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

CHARLESTON DIVISION

DIANNE M. BELLEW,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-22473

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motions *in Limine*)

Pending before the court are the following motions in limine brought by the plaintiff, Dianne M. Bellew, and by the defendants, Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"): Ethicon's Motion *in Limine* to Exclude Evidence of Plaintiff's Allegations of Spoliation [Docket 184], Ethicon's Omnibus Motion *in Limine* [Docket 206], the plaintiff's Motion to Preclude Improper Deposition Designations [Docket 185], the plaintiff's Omnibus Motions *in Limine* Nos. 1–3 Limiting Defense Medical Experts [Docket 188], the plaintiff's Motion *in Limine* No. 4 to Preclude Defendants from Defending Based on a Long History of Use of Polypropylene in the Human Body [Docket 190], the plaintiff's Omnibus Motions *in Limine* Nos. 5–13 Precluding Improper Case Specific Arguments or Evidence [Docket 192], the plaintiff's Omnibus Motions *in Limine* Nos. 14–20 Regarding General Issues [Docket 194], the plaintiff's Omnibus Motions *in Limine* Nos. 21–24 to Preclude Improper Liability Defenses [Docket 196], the plaintiff's Motion *in Limine* No. 25 Establishing the Admissibility of Ethicon's Decision to Discontinue the Sale and Marketing of the Prolift [Docket 198], the plaintiff's Omnibus Motions *in Limine* Nos. 26–31 to Exclude Improper Opinion Testimony From Treating

Physicians [Docket 200], the plaintiff's Omnibus Motions *in Limine* Nos. 32–34 Limiting FDA Related Evidence [Docket 202], and the plaintiff's Motion to Strike [Docket 277].

The court conducted a pretrial conference on November 24, 2014. At the time of filing, the transcript from this conference was not yet available. As stated in the record and for reasons appearing to the court, the following motions are **DENIED**: Plaintiff's Motion *in Limine* No. 4 to Preclude Defendants from Defending Based on a Long History of Use of Polypropylene in the Human Body [Docket 190]; Plaintiff's Omnibus Motions *in Limine* Nos. 5–13 Precluding Improper Case Specific Arguments or Evidence [Docket 192]; Plaintiff's Omnibus Motions *in Limine* Nos. 14–20 Regarding General Issues [Docket 194] with respect to No. 16: To Exclude Statements Regarding the Number of Randomized Controlled Trials that Allegedly Support the Safety of Prolift and Similar Products and No. 17: To Exclude Statements About Counsel; Plaintiff's Omnibus Motions *in Limine* Nos. 21–24 to Preclude Improper Liability Defenses [Docket 196]; Plaintiff's Motion *in Limine* No. 25 Establishing the Admissibility of Ethicon's Decision to Discontinue the Sale and Marketing of the Prolift [Docket 198]; Ethicon's Omnibus Motion *in Limine* No. 1 Concerning Evidence of Failure to Warn of Complications Not Alleged by Ms. Bellew, Including Cancer, Erosion, Infection, or Other Adverse Conditions [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 5 Concerning Photographic or Video Depiction of Actual Prolift Surgery [Docket 206].

As stated in the record and for reasons appearing to the court, the following motions are **GRANTED**: Ethicon's Omnibus Motion *in Limine* No. 6 concerning two irrelevant off-color email strings [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 14 concerning the use of deposition videos or testimony in opening statements [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 15 on the Heniford DVD concerning Kugel Composix hernia mesh [Docket 206];

Ethicon's Omnibus Motion *in Limine* No. 16 to exclude any argument, testimony, or other evidence of Ethicon's marketing Prolift prior to obtaining FDA clearance [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 17 to exclude evidence or argument criticizing the FDA's 510(k) clearance process or the effectiveness of the FDA's monitoring of medical devices [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 18 to exclude the evidence submitted by third parties to the FDA for the 2011 FDA Advisory Committee Meeting, as well as the transcript of the meeting and conclusions stated by the FDA at the meeting as to POP products [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 19 to exclude the 2012 FDA 522 orders and additional information letters [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 20 to exclude reference to the 1 May 2014 FDA proposed administrative orders regarding the reclassification of surgical mesh for transvaginal pelvic organ prolapse repair and the requirement of premarket approval regarding same [Docket 206]; Ethicon's Omnibus Motion *in Limine* No. 21 to exclude evidence of the FDA's 2005 483 action [Docket 206].

Finally, as stated in the record, I **GRANT in part** and **DENY in part** Ethicon's Omnibus Motion *in Limine* No. 2 concerning the February 19, 2009 email of Dr. Leong and any questioning or argument related to a "mutilated" or "permanently destroyed" vagina [Docket 206].

This Order explains the court's rulings on the remaining motions *in limine*.

The following motions *in limine* by the plaintiff are **GRANTED** because Ethicon does not oppose the exclusion: No. 18: To Exclude States Referencing Tort Reform or a Litigation Crisis and Otherwise Critical Comments About Lawsuits in General [Docket 194]; and No. 19: To Exclude Any Reference to Increases in the Costs of Health Care or Health Products [Docket 194]. Additionally, Ethicon's Motion *in Limine* No. 4 Evidence of Other Lawsuits [Docket 206]

is **GRANTED** because the plaintiff does not oppose the exclusion of evidence regarding other mesh lawsuits.[1]

For the reasons set forth below, the following motions by Ethicon are **DENIED**: Motion *in Limine* No. 3 to exclude evidence of anecdotal case reports or case series [Docket 206]; Motion *in Limine* No. 7 to exclude a 2008 physician survey conducted by a consulting group [Docket 206]; Motion *in Limine* No. 8 to exclude evidence of allegations regarding Johnson & Johnson or Ethicon products other than pelvic mesh products [Docket 206]; and Motion *in Limine* No. 9 to exclude evidence related to the accuracy of the New England Journal of Medicine's conflict-of-interest disclosures regarding the Altman study [Docket 206]. The following motions by Ethicon are **GRANTED**: Motion *in Limine* No. 11 to exclude evidence that Ethicon no longer sells Prolift [Docket 206]; Unopposed Motion *in Limine* No. 12 to exclude evidence concerning any Material Safety Data Sheets, including any suggestion that polypropylene causes or may cause cancer [Docket 206]; Unopposed Motion *in Limine* No. 13 to exclude reference to the designation of documents as confidential for purposes of discovery or to refer to the documents as "secret" documents or similar suggestion that because they were designated as confidential in connection with this litigation Ethicon was somehow hiding information [Docket 206]; and Motion *in Limine* to Exclude Evidence of Plaintiff's Allegations of Spoliation [Docket 184].

The following motions by the plaintiff are **DENIED**: Motion *in Limine* No. 1: To Limit Dr. Elser's Testimony [Docket 188]; Motion *in Limine* No. 2: To Limit Dr. Pramudji's Testimony [Docket 188]; Motion *in Limine* No. 15: To Exclude Testimony and Evidence Relating to Personal Experiences (and Personal Preferences) of Defendant's Employees and

[1] In the Pretrial Conference record, I mistakenly indicated that Ethicon's Motion *in Limine* No. 4 was "denied." To clarify, neither party may introduce evidence regarding other pelvic mesh lawsuits.

Expert Witnesses With Implanted TVM Devices [Docket 194]; and Motions *in Limine* Nos. 26–31 to Exclude Improper Opinion Testimony From Treating Physicians [Docket 200]. The following motions by the plaintiff are **GRANTED**: Motion *in Limine* No. 3: To Exclude the "Time to Rethink" Article [Docket 188]; Motion *in Limine* No. 32: Ethicon Cannot Defend Based on 510(k) Clearance or Compliance [Docket 202]; Motion *in Limine* No. 34: Ethicon and its Experts and Other Witnesses Should Be Barred From Commenting on or Discussing the Morgan Liscinsky Email [Docket 202]; and Plaintiff's Motion to Strike [Docket 277]. The following motions by the plaintiff are **GRANTED in part** and **DENIED in part**: Motion *in Limine* No. 14: To Exclude Evidence of Defendant's Prior or Unrelated "Good Acts" or "Good Reputation" [Docket 194]; Motion *in Limine* No. 20: To Exclude Any Evidence of Payments Which Have Been or May Have Be [sic] Made by Health Insurers or Others [Docket 194]; and Motion *in Limine* No. 33: Ethicon's Regulatory Expert, Timothy Ulatowski, Should be Barred or Limited in Testifying at Trial [Docket 202].

I **RESERVE** ruling on the plaintiff's Motion *in Limine* to Preclude Improper Deposition Designations [Docket 185].

I. Background

This bellwether 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 more than 67,000 cases currently pending, approximately 22,000 of which are in the Ethicon, Inc. MDL, MDL 2327. In this particular case, the plaintiff was surgically implanted with the Prolift Anterior Pelvic Floor Repair System ("Prolift"), a mesh product manufactured by Ethicon and Johnson & Johnson (collectively, "Ethicon") to treat POP. (*See* Short Form Compl. [Docket 1],

at 2).[2] The plaintiff received her surgery in Arizona. (*Id.* at 3). The plaintiff claims that as a result of implantation of the Prolift, she has experienced multiple complications, including mesh erosion, mesh contraction, inflammation, dyspareunia (pain during sexual intercourse), urinary incontinence, chronic pain, and recurring prolapse of organs. (Master Compl. ¶ 49). In addition, she had four subsequent operations to remove and revise the implanted mesh. (Pl. Fact Sheet [Docket 206-1], at 7). The plaintiff alleges negligence, failure to warn, design defect, common law fraud, fraudulent concealment, negligent misrepresentation, breach of express warranty, violation of consumer protection laws, gross negligence, and punitive damages. (Short Form Compl. [Docket 1], at 4).[3] The instant Motions *in Limine* involve the parties' efforts to exclude or limit certain evidence, arguments, and testimony at trial.

II. Ethicon's Motions

a. Motion *in Limine* to Exclude Evidence of Plaintiff's Allegations of Spoliation [Docket 184]

Ethicon has separately filed a motion *in limine* to exclude evidence of the plaintiff's allegations of spoliation [Docket 184]. I have previously reviewed allegations that Ethicon lost or destroyed documents relevant to this multidistrict litigation. *See Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3861778, at *5–6 (S.D. W. Va. Aug. 6, 2014). The parties in this case assert the same arguments regarding spoliation that I addressed in *Huskey*. To the extent that there are differences in fact or exhibits, the court does not find them sufficiently material. In *Huskey*, I ruled as follows:

[2] I have selected this case as a Prolift bellwether case in the Ethicon MDL. (*See* Pretrial Order # 98 [Docket 29], at 1).

[3] Since filing her short form complaint, the plaintiff has dropped several causes of action from her lawsuit. (*See* Pl.'s Opp'n to Defs.' Mot. for Summ. J. [Docket 153], at 1 n.1 ("Ms. Bellew will not pursue any causes of action for manufacturing defect, breach of implied warranty, constructive fraud, unjust enrichment, negligent infliction of emotional distress, or 'strict liability—product defect' (except to the extent the latter encompasses design defect and failure to warn).")).

> 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**.

Huskey, 2014 WL 3861778, at *5–6. Accordingly, Ethicon's motion *in limine* with regard to spoliation is **GRANTED**.

b. Defendants' Omnibus Motions *in Limine* [Docket 206]

i. No. 3: To Exclude Evidence of Anecdotal Case Reports or Case Series

Ethicon seeks to exclude anecdotal case reports or case series, which "describe a single patient's experience or outcome with a particular drug or medical device." (Defs. Mem. in Supp. of Omnibus Mot. *in Limine* ("Defs.' Mem. in Supp.") [Docket 207], at 8). Ethicon argues that these case reports are impermissible hearsay, irrelevant, and violate Rule 403. Ethicon also contends that this evidence will likely be offered by the plaintiffs "to suggest that harmful outcomes are widespread[.]" (*Id.* at 9).

Consistent with my rulings on similar motions *in limine* in prior cases, I **DENY** Ethicon's motion here. *See Eghnayem, et al. v. Boston Scientific Corp.*, No. 2:13-cv-07965, 2014 WL 5465741, at *13 (S.D. W. Va. Oct. 28, 2014); *see also Lewis, et al. v. Ethicon, Inc.*, No. 2:12-cv-

4301, 2014 WL 505234, at *5 (S.D. W. Va. Feb. 5, 2014). I lack the context needed to make a substantive ruling on this matter at this time.

ii. No. 4: To Exclude Evidence of Other Lawsuits

At the pretrial conference, I **DENIED** this motion. To clarify, this motion is moot because, in her response, the "plaintiff agrees she will not introduce evidence of other lawsuits in her case-in-chief." (Pl.'s Res. In Opp'n to Defs.' Omnibus Mot. *in Limine* ("Pl.'s Resp.") [Docket 232], at 7). Therefore, Ethicon's motion here is, in fact, **GRANTED**.

iii. No. 6: To Exclude Two Irrelevant Off-Color Email Strings

At the pretrial conference, I **GRANTED** Ethicon's motion *in limine* concerning two irrelevant off-color email strings. I clarify here that this motion is numbered Ethicon's Omnibus Motion *in Limine* No. 6.

iv. No. 7: To Exclude a 2008 Physician Survey Conducted by a Consulting Group

Ethicon moves to exclude evidence or argument concerning a 2008 physician survey report entitled "May 16-21, 2008 Physician IDPs." The study involved a consulting firm conducting 20 phone interviews with "top customers" at Ethicon's direction. (Pl.'s Resp. [Docket 232], at 11; *see* Defs.' Mem. in Supp. [Docket 207], at 16). Ethicon argues that the report is impermissible hearsay and violates Rule 403. Fed. R. Evid. 403. The plaintiff argues that the report falls within the business records exception to hearsay and, regardless, is admissible to prove that Ethicon had notice of complications associated with the Prolift.

As I explained in the pretrial conference with respect to several other motions *in limine*, this motion is an attempt to obtain a premature ruling which calls simply for the application of the rules of evidence. If this evidence is presented at trial, the defendant should object at that time. Therefore, I **DENY** this motion.

v. No. 8: To Exclude Evidence of Allegations Regarding Johnson & Johnson or Ethicon Products Other than Pelvic Mesh Products

Ethicon seeks to exclude evidence of alleged "bad acts" of Johnson & Johnson and Ethicon with regard to their non-pelvic mesh products. Ethicon argues that this evidence is irrelevant, unfairly prejudicial, and impermissible character evidence.

In this court's rulings in *Lewis*, I did not admit evidence of unrelated "(1) criminal guilty pleas and fines . . . (2) state attorney general actions . . . (3) consent decrees with the U.S. Department of Justice or FDA . . . (4) settlements or fines with the U.S. Department of Justice or Securities and Exchange Commission . . . and (5) any investigations or proceedings by any political bodies or enforcement agencies . . ." *See Lewis*, 2014 WL 505234, at * 4–5. However, I stated that:

> [S]ome other "bad acts" evidence may be relevant to the punitive damages claim or the negligence claim. At this stage, without knowing the precise evidence at issue and how the parties intend to use it, I cannot rule on the admissibility of all "bad acts" evidence. However, the plaintiffs are cautioned to tread carefully when introducing this kind of evidence. Accordingly, Ethicon's motion on this issue is **DENIED** without prejudice.

Id. at *4. I **ADOPT** this reasoning here. Therefore, I **DENY** Ethicon's motion on this matter.

vi. No. 9: To Exclude Evidence Related to the Accuracy of the New England Journal of Medicine's Conflict-of-Interest Disclosures Regarding the Altman Study

Ethicon seeks to exclude evidence or argument "related to conflict-of-interest disclosures published by the New England Journal of Medicine regarding a study of the Prolift product conducted by Dr. Daniel Altman and numerous other surgeons." (Defs.' Mem. in Supp. [Docket 207], at 20). It is premature for me to rule on this matter at this time. This motion is an attempt to obtain an advisory ruling which calls simply for the application of the rules of evidence. I do not know the context in which this evidence is to be admitted. Therefore, I **DENY** this motion.

vii. No. 11: To Exclude Evidence that Ethicon No Longer Sells Prolift

Ethicon seeks to exclude evidence that Ethicon no longer sells the Prolift product under Federal Rules of Evidence 401, 402, and 403. The plaintiff contends that she seeks to admit this evidence for impeachment purposes and that, therefore, it is admissible.

I **GRANT** this motion. Even if this evidence is admissible for impeachment purposes, Federal Rule of Evidence 403 precludes its admission. The probative value of this evidence is substantially outweighed by the risk of unfair prejudice. Fed. R. Evid. 403. Furthermore, this evidence is closely related to evidence concerning the FDA, and I will not risk the occurrence of a mistrial such as in *Cisson*. (*See* Defs.' Exhibit Q [Docket 206-17] (Trial Transcript for *Cisson* discussing mistrial)). Therefore, this motion is **GRANTED**.

viii. No. 12: To Exclude Evidence Concerning Any Material Safety Data Sheets, Including Any Suggestion that Polypropylene Causes or May Cause Cancer

Ethicon moves to exclude three specific Material Safety Data Sheets ("MSDS") and "*any* MSDS sheets that contain any suggestion that polypropylene causes or may cause cancer[.]" (Defs.' Mem. in Supp. [Docket 207], at 24). In her response, the plaintiff concedes that she "respects the Court's [previous] ruling [on this matter] and will not contest the motion except to say plaintiff may approach the Court and seek to introduce this evidence" in rebuttal. (Pl.'s Resp. [Docket 232], at 18). Therefore, this motion is **GRANTED**.

ix. No. 13: To Exclude Reference to the Designation of Documents As Confidential for Purposes of Discovery or to Refer the Documents As "Secret" Documents or Similar Suggestion that Because They Were Designated As Confidential in Connection With This Litigation Ethicon Was Somehow Hiding Information

Ethicon moves to exclude any reference to the designation of documents as confidential. The plaintiff concedes that she "will not make reference to the litigation stamp of 'confidential'

during the litigation for the discovery process." (Pl.'s Resp. [Docket 232], at 19–20). As I explained in *Tyree*, "'[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." *Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5445769, at *9 (S.D. W. Va. Oct. 22, 2014). I **ADOPT** this reasoning here. Therefore, I **GRANT** Ethicon's motion *in limine* with respect to this issue.

III. The Plaintiff's Motions

a. Motion to Preclude Improper Deposition Designations [Docket 185]

The plaintiff seeks to preclude Ethicon from (1) affirmatively designating deposition testimony of available witnesses; and (2) counter-designating deposition testimony, unless narrowly limited to testimony necessary for completeness and context of the plaintiff's affirmative designations. (Pl.'s Mot. to Preclude Improper Dep. Designations [Docket 185], at 1). Ethicon has failed to respond to the plaintiff's motion on this issue. Objections regarding deposition designations will be addressed by Magistrate Judge Eifert as a part of pre-trial discovery. It is my intent to adopt Judge Eifert's rulings. Accordingly, I **RESERVE** ruling on the plaintiff's motion *in limine* with regard to improper deposition designations.

b. Plaintiff's Omnibus Motions *in Limine* Nos. 1–3 Limiting Defense Medical Experts [Docket 188]

i. No. 1: To Limit Dr. Elser's Testimony; No. 2: To Limit Dr. Pramudji's Testimony

The plaintiff seeks to limit the testimony of Ethicon's expert witnesses, Dr. Denise Elser and Dr. Christina Pramudji. (Pl.'s Mem. of Law in Supp. of Omnibus Mots. in Limine Nos. 1–3 Limiting Def. Medical Experts ("Pl.'s Mem. *in Limine* Nos. 1-3") [Docket 189], at 2–5). I have previously reviewed the expert opinions of Dr. Elser and Dr. Pramudji under *Daubert*. (*See*

Mem. Op. & Order re: *Daubert* Mots. [Docket 265], at 32–37). I agree with Ethicon that this motion *in limine* is an attempt to "belatedly challeng[e] the credentials" of Dr. Elser and Dr. Pramudji. (Defs.' Resp. in Opp'n to Pl.'s Mots. *in Limine* Nos. 1–3 [Docket 220], at 1). My *Daubert* ruling on these two experts stands, and I will not consider any matters that should have been addressed in a prior motion. To the extent the plaintiff has further objections to Dr. Elser and Dr. Pramudji's expert opinions, which have not yet been ruled on, she is free to raise those objections at trial. Accordingly, the plaintiff's motion *in limine* with regard to Dr. Elser and Dr. Pramudji is **DENIED**.

ii. No. 3: To Exclude the "Time to Rethink" Article

The plaintiff also seeks to exclude reference to an article written by Ethicon and Boston Scientific consultants which was published in the International Urogynecology Journal because it "is an unscientific propaganda opinion piece[.]" (Pl.'s Mem. *in Limine* Nos. 1-3 [Docket 189], at 5–6). *See* Miles Murphy, et al., *Time to Rethink: An Evidence-Based Response from Pelvic Surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse"*, Int. Urogynecol. J. (Jan. 23, 2012). This article discusses a safety communication released by the FDA in July of 2011. Throughout these MDLs, I have held that the probative value of evidence related to the FDA is substantially outweighed by the risk of jury confusion. Accordingly, the plaintiff's motion *in limine* with regard to the "Time to Rethink" article is **GRANTED**, and the parties are precluded from referencing this article at trial.

In sum, the plaintiff's Omnibus Motions in Limine Nos. 1–3 Limiting Defense Medical Experts [Docket 188] is **DENIED in part** and **GRANTED in part**.

c. Plaintiff's Omnibus Motions *in Limine* Nos. 14–20 Regarding General Issues [Docket 194]

i. No. 14: To Exclude Evidence of Defendant's Prior or Unrelated "Good Acts" or "Good Reputation"

The plaintiff moves to exclude evidence regarding "prior acts of public benefit that are unrelated to the device in this case (*e.g.* community employment, charitable donations of money and medicine and medical contributions such as the development of new products) in order to convey a general 'good company' reputation." (Mem. in Supp. of Pl.'s Omnibus Mot. *in Limine* Nos. 14–20 Regarding General Issues ("Mem. *in Limine* Nos. 14–20") [Docket 195], at 1). The plaintiff contends that such evidence is irrelevant, unduly prejudicial, and improper propensity evidence. Ethicon represents that it will not offer evidence about community jobs, charitable donations, or its good reputation. (Defs.' Resp. in Opp'n to Pl.'s Mot. *in Limine* No. 14–20 ("Resp. Nos. 14–20") [Docket 223], at 1). In these respects, therefore, the plaintiff's motion *in limine* is **GRANTED**.

Ethicon states, however, that it will seek to prove that it develops new products, to the extent such evidence is relevant to this case, and complete exclusion of this subject matter at this time would be "too broad." (*Id.*) Given that I cannot presently discern the manner in which Ethicon will use evidence of new products—to prove a pertinent character trait or otherwise—I agree with Ethicon. I cannot properly rule on this issue prior to trial. Accordingly, the plaintiff's motion is **DENIED** in this respect.

For these reasons, the plaintiff's motion *in limine* No. 14 is **GRANTED in part** and **DENIED in part**.

ii. No. 15: To Exclude Testimony and Evidence Relating to Personal Experiences (and Personal Preferences) of Defendant's Employees and Expert Witnesses with Implanted TVM Devices

The plaintiff next requests exclusion of "any retrospective or hypothetical testimony

regarding Defendants' [witnesses'] willingness to have a pelvic mesh device implanted in themselves (or their family members)." (Mem. *in Limine* Nos. 14–20 [Docket 195], at 4). In the plaintiff's view, this evidence is irrelevant, confusing to the jury, and improper testimony from a lay witness or an expert witness. (*Id.* at 4–7). Ethicon responds that it does not intend to introduce evidence of this nature at trial unless the plaintiff "open[s] the door" to it. (Resp. Nos. 14–20 [Docket 223], at 2). Because a dispute does not seem to exist at this time regarding Motion *in Limine* No. 15, I **DENY** the plaintiff's motion and reserve judgment on this issue until trial, should it arise.

iii. No. 20: To Exclude Any Evidence of Payments Which Have Been or May Have Be [sic] Made by Health Insurers or Others

Relying on the collateral source rule, the plaintiff moves to exclude any evidence of payments made to Ms. Bellew through Medicare or Medicaid; health insurance companies; and Ms. Bellew's disability status. (Mem. *in Limine* Nos. 14–20 [Docket 195], at 11–12). Ethicon agrees not to present evidence regarding money or benefits received from collateral sources as compensation for Ms. Bellew's injuries alleged in this case. (Resp. Nos. 14–20 [Docket 223], at 4). Therefore, as to collateral compensation received by the plaintiff for her alleged injuries from the Prolift, the motion is **GRANTED**.

Ethicon maintains, however, that Ms. Bellew's disability compensation, which she has received since 2007 (two years before her Prolift surgery), relates to preexisting injuries, not injuries allegedly arising from the Prolift, and as a result, evidence of Ms. Bellew's disability status does not violate the collateral source rule. (*Id.*). The collateral source rule provides that "when an injured plaintiff has been compensated for his injuries from a source other than the defendant, the latter cannot benefit from the recovery." *Olivas v. United States*, 506 F.2d 1158, 1163 (9th Cir. 1978) (citing *United States v. Price*, 288 F.2d 448, 449 (4th Cir. 1961) ("[W]here

the injured plaintiff's compensation comes from a 'collateral source,' it should not be offset against the sum awarded for the tort nor considered in determining that award.")). Because the disability payments at issue are not intended to compensate Ms. Bellew for her alleged injuries arising from the Prolift and instead concern unrelated injuries she received in 2007, the collateral source rule does not apply to the disability payments. Therefore, the plaintiff's motion *in limine* on this point is **DENIED**.

In sum, the plaintiff's motion *in limine* No. 20 is **GRANTED in part** and **DENIED in part**.

d. Plaintiff's Omnibus Motions *in Limine* Nos. 26–31 to Exclude Improper Opinion Testimony From Treating Physicians [Docket 200]

The plaintiff next moves to exclude the opinion testimony of six treating physicians: (1) Dr. Terry Huff, one of Ms. Bellew's gynecologists who ultimately referred Ms. Bellew to a specialist after a short consultation; (2) Dr. Matthew Holland, a pain management doctor who treated Ms. Bellew for neck and back pain in 2010 and 2012; (3) Dr. Toure Knighton, a pain management doctor who treated Ms. Bellew's neck and back pain from June 2013 through August 2014; (4) Dr. Joseph Leano, a family medicine doctor who treated Ms. Bellew for various conditions from October 31, 2008, through August 7, 2012; (5) Dr. Javier Amadeo, a neurosurgeon who performed Ms. Bellew's cervical disk surgery in 2007; and (6) Dr. Mitar Vranic, a vascular surgeon who treated Ms. Bellew for varicose veins in 2013 and 2014. The plaintiff's arguments in support of exclusion are largely the same for each treating physician, and I can therefore address the motion in summary fashion.

The plaintiff first contends that Ethicon has not submitted a Rule 26 expert report for these physicians, and as such, any opinions offered that go beyond the scope of their treatment of the plaintiff is improper and should be excluded. This court has held that a Rule 26 report is not

required for treating physicians who testify solely about their treatment of the plaintiff. *See In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 615 (S.D. W. Va. 2013) ("[A]bsent evidence that a plaintiff's treating physician or surgeon is retained or specially employed to provide expert testimony, a Rule 26(a)(2)(B) written report will not be required." (internal quotations omitted)). And Ethicon has represented that it offers these physicians solely for this purpose. (Defs.' Resp. in Opp'n to Pl.'s Mot. *in Limine* No. 26–31 ("Resp. Nos. 26–31) [Docket 226], at 1 (stating that the defendants offer the treating physicians only to provide "opinions based on observed facts rendered for the course of treatment"). Rather than parsing through the deposition transcripts of each treating physician at issue, I simply reemphasize my prior ruling—absent an expert designation, a treating physician may only offer testimony that "addresses knowledge gained and opinions formed d*uring the course of treatment*." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 615 (emphasis added). The parties are represented by able counsel, and I trust they can abide by this rule and establish the proper content for these six physicians' trial testimony.[4]

Another consistent theme throughout the plaintiff's motion is relevancy. Specifically, the plaintiff asserts that testimony about Ms. Bellew's other medical conditions unrelated to the Prolift are irrelevant, confusing to the jury, and a waste of judicial time. (*See, e.g.*, Pl.'s Omnibus Mots. *in Limine* Nos. 26–31 to Exclude Improper Op. Test. from Treating Physicians ("Mem. *in Limine* Nos. 26–31") [Docket 201], at 7 (contending that the "defendants seek to defend themselves by overwhelming the jury with evidence of unrelated medical conditions," which the court should exclude as "irrelevant," "confusing and misleading," and a "waste of valuable

[4] The plaintiff continuously objects to the treating physicians' testimony as it relates to Ms. Bellew's smoking history. (*See, e.g.*, Mem. *in Limine* Nos. 26–31 [Docket 201], at 10 (moving to exclude Dr. Knighton's "irrelevant and highly prejudicial" testimony concerning Ms. Bellew's smoking history). I simply apply the same rule to this argument—if a treating physician took Ms. Bellew's smoking history into account when treating Ms. Bellew, then the opinion testimony on the topic is admissible. Note, however, that like all of this court's rulings denying a motion *in limine*, this allowance of testimony on Ms. Bellew's smoking history could change at trial, depending on the context and the merit of a proper objection.

judicial resources")). I disagree. Evidence about preexisting injuries, including neck and back pain, can conceivably serve various roles in Ethicon's case, such as demonstrating Ms. Bellew's pre-implant quality of life and pain management; breaking the chain of proximate causation; and establishing damages, or the lack thereof, existing in this case. While the plaintiff argues that these preexisting medical conditions are "wholly unrelated" to the plaintiff's claims, (*id.* at 10), the province of weighing the testimony and determining the relationship, if any, among Ms. Bellew's injuries belongs to the jury. Accordingly, the plaintiff's Motions *in Limine* Nos. 26–31 [Docket 200] are **DENIED**.

e. Plaintiff's Omnibus Motions *in Limine* Nos. 32–34 Limiting FDA Related Evidence [Docket 202]

i. No. 32: Ethicon Cannot Defend Based on 510(k) Clearance or Compliance

The plaintiff seeks to exclude any evidence related to the FDA's 510(k) clearance of the Prolift. In every previous case in these MDLs, this court has excluded evidence regarding the 510(k) clearance process of the product at issue.[5] I see no reason to depart from this position, which I succinctly described in *In re C. R. Bard, Inc.*:

[5] *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 756 (S.D. W. Va. 2014) (granting a motion to exclude evidence of the 510(k) process because 510(k) clearance "does not go to whether the [mesh] products are safe and effective") (internal quotations omitted); *Eghnayem, et al. v. Boston Scientific Corp.*, No. 2:13-cv-07965, 2014 WL 5461991, at *60 (S.D. W. Va. Oct. 27, 2014) ("I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy."); *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *64 (S.D. W. Va. Oct. 17, 2014) (same); *Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *37 (S.D. W. Va. Sept. 29, 2014) (same); *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3882186, at *3 (S.D. W. Va. Aug. 7, 2014) ("I now hold that the evidence of the FDA's 510(k) process is inadmissible in this case."); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 1883784, at *1 (S.D. W. Va. May 12, 2014) (same); *Cisson, et al. v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 3821280, at *7 (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 citation omitted). (*See also* Mem. Op. & Order [Docket 280], at 12 (concluding that the plaintiff's claims are not preempted by the 510(k) clearance of the Prolift because 510(k) clearance does not speak to the safety or effectiveness of a product)).

> After reviewing the motions, responses, and exhibits thereto, I **FIND** that evidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under Federal Rule of Evidence 403 because of the danger of misleading the jury, confusing the issues, and unfair prejudice. Given the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims, and if such evidence comes in via expert testimony, the expert would effectively be offering a legal conclusion.

No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013), *motion to certify appeal denied sub nom.*, No. 2:10-CV-01224, 2013 WL 4508339 (S.D. W. Va. Aug. 22, 2013). On these grounds, I **GRANT** the plaintiff's Motion *in Limine* No. 32.

ii. No. 33: Ethicon's Regulatory Expert, Timothy Ulatowski, Should be Barred or Limited in Testifying at Trial

The plaintiff also moves to bar or limit the testimony of Ethicon's regulatory expert, Timothy Ulatowski. The plaintiff maintains that Mr. Ulatowski's opinions "are based on speculation and/or net opinions, and/or are completely irrelevant to the issues in this trial." (Pl.'s Mem. in Supp. of Omnibus Mots. *in Limine* Nos. 32–34 Limiting FDA Related Evidence ("Mem. *in Limine* Nos. 32–34) [Docket 203], at 5). Ethicon responds that this motion *in limine* is actually an untimely *Daubert* motion and that Mr. Ulatowski's opinions "are highly relevant, and supported by knowledge and training about the 510(k) process, post-market surveillance, enforcement action, and design controls." (Defs.' Resp. in Opp'n to Pl.'s Mots. *in Limine* No. 32–34 [Docket 227], at 5).

To the extent that Mr. Ulatowski's opinions implicate the 510(k) clearance process in general or with respect to the Prolift specifically, his opinion is improper and therefore **EXCLUDED**. As explained above, this court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process. Furthermore, insofar as Mr. Ulatowski's opinions relate to FDA regulations or procedures, FDA decision-making, FDA

communications, or Ethicon's compliance with such, they are **EXCLUDED**. I have previously expressed concern with the risks of leading the jury into the confusing domain of the FDA. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *35–36 (S.D. W. Va. Sept. 29, 2014) ("Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations."). Particularly, I emphasized that "expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion . . . than enlightenment." *Id.* at *35. I have these same concerns about Mr. Ulatowski's opinions, which appear to entirely focus on FDA regulations, FDA procedures (the 510(k) clearance process as well as others), FDA communications, and Ethicon's compliance with FDA law. (*See* Ulatowski Report [Docket 202-4], at 6–38 (discussing FDA provisions "relevant to the subject case," in addition to other FDA requirements)). Thus, any opinion testimony on matters of the FDA is **EXCLUDED**, and the plaintiff's motion on this issue is **GRANTED**.

The plaintiff requests entire exclusion of Mr. Ulatowski's opinion. The plaintiff, however, failed to file a timely *Daubert* motion challenging Mr. Ulatowski as an expert. Accordingly, with respect to the portions of Mr. Ulatowski's opinion unrelated to the 510(k) process or the FDA, the plaintiff's motion *in limine* is **DENIED**.[6]

iii. No. 34: Ethicon and its Experts and Other Witnesses Should be Barred From Commenting on or Discussing the Morgan Liscinsky Email

Finally, the plaintiff asks this court to exclude reference to an email between FDA spokesperson Morgan Liscinsky and a reporter at Bloomberg News regarding Ethicon's failure to obtain 510(k) clearance before marketing the Prolift ("FDA email"). The plaintiff asserts that

[6] I note that based on my review of Mr. Ulatowski's expert report, very little of it, if any, provides permissible opinions unrelated to the FDA. Thus, it is quite possible that my ruling has indeed resulted in the entire exclusion of Mr. Ulatowski's opinion.

this email improperly relates to 510(k) clearance and "is pure hearsay." (Mem. *in Limine* Nos. 32–34 [Docket 203], at 7). Ethicon, on the other hand, argues that the FDA email is relevant because "it explains that Ethicon acted in a good faith belief that it was in compliance when it did not seek new 510(k) clearance for Prolift until 2008." (Resp. Nos. 32–34 [Docket 227], at 6). Because the email concerns the 510(k) process, which I have ruled as inadmissible under Federal Rule of Evidence 403, I similarly exclude the FDA email without addressing the hearsay arguments. The plaintiff's motion *in limine* on this point is therefore **GRANTED**.

In conclusion, I **GRANT in part** and **DENY in part** Plaintiff's Omnibus Motions *in Limine* Nos. 32–34 Limiting FDA Related Evidence [Docket 202].

f. Plaintiff's Motion to Strike [Docket 277]

Lastly, the plaintiff moves to strike Ethicon's Bench Memorandum Regarding the Admissibility of Plaintiff's Prior Medical History ("Ethicon's Bench Memorandum"). I have already rejected the plaintiff's objections to the admissibility of Ms. Bellew's prior medical history at this stage. Therefore, further argument on this issue, as stated in Ethicon's Bench Memorandum [Docket 276], is unnecessary. Accordingly, the plaintiff's Motion to Strike [Docket 277] is **GRANTED**.

IV. Conclusion

For the reasons stated above, the following motions *in limine* are **GRANTED in part** and **DENIED in part**: Ethicon's Omnibus Motion *in Limine* [Docket 206]; Plaintiff's Omnibus Motions *in Limine* Nos. 1–3 Limiting Defense Medical Experts [Docket 188]; Plaintiff's Omnibus Motions *in Limine* Nos. 14–20 Regarding General Issues [Docket 194]; Plaintiff's Omnibus Motions *in Limine* Nos. 32–34 Limiting FDA Related Evidence [Docket 202].

The following motions are **GRANTED**: Ethicon's Motion *in Limine* to Exclude

Evidence of Plaintiff's Allegations of Spoliation [Docket 184]; Plaintiff's Motion to Strike [Docket 277].

Plaintiff's Omnibus Motions *in Limine* Nos. 26–31 to Exclude Improper Opinion Testimony From Treating Physicians [Docket 200] is **DENIED**.

I **RESERVE** ruling on the plaintiff's Motion *in Limine* to Preclude Improper Deposition Designations [Docket 185].

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

ENTER: November 25, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE