

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

AMAL EGHNAYEM, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:13-cv-07965

BOSTON SCIENTIFIC CORPORATION,

Defendant.

**MEMORANDUM OPINION AND ORDER  
(Motions *in Limine*)**

Pending before the court are Boston Scientific Corporation's ("BSC") Initial Motions *in Limine* [Docket 197], BSC's Motion *in Limine* to Exclude Evidence of Dyspareunia [Docket 214], Plaintiffs' Omnibus Motions *in Limine* [Docket 199], and Plaintiff Amal Eghnayem's Motion *in Limine* # 3 [Docket 221]. For the reasons set forth below, BSC's Initial Motions *in Limine* [Docket 197] are **GRANTED in part** and **DENIED in part**, BSC's Motion *in Limine* to Exclude Evidence of Dyspareunia [Docket 214] is **DENIED without prejudice**, Plaintiffs' Omnibus Motions *in Limine* [Docket 199] are **DENIED**, and Plaintiff Amal Eghnayem's Motion *in Limine* # 3 [Docket 221] is **GRANTED in part** and **DENIED in part**.

**I. Background**

This consolidated case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are over 60,000 cases currently pending, over 13,000 of which are in the Boston Scientific Corporation MDL, MDL 2326. In this particular case, the four plaintiffs were surgically implanted with the Pinnacle Pelvic Floor Repair Kit ("the Pinnacle"), a mesh product

manufactured by BSC to treat POP. (*See* Pretrial Order # 91 [Docket 10], at 1–2).<sup>1</sup> All of the plaintiffs received their surgeries in Florida. The plaintiffs claim that as a result of implantation of the Pinnacle, they have experienced “erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.” (*Id.* at 3 (quoting the master complaint)). The plaintiffs allege negligence, design defect, manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (*Id.* at 1–2). The instant Motions *in Limine* involve the parties’ efforts to exclude or limit certain evidence, arguments, and testimony at trial.

## **II. BSC’s Motions**

### **1. Motion to Preclude Any Evidence or Argument Regarding Fraud on the FDA or Alleged Misbranding**

BSC seeks to preclude evidence that BSC “withheld information from the FDA, misled the [FDA], or misbranded their device as FDA-cleared.” (BSC’s Mem. in Supp. of Its Initial Mots. *in Limine* (“Def.’s Mem. Supp.”) [Docket 197], at 4). BSC argues that such evidence would only be relevant to a “fraud-on-the-FDA” claim, which is preempted under *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). Based on the court’s rulings on the inadmissibility of FDA evidence in similar cases, the plaintiffs “[a]gree that any evidence or argument regarding fraud on the FDA or alleged misbranding should be excluded from this

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<sup>1</sup> I originally consolidated the cases of five plaintiffs implanted with the Pinnacle. (*See* Pretrial Order # 91 [Docket 10] (naming Eghnayem, Dotres, Nunez, Dubois-Jean, and Betancourt as consolidated plaintiffs)). Four plaintiffs now remain in this action. (*See* Order [Docket 35] (removing Dubois-Jean from consolidated pool)).

case.” (Pls.’ Omnibus Resp. to BSC’s Initial Mots. *in Limine* (“Pls.’ Omnibus Resp.”) [Docket 212], at 1). Because the plaintiffs do not oppose this motion *in limine*, it is thus **GRANTED**.

## **2. Motion to Preclude Evidence Concerning Material Safety Data Sheets (“MSDS”)**

BSC seeks to preclude any evidence concerning the Phillips Sumika MSDS, specifically the Marlex Polypropylene MSDS containing a Medical Application Caution (“the Caution”). (Def.’s Mem. Supp. [Docket 197], at 6). BSC argues that the MSDS is irrelevant, misleading to the jury, unfairly prejudicial, and would result in an undue delay and waste of time. (*Id.*).

I find BSC’s arguments wholly unconvincing. First, BSC contends that the plaintiffs should be precluded from offering any evidence related to the MSDS because such evidence is irrelevant to the plaintiffs’ claims and will mislead the jury. (*Id.*). BSC bases this contention on the deposition testimony of Frank Zakrzewski, corporate representative for Chevron Phillips Chemical Company. (*See id.* at 6–8).

Evidence or argument as to the methods by which BSC acquired polypropylene resin is relevant to both the plaintiffs’ substantive claims and claims for punitive damages. *See In re C. R. Bard, Inc.*, MDL No. 2187, 2013 WL 3282926, at \*3 (S.D. W. Va. June 27, 2013) (denying Bard’s motion *in limine* seeking to preclude evidence concerning the same MSDS); (*see also* Mem. Op. & Order [Docket 232] (denying BSC’s motion for partial summary judgment on the plaintiffs’ punitive damages claims)). The MSDS served as a notification to BSC of the manufacturer’s concerns about the safety of its product for permanent implantation in the human body. Furthermore, the Caution in the MSDS is pertinent to BSC’s knowledge of potential safety concerns in its final product.

BSC attempts to bolster its argument by relying on a deposition that is both vague and

unclear. BSC contends that Mr. Zakrzewski unequivocally states that the Caution was not added based on any scientific concerns. However, BSC's particular reading of Mr. Zakrzewski's testimony is not an accurate reflection of his opinions. Mr. Zakrzewski clearly indicates he has no knowledge of who wrote the MSDS or why it was written. (*See* Zakrzewski Dep. [Docket 197-3], at 45 ("A: I would say that legal had some input into the MSDS, but I don't know that for certain because I didn't write it. Q: Do you know who wrote the MSDS? A: I do not.")). BSC improperly conflates Mr. Zakrzewski's lack of knowledge regarding scientific testing with a conclusive determination. I have made it clear in this MDL that I find the MSDS to be sufficiently relevant, and BSC's arguments do not change my mind. Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

### **3. Motion to Preclude Evidence Concerning Polyethylene Material Safety Data Sheets**

BSC seeks to preclude "testimony and evidence concerning the Material Safety Data Sheet for Marlex and MarFlex Polyethylenes . . . . as it does not apply to the Phillips Sumika Marlex Polypropylene contained in Boston Scientific's Pinnacle device." (Def.'s Mem. Supp. [Docket 197], at 9). BSC explains that BSC employees and consultants responded to questions concerning the polyethelene MSDS thinking they were responding to questions concerning the polypropylene MSDS. The plaintiffs attempt to highlight the fact that the polyethylene MSDS was written in 2001, three years before the polypropylene MSDS. (Pls.' Omnibus Resp. [Docket 212], at 4). However, BSC clearly states that polyethylene is not a material used in BSC's mesh. (Def.'s Mem. Supp. [Docket 197], at 10). Evidence related to materials not present in the device at issue is clearly outside the scope of the plaintiffs' claims and irrelevant. Accordingly, BSC's motion *in limine* on this issue is **GRANTED**.

#### **4. Motion to Preclude Evidence of BSC's Procurement of Polypropylene Resin**

BSC seeks to preclude “any evidence concerning BSC’s procurement of polypropylene resin, including, but not limited to, purchases of Phillips Sumika Marlex HGX-030-01 polypropylene resin from a Chinese distributor in July 2011.” (Def.’s Mem. Supp. [Docket 197], at 11). BSC argues that BSC’s procurement of polypropylene resin is irrelevant to the plaintiffs’ product defect claims, particularly any evidence regarding polypropylene resin not used in the manufacture of the plaintiffs’ Pinnacle devices. (*Id.*). I **FIND** that evidence as to the methods by which BSC acquired polypropylene resin is potentially relevant as to the plaintiffs’ substantive claims, as well as their claims for punitive damages. However, an evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC’s motion *in limine* on this issue is **DENIED without prejudice**.

#### **5. Motion to Preclude Evidence Regarding ProteGen Device**

BSC seeks to preclude “any evidence or testimony concerning the Boston Scientific ProteGen sling [ ], including but not limited to, Boston Scientific’s recall of that product.” (Def.’s Mem. Supp. [Docket 197], at 13). BSC argues that evidence concerning the ProteGen is irrelevant, misleading to the jury, unfairly prejudicial, and a cause of undue delay and wasted time because the ProteGen and the Pinnacle are “not substantially similar.” (*Id.*). BSC notes that the two products are made from different materials, use a different surgical technique, involve a different regulatory history, and are used to treat two different medical conditions. (*Id.*).

In *Lewis v. Ethicon*, I excluded evidence regarding the recall of the ProteGen sling because it would require extensive discussion of the FDA 510(k) clearance process, given that Ethicon used the ProteGen as a regulatory predicate device. *See* No. 2:12-cv-4301, 2014 WL 505234, at \*16 (S.D. W. Va. Feb. 5, 2014) (“A discussion of the 510(k) process, whether in the context of the clearance of a new device or the recall of a predicate product, presents the danger of unfair prejudice and confusing the jury.”). Here, BSC did not use the ProteGen as a regulatory predicate device, a fact that BSC itself points out. (*See* Def.’s Mem. Supp. [Docket 197], at 14). The ProteGen was a product that BSC developed, sold, and subsequently recalled. (Pls.’ Omnibus Resp. [Docket 212], at 7). An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. The context in which the plaintiffs seek to introduce evidence of the ProteGen is clearly different than that in the *Lewis* trial. However, I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC’s motion *in limine* on this issue is **DENIED without prejudice**.<sup>2</sup>

#### **6. Motion to Preclude Evidence of Argument Concerning BSC’s Intent, Motives, or Ethics**

BSC seeks to exclude evidence or testimony of its intent, motives, and ethics. BSC argues that this evidence or testimony “(A) is irrelevant to the Plaintiffs’ claims; and (B) would cause confusion, unfair prejudice, and undue waste of time; and (C) is beyond the scope of Plaintiffs’ experts’ knowledge.” (*See* Def.’s Mem. Supp. [Docket 197], at 16). I need more information about the particular piece of evidence or argument being challenged in this motion,

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<sup>2</sup> This finding is limited by my exclusion of any evidence related to the FDA 510(k) clearance process and enforcement.

and I lack the context needed to properly rule on the matter at this time. Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

**7. Motion to Preclude Any Evidence or Argument Concerning BSC's Decision to Stop Selling Pinnacle or Suggesting that the Pinnacle Was Recalled or Withdrawn**

BSC seeks to preclude any "evidence or argument on its discontinuation of certain pelvic mesh products, including the Pinnacle." (Def.'s Mem. Supp. [Docket 197], at 19). BSC argues that such evidence is irrelevant and has the potential to mislead the jury because it was a business decision, not a recall. (*See id.*). The plaintiffs state that they "will not suggest at trial that the Pinnacle product was recalled or withdrawn." (Pls.' Omnibus Resp. [Docket 212], at 11). Nevertheless, BSC's decision to stop selling the Pinnacle has the potential to be construed as a subsequent remedial measure. Under Federal Rule of Evidence 407, "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence; culpable conduct; a defect in a product or its design; or a need for a warning or instruction." Accordingly, BSC's motion *in limine* on this issue is **GRANTED**.

**8. Motion to Preclude Any Evidence or Argument Concerning Foreign Regulatory Actions**

BSC seeks to exclude any evidence or argument concerning foreign regulatory actions on BSC's pelvic mesh products. BSC argues that such evidence is irrelevant because all of the plaintiffs' BSC products were implanted in the United States, and such evidence would be unduly prejudicial, confusing to the jury, and a waste of time. (*See* Def.'s Mem. Supp. [Docket 197], at 22).

I have previously denied without prejudice a defendant's motion *in limine* concerning evidence of foreign regulatory actions. *See Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201, 2014 WL 3861778, at \*2 (S.D. W. Va. Aug. 6, 2014); *Bard*, 2013 WL 3282926, at \*2. Along with several other motions *in limine*, I found that granting a motion *in limine* on this subject was premature:

I simply cannot make a substantive ruling at this time without knowing the particular piece of evidence that the plaintiffs seek to introduce or argument that the plaintiffs seek to make, and the context in which the plaintiffs seek to introduce such evidence or make such argument. In short, a blanket exclusion of such evidence, argument or testimony is premature at this time[.]

*Id.* at \*2. At trial, this evidence may be inadmissible because different countries have different regulatory systems and schemes. This case arises under the laws of the United States, and, therefore, evidence concerning other countries' regulatory policies may confuse and mislead the jury. *See Deviner v. Electrolux Motor, AB, et al.*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988) (finding that district court did not abuse discretion when granting motion *in limine* to exclude "Swedish law and statistics" under the rationale that "Swedish Standards are not relevant in a U.S. product liability case involving a saw sold in the U.S.").

BSC provides a few examples of evidence related to foreign regulatory actions that the plaintiffs could possibly introduce at trial. However, the plaintiffs state that their evidence is not "of any 'foreign regulatory action'" and "raises no question regarding the applicability or interpretation of foreign law." (Pls.' Omnibus Resp. [Docket 212], at 13). The plaintiffs assert that their evidence instead "discusses serious health complications associated with these products and as such, is relevant to and admissible for purposes of establishing BSC's knowledge, notice and scienter, as well as the state of the art." (*Id.*).

As in *Bard*, I lack the specificity and context needed to properly rule on this matter at this time. See *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551–52 (S.D.N.Y. 2004) (“The Court finds no legal basis upon which now to rule . . . that testimony regarding foreign regulatory actions is irrelevant as a matter of law in a United States products liability case governed by American law . . . . Any ruling as to the relevancy of otherwise admissible evidence concerning foreign regulatory actions therefore would be premature.”). Therefore, BSC’s motion with respect to this matter is **DENIED without prejudice**.

**9. Motion to Preclude Any Evidence or Argument Concerning BSC’s Post-Implant Product Innovations Including LITE Mesh and Colored Mesh**

BSC seeks to preclude evidence of “subsequent changes or new product lines developed in Boston Scientific’s continuing study of its products, after Plaintiffs’ implant date” because such evidence is (1) inadmissible under Federal Rule of Evidence 407 as a subsequent remedial measure; (2) irrelevant to the plaintiffs’ product liability claims; and (3) confusing, unfairly prejudicial, and an undue consumption of time. (Def.’s Mem. Supp. [Docket 197], at 25). BSC notes that “[t]he exclusion of subsequent remedial measures is designed to encourage manufacturers to ‘make improvements for greater safety.’” (*Id.* (citation omitted)). Additionally, BSC argues that any subsequent product innovation is not relevant to the plaintiffs’ defect claims because such innovations would not have made a difference with respect to the plaintiffs’ alleged injuries. (*Id.* at 26).

Although it appears that BSC’s motion has merit, as evidence relating to other devices is outside the scope of the plaintiffs’ design defect claim, this issue is better suited to be handled at trial, as evidence is presented. Furthermore, evidence of subsequent remedial measures that is inadmissible to prove “negligence; culpable conduct; a defect in a product or its design; or a need

for warning or instruction,” may be admitted “for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.” Fed. R. Evid. 407. In other words, the admissibility of such evidence or argument depends on the context and method by which the plaintiffs seek to introduce it. Accordingly, BSC’s motion *in limine* on this issue is **DENIED without prejudice**.

**10. Motion to Preclude Any Evidence or Argument that BSC Owed or Breached a Duty to Warn the Individual Plaintiffs Directly**

BSC seeks to preclude evidence regarding BSC’s duty to directly warn the plaintiffs about the risks associated with the Pinnacle because in light of Florida’s learned intermediary doctrine, such evidence is irrelevant. I agree. In Florida, manufacturers of prescription drugs and ethical drugs that can be administered only under the direction of a physician must “provide an adequate warning only to the physician, or ‘learned intermediary.’” *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007) (“I agree with our sister Florida district courts, and with the great weight of authority to conclude that under Florida law, the learned intermediary doctrine applies to prescription medical devices as well as prescription drugs.”). Accordingly, BSC only owed a duty to warn the plaintiffs’ physicians of the Pinnacle’s potential risks to patients. Any evidence or argument that BSC owed or breached a duty to warn the plaintiffs directly is therefore irrelevant. The plaintiffs have agreed not to present evidence on this matter. (*See Pls.’ Omnibus Resp.*) [Docket 212], at 18).

The plaintiffs nevertheless ask this court to deny BSC’s motion *in limine* on this issue because “evidence of BSC’s warnings through the intermediary to Plaintiffs is directly relevant to whether Plaintiffs’ implanting physicians ‘would have changed’ their decisions to implant the

Pinnacle device.” (*Id.* at 17). BSC’s motion *in limine* on the duty to warn the plaintiffs directly does not affect the admissibility of this evidence. Therefore, I do not find the plaintiffs’ concerns persuasive. Under Federal Rule of Evidence 402, BSC’s motion on this point is **GRANTED**. *See* Fed. R. Evid. 402 (“Irrelevant evidence is not admissible.”).

**11. Motion to Preclude Any Evidence or Argument that BSC Owed or Breached a Duty to Train Plaintiffs’ Surgeons**

BSC moves to preclude evidence on BSC’s duty to train the treating physicians because such evidence is irrelevant: the plaintiffs have not asserted claims against their implanting physicians, and Florida does not recognize a duty to train a physician. I have previously denied a similar motion in the face of these reasons. In *Lewis*, I ruled that even though Texas does not recognize a duty to provide training to physicians, evidence or argument related to physician training might possibly be relevant for some other purpose, depending on the context and method by which it is introduced. *See Lewis*, 2014 WL 505234, at \*5. I see no reason to deviate from this ruling here. Therefore, BSC’s motion to preclude evidence and argument on the duty to train physicians is **DENIED without prejudice**.

**12. Motion to Preclude Any Evidence or Argument Concerning Marketing and Promotional Materials Not Seen by the Individual Plaintiffs or Their Surgeons**

BSC seeks to preclude “marketing materials that some of the Plaintiffs or their prescribing physicians did not read or see” on the basis that the materials are irrelevant and unfairly prejudicial. (Def.’s Mem. Supp. [Docket 197], at 33). I have rejected this argument before, finding that “[t]hese materials *may* be relevant to the plaintiffs’ other claims,” including negligence and punitive damages. *Bard*, 2013 WL 3282926, at \*6 (emphasis added). This finding applies here, where the plaintiffs have claimed negligent design and have asked for

punitive damages. I can address any further disputes about relevancy at trial, when the content and proffered use of the materials is apparent. Thus, BSC's motion *in limine* on this issue is **DENIED without prejudice.**

**13. Motion to Preclude Product Complaints, Adverse Event Reports, & Medical Device Reports Concerning [Products Other Than the Pinnacle Pelvic Floor Repair Kit].<sup>3</sup>**

BSC seeks to preclude evidence of product complaints, adverse event reports ("AERs"), or Medical Device Reports ("MDRs") for products other than the Pinnacle Pelvic Floor Repair Kit. BSC argues that such evidence is (1) inadmissible hearsay; (2) irrelevant to causation or notice; and (3) inadmissibly prejudicial under Rule 403. I have previously refused to exclude such evidence in the motions stage of MDL litigation on the basis that

there are simply too many factors that might determine whether the product complaints, AERs, and MDRs might be admissible. Without knowing the specific contents of any complaints, AERs or MDRs that the plaintiffs may seek to introduce, or how the plaintiffs might seek to use or introduce these complaints and reports, I cannot make a substantive ruling at this time. . . . [A] blanket exclusion of this evidence would be premature.

*Bard*, 2013 WL 3282926, at \*6. This ruling equally applies here.

First, I cannot determine whether these materials constitute inadmissible hearsay until I observe how the plaintiffs use them at trial. In *Bard*, I found that the materials fell within the hearsay exceptions provided in Federal Rules of Evidence 803(6) and 803(8) and that "to the extent an expert might rely upon AERs in reaching certain opinions," experts can rely on otherwise inadmissible evidence to reach their opinions. *Id.* at \*5 (citing *Mahaney ex rel. Estate of Kyle v. Novartis Pharms. Corp.*, 835 F. Supp. 2d 299, 312 (W.D. Ky. 2011)). These same

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<sup>3</sup> BSC's Motion *in Limine* entitles this motion "Motion to Preclude Product Complaints, Adverse Event Reports, and Medical Device Reports Concerning Patients Other Than Plaintiffs," but the substance of the motion concerns reports on "products other than the Pinnacle Pelvic Floor Repair Kit." (Def.'s Mem. Supp. [Docket 197] at 35). I review the motion based on its substance, rather than its title.

hearsay exceptions might come into play at trial in this case.

Second, contrary to BSC's position, "courts have held that [AERs and MDRs] may show notice and provide support for causation," so long as the evidence of injuries are "substantially similar to those in the case at bar." *Id.* Finally, if it appears that the plaintiffs' introduction of AERs and MDRs will create unfair prejudice, BSC should object at that time, informed by the content of the proffered materials and the context in which they are introduced. For these reasons, I **DENY without prejudice** BSC's motion *in limine* on this matter.

#### **14. Motion to Preclude Any Evidence or Argument that Pelvic Mesh Can Cause Complications Not Experienced by the Individual Plaintiffs**

BSC moves to preclude any evidence of "medical complications purportedly caused by Boston Scientific's devices, but not experienced by Plaintiffs themselves," such as evidence that polypropylene mesh causes "gross hematuria, inflammatory myofibroblastic tumors, and cancer." (Def.'s Mem. Supp. [Docket 197], at 38). Because none of the plaintiffs has alleged these injuries, BSC argues that such evidence is irrelevant and unfairly prejudicial.

I agree that evidence of complications that no plaintiff experienced is irrelevant and lacking in probative value. For the claims that require evidence of injury (strict liability for failure to warn, strict liability for design defect, and negligence), only the injuries experienced by the complainant are relevant. Strict liability for failure to warn, for instance, requires the plaintiff to show that the inadequate warning "made the product unreasonably dangerous" and that it "was a legal cause of the loss, injury, or damage to [the] person for whose injury claim is made." *In re Standard Jury Instructions in Civil Cases, Report No. 09-10 (Prods. Liab.)*, 91 So. 3d 785, 799 (Fla. 2012) (providing preliminary approval). Strict liability for defective design also focuses on the plaintiff's injuries. *See id.* (providing that strict liability concerns whether the product's

defect “was a legal cause of the loss, injury, or damage to [the] person for whose injury claim is made”). With respect to negligence, the concern is also for injuries caused to the claimant. *Id.* at 800. Accordingly, evidence that the Pinnacle causes injuries not experienced by the plaintiffs has little value. Moreover, elaborating on injuries that the plaintiffs did not incur risks “needless presentation of cumulative evidence.” Fed. R. Evid. 403. Therefore, BSC’s motion *in limine* on this issue is **GRANTED**.

**15. Motion to Preclude Any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Pelvic Mesh Products**

On the basis that the evidence is irrelevant, unfairly prejudicial, and misleading to the jury, BSC moves to preclude any evidence of “complaints or lawsuits against other manufacturers of pelvic mesh to argue that Boston Scientific’s products were defective, inadequately labeled, or unreasonably dangerous.” (Def.’s Mem. Supp. [Docket 197], at 40). Pointing to my previous ruling in *Bard*, the plaintiffs counter that disputes about admissibility of this evidence should be reserved for trial if “BSC opens the door on this issue.” (Pls.’ Omnibus Resp. [Docket 212], at 27).

The use of motions *in limine* that lack specificity and are without context have led the court in the past to defer judgment on several evidentiary issues, including this one. *See Bard*, 2013 WL 3282926, at \*2. Having gained greater familiarity, however, the court was confident in substantively ruling on the admissibility of other lawsuits against the same defendant in *Lewis*:

[E]vidence of lawsuits is generally considered inadmissible hearsay. . . . Further, evidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the [product] is defective, the jury must still find that the [product] caused [the plaintiff’s] injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to [the defendant].

2014 WL 505234, at \*6. I find this rationale, as applied to exclude lawsuits against the *same* defendant, to be exceedingly appropriate here, where the plaintiffs seek to introduce evidence of lawsuits against *other* manufacturers. Even assuming evidence about lawsuits brought against other manufacturers has some relevance to the present case, the relevance is dwarfed by the risk of unfair prejudice posed by requiring BSC to attest for lawsuits in which it was not involved. Accordingly, pursuant to Federal Rule of Evidence 403, I **GRANT** BSC's motion *in limine* on this issue.

#### **16. Motion to Preclude Any Evidence or Argument Concerning Other Mesh Lawsuits, Investigations, Claims, Verdicts, and Trials Against BSC**

BSC moves to preclude any evidence or argument concerning “other lawsuits, claims, investigations, regulatory actions, or settlements involving Boston Scientific’s mesh products—whether or not related to the Pinnacle Pelvic Floor Repair Kit.” (Def.’s Mem. Supp. [Docket 197], at 42). BSC argues that this evidence should be precluded because it is irrelevant under Federal Rule of Evidence 401, “unfairly prejudicial and confusing” under Federal Rule of Evidence 403, and inadmissible hearsay. (*Id.*).

I granted a motion *in limine* in *Lewis* to exclude evidence of other mesh lawsuits against the defendant. *See Lewis*, 2014 WL 505234, at \*5–6. I noted that “evidence of lawsuits is generally considered inadmissible hearsay[.]” and ultimately excluded the evidence on Rule 403 grounds. I explained:

[E]vidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the [product] is defective, the jury must still find that the [product] caused [the plaintiff’s] injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to [the defendant]. Accordingly, Ethicon’s motion on this issue is **GRANTED**.

*Id.* I apply this reasoning to the evidence challenged by BSC in the instant motion *in limine*. Therefore, I **GRANT** BSC's motion on this matter.

**17. Motion to Preclude Any Evidence or Argument Concerning Unrelated FDA Corporate Warnings and 483 Letters, All Pertaining to Cardiac Devices**

BSC seeks to preclude evidence of a 2006 corporate warning and FDA 483 letters because such evidence concerns devices unrelated to pelvic mesh. (Def.'s Mem. Supp. [Docket 197], at 44). BSC argues that "[t]his evidence should be excluded because it is (A) irrelevant, (B) improper character evidence, and (C) unfairly prejudicial." (*Id.*). Based on the court's rulings on the inadmissibility of FDA evidence in similar cases, the plaintiffs have stated that they "will not introduce evidence or arguments regarding BSC's correspondence with FDA, including 483 corporate warning letters." (Pls.' Omnibus Resp. [Docket 212], at 30). Because the plaintiffs do not oppose this motion *in limine*, it is thus **GRANTED**.

**18. Motion to Preclude Any Evidence or Argument Concerning the Parties' Litigation Conduct**

BSC moves to preclude evidence or argument concerning the parties' litigation conduct, such as:

- A) Evidence of mediation or settlement negotiations;
- B) Boston Scientific's designation of any documents as confidential or any suggestion that Boston Scientific's actions were improper or an attempt to keep certain documents secret; and
- C) Evidence of Boston Scientific's litigation conduct and of Court rulings such as motions *in limine* or objections during discovery.

(Def.'s Mem. Supp. [Docket 197], at 47). BSC argues that evidence of mediation or settlement negotiations should be excluded because "such evidence is not admissible to prove liability or invalidity of the claim or amount" under Federal Rule of Evidence 408. (*Id.*). BSC contends that

evidence concerning the designation of confidential documents, BSC's litigation conduct, and court rulings should be excluded under Federal Rules of Evidence 401, 402, and 403.

I have previously ruled on similar motions *in limine* in other cases. *See Bard*, 2013 WL 3282926, at \*8 (challenging the same three types of evidence); *Lewis*, 2014 WL 505234, at \*9 (ruling on motion *in limine* to preclude plaintiffs from referring to the designation of documents as confidential for purposes of discovery).

As for evidence of mediation or settlement negotiations, BSC is correct that "such evidence is not admissible 'either to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction.' Fed. R. Evid. 408(a). However, under Rule 408(b), this evidence may be admitted for other purposes." *Bard*, 2013 WL 3282926, at \*8.

As for evidence concerning BSC's litigation conduct and court rulings, I think it highly unlikely that such matters will be permitted, but it is impossible to determine the relevancy of any argument or evidence concerning these issues at this stage. Accordingly, I **FIND** that a blanket exclusion of such evidence and argument would be premature at this time[.]" *Id.* Therefore, I **DENY without prejudice** BSC's motion *in limine* with respect to evidence of mediation or settlement negotiations and evidence concerning BSC's litigation conduct and court rulings.

As for evidence concerning the designation of confidential documents, "[w]hether a party designates a document as confidential during the litigation process is absolutely irrelevant." *Lewis*, 2014 WL 505234, at \*7. The jury will be instructed at trial to disregard the confidential marking on documents. Therefore, I **GRANT** BSC's motion *in limine* with respect to this issue.

Thus, I **GRANT IN PART** and **DENY IN PART** BSC's motion *in limine* on this matter.

**19. Motion to Preclude Any Evidence or Argument Concerning BSC's Finances or Employment Decisions**

BSC seeks to preclude any evidence or argument concerning BSC's finances or employment decisions because "such evidence is irrelevant to this lawsuit and carries the risk of jury confusion and unfair prejudice." (Def.'s Mem. Supp. [Docket 197], at 50). BSC argues that the plaintiffs are attempting to "[paint] [BSC] as a bad actor improperly motivated by profit" and "induce the jury to render a verdict simply because Boston Scientific is a large company with significant resources[.]" (*Id.* at 50–51). I note that I denied BSC's motion for partial summary judgment on the issue of punitive damages and found that Florida substantive law applies to the plaintiffs' punitive damages claims. (*See* Mem. Op. & Order [Docket 232]).

Under Florida law, a jury should consider the "financial resources of the defendant" and "whether the wrongful conduct was motivated solely by unreasonable financial gain," among other things, when determining an amount of punitive damages. *In re Standard Jury Instructions In Civil Cases-Report No. 09-01 (Reorganization of the Civil Jury Instructions)*, 35 So. 3d 666, 793, 798 (Fla. 2010) (alterations omitted) (approving and authorizing for publication the reorganization of the standard civil jury instructions, including instructions on punitive damages). Therefore, to the extent that certain financial information paints BSC as a bad actor improperly motivated by profit, it may be relevant to the question of the amount of punitive damages. Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

**20. Motion to Preclude Any Evidence or Argument Concerning Any Plaintiff's Implanting Physician's Decision to Discontinue Using the Pinnacle to Treat POP**

BSC moves to preclude evidence that Dr. Salom (implanting physician for Ms. Dotres and Ms. Nunez) and Dr. Gomez-Madrado (implanting physician for Ms. Betancourt) recently decided to discontinue use of the Pinnacle and other polypropylene mesh products in their medical practice for treatment of POP. BSC contends that such evidence would “improperly suggest” that the doctors’ decisions “imply a defect in the Pinnacle.” (Def.’s Mem. Supp. [Docket 197], at 52). The plaintiffs respond that the motion should be denied because this evidence provides a rebuttal to any testimony implying that the doctors “have no concerns whatsoever with the Pinnacle.” (Pls.’ Omnibus Resp. [Docket 212], at 34).

Given the various ways in which the parties could use this information at trial, I cannot make a pre-trial substantive ruling on this matter. Moreover, not all of the physicians’ testimony on this issue casts BSC in a negative light, and as a result, I cannot ascertain the prejudicial nature of this evidence without knowing the specific testimony that the plaintiffs seek to offer. (*See, e.g.*, Salom Dep. [Docket 197-16], at 18:12–21 (assenting that his experience with the Pinnacle sling was “favorable” and that he “enjoy[ed] the delivery system”); Gomez-Madrado Dep. [Docket 197-11], at 85:18–21 (confirming that he had a “good” clinical experience with the Pinnacle)). For these reasons, I **DENY without prejudice** BSC’s motion *in limine* concerning the physicians’ reasons for discontinuing use of the Pinnacle.

## **21. Motion in Limine to Exclude Evidence of Dyspareunia**

BSC seeks to preclude “all evidence and testimony relating to Plaintiff Margarita Dotres’[s] alleged claim of dyspareunia.” (BSC’s Mot. *in Limine* to Exclude Evidence of Dyspareunia [Docket 214], at 1). BSC argues that such evidence is (1) irrelevant to Ms. Dotres’s active claims; (2) unfairly prejudicial to BSC; and (3) confusing for the jury. (*Id.*). While I agree

with BSC's contention that evidence related to dismissed claims is irrelevant, a blanket exclusion of dyspareunia would be premature at this time. First, the three other plaintiffs continue to pursue their dyspareunia claims; therefore, the issue of dyspareunia will be referenced repeatedly throughout trial. Second, even if I attempt to exclude evidence of dyspareunia solely relating to Ms. Dotres, the mere mention of dyspareunia is still potentially relevant and necessary to Ms. Dotres's claims for pelvic pain generally, as well as her physician's testimony. (*See* Pl.'s Resp. in Opp. to BSC's Mot. *in Limine* to Exclude Evidence of Dyspareunia [Docket 223], at 2-3). This is clearly a matter that can be handled by the court at trial. If necessary, BSC is free to make clear that Ms. Dotres is not pursuing a claim for dyspareunia. The parties are represented by experienced and able trial counsel, and I trust that counsel know and intend to abide by the Federal Rules of Evidence and their agreement. Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

### **III. The Plaintiffs' Motions**

#### **1. Plaintiffs' Omnibus Motion in Limine**

##### **a. Motion in Limine No. 1 – The Use of “Standard of Care” Language**

The plaintiffs seek to preclude “‘standard of care’ language in relation to any and all treating physicians’ decisions to implant Plaintiffs with a Pinnacle Pelvic Floor Repair kit (“PFR Kit”) for treatment of their pelvic organ prolapse.” (Pls.’ Omnibus Mots. *in Limine* [Docket 199], at 2). The plaintiffs argue that the use of the term “‘standard of care’ . . . should be limited to what a reasonable *manufacturer* would have done when placing a medical device onto the marketplace,” given that the plaintiffs have not brought any negligence claims against the treating physicians. (*Id.* at 2, 4 (emphasis added)). I disagree. Whether the Pinnacle is the

“standard of care” is highly probative: it goes to the very essence of whether the Pinnacle is unreasonably dangerous or whether there exists a safer alternative design. If the plaintiffs believe that the term “standard of care” is confusing or that BSC’s experts have contradicted themselves, they are free to address those problems at trial through cross-examination. Accordingly, the plaintiffs’ motion *in limine* on this issue is **DENIED**.

**b. Motion in Limine No. 2 – AUGS/SUFU & IUGA**

The plaintiffs move to preclude evidence relating to position statements made by the American Urogynecologic Society (“AUGS”) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (“SUFU”) and by the International Urogynecological Association (“IUGA”) concerning mid-urethral slings in the treatment of stress urinary incontinence (“SUI”). The plaintiffs argue that these statements are irrelevant under Federal Rule of Evidence 401 and 402 because this case involves POP repair kits. They also argue that the statements lack a scientific basis and are, thus, not admissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579 (1993).

First, I do not agree with the plaintiffs that these statements are entirely irrelevant to this case. The position statements challenged in this motion relate to more than merely mid-urethral slings in the treatment of SUI. (*See, e.g.*, AUGS & SUFU Position Statement [Docket 199-1], at 2 (stating “[p]olypropylene material is safe and effective as a surgical implant.”); IUGA Position Statement [Docket 199-2], at 1 (citing to “scientific publications [which] studied all types of patients, including those with co-morbidities such as prolapse.”).

I have previously denied motions *in limine* as to this issue. *See Huskey*, 2014 WL 3861778, at \*2; *Lewis*, 2014 WL 505234, at \*2. I explained:

First, to the extent that the Position Statement is relied upon by an expert witness, it may be admissible under the learned treatise exception to the hearsay rule. *See* Fed. R. Evid. 803(18). Second, under Rule 703, experts are permitted to rely on otherwise inadmissible information provided that they “would reasonably rely on those kinds of facts or data in forming an opinion on the subject.” Fed. R. Evid. 703. Third, Ethicon’s state of mind is relevant to the punitive damages claim, and “[a]n out-of-court statement that is offered to show its effect on the hearer’s state of mind is not hearsay under Rule 801(c).” *United States v. Thompson*, 279 F.3d 1043, 1047 (D.C. Cir. 2002). Provided that Ethicon properly introduces this evidence, the plaintiffs’ motion on this issue is **DENIED**.

*Huskey*, 2014 WL 3861778, at \*2; *see Lewis*, 2014 WL 505234, at \*2. Accordingly, in this case, the plaintiffs’ motion with respect to this issue is **DENIED**.

## **2. Plaintiff Amal Eghnayem’s Motion in Limine # 3**

The plaintiff, Amal Eghnayem, seeks to preclude testimony or evidence concerning (1) social media websites; (2) bankruptcy; (3) unrelated medical conditions and procedures; and (4) prior unrelated injuries because they are irrelevant “to the issues to be determined by the jury.” (Pl.’s Mot. *in Limine* # 3 [Docket 221], 1-3). BSC does not intend to offer evidence on Ms. Eghnayem’s 2001 bankruptcy. (BSC’s Resp. to Pl[.]’s Mot. *in Limine* # 3 [Docket 228], at 1). Because BSC does not oppose the plaintiff’s motion *in limine* with regard to bankruptcy, it is thus **GRANTED**. I review the remaining objections in turn.

Next, the plaintiff seeks to exclude all evidence relating to her Facebook account. However, an evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, the plaintiff’s motion *in limine* with regard to social media websites is **DENIED without prejudice**.

Lastly, the plaintiff seeks to exclude “any and all evidence of Plaintiff’s unrelated medical conditions, including medical procedures,” as well as “prior unrelated injuries.” (Pl.’s Mot. *in Limine* # 3 [Docket 221], at 2-3). In addition to this motion being overly broad, I **FIND** that evidence relating to medical conditions, procedures, and prior injuries is potentially relevant to the plaintiff’s claims. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, the plaintiff’s motion *in limine* with regard to medical conditions, procedures, and prior injuries is **DENIED without prejudice**.

#### **IV. Conclusion**

For the reasons stated above, BSC’s Initial Motions *in Limine* [Docket 197] are **GRANTED in part** and **DENIED in part**, BSC’s Motion *in Limine* to Exclude Evidence of Dyspareunia [Docket 214] is **DENIED without prejudice**, Plaintiffs’ Omnibus Motions *in Limine* [Docket 199] are **DENIED**, and Plaintiff Amal Eghnayem’s Motion *in Limine* # 3 [Docket 221] is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER:        October 28, 2014

  
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JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE