . . . [that] is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes[,]" and is "known to cause adverse reactions in the human body." (SAC (Dkt. No. 25) ¶¶ 76-78, 96) According to Plaintiff, "[p]olyester degrades when implanted into the human body" and is "prone to tearing, ripping, and/or fraying." (Id. ¶¶ 79-80) "Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body[,]" which "create[s] an inflammatory response." (Id. ¶¶ 81-82) While the Symbotex Mesh is coated in a "collagen film" that "is designed to make the polyester material more tolerable to the body[,]" the collagen film is "extremely delicate[,]" and "[o]nce [it] dissolves, it leaves the internal organs unprotected and

increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue." (Id. ¶¶ 84-87)

Second, the "macroporous design of the [Symbotex Mesh] creates pores (holes) throughout the mesh used in it[,]" and after the mesh is implanted, "[n]erves grow into these pores and attach to the mesh[.]" (Id. ¶¶ 89, 93) Because "[p]olyester mesh contracts over[]time[,] . . . [t]he stretching of the nerves [attached to the mesh] causes debilitating pain." (Id. ¶¶ 91-92) The mesh also "erodes and moves through the inguinal canal[,] . . . pull[ing] and stretch[ing] the nerves attached to it." (Id. ¶ 94) The "pain caused from the stretching of the nerves is essentially unable to be treated." (Id. ¶ 92)

As to alternative design, the SAC alleges that it is feasible to use "polycarbonate and polystyrene[,]" "a flat mesh and/or non-woven mesh[,]" or "hemp or biologic materials including animal byproduct[s]" as alternatives to polyester. (Id. ¶ 97) According to Plaintiff, each of these alternatives is "less dangerous, equally effective if not more effective, and economically feasible and/or financially equivalent[.]" (Id. ¶ 97) As to the use of hemp as an alternative to polyester, the SAC pleads that hemp is a "high-yield crop" that is easily cultivated "without the use of harmful chemicals," thus "reducing the body's risk of adverse reaction to the material and reducing the chance of an inflammatory effect." (Id. ¶¶ 98-99) Hemp "is also hypoallergenic, which reduces the chance of inflammation and adverse reactions[.]" (Id. ¶ 99)

The SAC repeats the Amended Complaint's allegations that "the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair" techniques are "safer and more effective alternatives to implanting synthetic hernia mesh, including the [Symbotex Mesh]." (Id. ¶ 34; see also Am. Cmplt. (Dkt. No. 14) ¶ 29)

As to the first element of a defective design claim – whether Plaintiff has pled facts demonstrating that the product as designed poses a substantial likelihood of harm – the Court concludes that the SAC is sufficient. The SAC alleges that the polyester used in the Symbotex Mesh causes an inflammatory response; that the collagen barrier designed to make the polyester material more "tolerable" dissolves and does not perform its intended function; and that nerves attach to the Symbotex Mesh design, which causes pain as the mesh shrinks, travels, and erodes over time. (Id. ¶¶ 76-82, 84-87, 89, 91-94, 96)

Plaintiff also adequately alleges at least one feasible alternative – the use of hemp in place of polyester. According to Plaintiff, hemp is hypoallergenic and is processed without the use of harsh chemicals, thereby reducing the risk of inflammation. (Id. ¶¶ 97-99)[2]

Although the SAC adequately pleads the first two elements of a defective design claim – a substantial likelihood of harm and feasible alternatives – the SAC founders on the third element – causation. The SAC alleges only that "[a]s a result of Defendant's failure to design and/or manufacture a reasonably safe product, including but not limited to by using alternative materials or promoting alternative procedures, Plaintiff has suffered serious bodily injuries. . . ." (SAC (Dkt. No. 25) ¶ 120) This generic statement of causation does not explain how the Symbotex Mesh's defective design proximately caused Plaintiff's specific injuries. See Krulewich v. Covidien, LP, No. 19-CV-2857 (JGK), 2020 WL 5995103, at *5 (S.D.N.Y. Oct. 9, 2020) (ruling that plaintiff's "threadbare allegation that 'Defendant's design and use of polyester

[2] The remaining alleged alternatives are not adequately pled. While Plaintiff suggests "polycarbonate and polystyrene" and "flat mesh and/or non-woven mesh" as additional alternatives, she does not explain what advantages they offer over the Symbotex Mesh. (Id. ¶ 97) And, as this Court previously held, Plaintiff's conclusory allegation that "the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair [techniques]" are feasible alternatives to the Symbotex Mesh is not sufficient. (August 30, 2019 Order (Dkt. No. 22) at 5 (citing Kennedy, 2019 WL 1429979, at *4))

material in its hernia mesh Product posed a substantial risk for [severe] . . . inflammation and was a substantial factor in causing [Plaintiff's] . . . injuries'" was insufficient to adequately allege causation in design defect claim); Quintana v. B. Braun Med. Inc., No. 17-CV-06614 (ALC), 2018 WL 3559091, at *4 (S.D.N.Y. July 24, 2018) (ruling that plaintiff failed to adequately allege causation in design defect claim where plaintiff did not "state any facts to indicate how [the product's] . . . defect was a substantial factor in causing her injuries") (emphasis in original).

Moreover, the SAC does not "even endeavor[] to explain why the mesh is a more likely, let alone proximate, cause of [Plaintiff's] alleged harms." Rincon v. Covidien, No. 16-CV-10033 (JMF), 2017 WL 2242969, at *1 (S.D.N.Y. May 22, 2017); Krulewich, 2020 WL 5995103, at *5 ("As courts considering similar issues have concluded, the plaintiffs in this case 'do[ ] not address the numerous plausible alternative explanations for [Mr. Krulewich's] medical problems, including natural complications from his hernia disease or the development of a new hernia.'") (quoting Dunham v. Covidien LP, No. 19 CIV. 2851 (LLS), 2019 WL 2461806, at *3 (S.D.N.Y. May 22, 2019))

Accordingly, Plaintiff's strict products liability defective design claim will be dismissed.

B. Defective Manufacturing

This Court previously dismissed Plaintiff's strict products liability manufacturing defect claim because Plaintiff had not adequately alleged that the Symbotex Mesh contains a manufacturing defect, or that any such defect caused Plaintiff's injuries. (See August 30, 2019 Order (Dkt. No. 22) at 7-8)

In the SAC, Plaintiff has done nothing to cure the pleading deficiencies in her manufacturing defect claim. The SAC alleges only that "[d]ue to an error in the manufacturing process, or through use of defective materials to manufacture the [Symbotex Mesh], the

[Symbotex Mesh] that was implanted in the Plaintiff deviated from the specifications or design of the [Symbotex Mesh.]" (SAC (Dkt. No. 25) ¶ 108) In order to state a claim for defective manufacturing, however, "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[.]'" Colon, 199 F. Supp. 2d at 85 (quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 129 (1981)). As in the Amended Complaint, the SAC does not plead facts showing how Defendant's manufacturing process was flawed, or in what way the mesh product at issue deviated from Defendant's design.

Plaintiff asserts, however, that she is "not required to allege specific facts about Defendant's manufacturing process due to the fact that the inner workings of the product are unknown[,]" and that requiring Plaintiff to make such allegations "would contravene the notice pleading requirement of Rule 8, even under the Iqbal-Twombly standard."[3] (Pltf. Opp. Br. (Dkt. No. 38) at 7) She asserts that the circumstantial evidence she alleges – Plaintiff's "constant pain and recurring hernias since being implanted with the Defendant's mesh products" – is sufficient. (Id. at 8)

Plaintiff is correct that the SAC need not plead "specific facts" in support of this claim in order to survive a motion to dismiss. See Erickson v. Pardus, 551 U.S. 89, 93 (2007); Boykin v. KeyCorp, 521 F.3d 202, 215 (2d Cir. 2008) ("[B]oth Twombly and Erickson explicitly

[3] Plaintiff contends that dismissal is appropriate only where "'it appears beyond doubt that the plaintiff can prove no set of facts which would entitle . . . her to relief.'" See Pltf. Opp. Br. (Dkt. No. 38) at 5 (quoting Sweet v. Sheahan, 235 F.3d 80, 83 (2d Cir. 2000)) This is an outdated and incorrect statement of the pleading standard. In Twombly, the Supreme Court abrogated the "no set of facts" pleading standard. See Twombly, 550 U.S. at 561-63 (holding that the "no set of facts" standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46 (1957), should be "forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint").

disavow that Rule 8(a) requires any plaintiff – let alone a pro se plaintiff – to plead 'specific facts.'") (citing Twombly, 550 U.S. at 570); Erickson, 551 U.S. at 93)). However, while a plaintiff "may rely upon the circumstances of an accident to prove the existence of a manufacturing defect[,]" plaintiff must also show that "the product did not perform as intended and [that] the possibility of other causes [of plaintiff's injury have] been excluded." Williamson v. Stryker Corp., No. 12 Civ. 7083 (CM), 2013 WL 3833081, at *5 (S.D.NY. July 23, 2013) (citing Sanchez v. Stanley-Bostitch, Inc., No. 98 CIV 0494 LMM, 2000 WL 968776, at *2 (S.D.N.Y. July 13, 2000)).

And, as this Court previously noted in dismissing the Amended Complaint's manufacturing defect claim,

> [d]efective manufacturing is not shown merely by proof that a consumer was injured. . . . "If Plaintiff is going to rely on the circumstantial theory of liability described in New York case law, she must allege [facts] to nudge her claim above the level of speculation and into the realm of the plausible." Goldin v. Smith & Nephew, Inc., No. 12 Civ. 9217 (JPO), 2013 WL 1759575, at *3 (S.D.N.Y. Apr. 24, 2013)). Moreover, Plaintiff's alleged injuries – recurring hernias and abdominal pain – are among the complications listed on the Symbotex Mesh warning label. (Am. Cmplt. (Dkt. No. 14) ¶ 79 ("The possible complications associated with the use of [the Symbotex Mesh include] recurrence . . . [and] chronic pain. . . .")) Courts have dismissed manufacturing defect claims based on circumstantial evidence, where that evidence includes injuries that appear on the product's warning label: "[T]he Complaint contains warnings of the conditions Plaintiff complains of, thus leading to the inference that the product was manufactured and performed as intended." Kennedy, 2019 WL 1429979, at *4 (dismissing manufacturing defect claim in a hernia mesh products liability case).

(August 30, 2019 Order (Dkt. No. 22) at 7-8)

The SAC does nothing to cure the pleading deficiencies in Plaintiff's strict products liability manufacturing defect claim. Accordingly, Plaintiff's manufacturing defect claim will be dismissed.

C. Failure to Warn

To state a claim for failure to warn, a plaintiff "must show that (1) [the defendant] had a duty to warn against dangers resulting from foreseeable uses about which it knew or should have known; and (2) that failure to do so was the proximate cause of [the plaintiff's injury]." Adesina v. Aladan Corp., 438 F. Supp. 2d 329, 338 (S.D.N.Y. 2006) (citing Santoro ex rel. Santoro v. Donnelly, 340 F. Supp. 2d 464, 485 (S.D.N.Y. 2004); Crespo v. Chrysler Corp., No. 97 Civ. 8246 (JSR), 1998 WL 542304 (S.D.N.Y. Aug. 25, 1998). "At the motion to dismiss stage, a plaintiff must plead facts pertaining to how the warning was inadequate or insufficient." Kennedy, 2019 WL 1429979, at *5 (citing Reed, 839 F. Supp. 2d at 575).

In dismissing the Amended Complaint's failure to warn claim, this Court ruled that Defendant's warnings for the Symbotex Mesh specifically warned of the injuries Plaintiff allegedly suffered, and that Plaintiff had not plausibly alleged that Defendant's warnings were misleading or inaccurate. (August 30, 2019 Order (Dkt. No. 22) at 9)

As in the Amended Complaint, the SAC alleges that Defendants' warnings for the Symbotex Mesh "were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications." (SAC (Dkt. No. 25) ¶ 123; see also Am. Cmplt. (Dkt. No. 14) ¶ 72) The SAC's new allegations are that Defendant failed to warn of the risk of "mesh migration or 'sliding' out of place, bowel incarceration, the need for removal surgery and the development of chronic pain syndrome, all of which Plaintiff has suffered." (Id. ¶ 127)

According to the SAC, Defendant's warnings for the Symbotex Mesh read as follows: "The possible complications associated with the use of [the Symbotex Mesh] are those

typically associated with surgically implanted mesh: seroma, hematoma, recurrence, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product." (Id. ¶ 130) In the SAC, Plaintiff further complains that the Symbotex Mesh brochure – which "refers its users, including Plaintiff, Plaintiff's physicians, and others, to the package insert for complete instructions, contraindications, warnings and precautions" – does not itself include warnings. (Id. ¶ 125)

As this Court ruled in dismissing the Amended Complaint's failure to warn claim, Defendant's warning for the Symbotex Mesh product specifically addresses many of the injuries that Plaintiff allegedly suffered, including recurring hernias, chronic pain, and adhesions. (See August 30, 2019 Order (Dkt. No. 22) at 9; SAC (Dkt. No. 25) ¶ 130) Moreover, while the warning Plaintiff cites in the SAC does not list "mesh migration or 'sliding' out of place, bowel incarceration, [or] the need for removal surgery," Defendant warns of these risks in the Symbotex Mesh's "Instructions for Use," which Defendant attaches to its motion to dismiss. (See id. ¶ 127; Instructions for Use (Dkt. No. 29-1))

Documents outside a complaint generally may not be considered on a Rule 12(b)(6) motion to dismiss. Courts may, however, consider documents "incorporated by reference in the complaint." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010) (citing Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002); Hayden v. Cty. of Nassau, 180 F.3d 42, 54 (2d Cir. 1999)). "Where a document is not incorporated by reference, the court may [nevertheless] consider it where the complaint 'relies heavily upon its terms and effect,' thereby rendering the document 'integral' to the complaint." Id. (quoting Mangiafico v. Blumenthal, 471 F.3d 391, 398 (2d Cir. 2006)) Before considering such a document on a motion to dismiss, however, "it must be clear on the record that no dispute exists regarding the

authenticity or accuracy of the document . . . [and] that there exist no material disputed issues of fact regarding the relevance of the document." Faulkner v. Beer, 463 F.3d 130, 134 (2d Cir. 2006). "This principle is driven by a concern that a plaintiff may lack notice that the material will be considered to resolve factual matters." Nicosia v. Amazon.com, Inc., 834 F.3d 220, 231 (2d Cir. 2016) (citing Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 48 (2d Cir. 1991))

Here, the Court finds that it may consider the Instructions for Use in connection with Defendant's motion, because this "is the very document that gives doctors the warnings that the [SAC] claims were insufficient," and is therefore "integral to the [SAC]." Dunham, 2019 WL 6341179, at *4 (citing Faulkner, 463 F.3d at 134; Cortec Indus., Inc., 949 F.2d at 47-48). Moreover, Plaintiff "has not challenged the authenticity, accuracy, or relevance of the [Instructions for Use] in any of [her] filings," although she has had ample opportunity to do so, given that Defendant attached the Instructions for Use to both its past and present motions to dismiss. Id. (citing Faulkner, 463 F.3d at 134; Def. Br., Ex. A (Dkt. No. 19-1))

The Instructions for Use warn of each injury Plaintiff alleges. The Instructions for Use state that "possible complications" of using the Symbotex Mesh "are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, adhesions, fistula formation, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product." (Instructions for Use (Dkt. No. 29-1) at 2) They also warn of "organ injury (including bowel and visceral injury) . . . [and] bowel obstruction[,]" and caution that the Symbotex Mesh "should be used with the understanding that infection may require removal of the device." (Id.)

Although Plaintiff complains that the Symbotex Mesh brochure and website do not warn of the risks associated with implantation, she cites no case law suggesting that product

warnings must be included in informational or marketing brochures or websites associated with such products. (SAC (Dkt. No. 25) ¶¶ 124-25) Under New York law, "the manufacturer's duty to caution against . . . side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." Martin v. Hacker, 83 N.Y.2d 1, 9, (1993) (citing Glucksman v. Halsey Drug Co., 1st Dept. 1990); Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61 (4th Dept. 1979)). Accordingly, "[i]f the doctor is sufficiently warned, the product is not defective." Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2d Cir. 1991) (citing Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980)).

Here, Plaintiff acknowledges that the Symbotex Mesh brochure "refers its users, including Plaintiff, Plaintiff's physicians, and others, to the package insert for complete instructions, contraindications, warnings and precautions." (Id. ¶ 125) Accordingly, Plaintiff's failure to warn claim cannot succeed on the basis of Defendant's failure to include warnings in its brochures, marketing materials, or on its website.

Plaintiff's failure to warn claim will be dismissed.

III. NEGLIGENCE

As in the Amended Complaint, the SAC alleges that Defendant was negligent in "designing, manufacturing, and selling the hernia mesh products[,]" and "fail[ed] to adequately warn Plaintiff and/or her physicians . . . [of the] risks associated with the [Symbotex Mesh]." (SAC (Dkt. No. 25) ¶¶ 144-45; Am. Cmplt. (Dkt. No. 14) ¶¶ 87, 91)

As this Court previously noted in dismissing Plaintiff's negligence claim,

> " . . . claims for negligent design and design-based strict products liability should be analyzed under the same standard in products liability cases." Kennedy, 2019 WL 1429979, at *5) (citing Denny v. Ford Motor Co., 87 N.Y.2d 248, 258 (1995)); Adams v. Genie Indus[]., Inc., 14 N.Y.3d 535, 542–43 (2010) (confirming that the standard set forth in Voss v. Black & Decker [Mfg.] Co., 59 N.Y.2d 102 (1983) applies to both strict products liability and negligence claims)).

(August 30, 2019 Order (Dkt. No. 22) at 9-10) Because the SAC fails to adequately plead claims for strict products liability, Plaintiff's negligence claim likewise fails. See Kennedy, 2019 WL 1429979, at *5.

IV. BREACH OF IMPLIED WARRANTY

"'The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection.'" Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 433 (2d Cir. 2013) (quoting Saratoga Spa & Bath, Inc. v. Beeche Sys. Corp., 230 A.D.2d 326, 330 (3d Dept. 1997)). "To the extent that Plaintiff's breach of implied warranty claim is based on design defect, under New York law such a claim 'requires proof of the following three elements: (1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident.'" Morrison v. Hoffmann-La Roche, Inc., No. 14-CV-4476 (DLI) (RML), 2016 WL 5678546, at *11 (E.D.N.Y. Sept. 29, 2016) (quoting Simon, 990 F. Supp. 2d at 407).

This Court dismissed the Amended Complaint's breach of implied warranty claim because it erroneously alleged that the Symbotex Mesh was defective because of its microporous, rather than macroporous, design. (August 30, 2019 Order (Dkt. No. 22) at 12) As discussed above, in its opposition to Defendant's motion to dismiss the Amended Complaint, Plaintiff conceded that the Symbotex Mesh has a macroporous design. (Id. at 4, 12; Pltf. Opp. Br. (Dkt. No. 17) at 11).

In the SAC, Plaintiff alleges that "Defendant impliedly warranted to Plaintiff and all others similarly situated that the [Symbotex Mesh] was reasonably fit for its intended use[,]" but that the Symbotex Mesh was "defective as set forth above, was not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering, and

industry standards." (SAC (Dkt. No. 25) ¶¶ 150-51) According to Plaintiff, the SAC adequately pleads a claim for breach of implied warranty because it "alleges significant risks associated with Defendant's design and use of polyester" in the Symbotex Mesh. (Pltf. Opp. Br. (Dkt. No. 38) at 11-12)

As discussed above, however, Plaintiff has not pled facts sufficient to demonstrate that the defects in the Symbotex Mesh caused Plaintiff's specific injuries. Accordingly, Plaintiff's claim for breach of implied warranty will be dismissed.

V. NEGLIGENT AND FRAUDULENT MISREPRESENTATION

Like the Amended Complaint, the SAC asserts claims for both negligent and fraudulent misrepresentation. (SAC (Dkt. No. 25) ¶¶ 153-94) In dismissing the Amended Complaint's negligent and fraudulent misrepresentation claims, this Court ruled that both claims sounded in fraud, and were therefore subject to the heightened pleading requirements set forth in Fed. R. Civ. P. 9(b). (August 30, 2019 Order (Dkt. No. 22) at 12-14) The SAC adds new allegations in support of Plaintiff's misrepresentation claims. (SAC (Dkt. No. 25) ¶¶ 156-57, 170-71)

As in the Amended Complaint, the SAC's fraudulent and negligent misrepresentation claims both assert that Defendant intentionally made false and material misrepresentations to Plaintiff and her physicians concerning the safety of the Symbotex Mesh. (SAC (Dkt. No. 25) ¶¶ ¶¶ 154-94 (fraudulent misrepresentation claim alleging that Defendant "made misrepresentations of material fact from 2013 to present to Plaintiff and her physicians[] to induce them to use [the Symbotex Mesh] for hernia repair"; negligent misrepresentation claim alleging that Defendant knowingly made false representations about the Symbotex Mesh's safety and "intentionally concealed the truth regarding" its dangers); see also Am. Cmplt. (Dkt. No. 14) ¶¶ 97-134) Accordingly, both the fraudulent and negligent misrepresentation claims sound in

fraud, and Rule 9(b) applies to both claims. See Tyman v. Pfizer, Inc., 16-CV-06941 (LTS) (BCM), 2017 WL 6988936, at *8 (S.D.N.Y. Dec. 27, 2017), report and recommendation adopted, No. 16 CV 6941-LTS-BCM, 2018 WL 481890 (S.D.N.Y. Jan. 18, 2018) ("'Whether or not Rule 9(b)'s heightened standard applies to all claims of negligent misrepresentation,' . . . it must be applied where 'the claim sounds in fraud.'") (quoting Riker v. Premier Capital, LLC, 15-CV-8293, 2016 WL 5334980, at *5 (S.D.N.Y. Sept. 22, 2016)); Woori Bank v. RBS Sec., Inc., 910 F. Supp. 2d 697, 705 (S.D.N.Y. 2012) ("District courts in this Circuit have concluded that . . . Rule [9(b)] is applicable to negligent misrepresentation claims that are premised on fraudulent conduct.") (citing Ellington Credit Fund, Ltd. v. Select Portfolio Servicing, Inc., 837 F. Supp. 2d 162, 200 (S.D.N.Y. 2011)).

As this Court previously explained,

> "[t]o state a claim for fraudulent misrepresentation under New York law 'a plaintiff must show that (1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiff thereby, (3) the plaintiff reasonably relied upon the representation, and (4) the plaintiff suffered damage as a result of such reliance.'" Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y., 375 F.3d 168, 186–87 (2d Cir. 2004) (quoting Banque Arabe et Internationale D'Investissement v. Md. Nat'l Bank, 57 F.3d 146, 153 (2d Cir. 1995)). "'Under New York law, the elements for a negligent misrepresentation claim are that (1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment.'" Fisher v. APP Pharm[s]., LLC, 783 F. Supp. 2d 424, 432 (S.D.N.Y. 2011) (quoting Hydro [Inv'rs], Inc. v. Trafalgar Power Inc., 227 F.3d 8, 20 (2d Cir. 2000)). . . .
>
> To satisfy the particularity requirement of Rule 9(b), a claim must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Harsco Corp. v. Segui, 91 F.3d 337, 347 (2d Cir. 1996) (citing Shields v. Citytrust Bancorp., Inc., 25 F.3d 1124, 1128 (2d Cir.1994); Ouaknine v. MacFarlane, 897 F.2d 75, 79 (2d Cir.1990). "In this Circuit, a complaint may establish the requisite 'strong

> inference' of fraudulent intent either (a) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness, or (b) by alleging facts to show that defendants had both motive and opportunity to commit fraud." Stevelman, 174 F.3d at 84 (citing Chill[v. Gen. Elec. Co.], 101 F.3d [263, 267 (2d Cir. 1996)]; Shields, 25 F.3d at 1128).

(August 30, 2019 Order (Dkt. No. 22) at 12-13)

In the August 30, 2019 Order, this Court dismissed the Amended Complaint's fraudulent and negligent misrepresentation claims for failure to plead specific false and fraudulent statements. (Id. at 15-17)

In the SAC, Plaintiff includes new allegations identifying specific misstatements in Defendant's "Mesh Value Analysis Brochure" and "Value Analysis Committee Product Information Kit," both of which are available on Defendant's website. (SAC (Dkt. No. 25) ¶¶ 156, 170) The misstatements Plaintiff cites include the following:

> that "Covidien's new Symbotex™ composite Mesh provides surgeons improved ease of use, and optimal performance to minimize visceral tissue attachments, for meeting hernia repair solution needs"[;]
>
> that the [Symbotex Mesh] "provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair"[; and]
>
> that the [Symbotex Mesh] has "[e]xclusive 3-D mesh structure delivering reinforced textile strength and significant tissue ingrowth support."

(Id. ¶¶ 157, 170-71)

According to Plaintiff, these statements are false. The Symbotex Mesh "actually had a poor rate of integration, evidenced by the Plaintiff's need for surgery due to improper adhesions, and the bowel obstruction she suffered." (Id. ¶ 172) Plaintiff further contends that Defendant's "various advertisement materials lack detailed warnings about the known complications associated with implantation of [the Symbotex Mesh]," and "the very limited

warnings of potential complications associated with the [Symbotex Mesh] were wholly inadequate." (Id. ¶ 159)

While the SAC cites specific misstatements, Plaintiff has not shown that these statements are false or that Defendant intended to defraud Plaintiff. The "improper adhesions" and bowel obstruction Plaintiff experienced does not prove that Defendant's representations about the Symbotex Mesh are false, because Defendant warned that adhesions and bowel obstructions could occur with use of its mesh product. (See Instructions for Use (Dkt. No. 29-1) at 2) "The absence of a factual basis to support the plaintiffs' claims that the defendant's representations were either false or misleading is fatal to [a misrepresentation] claim." Krulewich, 2020 WL 5995103, at *8 (dismissing fraudulent and negligent misrepresentation claim where plaintiff "challenge[d] the defendant's representations in its brochure," but failed to "allege[] any factual basis for their claims that the defendants representations were false[,]" given that "the defendant did specifically warn of pain, adhesion, and recurrence as common injuries and known side effects of hernia surgeries using Mesh"); see also Kennedy, 2019 WL 1429979 at *7 ("Absent from these allegations is any factual basis for Plaintiff's conclusion that the representations made by the Defendant were false or misleading. In fact, the advertising material incorporated into the Complaint appears to have disclosed the risks of the conditions that Plaintiff has allegedly suffered.")

Because the SAC does not plead facts demonstrating that Defendant's statements were false and misleading, Plaintiff's fraudulent and negligent misrepresentation claims will be dismissed.

VI. UNJUST ENRICHMENT

As this Court explained in dismissing the Amended Complaint's unjust enrichment claim,

> "[t]o state a claim for unjust enrichment under New York law, a plaintiff must allege that '(1) the defendant was enriched, (2) at the expense of the plaintiff, and (3) . . . it would be inequitable to permit the defendant to retain that which is claimed by the plaintiff.'" Koenig[,] . . . 995 F. Supp. 2d [at] 290 . . . (quoting Baron v. Pfizer, Inc., 42 A.D.3d 627, 629 (2007) (citing Clifford R. Gray, Inc. v. LeChase Constr. Servs., LLC, 31 A.D.3d 983, 988[] (2006))). However, "an unjust enrichment claim cannot survive 'where it simply duplicates, or replaces, a conventional contract or tort claim.'" Id. (quoting Corsello[,] . . . 18 N.Y.3d [at] 790–91 . . . ; citing Ebin v. Kangadis Food Inc., No. 13 Civ. 2311 (JSR), 2013 WL 6504547, at *7 (S.D.N.Y. Dec. 11, 2013)). Rather, this claim "'is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff.'" Weisblum v. Prophase Labs, Inc., 88 F. Supp. 3d 283, 296–97 (S.D.N.Y. 2015) (quoting Corsello, 18 N.Y.3d at 790; citing Samiento v. World Yacht Inc., 10 N.Y.3d 70, 81 (2008)).

(August 30, 2019 Order (Dkt. No. 22) at 17-18)

This Court dismissed Plaintiff's unjust enrichment claim because it was "'based on the same allegations as those set forth in support of [her] other claims, and Plaintiff [has] not shown how [her] unjust enrichment claim differs from [her] other claims.'" (Id. at 18 (quoting Greene v. Gerber Prods. Co., 262 F. Supp. 3d 38, 77 (E.D.N.Y. 2017) (alterations in August 30, 2019 Order)

In the SAC, Plaintiff has not substantively amended her unjust enrichment claim. As in the Amended Complaint, the SAC's unjust enrichment claim is based on the same facts alleged in support of Plaintiff's other claims. (SAC (Dkt. No. 25) ¶¶ 195-202) Accordingly, Plaintiff's unjust enrichment claim will be dismissed.

VII. NEW YORK GENERAL BUSINESS LAW CLAIMS

This Court dismissed the Amended Complaint's claims under New York General Business Law Sections 349 and 350, because Plaintiff "d[id] not quote or attach any consumer-oriented marketing material [to the Amended Complaint] . . . [or] explain how that material misrepresented the risks of using the Symbotex Mesh." (August 30, 2019 Order (Dkt. No. 22) at 19)

GBL Sections 349 and 350 prohibit deceptive trade practices and false advertising. See Greene, 262 F. Supp. 3d at 67 (citing N.Y. Gen. Bus. Law §§ 349–50). To show a violation of either section, "the plaintiff must allege that the defendant has engaged in '(1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.'" Kennedy, 2019 WL 1429979, at *7 (quoting Orlander v. Staples, Inc., 802 F.3d 282, 300 (2d Cir. 2015)). While Rule 9(b)'s heightened pleading standard does not apply to claims brought under the GBL, see Greene, 262 F. Supp. 3d at 67, "a plaintiff still must show that the alleged deceptive acts would mislead a reasonable consumer acting reasonably under the circumstances." Kennedy, 2019 WL 1429979, at *7 (citing Stutman v. Chem. Bank, 95 N.Y.2d 24, 28-29 (2000)).

In the SAC, Plaintiff adds statements from the "Mesh Value Analysis Brochure," including that the Symbotex Mesh has "[e]xcellent tissue integration," "[m]inimized visceral attachment," and "significant tissue ingrowth support." (SAC (Dkt. No. 25) ¶¶ 208-09) Plaintiff asserts that these statements are false because Plaintiff needed "surgery due to improper adhesions, and the bowel obstruction she suffered." (Id. ¶ 210)

Plaintiff's GBL claims fail for the same reasons that her fraudulent and negligent misrepresentation claims fail. As discussed above, Defendant warned of the precise injuries that Plaintiff allegedly suffered. Accordingly, Plaintiff has not shown that Defendant's statements are "materially misleading" or that they "would mislead a reasonable consumer acting reasonably under the circumstances." Kennedy, 2019 WL 1429979, at *7. Accordingly, Plaintiff's GBL claims will be dismissed.

VIII. PUNITIVE DAMAGES

In the SAC, Plaintiff again pleads a cause of action for punitive damages (SAC ¶¶ 222-33), even though this Court previously ruled that "'a claim for punitive damages may not be maintained as a separate cause of action.'" (August 30, 2019 Order (Dkt. No. 22) at 19-20) (quoting La Porta, 142 A.D.3d at 853 (citing Rocanova, 83 N.Y.2d at 616-17)) "[P]unitive damages are a remedy and not a cause of action." Pyatt v. Raymond, No. 10 Civ. 8764 (CM), 2011 WL 2078531, at *10 (S.D.N.Y. May 19, 2011), aff'd, 462 F. App'x 22 (2d Cir. 2012), as amended (Feb. 9, 2012) (citing In re Terrorist Attacks on Sept. 11, 2001, 718 F.Supp.2d 456, 492 n.14 (S.D.N.Y. 2010)); see also Rocanova, 83 N.Y.2d at 612 ("A demand or request for punitive damages is parasitic and possesses no viability absent its attachment to a substantive cause of action such as fraud."). Accordingly, the SAC's cause of action for punitive damages will be dismissed.

IX. LEAVE TO AMEND

In Plaintiff's opposition brief, Plaintiff states that "[s]hould this Court . . . find that all or part of the Plaintiff's complaint should be dismissed, Plaintiff respectfully submits that leave to amend should be freely given." (Pltf. Opp. Br. (Dkt. No. 38) at 15) Plaintiff does not address the fact that three complaints have already been filed in this case, none of which have pleaded a cause of action.

"[I]t is often appropriate for a district court, when granting a motion to dismiss for failure to state a claim, to give the plaintiff leave to file an amended complaint." Van Buskirk v. N.Y. Times Co., 325 F.3d 87, 91 (2d Cir. 2003) (citing Branum v. Clark, 927 F.2d 698, 705 (2d Cir. 1991)). Leave to amend "is within the discretion of the District Court," however, and may be denied for reasons "such as undue delay, bad faith or dilatory motive . . . , repeated failure to

cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc." Foman v. Davis, 371 U.S. 178, 182 (1962); see also De Jesus v. Sears, Roebuck & Co., 87 F.3d 65, 72 (2d Cir. 1996) (holding that it is appropriate to deny leave to amend "when a party has been given ample prior opportunity to allege a claim") (citing Armstrong v. McAlpin, 699 F.2d 79, 93-94 (2d Cir. 1983); Luce v. Edelstein, 802 F.2d 49, 57 (2d Cir. 1986)); Ruffolo v. Oppenheimer & Co., 987 F.2d 129, 131 (2d Cir. 1993) ("Where it appears that granting leave to amend is unlikely to be productive, . . . it is not an abuse of discretion to deny leave to amend.").

This Court has on two prior occasions granted Plaintiff leave to amend to cure pleading deficiencies, and has explained in detail the nature of the pleading deficiencies. (See July 19, 2018 Order (Dkt. No. 13) (granting Plaintiff leave to file an amended complaint); August 30, 2019 Order (Dkt. No. 22) at 20 (granting Plaintiff leave to file a second amended complaint)) While Plaintiff again asserts "that leave to amend should be freely given" (Pltf. Opp. Br. (Dkt. No. 38) at 15), "[t]he fact that leave to amend 'shall be freely given when justice so requires,' Fed. R. Civ. P. 15(a), does not mean that leave to re-plead is to be granted in perpetuity." Arnold v. KPMG LLP, 543 F. Supp. 2d 230, 238 (S.D.N.Y. 2008), aff'd, 334 F. App'x 349 (2d Cir. 2009). Moreover, Plaintiff has not formally sought leave to amend, has not submitted a proposed third amended complaint, and has not explained how the defects repeated in the SAC will be cured in a third amended complaint. "'[I]t is within the court's discretion to deny leave to amend . . . when [as here] leave is requested informally in a brief filed in opposition to a motion to dismiss.'" Krulewich, 2020 WL 5995103, at *11 n.2 (quoting Chechele v. Scheetz, 466 F. App'x 39, 41 (2d Cir. 2012)) (alteration in Chechele).

Granting Plaintiff leave to amend yet again is "unlikely to be productive," because Plaintiff has failed to cure pleading deficiencies, despite detailed explanations from the Court as to the nature of the pleading defects. "'[P]leading [an adequate complaint] is not . . . an interactive game in which plaintiffs file a complaint, and then bat it back and forth with the Court over a rhetorical net until a viable complaint emerges.'" CVR Energy, Inc. v. Wachtell, Lipton, Rosen & Katz, No. 14-CV-6566 (RJS), 2019 WL 8165893, at *5 (S.D.N.Y. Oct. 9, 2019), aff'd, 830 F. App'x 330 (2d Cir. 2020) (quoting In re Refco Capital Mkts., Ltd. Brokerage Customer Sec. Litig., No. 06-cv-643 (GEL), 2008 WL 4962985, at *2 (S.D.N.Y. Nov. 20, 2008), aff'd sub nom. Capital Mgmt. Select Fund Ltd. v. Bennett, 680 F.3d 214 (2d Cir. 2012)) (alteration in CVR Energy, Inc.).

As discussed above, the SAC contains many of the same deficiencies that this Court identified in its order dismissing the Amended Complaint. For example, despite this Court's earlier ruling that Plaintiff's unjust enrichment claim cannot be based on the same facts alleged in support of her other claims, Plaintiff's unjust enrichment claim in the SAC is based on the same facts supporting her other claims. (See August 30, 2019 Order (Dkt. No. 22) at 17-18; SAC (Dkt. No. 25) ¶¶ 195-202) And while this Court dismissed the Amended Complaint's cause of action for punitive damages, because "'a claim for punitive damages may not be maintained as a separate cause of action,'" (Order (Dkt. No. 22) at 19-20) (quoting La Porta, 142 A.D.3d at 853)), the SAC again pleads a separate cause of action for punitive damages. (See SAC (Dkt. No. 25) ¶¶ 222-33) Granting "leave to amend would be futile because plaintiff has already had two bites at the apple and they have proven fruitless." Harris v. Westchester Cty. Med. Ctr., No. 08 Civ. 1128, 2011 WL 2637429, at *4 (S.D.N.Y. July 6, 2011) (quoting Treppel v. Biovail Corp., No. 03 Civ. 3002 (PKL), 2005 WL 2086339, at *12 (S.D.N.Y. Aug. 30, 2005)).

It is also clear that a number of Plaintiff's claims are likely not subject to cure. For example, the SAC's failure to warn and misrepresentation claims are premised on injuries that are specifically cited in Defendant's warnings, as this Court pointed out in its Order dismissing the Amended Complaint. (See August 30, 2019 Order (Dkt. No. 22) at 9) (noting that "the injuries that Plaintiff allegedly suffered . . . are included in Defendant's warnings") (emphasis in August 30, 2019 Order); SAC (Dkt. No. 25) ¶¶ 123-39, 153-94) In sum, there is no factual basis for the assertion that Defendant failed to warn of injuries Plaintiff suffered, or that defendant made false or misleading representations regarding the risk of those injuries. Amendment would therefore be futile. See Krulewich, 2020 WL 5995103, at *11 (S.D.N.Y. Oct. 9, 2020) (denying leave to amend second amended complaint where the court had "already dismissed the plaintiffs' First Amended Complaint . . . [and] explained why the plaintiffs' pleading was defective, [but] plaintiffs failed to cure the defects"); see also Phila. Indem. Ins. Co. v. Lennox Indus., Inc., No. 3:18-CV-00217 (CSH), 2020 WL 705263, at *9 (D. Conn. Feb. 12, 2020) (denying leave to amend where plaintiff "had ample opportunity to cure the deficiencies of its . . . claims following the [court's prior] [r]uling, which thoroughly explained why these claims were inadequately stated[,]" but plaintiff "fail[ed] to comply with the careful guidance" of the prior ruling).

Plaintiff's contradictory pleadings provide further reason to deny leave to amend. In the Amended Complaint, Plaintiff alleged that the Symbotex Mesh's microporous – rather than macroporous – design is the cause of its deficiencies (Am. Cmplt. (Dkt. No. 14) ¶ 60), but Plaintiff later conceded that the Symbotex Mesh is, in fact, a macroporous product (see Pltf. Br. (Dkt. No. 17) at 11), and pleads as much in the SAC. (SAC (Dkt. No. 25) ¶ 46) Whether the Symbotex Mesh is microporous or macroporous has always been central to Plaintiff's claims,

and the contradictory pleadings on this point further suggest that leave to amend should be denied.

Finally, allowing a third amendment to the complaint would cause undue prejudice to Defendant. As discussed above, Plaintiff has been afforded ample opportunity to cure the deficiencies in her pleadings since she filed this lawsuit more than three years ago. "[F]urther leave to amend would cause undue prejudice to the defendant because it would force [Defendant] to continue litigating a claim for which the plaintiffs have no legal basis." Krulewich, 2020 WL 5995103, at *11; see also United States ex rel. Hussain v. CDM Smith, Inc., No. 14-CV-9107 (JPO), 2018 WL 11217206, at *2 (S.D.N.Y. Jan. 31, 2018) ("In considering prejudice to the Defendants, 'the Court also notes that allowing [Relator] to amend his complaint a third time would further delay the disposition of a case that has been pending for over [three] years.'") (quoting McKethan v. N.Y. State Dep't of Corr. Servs., No. 10 CIV. 3826 PAE, 2012 WL 2333415, at *2 (S.D.N.Y. June 19, 2012)) (alterations in Hussain). "Put simply, the Court will not indulge Plaintiff's attempts at piecemeal pleading, whereby Plaintiff hopes to eventually cobble together an adequate complaint under the Court's guidance while inflicting significant prejudice on Defendant[]." CVR Energy, 2019 WL 8165893, at *5.

Accordingly, leave to amend the SAC is denied.

CONCLUSION

For the reasons stated above, Defendants' motion to dismiss is granted. The Clerk of Court is directed to terminate the motion (Dkt. No. 28) and to close this case.

Dated: New York, New York
March 30, 2021

SO ORDERED.

Paul G. Gardephe
United States District Judge