UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

NYOKA SMITH,

Plaintiff,

vs. Case No. 3:21-cv-815-MMH-LLL

BOSTON SCIENTIFIC CORPORATION,

Defendant.
_____/

O R D E R

THIS CAUSE is before the Court on Defendant Boston Scientific Corporation's Motion to Dismiss Plaintiff's Amended Complaint and Memorandum of Law (Doc. 15; Motion), filed November 9, 2021. In the Motion, Boston Scientific Corporation (Boston Scientific) requests that the Court dismiss portions of Plaintiff Nyoka Smith's First Amended Complaint and Demand for Jury Trial (Doc. 7; Amended Complaint), filed September 10, 2021. Smith timely filed a response in opposition to the Motion. See Plaintiff's Response to Defendant's Motion to Dismiss and Memorandum in Opposition (Doc. 17; Response), filed November 30, 2021. Accordingly, this matter is ripe for review.

I. Legal Standard

In ruling on a motion to dismiss, the Court must accept the factual allegations set forth in the complaint as true. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002); see also Lotierzo v. Woman's World Med. Ctr., Inc., 278 F.3d 1180, 1182 (11th Cir. 2002). In addition, all reasonable inferences should be drawn in favor of the plaintiff. See Randall v. Scott, 610 F.3d 701, 705 (11th Cir. 2010). Nonetheless, the plaintiff must still meet some minimal pleading requirements. Jackson v. Bellsouth Telecomm., 372 F.3d 1250, 1262–63 (11th Cir. 2004) (citations omitted). Indeed, while "[s]pecific facts are not necessary[,]" the complaint should "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Erickson v. Pardus, 551 U.S. 89, 93 (2007) (per curiam) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Further, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). A "plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" Twombly, 550 U.S. at 555 (internal quotations omitted); see also Jackson, 372

F.3d at 1262 (explaining that "conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal") (internal citation and quotations omitted). Indeed, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions[,]" which simply "are not entitled to [an] assumption of truth." Iqbal, 556 U.S. at 678, 680. In addition, "[a] court need not accept as true allegations in a complaint that contradict or are inconsistent with judicially-noticed facts." Chapman v. Abbott Labs., 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013).[1] Thus, in ruling on a motion to dismiss, the Court must determine whether the complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face[.]'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570).

II. Background[2]

During a surgery in 2018, Smith's physician implanted a Boston Scientific Obtryx II Halo System and a Boston Scientific Upsylon Y Mesh product

[1] The Court notes that although decisions of other district courts are not binding, they may be cited as persuasive authority. See Stone v. First Union Corp., 371 F.3d 1305, 1310 (11th Cir. 2004) (noting that, "[a]lthough a district court would not be bound to follow any other district court's determination, the decision would have significant persuasive effects").

[2] In considering the Motion, the Court must accept all factual allegations in the Amended Complaint as true, consider the allegations in the light most favorable to Smith, and accept all reasonable inferences that can be drawn from such allegations. Hill v. White, 321 F.3d 1334, 1335 (11th Cir. 2003); Jackson v. Okaloosa County, 21 F.3d 1531, 1534 (11th Cir. 1994). As such, the facts recited here are drawn from the Amended Complaint and may well differ from those that ultimately can be proved.

(collectively, the "Mesh Products") into Smith to treat stress urinary incontinence and vaginal vault prolapse. See Amended Complaint ¶¶ 1–2. Boston Scientific designed, manufactured, and marketed the Mesh Products, which are medical devices available only by prescription. See id. ¶¶ 1, 48, 59, 82, 107; Motion at 2–3. According to Smith, Boston Scientific knew or should have known that the Mesh Products had a propensity to cause numerous dangerous complications, including several types of pain, urinary dysfunction, perforation and vaginal scarring, and the need for future surgeries. See Amended Complaint ¶¶ 35–36, 50, 59, 109, 117. Prior to Smith's surgery, the Food and Drug Administration (FDA) and several medical scholars "examined each of these injuries, conditions, and complications, and . . . reported that they [were] casually related to the pelvic mesh products." Id. ¶¶ 19–22, 37.

As alleged in the Amended Complaint, Boston Scientific had a duty to "provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities" of the Mesh Products. Id. ¶ 64. Smith asserts that Boston Scientific failed to adequately warn her, her health care providers, or the public of the Mesh Products' risks or the frequency, magnitude, and scope of those risks. See id. ¶¶ 34, 67–68, 71, 109, 111, 114–15. Because Boston Scientific provided inadequate warnings, Smith and her healthcare providers were unaware that using the Mesh Products exposed her to these risks. See id. ¶¶ 47, 69, 71, 118, 120. Smith alleges that, as a proximate cause

of Boston Scientific's failure to warn, her physician implanted the Mesh Products into Smith. See id. ¶¶ 77, 118, 120–21. The Mesh Products caused Smith to experience numerous types of physical and mental pain, recurrence of incontinence, perforation and vaginal scarring, additional medical treatment, and financial loss. See id. ¶¶ 42, 77, 124. According to Smith, her injuries are "of the exact type" reported by the FDA and the other medical literature. Id. ¶ 125.

Based on these and other allegations, Smith initiated this action on August 23, 2021, by filing a Complaint for Damages and Jury Demand (Doc. 1; Complaint). After the Court sua sponte struck the Complaint, see Order (Doc. 5), filed August 27, 2021, Smith filed her Amended Complaint. In the Amended Complaint, Smith alleges three causes of action. In Count One, Smith asserts a negligence claim based on Boston Scientific's product design, manufacturing, testing, and warnings. See Amended Complaint ¶¶ 48–78. In Count Two, she alleges that Boston Scientific is strictly liable for its defective design of the Mesh Products. See id. ¶¶ 79–106. And, in Count Three, Smith asserts another strict liability claim based on Boston Scientific's failure to adequately warn physicians and patients of the Mesh Products' risks. See id. ¶¶ 107–23.

III. Parties' Arguments

In its Motion, Boston Scientific asks the Court to dismiss Count Three and the portion of Count One that alleges a negligent failure to warn. See

Motion at 15. Boston Scientific states that, under Florida law, "a manufacturer has no duty to warn of product risks where those risks are obvious or already known to the product's user." Id. at 8. Boston Scientific then represents that federal courts have applied this rule to the learned intermediary doctrine and held "that 'a manufacturer's duty to warn physicians is limited and does not extend to risks already known to the medical community.'" Id. (quoting Aquino v. C.R. Bard, Inc., 413 F. Supp. 3d 770, 790 (N.D. Ill. 2019)). Boston Scientific contends that the FDA publications and other medical literature cited in the Amended Complaint demonstrate that the medical community knew the risks of the Mesh Products before Smith's physician recommended that she receive the Mesh Products.[3] See id. at 9–13. Boston Scientific further argues that, because the medical community already knew of the Mesh Products' risks, Boston Scientific had no duty to warn Smith's physician. See id. at 14. Thus, according to Boston Scientific, Smith's citations to the FDA publications and other literature fatally undermine and render implausible her allegation that Boston Scientific had a duty to warn of the Mesh Products' risks. See id.

In her Response, Smith asserts that Boston Scientific misrepresents both allegations of the Amended Complaint and the law. See Response at 6–9.

[3] Boston Scientific attached several of these documents to its Motion and urges the Court to consider them. See Motion at 10–12. The Court declines to decide whether it may take judicial notice of the documents because the Motion is due to be denied whether or not the Court considers them.

Smith argues that, in the Amended Complaint, she alleges that Boston Scientific hid the magnitude and frequency of the problems caused by the Mesh Products. See id. at 7. In addition, Smith contends that some of the injuries she alleges—including neuromuscular pain and lifelong, life-altering pain—were not known to the medical community at large and that the magnitude and severity of the complications were not known. See id. at 9. In addition, she argues that Boston Scientific misrepresents Florida law. See id. at 7–8.

IV. Discussion

Having reviewed the filings and applicable law, the Court finds that the Motion is due to be denied because Boston Scientific has not provided authority demonstrating that Florida law supports its position. In this diversity action, the Court must apply Florida law. See Salinero v. Johnson & Johnson, 995 F.3d 959, 964 (11th Cir. 2021). Under Florida law, a manufacturer has a duty to warn "where a product is inherently dangerous or has dangerous propensities" unless the danger is obvious or already known to the product's user. Rodriguez v. New Holland N. Am., Inc., 767 So. 2d 543, 544–45 (Fla. 3d DCA 2000) (per curiam) (quoting Siemens Energy & Automation, Inc. v. Medina, 719 So. 2d 312, 314 (Fla. 3d DCA 1998) (per curiam)) (addressing a negligence claim); see Pinchinat v. Graco Children's Prods., Inc., 390 F. Supp. 2d 1141, 1146 (M.D. Fla. 2005) (addressing a strict liability claim). For a manufacturer of prescription drugs or medical devices, the Florida Supreme Court has

instructed that the duty to warn is "directed to the physician," who acts as a learned intermediary between the manufacturer and the patient. Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989); see Salinero, 995 F.3d at 964.

Here, Boston Scientific does not contend that Smith has failed to plead enough facts to state plausible failure-to-warn claims. Rather, Boston Scientific argues that Smith has pled too much. See Motion at 14 ("Plaintiff's own allegations about the broad publication of the very mesh-related risks she claims to have experienced fatally undercut[] her claims of strict liability and negligent failure to warn . . . ."). Boston Scientific's argument rests on its assertion that, as an application of the learned intermediary doctrine, "federal courts have consistently held that 'a manufacturer's duty to warn physicians is limited and does not extend to risks already known to the medical community.'" Id. at 8 (quoting Aquino, 413 F. Supp. 3d at 790). However, the Court finds no support for this assertion in Florida law. The cases cited by Boston Scientific are inapposite. Three of the cited cases apply Illinois law. See Aquino, 413 F. Supp. 3d at 790; Carlen v. Coloplast Corp., No. 3:19-cv-01304-GCS, 2020 WL 5645308, at *2 (S.D. Ill. Sept. 22, 2020); In re Zyprexa Prods. Liab. Litig., Nos. 04–MD–1596, 06–CV–3457, 2010 WL 348276, at *9–10 (E.D.N.Y. Jan. 22, 2010). One cited case applies the Vaccine Act, 42 U.S.C. § 300aa-22, in relation to a claim brought pursuant to Nevada law. See Holmes v. Merck & Co., No.

2:04-cv-00608-BES-GWF, 2007 WL 9728627, at *3–4 (D. Nev. Nov. 1, 2007). These cases shed no light on the law applicable here.

Although Boston Scientific cited one case decided by the Florida Supreme Court, it is readily distinguishable. See generally Felix, 540 So. 2d 102. In Felix, the "prescribing physician testified that he fully understood the warnings and also had prior knowledge" of the risk of the harm suffered by the plaintiff. Id. at 105. Because the prescribing physician was fully informed of the relevant risk, the Florida Supreme Court held that the alleged inadequate warning could not have been the proximate cause of the injury. See id. Thus, Boston Scientific has produced no legal authority for its proposition that Florida applies Boston Scientific's suggested extension of the learned intermediary doctrine. Moreover, the situation in Felix is different from the situation here because Smith specifically alleges that her prescribing physician was not adequately informed of the Mesh Products' risks. See Amended Complaint ¶¶ 71, 120.

More importantly, Boston Scientific's argument appears to be inconsistent with Florida law. As previously stated, a manufacturer has no duty to warn of obvious or known dangers. Rodriguez, 767 So. 2d at 544–45. Courts have found a risk to be obvious when the danger "is apparent to any reasonable individual," Rodriguez v. Akal Sec., Inc., 12-20550-CIV, 2013 WL 435947, at *3 (S.D. Fla. Feb. 4, 2013), aff'd, 534 F. App'x 921 (11th Cir. 2013), or "well known to all except those of the tenderest age," Insua v. JD/BBJ, LLC,

913 So. 2d 1262, 1264 (Fla. 4th DCA 2005) (quoting Richmond v. Fla. Power & Light Co., 58 So. 2d 687, 688 (Fla. 1952)); see also Cohen v. GM Corp., Cadillac Div., 427 So. 2d 389, 390–91 (Fla. 4th DCA 1983) (finding that it is obvious that "when the brake was released, the [running] car would move in accordance with the gear"). Florida courts have also found no duty to warn when the injured user actually knew of the risk. See Rodriguez, 767 So. 2d at 545 ("[T]here is no duty to warn the plaintiff of a danger that he is aware of."); Perez v. Nat'l Presto Indus., Inc., 431 So. 2d 667, 669 (Fla. 3d DCA 1983); Clark v. Boeing Co., 395 So. 2d 1226, 1228–29 (Fla. 3d DCA 1981); see also Scheman-Gonzalez v. Saber Mfg. Co., 816 So. 2d 1133, 1139 (Fla. 4th DCA 2002) (finding that a significant question of fact remained as to whether the product's user knew of the particular danger involved).

Here, Boston Scientific does not demonstrate how the knowledge of the medical community establishes that the Mesh Products' dangers were obvious or known to Smith or her prescribing physician. Notably, at this stage of the proceedings, all inferences are drawn in Smith's favor, and the very fact that members of the medical community had to research the Mesh Products' risks weighs against a finding that the risks were obvious. In addition, the knowledge of the medical community in general neither proves nor refutes Smith's allegations about what she or her individual physician knew and did not know. Therefore, Boston Scientific's argument that the knowledge of the

medical community at large can eliminate a manufacturer's duty to provide adequate warnings to the relevant prescribing physician appears to be inconsistent with Florida law. Mindful that, "[w]ithout some indication that Florida intends to recognize so significant a change in the law, a federal court sitting in diversity ought not to do so," Salinero, 995 F.3d at 968, the Court declines to apply Boston Scientific's proposed construction of the learned intermediary doctrine and the medical community's knowledge.

Even if the Court assumed arguendo that Boston Scientific has correctly stated Florida's approach to the learned intermediary doctrine, the Court still would find that Boston Scientific's argument is unavailing. This is so because Boston Scientific's argument is based on the unsupported assumption that the existence of some medical literature warning of the Mesh Products' risks establishes that the medical community at large knew of the risks. See Motion at 7 ("Plaintiff's own Complaint asserts that the adverse effects and injuries she claims to have suffered 'are of the exact type' that were publicly disseminated by the FDA and medical organizations, and thus well-known to the medical community, years before her 2018 implant." (emphasis added) (quoting Amended Complaint ¶ 125)). The FDA publications and other medical articles may provide some evidence that, as a matter of fact, some members of the medical community knew of the Mesh Products' risks. But the public availability of information concerning the Mesh Products' risks does not

necessarily mean that the information was so well-known that, as a matter of law at the pleadings stage, the medical community in general knew of the risks. Boston Scientific cites no authority holding that Florida law requires such a logical leap. Without this assumption, Smith's allegations concerning some medical publications do not establish the knowledge of the medical community, much less the knowledge of Smith or her provider. Boston Scientific's failure to support this critical assumption provides an additional reason to deny the Motion. Therefore, because Boston Scientific's argument is unsupported by Florida law and relies on an unwarranted assumption, the Court finds that the Motion is due to be denied.

Accordingly, it is

ORDERED:

Defendant Boston Scientific Corporation's Motion to Dismiss Plaintiff's Amended Complaint and Memorandum of Law (Doc. 15) is **DENIED.**

DONE AND ORDERED in Jacksonville, Florida, on July 27, 2022.

MARCIA MORALES HOWARD
United States District Judge

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Copies to:

Counsel of Record