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

CHARLESTON DIVISION

TONYA EDWARDS, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-CV-09972

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motions in Limine)

Pending before the court are the Plaintiffs' Motions in Limine [Docket 142], the Defendants' Omnibus Motion in Limine [Docket 147], and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 141]. In accordance with this opinion, the Plaintiffs' Motions in Limine [Docket 142] are **DENIED**, the Defendants' Omnibus Motion in Limine [Docket 147] is **DENIED in part** and **GRANTED in part**, and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 141] is **GRANTED**.

I. Background

This case is one of more than 60,000 that have been assigned to me by the Judicial Panel on Multidistrict Litigation in seven MDLs involving pelvic mesh products. Approximately 20,000 of these cases reside in the *In re Ethicon, Inc.* MDL, MDL No. 2327. The device at issue in this case is the Gynecare TVT Obturator ("TVT-O"), manufactured by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, "Ethicon"). The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra

to treat stress urinary incontinence. Having resolved the parties' motions for summary judgment, the following claims remain for trial: negligence, strict liability for design defect, strict liability for failure to warn, negligent infliction of emotional distress, gross negligence, and punitive damages. (*See* Short Form Compl. [Docket 1], at 4-5; *see generally* Mem. Op. & Order [Docket 272]).

II. Motions in Limine

The plaintiffs filed 21 motions in limine and Ethicon filed 19. Many of these motions are silly. For the vast majority of them, I simply cannot make a substantive ruling at this time without knowing the particular piece of evidence that a party seeks to introduce or argument that a party seeks to make. Nor can I make a ruling without knowing the context in which that party seeks to introduce such evidence or argument. In short, a blanket exclusion of such evidence or argument is premature at this time. For instance, Ethicon asks that I exclude "all evidence and argument" related to "off-color" emails that are irrelevant, unfairly prejudicial, and inadmissible hearsay. (Ethicon's Mem. in Supp. of Omnibus Mot. in Limine [Docket 148], at 29-30). Ethicon points to a few emails, but asks me to rule on many that I have not seen. It is probable that some of the emails are inadmissible, but I need not make a ruling at this stage. The plaintiffs filed several motions in limine that the defendants do not oppose, but that are devoid of any argument regarding *why* the court should exclude the evidence at issue. As a result, it is unnecessary that I rule at this time. For example, the plaintiffs include a motion in limine asking the court to exclude "[a]ny reference to or suggestion that Plaintiffs would possibly be able to obtain free medical treatment and/or other types of assistance from any governmental or charitable organization, based upon either age or condition." (Pls.' Mots. in Limine [Docket 142], at 16). That is the entirety of the plaintiffs' motion.

Many of the pending motions in limine are unopposed. There is no need for me to rule on such motions. The parties are expected to abide by these concessions.

Where evidence is not admissible pursuant to the Federal Rules of Evidence, it will not be admitted. Otherwise, it will be admitted. The parties are represented by able counsel, and I trust they can distinguish the difference. I expect counsel to know the rules of evidence and for only matters which they believe in good faith to be admissible, I expect objection only where the opposing part believes in good faith that the evidence is inadmissible. I expect lawyers to make informed decisions about the proof of their case without asking me elementary questions.

For these reasons, the following motions are **DENIED without prejudice**: Ethicon's Motions in Limine Nos. 1, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 16, 17; and the plaintiffs' Motions in Limine Nos. 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21. My denial of these motions without prejudice is not an invitation for the parties to relitigate these matters at trial. The parties are cautioned to use their best judgment in offering and objecting to evidence.

Having denied the majority of the motions in limine without prejudice, several remaining motions in limine nevertheless merit rulings at this time. I discuss those motions below.

- **Plaintiffs' Motion 1: To Exclude TVT-O Complication Rates**

The plaintiffs seek to exclude information regarding the TVT-O's complication rates. The plaintiffs argue that Ethicon cannot accurately calculate complication rates because it does not know the number of TVT-O devices that have been implanted. This is the same argument that the plaintiffs raised in *Lewis v. Ethicon*. In that case, I stated:

> I will not admit anecdotal evidence of complication rates because that evidence has little probative value and it is highly misleading. However, evidence of complication rates may be admitted where it is based on reliable, scientific statistics, peer-reviewed literature, or where it has been or may be tested. At this

> stage, I cannot determine which particular complication rate evidence Ethicon seeks to introduce.

Lewis v. Ethicon, No. 2:12-cv-4301, 2014 U.S. Dist. LEXIS 14971, at *4-5 (S.D. W. Va. Feb. 5, 2014). The same is true here. Anecdotal evidence regarding complication rates will not be admitted, but evidence of complications may be admitted where it is based on reliable, scientific statistics, or where it has been tested. Therefore, the plaintiffs' motion is **DENIED without prejudice**.

- **Plaintiffs' Motion 3: Motion to Exclude Evidence of 510(k) Clearance of the Ethicon Mesh Products by the United States Food and Drug Administration ("FDA"), or Lack of FDA Enforcement Action**

The plaintiffs seek to exclude any evidence or testimony related to the FDA's 510(k) clearance of Ethicon products and/or the FDA's lack of enforcement action related to these products. As I held in *Lewis*:

> In sum, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g.*, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 183718 (S.D. W. Va. July 1, 2013), [Docket 309], at 3-4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 90210 (S.D. W. Va. June 27, 2013) [Docket 302], at 3-4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403).

Lewis v. Johnson & Johnson, No. 2:12-cv-04301, 2014 U.S. Dist. LEXIS 4985, at *17-18 (S.D. W. Va. Jan. 15, 2014). This reasoning is equally applicable here. The plaintiffs' motion on this issue is **GRANTED**.

- **Plaintiffs' Motion 17: To Exclude Any Statement or Opinion Published by Any Professional Organization Regarding the Safety and/or Efficacy of Transvaginal Mesh products**

The plaintiffs, without any elaboration or discussion of what evidence they are specifically referring to, seek to exclude all statements or opinions published by professional organizations regarding the safety of transvaginal mesh products. This evidence may be admissible for several reasons. 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**.

- **Ethicon's Motion 2: To Exclude Brian Luscombe's Internal Marketing Presentation**

Ethicon moves to exclude an internal marketing presentation mimicking David Letterman's "Top Ten" lists. The presentation is styled as the "Top Ten Reasons to Pursue Gynecare TVT Obturator Approach." (Presentation [Docket 147-2]). It then lists ten sarcastic reasons that surgeons should use the TVT-O, including:

> 10: For the surgeon who likes to point their needles too far lateral (and hit things like the external iliac), this gives them something new to go after!!!!
>
> 9: Since the needles don't enter the retropubic space, bladder perforations SHOULD be reduced
>
> . . .
>
> 7: Small Bowel . . . when things just aren't in the right place . . . enough said
>
> . . .
>
> 1: MAMA NEEDS A NEW PAIR OF SHOES!!!!

(*Id.*). Ethicon contends that the presentation was intended as a "sarcastic, lighthearted 'ice breaker' for Ethicon's sales force, rather than a serious presentation." (Ethicon's Mem. in Supp. of Omnibus Mot. in Limine [Docket 148], at 3). According to Ethicon, the employee who created it designed it as a joke to lighten up training events for sales representatives. (*See id.*). Ethicon asserts that it will have to explain this context to the jury, as well as David Letterman's "Top Ten" list, if this evidence is admitted. Ethicon therefore contends that the presentation is irrelevant, unfairly prejudicial, and risks confusing the jury and wasting time during trial.

The plaintiffs argue that the presentation is probative because it demonstrates the potential benefits that Ethicon claimed the TVT-O provided and because it shows why Ethicon developed the TVT-O. I disagree. The presentation is a poor attempt at humor. It is not probative to any claims in this case. Even if it were probative, I would exclude it under Rule 403 for its risk of unfair prejudice and its potential to waste time in trial. Accordingly, Ethicon's motion on this issue is **GRANTED**.

- **Ethicon's Motion 10: To Exclude Evidence of PA Consulting Group Report**

Ethicon argues that the PA Consulting Group report titled "Investigating Mesh Erosion in

Pelvic Floor Repair" should be excluded as irrelevant. It argues that the report was created to aid in producing a new mesh product for the treatment of pelvic organ prolapse, not stress urinary incontinence. It also argues that the erosion rates used in the report are irrelevant and unfairly prejudicial because they are not specifically related to the TVT-O, but rather to many other polypropylene mesh products. I denied this same motion in *Lewis v. Johnson & Johnson*:

> Ethicon's arguments are misleading. While Ethicon argues that the report was written only to address issues related to pelvic organ prolapse, the report itself states that Ethicon asked PA Consulting Group "to conduct a broad analysis of the problem of mesh erosion[.]" . . . The report does not state anywhere that it was examining erosion only as it relates to pelvic organ prolapse; rather, it discusses mesh erosion generally, in line with the broad analysis requested by Ethicon. Although the overall purpose of the report may have been to aid Ethicon in developing a next-generation device for pelvic organ prolapse, its discussion of general mesh erosion is relevant to the plaintiffs' claims. It also contains erosion rates of mesh, which have probative value.

In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-cv-4201, 2014 WL 505234, at *11 (S.D. W. Va. Feb. 5, 2014). This reasoning applies with equal force here. Accordingly, Ethicon's motion on this issue is **DENIED**.

- **Ethicon's Motion 15: To Exclude Evidence Regarding Alleged Problems with TVT-O Sheath Removal**

Ethicon moves to exclude evidence or argument that physicians have encountered problems removing the sheath from the TVT-O before implantation. According to one of the plaintiffs' experts, physicians experienced difficulty removing the sheath, which can potentially cause roping and curling of the mesh. (*See* Rosenzweig Report [Docket 106-3], at 64-67). Ethicon argues that this evidence is irrelevant, overly prejudicial, and a waste of time because no witness will testify that there was a problem with the removal of the sheath attached to Ms. Edwards's

TVT-O, or that Ms. Edwards sustained any injury as a result of sheath removal. (*See* Ethicon's Mem. in Supp. of Omnibus Mot. in Limine [Docket 148], at 26).

Contrary to Ethicon's suggestions, this evidence is relevant. As I held in *Huskey v. Ethicon*, "the TVT-O's potential to rope and fray . . . and complications associated with small pore mesh are" relevant to the plaintiffs' failure-to-warn claim. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *5 (S.D. W. Va. July 8, 2014). Thus, hearing this evidence will not be a waste of time or unfairly prejudicial. Accordingly, this motion is **DENIED**.

III. Spoliation

Ethicon has separately filed a motion in limine to exclude evidence related to spoliation [Docket 141]. The plaintiffs have repeatedly alleged that Ethicon lost or destroyed documents relevant to this multidistrict litigation. On February 4, 2014, Magistrate Judge Eifert held that Ethicon's actions were negligent, not willful or deliberate, and denied the plaintiffs' motions for severe sanctions, such as default judgment, striking of defenses, or offering an adverse instruction in every case. (*See In re Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2327, Pretrial Order #100 [Docket 1069]). However, Judge Eifert recommended that I allow the plaintiffs "the opportunity to introduce evidence regarding Ethicon's loss of relevant documents on a case-by-case basis, and, when appropriate, to tender an adverse inference instruction." (*Id.* at 42-43). The plaintiffs have since asked Judge Eifert to reconsider Pretrial Order #100, claiming that they have discovered new evidence that establishes that Ethicon's duty to preserve evidence began earlier than previously thought. (*See* Pls.' Request for Clarification and Reconsideration, *In re Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2327 [Docket 1099]).

While a motion for reconsideration is pending before Judge Eifert, the parties have indicated that they do not desire a ruling on the motion at this time. If and until Judge Eifert rules on the motion to reconsider, her original ruling remains in force and effect. Moreover, the plaintiffs have offered no evidence or argument that evidence of spoliation will be relevant *in this case*. Therefore, Ethicon's motion in limine on the issue of spoliation is **GRANTED**.

IV. Conclusion

For the reasons discussed above, Plaintiffs' Motions in Limine [Docket 142] are **DENIED**, the Defendants' Omnibus Motion in Limine [Docket 147] is **DENIED in part** and **GRANTED in part**, and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 141] is **GRANTED**.

ENTER: August 6, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE