UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

RODNEY G. SPARKS,

Plaintiff,

v. Case No. 8:20-cv-3074-SCB-TGW

MEDTRONIC, INC. and
COVIDEN LP,

Defendants.
_____/

ORDER

This cause comes before the Court on Defendants' Motion to Dismiss. (Doc. No. 29). Plaintiff opposes the motion. (Doc. No. 30). As explained below, Defendants' motion is granted.

I. Standard of Review

In deciding a motion to dismiss, the district court is required to view the complaint in the light most favorable to the plaintiff. See Murphy v. Federal Deposit Ins. Corp., 208 F.3d 959, 962 (11th Cir. 2000)(citing Kirby v. Siegelman, 195 F.3d 1285, 1289 (11th Cir. 1999)). The Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim. Instead, Rule 8(a)(2) requires a short and plain statement of the claim showing that the pleader is entitled to relief in order to give the defendant fair notice of what the

claim is and the grounds upon which it rests. See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)(citation omitted). As such, a plaintiff is required to allege "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. (citation omitted). While the Court must assume that all of the allegations in the complaint are true, dismissal is appropriate if the allegations do not "raise [the plaintiff's] right to relief above the speculative level." Id. (citation omitted). The standard on a 12(b)(6) motion is not whether the plaintiff will ultimately prevail in his or her theories, but whether the allegations are sufficient to allow the plaintiff to conduct discovery in an attempt to prove the allegations. See Jackam v. Hospital Corp. of Am. Mideast, Ltd., 800 F.2d 1577, 1579 (11th Cir. 1986).

II. Background

Plaintiff alleges the following in his second amended complaint (Doc. No. 28): Plaintiff Rodney G. Sparks had hernia repair surgery on January 19, 2018. Defendants Medtronic, Inc. and Coviden LP manufactured a product known as Coviden Pro Grip self-gripping polyester mesh ("the Mesh"), which was used during Plaintiff's surgery. On January 20, 2019, Plaintiff bent over to look under a vanity to locate a leak, and when he stood back up, he felt a sharp pain in his right side. Plaintiff contends that the Mesh was defectively designed, which caused

Plaintiff to develop a second hernia. Plaintiff had a second hernia surgery on February 20, 2019.

Based on the above, Plaintiff filed his second amended complaint, in which he asserts a claim of strict product liability against each of the defendants for a design defect in the Mesh. Specifically, Plaintiff alleges the following:

- The Mesh is made using polyester. When compared to polypropylene hernia mesh, polyester hernia mesh has higher hernia recurrence rates and higher mesh shrinkage rates.
- A reasonable alternative design is available utilizing polypropylene instead of polyester.
- The Mesh implanted in Plaintiff was in substantially the same condition as it was when it was sold by Defendants.
- The Mesh failed to perform as safely as an ordinary consumer would expect when used as it was intended to be used.
- The risk of danger in the design of the Mesh outweighs the benefits.
- As a direct and proximate result of the design defect, Plaintiff suffered injury and was damaged.

III. Motion to Dismiss

In response to Plaintiff's second amended complaint, Defendants move for dismissal, arguing that Plaintiff fails to sufficiently plead his strict liability design defect claims.[1] In order to properly plead his claims, Plaintiff must allege the following: "[1] the manufacturer's relationship to the product in question, [2] the defect and unreasonably dangerous condition of the product, and [3] the existence of the proximate causal connection between such condition and the [plaintiff's] injuries or damages." West v. Caterpillar Tractor Co., Inc., 336 So. 2d 80, 87 (Fla. 1976). Defendants argue that the claims should be dismissed, because Plaintiff fails to sufficiently identify a design defect in the Mesh or adequately plead causation. Upon consideration, the Court finds that the claims must be dismissed.

Plaintiff alleges that the Mesh was defectively designed, because it is made using polyester. Plaintiff further alleges that when compared to polypropylene hernia mesh, polyester hernia mesh has higher hernia recurrence rates and higher mesh shrinkage rates. Plaintiff alleges that instead of using polyester, the Mesh should have been made using polypropylene.

[1] [1] In his original complaint, Plaintiff asserted strict liability and negligence claims based on a manufacturing defect in the Mesh. (Doc. No. 1-1). In his first amended complaint, Plaintiff dropped the negligence claims and asserted only strict liability manufacturing defect claims. (Doc. No. 18). In his second amended complaint, Plaintiff now asserts design defect claims. (Doc. No. 28).

Assuming, without deciding, that Plaintiff has sufficiently alleged a design defect, Plaintiff still must sufficiently allege causation. Plaintiff, however, merely asserts the conclusory statement that as a direct and proximate result of the design defect, he suffered injury and was damaged. Plaintiff does not allege any facts to support his assertion.

For example, Plaintiff does not allege that the Mesh implanted in him shrank as a result of the design defect and that the shrinkage caused his second hernia. Nor is Plaintiff's allegation—that polyester hernia mesh has higher hernia recurrence rates—sufficient to allege that the polyester used in the Mesh was actually the cause of his second hernia. Finally, Plaintiff does not explain why he believes that his second hernia was caused by the Mesh as opposed to being a normal complication of a hernia repair, which can occur with or without the use of mesh.[2] As such, the Court finds that Plaintiff has failed to sufficiently allege causation. See Dunham v. Coviden, LP, 498 F. Supp.3d 549, 558-59 (S.D.N.Y. 2020) (finding that the plaintiff did not adequately allege causation, because she did not adequately allege that the use of polyester in the mesh actually caused her

[2] According to the FDA website, a "common adverse event[] for all surgical repair of hernias—with or without mesh—[includes] . . . hernia recurrence." See *Hernia Surgical Mesh Implants*, U.S. FOOD & DRUG ADMIN. (Feb. 4, 2018), accessed at: https://www.fda.gov/medical-devices/implants-and-prosthetics/hernia-surgical-mesh-implants. "[T]he Court may take judicial notice of publicly-available documents produced by the FDA." Rhodes v. Covidien LP, 2019 WL 2162845, at *3 n.30 (E.D. La. May 17, 2019) (citing Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011)).

injuries, nor did she address numerous other plausible alternative explanations for her injuries); Krulewich v. Coviden, LP, 498 F. Supp.3d 566, 576 (S.D.N.Y. 2020) (same); Green v. Coviden LP, 2021 WL 1198833, at *5 (S.D.N.Y. Mar. 30, 2021) (finding that the plaintiff's generic statement—that the defective design of the mesh caused her injuries—was not sufficient to allege causation, and also noting that the plaintiff did not attempt to explain why the mesh was a more likely cause of her injuries than other possible causes); Rincon v. Coviden, 2017 WL 2242969, at *1 (S.D.N.Y. May 22, 2017) (finding that the plaintiff had failed to sufficiently allege causation, because she had failed to explain why the mesh was a more likely cause of her injuries than other plausible explanations). Therefore, the Court finds that Plaintiff's design defect claims must be dismissed.

On page three at the end of his response brief, Plaintiff asks that the Court again grant him leave to amend his complaint if the Court finds that Defendants' motion should be granted. Plaintiff has already amended his complaint twice, and there is no reason to believe that a third amendment would not be futile. Plaintiff does not explain what factual allegations he might be able to add in order to withstand another motion to dismiss. As such, the Court denies Plaintiff's request to file a third amended complaint.

IV. Conclusion

Accordingly, it is ORDERED AND ADJUDGED that:

(1) Defendants' Motion to Dismiss (Doc. No. 29) is **GRANTED**.

(2) The Clerk is directed to enter judgment for Defendants and to close this case.

DONE AND ORDERED at Tampa, Florida, this 28th day of June, 2021.

Susan C. Bucklew

SUSAN C. BUCKLEW
United States District Judge

Copies to:
Counsel of Record