UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

JENNA THOMPSON

VERSUS

BOSTON SCIENTIFIC CORPORATION

CIVIL ACTION

NO. 21-CV-594-JWD-RLB

RULING AND ORDER

Before the Court is *Defendant Boston Scientific Corporation's Motion to Dismiss Plaintiff's Complaint* ("*Motion*") brought by defendant Boston Scientific Corporation ("BSC" or "Defendant"). (Doc. 7.) It is opposed by plaintiff Jenna Thompson ("Plaintiff" or "Thompson"). (Doc. 16.) BSC filed a reply. (Doc. 19.) The Court has carefully considered the law, the facts as alleged in the Complaint, and the arguments and submissions of the parties and is prepared to rule. For the reasons which follow, the *Motion* is granted in part and denied in part. The *Motion* is granted in that Plaintiff's claim for punitive damages and attorney's fee is dismissed. In all other respects, the *Motion* is denied.

I. BACKGROUND

On June 2, 2020, Plaintiff Jenna Thompson underwent an operation by Dr. Randall Brown at Woman's Hospital in Baton Rouge, Louisiana, to surgically implant a pelvic mesh stress device called a "Lynx." (Doc. 1, ¶¶ 1, 81.) The Lynx was designed and manufactured by BSC primarily for the treatment of stress urinary incontinence ("SUI"), the condition for which Plaintiff was undergoing surgery. (*Id.* ¶¶ 10-11.)[1] "Four months after Dr. Brown implanted the Lynx pelvic mesh device, it was found to be buried in her vaginal wall, causing [Plaintiff] to experience

[1] According to BSC, "[t]he Lynx is a prescription-only medical device that is used as a mid-urethral sling to provide support and prevent urine leakage." (Doc. 7-1 at 2-3.)

significant dyspareunia (painful intercourse), neuromuscular pain, disabling pelvic pain, abdominal pain, groin pain, recurrence of incontinence, erosion and vaginal scarring." (Doc. 16 at 2 (citing Doc. 1, ¶¶ 82, 86-87).)

In her Complaint, Thompson alleges that the Lynx device was defective in design, (Doc. 1, ¶¶ 54-65), and that BSC failed to adequately warn her physician of Lynx's defects (*id*. ¶¶ 66-76). In addition to requesting compensatory damages, (*id*. ¶ 127, Prayer ¶ 1a-g), Thompson demands punitive damages and attorney fees (*id*. ¶ 125, Prayer ¶ 2).

II. ARGUMENTS OF THE PARTIES

A. BSC's Opening Brief (Doc. 7)

Defendant argues that Plaintiff's unreasonably dangerous design claim and her failure to warn claim are insufficiently pled, fail as a matter of law, and must be dismissed. (Doc. 7 at 1; Doc. 7-1 at 1-2.) Plaintiff's demand for punitive damages and attorney fees should also be dismissed since these items of damage are not allowed under the Louisiana law of products liability. (*Id*.)

a. Failure to Warn

As to her failure to warn claim, BSC charges that Plaintiff admits that "the adverse effects and injuries she claims to have suffered were of the same type that were publicly disseminated by FDA and medical organizations, and thus well-known to the medical community, years before her 2020 implant." (Doc. 7-1 at 5 (citing Doc. 1, ¶ 37).) Because Louisiana recognizes the learned intermediary doctrine, a plaintiff's failure to warn claim is "premised on 'the manufacturer['s] fail[ure] to adequately warn the *treating physician*.' " (*Id*. at 6 (quoting *Celino v. Biotronik, Inc.*, 536 F. Supp. 3d 89, 108 (E.D. La. 2021) (emphasis in *Celino*).) A plaintiff can only succeed in such a claim "if the warnings were inadequate with respect to the prescribing physician, and the

physician relied upon those warnings in prescribing the product." (*Id*. (citations omitted); *see also id.* at 15 ("Plaintiff's failure to warn claims should be dismissed to the extent they are premised on any duty owed by [BSC] to anyone other than Ms. Thompson's treating physician.").)

Plaintiff states in her Complaint that beginning in 2008, the FDA publicly warned of certain risks and complications associated with transvaginal pelvic mesh products, (*id*. at 3 (citing Doc. 1, ¶¶ 17, 32-43), and, starting in 2011, professional medical organizations like the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") did the same (*id*. (citing Doc. 1, ¶¶ 36-37).)[2] Defendant urges that, because "the adverse effects and injuries [Plaintiff] claims to have suffered were of the same type that were publicly disseminated by FDA and medical organizations, and thus well-known to the medical community, years before her 2020 implant[,]" (*id*. at 5), BSC had "no duty to warn of those risks" since they were "obvious or already known to the product's user" (*id*. at 6).

According to Defendant, Plaintiff must show "that the defendant failed to warn the physician of a risk associated with the use of the product, ***not otherwise known to the physician***." (*Id*. at 7 (quoting *Willett v. Baxter Int'l., Inc*., 929 F.2d 1094, 1098 (5th Cir. 1991)) (emphasis by BSC).) Because the mesh-related risks of which Plaintiff is complaining were "well known to the FDA and to the medical community years before she was implanted with the Lynx[,] [BSC] cannot be held liable based on a failure to warn of known risks. . . . [and] Plaintiff's warning-based claims therefore fail as a matter of law." (*Id*. at 8.)

Although Defendant acknowledges that Plaintiff "makes vague, general allegations that [BSC] failed to warn her doctors about the risks of mesh devices and thus prevented her doctors

[2] In support of its position, BSC quotes from and attaches to its *Motion* FDA publications. (Doc. 7-1 at 9 (citing to and quoting Docs. 7-3, 7-4, 7-5, 7-6.) BSC argues that the Court can and should consider these outside documents. (Doc. 7-1 at 4-5 (including n.1 at 5) and Doc 19 at 5.) Plaintiff argues the Court should not consider them. (Doc. 16 at 10-11.) The Court resolves the issue later in this Ruling.

from knowing about those risks," this is inconsistent with Plaintiff's specific allegation that her injuries were "of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion." (*Id*. at 10 (quoting Doc. 1, ¶ 37).) Thus, "there can be no causation when the failure to warn involves a risk that . . . is already known in the medical community." (*Id*. at 10 (quoting *Toups v. Synthes, Inc*., 2015 WL 6738541, at *7 (E.D. La. Nov. 4, 2015).)

Furthermore, Plaintiff's allegations regarding inadequate warning are deficient in that they fail to "explain how such warnings were inadequate, or show that her physician's receipt of an adequate warning would have changed the prescribing decision to use the Lynx." (Doc. 7-1 at 15.)

b. Defective Design

Regarding Plaintiff's second products liability claim, unreasonably dangerous design, BSC argues that "Plaintiff has failed to plead basic facts necessary to state her claims under Louisiana law." (*Id.* at 11.) Specifically, BSC contends that Plaintiff's allegations regarding alternative design are fatally defective in three ways. First, Plaintiff "must show that an alternative design existed for the Lynx device itself, as opposed to other products, (*id*. at 12 (citing *Braswell v. Agri-Fab, Inc*., 2007 WL 9701056, at * 5 (M.D. La. Mar. 14, 2007)), and yet, Plaintiff's proposed alternative designs are "tie[d] to different products entirely, including those that treat conditions other than SUI" (*id*. at 12-13). Secondly,

> Plaintiff fails to plead facts adequately identifying: a design that would have been safer than the Lynx product at issue in this case; how this alternative design would have been safer than the Lynx; and/or how these unspecified alternative designs would have prevented or significantly reduced the risk of Plaintiff's injuries.

(*Id*. at 13.)

Finally, BSC maintains that "Plaintiff fails to allege how 'the improvements represented by . . . alternative design[s] outweighed the burden on the manufacturer of adopting such alternative design.' " (*Id*. (quoting *Baptist v. C.R. Bard, Inc*., 2018 WL 1843937, at *4 (E.D. La.

Apr. 17, 2018) and citing *Dubroc v. Bristol-Myers Squibb*, 2019 WL 3756469, at *4 (M.D. La. Aug. 8, 2019)) (quotation marks omitted).) Plaintiff's allegation in this respect is merely conclusory and insufficient to meet this pleading requirement. (*Id*. at 14.)

c. Punitive Damages and Attorney Fees

BSC argues that Plaintiff's demand for these two items of damage must be dismissed since neither is allowed under the Louisiana law of products liability. (*Id*. at 16-17.)

B. Plaintiff's Opposition Brief (Doc. 16)

While Plaintiff "acknowledges that neither [punitive damages nor attorney fees] are recoverable under Louisiana law on the allegations currently pled in her complaint," (Doc. 16 at 2, n.1), Plaintiff argues that Defendant's *Motion* should be denied in all other respects. Specifically, Plaintiff contends her claims for failure to warn and defective design are "sufficient to satisfy the requirements of Federal Rule of Civil Procedure 8(a)." (*Id*. at 2.)

a. Failure to Warn

Plaintiff points the Court to paragraph 67 of her Complaint, where she identifies 15 specific deficiencies in BSC's warnings, (*Id.* at 3 (citing Doc. 1, ¶ 67)), and paragraph 117, where Plaintiff "outlines in detail the specific information she contends BSC omitted '[i]n their [Directions for Use], as well as marketing materials they prepared and disseminated to patients and healthcare providers' " (*id*. (quoting Doc. 1, ¶ 117)). Plaintiff states that paragraph 118 "further outlines how BSC failed to instruct her healthcare providers 'as to the proper candidates for, and the safest and most effective methods of, implantation and use of' the Lynx pelvic mesh device." (*Id.* (quoting Doc. 1, ¶ 118).) Finally, she quotes paragraph 119, wherein Plaintiff alleges, in pertinent part, that "[h]ad Defendant properly and adequately warned and instructed [Plaintiff] and her healthcare

providers . . . , [Plaintiff] would not have been recommended implantation of the Lynx pelvic mesh product[.]" (*Id*. at 3-4 (quoting Doc. 1, ¶ 119).)

These and other facts alleged in the Complaint, argues Plaintiff, "sufficiently establish BSC's liability under governing Louisiana law." (*Id.* at 5 (citing *Holbrook v. Bos. Sci. Corp*., 487 F. Supp. 3d 100, 110 (D. Mass. 2020) (applying Louisiana law)).) The erroneous and fatal premise of BSC's argument is that the proper standard is what is "known to the medical community" rather than what was known to Plaintiff's treating physician. (*Id*. at 6.) "BSC fails to cite a single Louisiana or Fifth Circuit case that applies the 'known to the medical community' standard it presses this Court to adopt." (*Id.*) Plaintiff distinguishes the cases cited by BSC because BSC either misreads the standard applied by the court or because the facts were different in significant respects. (*Id*. at 6-7.) "Even read generously," none of the cases from other jurisdictions cited by BSC apply the "known in the medical community" standard. (*Id*. at 8.)

Assuming arguendo, however, that this is the proper standard, Plaintiff's Complaint satisfies it because, contrary to BSC's misreading of Plaintiff's Complaint, key information was not known by the medical community and was withheld by BSC from the medical community.

> [W]hile ***some of the problems*** associated with the pelvic mesh products, including the Lynx pelvic mesh product, were made known to physicians, ***the magnitude and frequency of these problems were not disclosed and were hidden*** from physicians.

(Doc. 16 at 9 (quoting Doc. 1, ¶ 61) (emphasis by Plaintiff); *see id.* at 9-10 (Plaintiff points the Court to paragraph 52 as another example of Defendant's withholding of important information).)

Plaintiff takes issue with BSC's suggestion that the Court take judicial notice of the FDA documents attached to BSC's *Motion* since "the medical facts set forth in the FDA documents, and the medical community's 'knowledge' of those fact, are not 'adjudicative facts' appropriate for judicial notice as BSC proposes." (Doc. 16 at 10 (citing *Jackson v. Biedenharn*, 429 F. App'x 369,

373 (5th Cir. 2011).) Plaintiff points out that BSC itself "refuses to concede 'the accuracy of the validity of any of the statements or findings' in the FDA documents." (*Id*. at 10-11 (citing Doc. 7-1 at 4, n.7).)

However, regardless of whether the Court can consider the FDA documents, Plaintiff contends that these documents do not discuss all of the risks and injuries involved in this case. (*Id*. at 11 ("As just one example, the risks that the Lynx pelvic mesh device can cause neuromuscular pain, and long-term, life-altering pain when used to treat[ ] stress urinary incontinence are nowhere discussed in these materials.").)

Plaintiff concludes by stressing that "whether Dr. Brown already knew the risks of using BSC's Lynx pelvic mesh device is a question for the jury and not for this Court to decide as a matter of law based on the purported knowledge of the 'medical community.' " (*Id*.)

Regarding Plaintiff's allegation that, had Dr. Brown been properly advised and warned, her damages would have been avoided, Plaintiff argues that the allegations found in paragraphs 67, 117, 118, and 119 adequately allege the causation element of her case. (*Id.* at 15.)

b. Defective Design

Plaintiff insists that she has "alleged more than enough factual detail [regarding a safer alternative design] to satisfy Federal Rule of Civil Procedure 8(a)." (Doc. 16 at 12.) Plaintiff agrees with BSC that part of Plaintiff's burden at trial is to prove that, "at the time the product left BSC's control, (1) 'an alternative design existed for the product that was capable of preventing the alleged damage,' and (2) 'the alternative design would prevail in a traditional risk/utility analysis.' " (*Id*. (quoting *Grenier v. Med. Eng'g Corp*., 99 F. Supp. 2d 759, 764 (W.D. La. 2000) (citing La. R.S. 9:2800.56)).) But Plaintiff stresses that for purposes of the sufficiency of the Complaint, the question "is not whether the plaintiff has *proven* the elements to succeed on a products liability

claim, or even whether he has made 'detailed factual allegations.' Rather, the Court must simply determine whether the plaintiff 'has plausibly alleged enough information that, *with discovery*, he could prove' the defendants are liable." (Doc. 16 at 12 (quoting *Flagg v. Stryker Corp*., 647 F. App'x 314, 319 (5th Cir. 2016) (emphasis in *Flagg*)) (cleaned up).)

Plaintiff claims her alternative design pleadings "far exceed[ ] the pleading that the Fifth Circuit found sufficient in *Flagg*, by specifically identifying *multiple* examples of safer alternative designs[.]" (*Id.* at 13 (citing Doc. 1, ¶¶ 64, 107).) The level of detail provided by Plaintiff in this case distinguishes some of the cases relied on by BSC and others are distinguishable because the cases involved a motion for summary judgment and not a motion to dismiss. (*Id*. at 13-14.)

c. Punitive Damages and Attorney Fees

As mentioned earlier in this ruling, Plaintiff admits that the Louisiana law of products liability does not allow the recovery of punitive damages and attorney fees. (Doc. 16 at 2, n.1.)

C. BSC's Reply Brief (Doc. 19)

a. Failure to Warn

To support its position that "what is known to the medical community" and not just the prescribing physician governs the failure to warn standard, BSC points the Court to the wording of La. R.S. 9:2800.57(B)(1).

> A manufacturer is not required to provide an adequate warning about his product when . . . [t]he product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, ***with the ordinary knowledge common to the community as to the product's characteristics***.

(Doc. 19 at 2 (quoting La. R.S. 9:2800.55(B)(1)) (emphasis by BSC).)

BSC argues that when this rule is placed in the context of the learned intermediary doctrine, the duty to warn only "require[s] an adequate warning of inherent dangers ***not within*** the knowledge of or obvious to ***the average learned intermediate***." (*Id*. (quoting *Willett,* 929 F.2d at

1098, n.16) (emphasis by BSC).) Thus, argues BSC, it "had no duty to warn Plaintiff's prescribing physician of risks that [were] 'common knowledge' or generally known within the medical community." (*Id*. at 3 (citation omitted).) BSC returns to Plaintiff's Complaint, highlighting the specific passages in which it is alleged that the problems about which she now complains "were generally known to the medical community." (*Id*.) Indeed, Plaintiff admits that her injuries were "***of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion***." (*Id*. at 4 (quoting Doc. 1 at ¶ 37) (emphasis by BSC).)

BSC denies Plaintiff's charge that it is attempting to create new law; rather, it is merely maintaining that a manufacturer has no duty to warn a prescribing physician of risks which are commonly known in the medical community, "regardless of whether Plaintiff alleges that she and her prescribing physician were uniquely unaware of these risks." (*Id*.)

b. Defective Design

BSC reiterates that Plaintiff's defective design claim fails because she has failed to sufficiently plead an alternative design specific to the Lynx device (*Id*. at 5-6 (citing *Braswell v. Agri-Fab, Inc.*, 2007 WL 9701056, at *5 (M.D. La. Mar. 14, 2007)).) Additionally, she has failed to properly plead how Plaintiff's alternative design would meet the risk/utility analysis, Plaintiff merely "parrot[ing] the pleading requirement established by the LPLA." (*Id*. at 6.) Finally, BSC repeats its charge that Plaintiff has failed to sufficiently allege that a proper warning would have changed the outcome. (*Id*. at 7-8.)

III. STANDARD

In *Johnson v. City of Shelby*, 574 U.S. 10, 11 (2014), the Supreme Court explained: "Federal pleading rules call for 'a short and plain statement of the claim showing that the pleader

is entitled to relief,' Fed. R. Civ. P. 8(a)(2); they do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted."

Interpreting Rule 8(a) of the Federal Rules of Civil Procedure, the Fifth Circuit has explained:

> The complaint (1) on its face (2) must contain enough factual matter (taken as true) (3) to raise a reasonable hope or expectation (4) that discovery will reveal relevant evidence of each element of a claim. "Asking for [such] plausible grounds to infer [the element of a claim] *does not impose a probability requirement* at the pleading stage; it simply calls for enough facts to raise a reasonable expectation that discovery will reveal [that the elements of the claim existed]."

Lormand v. U.S. Unwired, Inc., 565 F.3d 228, 257 (5th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

Applying the above case law, the Western District of Louisiana has stated:

> Therefore, while the court is not to give the "assumption of truth" to conclusions, factual allegations remain so entitled. Once those factual allegations are identified, drawing on the court's judicial experience and common sense, the analysis is whether those facts, which need not be detailed or specific, allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." [*Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009)]; *Twombly*, 55[0] U.S. at 556, 127 S. Ct. at 1965. This analysis is not substantively different from that set forth in *Lormand, supra*, nor does this jurisprudence foreclose the option that discovery must be undertaken in order to raise relevant information to support an element of the claim. The standard, under the specific language of Fed. R. Civ. P. 8(a)(2), remains that the defendant be given adequate notice of the claim and the grounds upon which it is based. The standard is met by the "reasonable inference" the court must make that, with or without discovery, the facts set forth a plausible claim for relief under a particular theory of law provided that there is a "reasonable expectation" that "discovery will reveal relevant evidence of each element of the claim." *Lormand*, 565 F.3d at 257; Twombly, 55[0] U.S. at 556, 127 S. Ct. at 1965.

Diamond Servs. Corp. v. Oceanografia, S.A. De C.V., No. 10-177, 2011 WL 938785, at *3 (W.D. La. Feb. 9, 2011).

The Fifth Circuit further explained that all well-pleaded facts are taken as true and viewed in the light most favorable to the plaintiff. *Thompson v. City of Waco*, 764 F.3d 500, 502–03 (5th

Cir. 2014). The task of the Court is not to decide if the plaintiff will eventually be successful, but to determine if a "legally cognizable claim" has been asserted." *Id.* at 503.

IV. DISCUSSION

"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 by the claimant or another person or entity." La. R.S. 9:2800.54(A). Thus, as the Fifth Circuit has explained:

> To maintain a successful products liability action under the LPLA, a plaintiff must establish four elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else.

Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 260–61 (5th Cir. 2002) (citing La. R.S. 9:2800.54(A)).

A product is "unreasonably dangerous" under the LPLA "if and only if" the product is (1) "unreasonably dangerous in construction or composition"; (2) "unreasonably dangerous in design"; (3) "unreasonably dangerous because an adequate warning about the product has not been provided"; or (4) the product fails to "conform to an express warranty of the manufacturer about the product." La. R.S. 9:2800.54(B) (referencing definitions in La. R.S. 9:2800.55 – 58).

Plaintiff's Complaint is 45 pages and 127 paragraphs long and provides an exquisitely detailed history of pelvic mesh products generally and the Lynx product specifically. It is also detailed in its criticism of the product's design and warnings. Plaintiff focuses her allegations that the Lynx pelvic mesh device was unreasonably dangerous in design in Doc. 1, ¶¶ 54-65, although references to the allegedly defective design are scattered elsewhere in the Complaint (*see, e.g.*, Doc. 1, ¶ 30(a)-(h)). Her allegations regarding the allegedly inadequate instructions and warnings

are detailed in Doc. 1, ¶¶ 66-76, but other references to the deficient warnings are found throughout the Complaint (*see, e.g., id*. at ¶¶ 29-31, 45, 46, 49, 52). Plaintiff alleges that these deficiencies in warnings and design entitle her to, among other items of damage demanded, punitive damages and attorney fees. (*Id.* ¶ 125 and Prayer, ¶ 2.) These matters will be taken up in turn.

A. Matters Which May Be Considered

In her Complaint, Plaintiff makes repeated references to the FDA's involvement in the collection of information regarding the dangers and risks of the pelvic mesh products and the FDA's notifications regarding same to the public and the medical profession. (*See, e.g.,* Doc. 1, ¶¶ 32-35, 37-44.) Plaintiff does the same with respect to the ACOG/AUGS. (*Id*. ¶¶ 36, 37, 44.) In these paragraphs, Plaintiff alleges that the risks described by the FDA and ACOG/AUGS were known to BSC, but that additional risks known only to BSC were withheld from the public and medical community.

Attached to Defendant's *Motion* are four FDA publications regarding pelvic mesh products. (Docs. 7-3, 7-4, 7-5, 7-6.) Throughout its briefing, Defendant argues that these publications demonstrate that the risks of pelvic mesh devices like the Lynx device were already known to the medical community and therefore it had no duty to warn of same to Dr. Brown or anyone else. BSC contends that the Court can consider the FDA documents for two reasons. First, for purposes of a motion to dismiss, a court can consider "the complaint, its proper attachments, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. . . ." (Doc. 7-1 at 4 (quoting *Jones v. Caliber Home Loans, Inc*., 2020 WL 4342219, at * 4 (M.D. La. 2020) (in turn quoting *Randall D. Walcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 763 (5th Cir. 2011))).) Second, argues BSC, the Court can take judicial notice of these records under Federal Rule of Evidence 201. (*Id*. at 5.)

Plaintiff counters that "the medical facts set forth in the FDA documents, and the medical community's 'knowledge' of those facts, are not 'adjudicative facts' appropriate for judicial notice as BSC proposes." (Doc. 16 at 10 (citing *Jackson v. Biedenharn*, 429 F. App'x 369, 373 (5th Cir. 2011)).) In its reply, Defendant responds by pointing the Court to multiple instances in which Plaintiff referred to FDA publications. (Doc. 19 at 3-4.)

This Court recently summarized the pertinent rule as follows:

> The general rule regarding what may be considered in deciding a Rule 12(b)(6) motion is well known.
>
> > In determining whether a plaintiff's claims survive a Rule 12(b)(6) motion to dismiss, the factual information to which the court addresses its inquiry is limited to (1) the facts set forth in the complaint, (2) documents attached to the complaint, and (3) matters of which judicial notice may be taken under Federal Rule of Evidence 201.
>
> *Gomez v. Galman*, 18 F.4th 769, 775 (5th Cir. 2021) (per curium) (quoting *Walker v. Beaumont Indep. Sch. Dist.*, 938 F.3d 724, 735 (5th Cir. 2019)). *See also Innova Hosp. San Antonio, Ltd. P'ship v. Blue Cross & Blue Shield of Georgia, Inc.*, 892 F.3d 719, 726 (5th Cir. 2018).
>
> However, there is an exception to this rule: a court may consider documents attached to a motion to dismiss "where the complaint refers to the documents and they are central to the claim." *Kane Enters. v. MacGregor (USA) Inc.*, 322 F.3d 371, 374 (5th Cir. 2003) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000)). *See also Wilson v. GMFS LLC,* No. 18-840, 2019 WL 8301667, at *3 (M.D. La. May 24, 2019); *McCann v. Best Buy Co.*, No. 17-108, 2017 WL 5985570, at *2 (M.D. La. Dec. 1, 2017).

Liberty Mut. Fire Ins. Co. v. Shaw Grp., Inc., No. 20-871, 2022 WL 896804, at *10 (M.D. La. Mar. 25, 2022) (deGravelles, J.).

Because the FDA documents are referred to extensively in Plaintiff's Complaint and because of the central role they play in Plaintiff's narrative and allegations, it is proper to consider the FDA documents attached to BSC's *Motion*, (Docs. 7-3 through 7-6), as well as the allegations regarding same in Plaintiff's Complaint.

B. Punitive Damages and Attorney Fees

Plaintiff candidly admits that Louisiana's law of products liability does not provide for the recovery of punitive damages and attorney fees. (Doc. 16 at 2, n.1.) Plaintiff is correct and this part of Plaintiff's claim is therefore dismissed with prejudice. *Saienni v. Peters*, 2015 WL 520765, at *1 (M.D. La. Feb. 9, 2015); *Bladen v. C.B. Fleet Holding Co*., 487 F. Supp. 2d 759, 770 (W.D. La. 2007). ("The [LPLA], which specifically limits those claims which can be made against a manufacturer for use of its product by a consumer provides the exclusive theory of liability available against a manufacturer and does not authorize punitive damages.") Nor does the LPLA include attorneys' fees within its statutory definition of allowable damages. *See* La. R.S. 9:2800.53 ("Attorneys' fees are not recoverable under this Chapter"); *Chevron USA, Inc. v. Aker Mar., Inc*., 604 F.3d 888, 900–901 (5th Cir. 2010); *Holbrook v. Bos. Sci. Corp*., 487 F. Supp. 3d 100, 111 (D. Mass. 2020) (accord, interpreting Louisiana law).

C. Failure to Warn

> To recover for a failure to warn under this doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used or prescribed the product.

Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1098–99. *See also In re Taxotere (Docetaxel) Prod. Liab. Litig.*, 994 F.3d 704, 708 (5th Cir. 2021).

Defendant makes two main arguments in support of its motion to dismiss Plaintiff's failure to warn claim: first, that Defendant has no duty to warn about risks and injuries which are already known in the medical community and to the "average learned intermediate." (*See, e.g.,* Doc. 19 at 2 (quoting *Willett*, 929 F.2d at 1099, n.16).) Because Plaintiff alleges that her injuries were of the

type reported to the medical community years before her surgery by way of the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion, her failure to warn claim fails as a matter of law. (*Id*. at 4 (quoting Doc. 1, ¶ 37).) Second, Plaintiff fails to "explain how such warnings were inadequate, or show that her physician's receipt of an adequate warning would have changed the prescribing decision to use the Lynx[.]" (Doc. 7-1 at 15.)

Plaintiff responds to Defendant's first argument in three ways. Plaintiff argues first that BSC misconstrues and misrepresents the scope of its duty as a designer, manufacturer, and distributor of a medical product. Correctly stated, "the learned intermediary doctrine requires the plaintiff to show that the defendant failed to warn of a risk "not otherwise known to **the physician**." (Doc. 16 at 6 (quoting *Willett*, 929 F.2d at 1098) (emphasis by Plaintiff).) There is no "known to the medical community" component in the standard and since Plaintiff alleges that her treating doctor was not warned, it is irrelevant what may have been known by "the medical community." (*Id*. at 6-7.)

Second, even if Defendant's interpretation of its duty was correct, Plaintiff has alleged fifteen "specific deficiencies in BSC's warnings," (Doc. 16 at 3 (citing Doc. 1, ¶ 67)); has "outline[d] in detail the specific information she contends BSC omitted from its" directions for use and marketing materials, (*id*. (citing Doc. 1, ¶ 117)); and has "outline[d] how BSC failed to instruct her healthcare providers 'as to the proper candidate for and the safest and most effective methods of implantation and use (*id*. (citing Doc. 1, ¶ 118); *see also id*. at 11).

Third, Plaintiff points to her Complaint at paragraph 67, where she specifically alleges that BSC failed to provide information *not* provided earlier by FDA and ACOG/AUGS.

> Further, while ***some of the problems*** associated with the pelvic mesh products, including the Lynx pelvic mesh product, were made known to physicians, ***the magnitude and frequency of these problems were not disclosed and were hidden*** from physicians.

(Doc. 16 at 9 (quoting Doc. 1, ¶ 61) (emphasis by Plaintiff).)

Regarding BSC's second grounds for dismissal of this claim (failing to explain how the warnings were inadequate or why and how adequate warnings would have altered the outcome), Plaintiff responds that she has indeed addressed the specifics of BSC's warning deficiencies in the above paragraphs and alleged specifically that had Plaintiff's doctors been "properly and adequately warned and instructed . . . [Plaintiff] would not have been recommended implantation of the Lynx pelvic mesh product, and [Plaintiff] would not have proceeded with implantation[.]" (*Id*. at 3-4 (quoting Doc. 1, ¶ 119).)

The Court finds that Defendant is correct that Plaintiff alleges that her injuries "are of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion." (Doc. 1, ¶ 37.) Defendant is also correct that Plaintiff details the research done before Plaintiff's surgery that identified certain dangers and risks associated with pelvic mesh implants, (*see, e.g.,* Doc. 1, ¶¶ 17-21), which were disseminated to the public and medical community through FDA communications, (*see e.g., id.* ¶¶ 32-36, 39-43), and that of professional medical groups (*id*. ¶ 36).

But Defendant ignores numerous paragraphs in which she alleges that, despite this research, BSC, in its advertising, marketing, and other communications to the medical profession and public, "exaggerated and misle[d] expectations as to the safety and utility of this product." (*Id*. ¶ 29.) According to Plaintiff, "contrary to [its] representations and marketing[,]" BSC failed to report "high failure, injury, and complication rates" and instances in which its product "caused severe and irreversible injuries, conditions and damage . . ." (*Id*. ¶ 30.) Indeed, Plaintiff charges:

> Defendant has consistently underreported and withheld information about the propensity of . . . the Lynx pelvic mesh product to fail and cause injury and

> complications, and misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

Id. ¶ 31.

> Defendant knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous injury [and] were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

Id. ¶ 52.

In paragraph 67 (A-V), Plaintiff details twenty-two specific ways in which BSC's warnings were deficient. (Doc. 1, ¶ 67 (A) – (V).) In paragraph 117, Plaintiff again details the allegedly defective warnings, specifying 28 ways in which the warnings were inadequate. (*Id*. ¶ 117 (a. – bb); *see also id*. ¶¶ 45(C), 46, 49, 67, 68, 72.) Plaintiff alleges that not only did BSC withhold information, underreport data, and "actively and intentionally" mislead the profession and regulators regarding the dangers and risks of its product, but it failed to advise of "magnitude and frequency of those risks." (*Id*. ¶ 73.)

> *** Further, while some of the problems associated with the Pelvic Mesh Products, including the Lynx pelvic mesh product, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

(Doc. 1, ¶ 61.)

Plaintiff and Defendant disagree on whether it is the prescribing physician or the medical community who must be made aware of the risks and dangers of the medical product. There is certainly language in the case law suggesting the former.

> An adequate warning is one that "would lead an ordinary reasonable user ... to contemplate the danger in" the use of the product. LA. STAT. ANN. § 9:2800.53(9) (West 2013). Under the "learned intermediary doctrine," however, a *patient's physician* acts as an informed intermediary between the drug company and the patient. *Brown v. Glaxo, Inc*., 790 So. 2d 35, 38-39 (La. App. 1 Cir. 2000), *writs denied*, 785 So. 2d 827 and 785 So. 2d 832 (La. 2001). Thus, *a drug manufacturer has a duty to warn the prescribing physician,* rather than the patient, of potential

> risks associated with the use of the drug. *Mikell v. Hoffman-LaRoche, Inc*., 649 So.2d 75, 79-80 (La. App. 1 Cir. 1994).

In re Taxotere (Docetaxel) Prod. Liab. Litig., 994 F.3d, 704, 708 (5th Cir. 2021) (emphasis added).

But Defendant is correct that the Fifth Circuit has also stated, "We, therefore, interpret the duty to warn in the learned intermediate context to require an adequate warning of inherent dangers not within the knowledge of or obvious to the *average learned intermediate*." *Willett v. Baxter Int'l, Inc.*, 929 F.2d at 1098, n.16 (emphasis added). The reason for the Fifth Circuit's statement seems clear. To adopt Plaintiff's position would transform a medical product manufacturer's duty to warn into a purely subjective one, turning totally on the knowledge (or lack thereof) of one doctor, the treating doctor, regardless of how competent or incompetent, trained or untrained, that physician might be. As the Eastern District recently held in the context of another medical product liability case, "[t]he ordinary users and handlers of the ReShape balloon at issue are *bariatric surgeons like Dr. Lavin*, and there is no evidence in the record that Dr. Lavin lacked 'ordinary knowledge common to *[his] community [of physicians]* as to the product's characteristics.' " *Vesoulis v. ReShape Lifesciences, Inc.*, No. CV 19-1795, 2021 WL 1909725, at *5 (E.D. La. May 12, 2021) (emphasis added).

However, for purposes of the present analysis, it makes no difference who is right. Whether one focuses on the adequacy of the warning vis a vis Plaintiff's treating physician, Dr. Brown (as Plaintiff urges), or what was known by "the average learned intermediate," (as Defendant posits), the result is the same: Plaintiff's allegations are sufficient. Although Plaintiff's Complaint alleges that the medical community was already aware of *some* dangers of the product at the time of Plaintiff's surgery, Plaintiff also alleges that much more was known to BSC about the product's dangers which it failed to disclose in its instructions and warnings. The Court finds that Plaintiff's

allegations regarding the inadequacy of Defendant's instructions and warnings are sufficient for Rule 8(a)(2) purposes.

The Court also finds that Plaintiff has adequately pled the causation element of her warnings claim. In paragraph 119, Plaintiff alleges:

> Had Defendant properly and adequately warned and instructed [Plaintiff] and healthcare providers with [sic] regarding to [sic] the Lynx pelvic mesh products' Risks and Potential Complications, upon information and belief, [Plaintiff] would not have been recommended implantation of the Lynx pelvic mesh product, and [Plaintiff] would not have proceeded with implantation of the Lynx pelvic mesh product, thus avoiding the injuries [Plaintiff] has alleged herein.

(Doc. 1, ¶ 119.)

This paragraph also meets Rule 8(a)(2) muster, especially when read in connection with paragraphs 61, 117, and 118 of the Complaint. *Donald v. AstraZeneca Pharms., LP*, No. CV 16-17753, 2017 WL 1079186, at *3 (E.D. La. Mar. 22, 2017) (Approving the plaintiff's complaint which alleged that her treating physician would not have prescribed her Nexium had the physician been properly warned of the risks of kidney injuries. "In following with the Fifth Circuit's quite generous instruction on specificity required at the pleading stage for an LPLA claim, the Court finds that the plaintiff's complaint provides 'facial plausibility' for a failure to warn claim.").

In sum, the deficient warnings allegations made in Plaintiff's Complaint more than satisfy the requirements of Federal Rule of Civil Procedure 8(a)(2). *Holbrook v. Bos. Sci. Corp.*, 487 F. Supp. 3d 100, 109–10 (D. Mass. 2020) (applying Louisiana law); *see also Batiste v. Stryker Corp.*, No. 19-574, 2021 WL 1171880, at *7 (M.D. La. Mar. 26, 2021) (deGravelles, J.).

D. Design Defect – Alternative Design

Defendant alleges that Plaintiff's allegations regarding proposed safer alternative designs are deficient in that they are not alternative designs specific to the Lynx mesh product and furthermore, Plaintiff fails to properly allege the risk/utility evaluation. Plaintiff counters that her

allegations are more than sufficient in both respects, relying on *Flagg v. Stryker Corp*., 647 F. App'x at 319.

In *Flagg v. Stryker Corp*., 647 F. App'x 314, 315 (5th Cir. 2016), the Fifth Circuit considered Rule 8(a)(2) pleading requirements in the context of a claim brought under the LPLA. The Court observed:

> [W]e have never squarely addressed how much detail and specificity is required to plead that a product was unreasonably dangerous under the LPLA due to defective design, construction, or composition.
>
> We conclude that Flagg's allegations provide sufficient information to "raise a reasonable expectation that that discovery will reveal evidence" to support the Manufacturing Defendants' liability. *See In re S. Scrap Material Co*., 541 F.3d at 587 (citation omitted). Requiring Flagg and other plaintiffs to plead extremely "detailed factual allegations" that satisfy each element of a products liability action under the LPLA creates a situation where a manufacturer will not be held liable for defective products because it has sole possession of the necessary document to ultimately prove the claim. *See Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937 (noting that pleadings need not contain "detailed factual allegations" (quoting *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955)); *see also Bertrand v. Eli Lilly & Co*., No. 12–0853, 2013 WL 4093556, at *5 (W.D. La. Aug. 13, 2013) (noting plaintiffs in products liability suits face a likely impossible task of stating more specific allegations about manufacturing and design when the defendants have possession of the necessary information).

Flagg, 647 F. App'x at 317–18. *See also Price v. Luster Prod. Inc*., No. CV 21-1036, 2022 WL 1719274, at *8 (E.D. La. May 27, 2022).

Flagg involved a medical products liability claim against the manufacturer of a toe implant which broke. *Id*. at 315. As to his alternative design allegations, the Court stated,

> Although Flagg does not plead that the alternative alloy and design were available when the implants were produced or that the danger of the damage outweighs the burden of adopting the design, those very detailed and specific allegations are not required to plead a plausible claim at this this stage, before Flagg has had an opportunity for discovery. (citations omitted)

Flagg v. Stryker Corp., 647 F. App'x at 318.

Here the Court has carefully considered Plaintiff's proposed alternative design and risk/utility allegations. (Doc. 1, ¶¶ 64, 107.) Plaintiff offers eight separate alternative designs currently in use which, she alleges, were "safer [and] economically and technologically feasible" at the time the Lynx product "left the control of the Defendant." (*Id.* ¶ 64.) Plaintiff alleges these alternative designs would have prevented or significantly reduced the risk of Plaintiff's injuries. (*Id.* ¶ 107.) Plaintiff alleges that "[t]he likelihood that the Lynx pelvic mesh product's design would cause [Plaintiff's] damage and the gravity of that harm outweighed the burden on Defendant of adopting such an alternative design[.]" (*Id.*)

The Court concludes that Plaintiff's allegations are more than sufficient to meet the pleading requirements at this stage. *Flagg*, 647 F. App'x at 318; *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1198 (E.D. La. 2016) (although the plaintiff did "not offer a specific alternative design that would have prevented her injury," the court found that "whether the plaintiff can demonstrate an alternative design that satisfies the test under the LPLA is a question of fact to be assessed upon discovery."); *Kaylor v. Eisai Inc.*, No. CV 21-58, 2022 WL 983657, at *4 (W.D. La. Mar. 30, 2022) (finding that "the Amended Petition adequately [pled] that the dangers the original product posed to consumers like Mrs. Kaylor outweighed the burden of switching to the proposed alternative design."); *Donald v. AstraZeneca Pharms., LP*, No. CV 16-17753, 2017 WL 1079186, at *3 (E.D. La. Mar. 22, 2017) (finding that while "the complaint does not address whether the danger outweighed the burden on the manufacturer of adopting an alternative design . . . such an omission is not so fatal as to give rise to dismissal under 12(b)(6) at this stage in the litigation.").

Defendant's claim that Plaintiff's alternative design must be tied to the specific features of its product is without merit.

> "This Court has found that a complaint sufficiently pleads a design defect claim by alleging an alternative design in general terms, including the general characteristics of the alternative design." *Baudin v. AstraZeneca Pharm*. LP, 413 F. Supp. 3d 498, 506 (M.D. La. 2019) (citing *Boutte v. Stryker Biotech, LLC*, 67 F. Supp. 3d 732, 736–37 (M.D. La. 2014); *Crochet v. Bristol-Myers Squibb*, No. 16-36, 2016 WL 3580670, *3 (M.D. La. June 28, 2016); and *Brooks v. Amgen, Inc.,* No. 18-657, 2019 WL 507491, *5 (M.D. La. Feb. 8, 2019)). This Court has also found that the requirement that a plaintiff plead that the gravity of harm outweighs the burden to the manufacturer of adopting the suggested alternative design is satisfied by allegations that the design of other existing comparable products does not contain the risks associated with the defendant's product. *Id*. at 507 (finding that "[t]he Complaint sufficiently alleges that the risk of gastric cancer outweighs the burden of utilizing alternative H2 receptor antagonist pharmaceuticals in lieu of PPI's.").

Batiste v. Stryker Corp., 2021 WL 1171880, at *6.

V. CONCLUSION

In conclusion, the Court finds that *Defendant Boston Scientific Corporation's Motion to Dismiss Plaintiff's Complaint* (Doc. 7) should be and is hereby **GRANTED** as to Plaintiff's claim for punitive damages and attorney fees. In all other respects, the *Motion* is **DENIED**.

Signed in Baton Rouge, Louisiana, on September 29, 2022.

JUDGE JOHN W. deGRAVELLES
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA