IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PATRICIA HOSBROOK, Plaintiff, v. ETHICON, INC., et al., Defendants.	:	Case No. 3:20-cv-88 JUDGE WALTER H. RICE

DECISION AND ENTRY SUSTAINING IN PART AND OVERRULING IN PART PLAINTIFF'S OMNIBUS MOTION IN LIMINE (DOC. #127) AND SUSTAINING IN PART AND OVERRULING IN PART DEFENDANTS' MOTIONS IN LIMINE (DOC. ##101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113 and 126)

Plaintiff, Patricia Hosbrook (Plaintiff) has filed an Omnibus Motion *in Limine*, Doc. #127, consisting of eight motions ("Plaintiff's MIL"), and Defendants, Ethicon, Inc., and Johnson & Johnson (collectively "Ethicon" or "Defendants) have filed 14 Motions *in Limine*, Doc. ##101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113 and 126 (Defendants' Motions). Responses to these motions have been filed by Defendants, Doc. #139, and by Plaintiff, Doc. ##147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158 and 159. Defendants have also filed replies, Doc. ##164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174 and 175. Oral argument before the Court was held on September 17, 2021. Following oral argument, Plaintiff filed a Notice of Supplemental Authority. Doc. # 180. For the reasons set

forth below, Plaintiff's MIL and Defendants' Motions are sustained in part and overruled in part.

I. Procedural Background

Ethicon, a subsidiary of Johnson & Johnson, designed and manufactured Prolift, a mesh product used to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). On March 27, 2007, the Prolift was surgically implanted in Plaintiff in Livingston, Tennessee, and on May 14, 2012, she underwent surgery in Dayton, Ohio, for the "excision of extruded vaginal mesh and rectocele repair." Doc. #33-1. On November 16, 2012, Plaintiff filed a "Short Form Complaint" against Defendants in certain multidistrict litigation pending in the United States District Court for the Southern District of West Virginia entitled "*In re Ethicon Inc., Pelvic Repair System Products Liability Litigation, MDL No.* 2327." Doc. #1. Her case was remanded to this Court's docket on March 9, 2020, for trial.

On April 23, 2021, the Court sustained Defendants' Motion for Partial Summary Judgment. Doc. #120. As a result of this Decision and Entry, Plaintiff's sole claim is for design defect under Tennessee law, as codified in the Tennessee Products Liability Act of 1978, Tennessee Code Annotated § 29-28-101, et seq. ("TPLA"). Doc. #120.[1]

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[1] The Court also sustained in part and overruled in part Defendants' Motion to Dismiss the Case-Specific Opinions of Bruce Rosenzweig, M.D. Doc. #120.

II. Standard of Review

Although neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize the Court to rule on an evidentiary motion *in limine*, the Supreme Court has noted that the practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). The purpose of a motion *in limine* is to allow the Court to rule on issues pertaining to evidence in advance of trial in order to both avoid delay and ensure an evenhanded and expeditious trial. *See Indiana Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp.2d 844, 846 (N.D. Ohio 2004) (citing *Jonasson v. Lutheran Child & Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997)). Pretrial orders also often save the parties time and cost in preparing for trial and presenting their cases.

Courts are generally reluctant to grant broad exclusions of evidence *in limine*, however, because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp.2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber* Co., 519 F.2d 708, 712 (6th Cir. 1975). A court should not make a ruling *in limine* unless the moving party meets its burden of showing that the evidence in question is clearly inadmissible. *Indiana Ins. Co.*, 326 F. Supp.2d at 846; *Koch*, 2 F. Supp.2d at 1388. If this high standard is not met, evidentiary rulings should be deferred so that the issues may be resolved in the context of the trial. *Indiana Ins. Co.*, 326 F. Supp.2d at 846.

III. Law of the Case Doctrine

The law of the case doctrine exists to prevent re-litigation of issues in a case that have already been decided. "[W]hen a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983). Although the Sixth Circuit has noted that the "'law of the case' doctrine is 'directed to a court's common sense' and is not an 'inexorable command,'" *Hanover Ins. Co. v. Am. Eng'g Co.*, 105 F.3d 306, 312 (6th Cir. 1997) (quoting *Petition of U.S. Steel Corp.*, 479 F.2d 489, 494 (6th Cir. 1973)), the Supreme Court has held that "courts should be loathe" to "revisit prior decisions of its own or a coordinate court in the absence of extraordinary circumstances." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quoting *Arizona*, 460 U.S. at 618 n.8). Three reasons exist to reconsider a prior ruling of the court: "(1) where substantially different evidence is raised on subsequent trial; (2) where a subsequent contrary view of the law is decided by the controlling authority; or (3) where a decision is clearly erroneous and would work a manifest injustice." *Hanover Ins. Co.*, 105 F.3d at 312 (citations omitted).

In the Ethicon Pelvic Mesh Multidistrict Litigation ("MDL"), the cases were divided into "waves" with this case being included in the "Ethicon Wave 5 cases." Doc. #20. Judge Goodwin of the MDL Court ruled on all pretrial matters in the waves, including discovery and evidentiary issues. Here, the Court will adopt all

of the MDL opinions unless it determines that "extraordinary circumstances" exist.[2]

IV. Plaintiff's Omnibus Motion (Doc. #127)

A. Motion *in Limine* No. 1: Exclude Evidence, Argument or Reference to the FDA's § 510(k) Clearance Process (PageID#25797)

In her first MIL, Plaintiff seeks to exclude any "evidence, argument or reference" by Defendants to the Food and Drug Administration's ("FDA's") "[§]510(k) mesh product process." She asserts that this process is only a "clearance process" for marketing purposes as opposed to one of "approval" of safety.[3] In further support of her argument, she states that the MDL Court has

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[2] Although the Sixth Circuit has not addressed the applicability of the doctrine of the law of the case after remand from an MDL court, the Fifth Circuit in *In re Ford Motor Co.*, 591 F.3d 406, 411 (5th Cir. 2009) and the D.C. Circuit in, *In re Multi Piece Rim Prods. Liab. Litig.*, 653 F.2d 671, 678 (D.C. Cir. 1981), as well as other courts within this circuit, *Mathews v. Novartis Pharmaceuticals Corp.*, No. 3: 12-cv-314, 2013 WL 5780415, at *16 (S.D. Ohio Oct. 25, 2013)(Rice, J.), *Smith v. Pfizer, Inc.*, 688 F. Supp. 2d 735, 752 (M.D. Tenn. 2010) and *In re Welding Fume Prods. Liability Litig.*, 1: 03-CV-17000, 2010 WL 7699456, at *2 (N.D. Ohio June 4, 2010), have found that the doctrine applies to rulings rendered by an MDL court. *See, Cutter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 2060342, at *2 (E.D. Ky. Apr. 29, 2020).

[3] "Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97.

"consistently and unequivocally" excluded evidence of the FDA's § 510(k) process in the vaginal mesh cases pursuant to Fed. R. Evid. 401, 402 and 403.[4] *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 744 (S.D. W. Va. 2014) ("[a]s I have repeatedly ruled in relation to this multidistrict litigation, and as I now hold in this case, no party will be permitted to introduce evidence relating to the FDA or the [§]510(k) clearance process"). In *Sanchez*, the MDL Court cited to its earlier decision in *Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748, 754 (S.D. W.Va. 2014), stating that such evidence "poses a substantial risk of misleading the jury and confusing the issues," is "not relevant to state tort law" and "runs the risk of misleading the jury to believe that [the] FDA [§] 510(k) clearance might be dispositive of the plaintiffs' state law claims." The MDL Court further noted that "[T]he prejudicial value of evidence regarding the § 510(k) process far outweighs its probative value." *See Hovey v. Cook, Inc.*, No. 2:13-cv-18900, 2015 WL 1405558,

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[4] Rule 401. Test for Relevant Evidence. Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.

Rule 402. General Admissibility of Relevant Evidence. Relevant evidence is admissible unless any of the following provides otherwise: • the United States Constitution; • a federal statute; • these rules; or • other rules prescribed by the Supreme Court. Irrelevant evidence is not admissible.

Rule 403. Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons. The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

at *2 (S.D. W. Va. Mar. 26, 2015) ("[T]his court has excluded FDA evidence in every MDL trial to date based on [Federal Rules of Evidence 401, 402, and 403]"). Plaintiff asserts that the exclusion of this evidence pursuant to Fed. R. Evid. 401, 402 and 403 has been upheld by the Eleventh Circuit, *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1317–18 (11th Cir. 2017), the Fourth Circuit, *Huskey v. Ethicon, Inc.*, 848 F.3d 151 (4th Cir. 2017) and *Campbell v. Boston Scientific Corp.*, 882 F.3d 70 (4th Cir. 2018) and the Seventh Circuit, *Kaiser v. Johnson & Johnson*, 947 F.3d 996 (7th Cir. 2020).

In response, Defendants acknowledge that "the MDL Court and other courts . . . have excluded all evidence of the FDA's regulation of pelvic mesh products on the ground that it does not speak to a device's 'safety' or 'efficacy.'" Doc. #139, PageID#29164. They "respectfully disagree for purposes of appeal." *Id.*

The Court finds that admission of evidence, argument or reference to the FDA's § 510(k) process concerns "equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (explaining that premarket approval imposes requirements and the § 510(k) process is an "exemption from federal safety review"). Accordingly, evidence of the § 510(k) process concerning Prolift is excluded based on the law of the case doctrine as well as Fed. R. Evid. 401, 402 and 403. Under Rule 401, evidence of this process is not relevant since it does not establish that the Prolift is safe and effective; therefore, it has no "tendency to make a fact more or less probable than it would be without the evidence." Because evidence of this FDA process does not

go to the Prolift's safety and efficacy, it is irrelevant evidence and not admissible pursuant to Rule 402. Even assuming that evidence of compliance with the FDA regulations is relevant, the Court finds that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues and/or misleading the jury. Plaintiff's MIL No. 1 is SUSTAINED.

B. Motion *in Limine* No. 2: Preclude any Evidence, Argument or Reference by Ethicon that Plaintiff's Claims are Federally Preempted (PageID#25801)

Plaintiff's second MIL asserts that Defendants should be precluded from arguing that Plaintiff's claims are "preempted" by federal law. Defendants respond that preemption is not the proper subject of a MIL and state they do not intend to offer any such evidence. Accordingly, the Court OVERRULES as moot Plaintiff's MIL No. 2.

C. Motion in Limine No. 3: Preclude any Evidence, Argument, or Reference by Ethicon that Plaintiff's Claims are Barred as a Result of "Compliance with all Applicable Federal Statutes and Regulations" (PageID#25802)

Although Plaintiff's third MIL is similar to her first MIL, the present motion is not strictly limited to the FDA's § 510(k) mesh product clearance process. Instead, this MIL includes Defendants alleged compliance "with all applicable federal statutes and regulations." She contends that such evidence, argument or reference violates Fed. R. Evid. 403, since it misleads the jury and is unfairly prejudicial. Doc. #127 PageID#25802. She further asserts that such evidence is

routinely excluded by the MDL Court as well as other courts on remand. Defendants disagree "for the purpose of preserving the issue for appeal," citing § 29-28-104(a) of the TPLA which raises a presumption of no defect if compliance with all applicable federal and state regulations exist. They acknowledged in oral argument, however, that they are bound by the MDL rulings "as the law of the case."

Neither party cites the Court to any specific federal statute or regulation that Defendants have allegedly complied with other than § 510(k) process which the Court excluded earlier in this Decision and Entry pursuant to the law of the case doctrine and Fed. R. Evid. 401, 402 and 403. Accordingly, for the same reasons stated in MIL No. 1, pursuant to the law of the case doctrine and Fed. R. Evid. 401, 402 and 403, Plaintiff's MIL No. 3 is SUSTAINED.

D. Motion *in Limine* No. 4: Exclude any Evidence or Argument that this Lawsuit or Transvaginal Mesh Litigation is Attorney Driven Litigation (PageID#25803)

Plaintiff argues that evidence or argument by Defendants that the suit or "transvaginal mesh litigation" is "attorney driven" should be excluded as irrelevant pursuant to Fed. R. Evid. 401 and is unfairly prejudicial pursuant to Rule 403. Defendants state that they do not intend to make any such argument. Doc. #139, PageID#29166. Accordingly, Plaintiff's MIL No. 4 is OVERRULED as moot.

E. Motion *in Limine* No. 5: Exclude Evidence, Argument or Reference to the Number of Women Allegedly Treated with Pelvic Mesh for SUI or POP (PageID#25803)

Plaintiff seeks to exclude any evidence, argument or reference concerning "the number of women allegedly treated with pelvic mesh" for stress urinary incontinence ("SUI") or pelvic organ prolapse ("POP"). She argues that evidence from Defendants that the Prolift has been "implanted in millions of women around the world," or claims of satisfaction by women treated with transvaginal mesh products is irrelevant under Fed. R. Evid. 401. Additionally, Plaintiff argues that the evidence is unfairly prejudicial under Rule 403, in part, because these women are unidentified, their medical records have not been examined and they have not been deposed.

In response, Defendants argue that "[t]he fact that millions of women have been treated with pelvic mesh and have not had major complications is directly relevant" and admissible for two reasons. They first argue that Plaintiff must show under § 29-28-105(a) that the Prolift was in a "defective condition or unreasonably dangerous" when it left Ethicon's control,[5] and that here "unreasonably dangerous" is determined under the "prudent manufacturer test"

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[5] § 29-28-105. Defective or dangerous conditions; determination
(a) A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

and not the "ordinary consumer test." [6] They contend that only the "prudent manufacturer test" applies because the Prolift is a "complex product" and "an ordinary consumer would have no reasonable expectation" of it. In support of their argument, Defendants cite to *Ray by Holman v. BIC Corp.*, 925 S.W.2d 527, 532 (Tenn. 1996). They argue that this case lists the relevant factors under the "prudent manufacturer test" as including "the usefulness and desirability of the product," "the user's ability to avoid danger[7]" and "awareness of the danger," *Id.* at 532, making evidence that the Prolift has been "implanted in millions of women around the world" without major complications relevant. Ethicon also argues that evidence of Prolift's use by "millions of women" without major complications is relevant to its state-of-the-art defense in § 29-28-105(b).[8]"

Under Tennessee law, the "prudent manufacturer test" and the "ordinary consumer test" are not mutually exclusive." *Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 806 (Tenn. 2001). Additionally, "[e]ven a technically complex failure

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[6] § 29-28-102 (8) defines an "unreasonably dangerous" product as one that is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition."

[7] Ethicon contends that the "intended users" of the Prolift are pelvic floor surgeons.

[8] (b) In making this determination, the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable. Consideration is given also to the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products.

may involve a subject about which an ordinary consumer may have an expectation[,]" as the expectation "'does not depend necessarily on a product's complexity in technology or use' but, instead, relies on the common knowledge of consumers as to a product's characteristics and performance." *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 968-69, 972 (M.D. Tenn. 2002) (quoting *Jackson*, 60 S.W.3d at 805).

Although the "state of the art defense" is permitted under § 29-28-105(b), the blanket statement of the use of Prolift by "millions of women" without major complications, does not establish what "scientific and technological knowledge" was available to Ethicon as the manufacturer at the time Prolift was placed on the market, nor does it show "the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products." *Ray by Holman* 925 S.W.2d at 532.

At this early stage in the proceedings, the Court is unable to determine whether evidence, argument or reference concerning "the number of women allegedly treated with pelvic mesh" for stress urinary incontinence ("SUI") or pelvic organ prolapse ("POP") or that the Prolift has been "implanted in millions of women around the world" without major complications, or with complications, generally, is admissible. Therefore, the Court reserves any ruling on this motion until trial. Until the Court hears more evidence, neither party may refer to the number of women who have undergone Prolift surgery, without major complications or with complications, in either *voir dire* or opening statement. If

counsel for Plaintiff and/or Defendants wishes to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

Accordingly, Plaintiff's MIL No.5 is OVERRULED, without prejudice to renewal at trial.

F. Motion *in Limine* No. 6: Exclude Evidence, Argument or Reference to Ethicon's Prior or Unrelated "Good Acts" or "Reputation" (PageID#25805)

In her sixth MIL, Plaintiff moves the Court to exclude evidence of Defendants' prior or "unrelated good acts or reputation." In this motion, she specifically references any evidence from Defendants of the "beneficial nature" of other products that they manufacture or market, monies donated to women's health or charitable issues and other "good acts." Defendants assert that Plaintiff's motion is "overbroad" because it seeks to preclude all evidence of their "good product development story" and that this evidence should not be excluded at the pretrial stage.

At this early stage in the proceedings, the Court is unable to determine whether "evidence argument or reference concerning Defendants' "prior or unrelated good acts or reputation" is admissible. Therefore, the Court reserves any ruling on this motion until trial. Until the Court hears more evidence, neither party may refer to this subject in either *voir dire* or opening statement. If counsel for Defendants wish to introduce evidence concerning this subject, this motion

can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

Accordingly, Plaintiff's MIL No. 6 is OVERRULED, without prejudice to renewal at trial.

G. Motion *in Limine* No. 7: Exclude any Evidence or Testimony Concerning Collateral Sources (PageID#25806)

Although Plaintiff mistakenly argues that Florida law, as opposed to that of Tennessee, applies to bar evidence of certain collateral source payments, Tennessee also precludes evidence of collateral source payments. *Dedmon v. Steelman*, 535 S.W. 3d 431, 434 (2017) (defendants in a personal injury case are precluded from submitting evidence of discounted rates accepted by medical providers from the insurer to rebut the plaintiffs' proof that the full, undiscounted charges are reasonable medical expenses); Tenn. Code Ann.§ 24-5-113 (procedure for evidence of bills for health care and treatment). Defendants state that they do not "intend to offer any evidence that would violate this rule," and "reserve the right to present relevant evidence regarding necessity, reasonableness, and whether a claimed service was actually paid." Doc. #139, PageID#29168-29169. In support, they cite to *Fye v. Kennedy*, 991 S.W.2d 754, 764, 1998 WL 338198 (Tenn. Ct. App. 1998). *Fye*, however, held that "a defendant is permitted to introduce relevant evidence regarding necessity, reasonableness, and whether a claimed

service was actually rendered," as opposed to whether it was "actually paid." *Id.* at 764.

Accordingly, Plaintiff's MIL No. 7 is SUSTAINED.

H. Motion *in Limine* No. 8: Exclude Evidence and Testimony Regarding Personal Experiences and/or Preferences of Witnesses as to Transvaginal Mesh Implants (PageID#25807)

In this MIL, Plaintiff seeks to exclude testimony from Defendants' employees, lay witnesses or experts concerning their "personal experiences with pelvic mesh devices" or those of a friend or family member. She also includes in this motion exclusion of any "retrospective or hypothetical testimony" that these women would "be willing to (or prefer to) have a sling implanted" if they were "suffering from SUI." Doc. #127, PageID#25807. She argues that such evidence is irrelevant pursuant to Fed. R. Evid. 401 and is more prejudicial than probative pursuant to Fed. R. Evid. 403. Defendants contend that this exclusion of evidence is overbroad since it potentially excludes all of Defendants' testimony, including from their medical directors and licensed physicians employed to assess the safety and efficacy of the Prolift, as well as testimony from their expert witnesses who are qualified to render opinions pursuant to Fed. R. Evid. 702, based on their "knowledge, skill, experience, training or education." Finally, Defendants state that they do not intend to elicit testimony from their witnesses as to any recommendations of the product and request that Plaintiff's witnesses be barred from testimony that they would not recommend use of the products.

Because the parties agree that there will be no testimony from any lay witness concerning the recommendations of the use or non-use of the Prolift product, the Court OVERRULES as moot this portion of Plaintiff's MIL No. 8. Concerning the exclusion of testimony from Defendants' medical directors and expert witnesses of their experiences with the product, the Court reserves ruling on this motion until trial. Until the Court hears more evidence, neither party may refer to this subject in either *voir dire* or opening statement. If counsel for Plaintiff or Defendants wishes to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

Accordingly, Plaintiff's MIL No. 8 is OVERRULED, without prejudice to renewal at trial.

V. DEFENDANTS' MOTIONS

A. Motion *in Limine* No. 1: to Exclude Evidence or Argument in Support of Plaintiff's Non-Existent Failure to Warn Claims (Doc. #101)

Defendants' first Motion moves to exclude all evidence or argument in support of Plaintiff's dismissed claim of failure to warn. They argue that this includes the Prolift "Instructions for Use" ("IFU") document, patient brochure, all revisions to these documents after Plaintiff's 2007 implantation surgery and any expert testimony that Defendants failed to warn physicians of certain risks associated with the use of the Prolift. They argue that this Motion should be

sustained since the Court has dismissed Plaintiff's failure to warn claim in its Decision and Entry on their Partial Motion for Partial Summary Judgment. Doc. #120. Because of the Court's ruling, they contend that "warning evidence" is irrelevant pursuant to Fed. R. Evid. 401 and is not admissible under Rule 402. Additionally, Defendants argue that some of the warning related evidence is inadmissible as a subsequent remedial measure pursuant to Fed. R. Evid 407.[9] Plaintiff argues that this evidence is relevant since it "shows what Ethicon was communicating about its products to the medical field and potential patients." Doc. #147, PageID#29794. Finally, she asserts that this evidence is admissible since Defendants "will offer this type of evidence touting certain benefits" to prove their "state-of-the-art defense" and that evidence concerning warnings and instructions is relevant to prove punitive damages.[10] *Id.* at PageID#29795.

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[9] Fed. R. Evid. 407, provides that if 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." Such evidence is admissible, however, if it is "for another purpose, such as impeachment or--if disputed--proving ownership, control, or the feasibility of precautionary measures."

[10] Plaintiff has filed a motion to apply New Jersey law to her claim for punitive damages. Doc. #135. Defendants do not object. Doc. #137. N.J. S. A. 2A:58C-5 c. reads as follows: "Punitive damages shall not be awarded if a . . . device . . . which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration . . . and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information

Plaintiff's claim of failure to warn has been dismissed from this case. Doc. #120. Accordingly, Defendants' Motion No. 1, barring any testimony, evidence or opinions regarding warnings or of Plaintiff's lack of informed consent from any witness, including her expert, Dr. Rosenzweig, as well as testimony or evidence of the Prolift "Instructions for Use" ("IFU") document, patient brochure or revisions to these documents is SUSTAINED.

B. Motion *in Limine* No. 2: to Exclude Evidence of Alleged Complications Associated with the Device other than those Alleged by Plaintiff (Doc. #102)

In this Motion, Defendants argue that because Plaintiff has alleged complaints of pain, bleeding, mesh erosion and mesh extrusion and a recurrent rectocele, there should be no evidence of other possible complications such as "pain with intercourse." They contend that any complication that Plaintiff has not claimed, including complications experienced by others, have no connection to this case and are irrelevant and would confuse the jury. They cite to numerous cases involving Ethicon as well as a transcript from the Ethicon Pelvic Mesh MDL in which Magistrate Judge Eifert stated "If there was an injury in that product but it wasn't suffered or claimed by the plaintiff in the case, [the MDL Court] wasn't letting any evidence in about it." Doc. #102, PageID#18075. Defendants also cite to the MDL Court's holding in *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, Order at

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required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. . .

19-20 (S.D. W. Va. Nov. 20, 2014) that "[E]vidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value."[11] In response, Plaintiff argues that such evidence is relevant and cites to three Sixth Circuit cases concerning aircraft accidents, accidents at railroad crossings and automobile accidents in which the Court deemed such evidence admissible.

The Court finds that any evidence of injuries that Plaintiff has not sustained are excluded under the law of the case doctrine and is also not relevant pursuant to Fed. Rule 401. Accordingly, Defendants' Motion No. 2 is SUSTAINED.

C. Motion *in Limine* No. 3: to Exclude Evidence Concerning the Decommercialization of Prolift (Doc. #103)

In 2012, five years after Plaintiff's implantation of the Prolift, Ethicon removed this product and several other pelvic mesh products from the marketplace. Defendants seek to exclude from evidence the "decommercialization of the product." They contend that removal of the product was not mandated by the FDA but was done because of the "complexities of clinical study requirements, adverse publicity, the litigation environment, the size and competitiveness of the marketplace and the availability of other treatment options." Doc. #103, PageID#18185. Based on this, they argue that admitting evidence of the withdrawal of the product is irrelevant pursuant to Fed. R. Evid.

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[11] *Bellew* was selected by Judge Goodwin "as a Prolift bellweather case in the Ethicon MDL case." *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 12685965 *1 (S.D. W.Va. Nov. 20, 2014

401 and 402 and that, even if relevant, any probative value is substantially outweighed by being unfairly prejudicial pursuant to Fed. R. Evid. 403, since it will be seen by the jury as an admission of liability. Finally, Defendants assert that if this evidence is offered by Plaintiff as proof of a design defect, it should be excluded as a "subsequent remedial measure" pursuant to Fed. R. Evid. 407.[12] Plaintiff argues that removal of the product is evidence of Defendants' recognition that "the failure rate of the product warranted removal." *Marion v Smith & Nephew Inc.*, 2016 Dist. LEXIS 9949, at * 12 (D. Utah July 27, 2016). She also contends that although it may be inadmissible pursuant to Fed. R. Evid. Rule 407, it may be admissible for other purposes "such as impeachment or--if disputed--proving ownership, control, or the feasibility of precautionary measures." *Id.*

Defendants' Motion No. 3, is SUSTAINED. The Court finds that the decommercialization of the Prolift is a subsequent remedial measure pursuant to Fed. R. Evid. 407 and is not admissible to prove a defect in the design of the product. Unless Plaintiff can show that evidence of decommercialization is permissible for purposes of impeachment or, if disputed, to prove ownership, control or the feasibility of precautionary measures, as set forth in Rule 407, any evidence of the decommercialization of the Prolift is excluded. Should counsel for Plaintiff wish to examine a witness on this subject, he must make any arguments to the Court, outside of the presence of the jury.

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[12] See n. 10, infra

D. Motion *in Limine* No. 4: to Exclude Post-Implant Company Documents (Doc. #104)

Defendants seek to exclude all company documents after 2007, the date of Plaintiff's surgery. They argue that because these documents are dated after her Prolift implantation, they are irrelevant since § 29-28-105(a) requires the product must to be in a defective or unreasonably dangerous condition at the time it left Ethicon's control. They further assert that, in this case, "unreasonably dangerous" is proven by whether a "prudent manufacturer" would put the product on the market "assuming the manufacturer . . . knew of its dangerous condition." TPLA § 29-28-102(8).[13] If, however, the Court finds that the company documents after 2007 are relevant, Defendants contend the "limited probative value" is outweighed by the danger of unfair prejudice requiring exclusion under Fed. R. Evid. 403. Defendants specifically argue for the exclusion of two documents: (1) the 2008 Prolift Physicians In-Depth Interviews ("IDIs") and (2) the PA Consulting Group Report, published in 2011, entitled "Investigating Mesh Erosion in Pelvic Floor Repair." Defendants assert that the Prolift IDIs were conducted by a consulting group and are "replete with the hearsay statements of 20 anonymous physicians." Doc. #104, PageID#18209. Concerning the PA Consulting Group's Report, they argue that it discusses potential causes for pelvic mesh erosion generally and reviews existing data for multiple Ethicon products as

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[13] *See* n. 6, *infra*.

well as those of other manufacturers. *Id.* In response, Plaintiff argues that the date of publication of company documents should not control whether the Prolift was in a defective condition and unreasonably dangerous when it left Ethicon's control and that these documents are relevant to show evidence of design defect, causation and are relevant to punitive damages. She further asserts that the PA Consulting Group Report interviewed Ethicon employees who designed and tested its mesh products. Doc. #150, PageID#29805. Finally, Plaintiff argues that Defendants may make certain arguments at trial that are directly rebutted by the Prolift Physicians IDIs and the PA Consulting Group Report.

The Court does not find that the date of any company document necessarily controls its admissibility or use at trial in this strict liability design defect case. To succeed in a TPLA action, a plaintiff must establish that "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008). Although, under § 29-28-105(a), the relevant inquiry is whether the product was in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller, exclusion is not necessarily determined by the date of the company documents, since statements, findings and research contained therein may show that Ethicon knew that the Prolift was "unreasonably dangerous" at the time that it put the Prolift on the market and, thus, Ethicon was not acting as a "reasonably prudent manufacturer"

pursuant to § 29-28-102 (8).[14] However, because at this early stage in the proceedings the Court is unable to determine whether these documents and "all post-implant company documents should be excluded, the Court OVERRULES this motion, without prejudice to renewal at trial. Until the Court hears more evidence, neither party may refer to this subject in either *voir dire* or opening statement. If counsel for Plaintiff wishes wish to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

E. Motion *in Limine* No. 5: to Exclude Evidence of Post-2011 FDA Regulatory Actions and Other Related Issues (Doc. #105)

Defendants move to exclude evidence of the FDA's regulatory actions concerning transvaginal prolapse mesh products issued "years after Plaintiff's implantation of the Prolift Posterior." They specifically move to exclude three FDA regulatory actions: (1) third-party submissions, transcripts and FDA statements from a 2011 FDA Advisory Committee meeting; (2) the FDA's 2012 "522 letters;" and (3) the FDA's 2014, 2016 and 2019 orders concerning the classification of transvaginal prolapse mesh. They argue that all three of the FDA regulatory actions are irrelevant under Fed. R. Evid. 401 and that, even if the 2011 FDA Advisory Committee meeting submissions, transcripts and statements and the 2014, 2016 and 2019 FDA orders are relevant, their probative value is substantially

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[14] *See* n. 5, *infra*.

outweighed by the danger of unfair prejudice. Finally, they argue that the 2011 FDA Advisory Committee meeting contains inadmissible hearsay.

Plaintiff argues that it is immaterial whether the dates of the FDA publications are after Plaintiff's 2007 surgery and that the FDA public health notifications for 2008, 2011 and 2019 concerning the surgical mesh products "bear directly on Plaintiff's design defect claims demonstrating that the risks (particularly for POP mesh products like the Prolift) outweigh the benefits." Doc. #151, Page ID#29820. She further argues that this evidence is admissible to prove causation, punitive damages and to rebut Ethicon's claims that the Prolift was safe and effective under its state-of-the-art defense. *Id.*

Several reasons exist requiring exclusion of this evidence. First, pursuant to § 28-29-105(b) of the TPLA, the relevant date to determine whether a product is in a defective condition or unreasonably dangerous is "at the time it left the control of the manufacturer or seller." Here, that date is 2007, the date of Plaintiff's implantation. Additionally, in *Bellew v. Ethicon, Inc.*, No. 2:13–cv–22473, 2014 WL 6680356, at *1 (S.D. W. Va. Nov. 25, 2014), a Prolift bellweather case in the Ethicon Pelvic Mesh MDL, Judge Goodwin excluded all evidence of the 2011 FDA Advisory Committee meeting including submission made by third parties to the FDA, the transcript of the meeting and conclusions stated at the meeting by the FDA as to POP products. He also excluded all evidence of the "522 Orders" sent by the FDA to Ethicon and other pelvic mesh manufacturers in 2012, as well as references to the FDA's 2014 proposed administrative orders regarding the

reclassification of surgical mesh for transvaginal pelvic organ prolapse repair and the requirement of premarket approval. Additionally, this Court further finds that the 2011 FDA Advisory Committee third-party submissions, transcripts and FDA statements, are out of court statements and are inadmissible hearsay pursuant to Fed. R. Evid. 802, and that this evidence from the 2011 FDA Advisory Committee meeting, the "522 letters" and the FDA's 2014 orders concerning the classification of transvaginal prolapse mesh, are irrelevant under Fed. R. Evid 401. Even assuming relevance, the Court finds that this evidence is excluded under Rule 403 since its probative value is outweighed by the danger of unfair prejudice, confusion of the issues and/or misleading the jury. Finally, as to the FDA's Public Health Notifications and 2016 and 2019 enforcement action, which were not at issue in *Bellew*, the Court finds this evidence to be irrelevant under Rule 401 for the reasons stated earlier and because Ethicon stopped selling the Prolift in 2012. The probative value of such information, even if relevant, is outweighed by the danger of unfair prejudice, confusion of the issues and/or misleading the jury. Simply stated, these three regulatory actions do not show whether the Prolift was defectively designed under the TPLA, and that admission of these three regulatory actions will require an explanation of the FDA's decision-making operations and a "mini-trial" on the FDA process causing both undue delay and wasting the jury's time.

For the reasons stated above, Defendants' Motion No. 5 is SUSTAINED.

F. Motion *in Limine* No. 6: to Exclude Foreign Regulatory Issues and other Foreign Evidence (Doc. #106)

Defendants move to exclude evidence of foreign regulatory issues including websites, labels or other documents as well as suspensions of product sales and/or types of pelvic floor surgeries in other countries. They argue that any regulatory evidence from foreign countries, like that of the FDA, is irrelevant pursuant to Fed. R. Evid. 401 and 402 and that even if relevant, the probative value is outweighed by the danger of unfair prejudice and confusion of the issues and/or misleading the jury and must be excluded under Rule 403. Plaintiff responds to this Motion by requesting that the Court reserve ruling on this issue until trial and argues, despite Defendants' arguments, that this evidence "raises no question regarding the interpretation of foreign law" and instead "discusses health complications" with the mesh products making it "relevant and admissible for establishing knowledge, notice" and Defendants' state-of-the-art defense. Doc. #152, PageID#29866.

The Court finds, for the reasons set forth in its ruling excluding the FDA regulatory actions in Defendants' Motion No. 5, that evidence of foreign regulatory issues and other foreign evidence are irrelevant as to whether the Prolift was defectively designed under the TPLA. Even if relevant, under Rule 403, the probative value of this evidence is outweighed by the danger of unfair prejudice, confusion of the issues and/or misleading the jury. See also, *Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1327 (6th Cir. 1992) (concluding in explosion of

acetylene cylinder that "foreign legal standards have been found excludable by the 11th Circuit, and we now follow that holding") (citation omitted)).

Accordingly, Defendants' Motion No. 6 is SUSTAINED.

G. Motion *in Limine* No. 7: to Exclude Certain Irrelevant and Unfairly Prejudicial Company Documents, Emails and Argument (Doc. #107)

Defendants move to exclude two email chains: (1) an email string between Terry Courtney, an Ethicon salesman and Martin Weisberg, a surgeon, (the "Courtney-Weisberg email chain");[15] and (2) an email chain between Ethicon employees and European surgeons (the "TVM Group"), discussing potential follow-up questions directed towards the Prolift surgical patients.[16] Defendants also move to bar Plaintiff from referring to any document produced in discovery as "secret" or "confidential." They assert that both email chains should be excluded because they are irrelevant under Fed. R. Evid. 401 and that even if the Court determines them relevant, they must be excluded pursuant to Rule 403,

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[15] Defendants summarize the string as follows: "an email string between Terry Courtney and Dr. Martin Weisberg where, in the course of a discussion regarding a woman's complaint about the erosion of a TVT product and her husband's remark that 'sex felt like screwing a wire brush,' Dr. Weisberg made the comment that the situation '[s]ounds like a buttonhole. It can be locally excised. I've never tried the wire brush thing so I won't comment.' Ex. 1, July 9, 2003 email." Doc. #107, PageID#18369; Doc. #107-1.

[16] Defendants summarize this email string as follows: "An email chain between Ethicon employees and European surgeons discussing potential follow-up questions directed towards Prolift surgical patients, including commentary from one surgeon regarding questions directed towards "fellatio, sodomy, [etc.]" Ex. 2, Sept. 2005-Oct. 2005 email chain. In response, another surgeon commented on the complexity of human sexuality, and stated "[i]sn't it this concern that has lead [sic] me to say (and I don't think I'll be the only [sic] for a while ...) that I would not like for my wife to undergo this procedure." Doc. #107, PageID#18370, Doc. #107-2.

since the probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues and/or misleading the jury. Defendants also assert that these email chains contain inadmissible hearsay.

The "Courtney-Weisberg" email chain concerns an email that Courtney, identified in the email chain as "Sales Representative for Gynecare, a Division of Ethicon, Inc.," forwarded to Weisberg, an Ethicon medical director. The forwarded email from Courtney concerned a report from a doctor regarding a patient's issue with mesh erosion, the statement from the patient's husband and how the doctor surgically corrected the erosion the patient was experiencing. The patient, her husband and the doctor are not identified and the product is not the Prolift, but the Gynecare TVT, a different product used to treat stress urinary incontinence and not pelvic organ prolapse. Defendants argue for exclusion of this email chain since the product is not the Prolift and the unidentified patient is experiencing dyspareunia, pain with sexual intercourse, which is a condition that Plaintiff does not allege. Plaintiff argues that this email chain is not hearsay since it is an admission by a party-opponent and admissible pursuant to Fed. R. Evid. 801(d)(2). She asserts that because the Courtney-Weisberg email chain was written in 2003, before Plaintiff's implantation surgery, Ethicon had notice of Plaintiff's design defect. Finally, she argues it supports her claim for punitive damages.

The second TVM Group email chain is characterized by Defendants as between "Ethicon employees and European surgeons" and ranges in dates from

September 20, 2005, through October 10, 2005. Ethicon does not state who in this email chain is an Ethicon employee and who is a European surgeon. Also, it is unknown how this email chain came into Ethicon's possession. Included in this chain is an email from Claude Rosenthal concerning "a quick word about sexuality" including "fellatio, sodomy, [etc.]," and possible questions to "surgical patients" concerning intercourse before and after the surgery. Doc. #107-2, PageID#18384. A response to Rosenthal's email is from Dr. Jacquetin Bernard, who is identified by Plaintiff as "the inventor of the Prolift and its procedure." In response to Rosenthal's email, Bernard states "[i]sn't it this concern that has lead me to say (and I don't think I'll be the only [one] for a while ...) that I would not like for my wife to undergo this procedure." *Id.*, at 18383. She further asserts that the surgeons in this email chain are a French "group of physicians who helped develop the Prolift and performed the original study for the product." Doc. # 153, PageID#29870. Plaintiff argues that this email chain is admissible because it concerns the Prolift, was written two years prior to Plaintiff's surgery and is from the inventor of the product.

Finally, Plaintiff states that she does not intend to comment on the confidential or secretive nature of Ethicon's documents, but will refer to them as "internal."

The Court SUSTAINS Defendants' Motion No. 7 as it pertains to the Courtney-Weisberg email. This email is irrelevant under Fed. R. Evid. 401, since it concerns the TVT product and not the Prolift, as well as a complaint that Plaintiff

does not allege. Even if this email chain is relevant, any probative value is substantially outweighed by the danger of causing unfair prejudice to Ethicon or confusion of the issues under Fed. R. Evid. 403.

As to the TVM Group email chain, without additional evidence, the Court is unable to determine whether it is admissible. Accordingly, the Court OVERRULES this motion without prejudice to renewal at trial. Until the Court hears more evidence, neither party may refer to this email chain in either *voir dire* or opening statement. If counsel for Plaintiff wishes to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

Defendants also move to exclude Plaintiff's counsel or her witnesses from referring to the confidential status of documents produced in discovery and Ethicon documents not disseminated publicly as "secret" or "confidential" company documents. In response, Plaintiff's counsel states that he "does not intend to comment on the confidential designations of Ethicon's internal documents" and will, instead, refer to these documents as "Ethicon internal documents." He will also argue that the information contained in these internal company documents was not shared with physicians. Based on this representation, Defendants' Motion concerning Plaintiff or her witnesses commenting on the confidential or secretive nature of Ethicon's documents is OVERRULED as moot.

H. Motion *in Limine* No. 8: to Exclude Other Lawsuits, Claims, and Investigations (Doc. #108)

In Defendants Motion No. 8, they move to exclude evidence of other lawsuits and claims relating to pelvic mesh products manufactured by Ethicon, as well as unrelated governmental or other investigations involving other Johnson & Johnson companies. They argue that such evidence is "irrelevant and unfairly prejudicial, amounts to improper 'bad acts' evidence, and constitutes inadmissible hearsay." They cite to two MDL cases, *Lewis v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 505234, at *6 (S.D. W. Va. Feb. 5, 2014) and *Bellew v. Ethicon, Inc.*, 2014 WL 6680356, at *2 (S.D. W. Va. Nov. 25, 2014), as well as several other cases, and argue that evidence of other lawsuits and claims are inadmissible, given that Plaintiff's case is not "substantially similar" to other mesh cases. *Croskey v. BMW of North Am., Inc.*, 532 F.3d 511, 518 (6th Cir. 2008) (other accidents must have occurred under "substantially similar circumstances or share the same cause" to be admitted into evidence). They assert that such testimony is also irrelevant under Fed. R. Evid. 401 and that, even if relevant, the probative value under Rule 403 is outweighed by confusion of the issues and would result in a waste of the jury's time since it would create a "mini-trial" of the other cases. Defendants also argue that testimony of other pelvic mesh lawsuits or claims is inadmissible hearsay. As for unrelated investigations, Defendants move to exclude evidence of fines, consent decrees, recalls and misdemeanor guilty pleas as irrelevant and

unfairly prejudicial pursuant to Fed. R. Evid. 401 and 403, and also pursuant to 404(b)(1), since it constitutes inadmissible character evidence.

In response, Plaintiff argues that this evidence is admissible because Ethicon "imitated other pelvic mesh products to create Prolift and TVT" and that all cases share the "common characteristic of monofilament polypropylene material," an issue that Defendants dispute. She further contends that such cases constitute "notice" to Defendants of problems and that evidence of lawsuits and claims are needed so Plaintiff can "impeach and rebut" Defendants "averments that vaginal mesh is safe and has been in use for years without any significant problems" or that Plaintiff's physical problems are "unique." Finally, Plaintiff requests that the Court wait until trial before ruling on this Motion.

Because at this early stage in the proceedings the Court is unable to determine whether evidence of other lawsuits, claims, and investigations of other Johnson & Johnson companies should be excluded, the Court OVERRULES this motion without prejudice to renewal at trial. Until the Court hears more evidence, neither party may refer to this subject in either *voir dire* or opening statement. If counsel for Plaintiff wishes to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury based on evidence that has been introduced thus far in the case.

I. Defendants' Motion *in Limine* No. 9: to Exclude Material Safety Data Sheets (Doc. #109)

Defendants move to exclude any attempt by Plaintiff to introduce or refer to the following Material Safety Data Sheets ("MSDS"): (1) the Chevron-Phillips MSDS for Marlex® Polypropylene Mesh (1/28/2014); (2) the Sunoco MSDS for C4001 Polypropylene Homopolymer (4/13/2005); and (3) the Braskem MSDS. They argue the following: (1) all the MSDSs should be excluded as irrelevant under Fed. R. Evid. 401, since they concern raw polypropylene and are intended only for workplace use and not finished products regulated by the FDA; (2) even if not excluded because they are intended only for workplace use, the MSDSs for Chevron-Philips and Braskem must be excluded, since Ethicon does not use their polypropolene; and (3) the Sunoco MSDS should be excluded since it warns of cancer, a condition that Plaintiff is not alleging as an injury. Defendants also argue that, even if relevant, any probative value that might exist in these documents is outweighed by the danger of unfair prejudice and misleading the jury, making them excludable under Fed. R. Evid. R. 403. Finally, Defendants argue that the documents are hearsay.

At oral argument, Plaintiff conceded that because Sunoco was the only supplier to Ethicon it is the only MSDS at issue. She argues, however, that it is admissible because its MSDS warns users that polypropylene is incompatible with "strong oxidizers," Doc. #109-2, PageID#18474, and that "[A]s Plaintiff's expert Dr. Rosenzweig notes, the vagina is a ready source of oxidizing agents. The

application of those oxidizing agents to Ethicon's polypropylene mesh contributes to causing the mesh to degrade *in vivo*, which causes pain and the need for revision surgery." Doc. #155, PageID#29952.

Although the Court OVERRULES as moot Defendants' Motion No. 9 concerning the Chevron-Phillips MSDS for Marlex® Polypropylene Mesh (1/28/2014) and the Braskem MSDS, since only the Sunoco polypropolene was used by Defendants in the manufacture of the Prolift, the Court will not exclude the Sunoco MSDS in its entirety. *In re Davol*, 2:18-cv-01509, Case No. 2:18-md-2846, 2020 WL 6603657 at *4, Oct. 20, 2020 (Sargus, J) (admitting MSDS for Chevron-Phillips Marlex Polypropolene, with limiting instruction in polypropylene hernia mesh products finding that "[T]he allegedly dangerous characteristics of a component of a device are certainly relevant to the question of whether a finished device has dangerous characteristics."). The Court SUSTAINS Defendants' Motion to exclude the Sunoco MSDS, excepting the portion on "Section 10, Stability and Reactivity, Incompatibility," Doc. #109-2, PageID#18474, warning that polypropylene is incompatible with "strong oxidizers" Doc. #109-2, PageID#18474. As to this issue, until the Court hears more evidence, presumably from Plaintiff's expert witness, Dr. Rosenzweig, neither party may refer to this subject in either *voir dire* or opening statement. If counsel for Plaintiff wishes to introduce evidence concerning this portion of the Sunoco MSDS and her expert witness, counsel for Plaintiff and Defendants can argue this motion further to the Court

outside of the presence of the jury, including objections based on hearsay and the danger of unfair prejudice and confusion of the issues under Fed. R. Evid 403.

J. Defendants' Motion *in Limine* No. 10: to Preclude Plaintiff's Experts from Acting as Conduits for Corporate Information and Improper Opinions (Doc. #110)

In this Motion, Defendants move to exclude Plaintiff's expert witnesses from "reading corporate documents" to the jury and, then, interpreting what the documents mean and inferring the author's state of mind or intent. They contend that this is a "narrative summary" and an "abuse of Fed. R. Evid. 703," since it permits Plaintiff's experts to "invade the province of the jury" instead of letting the documents speak for themselves. Doc. #110, PageID#18506. In support, Defendants cite to Judge Goodwin's order concerning one of Plaintiff's expert witness, Dr. Daniel Elliott.

> [M]any of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions - assuming the expert opinions are otherwise admissible-he or she may not offer testimony that is solely a conduit for corporate information.

In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2018 U.S. Dist. LEXIS 130869, *15 (S.D.W. Va. Aug. 1, 2018)

Plaintiff has indicated that she will abide by Judge Goodwin's order. Accordingly, Defendants' Motion No. 110 is OVERRULED as moot. If at trial counsel believes that an expert witness is acting as a "conduit for corporate

information" and simply reading company documents to the jury, an objection can be made at that time.

K. Defendants' Motion *in Limine* No. 11: to Preclude the Use of Video Deposition Testimony or other Videos during Opening Statement (Doc. #111)

Defendants move to prevent Plaintiff from showing any video deposition or other videos during opening statements. Plaintiff states that he does not intend to play any video clips at that time. Defendants' Motion No. 11 is OVERRULED as moot.

L. Defendants' Motion *in Limine* No. 12: to Exclude Surgical Videos and Photographs (Doc. #112)

Defendants' Motion No. 12 moves to exclude Plaintiff from offering into evidence surgical training videos depicting a Prolift implantation surgery. They contend that it is a video designed for surgeons, not lay people, contains graphic images and will not assist the jury in finding that the Prolift is a dangerous device. Accordingly, they assert that it has "no tendency to make any fact of consequence in this case more probable" and should be excluded pursuant to Fed. R. Evid. 401. Additionally, they argue that its "marginal probative value" is "substantially outweighed by the significant danger of unfair prejudice to Ethicon," requiring exclusion under Fed. R. Evid. 403. Defendants propose that animations can be used to explain the process to the jury and further argue that, if the Court is inclined to permit these surgical training videos, it should first view them. Plaintiff

responds to this Motion by stating that she intends to use only "direct relevant video depictions of the exact procedure performed on Plaintiff that have been produced by Ethicon and performed by Ethicon key opinion leaders." She asserts that this will assist the jury in understanding the evidence and that the Court can give a "warning" to the jury prior to showing them. Animations, she contends, "falsely depict" portions of the surgery since it shows the mesh arms "coming through the cannulas and lying flat in perfect position, contrary to live surgery." The result, Plaintiff argues, is misleading to the jury. Finally, she states that she would be "judicious" in her use of videos and argues that the videos are necessary to counter Defendants' defense that the Prolift surgery "was an easy, low risk non -invasive procedure" and/or that other procedures were more invasive.

Because of the Court's concern with the unfairly prejudicial effect of these surgical training videos on the jury, the Court will need to view the video prior to it being shown to the jury or before any testimony concerning it and defers ruling on this Motion at this time. Accordingly, this motion is OVERRULED, without prejudice to renewal at trial. Until the Court is able to view the surgical video(s) to determine their admissibility, counsel for Defendants and Plaintiff are not permitted to characterize the Prolift surgery as an "easy, low risk non-invasive procedure" or that it is a "difficult, risky or invasive procedure."

M. Defendants' Motion *in Limine* No. 13: to Exclude Evidence of Plaintiff's Allegations of Spoliation (Doc. #113)

Defendants move to exclude testimony from Plaintiff that Defendants engaged in spoiliation of evidence. In particular, they contend that Plaintiff will use Ethicon's corporate representative, "Mr. Mittenthal," who was retained to testify about Ethicon's document retention policies and to investigate plaintiffs' allegations of spoilation, to insinuate that relevant documents are missing. They contend that these arguments are irrelevant under Fed. R. Evid. 401 and should also be excluded under Fed. R. Evid. 403, since the probative value is substantially outweighed by unfair prejudice, unfair prejudice, confusion of the issues and/or misleading the jury. Finally, it states that the MDL Court has rejected motions for litigation sanctions, *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 299 F.R.D. 502, 507 (S.W. W. Va. 2014), and that over 60 federal courts have also considered and rejected this issue. Doc. #113, PageID#18545. Plaintiff states that, consistent with several MDL Court's rulings, she does not intend to argue to the jury that Ethicon "spoiiated evidence," but that "it may indeed be relevant for the jury to know that there are relevant documents that are unaccounted for." She requests that the Court defer ruling on this issue until trial.

Because Plaintiff does not intend to argue spoiliation but, instead, will state that "there are relevant documents that are unaccounted for," the Court OVERRULES as moot Defendants' Motion No. 13, without prejudice to renewal at trial.

N. Defendants' Motion *in Limine* No. 14: to Preclude Improper Arguments by Plaintiff's Counsel (Doc. #126)

Defendants have filed a motion to prevent Plaintiff's counsel from making improper arguments that are "unfairly prejudicial" and that have "no purpose other than to inflame the passions and prejudices of the jury." They assert that "these tactics are a part of the Schlesinger firm's 'closing argument template.'" They include with their Motion nine different trial transcripts in support. Plaintiff filed no response, but has argued that whether an argument is improper depends on the context. Because there is no evidence at this time that Plaintiff will make an "unfairly prejudicial" closing argument with no purpose but to "inflame the passions and prejudices of the jury," the Court OVERRULES Defendants Motion No. 14.

VI. Conclusion

Accordingly, for the reasons stated above, Plaintiff's Omnibus Motion *in Limine*, Doc. #127, are SUSTAINED in part and OVERRULED in part. Defendants' Motions *in Limine*, Doc. ##101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113 and 126, are SUSTAINED in part and OVERRULED in part.

Date: September 29, 2021

Walter H. Rice

WALTER H. RICE
UNITED STATES DISTRICT JUDGE