UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

MEAGAN S. LIRETTE & WAYNE P. LIRETTE, JR.	*	**CIVIL ACTION NO. 2:13-cv-2892**
Plaintiff	*	
	*	**JUDGE PATRICIA MINALDI**
V.	*	
DEPUY MITEK, L.L.C., ET AL.	*	
	*	**MAGISTRATE JUDGE KAY**
Defendants	*	

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MEMORANDUM RULING

Before the court is a Motion to Dismiss [Doc. 13] pursuant to Federal Rule of Civil Procedure 12(b)(6), filed by the defendants, DePuy Mitek, L.L.C., and DePuy Orthopedics, Inc. (defendants), to which the plaintiffs have filed an Opposition [Doc. 19], and the defendants have filed a Reply [Doc. 23]. For the following reasons, the defendants' Motion [Doc. 13] is hereby **DENIED** at this time, and the plaintiffs are hereby granted leave to amend their complaint within twenty-one (21) days of the filing of this Memorandum Ruling into the record, should they choose to do so.

FACTS & PROCEDURAL HISTORY

Meagan Lirette underwent anterior cruciate ligament (ACL) surgery on May 18, 2012, to alleviate pain from a knee injury caused by an incident while she was jumping rope.[1] Specifically, the plaintiff "underwent a left knee anthroscopically assisted anterior cruciate ligament reconstruction with tibialis graft, 15 mm endo button loop and a 42 x 4.5 mm washer."[2]

[1] Pet. [Doc. 1-2], at ¶ 7, 9.
[2] *Id.* at ¶ 9.

The initial surgery was performed by Dr. Brett Cascio (Dr. Cascio).[3] During the surgery, Dr. Cascio stated that he was not satisfied with the graft structure once it was placed inside the knee.[4] According to the plaintiffs' complaint, the Bio-Intrafix sheath and screw, which is manufactured and distributed by the defendants and was used to secure the graft structure, had "split open" in Mrs. Lirette's knee.[5] Dr. Cascio removed the device and placed a new graft into the knee.[6] Dr. Cascio then "fixed the tibial side with another Bio-Intrafix sheath and screw."[7] However, the screw was prominent inside the joint; in response, Dr. Cascio removed the screw, and then fixed the tibial side of the graft with a metal screw and washer construction.[8] The plaintiffs allege that, in fixing the tibial side of the graft using the aforementioned metal screw and washer construction, Dr. Cascio screwed the graft in too tightly.[9]

Mrs. Lirette continued to suffer pain following the surgery and was advised by Dr. Cascio to have a second operation.[10] On November 12, 2012, Mrs. Lirette underwent a second surgery, as advised.[11] During the operation, Dr. Cascio removed "loose bodies"—pieces of loose matter that were discovered floating inside the knee that are known to cause discomfort—some of which he stated appeared to be pieces of the tibial Bio-Intrafix sheath that had been used to repair the tibial side of the graft during the initial operation on May 18, 2012.[12]

Despite the two surgeries, Mrs. Lirette's pain continued and she eventually sought a second opinion.[13] Mrs. Lirette underwent a third procedure on her left knee on May 10, 2013,

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[3] *Id.*
[4] Am. Compl. [Doc. 18], at ¶ 10.
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Am. Compl. [Doc. 18], at ¶ 10.
[10] *Id.* at ¶ 12.
[11] *Id.*
[12] *Id.*
[13] Pet. [Doc. 1-2], at ¶ 13.

wherein Dr. Barry Henry removed fragments and debris from the previous surgeries and reconstructed the previous graft.[14]

Wayne and Meagan Lirette, husband and wife, the plaintiffs herein, thereafter filed suit against DePuy Mitek, L.L.C. and DePuy Orthopedics, Inc., the defendants, in the Fourteenth Judicial District Court for the Parish of Calcasieu, on August 27, 2013.[15] The defendants removed the case to federal court on October 18th, 2013, pursuant to 28 U.S.C. § 1332, on the basis of diversity of citizenship subject matter jurisdiction.[16]

The plaintiffs allege that the defendants are the manufacturers, designers, marketers, and distributors of the Bio-Intrafix tibial sheath.[17] They also allege that the defendants are liable under the Louisiana Products Liability Act (LPLA) due to Mrs. Lirette's injury resulting from the product's unreasonably dangerous condition.[18] The plaintiffs allege that the product was unreasonably dangerous in construction or composition; design; due to a lack of adequate warning; and that the product did not conform to its express warranty.[19]

The plaintiffs have brought suit against the operating physician, Dr. Cascio, and Southwest Louisiana Healthcare Systems, Inc., alleging that Dr. Cascio, among other things, negligently performed the surgery while using the defendants' product, and that Dr. Cascio failed to remove all loose bodies during the second surgery.[20] The action against Dr. Cascio and Southwest Louisiana Healthcare Systems is presently before a Medical Review Panel.[21]

Mrs. Lirette seeks monetary damages under theories of products liability, and Mr. Lirette seeks monetary damages for the value of special services while functioning as a nurse and

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[14] *Id.*
[15] Not. of Removal [Doc. 1], at ¶ 1.
[16] Not. of Removal [Doc. 1], at ¶ 3.
[17] Pet. [Doc. 1-2], at ¶ 20, 23.
[18] *Id.* at ¶ 21.
[19] *Id.* at ¶ 22.
[20] *Id.* at ¶ 17.
[21] Pet. [Doc. 1-2], at 3.

attendant for Mrs. Lirette since the time of her injury, and in the future, as well for loss of consortium.[22] The defendants filed the instant Motion to Dismiss [Doc. 13] seeking the dismissal of the plaintiffs' claims for damages under the Louisiana Products Liability Act.[23]

LAW & ANALYSIS

A. Motion to Dismiss

A Rule 12(b)(6) motion may be granted when a plaintiff fails to state a legally cognizable claim for which relief may be granted. *See* FED. R. CIV. P. 12(b)(6). A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *See* FED. R. CIV. P. 8(a)(2). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need 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) (internal citations omitted). When plaintiffs have "not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." *Id.* at 570. "This standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re S. Scrap Material Co., L.L.C.*, 541 F.3d 584, 587 (5th Cir. 2008) (*citing Twombly*, 550 U.S. at 556).

"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." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). A complaint must contain "direct allegations on every material point necessary to sustain a recovery . . . or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial." *Rios v. City of Del Rio,* 444 F.3d 417, 420–21 (5th Cir.2006) (citations omitted). "[A] district court

[22] *Id.* at ¶ 26-27.
[23] Mot. [Doc. 13], at ¶ 1.

'must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (*citing Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)).

A motion to dismiss under rule 12(b)(6) is generally "viewed with disfavor and is rarely granted." *Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009) (*citing Gregson v. Zurich American Ins. Co.*, 322 F.3d 883, 885 (5th Cir.2003)) (internal citations omitted). Courts address the "*sufficiency* of the facts plead, not their truth or the ultimate substantive application of those facts." *Bertrand v. Eli Lilly & Co.*, No. 12-cv-0853, 2013 WL 4093556 *1 (W.D. La. Aug. 13, 2013) (emphasis in original). Courts "accept[] all well-pleaded facts as true and view[] those facts in the light most favorable to the plaintiff." *Bustos v. Martini Club Inc.*, 599 F.3d 458, 461 (5th Cir. 2010) (*citing True v. Robles*, 571 F.3d 412, 417 (5th Cir. 2009)).

B. Louisiana Products Liability Act

The LPLA establishes the exclusive theories of liability in actions against manufacturers for damage caused by their products. *See* LA. REV. STAT. ANN. § 9:2800.52. "The manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product." LA. REV. STAT. ANN. § 9:2800.54(A). A product may be unreasonably dangerous: (1) in construction or composition; (2) in design; (3) due to an inadequate warning; or (4) because it does not conform to an express warranty. *King v. Bayer Pharm. Corp.*, No. 09-cv-0465, 2009 WL 2135223 *4 (W.D. La. June 8, 2009) (*citing* LA. REV.

STAT. ANN. § 9:2800.54(B)). A plaintiff seeking damages under the LPLA must prove: "(1) that the defendant manufactured the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that characteristic made the product 'unreasonably dangerous;' and (4) that the claimant's damage arose from a reasonably anticipated use of the product." *Butler v. Louisiana State Univ. Health Sciences Ctr.*, No. 12-cv-1838, 2012 WL 3263888 *2 (W.D. La. Aug. 9, 2012) (*citing Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265-66 (5th Cir. 2002)).

1. Unreasonably Dangerous in Construction or Composition

"A product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." LA. REV. STAT. ANN. § 9:2800.55. Absent factual allegations addressing how the product deviated from the defendant's normal production standards, a plaintiff fails to meet the plausibility standard. *Watson v. Bayer Healthcare Pharm., Inc.*, No. 13-cv-212, 2013 WL 1558328 *4 (E.D. La. Apr. 11, 2013).

In *Butler*, the plaintiff sought damages for the alleged failure of the defendant's contraceptive product. *Butler*, 2012 WL 3263888, at *3. In ruling on the defendant's motion to dismiss, the court found that the plaintiff's complaint did not identify the nature of the defect, how the defect made the product unreasonably dangerous, or explain how the product caused the alleged injuries. *Id.* Such claims did not satisfy the standards set under *Twombly* and *Iqbal*.

In *Watson*, the plaintiff used a birth control product inserted by her doctor. *Watson*, 2013 WL 1558328, at *1-2. The plaintiff claimed that the product's "condition when sold to her was the proximate cause of [her] injuries." *Id.* at *4. The court stated that the plaintiff failed to

sufficiently allege facts explaining how the unknown manufacturing defect caused her alleged injuries. *Id.* The court found that because the plaintiff failed to show how the product's condition deviated from the intended design, or how the defect caused her injuries, the motion to dismiss should be granted. *Id.*

The instant plaintiffs argue that there are sufficient facts to show that the defendants' Bio-Intrafix Large Tibial Sheath was unreasonably dangerous due to its malfunction and splitting during the operation, as well as the loose bodies found in the second surgery that were allegedly thought to be part of the defendants' product.[24] However, the plaintiffs do not state how the product is allegedly unreasonably dangerous due to a defect, nor do they allege that the pain suffered by the plaintiff was proximately caused by the defect. Similar to the plaintiff in *Butler*, the plaintiffs have simply stated the elements of a products liability claim without providing any factual allegations that the product was unreasonably dangerous due to it splitting or that the product was the proximate cause of the injury. Rather, the plaintiffs have specifically alleged that Dr. Cascio's negligence caused the graft to split, and his negligence in screwing in the tibial sheath resulted in increased pain, inflammation, and a decreased range of motion in Mrs. Lirette's left knee.[25] The plaintiffs' vague assertions do not set forth a claim in this regard that is plausible on its face.

2. Unreasonably Dangerous in Design

The plaintiffs' second claim seeks to recover under a design defect theory.[26]

> Under Louisiana law, a product is considered unreasonably dangerous in design if at the time it left the manufacturer's control: (1) there existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) the likelihood that the product's design would cause the claimant's damage and the

[24] Memo. in Supp. of Opp. [Doc. 19-1], at 4.
[25] Pet. [Doc. 1-2], at ¶ 17.
[26] *Id. at* ¶ 22.

> gravity of that damage outweighed the burden on the manufacturer of adopting the alternative design.

Johnson v. Teva Pharm. USA, Inc., No. 2:10-cv-404, 2012 WL 1866839 *4 (W.D. La. May 21, 2012) (*quoting* LA. REV. STAT. ANN. § 9:2800.56). The fact finder should not presume that there was an unreasonably dangerous design "solely from the fact that injury occurred." *McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999) (*citing Ashley v. Gen. Motors Corp.*, 666 So. 2d 1320, 1322 (La. Ct. App. 1996)). When a plaintiff fails to allege even the existence of an alternative design, the plaintiff has failed to state a claim under a design defect theory under the LPLA. *Ivory v. Pfizer Inc.*, No. 09-cv-0072, 2009 WL 3230611 *3 (W.D. La. Sept. 30, 2009) (*citing Guidry v. Events Pharms., Inc.*, 418 F. Supp. 2d 835, 842 (M.D. La. 2006) (additional citations omitted)).

The plaintiffs do not allege the existence of an alternative design to which the defendants could have adhered. The plaintiffs' petition states that Dr. Cascio and the hospital were negligent in performing the surgery on Mrs. Lirette.[27] They also specifically allege that Dr. Cascio "negligently placed and secured the grafts, left foreign and loose bodies inside of the plaintiff's knee, tightened the second graft too tightly, and *negligently split the graft*" made by the defendants.[28] The plaintiffs have failed to allege sufficient facts to support recovery under a design defect theory.

3. Unreasonably Dangerous Due to an Inadequate Warning

Under the LPLA, an adequate warning "has not been provided if, at the time the product left its manufacturer's control, it possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger." *See* LA. REV. STAT. ANN. § 9:2800.57. Louisiana courts have stated, with

[27] Pet. [Doc. 1-2], at ¶ 17.
[28] *Id.* (emphasis added).

regards to prescription drugs and medical equipment, that once a company informs the treating physician of the risks of harm so that they may intelligently decide on its use and advise the patient, the obligation to the consumer is fulfilled. *Mikell v. Hoffman-Laroche, Inc.*, No. 94-CV-0242, 649 So. 2d 75, 79-80 (La. Ct. App. 1994) (*citing Rhoto v. Ribando,* 504 So.2d 1119, 1123 (La. Ct. App. 1887), *writ denied,* 506 So.2d 1225 (La.1987) (additional citations omitted)). The doctor acts as an informed intermediary, and the decision to use the product in a particular circumstance rests with the doctor and the patient, not the manufacturer. *Id. See also Grenier v. Med. Eng'g Corp.*, 99 F. Supp. 2d 759, 765 (W.D. La. 2000) (*citing Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995)) (stating that Louisiana law applies the learned intermediary doctrine to an inadequate warning analysis involving either "drugs or medical devices dispensed by a physician").

There is a two-prong test governing inadequate-warning claims under the LPLA when the learned intermediary doctrine is applicable. *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265-66 (5th Cir. 2002) (*citing Willett v. Baxter Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir.1991)). First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. *Id.* Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. *Id.*

The plaintiffs do not allege that the defendants failed to provide an adequate warning to Dr. Cascio. The complaint alleges that the defendants' product was unreasonably dangerous due to an inadequate warning.[29] For the plaintiffs to allege that the defendants' obligation to the plaintiffs was not discharged by appropriately informing the physician of all necessary side

[29] Pet. [Doc. 1-2] at ¶ 22.

effects and risks would require more than the bare recitation of the elements provided by the plaintiffs.

4. Unreasonably Dangerous Due to Nonconformity with an Express Warranty

"A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." *See* LA. REV. STAT. ANN. § 9:2800.58. "Plaintiffs are not required to identify specific language offered by a manufacturer" to allege a breach of express warranty; rather, "a manufacturer may not 'suppress information' and 'make false representations of . . . superiority and efficacy' when gaining significant market share with a defective product." *Kennedy v. Pfizer, Inc.*, No. 12-cv-01858, 2013 WL 4590331, at *5 (W.D. La. Aug. 28, 2013) (*citing Harris v. Merck & Co., Inc.*, No. 12-cv-1446, 2012 WL 5384720, *5 (W.D. La. Nov. 1, 2012)).

As previously stated, with respect to the claim of inadequate warnings, the plaintiffs have made no allegation how the defendants' product did not conform to an express warranty. The plaintiffs have made no allegation that the defendants suppressed information or made false representations regarding the product in question. The plaintiffs offer no information describing how an express warranty induced the physician or hospital to use the product, or any allegation that such a warranty even existed. Rather, all that was mentioned in the complaint were the elements of a claim under the LPLA for nonconformity with an express warranty.[30] This is insufficient to plead a claim for breach of an express warranty.

[30] *Id.*

C. Leave to Amend

Federal Rule of Civil Procedure 15 empowers the court to grant a party leave to amend a complaint "when justice so requires." FED. R. CIV. PRO. 15(a)(2). *See also Simmons v. Sabine River Auth. La.*, 732 F.3d 469, 478 (5th Cir. 2013) (citations omitted).[31] District courts possess broad discretion in determining whether to permit amended complaints. *Crostley v. Lamar Cnty., Texas*, 717 F.3d 410, 420 (5th Cir. 2013) (*citing McLean v. Int'l Harvester Co.*, 817 F.2d 1214, 1224 (5th Cir.1987)) (additional citations omitted). The plaintiffs' claims fall short of the plausibility standard created by *Twombly* and *Iqbal*. However, the granting of a motion to dismiss for failure to state a claim should not be liberally granted, and there is no compelling reason to deny the plaintiffs leave to amend. Accordingly,

IT IS ORDERED that the defendants' Motion to Dismiss for Failure to State a Claim [Doc. 13] be and hereby is **DENIED** at this time.

IT IS FURTHER ORDERED that the plaintiffs are hereby granted leave to amend their complaint within twenty-one (21) days of the filing of this Memorandum Ruling into the record. If the plaintiffs fail to do so, the defendants may request dismissal pursuant to Rule 12(b)(6) for the reasons stated herein.

Lake Charles, Louisiana, this 1 day of July, 2014.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE

[31] The court will not address any issues as to the possible applicability of the provisions of the Food, Drug, and Cosmetic Act (FDCA), or the Medical Device Amendments (MDAs), as no party has submitted any argument regarding whether the MDAs are applicable, or whether the device in question was subject to pre-market approval. *See* 21 U.S.C. §§ 360, *et seq.*