UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

PAULINE S. BRANDT,

Plaintiff,

-vs- **Case No. 6:10-cv-306-Orl-19KRS**

DEPUY ORTHOPAEDICS, INC.,

Defendant.

ORDER

This case comes before the Court on the Motion to Dismiss by Defendant Depuy Orthopaedics, Inc. (Doc. No. 3, filed Mar. 3, 2010.) Plaintiff Pauline Brandt filed no response in opposition.

Background

On or about September 18, 2006, Plaintiff Pauline Brandt underwent a left total knee arthroplasty performed by Frank L. Denoff, M.D., who utilized knee components manufactured and distributed by Defendant Depuy Orthopaedics, Inc. ("Depuy") for Brandt's procedure.[1] (Doc. No. 3 ¶¶ 5-6.) Following the procedure, Plaintiff presented to Dr. Denoff's office with complaints of pain and swelling of the left knee. (*Id.* ¶ 8.) On February 14, 2007, Plaintiff underwent an arthroscopic debribement surgery of the left knee, which failed to relieve Plaintiff's pain and swelling. (*Id.* ¶ 9.) On March 29, 2007, Mark W. Hollmann, M.D., evaluated Plaintiff's left knee. (*Id.* ¶ 10.) After reviewing the results of radiographic images, Dr. Hollmann's impression was that Plaintiff suffered

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[1] These facts are only recited for contextual purposes and are set forth in the light most favorable to the Plaintiff.

from significant valgus alignment and a possible loosening femoral component of the left knee. (*Id*.) Plaintiff subsequently underwent a left revision total knee arthroplasty to repair the femoral component. (*Id*. ¶ 12.)

On November 2, 2009, Plaintiff filed the present action against Depuy in the Circuit Court of the Seventh Judicial Circuit in and for Volusia County, Florida asserting claims of strict liability and negligence. (*Id*.) Depuy timely removed the case to the Middle District of Florida on grounds of diversity jurisdiction. (Doc. No. 1, filed Feb. 24, 2010.) Depuy now seeks to dismiss the Complaint, arguing that Plaintiff fails to state a claim upon which relief may be granted. (Doc. No. 3.)

Standard of Review

When ruling on a motion to dismiss for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6), a court must limit its consideration to the complaint, the written instruments attached to it as exhibits, "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007); *GSW, Inc. v. Long County, Ga.*, 999 F.2d 1508, 1510 (11th Cir. 1993). In determining the merits of the motion, a court must "accept all factual allegations in the complaint as true." *Tellabs, Inc.*, 551 U.S. at 323. However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937, 1949 (2009). Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

Once a court "identif[ies] pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth," the court must next determine whether the well-pled facts "'state

a claim to relief that is plausible on its face.'" *Id.* at 1949-50 (quoting *Twombly*, 550 U.S. at 570). "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." *Id.* at 1949 (citing *Twombly*, 550 U.S. at 556). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950 (citation omitted). As the United States Supreme Court explained:

> The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Id. at 1949 (quotation marks and internal citations omitted) (quoting *Twombly*, 550 U.S. at 557). On a Rule 12(b)(6) motion to dismiss, when a court considers the range of possible interpretations of the defendant's alleged conduct, if the "more likely explanations" involve lawful, non-actionable behavior, the court should find that the plaintiff's claim is not plausible. *Id.* at 1950-51.

Analysis

I. Strict Liability

Count I alleges that Depuy is strictly liable for Plaintiff's injuries because the femoral knee component was defective as to design, manufacture, and warnings. (Doc. No. 2 ¶¶ 15-18.) Depuy seeks to dismiss Count I, arguing that Plaintiff fails to plead sufficient facts to support a claim for strict liability. (Doc. No. 3 at 5.)

To state a cause of action for strict liability under Florida law, a plaintiff must allege: (1) the manufacture's relationship to the product in question; (2) the unreasonably dangerous condition of the product; and (3) the existence of a proximate causal connection between the condition of the

product and the plaintiff's injury. *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999); *West v. Caterpillar Tractor Co., Inc.*, 336 So. 2d 80, 87 (Fla. 1976).

As to the first element, Plaintiff alleges that Depuy manufactured and distributed the femoral knee component used in Plaintiff's surgery on September 18, 2006. (Doc. No. 2 ¶¶ 13, 16.) As to the second element, Plaintiff alleges that the product used in her operation was "defective as to design, manufacture and warning." (*Id*. ¶ 16.) More specifically, Plaintiff alleges that the "knee prosthesis utilized in the surgery performed by Dr. Denoff delaminated or otherwise malfunctioned." (*Id*. ¶ 17.) Finally, as to the third element, Plaintiff alleges that the defective and dangerous condition of Depuy's femoral knee component was the direct and proximate result of Plaintiff's injuries. (*Id.* ¶ 18.)

Depuy contends that Count I should be dismissed because Plaintiff failed to allege both the source of the defect and the specific type of defect Plaintiff believes Depuy's product suffers from (design, warning, or manufacture). (Doc. No. 3.) With respect to the source of the defect, the Complaint alleges specific defects, mainly that the femoral knee component delaminated or otherwise malfunctioned. (Doc. No. 2 ¶ 17.) Such allegations plausibly establish that the femoral knee component was in an unreasonably dangerous condition. *Compare Bailey*, 288 F. App'x at 607-08 (finding allegations that the protective liner and functional layers of a fentanyl patch failed sufficient to permit defendants to form a responsive pleading), *and Krywokulski v. Ethicon, Inc.*, No. 8:09-CV-980-T-30MAP, 2010 WL 326166, at * 2-3 (M.D. Fla. Jan. 21, 2010) (finding allegation that defective surgical patches delaminated and/or malfunctioned sufficient to withstand a motion to dismiss), *with Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159, 1163 (S.D. Fla. 2009) (finding allegations that the

products were defective because their intended use resulted in a substantial and unreasonable likelihood of injury insufficient to withstand a motion to dismiss).

With respect to Depuy's argument that Plaintiff must allege the specific type of defect, courts have recognized that "[i]t is difficult for a plaintiff at this stage in the litigation to know the source of the defect that was responsible for the harm caused: whether there was surprising manufacturing problem, a systemic issue with a product in its design, or a failure on the part of the manufacturer to warn . . . ." *Bailey v. Janssen Pharmaceutica*, 288 F. App'x 597, 605-06 (11th Cir. 2008) (citing *West*, 336 So. 2d at 87). In light of this difficulty, Florida law does not require that a plaintiff specifically set out the type of defect (design, manufacturing, or failure to warn) at the pleadings stage. *Id.* Thus, Plaintiff's allegations that the femoral knee component was defective as to design, manufacture, and warning are sufficient to state a claim for strict liability, and Depuy's Motion to Dismiss Count I will be denied.

II. Negligence

Count II alleges that the femoral knee component manufactured by Depuy was unfit for its intended purpose such that it malfunctioned and led to the injuries suffered by the Plaintiff. (Doc. No. 2 ¶ 20.) Depuy seeks to dismiss Count II, arguing that Plaintiff fails to plead duty and breach. (Doc. No. 3.)

In order to state a cause of action for negligence under Florida law, a plaintiff must allege that the defendant owed a duty, that the defendant breached that duty, and that this breach caused the plaintiff damages. *Fla. Dep't of Corr. v. Abril*, 969 So. 2d 201, 204-05 (Fla. 2007). Whether a duty of care exists is a threshold question of law. *Wallace v. Dean*, 3 So. 3d 1035, 1046 (Fla. 2009). "The duty element of negligence focuses on whether the defendant's conduct foreseeably created a broader

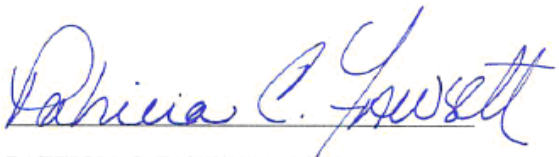
'zone of risk' that poses a general threat of harm to others." *McCain v. Fla. Power Corp.*, 593 So. 2d 500, 502 (Fla. 1992). Where a product is alleged to be defective "and that defect rises to the level of a dangerous condition, the manufacturer or designer has created a zone of risk to all parties who may come in contact with the product." *Stazenski v. Tennant Co.*, 617 So. 2d 344, 346 (Fla. 1st DCA 1993). Thus, the manufacturer of a products has "a duty to use reasonable care to design a product that is reasonably safe for its intended use and for other uses which are foreseeably probable." *Vincent v. C.R. Bard, Inc.*, 944 So. 2d 1083, 1085 (Fla. 2d DCA 2006) (internal quotation omitted).

In the present case, Plaintiff alleges that Depuy manufactured and distributed the femoral knee component that was utilized during Plaintiff's September 18, 2006 procedure. (Doc. No. 2 ¶¶ 13, 16.) Plaintiff, a surgical patient, was a foreseeable user of the femoral knee component. (*Id.* ¶ 13.) Such allegations plausibly establish that Depuy owed Plaintiff a duty to exercise reasonable care in the design and manufacture of the component. *See, e.g., Vincent*, 944 So. 2d at 1085 (manufacturer of a surgical product found to owe a duty to a foreseeable patient to exercise reasonable care in the design and manufacture of the product). Next, Plaintiff sufficiently pleads breach of that duty by alleging that Depuy knew or should have known that the femoral knee component was defective and that Depuy should have corrected said defects. (*Id.* ¶ 22.) Finally Plaintiff plausibly establishes that Depuy's breach resulted in her injures by alleging that she sustained a variety of injuries as a direct and proximate result of the defective and dangerous condition of the femoral knee component. (*Id.* ¶ 23.) Accordingly, Plaintiff sufficiently pleads each element of a claim of negligence against Depuy, and the Motion to Dismiss will be denied.

Conclusion

Based on the foregoing, the Motion to Dismiss by Defendant Depuy Orthopaedics, Inc. (Doc. No. 3, filed Mar. 3, 2010) is **DENIED**.

DONE and **ORDERED** in Orlando, Florida on June 28, 2010.



PATRICIA C. FAWSETT, JUDGE
UNITED STATES DISTRICT COURT

Copies furnished to:

Counsel of Record
Unrepresented Parties