UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

DONALD WADE,

Plaintiff,

v. Case No. 8:23-cv-1483-TPB-TGW

B. BRAUN MEDICAL INC., and
B. BRAUN MEDICAL,

Defendants.
_____/

ORDER GRANTING IN PART, AND DENYING IN PART, DEFENDANT'S "MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR FAILURE TO STATE A CLAIM"

This matter is before the Court on Defendant B. Braun Medical Inc.'s "Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim," filed by counsel on September 13, 2023. (Doc. 13). On October 10, 2023, Plaintiff Donald Wade filed a response in opposition to the motion. (Doc. 17). After reviewing the motion, response, court file, and the record, the Court finds as follows:

Background[1]

Vena Tech filters are surgically implanted in a patient's vena cava (a vein that returns blood to the heart from the lower portion of the body) to prevent recurrent pulmonary embolisms. Defendant B. Braun Medical (B. Braun France) is a French

[1] The Court accepts as true the facts alleged in Plaintiff's complaint for purposes of ruling on the pending motion to dismiss. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007) ("[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint."). The Court is not required to accept as true any legal conclusions couched as factual allegations. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986).

company that designs, manufactures assembles, advertises, distributes, and sells medical products such as Vena Tech IVC filters, including the Vena Tech 30D IVC filter at issue in this case. Defendant B. Braun Medical Inc. ("BMI"), an affiliate of B. Braun France, distributed Vena Tech filters and was B. Braun France's exclusive distributor in the United States in 2005. BMI was responsible for the labeling and user information provided with the filters.

On March 3, 2005, medical professionals at Brandon Regional Hospital in Brandon, Florida, implanted a Vena Tech 30D IVC filter into Plaintiff Donald Wade. Defendants represented that the device was safe for permanent placement. However, on December 12, 2019, Plaintiff underwent a percutaneous procedure to remove the filter, which had tilted and perforated the IVC wall. The filter fractured, and pieces traveled to Plaintiff's lung and heart, where they remain today. According to Plaintiff, as a result of the filter's failure, he is at risk for future migrations, perforations, and hemorrhaging. He will require ongoing medical care and faces numerous health risks, including death.

Legal Standard

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing the [plaintiff] is entitled to relief." Fed. R. Civ. P. 8(a). While Rule 8(a) does not demand "detailed factual allegations," it does require "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 (2007). In order to survive a motion to dismiss, factual

allegations must be sufficient "to state a claim to relief that is plausible on its face." *Id.* at 570.

Federal Rule of Civil Procedure 9(b) requires a party alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). As courts have explained, the purpose of Rule (9)(b) is to ensure that defendants have sufficient notice and information to formulate a defense. *See Trinity Graphic, USA, Inc. v. Tervis Tumbler Co.*, 320 F. Supp. 3d 1285, 1294 (M.D. Fla 2018). "Essentially, a plaintiff satisfies Rule 9(b) by alleging who, what, when, where, and how." *Id.* (citing *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1262 (11th Cir. 2006)).

When deciding a Rule 12(b)(6) motion, review is generally limited to the four corners of the complaint. *Rickman v. Precisionaire, Inc.*, 902 F. Supp. 232, 233 (M.D. Fla. 1995). Furthermore, when reviewing a complaint for facial sufficiency, a court "must accept [a] [p]laintiff's well pleaded facts as true, and construe the [c]omplaint in the light most favorable to the [p]laintiff." *Id.* (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). "[A] motion to dismiss should concern only the complaint's legal sufficiency, and is not a procedure for resolving factual questions or addressing the merits of the case." *Am. Int'l Specialty Lines Ins. Co. v. Mosaic Fertilizer, LLC*, 8:09-cv-1264-T-26TGW, 2009 WL 10671157, at *2 (M.D. Fla. Oct. 9, 2009) (Lazzara, J.).

Analysis

In his complaint, Plaintiff generally alleges that Defendants failed to disclose to physicians and patients that its permanent IVC filters, including the Vena Tech 30D IVC filter, were defective because they could not "withstand the normal anatomical and physiological loading cycles exerted in vivo." He brings claims for negligence (Count I), strict products liability (failure to warn) (Count II), strict products liability (design defect) (Count III), negligent misrepresentation (Count IV), and punitive damages.[2] BMI moves to dismiss each count of the complaint for failure to state a claim.[3]

Failure to Warn

BMI argues that Plaintiff's failure to warn claims in Counts I and II are insufficiently pled. First, BMI argues that the claims are not factually supported due to the application of the learned intermediary doctrine. To the extent that Plaintiff's claims are based on a failure to warn Plaintiff personally, BMI correctly points out that medical device manufacturers do not have a duty to directly warn a patient – rather, they are only required to provide physicians with sufficient information about a product's risks. However, Plaintiff also alleges that Defendants failed to adequately warn his physicians of the risks of the filter. As such, the complaint properly alleges that Defendants breached their duties. *See Pritchett v.*

[2] There is a scrivener's error regarding the count number for punitive damages in the complaint.
[3] The Court notes B. Braun France has not yet appeared in this case, and no return of service has been filed.

Argon Med. Devices, Inc., No. 6:21-cv-1400-PGB-GJK, 2022 WL 19914513, at *3 (M.D. Fla. Jan. 13, 2022).

To the extent the claims are based on BMI's failure to warn physicians, BMI argues that Plaintiff's allegations are comprised of only vague legal conclusions. The complaint explicitly alleges that Defendants failed to adequately warn of the filter's inability "to withstand the normal anatomical and physiological loading cycles exerted in vivo," along with its high risk of device failure, including "fracture, migration, tilting, causing thrombosis, occlusion and/or perforation of the vena cava wall." Plaintiff has sufficiently alleged his failure to warn claims. The motion is denied as to these grounds.

Design Defect

BMI also argues that Plaintiff fails to state a strict liability design defect claim because he does not specify what part of the design Defendants should have changed to improve the filter. "To state a claim in Florida for strict products liability based on a design or manufacturing defect a plaintiff must plead three elements: (1) a relationship between the defendant and the product; (2) a defect which caused the product to be unreasonably dangerous; and (3) causation between the defect and the harm suffered by the user. The complaint must contain factual allegations about what was in fact defective about the product." *Id*. at 3 (citing *Merino v. Ethicon, Inc.*, 536 F. Supp. 3d 1271, 1281 (S.D. Fla. 2021)).

In the complaint, Plaintiff alleges that the Vena Tech 30D IVC filter design is unable to "withstand the normal anatomical and physiological loading cycles

exerted in vivo" and has "insufficient strength or structural integrity to withstand normal placement within the human body," creating risks of "fracture, migration, tilting…and…perforation of the vena cava wall." Although a closer call, because Plaintiff identifies issues with the product's strength and structure, the Court finds that these allegations are sufficient to state a design defect claim. *See id*. at 3; *Suttman-Villars v. Argon Med. Devices, Inc.*, 553 F. Supp. 3d 946, 958 (D.N.M. 2021); *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 825 (D.N.J. 2019); *Douse v. Boston Sci. Corp.*, 314 F. Supp. 3d 1251, 1260 (M.D. Fla. 2018). The motion is denied as to this ground. This argument may, of course, be revisited, if appropriate, at summary judgment.

Negligence

BMI next argues that Plaintiff fails to adequately state any plausible negligence claims. The elements of a negligence claim are "(1) a legal duty owed by defendant to plaintiff, (2) breach of that duty by defendant, (3) injury to plaintiff legally caused by defendant's breach, and (4) damages as a result of that injury." *Id*. at 1259. In this case, Plaintiff alleges Defendants had a duty to exercise reasonable care in "development, testing, design, manufacture, inspection, marketing, advertising, labeling, promotion, distribution, and sale" of the filters, that Defendants breached these duties in several identified ways, and that Plaintiff suffered serious injuries as a result of Defendants' conduct. These allegations are

generally sufficient to state plausible negligence claims. *See Douse*, 314 F. Supp. 3d at 1259. The motion is denied as to this ground.[4]

Negligent Misrepresentation

BMI argues the complaint fails to meet the Rule 9(b) heightened pleading standard required for negligent misrepresentation. "To plead negligent misrepresentation under Florida law, a plaintiff must allege: (1) the defendant made a statement of material fact that the defendant believed was true but was actually false; (2) the defendant was negligent because he should have known the statement was false; (3) the defendant intended to induce the plaintiff to rely on the false statement; and (4) an injury resulted to the plaintiff acting in justifiable reliance on the false statement." *Collins v. Countrywide Home Loans, Inc.*, 680 F. Supp. 2d 1287, 1293 (M.D. Fla. 2010).

The specificity requirements of Federal Rule of Civil Procedure 9(b) apply to claims for negligent misrepresentation, which sounds in fraud. *See, e.g.*, *Linville v. Ginn Real Estate Co., LLC*, 697 F. Supp. 2d 1302, 1306 (M.D. Fla. 2010). To satisfy the requirements of Rule 9(b), a plaintiff must allege the following:

> (1) Precisely what statements were made in what documents or oral representations or what omissions were made[;] … (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same[;] … (3) the content of such statements and the manner in

[4] The Court notes that some of Plaintiff's negligence claims may be subsumed into his design defect and failure to warn claims. *See Shapiro v. NuVasive*, *Inc.*, No. 19-23163-Civ-Scola, 2019 WL 5742159, at *2 (S.D. Fla. Nov. 5, 2019). However, at this stage of the proceedings, and due to the limited nature of the briefing, the Court will permit the negligence claims to proceed in full at this time. However, this issue may be revisited at summary judgment, if appropriate.

> which they misled the plaintiff[;] and (4) what the defendants obtained as a consequence of the fraud.

Drilling Consultants, Inc. v. First Montauk Sec. Corp., 806 F. Supp. 2d 1228, 1234 (M.D. Fla. 2011) (quoting *Ziemba v. Cascade Int'l Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001)).

Plaintiff alleges that through fraudulent advertisements, reports, and other marketing materials, Defendants negligently provided the medical community – including Plaintiff's physicians – with false or incorrect material information concerning the Vena Tech IVC filter, including misrepresentations related to the safety, efficacy, failure rate and approved uses of the filter. Plaintiff specifically identifies several misrepresentations, and he states that these misrepresentations allowed Defendants to sell the filters, including the one that was implanted into Plaintiff. As such, the complaint adequately states a claim for negligent misrepresentation. *See Pritchett,* 2022 WL 19914513, at *3. The motion to dismiss is denied as to this ground.

Punitive Damages

In Count V, Plaintiff asserts an independent claim for punitive damages. But punitive damages "is not an independent cause of action." Rather, certain causes of action may provide for the recovery of punitive damages. *See Byrne v. Nezhat*, 262 F. 3d 1075, 1093 n.34 (11th Cir. 2001). Accordingly, the motion is granted, and this count is dismissed to the extent punitive damages is asserted as a stand-alone cause of action.

To the extent that BMI argues Plaintiff's prayer for punitive damages should otherwise be stricken, the Court finds that Plaintiff has pled sufficient factual allegations to support a claim for punitive damages at this time. However, issues related to punitive damages may be revisited at summary judgment, if appropriate.

Accordingly, it is

ORDERED, **ADJUDGED**, and **DECREED**:

(1) Defendant B. Braun Medical Inc.'s "Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim" (Doc. 13) is **GRANTED** to the extent that Count V is dismissed as an independent claim for relief.

(2) The motion to dismiss is otherwise **DENIED**.

(3) BMI is directed to file an answer on or before December 18, 2023.

DONE and **ORDERED** in Chambers, in Tampa, Florida, this 4th day of December, 2023.

TOM BARBER
UNITED STATES DISTRICT JUDGE