UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BETTY DUPERE, Plaintiff, -v- ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	21cv2605 (DLC) OPINION AND ORDER

APPEARANCES:

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DENISE COTE, District Judge:

Betty Dupere brings claims against the defendant medical device companies for products liability, negligence, and fraud in connection with the surgical implantation of Gynecare TVT ("TVT"). The defendants, Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J"; together, "Defendants"), have moved to

partially dismiss the complaint. For the following reasons, the motion is granted.

Background

The following facts are derived from the first amended complaint ("FAC") of June 18, 2021 and are assumed to be true for the purposes of this motion. Ethicon is a wholly owned subsidiary of J&J, a medical and diagnostics company based in New Jersey. Ethicon designed, manufactured, and marketed TVT, the brand name of its polypropylene mesh product (commonly known as pelvic mesh). Pelvic mesh describes a class of medical devices implanted in the vaginal wall that are intended to treat women who suffer from pain, discomfort, stress urinary incontinence, or pelvic organ prolapse.

Ethicon and J&J obtained approval to market their pelvic mesh products for treatment of these conditions from the Food and Drug Administration ("FDA") under § 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics Act ("FDCA"). 21 U.S.C. § 360c. Section 501(k) permits the marketing of a medical device upon an application showing that the device is substantially equivalent to a legally marketed device.

Ethicon and J&J marketed pelvic mesh products, including TVT, as safe, effective, and reliable medical devices through

websites, sales representatives, "marketing materials, patient brochures, products guides, [Instructions for Use], and other materials/communications." TVT had an Instructions for Use ("IFU") label that listed, among other warnings about proper surgical practice, contraindications that the TVT should not be implanted in pregnant patients or in women with plans for future pregnancy. The IFU also listed adverse reactions that could occur, including, inter alia, "[p]unctures or lacerations of vessels, nerves, bladder or bowel . . . during needle passage," "transitory local irritation," and "transitory foreign body response."

In 2008, the FDA issued a Public Health Notification about several pelvic mesh products after receiving over one thousand adverse event reports. In 2011, the FDA released an analysis of adverse events reported from transvaginal implantation of surgical mesh to treat pelvic organ prolapse and concluded that serious complications requiring surgical treatment and hospitalization were "not rare." The FDA also explained that removal of the mesh "may involve multiple surgeries" and that "[c]omplete removal may not be possible."

One complication is that implanted pelvic mesh may contract over time, which can compress nerves, cause inflammation and

fibrosis of muscles and soft tissues, impair sexual function, mobility, and bowel and bladder function, and cause chronic pelvic pain. The mesh may also erode.

In January 2012, the FDA ordered Ethicon and J&J to conduct randomized controlled clinical testing of their pelvic mesh products or cease manufacture, marketing, and sale. In June of that same year, the Defendants withdrew some of their products from the market.

Dupere is a Florida resident. Over ten years ago and upon the recommendation of her physician, she agreed to undergo surgery to implant pelvic mesh in order to treat stress urinary incontinence. On March 9, 2010, Dupere received a surgical implantation of Ethicon's TVT product at Mount Sinai Medical Center in New York. She eventually developed vaginal mesh exposure. On March 1, 2019, Dupere underwent a second surgery to remove the TVT device at Wellington Regional Medical Center in Florida. As a result, she suffered emotional and physical pain.

Dupere brought this action against Ethicon and J&J on March 25, 2021.[1] The Defendants moved to dismiss the complaint in its

[1] This action was commenced after the close of multidistrict litigation ("MDL") concerning the use of transvaginal surgical mesh that had been consolidated and assigned to the Honorable

entirety on June 3. The complaint was then amended on June 18, asserting nine claims and seeking compensatory and punitive damages.[2] On July 9, the Defendants filed a motion to dismiss the majority of the nine claims. The motion became fully submitted on August 11. This action was reassigned to this Court on September 9.

Discussion

The FAC brings two causes of action against the Defendants under a strict liability theory for failure to warn (Count I) and defective design (Count II). The FAC also brings claims for negligence (Count III), negligent misrepresentation (Count IV), fraud (Count V), fraudulent concealment (Count VI), constructive fraud (Count VII), violation of the New York Consumer Protection Act (Count VIII), and gross negligence (Count IX). The Defendants have moved to dismiss part of Count III and the

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Joseph R. Goodwin in the Southern District of West Virginia in 2012. See, e.g., In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig., No. 2:13-CV-03792, 2015 WL 4506707, at *1 (S.D.W. Va. July 23, 2015), aff'd, 643 F. App'x 304 (4th Cir. 2016). That MDL concluded in March 2021. S.D.W.Va., MDL 2327 Ethicon, Inc., Pelvic Repair System Products Liability Litigation (last updated Apr. 19, 2021), https://www.wvsd.uscourts.gov/mdl/ethicon/index.html.

[2] An Order of June 1 gave the plaintiff a chance to amend the complaint and warned that another opportunity to amend was unlikely.

entirety of Counts IV-IX for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6).

In order to survive a motion to dismiss, "[t]he complaint must plead 'enough facts to state a claim to relief that is plausible on its face.'" Green v. Dep't of Educ. of City of New York, 16 F.4th 1070, 1076–77 (2d Cir. 2021) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "In determining if a claim is sufficiently plausible to withstand dismissal," a court "accept[s] all factual allegations as true" and "draw[s] all reasonable inferences in favor of the plaintiffs." Melendez v. City of New York, 16 F.4th 992, 1010 (2d Cir. 2021) (citation omitted).

I. Negligence Claims

A. Negligence (Count III)

In Count III, the FAC brings a claim of negligence in the design of the pelvic mesh products and negligence in the failure to adequately warn of the risks in using the products. The Defendants do not seek to dismiss this portion of Count III.

In addition, the FAC in Count III alleges that the Defendants breached a duty to adequately test TVT for safety before and after launching the product, rendering the product unreasonably dangerous and defective. The Defendants argue that New York does not recognize a standalone negligence claim for failure to test a product and that the FAC has failed in any event to adequately plead such negligence.

"Where the substantive law of the forum state is uncertain or ambiguous, the job of the federal courts is carefully to predict how the highest court of the forum state would resolve the uncertainty or ambiguity." Yukos Cap. S.A.R.L. v. Feldman, 977 F.3d 216, 241 (2d Cir. 2020) (citation omitted). Where the New York Court of Appeals has not ruled directly on an issue of state law, a court may consult resources including "state decisional law" and "scholarly works and any other reliable data tending to indicate how the New York Court of Appeals would resolve the issue." Travelers Ins. Co. v. 633 Third Assocs., 14 F.3d 114, 119 (2d Cir. 1994) (citation omitted).

A plaintiff injured by an allegedly defective product may pursue a claim under New York law for products liability based on four theories: strict liability, negligence, express warranty, and implied warranty. Voss v. Black & Decker Mfg.

Co., 59 N.Y.2d 102, 106 (1983). In general, "[t]he elements of a negligence claim under New York law are: (i) a duty owed to the plaintiff by the defendant; (ii) breach of that duty; and (iii) injury substantially caused by that breach." Pasternack v. Lab. Corp. of Am. Holdings, 807 F.3d 14, 19 (2d Cir. 2015) (citation omitted).

> Manufacturers and sellers in the normal course of business are liable for injuries caused by ordinary negligence, and are therefore under a duty to exercise reasonable care so as to avoid the occurrence of injuries by any product which can reasonably be expected to be dangerous if negligently manufactured or sold.

Gebo v. Black Clawson Co., 92 N.Y.2d 387, 394 (1998).

In New York, "[b]oth negligence and strict products liability . . . require a showing of a product 'defect.'" Kosmynka v. Polaris Indus., Inc., 462 F.3d 74, 86 (2d Cir. 2006) (citation omitted). Unlike strict liability, in an action for negligence "the plaintiff must also prove that the injury caused by the defect could have been reasonably foreseen by the manufacturer." Id. In other words, a "cause of action in negligence will lie where it can be shown that a manufacturer was responsible for a defect that caused injury, and that the manufacturer could have foreseen the injury." Id. (citation omitted).

The New York Court of Appeals describes three activities for which a manufacturer of a defective product may be held liable for negligence. "[A] product has a defect that renders the manufacturer liable for the resulting injuries if it: (1) contains a manufacturing flaw; (2) is defectively designed; or (3) is not accompanied by adequate warnings for the use of the product." In re New York City Asbestos Litig., 27 N.Y.3d 765, 787 (2016) ("In re N.Y.C. Asbestos"). Notably, the Court of Appeals did not include among its list of activities a manufacturer's liability for negligence in testing.

The Court of Appeals has not explicitly rejected a claim against a manufacturer of a defective product for negligence in testing. To the extent that this creates any uncertainty, resort to resources that may be appropriately consulted indicates that it would reject such a claim.

Applying New York law, a federal district court has concluded that New York does not recognize a "stand-alone failure-to-test cause of action." In re Zimmer NexGen Knee Implant Prod. Liab. Litig., No. 11 C 5468, 2017 WL 36406, at *13 (N.D. Ill. Jan. 3, 2017). Treatises on which the New York Court of Appeals relies recognize three theories of manufacturer liability for negligence and not a fourth independent theory

based on a failure to test. See In re N.Y.C. Asbestos, 27 N.Y.3d at 787 (listing the Restatement and other authoritative sources of law).

First and foremost, the Third Restatement of Torts defines only three activities creating product liability: liability for a manufacturing defect due to a defect in design, the manufacturing process, or in a failure to warn. It states,

> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:
>
> (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
>
> (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
>
> (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Restatement (Third) of Torts: Prod. Liab. § 2 (1998) ("R.3d. Torts") (emphasis supplied).

The Second Edition of Michael Weinberger's treatise on New York Products Liability law follows the same lines:

> The key concept in products liability jurisprudence is that of a product "defect." A product may generally be deemed defective if it has a manufacturing flaw or a design defect, or is manufactured without adequate warnings for its use.

1 N.Y. Products Liability 2d § 1:2 (2021). As a final authority, American Jurisprudence explicitly adopts the Restatement's formulation, and describes a products liability action as addressing "a defect in a product" that consists of "a mistake in manufacturing, improper design, or the inadequacy or absence of warnings regarding the use of the product." 63 Am. Jur. 2d Products Liability § 10 (2022).

Of course, evidence of a testing regimen or its absence may be submitted in connection with a particular claim, for instance to defend against or support a claim of negligence in product design. But negligent testing is not an independent products liability claim. See, e.g., R.3d. Torts § 2 cmt. m., n. Thus, evidence that the defendant "did or did not conduct adequately reasonable research or testing before marketing the product may be admissible (but is not necessarily required) regardless of whether the claim is based on negligence, strict liability, or implied warranty of merchantability." Id. at cmt. n.

Relying on the description in In re N.Y.C. Asbestos, 27 N.Y.3d at 787, of the torts available in New York to assert a product liability claim for negligence against a manufacturer, and on the statements of the law of products liability in authorities on which the New York Court of Appeals regularly relies, this Court predicts that New York's highest court would not recognize a tort imposing liability for a manufacturer's alleged failure to test. In other words, to the extent that the FAC has alleged a failure to test, that failure, taken as true for the purposes of this motion, is subsumed by the FAC's claim of negligence in design of the product.

In opposition, Dupere cites Kramer v. Showa Denko K.K., 929 F. Supp. 733, 747 (S.D.N.Y. 1996). Kramer does not opine that there is an independent cause of action for a manufacturer's negligent failure to test a product in New York.

Dupere next purports to cite to subsection 2:125 of the New York Pattern Jury Instructions ("NYPJI") for negligence in products liability.[3] The instruction quoted by the plaintiff reads:

[3] The plaintiff appears to have included an incorrect citation to the NYPJI. Section 2:125 in the editions of the NYPJI for each year from 2010 to the present does not contain the language cited by the plaintiff.

> Generally speaking, the negligence theory requires the plaintiff to prove that the manufacturer failed to exercise "reasonable care" in making the product for its intended (normal) or foreseeable uses. The negligence theory can also extend into examination of whether the defendant exercised reasonable care in inspecting or testing the product.

This description of evidence a jury may consider in deciding whether the plaintiff has shown negligence in the manufacture of the product does not indicate that a separate cause of action for a failure to test exists under New York law. Moreover, the 2021 edition of the NYPJI contains no independent pattern charge for negligent failure to test.[4]

B. Gross Negligence (Count IX)

The Defendants move to dismiss the FAC's claim of gross negligence contained in Count IX. A claim for gross negligence under New York law will survive "only if the plaintiff alleges facts plausibly suggesting that the defendant's conduct evinces a reckless disregard for the rights of others or smacks of intentional wrongdoing." Bayerische Landesbank, New York Branch v. Aladdin Cap. Mgmt. LLC, 692 F.3d 42, 61 (2d Cir. 2012)

[4] Four subsections of the NYPJI for products liability negligence lay out pattern jury charges for "Negligent Manufacture," the "Negligence of [a] Maker of Assembled Product," "Negligence of a Repairer of [a] Product," and "Negligent Design." N.Y. Pattern Jury Instr. -- Civil 2:125, 2:125A, 2:125B, 2:126 (2021).

(citation omitted). "Recklessness in the context of a gross negligence claim means an extreme departure from the standards of ordinary care, such that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. (citation omitted).

The FAC fails to plead facts sufficient to meet this high standard. The FAC does not plead facts that reflect of an extreme departure from the standards of ordinary care.

II. Claims Subject to Rule 9(b)

The Defendants move to dismiss the following four claims for the FAC's failure to plead these causes of action with the particularity required in Rule 9(b) of the Federal Rules of Civil Procedure: negligent misrepresentation (Count IV), fraud (Count V), fraudulent concealment (Count VI), and constructive fraud (Count VII). Rule 9(b) requires that a party alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Under these requirements, the complaint 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." Loreley Fin. (Jersey) No. 3 Ltd. v.

Wells Fargo Sec., LLC, 797 F.3d 160, 171 (2d Cir. 2015) ("Loreley I") (citation omitted).

As a threshold matter, Dupere does not contest that Rule 9(b) applies.[5] Each of these four claims must be dismissed for failure to plead with the particularity required by Rule 9(b).

All four claims require the plaintiff to plausibly allege that the Defendants made a specific misrepresentation or omitted to state a material fact. See Loreley I, 797 F.3d at 170 (listing elements of fraud in New York, including "a material misrepresentation or omission of a fact"); Monaco v. New York Univ. Med. Ctr., 623 N.Y.S.2d 566, 568 (1st Dep't 1995) (same for constructive fraud); Anschutz Corp. v. Merrill Lynch & Co., Inc., 690 F.3d 98, 114 (2d Cir. 2012) (same for negligent misrepresentation). For alleged frauds based on omissions of material fact, "a concealment of facts supports a cause of action for fraud only if the non-disclosing party has a duty to disclose." Remington Rand Corp. v. Amsterdam-Rotterdam Bank, N.V., 68 F.3d 1478, 1483 (2d Cir. 1995). "A duty to disclose

[5] While the Second Circuit has not determined whether claims for negligent misrepresentation are subject to the heightened pleading standard under Rule 9(b), district courts in this circuit have tended to hold that the rule does apply. See Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 188 (2d Cir. 2004).

may arise in two situations: first, where the parties enjoy a fiduciary relationship, and second, where one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of mistaken knowledge." Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 13 F.4th 247, 263 (2d Cir. 2021) ("Loreley II"); see also Am. L. Prod. Liab. 3d § 25:11.

Additionally, to meet Rule 9(b)'s heightened pleading standard in a claim for actual or constructive fraud, the complaint must (1) detail the events giving rise to the fraud, such as the statement or omission that is alleged to be fraudulent, the identity of the speaker, the location of the fraud, and the reason the statement is fraudulent and (2) allege facts "that give rise to a strong inference of fraudulent intent." Loreley I, 797 F.3d at 171; see also Cohen v. S.A.C. Trading Corp., 711 F.3d 353, 359 (2d Cir. 2013); Monaco, 623 N.Y.S.2d at 568. A strong inference of fraudulent intent "may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Eternity Glob. Master Fund Ltd., 375 F.3d at 187 (citation omitted).

Finally, to state a claim for negligent misrepresentation under New York law, a plaintiff must plead that "the defendant had a duty, as a result of a special relationship, to give correct information." Anschutz, 690 F.3d at 112. To show the requisite special relationship, a plaintiff may plead that the defendant "possess[ed] unique or specialized expertise, or [was] in a special position of confidence and trust with the injured party such that reliance on the negligent misrepresentation [was] justified." Mandarin Trading Ltd. v. Wildenstein, 16 N.Y.3d 173, 180 (2011) (citation omitted). "[E]xpertise alone cannot create a special relationship where otherwise the relationship between the parties is too attenuated." Id. at 181. A special relationship is "privity-like," id. at 180, and typically involves statements by "[p]rofessionals, such as lawyers and engineers, [who] by virtue of their training and expertise, may have special relationships of confidence and trust with their clients." Kimmell v. Schaefer, 89 N.Y.2d 257, 263 (1996).

The FAC has failed to identify with particularity any misrepresentations about TVT by the Defendants, much less when they were made, and how they were made. The FAC generally alleges that Dupere and her physician relied on the Defendants'

statements about the safety and effectiveness of TVT compared to other pelvic mesh products that were made in various marketing materials and by sales representatives. It does not specify which statements Dupere or her physician viewed or heard, how or when they were exposed to those statements, or why those statements were fraudulent.

The FAC also fails to assert other than in a conclusory manner that the Defendants acted knowingly and with fraudulent intent. Dupere does not allege facts showing when or if Ethicon or J&J knew that implanting TVT risked serious undisclosed complications, and that those complications included a possibility that the product would contract over time or become exposed following implantation. In opposition to this motion, she does not explain why her allegations should give rise to a strong inference of fraudulent intent. She merely repeats the same vague and general allegations from the FAC that are insufficient to meet the Rule 9(b) heightened standard. See Loreley I, 797 F.3d at 170.

To the extent these causes of action rely on a theory of omission -- such as the failure to disclose TVT's failure rates -- Dupere additionally fails to plead the source of the Defendants' duty to Dupere. The FAC alleges in conclusory

fashion that the Defendants were in a superior position to know that TVT presented complications but, as above, has failed to identify any details of when or how Ethicon and J&J knew about complications associated with TVT that were otherwise unknown to the public, or when the Defendants knew that physicians were prescribing TVT implantation to patients under a mistaken perception that those risks did not exist. See Remington Rand Corp., 68 F.3d at 1484 ("[A] disclosure duty ripens only when it becomes apparent to the non-disclosing party that another party is operating under a mistaken perception of a material fact.").

In opposition to this motion, Dupere asserts that it is Ethicon's role as a medical device manufacturer that creates a special relationship and cites Williamson v. Stryker Corp., No. 12 CIV. 7083 (CM), 2013 WL 3833081, at *11-*12 (S.D.N.Y. July 23, 2013). In Williamson, the court found such a duty to speak where the plaintiffs alleged that they spoke with representatives of the manufacturers and that at least one of them had "established a relationship of trust" with the manufacturer prior to deciding whether to undergo surgery. Id. No such facts are pleaded in the FAC. Accordingly, Dupere's claims based on various theories of fraud are dismissed.

III. New York Consumer Protection Act (Count VIII)

Finally, the Defendants move to dismiss Count VIII, which asserts a claim generally under New York's Consumer Protection Act. The Court construes this claim as alleging deceptive practices and false advertising under the New York Consumer Protection Act, N.Y. Gen. Bus. Law §§ 349(a), 350.[6] This claim in not subject to the pleading requirements of Rule 9(b). Pelman ex rel. Pelman v. McDonald's Corp., 396 F.3d 508, 511 (2d Cir. 2005).[7]

New York law prohibits "false advertising" and "deceptive acts or practices in the conduct of any business, trade, or commerce in the furnishing of any service in this state." N.Y. Gen. Bus. Law §§ 349(a), 350. A plaintiff bringing a claim under these statutes must allege "(1) that the defendant's deceptive acts were directed at consumers, (2) the acts are

[6] The FAC does not identify the subsection of the New York General Business Law under which the claim is being brought. Rather, it alleges generally that the "Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Article 22-A – (349 – 350-F-1)." Dupere's opposition brief does not clarify which provision of New York law she intends to invoke.

[7] The Defendants' motion to dismiss based on a failure to plead a violation of the New York General Business Law with the particularity required by Rule 9(b) is denied.

misleading in a material way, and (3) the plaintiff has been injured as a result." Chufen Chen v. Dunkin' Brands, Inc., 954 F.3d 492, 500 (2d Cir. 2020) (citation omitted). An act is materially misleading if it is "likely to mislead a reasonable consumer acting reasonably under the circumstances." Fink v. Time Warner Cable, 714 F.3d 739, 741 (2d Cir. 2013). "It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have mislead a reasonable consumer." Id.

Dupere fails to state a claim under §§ 349(a) or 350 of the New York General Business Law for the simple reason that she has failed to identify even one false advertisement or misleading consumer-facing statement regarding TVT. Thus, Dupere's consumer protection claim must also be dismissed.

Conclusion

The Defendants' July 9, 2021 motion to dismiss part of Count III and Counts IV to IX of the FAC is granted.

Dated: New York, New York
February 22, 2022

DENISE COTE
United States District Judge