UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

KELLY NELSON,

Plaintiff,

v. Case No: 2:21-cv-423-JES-MRM

HOLOGIC, INC.,

Defendant.

OPINION AND ORDER

This matter comes before the Court on defendant Hologic Inc.'s Motion to Dismiss and Incorporated Memorandum of Law (Doc. #10) filed on June 3, 2021. Plaintiff filed a Response in Opposition (Doc. #29) on August 6, 2020, to which defendant filed a reply (Doc. #33) on August 17, 2021. For the reasons set forth below, the motion is denied.

I.

Plaintiff Kelly Nelson's (Plaintiff or Ms. Nelson) Complaint makes the following factual allegations: Ms. Nelson had Stage IV breast cancer, and as part of her cancer treatment she underwent a partial mastectomy on January 28, 2019. (Doc. #4, ¶¶ 6-7.) During the partial mastectomy, the surgeon implanted a Biozorb® 3D Bioabsorbable Marker (the Marker) designed and manufactured by Hologic, Inc. (Hologic or Defendant) (Id., ¶¶ 49-53) into her body. The Marker is supposed is "track and target radiation," and part

of it was designed to be absorbed into the body post-surgery. (Id., ¶¶ 11, 14.) The Marker's Instructions For Use[1] state that it is

> comprised of a bioabsorbable spacer that holds Titanium radiopaque marker clips. The bioabsorbable spacer material (poly lactic acid) is resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site. . . . The bioabsorbable spacer is resorbed by a process of hydrolysis whereby the degradation products of the spacer material are metabolized by the body. The spacer material retains its functional integrity for approximately 2 months, while complete resorption may require up to one or more years.

(Doc. #10-1, p. 2.) The Marker was implanted without any complications. (Doc. #4, ¶¶ 8, 10-11.) Ms. Nelson nevertheless experienced physical, mental and emotional issues[2] for eighteen months thereafter, which she alleges "stem directly from [the Marker] not performing as it was intended to." (Id., ¶¶ 16, 38.)

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[1] Defendant has submitted the Marker's Instructions For Use in connection with its motion to dismiss and requests that the Court take judicial notice of the Instructions since it is central to any claim regarding BioZorb Marker's design and manufacture. (Doc. #10, p. 3 n.1.) The Court will do so. Horne v. Potter, 392 F. App'x 800, 802 (11th Cir. 2010) ("A district court may take judicial notice of certain facts without converting a motion to dismiss into a motion for summary judgment.").

[2] Such issues included a drop in white blood cell count, thyroid and hormonal problems, severe shooting pains, uncontrollable hot flashes, swelling, and fever, being "riddled with feelings of rage, depression, sadness, loss of sleep and emotional distress," difficulty sleeping, contracting the Shingles virus, loss of appetite, and the onset of an eating disorder. (Doc. #4, ¶¶ 17-24.) The Complaint further alleges that following removal of the Marker, Plaintiff experienced a yeast and fungal infection and was permanently disfigured. (Id., ¶¶ 35, 43-46.)

The Complaint asserts a single claim for strict products liability against Hologic under Florida law.[3] (Id., p. 5.) Specifically, Plaintiff alleges the Marker is "either defectively designed, defectively manufactured, or [Hologic] knew or should have known the risks and failed to warn [her]." (Id., ¶ 51.) Ms. Nelson has clarified, however, that the Complaint is not intended to state a claim against Hologic for failure to warn,[4] so the Court will strike the phrase "or knew or should have known the risks and failed to warn [her]" from the Complaint.

II.

Under Federal Rule of Civil Procedure 8(a)(2), a Complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This obligation "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (citation omitted). To survive dismissal, the factual allegations must be "plausible" and "must be enough to raise a right to relief above the speculative level." Id. See also Phx. Entm't Partners, LLC v.

[3] In diversity cases, federal courts apply the substantive law of the state in which the case arose, which in this case is Florida. Pendergast v. Sprint Nextel Corp., 592 F.3d 1119, 1132-33 (11th Cir. 2010).

[4] See (Doc. #29, ¶ 65.)

Casey Rd. Food & Bev., LLC, 728 F. App'x 910, 912 (11th Cir. 2018). This requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (citations omitted).

In deciding a Rule 12(b)(6) motion to dismiss, the Court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff, Erickson v. Pardus, 551 U.S. 89, 127 S. Ct. 2197, 167 L. Ed. 2d 1081 (2007), but "[l]egal conclusions without adequate factual support are entitled to no assumption of truth." Mamani v. Berzaín, 654 F.3d 1148, 1153 (11th Cir. 2011) (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. "Factual allegations that are merely consistent with a defendant's liability fall short of being facially plausible." Chaparro v. Carnival Corp., 693 F.3d 1333, 1337 (11th Cir. 2012) (internal citations omitted). Thus, the Court engages in a two-step approach: "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

III.

Defendant seeks dismissal, asserting that the Complaint is devoid of well-pleaded facts necessary to establish either a

plausible claim of a design or manufacturing defect, or a plausible basis for medical causation. (Doc. #10, pp. 1-2.) The Court finds that the Complaint sufficiently plead both elements.

Florida law recognizes strict liability claims based on a manufacturing defect. See Dye v. Covidien LP, 470 F. Supp. 3d 1329, 1334 (S.D. Fla. 2020). "In order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages." Aubin v. Union Carbide Corp., 177 So. 3d 489, 502-03 (Fla. 2015) (quoting West v. Caterpillar Tractor Co., 336 So.2d 80, 86-87 (Fla. 1976)). Thus, under Florida strict liability law, "the manufacturer of a defective product can be held liable if the manufacturer made the product in question, if the product has a defect that renders it unreasonably dangerous, and if the unreasonably dangerous condition is the proximate cause of the plaintiff's injury." Jennings v. BIC Corp., 181 F. 3d 1250, 1255 (11th Cir. 1999). As relevant to this case, a product may be defective based on a defective design or a manufacturing defect.

Here, Defendant argues that Plaintiff has not sufficiently plead a defect in the Marker. (Doc. #10, pp. 6-7.) The Court does

not agree, finding that the Complaint established minimally sufficient factual allegations.

Plaintiff alleges that although the non-metallic portion of the Marker was designed to dissolve, it was removed approximately eighteen months after implantation and was found to be "intact." (Doc. #4, ¶¶ 27, 40, 53.) Plaintiff therefore alleges that the Marker "did not absorb as marketed," nor did it "dissolve once it performed its function." (Id., ¶¶ 39-40, 51.) Viewing the allegations in the light most favorable to Plaintiff, the Court reasonably infers that the Marker being "intact" demonstrates that it did not dissolve at all, which after eighteen months is adequate to state a plausible defective manufacturing claim.

Defendant also argues that the Complaint fails to plead sufficient facts showing that the alleged defect in the Marker caused Plaintiff's injuries. (Doc. #10, p. 9.) The Complaint alleges that Plaintiff suffered various physical, mental, and emotional complications,[5] which Plaintiff, along with her "medical caregivers," believe "all stem directly from [the Marker] not performing as it was intended to." (Doc. #4, ¶¶ 16-25, 38.) Plaintiff further alleges that all of her aliments described in the Complaint were directly and/or proximately cause by the Marker. (Id., ¶ 52.)

[5] See supra note 2.

Defendant maintains that dismissal is appropriate because Plaintiff summarily concluded that her myriad injuries were "proximately caused" by the Marker, but she cites to no medical literature, regulatory actions or statements, or any other factual basis to connect her injuries to the Marker. (Doc. #10, p. 10.) The Court is not persuaded that citation to medical literature or regulatory actions are necessary at this stage of litigation. The allegations of causation contain minimally sufficient facts to give notice to Defendant as to the injuries Plaintiff claims were caused by the Marker. See Merino v. Ethicon Inc., No. 20-25308-CIV, 2021 U.S. Dist. LEXIS 84942, at *17 (S.D. Fla. May 4, 2021) (finding that where plaintiff alleged a device was implanted in her body, she suffered complications in her pelvic area following implantation, and as a direct and proximate result of the devices defects Plaintiff had to undergo medical treatment was sufficient to allege causation at motion to dismiss stage); contra Jackson v. St. Jude Med. Neuromodulation Div., No. 2:14-cv-717-FtM-38DNF, 2015 U.S. Dist. LEXIS 40329, at *18 (M.D. Fla. Mar. 30, 2015)(finding plaintiff failed to state a claim as to causation where he simply alleged an implant caused him to be "injured"). Indeed, "[u]nder Florida law, plaintiffs are not required to set forth [in the complaint] the precise chemical, biological, or other process by which the defective product causes the alleged harm [to defeat] a motion to dismiss." Dye, 470 F. Supp. 3d at 1336. Florida

law recognizes a legal inference that the product is defective when the product malfunctions during normal operation. See McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1258 (11th Cir. 2002). While expert testimony may be needed later, Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1334 n.4 (11th Cir. 2010), it is not essential at the pleading stage.

Accordingly, it is now

ORDERED:

1. Defendant Hologic Inc.'s Motion to Dismiss and Incorporated Memorandum of Law (Doc. #10) is **DENIED.**
2. The Court strikes the phrase "or knew or should have known the risks and failed to warn [her]" from ¶ 51 of the Complaint. (Doc. #4, ¶ 51.)

DONE AND ORDERED at Fort Myers, Florida, this 6th day of December, 2021.

JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:
Counsel of record