UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

LAURIE BROCATO	**CIVIL ACTION**
VERSUS	**NO. 14-2607**
DEPUY ORTHOPAEDICS, INC., ET AL.	**SECTION "B"(1)**

ORDER AND REASONS

I. NATURE OF MOTION AND RELIEF SOUGHT

Before the Court is Defendants', DePuy Orthopaedics, Inc. and Johnson & Johnson, ("Defendants") Motion to Dismiss for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6) (Rec. Doc. 8). Plaintiff opposes the instant motion. (Rec. Doc. 18).

II. FACTS AND PROCEDURAL HISTORY

Plaintiff, Laurie Brocato, is a citizen of the State of Louisiana. (Rec. Doc. 1 at 2). Defendant DePuy Orthopaedics, Inc. is a corporation organized under the laws of the State of Indiana, with its principal place of business in Warsaw, Indiana. (Rec. Doc. 1 at 2). Defendant Johnson & Johnson is a corporation organized under the laws of the State of New Jersey, with its principal place of business in New Brunswick, New Jersey. (Rec. Doc. 1 at 2).

Plaintiff filed the instant suit alleging products liability claims under the Louisiana Products Liability Act, La. Rev. Stat. ann. § 9:2800.51, *et seq.*, (the "LPLA") in the Civil District Court for the Parish of Orleans on July 24, 2014. (Rec. Doc. 1). Defendants filed a notice of removal on November 14,

2014, invoking this Court's federal diversity subject matter jurisdiction pursuant to 28 U.S.C. § 1332. (Rec. Doc. 1).

Plaintiff's petition alleges that on March 20, 2014, she underwent knee replacement surgery in both her left and right knees. (Rec. Doc. 8 at 2). She further alleges that DePuy Smartset GHV Bone Cement, manufactured by Defendants, was used in both operations. (Rec. Doc. 8 at 2). Plaintiff claims that following her surgeries, she experienced pain in both knees, which required her to undergo a total revision surgery in her left knee on November 11, 2014, and that she presently contemplates a similar revision in the right knee. (Rec. Doc. 8 at 2). According to Plaintiff, her complications were caused by defects in Defendants' bone cement which caused loosening of her tibial implant from its cement mantle. (Rec. Doc. 1-1 at 3). Thus, Plaintiff seeks to recover damages for the revision surgeries, as well as for: (1) significant harm, conscious pain and suffering, physical injury and bodily impairment; (2) significant mental anguish, emotional distress and loss of quality of life, continued physical limitations, pain, injury, damages, harm, and future mental and emotional distress; and (2) medical expenses and other economic harm, including loss of income. (Rec. Doc. 1 at 4).[1]

[1] Louisiana law prohibits a plaintiff from specifying a numerical dollar amount in the complaint; however, Defendants have satisfied their burden in the context of the instant notice of removal of proving by a preponderance of the evidence that the amount-in-controversy exceeds $75,000 for purposes of diversity jurisdiction. See La. Code Civ. Proc. Art. 893(A)(1); *Earl v. Myers*, 2010 WL 4875656, at *2 (E.D. La. Nov. 23, 2010)(dollar amount);

Defendants move to dismiss Plaintiff's claims under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. For the reasons that follow, **IT IS ORDERED** that Defendants' Motion **GRANTED IN PART, AND DENIED IN PART.**

III. CONTENTIONS OF MOVANT

Defendants argue Plaintiff has failed, in the context of the instant Motion to Dismiss, to allege sufficient factual content to bring her allegations beyond the realm of the merely conclusory. Thus, Defendants argue, Plaintiff's Complaint fails to satisfy the requirements of federal pleading standards as prescribed in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

IV. CONTENTIONS OF OPPONENTS

In opposition to dismissal, Plaintiff sought and was granted leave to file an Amended Complaint (Rec. Doc. 21), which, Plaintiff argues, succeeds in allowing her LPLA claims to hurdle the standards of Rule 12(b)(6).

V. MOTION TO DISMISS STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure allows a party to move for dismissal of a complaint for failure to state a claim upon which relief can be granted. Such a motion is rarely granted because it is viewed with disfavor. *See Lowrey v. Tex. A & M Univ. Sys.,* 117 F.3d 242, 247 (5th Cir.1997)

DeAguillar v. Boeing, 11 F. 3d 55, 58 (5th Cir. 1993)(the defendant's burden for removal purposes).

(quoting *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.,* 677 F.2d 1045, 1050 (5th Cir. 1982)).

When reviewing a motion to dismiss, courts must accept all well-pleaded facts as true and view them in the light most favorable to the non-moving party. *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). However, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Gonzales v. Kay*, 577 F.3d 600, 603 (5th Cir. 2009)(quoting *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009))(internal quotation marks omitted). The Supreme Court in *Iqbal* explained that *Twombly* promulgated a "two-pronged approach" to determine whether a complaint states a plausible claim for relief. *Iqbal*, 129 S.Ct. at 1950. First, courts must identify those pleadings that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id*. Legal conclusions "must be supported by factual allegations." *Id*. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. at 1949.

Upon identifying the well-pleaded factual allegations, courts "assume their veracity and then determine whether they plausibly give rise to an entitlement of relief." *Id*. at 1950. 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. This is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. The plaintiffs must "nudge[] their claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

VI. DISCUSSION

Under Louisiana law, the LPLA establishes the exclusive theories of liability for manufacturers for damage caused by their products. La. Rev. Stat. ann. § 9:2800.52; *Jefferson v. Lead Indus. Ass'n Inc.*, 106 F.3d 1245, 1248 (5th Cir. 1997).[2] The act allows a plaintiff to recover for damage caused by a product, only if it is shown that the product was "unreasonably dangerous" in one of four ways: (A) in construction or composition, (B) in design, (C) through inadequate warning, or (D) via nonconformity with an express warranty. La. Rev. Stat. ann. §§ 9:2800.54(1)-(4). Thus, a *prima facie* case under the LPLA requires the plaintiff to establish four general elements: (1) that the defendant is a manufacturer of the product within the meaning of the act, (2) that the claimant's damage was proximately caused by a characteristic of the product, (3) that said characteristic rendered the product "unreasonably dangerous" in one of the four foregoing manners, and (4) the claimant's damage arose from a reasonably anticipated use of the

[2] No party disputes Defendants' status as "manufacturers" for purposes of the LPLA, nor applicability of that legislation in the instant matter.

product by the claimant or someone else. *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 21 (5th Cir. 2002). In the instant case, Plaintiff asserts claims under all four of the statutorily recognized theories of liability; each is addressed in turn.

A. 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. Thus, the pertinent provision of the LPLA provides a remedy for damages caused by a product that is defective due to a mistake in the manufacturing process. *Stahl*, *supra*, 283 F.3d at 263. This must be kept distinct from a product whose defect inheres in its design (e.g., where all units of the same product model suffer from the same inherent flaw).

In her amended complaint/opposition, Plaintiff sets forth an explanation of the process by which bone cements, generally, operate. (See Rec. Doc. 18 at 3). According to Plaintiff, bone cements consist of two components: a liquid monomer and a solid powder. (Rec. Doc. 18 at 3). When the two components mix, they begin to dissolve, resulting in a viscous mix of dissolved small particles (from the powder) and partially dissolved large polymer particles. *Id.* Importantly, if the smaller particles are coated with another substance or consist of a mix of polymer and

another material, the dissolution process is impeded, resulting in unpredictable viscosity behavior, which Plaintiff alleges results in a lack of fixation of implants. *Id.*

In the instant case, Plaintiff alleges that Defendants' product is defective because gentamicin sulfate, a compound used in the bone cement, preferentially locates on or in the small particles. (Rec. Doc. 18 at 3). This, Plaintiff argues, makes the resulting viscosity unpredictable and greatly affects the handling and efficacy of the cement. (Rec. Doc. 18 at 3).

The particularities of the process by which bone cements operate as a general product category are not germane to the instant cause of action, in which context Plaintiff must establish that the *particular bone cement* used in Plaintiff's surgeries either deviated from Defendants' own performance standards or specifications, or identical products manufactured by Defendants. In support of her claims of defective construction or composition, Plaintiff points to two alleged "performance standards" contained in an Instruction Leaflet promulgated by Defendants as well as a 510(k) premarket notification submitted by Defendants. (See Rec. Doc. 18 at 6). The cited provisions state:

> Smartset® GHV Gentamicin, SmartSet® GMV Endurance Gentamicin DePuy® CMW 1 Gentamicin, DePuy® CMW 2 Gentamicin and DePuy® CMW3 Gentamicin bone cements are self-curing, radiopaque, polymethyl methacrylate based cements, which contain 1 gram of (active) gentamicin in 40 grams of bone cement powder and which are used for

> securing a metal or polymeric prosthesis to living bone in arthroplasty procedures.
> . . .
>
> Smartset GHV Bone Cement is a self curing cement, to which one gram of (active) Gentamicin is included in 40 grams of bone cement powder and 0.5 grams of (active) gentamicin is included in 20 grams of bone cement powder, for allowing the seating and securing of a metal or plastic prosthesis to living bone.

(Rec. Doc. 18 at 6). Assuming, *arguendo*, that the foregoing may properly be characterized as design specifications and/or performance standards, Plaintiff makes absolutely no allegations as to how Defendants' product deviated therefrom in a material way. Plaintiff asserts that "the design specifications by which the seating and securing of metal or plastic prosthesis to living bone, including the design specifications employed by the Defendants, are described in Paragraphs 12A and 12B" (the substance of which the Court has paraphrased, *supra*). (Rec. Doc. 18 at 6). Further, she argues:

> The descriptions of the defect contained in Defendants' bone cement set out in Paragraphs 12A through 12F also describe how Defendants' bone cement deviated in a material way from their specifications and performance standards at the time the bone cement left the Defendants' control.

Id. This statement apparently relates to the description of how gentamicin sulfate contributes to unpredictable curing behavior. Plaintiff's arguments, however, contain no allegation that the bone cement used in Plaintiff's operation did not, for example, include the specified proportions of bone cement powder to

gentamicin sulfate, nor even that the subject bone cement is not used for "allowing the seating and securing of a metal or plastic prosthesis to living bone," as described in the Leaflet, *supra*. Nor do the "performance standards" contain any statements relating to predictability of curing behavior or viscosity.

Plaintiff seems to believe her contention that the composition of Defendants' bone cement causes unpredictable viscosity levels (which her arguments necessarily suggest is a condition affecting all units of the particular DePuy Smartset GHV bone cement presently at issue) satisfies her burden under the construction/composition provision of the LPLA. This reflects a misapprehension of the distinction between claims of defective construction or composition and claims of design defects. Because Plaintiff has failed to articulate in any way that the particular bone cement used in her procedures either did not meet the cited performance standards or specifications, or that it deviated from the construction or composition of identical bone cements manufactured by Defendants (i.e., that some manufacturing defect resulted in anomalous composition of the particular bone cement used when compared with other units of DePuy Smartset GHV), she has failed to state a cause of action for defective construction or composition under the LPLA and applicable federal pleading standards. *See Welch v. Technotrim, Inc.*, 34-355 (La. App. 2 Cir. 1/24/01), 778 So. 2d 728, 733 ("claimant must demonstrate not only what a manufacturer's specifications or performance standards are for a

particular product, but how *the product in question* materially deviated from those standards")(emphasis added). **IT IS ORDERED** therefore that Defendants' motion to dismiss Plaintiff's claims of defective construction or composition under the LPLA is **GRANTED**.

B. Defective Design

A product is unreasonably dangerous in design if, at the time the product left its 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 gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. La. Rev. Stat. ann. § 9:2800.56.

As noted above, Plaintiff's principal allegation of a defect in Defendants' bone cement is that the use of gentamicin sulfate and the composition of the cement contribute to unpredictable viscosity and curing behavior which hinders its effective operation in procedures such as those undergone by Plaintiff.[3] In support of this conclusion, Plaintiff cites data from the Manufacturer and User Facility Device Experience

[3] The Court notes that here the focus is on the intended composition of Defendants' product generally, which condition may, under the right circumstances, support a design defect claim under the LPLA. This is in contrast with a defective construction or composition claim which requires the particular product to deviate in construction or composition from identical products manufactured by the defendant. This distinction forms the basis of Plaintiff's failure to adequately state a claim under the construction/composition theory of the LPLA, discussed *supra*.

("MAUDE") database maintained by the federal Food and Drug Administration ("FDA"). (Rec. Doc. 18 at 5). According to Plaintiff, the MAUDE data indicate that:

> [S]ince its introduction, the reported yearly rate of loosening of implants due to failure of DePuy Smartset GHV has increased from zero per year in 2005, to approximately 25 per year in 2014. In that nine year span, approximately 123 instances of loosening of implants due to DePuy Smartset GHV cement failure have been reported.

(Rec. Doc. 18 at 4). By comparison, Plaintiff argues that bone cements produced by competitors using different compositions resulted in much lower recorded failure rates. Plaintiff states:

> In contrast to DePuy Smartset GHV, the MAUDE database shows that similar cements had much lower loosening rates in the same time period; E.G., Simplex P with tobramycin had only one reported loosening during the same nine years, and Palacos R + G, with gentamicin, had only three reported loosenings in the same nine years.

(Rec. Doc. 18 at 4). Accordingly, Plaintiff argues the higher rates of loosening seen in Defendants' products as opposed to those of competitors establishes that an alternative design capable of preventing Plaintiff's damage existed at the time Defendants' product left their control. She further argues that the presence on the market of similar bone cements with more favorable performance-results establishes that Plaintiff's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting the alternative design and the adverse effect, if any, of such alternative design on the utility of the product. La. Rev. Stat. ann. § 9:2800.56.

While Plaintiff's allegations relating to the issues created by the composition of Defendants' bone cement and the existence of alternative products on the market would not support her burden of proof at trial or in the context of a motion for summary judgment, she has asserted factual allegations which, accepted as true, assert plausible claims for relief sufficient to survive dismissal. In the instant matter, Plaintiff alleges that the composition of Defendants' bone cement, particularly through use of gentamicin sulfate, causes DePuy Smartset GHV to exhibit unstable curing and fixing behavior, which resulted in loosening of her tibial implant. She has demonstrated that similar products with different compositions exist on the market and has produced preliminary data that such products demonstrate fewer instances of loosening than Defendants' product. Thus, she has stated a cause of action under the LPLA for defective design. *Compare*, *Watson v. Bayer Healthcare Pharmaceuticals, Inc.*, No. 13-212, 2013 WL 1558328 (E.D.La. Apr. 11, 2013)(granting dismissal of defective design claims where the plaintiff "failed to allege how [the product's] design is defective, what aspect of [its] design caused her injuries, or how the defective design relates to her injuries.")

Accordingly, **IT IS ORDERED** that Defendants' motion to dismiss Plaintiff's design defect claim is **DENIED.**

C. Inadequate Warning

A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time

the product left its manufacturer's control, the product 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 to users and handlers of the product. La. Rev. Stat. ann. § 9:2800.57. Importantly, such a claim requires the plaintiff to show both: (1) the inadequacy of the warning provided *and* (2) that the inadequate warning was the cause of his injuries. *Broussard v. Procter & Gambel Co.*, 463 F. Supp. 2d 596, 609-10 (W.D. La. 2006)(citing La. Rev. Stat. ann. §§ 9:2800.54(A), 9:2800.57A(A)).

Defendants argue that Louisiana applies the "learned intermediary doctrine" to LPLA claims involving medical devices, such that the manufacturer's duty to warn extends only to the claimant's physician. (Rec. Doc. 8-1 at 9)(citing *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 265-66, 268 (5th Cir. 2002)). Thus, according to Defendants, Plaintiff's failure to allege that a proper warning would have changed the decision of the treating physician, fails to state a claim to relief under the LPLA for inadequate warning. The cited authority, however, reveals that Defendants misconstrue how the doctrine applies in practice.

In *Stahl*, *supra*, the Fifth Circuit considered various Louisiana decisions to conclude that a "line of Louisiana authority suggests that a warning regarding a particular adverse drug reaction is adequate as a matter of law if the package

insert clearly and unambiguously mentions the specific ailment suffered by the plaintiff *AND* the plaintiff's prescribing physician *unequivocally* testifies that the information provided in the warning was adequate to provide that physician with a reasonable understanding of the risks involved." 283 F.3d at 267 (citing *White v. Slidell Mem'l Hsop. & Med. Ctr.*, No. 89-2691, 1990 WL 111447 (E.D. La. July 26, 1990); *Cobb v. Syntex Labs, Inc.*, 444 So.2d 203, 205-06 (La. App. 1983); *Timm v. Upjohn Co.*, 624 F.3d 536, 539 (5th Cir. 1980)). The Court then concluded: "For summary adjudication of an inadequate warning claim to be appropriate, the plaintiff's prescribing physician must also unequivocally testify that the warning was inadequate to inform him or her of the risks involved in prescribing the drug." *Id.* at 267.

The "learned intermediary doctrine" is an affirmative defense under which Defendants bear the burden of establishing that they adequately informed the intermediate physician of the risks associated with use of their product. *See, e.g., Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 772 (S.D. Tex. Jan. 29, 2008)(citing *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974)("Defendant has the initial burden of proving that decedent received the medication through a physician with whom the decedent had a physician-patient relationship and that the warning Defendant provided to the prescribing physician was adequate."). As noted above, the Fifth Circuit has interpreted Louisiana jurisprudence in this area to condone summary

adjudication only where the defendant points both to an unambiguous mention of the subject risk and testimony of the treating physician establishing his understanding of such risk based on the warning. Plaintiff's opposition cites to an "Instruction Leaflet for the Personal Attention of the Surgeon" allegedly posted on the internet by Defendants, which includes what Plaintiff characterizes to be a "generic" warning that: "The most frequent adverse reactions reported with acrylic bone cements are: . . . Pain and/or loss of function. . . . Loosening or displacement of the prosthesis." (Rec. Doc. 18-1 at 8). Assuming without resolving that this amounts to an unambiguous mention of the specific ailment suffered by Plaintiff, Defendants have not come forward with unequivocal testimony of Plaintiff's treating physician as to the adequacy of this warning. They have further failed to make any claim or showing as to the adequacy of this warning in pleadings. Plaintiff has, however, amended her complaint to allege that her treating physician would not have used Defendants' bone cement had he been aware of the risks associated therewith. (See Rec. Doc. 18-1 at 8). Particularly in light of the MAUDE data cited by Plaintiff, which appears to show a higher incidence of loosening associated with Defendants' product than its competitors', Plaintiff has carried her burden of making a plausible showing of entitlement to relief on her inadequate warning claim under the LPLA.[4] Defendants have failed to make out their affirmative

[4] Under the LPLA, a manufacturer who acquires *post hoc* knowledge of a

"learned intermediary" defense under relevant jurisprudence. Whether Plaintiff will succeed beyond the summary judgment phase or at trial on this issue is for another day. Accordingly, **IT IS ORDERED** that Defendants' motion to dismiss Plaintiff's inadequate warning claims under the LPLA is **DENIED**.

D. Breach of 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. La. Rev. Stat. ann. § 9:2800. 58. Thus, under this provision, Plaintiff bears the burden of establishing: (1) that an express warranty relating to the product existed, (2) that such warranty induced Plaintiff's or another person's use of the product, and (3) that her damage was caused because the express warranty was untrue (i.e., that the product failed to conform to the warranty). *See Caboni v. General Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002).

"Express warranty" is defined under the LPLA as:

> [A] representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the

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characteristic of the product that may cause damage and the danger of such characteristic is "liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." La. Rev. Stat. ann. § 9:2800.57. Thus, if Defendants learned after introduction of their product into the market of the failures reported in the MAUDE database, they may have come under a duty to supplement their warnings, instructions, etc.

> product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance. [It] does not mean a general opinion about or general praise of a product.

La. Rev. Stat. ann. § 9:2800.54(6)(emphasis added).

In the instant case, Plaintiff alleges: "Defendants represented to the medical community that its [sic] bone cement was safe and fit for its intended purpose, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested." (Rec. Doc. 18-1 at 10). According to Plaintiff, these representations were made via, *inter alia*, Defendants' labeling, advertising, marketing materials, detail persons, seminar representations, publications, notice letters, and regulatory submissions. (Rec. Doc. 18-1 at 11). Plaintiff points to no specific characteristic, quality, or level of performance of which Defendants are alleged to have made statements or representations concerning their bone cement. It is axiomatic that an "express warranty" must be expressed. Plaintiff's statements that "Defendants concealed in these representations their knowledge of the defect," as well as their statements above, reveal -- at most -- mere implied warranties or the basis for an inadequate warning claim.

Even if the Court were to construe Plaintiff's claims, set forth, *supra*, in the discussion relating to defective composition or construction, to represent specified "performance

standards," as noted in that section, Plaintiff makes no allegation as to how Defendants' bone cement failed to adhere to those standards (e.g., by manifesting a composition with different proportions of ingredients than those represented). In any event, Plaintiff has made absolutely no showing as to the existence of an express warranty, and **IT IS ORDERED** that Defendants' motion to dismiss Plaintiff's claims under the LPLA for breach of express warranty is **GRANTED**.

VII. CONCLUSION

In light of the above, **IT IS ORDERED** that Defendants' Motion to Dismiss is **GRANTED** as to Plaintiffs' defective construction/composition and breach of express warranty claims, but **DENIED** as to Plaintiffs' inadequate warning and design defect claims under the LPLA.

New Orleans, Louisiana, this 25th day of February, 2015.

UNITED STATES DISTRICT JUDGE