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

CHARLESTON DIVISION

JACQUELYN TYREE, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-08633

BOSTON SCIENTIFIC CORPORATION,

Defendant.

AMENDED MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

The Memorandum Opinion and Order (*Daubert* Motions) entered on October 17, 2014 [Docket 444] is **AMENDED.** The only changes to this decision are on pages 11 and 49 to correct minor typographical errors (changing "his expert opinion" to "BSC's motion"). These changes do not alter my rulings.

The following motions have been brought by the defendant, Boston Scientific Corporation ("BSC"): (1) Defendant's Motion to Exclude Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 227]; (2) Defendant's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 237] (3) Defendant's Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. [Docket 235]; (4) Defendant's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 221]; (5) Defendant's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D., RAC, FRAPS [Docket 219]; (6) Defendant's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 223]; (7) Defendant's Motion to Exclude the

Opinions and Testimony of Donald R. Ostergard, M.D. [Docket 217]; (8) Defendant's Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 225]; (9) Defendant's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 239]; (10) Defendant's Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE [Docket 241]; (11) Defendant's Motion to Exclude the Opinions and Testimony of Bruce Allen Rosenzweig, M.D. [Docket 251]; (12) Defendant's Motion to Exclude the Opinions of Christopher Walker, M.D. [Docket 247]; and (13) Defendant's Motion to Strike Rebuttal Report of Dr. Abbas Shobeiri [Docket 400].

The following motions have been brought by the plaintiffs: (1) Plaintiffs' Motion to Exclude the Testimony of Stephen H. Spiegelberg, Ph.D. [Docket 215]; (2) Plaintiff's Motion to Exclude the Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 213]; (3) Plaintiffs' Motion to Exclude the Testimony of Gary L. Winn, Ph.D. [Docket 229]; (4) Plaintiffs' Motion to Exclude or Limit Testimony of Christine Brauer, Ph.D. [Docket 231]; (5) Plaintiffs' Motion to Limit the Testimony of Patrick Culligan, M.D. [Docket 233]; and (6) Plaintiffs' Motion to Limit the Testimony of Lonny Green, M.D. [Docket 354].

For the reasons explained below, the defendant's motion with respect to Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 227] is **DENIED**. The defendant's motion with respect to Dr. Margolis [Docket 237] is **GRANTED IN PART** and **DENIED IN PART** and **RESERVED IN PART**. The defendant's motion with respect to Dr. Trepeta [Docket 235] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Drs. Mays and Gido [Docket 221] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Pence [219] is **GRANTED**

IN PART and **DENIED IN PART**. The defendant's motion with respect to Dr. Barker [Docket 223] is **GRANTED**. The defendant's motion with respect to Dr. Ostergard [Docket 217] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Iakovlev [Docket 225] is **GRANTED**. The defendant's motion with respect to Dr. Blaivas [Docket 239] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Vredenburgh [Docket 241] is **GRANTED**. The defendant's motion with respect to Dr. Rosenzweig [Docket 251] is **DENIED**. The defendant's motion with respect to Dr. Walker [Docket 247] is **DENIED**. The defendant's motion to strike the rebuttal report of Dr. Shobeiri [Docket 400] is **GRANTED**.

The plaintiffs' motion with respect to Dr. Spiegelberg [Docket 215] is **RESERVED IN PART** and **GRANTED IN PART**. The plaintiffs' motion with respect to Dr. Badylak [Docket 213] is **RESERVED IN PART** and **GRANTED IN PART**. The plaintiffs' motion with respect to Dr. Winn [Docket 229] is **GRANTED**. The plaintiffs' motion with respect to Dr. Brauer [Docket 231] is **GRANTED**. The plaintiffs' motion with respect to Dr. Culligan [Docket 233] is **GRANTED**. The plaintiffs' motion with respect to Dr. Green [Docket 354] is **GRANTED IN PART** and **DENIED IN PART**.

I. Background

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

Transobturator Mid-Urethral Sling System ("the Obtryx"), a mesh product manufactured by BSC. (*See* Pretrial Order #78 [Docket 9], at 1–2).[1] All of the plaintiffs received their surgeries in West Virginia. They claim that as a result of implantation of the Obtryx, they have experienced "erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain." (*Id.* at 4 (quoting the master complaint)). The plaintiffs allege negligence; strict liability for design defect; strict liability for manufacturing defect; strict liability for failure to warn; breach of express warranty; breach of implied warranty; and punitive damages. (*Id.* at 2). The spouse of one plaintiff (Ms. Tyree) has also alleged loss of consortium. (*Id.*). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4)

[1] I originally consolidated the cases of eleven plaintiffs implanted with the Obtryx. (*See* Pretrial Order #78 [Docket 9], at 1 (naming Canterbury, Billings, Sexton, Hendricks, Moore, Tyree, Campbell, Blankenship, Pugh, Workman, and Wilson as consolidated plaintiffs). Four plaintiffs now remain in this action. (*See* Pretrial Order #94 [Docket 67], at 1 (removing *Sexton* case from the consolidated West Virginia cases); Stipulation of Dismissal [Docket 104] (dismissing the claims of Donna Billings with prejudice); Order Dismissing Canterbury Plaintiff [Docket 107], at 1 (dismissing the claims of Karen Canterbury with prejudice); Stipulation of Dismissal [Docket 123] (dismissing the claims of Neasha Workman with prejudice); Stipulation of Dismissal With Prejudice[Docket 426] (dismissing with prejudice the claims of Sharon Pugh, et al.); Stipulation of Dismissal With Prejudice [Docket 433] (dismissing plaintiff Tammy Hendricks with prejudice); Stipulation of Dismissal With Prejudice [Docket 427] (dismissing plaintiff Dreama Moore with prejudice)).

have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[2] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular

[2] With more than 60,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record immediately before me and the arguments of counsel.

scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262.

The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties' *Daubert* objections. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R.*

Bard, Inc., 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that

the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to BSC's *Daubert* motions.

III. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude certain opinion testimony of Dr. Michael Thomas Margolis; Dr. Richard W. Trepeta; Drs. Jimmy W. Mays and Samuel P. Gido; Dr. Peggy Pence; Dr. Thomas H. Barker; Dr. Donald R. Ostergard; Dr. Vladimir Iakovlev; Dr. Jerry Blaivas; Dr. Alison Vredenburgh; Dr. Bruce Allen Rosenzweig; Dr. Christopher Walker; and Dr. Abbas Shobeiri. BSC also seeks to preclude the plaintiffs' experts from opining on the alleged defects of polypropylene mid-urethral slings.

A. Motion to Exclude Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings are Defective

BSC moves to preclude any of plaintiffs' experts from opining that polypropylene mid-urethral slings are defective. BSC argues that this opinion should be excluded because it "has not been tested, is not based on published-peer-reviewed literature, and is not generally accepted in the relevant medical and scientific communities." (BSC's Mem. of Law in Support of its Mot. to Exclude Pls.' Experts' Op. That Polypropylene Mid-Urethral Slings Are Defective [Docket 228], at 2–3). The plaintiffs in *Sanchez* presented the same arguments. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4–5 (S.D. W. Va. September 29, 2014). I **ADOPT** my reasoning in *Sanchez*:

> Rule 702, by its plain terms, contemplates *Daubert* challenges directed at the opinions of *specific* experts, not the opinions of a collection of experts. While these experts may have come to similar conclusions, it is not the conclusions that the

> court must assess, but the reliability of the methods and procedures underpinning those conclusions. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). Two experts may come to a similar conclusion, but one or both experts' methodology in reaching that conclusion may be unreliable. Rule 702 directs the court to determine whether *an expert* is qualified, whether his or her opinions are the product of reliable methodology, and whether the opinions will be helpful to the jury. *See* Fed. R. Evid. 702. I can only conduct the required *Daubert* analysis on an individualized basis.

Id. at 5. Therefore, I **DENY** BSC's motion on the grounds explained in *Sanchez*.

B. Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D.[3][4]

BSC moves to exclude the opinions and testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist. He seeks to offer several opinions regarding polypropylene mesh slings, alternative procedures, and complications associated with mesh products. BSC argues that Dr. Margolis's opinions are unreliable because he failed to consider scientific literature contrary to his opinions and failed to provide any scientific basis for other opinions. (*See* Def. BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 238], at 2). BSC also contends that Dr. Margolis's specific causation opinions as to Ms. Tyree, Ms. Moore, and Ms. Campbell should be excluded because "he has not reliably applied his methodology to the facts of the cases" and did not perform a proper differential diagnosis. (*Id.*). In addition, BSC contends that

[3] I ruled in *Sanchez* on *Daubert* motions related to Dr. Margolis, Dr. Trepeta, Drs. Mays and Gido, Dr. Pence, and Dr. Barker. In *Sanchez*, I relied on excerpts of deposition testimony from these experts, most, but not all of which excerpts are attached as exhibits in this case. However, because the depositions cited in *Sanchez* are the same depositions taken on the same date, I have relied on some excerpts from *Sanchez* here. Also, I note that as to Drs. Margolis and Barker, the parties attached additional deposition testimony as exhibits in this case.

[4] On October 6, 2014, the plaintiffs in *Sanchez* filed a Motion for Reconsideration for Dr. Margolis, Dr. Slack, and Dr. Barker. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, [Docket 149]. I denied the motion on October 17, 2014. *See Sanchez*, No. 2:12-cv-05762, [Docket 151]. To the extent the arguments raised in the Motion for Reconsideration related to Dr. Margolis and Dr. Barker overlap (there is no motion in this case related to Dr. Slack) or may have been raised in this case, I incorporate my findings here.

Dr. Margolis's opinions "either (1) constitute legal opinions, (2) fall outside the scope of his expertise, or (3) consist of speculation regarding Boston Scientific's knowledge, intent and/or state of mind." (*Id.*). Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report. (*Id.*).

I have previously reviewed the opinion testimony of Dr. Margolis under *Daubert*. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *10–19 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert arguments on the admissibility of Dr. Margolis's expert opinion that I addressed in *Sanchez*. To the extent that there are differences in fact or exhibits, the court does not find them sufficiently material to this case. Thus, I **ADOPT** my prior ruling on Dr. Margolis as follows and thereby **GRANT IN PART**, **DENY IN PART**, and **RESERVE IN PART** BSC's motion. I will address additional arguments raised by the parties in this case below.

1. BSC Argues That Dr. Margolis Failed to Consider Contrary Scientific Studies in Forming His Opinions

BSC argues that Dr. Margolis failed to consider scientific studies that were contrary to his opinions without a scientific basis for doing so.

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a

particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

a. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe and Effective for SUI

First, BSC contends that Dr. Margolis's opinion that polypropylene mid-urethral slings are not safe and effective for the treatment of SUI is unreliable because he ignored peer-reviewed literature indicating otherwise. I addressed this argument in *Sanchez*:

> BSC's argument focuses on Dr. Margolis's testimony regarding the *Nilsson* seventeen-year follow-up study, which supports the conclusion that polypropylene slings are safe and effective. (*See* Margolis Dep. [Docket 132-2], at 193:5–20). Dr. Margolis rejected the *Nilsson* study without explaining a scientific basis for doing so. Instead, he merely indicated that he had "serious questions about the bias, the potential for bias and also the – the data in this article" but would not elaborate further:
>
> Q: You believe that this particular study is – is not reliable; is that your opinion?
>
> A: I question the reliability.
>
> Q: And you won't tell me why?
>
> A: I question it, and that's all I can say.
>
> . . .
>
> Q: So what you're telling the judge is I am dismissing this paper and not considering it reliable, but I'm not going to

tell you why?

A: Sure. I don't have to tell you why I don't consider something to be authoritative. I mean, I don't consider that to be a valid study. I have concerns about it. I have a right to hold that opinion. And I do hold that opinion.

Q: All right. Are there and –

A: I don't consider it authoritative and I consider it potentially flawed and potentially biased. That's my opinion. Right or wrong, that's my opinion.

(*Id.* at 196:1–3, 16-20; 199:10–22).

Sanchez, 2014 WL 4851989, at *12. I **ADOPT** this reasoning here and find his method to be unreliable. Therefore, this opinion is **EXCLUDED**.

b. Opinion Regarding the Complication Rates of Pain in Women with Polypropylene Mesh and Slings

BSC also argues that Dr. Margolis did not consider contrary studies showing lower complication rates of pain in women with polypropylene slings. In *Sanchez*, I cited to Dr. Margolis's deposition testimony, which reveals that he gives no scientific basis for disagreeing with these studies:

Q: Would you agree that there are studies that show that the rates of pain with polypropylene slings are in the low single digits?

. . .

A: I – there are studies.

Q: And do you discount those studies?

A: I disagree with those studies.

Q: And why?

> A: Because that's not what I have seen, read, studied, observed, and that's not biologically plausible.
>
> ([Margolis Dep. [Docket 132-2],] at 239:2–13). Without further explanation for his disagreement with these studies, Dr. Margolis's method is unreliable.

Sanchez, 2014 WL 4851989, at *13. I **ADOPT** this reasoning here. His opinion is **EXCLUDED**.

c. Opinions Regarding General Complication Rates in Women with Polypropylene Mesh

BSC also challenges Dr. Margolis's general opinions regarding high complication rates in women with polypropylene mesh products. In *Sanchez*, I cited to Dr. Margolis's deposition testimony, where he explains his belief that studies indicating low single digit complication rates are not accurate because complications are underreported and data is possibly fabricated. *See Sanchez*, 2014 WL 4851989, at *13. I also find that Dr. Margolis's method of "[g]iv[ing] the benefit of the doubt to the patient" is unreliable:

> Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." ([Margolis Dep. [Docket 132-2],] at 259:7–9). In other words, he "assume[s] the worst-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–259:23). Dr. Margolis eventually admits that he has been evaluating the literature and forming his opinions for this case according to that principle as well. (*See id.* at 259:20–260:14). "[G]iv[ing] the benefit of the doubt to the patient" is not a scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9).

Sanchez, 2014 WL 4851989, at *14. I **ADOPT** this reasoning here. Dr. Margolis's opinions as to this matter are **EXCLUDED**.

2. BSC Argues that Dr. Margolis Failed to Provide Any Scientific Basis For His Other Opinions

BSC next argues that Dr. Margolis failed to offer any scientific basis for his other opinions and based them solely on his experience.

a. Opinion Concerning the Lack of Sound Scientific Evidence Supporting the Clinical Benefits of Polypropylene Mesh in SUI

BSC challenges the reliability of Dr. Margolis's opinions concerning a lack of sound scientific evidence supporting the use of polypropylene mesh in treating SUI. (*See* BSC's Mem. re: Margolis [Docket 238], at 10–11). BSC points to Dr. Margolis's deposition testimony where he admits that there, in fact, are studies supporting the use of polypropylene in SUI. I addressed this argument in *Sanchez*:

> Inconsistent statements of a witness may be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir.1994) ("[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses ..."). However, here, Dr. Margolis's inconsistencies seem to directly shed light on the unreliability of his method. Even if Dr. Margolis is stating that there is a lack of *credible* evidence, as the plaintiffs argue, it is still unclear why Dr. Margolis believes these studies lack credibility. As a result, Dr. Margolis's opinions are rendered untrustworthy and unreliable.

Sanchez, 2014 WL 4851989, at *14. I **ADOPT** this reasoning here. Therefore, his opinions as to this matter are **EXCLUDED**.

b. Opinion that the Burch Procedure is More Effective than Polypropylene Mesh Slings

BSC challenges Dr. Margolis's opinion that the Burch procedure is more effective than polypropylene slings. BSC argues that this opinion is unreliable because Dr. Margolis could not identify direct comparison studies of the Burch procedure and the use of slings in his deposition. (*See* BSC's Mem. re: Margolis [Docket 238], at 11). In *Sanchez*, I nevertheless found his opinion to be reliable because his opinion was founded in scientific literature:

> Dr. Margolis cited in his report several scientific, peer-reviewed sources showing that the Burch procedure has high success rates. (*See* Margolis Report [Docket 58–

> 1], at 9 n.6 (citing J.W. Ross, *Post Hysterectomy Total Vaginal Vault Prolapse Repaired Laparoscopically.* Presented at 2nd World Symposium on Laparoscopic Hysterectomy, American Association of Gynecologic Laparoscopists, New Orleans, LA (Apr. 7–9, 1995) (reporting 93% success rate for laparoscopic Burch and 90% for open Burch in the treatment of SUI); Romano S. Bustan et al., *Burch Laparoscopic Procedure for Repairing Proven Stress Incontinence—Report of 32 Cases,* Harefuah 139 (9–10), 350–2, 407 (2000) (reporting 97% cure rate); E.G. Jacome et al., *Laparoscopic Burch Urethropexy in a Private Clinical Practice,* J. Am. Assoc. Gynecol. Laparosc. 6(1): 39–44 (1999) (reporting cure rate of 94% for laparoscopic Burch); R.D. Moore et al., *Laparoscopic Burch Colposuspension for Recurrent Stress Urinary Incontinence,* Jourdan of the Am. Assoc. of Gyneco. Laparasc. 8, no.8:389-92 (2001) (reporting 90% objective cure rate in patients having repeat Burch procedure laparoscopically); Todd R. Jenkins and C.Y. Liu, *Laparoscopic Burch Colposuspension,* 4 Current Opinion in Obstetrics & Gynec. 314, 314–18 (2007) (literature review noting a finding of cure rates between 76% to 95% for laparoscopic Burch procedures)). In addition, Dr. Margolis testified that the Burch procedure success rates reported in the data are higher than the rates for the polypropylene sling. (*See* Margolis Dep. [Docket 132-1], at 136:12–16).

Sanchez, 2014 WL 4851989, at *15. I **ADOPT** this reasoning here and find his opinion reliable.

Also, unlike my ruling in *Sanchez*, I find Dr. Margolis's opinion relevant in this case. *Sanchez* dealt with the Pinnacle device for the treatment of POP, and, since Dr. Margolis opined about the Burch procedure and polypropylene mesh slings in the treatment of SUI, I found that his opinion was irrelevant to Ms. Sanchez's claims. (*See id.*). However, the product at issue in this case is the Obtryx, which is a sling that treats SUI. As a result, Dr. Margolis's opinion that the Burch procedure is more effective than polypropylene mesh slings is relevant here. Therefore, I **DENY** BSC's motion with respect to this matter.

c. Opinion that Xenform Slings are More Effective than Polypropylene Slings

BSC challenges Dr. Margolis's opinion that Xenform slings are more effective than polypropylene slings in the treatment of SUI. BSC's argument focuses on Dr. Margolis's comparison of the different complication rates associated with Xenform slings versus

polypropylene slings and his failure to identify studies involving Xenform slings. (*See* BSC's Mem. re: Margolis [Docket 238], at 12). I addressed these arguments in *Sanchez*:

> Although Dr. Margolis has experience in this area, his method of comparing the complication rates of Xenform and polypropylene slings is problematic. In his deposition, Dr. Margolis explained that the 4% complication rate for Xenform slings is, in fact, "the complication rate that I understand all surgeons have when they take any patient into an operating room, whether it's vaginal surgery, abdominal surgery, bladder surgery, brain surgery, or toe surgery." (Margolis Dep., [Docket 132-1], at 122:18–24). His reasoning as to why Xenform has a lower complication rate than polypropylene slings is simply because Xenform uses no polypropylene mesh and, thus, has no mesh-related complications. (*See id.* at 123:22–124:11). This logic is not scientific. Dr. Margolis's conclusion that Xenform does not have mesh-related complications because it is not made from mesh could be reached by a jury without expert testimony.
>
> Moreover, Dr. Margolis cannot cite a single study involving use of Xenform slings to treat SUI. When asked if he could point to a study, Dr. Margolis responded "I am not prepared to present any studies to you today. I don't know any off the top of my head." (*Id.* at 133:14–19). When asked if he had seen any studies, Dr. Margolis testified "I'm sure I have. I don't have any names for you today." (*Id.* at 133:20–24). Without a scientific basis, Dr. Margolis's method is unreliable.

Sanchez, 2014 WL 4851989, at *16. I **ADOPT** this reasoning here. Therefore, his opinion regarding Xenform slings is **EXCLUDED**.

d. Opinion that the Infection Rate of Polypropylene Mesh is Up to 100%

BSC next challenges Dr. Margolis's opinion that the infection rate of polypropylene mesh is up to 100%. (*See* BSC's Mem. re: Margolis [Docket 238], at 12). As in *Sanchez*, BSC points to a slide presentation that Dr. Margolis has given which cites a study finding infection rates of 0% to 8%. (*See id.*). I addressed this issue in *Sanchez*:

> Dr. Margolis's inconsistent presentation does not automatically render his method unreliable. In his report, Dr. Margolis does cite to scientific studies to support his opinion. (*See* Margolis Report [Docket 58-1], at 16) (describing the *Vollebregt* study finding 83.6% of implants contained bacteria during surgical implantation, the *Boulanger* study finding 100% of mesh explants removed in the study due to

> complications contain bacteria, the *Shah* and *Badlani* study finding infection in mesh patients).
>
> However, as BSC points out, the study which Dr. Margolis cites to support his 100% figure is not directly applicable. The *Boulanger* study did not find that 100% of the mesh systems explanted for the study were infected; the study found that 100% of the mesh systems were contaminated with bacteria. (*See* Margolis Report [Docket 58-1], at 16; Boulanger et al., *Bacteriological Analysis of Meshes Removed for Complications After Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse,* 19 Int'l Urogynecol J. 827, 827 (2008) [Docket 58-5]). The authors of the *Boulanger* study are not certain that bacteria contamination leads to infection. (*See* Boulanger, *supra,* at 827, 830) (stating that the "exact role" of bacterial contamination "is not yet clear" and "must be explored by other experimental studies")). They even write that "[i]nfection is a rare complication of retropubic mid-urethral slings (0.7% of cases)" and that their "findings concur with previously published data" on this subject. (Boulanger, *supra,* at 830).
>
> The *Boulanger* study does not support the opinion that there is a 100% infection rate in women who undergo mesh implantation surgery. Therefore, Dr. Margolis's methodology of basing his opinion on this study is unreliable.

Sanchez, 2014 WL 4851989, at *17. I **ADOPT** this reasoning here. Therefore, his opinion as to this matter is **EXCLUDED**.

e. Opinion that the Complication Rate of Urethral Obstruction is Greater than Ten Percent with Polyproylene Mid-Urethral Slings

BSC challenges Dr. Margolis's opinion that the complication rate of urethral obstruction is greater than ten percent. (*See* BSC's Mem. re: Margolis [Docket 238], at 13). As in *Sanchez,* BSC supports its argument by quoting Dr. Margolis's deposition testimony:

> Q: . . . [A]re you offering an opinion as to how frequently shrinkage of a polypropylene midurethral sling chokes off the vagina as a result of shrinkage?
>
> A: Yes.
>
> Q: How often?
>
> A: Greater than ten percent.

Q: And is there a study that you're relying upon for that?

A: I'm looking. And I'm not finding it right now. So I don't have a study for you at this time.

(Margolis Dep. [Docket 237-3], at 262:6-16). The plaintiffs in *Sanchez* did not respond to this argument, and I found this opinion to be unreliable. *See Sanchez*, 2014 WL 4851989, at *17. In this case, the plaintiffs in response cite to Dr. Margolis's deposition testimony regarding mesh shrinkage and studies concerning mesh shrinkage to demonstrate that Dr. Margolis's opinion is, in fact, reliable. (*See* Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Opinions & Testimony of Michael Thomas Margolis, M.D. ("Pls. Resp. re: Margolis") [Docket 283], at 13–15).

However, the deposition testimony cited by the plaintiffs does not provide scientific support for Dr. Margolis's opinion. It only references studies that report a variety of mesh shrinkage rates, without any support for his opinion that slings cause urethral obstruction in 10% of the cases. (*See id.*). For the reasons stated above and in *Sanchez*, I find Dr. Margolis's opinion on this matter to be unreliable and, therefore, **EXCLUDED**.

f. Opinion on the Percentage or Number of BSC Products Dr. Margolis Has Removed

BSC challenges Dr. Margolis's opinion on the percentage or number of BSC products that he has removed. (*See* BSC's Mem. re: Margolis [Docket 238], at 13). I agreed with BSC in *Sanchez* on this point:

> Dr. Margolis testified that he has removed approximately 300 polypropylene mesh and sling products "throughout the last 15 or so years" and gives his "best guess" that 10% to 15% of those were Boston Scientific. (Margolis Dep. [Docket 132-1], at 74:23–76:1). Dr. Margolis explained that "[t]he exact numbers of each [product] I don't keep track of." (*Id.* at 74:11–19). When asked how he arrived at that 10% to 15% figure for Boston Scientific products, Dr. Margolis testified that these percentages are just to his "best recollection":

> Q: Have you tried to do a system—did you go back and try to do some kind of systematic count, or are you just doing that from recollection in terms of the percentage of Boston Scientific products?
>
> A: Best recollection.

(*Id.* at 76:13–18). Dr. Margolis testified that he cannot identify the mesh brand by sight after explantation, and he "tr[ies] to get the operative records from the implant" with the product manufacturing information but does not know how often he receives these records for his patients. (*Id.* at 76:2–9, 77:14–78:2).

> As a result, BSC argues that Dr. Margolis's opinion as to the number or percentage of BSC products he has removed is unreliable . . .
>
> Without a reliable basis, Dr. Margolis's opinions may be erroneous. *See Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014) (excluding expert's "analyses of the mesh implants" because they were not "controlled for error or bias"). Therefore, his opinions are **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *18. I **ADOPT** this reasoning here. His opinions as to this matter are **EXCLUDED**.

g. Plaintiffs' Argument Regarding the Daubert *Analysis of Dr. Margolis in* Lewis

The plaintiffs in this case make an additional argument regarding Dr. Margolis's expert opinions. The plaintiffs contend that "this Court has already decided that Dr. Margolis' methodology and qualifications are sufficient to defeat challenges under *Daubert* and Rule 702" in *Lewis* and that, therefore, his testimony should be admitted in this case. (*See* Pls. Resp. re: Margolis [Docket 283], at 6 (citing *Lewis v. Ethicon, Inc.*, No. 2:12-cv-04301, 2014 WL 186872, at *15–17) (S. D. W. Va. Jan. 15, 2014)).

However, *Lewis* was a different case involving a different plaintiff, a different defendant, and a different product. Also, in *Lewis*, Dr. Margolis submitted a different expert report which included expert opinions specific to the plaintiff in *Lewis*. As a result, I reject this argument.

h. Plaintiffs' Argument Regarding Dr. Margolis's Experience and Kumho Tire

Next, the plaintiffs in this case make an additional argument in response to BSC's contention that Dr. Margolis failed to provide any scientific basis for some of his opinions. (BSC's Mem. re: Margolis [Docket 238], at 2). The plaintiffs argue that Dr. Margolis's experience alone is enough basis for his opinions. Several times, the plaintiffs quote the Supreme Court in *Kumho Tire* stating "an expert might draw a conclusion from . . . extensive and specialized experience." (Pls. Resp. re: Margolis [Docket 283], at 2, 9, 12, 14, 16 (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999)).

However, "[p]roposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known." *Daubert*, 509 U.S. at 590. Dr. Margolis writes that he "considered the scientific literature" in forming his opinions, (*see* Margolis Report [Docket 237-1], at 5), yet, as I discuss in *Sanchez*, he is unable to provide scientific support for some of his opinions. *See Sanchez*, 2014 WL 4851989, at *14–18. Even though Dr. Margolis has experience, he must still base his opinions on a reliable, scientific method. (*See Daubert*, 509 U.S. at 590 ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method.")). The plaintiffs' argument is unavailing.

3. Specific Causation Opinions as to Ms. Campbell, Ms. Moore, and Ms. Tyree

BSC argues that Dr. Margolis's specific causation opinions as to Ms. Campbell, Ms. Moore, and Ms. Tyree should be excluded as unreliable. In particular, BSC makes the following arguments: (1) Dr. Margolis's specific causation opinions should be excluded because his general causation opinions are unreliable; (2) Dr. Margolis did not perform a proper differential diagnosis in regards to Ms. Campbell, Ms. Moore, and Ms. Tyree; (3) Dr. Margolis inconsistently applied his

methodology in evaluating the plaintiffs; and (4) Dr. Margolis's opinions regarding the plaintiffs' complications are unreliable. (BSC's Mem. re: Margolis [Docket 238], at 14–18).

Ms. Moore is no longer a plaintiff in this case. Therefore, BSC's motion as to Dr. Margolis's opinions related to Ms. Moore is **DENIED AS MOOT**. As in *Sanchez*, I **RESERVE** my ruling on Dr. Margolis's remaining specific causation opinions until trial.

4. BSC Argues that Dr. Margolis Offers Opinions Outside of His Area of Expertise

BSC argues that several of Dr. Margolis's opinions should be excluded because they are outside his area of expertise. (*See* BSC Mem. re: Margolis [Docket 238], at 19). In particular, BSC challenges Dr. Margolis's opinions as to: "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design and development, and marketing." (*Id.* (internal citations omitted)). As in *Sanchez*, the plaintiffs conceded that Dr. Margolis will not be offering these opinions at trial. (*See* Pls.' Resp. re: Margolis [Docket 283], at 19). Therefore, this aspect of BSC's motion is **DENIED AS MOOT**.

5. Impermissible Expert Opinions As To BSC's State of Mind

BSC also argues that Dr. Margolis seeks to offer testimony as to BSC's state of mind, knowledge, and intent during product development. As I explained in *Sanchez*, expert testimony about a defendant company's state of mind is impermissible. In *Lewis*, I excluded state of mind testimony of Dr. Margolis because "he is not qualified ... to opine on Ethicon's state of mind or knowledge." *Lewis*, 2014 WL 186872, at * 15. The plaintiffs concede that Dr. Margolis will not be offering these opinions at trial. (*See* Pls.' Resp. re: Margolis [Docket 283], at 19). Therefore, this aspect of BSC's motion is **DENIED AS MOOT**.

6. Opinions Offered by Dr. Margolis That Were Not Disclosed in His Expert Report

BSC argues that "Dr. Margolis testified to numerous opinions during his most recent depositions that he did not disclose in his Rule 26 expert report." (BSC's Mem. re: Margolis [Docket 238], at 20). However, BSC only points to his opinion on banding and his opinion that Ms. Campbell has chronic pelvic pain. (*See id.*) "Under Rule 26, expert reports must contain 'a complete statement of all opinions the witness will express and the basis and reasons for them.'" *Lewis*, No. 2:12-cv-4301, 2014 WL 186872, at *17 (citing Fed. R. Civ. P. 26(a)(2)(B)(i)).

In regards to banding, Dr. Margolis does mention banding in his case-specific report for Ms. Tyree. (*See History and Physical re: Jacquelyn Tyree* in Margolis Report [Docket 237-1], at App. D). Therefore, although I reserve my ruling on Dr. Margolis's remaining specific causation opinions until trial, I **FIND** that his banding opinions as to Ms. Tyree should not be excluded under BSC's Rule 26 reasoning here.

However, Dr. Margolis admits that he did not include in his report his opinion that Ms. Campbell has chronic pelvic pain:

> Q: In Ms. Tyree's case, you stated in your impression/plan that she had chronic pelvic pain. You make no such reference here. Does that mean that you – your opinion is that in Ms. Campbell's case, she does not have chronic pelvic pain related to her sling?
>
> A: No.
>
> Q: Why did you not include it?
>
> A: Error on my part. Failure to include that in there. It was a typo. My mistake.

(Margolis Dep. II [Docket 237-5], at 255:4–16) (objections omitted). However, according to Dr. Margolis's report on Ms. Campbell, her vaginal exam revealed that, "Palpation of the obturator

foramen bilaterally through the vaginal wall does reproduce her pain." (*See History and Physical re: Carol Campbell* in Margolis Report [Docket 237-1], at App. D). Although I reserve my ruling on Dr. Margolis's remaining specific causation opinions until trial, I **FIND** that his opinion that Ms. Campbell has chronic pelvic pain should not be excluded under BSC's Rule 26 argument.

Therefore, for the reasons stated above and in *Sanchez*, I **GRANT IN PART** and **DENY IN PART** and **RESERVE IN PART** BSC's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. *See Sanchez*, 2014 WL 4851989, at *10–19.

C. Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D.

In this case, the plaintiffs offer Dr. Trepeta to testify as an expert witness on the general pathology of vaginal mesh implantation (*see generally* Trepeta General Report [Docket 235-1]) and on the specific pathology of Plaintiff Jeanie Blankenship (*see generally* Trepeta Specific Report [Docket 235-2]). Among other things, Dr. Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. As part of his fellowship, he "establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases." (Trepeta General Report [Docket 235-1], at 2). Dr. Trepeta also examines vulvar–vaginal pathology samples through his private practice. (*See id.*). BSC moves to exclude Dr. Trepeta as an expert witness, raising two primary objections: (1) Dr. Trepeta is not qualified to opine on the properties of polypropylene mesh or the clinical responses to mesh implants; and (2) Dr. Trepeta's opinions are unreliable, irrelevant, and not helpful to the jury. (*See generally* BSC's Mem. in Supp. of its Mot. to Exclude Richard W. Trepeta ("BSC's Mem. re: Trepeta") [Docket 236]). As further explained below, I **GRANT In PART** and **DENY IN PART** BSC's Motion to Exclude Dr. Trepeta [Docket 235].

1. Dr. Trepeta's Qualifications

BSC begins by contending that Dr. Trepeta's background in pathology does not qualify him under Federal Rule of Evidence 702 to render the opinions he sets forth in his expert reports on the properties of polypropylene and the human clinical response to polypropylene implants.

a. Properties of Polypropylene Mesh

In his general report, Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that "[d]egradation occurs as either fragmentation of the mesh or oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues," and "[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size." (Trepeta General Report [Docket 235-1], at 5). BSC asserts that Dr. Trepeta is not qualified to put forth these opinions because he is not a material scientist, biochemist, or biomedical engineer. (*See* Trepeta Dep. [Docket 235-3], at 100:20–101:1). Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products. (*See id.* at 100:2–11).

In *Sanchez, et al. v. Boston Scientific Corp.*, I assessed this argument and disagreed with BSC:

> In making [its] argument, however, BSC downplays Dr. Trepeta's knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist "will be knowledgeable in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies." 33 Am. Jur. *Trials* § 17 (1986); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org (last visited Sept. 22, 2014) ("[Clinical pathologists] are involved in a broad range of disciplines, including surgical pathology, cytopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology."). Dr. Trepeta's thirty years' experience as a clinical pathologist therefore demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in

> particular, having examined fifty explant samples over the past five years. (*See* Trepeta General Report [Docket 86-1], at 2). According to Dr. Trepeta, by examining the mesh explants under a microscope, he has witnessed the polypropylene's chemical changes. (*See* Trepeta Dep. [Docket 110-3], at 217:14–19). Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I **FIND** that he is qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

No. 2:12-cv-05762, 2014 WL 4851989, at *20 (S.D. W. Va. Sept. 29, 2014). I **ADOPT** this holding here.

b. The Human Clinical Response to Polypropylene Mesh

Dr. Trepeta also opines that the "human body's pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function." (Trepeta General Report [Docket 235-1], at 6). BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of stress urinary incontinence and pelvic organ prolapse. (*See* Trepeta Dep. [Docket 235-3], at 109:21–23). In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta's opinions about the clinical response to mesh should be excluded.

In *Sanchez*, I addressed this argument and held:

> Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." [(*See* Trepeta Dep. [Docket 86-3], at 11:10–14)]. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. (*See id.*). Dr. Trepeta applied this pathologic

> process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id.*). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's motion on this point.

2014 WL 4851989, at *20 (footnote omitted). I **ADOPT** this holding here.

2. The Reliability and Relevance of Dr. Trepeta's Opinions

Next, BSC raises several objections to the reliability and relevancy of Dr. Trepeta's opinion testimony. I addressed each of these objections in *Sanchez* and consequently rely on *Sanchez* to explicate my conclusions here.

a. Reliability of Dr. Trepeta's Methodology in Formulating His Opinions

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. (Trepeta Dep. [Docket 235-3], at 61:10–12). He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 235-1], at 2). Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings correspond with the published research on mesh erosion and exposure in the vaginal wall. (*Id.* at 2–3). Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that "the pathology reports of

excised Boston Scientific Products . . . are consistent" with the acute, sub-acute, and chronic categories of the disease process. (*Id.* at 4).

As I held in *Sanchez*:

> BSC's strongest objection to Dr. Trepeta's methodology focuses on this third source of information. BSC argues that the twenty-four pathology reports were unreliable because: they were "hand-selected by Plaintiffs' counsel"; Dr. Trepeta only relied on seventeen of the twenty-four reports; and Dr. Trepeta did not review the medical records of any of the probed patients. (BSC's Mem. re: Trepeta [Docket 235], at 11–12). The plaintiffs respond that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five years and from his study of medical literature. Moreover, the plaintiffs argue that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. (*See* Pls.' Resp. in Opp. to Def.'s Mot. to Exclude Dr. Trepeta [Docket 110], at 13).
>
> The fact that each side's pathologist accepts this practice suggests that it is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency in that it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling the technique's operation"). The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the potential rate of error"). I confronted a similar situation in *Lewis, et al. v Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here are no assurances that [plaintiffs' counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan 15, 2014). Here, I similarly have no way to ensure that the plaintiffs' counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived from his review of the twenty-four pathology reports are **EXCLUDED**.

2014 WL 4851989, at *22. I **ADOPT** this holding, accepting Dr. Trepeta's opinions as reliable apart from those opinions based on his review of the twenty-four pathology reports.

b. Litigation Driven Opinions

BSC also argues Dr. Trepeta's opinions are unreliable because they are litigation-driven. Specifically, BSC asserts that Dr. Trepeta's "familiarity with the literature on polypropylene mesh comes only from his research and reading in connection with this litigation." (BSC's Mem. re: Trepeta [Docket 236], at 10). As in *Sanchez*, I disagree. Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Trepeta Report [Docket 235-1], at 2). In addition, he testified that he has "looked at mesh removed from the bodies of female vaginal walls under the microscope" and has seen degradation. (Trepeta Dep. [Docket 280-3], at 216:14–19). These activities occurred outside of this litigation. Thus, I **FIND** that Dr. Trepeta's opinions are not litigation-driven and **DENY** BSC's motion on this point.

c. Dr. Trepeta's Specific Causation Opinion

Dr. Trepeta also offers a specific causation opinion concerning Ms. Blankenship. Dr. Trepeta opines that Ms. Blankenship's

> symptoms of pain, infection, dyspareunia, voiding dysfunction and resulting diagnoses, and her medical treatment for urinary complications and pelvic pain complications are all directly attributable to the implantation of polypropylene surgical mesh in the Obtryx Trans-Obturator Tape surgical kit implanted April 8, 2009. . . . My personal experience as a pathologist with special training and focus on pathology of the vagina, as well as my knowledge and training, also evidences the known complications directly attributable to the pathological tissue response to a polypropylene implant such as [that] implanted in Ms. Blankenship.

(Trepeta Specific Report [Docket 235-2], at 4). Dr. Trepeta adds that the complications associated with the human body's pathologic response to the implantation of polypropylene mesh were present in Ms. Blankenship's medical records. (*Id.* at 5). BSC argues that Dr. Trepeta's specific causation opinion is unreliable because: (1) his general causation opinion is unreliable; (2) he is

not qualified to determine medical causation; and (3) he failed to conduct a reliable differential diagnosis.

Apart from Dr. Trepeta's review of the twenty-four pathology reports, I concluded that Dr. Trepeta's general causation opinion was reliable. Therefore, BSC's first argument fails. BSC's second argument also lacks merit because, as I have explained previously, a pathologist's job is to determine medical causation. *See In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) ("Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on [medical causation]."); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org (last visited Oct. 17, 2014) ("[Clinical pathologists] are physicians who use laboratory medicine and technology to identify and diagnose disease."). While Dr. Trepeta admits that examining women to diagnose pelvic pain and dyspareunia would go beyond his expertise as a pathologist, (*see* Trepeta Dep. [Docket 235-4], at 17:7–13, 20:6–9), Dr. Trepeta's opinion in this case is not based on his examination of women. Rather, he reaches his opinion by "review[ing] pathology slides and [correlating] that with the patient's symptoms." (*Id.* at 16:18–20). (*See also* Trepeta Dep. [Docket 280-5], at 46:18–21 ("Pathology is all about explaining clinical findings through tissue examination.")). Indeed, Dr. Trepeta applied this procedure in diagnosing Ms. Blankenship—he "personally reviewed three slides" belonging to Ms. Blankenship and observed reactions "typical of the reaction observed to polypropylene mesh." (Trepeta Report [Docket 235-2], at 4). In sum, as a pathologist, Dr. Trepeta is qualified to opine on medical causation based on his review of pathology slides.

BSC's final argument that Dr. Trepeta did not engage in a proper differential diagnosis presents a closer question. Dr. Trepeta admits that he did not "try to make a clinical diagnosis as to

why Miss Blankenship was having pelvic pain and pain on intercourse prior to receiving her Obtryx sling." (Trepeta Dep. [Docket 235-4], at 45:17–20). On the other hand, he explains that the foreign material present in Ms. Blankenship's pathology slides is "consistent with the Obtryx sling" because "by process of elimination, the patient has not had any other synthetic material implanted in that site." (Trepeta Dep. [Docket 280-5], at 85:18–20). Reviewing Dr. Trepeta's report and deposition testimony as a whole, I find that Dr. Trepeta has based his opinion in large part on reliable pathology methods—he reviewed pathology slides, considered the possible causes for the inflammation, and came to a diagnostic conclusion. (*See* Trepeta Rep. [Docket 235-2], at 4 (concluding that Ms. Blankenship's tissue inflammation appeared consistent with typical polypropylene mesh reactions)). Challenges to the accuracy of the diagnostic conclusion are better suited for cross-examination. Thus, I **DENY** BSC's motion to exclude Dr. Trepeta's specific causation opinions.[5]

In conclusion, Dr. Trepeta's general causation opinions satisfy *Daubert*, apart from his opinions based on the pathologic reports selected by the plaintiffs' counsel for his review, which are **EXCLUDED**. Dr. Trepeta's specific causation opinions likewise meet the standards of *Daubert*. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [Docket 235] is **GRANTED IN PART** and **DENIED IN PART**.

D. Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D.

[5] This holding is distinguishable from *Sanchez*, in which I excluded Dr. Trepeta's specific causation opinions. 2014 WL 4851989, at *23–24. In *Sanchez*, Dr. Trepeta did not examine any pathology slides in applying a differential diagnosis, instead supporting his opinion with Ms. Sanchez's medical records. *Id.* at *23. Although his failure to review Ms. Sanchez's tissue was not determinative in *Sanchez*, it contributed to the unreliability of his differential diagnosis in the face of damaging testimony. Here, however, Dr. Trepeta observed Ms. Blankenship's slides under a microscope, detected a foreign material, and concluded that the foreign material was polypropylene from the Obtryx sling by applying a process of elimination. Dr. Trepeta's personal review of the pathology slides brings a scientific basis to his correlation of Ms. Blankenship's symptoms and the presence of the mesh, which was lacking in *Sanchez*.

BSC seeks to exclude the opinions of Dr. Jimmy W. Mays and Dr. Samuel P. Gido. Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee, and Dr. Gido is an Associate Professor of Polymer Science and Engineering at the University of Massachusetts Amherst. (Mays & Gido Report [Docket 221-1], at 2, 4). Both have worked extensively in the area of polymer materials. Drs. Mays and Gido issued a joint expert report examining and assessing the polypropylene material mesh BSC used in the Obtryx product. (*Id.* at 5). In their report, Drs. Mays and Gido conclude that (1) polypropylene is susceptible to oxidation and degrades by an oxidative mechanism in the body; (2) analysis of explanted BSC Obtryx mesh shows clear sign of oxidative degradation; and (3) the Obtryx is thus defective and not suitable to serve as a permanent implant. (*Id.*). The report states that Drs. Mays and Gido relied upon their training and experience, provided materials, and underlying data from the testing in forming their opinions. (*Id.*). However, as discussed below, the deposition testimony proves otherwise. The reasoning in *Sanchez* substantially reflects the court's view of these issues as presented in this case. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. The *Sanchez* excerpts quoted throughout are to explicate the conclusions the court reaches below.

BSC argues that Drs. Mays and Gido's testing and the clinical conclusions drawn from that testing must be excluded because their testing is unreliable and their opinions are irrelevant. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Jimmy W. Mays, Ph.D. & Samuel P. Gido, Ph.D ("BSC's Mem. re: Mays & Gido") [Docket 222], at 2). Additionally, BSC argues that Drs. Mays and Gido's opinions are unreliable because they are litigation driven, as well as a poor fit that would not be helpful to the jury. (*Id.*). Finally, the defendant argues that some of the opinions offered by Drs. Mays and Gido should be excluded because they opine about BSC's

state of mind and make inadmissible legal conclusions. (*Id.*).

1. Chemical & Microscopic Testing

a. Background

As BSC takes particular issue with Drs. Mays and Gido's testing of the Obtryx explants, I will briefly discuss their testing procedures and results. Drs. Mays and Gido received exemplars of Obtryx products on September 24, 2013. (Mays & Gido Report [Docket 221-1], at 24). These exemplars were used as a control. (*Id.* at 18). The plaintiffs' counsel, Ms. Jennifer Black, arranged for Drs. Mays and Gido to also receive Obtryx mesh explants from Steelgate, a repository for explanted transvaginal mesh. (Aff. of Jennifer Black [Docket 272-7], ¶¶ 5–6, 12). Ms. Black identified the available BSC Obtryx explants by cross-referencing the firm's client list with the patient list retained by Steelgate. (*Id.* ¶¶ 9–11). Ms. Black determined that there were a total of fourteen such explants at Steelgate. (*Id.* ¶ 8). After identifying these explants, Ms. Black requested that the explants be sent to Dr. Gido with the appropriate chain of custody. (*Id.* ¶ 12).

On October 1, 2013, Dr. Gido received the fourteen explants. (Mays & Gido Report [Docket 221-1], at 24). The explants were sealed in plastic containers and came with chain of custody documentation. (*Id.*). Only eleven of the fourteen explants contained mesh suitable for testing. (*Id.*). Dr. Gido proceeded to conduct three microscopic analyses of the eleven explants: (1) Scanning Electron Microscopy ("SEM") to take pictures of the mesh fibers at high magnification and compare those images to the images published in the literature; (2) Energy Dispersive Spectroscopy ("EDS") to determine if there was oxygen in the mesh fibers; and (3) Transmission Electron Microscopy ("TEM") to identify amorphous regions in the mesh fibers that are more susceptible to oxidation. (*Id.* at 18).

Utilizing Steelgate's chain of custody, Dr. Gido sent the samples to Dr. Mays on October 22, 2013. (*Id.*). Only four of the samples sent by Dr. Gido had sufficient amounts of polypropylene mesh adequate for testing by Dr. Mays. Dr. Mays conducted three chemical analyses of the four samples: (1) Fourier Transform Infrared Spectroscopy ("FTIR"), a testing instrument that uses infrared to identify chemical groups containing oxygen; (2) Gel Permeation Chromotography ("GPC"), a test that separates molecules by size and quantifies the molecular weight of the polymer, which allowed Dr. Mays to estimate the reduction in molecular weight of the polypropylene explants; and (3) Thermogravimetric Analysis ("TGA") to determine if there were other additives or inorganic materials in the mesh. (Mays Dep. [Docket 221-2], at 49–50).

Drs. Mays and Gido included the following summary of results in their expert report:

SAMPLE	LENGTH OF TIME IMPLANTED	IMPLANT TIME CLASSIFICATION	MODEL	Cracking Observed by SEM	Oxidation In Fibers Observed by EDS	Oxidation In Fibers Observed by FTIR	Mz from GPC	Mw from GPC	Mw/Mn from GPC
Obtryx Control	—	None		0	no	no	1,030,000	377,000	4.26
Pinnacle Control 1	—	None		0	trace amounts	no	1,151,000	388,000	5.97
Pinnacle Control 2	—	None		0	no*	not tested			
XP-1	1 YR, 4 MOS.	Short	Obtryx Halo	2	yes	not tested			
XP-2	1 YR, 6.5 MOS.	Short	Pinnacle	0	yes	not tested			
XP-3	1 YR, 7 MOS.	Short	pinnacle	0	yes	yes	648,000	291,000	3.44
XP-4	1 YR, 10 MOS.	Short	Pinnacle	3	yes	not tested			
XP-5	2 YRS, 2.5 MOS.	Intermediate	Pinnacle	1	yes	not tested			
XP-6	2 YRS, 11 MOS.	Intermediate	Pinnacle	0	yes	not tested			
XP-7	3 YRS, 3 MOS.	Intermediate	Pinnacle	4	yes	yes	847,000	344,000	3.95
XP-8	4 YRS, 1 MO.	Long	Pinnacle	5	not tested	yes	735,000	326,000	3.53
XP-9	4 YRS, 4 MOS.	Long	Pinnacle	4	yes	not tested			
XP-10	4 YRS, 5 MOS.	Long	Pinnacle	3	yes	yes	742,000	314,000	3.91
XP-11	4 YRS, 9 MOS.	Long	Obtryx Halo	5	yes	not tested			

(Mays & Gido Report [Docket 221-1], at 19). However, Dr. Mays did not include the protocol or results of the TGA or TEM in the expert report. Instead, for the TGA, he produced that information to BSC in the form of his handwritten notes, which were taken from his lab notebook. (Mays Dep. [Docket 221-1], at 49–50).

b. Reliability

With respect to the reliability of Drs. Mays and Gido's testing, BSC makes several specific

arguments. However, I have previously reviewed the reliability of Drs. Mays and Gido's testing under *Daubert* and found their opinions unreliable because they (1) failed to control for error or bias and (2) did not establish or adhere to testing protocols. *See Sanchez*, 2014 WL 4851989, at *26. In *Sanchez*, I made the following findings:

> *i. Lack of Control for Error or Bias*
>
> Although plaintiffs' counsel selected the samples, counsel explained that these were the only Pinnacle and Obtryx samples available in the Steelgate repository. Therefore, unlike *Lewis*, where Dr. Klinge did not indicate whether the meshes examined constituted a large sample size of the repository's collection, here, these were the only samples available for testing. Furthermore, certain samples were not tested because they did not have enough mesh, not because of bias. Despite the differences in these two cases, the fact that Drs. Mays and Gido's sample was not very large or randomly selected affects the reliability of their testing. *See Edwards v. Ethicon*, No. 2:12-cv-09972, 2014 WL 3361923, at *39 (S.D. W. Va. July 8, 2014) (excluding plaintiffs' expert's analysis of pelvic mesh explants generally). Drs. Mays and Gido "[have] given no explanation as to whether [theirs] is a representative sample size . . . . Therefore I have no information as to the potential rate of error inherent in [their] observations." *Lewis*, 2014 WL 186872, at *8. Additionally, Drs. Mays and Gido have no knowledge of how the material they examined was explanted or how it was preserved and handled before reaching their lab. (Mays Dep. [Docket 99-1], at 304–05).
>
> Dr. Gido conducted EDS testing to differentiate between polypropylene fibers and biological material. In their report, Drs. Mays and Gido state that "the presence or absence (or near absence) of nitrogen as detected by EDS is the key discriminator between clean polypropylene fibers from which valid conclusions can be drawn or biomaterial covered fiber from which conclusions are less straightforward." (Mays & Gido Report [Docket 98-1], at 31). At his deposition, Dr. Gido acknowledged that on a relatively clean sample "there might be a little blip of nitrogen [in the EDS] and the question is, you know, is that nitrogen statistically significant." (Gido Dep. [Docket 99-2], at 154). However, Dr. Gido never determined the significance of potential "blips," although the data was available. (*Id.* ("I did not do that analysis, although the data is all there, and if that analysis needs to be done, I would contend it is not a new opinion.")).
>
> Similarly, in their report, Drs. Mays and Gido state that "[w]e need to base our conclusions related to fiber degradation on clean polypropylene fibers and make sure we are not looking at biological films coating the fibers." (Mays & Gido Report [Docket 98-1], at 31). However, both Dr. Mays and Dr. Gido admit in their

depositions that their inconsistent bleach treating techniques may have failed to remove all biologic material from the test samples. (*See* Mays Dep. [Docket 99-1], at 208; *see also* Gido Dep. [Docket 99-2], at 165). When asked explicitly whether they completed a statistical analysis or calculated a rate of error based on their tests, Dr. Gido admitted they did not. (Gido Dep. [Docket 99-2], at 154–55).

The key *Daubert* inquiry is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert II*, 43 F.3d at 1317. The small sample size and Drs. Mays and Gido's failure to determine the statistical significance of their results call into the question the reliability of their methods. Although *Daubert* is a flexible inquiry, these facts weigh heavily against the reliability of their opinions.

ii. Failure to Establish or Adhere to Testing Protocol

First and most simply, Dr. Mays states that "SEM is a very common tool," but when asked if he prepared any written methodology before completing the SEM testing, he admits that he did not. (Mays Dep. [Docket 99-1], at 162). In addition, Dr. Mays and Dr. Gido both reference Dr. Gido's completely subjective cracking standard he came up with for purposes of their testing. Dr. Mays admits that the standard cannot be found in any published material, and Dr. Gido admits that he has never created or used a cracking standard before. (*See id.* at 18; *see also* Gido Dep. [Docket 99-2], at 161).

Expanding on the brief discussion above, while the samples were with Dr. Gido for testing, Dr. Mays asked Dr. Gido to try bleach cleaning one of the explants to see if it was effective. (Gido Dep. [Docket 99-2], at 167). Dr. Gido used a 6% bleach concentration on explanted sample 11. (*See id.* at 193; Mays & Gido Addendum Report [Docket 111-5], at 2). In comparison, Dr. Mays used a 7.8% concentration to clean the explants and controls before testing. (*See* Mays & Gido Report [Docket 98-1], at 33). The bleach treatments were clearly inconsistent. Additionally, Drs. Mays and Gido have no explanation as to why a discussion of this testing was "mistakenly" omitted from their original report. (Mays Dep. [Docket 99-1], at 202).

Another mistake occurred after Dr. Gido returned the samples, and he discovered that he failed to conduct an EDS test on one of them, which he attributed to a mere oversight. (Gido Dep. [99-2], at 214–15). Finally, Dr. Mays conducted TGA testing on the explants to determine what additives were in the mesh, but for some reason did not include the results in their expert report. (*Compare* Mays Dep. [Docket 99-1], at 50, *with* Mays & Gido Report [Docket 98-1]).

Although Drs. Mays and Gido performed tests that are supported by the literature, the haphazard application of these tests, errors, and changes to their report lead to

> the conclusion that their methodology is unreliable. Vigorous adherence to protocols and controls are the hallmarks of "good science." *See Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 603 (S.D. W. Va. 1998). Accordingly, I **FIND** that the testing performed by Drs. Mays and Gido is unreliable, and therefore, **EXCLUDED**.

Sanchez, et al. v. Boston Scientific Corp., No. 2:12-cv-05762, 2014 WL 4851989, at *26–28 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert the same arguments regarding the reliability of Drs. Mays and Gido's testing that I addressed in *Sanchez*. Therefore, I **ADOPT** my prior ruling on the reliability of Drs. Mays and Gido's testing.

2. Expert Opinions Not Based on Testing[6]

a. Background

While BSC argues that Drs. Mays and Gido's unreliable testing should be excluded entirely, the plaintiffs respond by explaining that the testing "merely confirmed what [Drs. Mays and Gido] have long known because of their training, experience, and peer-reviewed published scientific literature." (Pls.' Mem. in Opp'n to Def.'s Mot. to Exclude Test. of Pls.' Expert ("Pls.' Mem. re: Mays & Gido") [Docket 272], at 4).[7] The plaintiffs contend that both the expert report and depositions support this explanation; however, they conveniently choose to cite only Dr. Mays's deposition in support of their proposition. (*See id.* at 4–5; *see also* Mays Dep. [Docket 272-5], at 65 ("I believe all of my conclusions are ones that one could reach simply by looking at

[6] I previously allowed a joint expert report, *see In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 644 (S.D. W. Va. 2013) (discussing the "Exponent Experts"), and there is "no reason to think the practice [is] always and inherently impermissible" under Rule 26. *Dale K. Barker Co., P.C. v. Valley Plaza*, 541 F. App'x 810, 815 (10th Cir. 2013) (explaining that "[c]o-authored expert reports aren't exactly uncommon"). For example, in *Barker*, the Tenth Circuit allowed a joint report when both experts "reviewed the same materials, and, working together, came to the same opinions." *Id.* at 816. However, when a joint report is not built on a reliable foundation, and instead, is confusing and contradictory, it becomes problematic and potentially inadmissible. *See id.* ("[I]f, for example, it isn't clear whether both experts adhere to all of the opinions in the report and they do not delineate which opinions belong to which expert." (citing *Dan v. United States*, No. CIV 01-25 MCA/LFG-ACE, 2012 WL 34371519, at * 2–3, *5 (D.N.M. Feb. 6, 2002)).

[7] Plaintiffs also argue that in addition to Drs. Mays and Gido's reliance on other sources, their testing is reliable, which is the same argument I considered and rejected above.

published literature on polypropylene that's been implanted into the human body combined with the knowledge of chemistry and polymer science and the behavior of polymeric materials."); *id.* at 140 ("So my opinion is based on my experience as a scientist, as a chemist. It's based on all the literature we looked at. It's based also on the testing that we did in this report."); *id.* at 260 ("My opinion in this case, and it was my opinion before I got involved in this case, is that polypropylene is so fundamentally susceptible to oxidative degradation that it's a poor choice for permanent implant where there's going to be tissue ingrowth.")).

The plaintiffs fail to point out or cite Dr. Gido's deposition testimony, which takes the opposite position. Dr. Gido explicitly states that "we're making this statement based on our own study and our own results. We're not getting it from the literature." (Gido Dep. [Docket 221-3], at 233). While Dr. Mays describes the testing as "confirmatory," Dr. Gido highlights the fact that he completed the testing first and then "got into the literature." (Mays Dep. [Docket 272-5], at 65; Gido Dep. [Docket 221-3], at 50). Dr. Gido admits that he had not reached his opinions before testing and emphasizes how important the data was in drafting his portions of the report. (*See* Gido Dep. [Docket 221-3], at 51 ("I would suspect the same – you know, I would probably conclude that there would likely be a problem with polypropylene, but I would not be as sure of it as I am having seen data that I took with my own hands and seen Dr. Mays's data.")). Based on the depositions, Drs. Mays and Gido clearly have different opinions regarding the nature and influence of the testing they performed.

I have determined that Drs. Mays and Gido's testing was unreliable, and Dr. Gido states that his opinions are based solely on the testing. Accordingly, I **FIND** that Dr. Gido's opinions are **EXCLUDED**. However, as discussed more fully below, because Dr. Mays indicates that he relied

primarily on other scientific sources, I **FIND** that Dr. Mays is permitted to testify generally about polypropylene degradation based on his experience and review of the literature.

b. Reliability

BSC argues that Dr. Mays's opinions are not reliable because they are litigation driven, not scientific, and not fair and balanced. With respect to the argument that Dr. Mays's expert testimony is litigation driven, I refer back to my above ruling that an expert's formulation of his opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. As I **FIND** Dr. Mays's opinions otherwise reliable, I need not address this argument further.

Next, BSC contends that Dr. Mays "selectively cite[s] several articles" and "fail[s] to include contrary statements or literature in [his] report." (BSC's Mem. re: Mays & Gido [Docket 222], at 14). I have previously reviewed the reliability of Dr. Mays's opinions under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *29. The parties in this case assert the same arguments regarding the reliability of Dr. Mays's expert opinions that I addressed in *Sanchez*. In *Sanchez*, I ruled as follows:

> Dr. Mays cites eight different studies supporting his proposition that polypropylene is not suitable as a permanent implant, many of which are the same peer-reviewed, published literature relied upon by other experts in previous MDL trials. *See Lewis*, 2014 WL 186872, at *11 (discussing plaintiffs' expert Dr. Uwe Klinge). Clearly these are studies reasonably relied upon in the field of polymer science. Additionally, Appendix C of the report lists 68 scholarly articles Dr. Mays considered in making his opinions, as well as hundreds of other documents. (Mays & Gido Expert Report App. C [Docket 111-3], at 1–22). If [BSC] take[s] issue with Dr. Mays's failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination.

Sanchez, 2014 WL 4851989, at *51.

Finally, BSC argues that Dr. Mays's opinions are a poor fit and would not be helpful to a jury because Dr. Mays was not able to correlate degradation to any clinical symptoms in an

individual patient. However, as I stated in *Sanchez*,

> I have repeatedly held that general causation testimony, including degradation opinions, is admissible under Rule 702, even if the plaintiffs might fail to carry their burden as to specific causation. *See, e.g.*, *Huskey*, 2014 WL 3362264, at *13. Additionally, in his deposition, Dr. Mays references complications that can arise in patients as a result of degradation. (Mays Dep. [Docket 99-1], at 131 ("I'm saying that degradation is the root cause of these devices failing to function the way they are designed in some cases and then the device not functioning properly is part of the problem.")). To the extent that BSC believes degradation is not clinically significant, it may cross examine Dr. Mays on that issue.
>
> Dr. Mays explicitly states that he relied not only on his knowledge and experience, but also on scientific literature, which are sufficiently reliable methods of forming his particular opinion. Accordingly, I **FIND** that Dr. Mays is permitted to testify generally that polypropylene is susceptible to oxidation and degrades, without specifically referencing the unreliable testing he conducted with Dr. Gido.

Sanchez, 2014 WL 4851989, at *51–52. Therefore, I **ADOPT** my prior ruling on Dr. Mays, as stated in *Sanchez*, and **FIND** that his opinions based on his experience and review of scientific literature should not be excluded.

3. State of Mind

Dr. Mays offers two opinions regarding BSC's state of mind and its knowledge of risks associated with polypropylene. (*See* Mays & Gido Report [Docket 221-1], at 5 ("BSC did not take into account polypropylene's propensity for oxidation during design of its Pinnacle and Obtryx mesh."); *id.* at 17 ("If the developers of Pinnacle and Obtryx were ignorant of this information on implantation of PP materials then they were incompetent to be in their line of business. If they were aware of these facts and chose to proceed anyway, they were taking an unconscionable, calculated gamble with the lives and wellbeing of others for the sake of their own profits.")). As I previously discussed, expert opinions on BSC's knowledge or state of mind are not helpful to the jury. *See* Fed. R. Evid. 702. Therefore, these opinions are **EXCLUDED**.

4. Legal Opinions

Dr. Mays offers two opinions that draw legal conclusions from the facts. (*See* Mays & Gido Report [Docket 221-1], at 17; *id.* at 19 ("The results of our own testing completely support and greatly strengthen this opinion that choice of PP as the material for the explants we tested rendered them unacceptably susceptible to degradation and was thus *incompetent and or negligent*.") (emphasis added)). In the Fourth Circuit, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Whether BSC failed to act as a reasonable and prudent medical device manufacturer is a question for the jury. To be clear, Dr. Mays may offer opinions that, as a polymer scientist, he does not believe the Obtryx is suitable to serve as a permanent implant, but his opinions cannot be phrased as legal conclusions. Therefore, these statements are **EXCLUDED**.

E. Motion to Exclude the Opinions and Testimony of Dr. Peggy Pence

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." (Pence Report [Docket 219-1], at 1). During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices; the development and content of product labeling; and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. (*See id.* at 1–4). In this matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of the Obtryx product prior to placing them on the market; (2) the Obtryx product was inadequately

labeled; (3) patients could not adequately consent to the surgical implantation of the Obtryx due to the misbranding of these products; and (4) BSC failed to meet the postmarket vigilance standard of care for their products, leading to further misbranding. BSC seeks to exclude Dr. Pence's testimony in its entirety.

I have previously reviewed the opinion testimony of Dr. Pence under *Daubert*. *See Sanchez et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *32–36 (S.D. W. Va. Sept. 29, 2014). The reasoning in *Sanchez* substantially reflects the court's view of this issue as presented here. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material as to the ruling on Dr. Pence. Therefore, I **ADOPT** my prior ruling on Dr. Pence as follows and thereby **GRANT IN PART** and **DENY IN PART** her expert opinion.

1. Dr. Pence's Qualifications

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence's opinions on BSC's medical devices cannot withstand *Daubert*.

In *Sanchez*, I ruled as follows, and I **ADOPT** that ruling here:

> The absence of a medical degree on Dr. Pence's curriculum vitae does not call into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like the [Obtryx]. Dr. Pence has over forty years of experience in the research and development of medical devices. (Pence Report [Docket 118-1], at 1). Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, . . . I **FIND** that Dr. Pence is qualified to render the opinions set forth

> in her expert report, including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding.

Sanchez, 2014 WL 4851989, at *33.

2. Dr. Pence's Opinions on Appropriate Pre-Market Testing

Having found that Dr. Pence is qualified to offer these opinions, I next address whether her opinions are relevant and reliable.

In her report, Dr. Pence opines:

> BSC should have performed adequate preclinical and clinical testing of the Obtryx Sling and Pinnacle PFR Kits prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device manufacturer.

(Pence Report [Docket 219-1], at 44). In reaching this conclusion, Dr. Pence considered the risks associated with polypropylene mesh (*id.* at 31–36); the statements in Material Safety Data Sheets provided by the polypropylene supplier in 2004 indicating that polypropylene should not be used for permanent implantation in the human body (*id.* at 36–40); and the developmental history of BSC products (*id.* at 41–43).

In *Lewis, et al. v. Ethicon*, Dr. Pence gave a similar opinion. No. 2:12-cv-4301, 2014 WL 186872, at *18–19 (S.D. W. Va. Jan. 15, 2014). She opined that the defendant did not conduct the required investigative tests on the specific risks of a transvaginal mesh product, but she failed to support this opinion with any authority suggesting that the performance of such tests was needed. *Id.* at 18. Without a reliable foundation, I excluded Dr. Pence's opinion as unreliable. *Id.* at 19. Here, BSC argues that Dr. Pence's expert report should again be excluded as unreliable because it fails to point to any authority requiring BSC to perform the tests that Dr. Pence believes should have been conducted. The plaintiffs counter that Dr. Pence has revised her report to fix the

deficiencies identified in *Lewis*. This time around, the plaintiffs argue, Dr. Pence has "clearly demonstrated that her methodology and opinions were not based upon her 'professional opinion' alone" and instead arose from her review of a "voluminous amount of peer-reviewed scientific articles, data, government codes and regulation, deposition testimony provided in this litigation, and internal documents received from BSC." (Pls.' Resp. in Opp. To Def.'s Mot. to Exclude Dr. Peggy Pence [Docket 274], at 5).

In *Sanchez*, I agreed with the plaintiffs and concluded that

> Dr. Pence's bolstered expert report [Docket 118-1] has tempered my previous concerns about the reliability of her opinion on this issue. Dr. Pence has cited to multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product. For instance, she describes a 2006 study conducted by the French National Authority for Health ("HAS"), in which it evaluated the safety and efficacy of vaginally implanted mesh for the treatment of genital prolapse. (Pence Report [Docket 118-1], at 9). HAS concluded that "the use of mesh implants for transvaginal correction of genital prolapse remained a matter of clinical research" and recommended prospective studies on the anatomical and functional outcomes of mesh implantation, the mid- to long-term effects, possible adverse events like erosion, and the management of erosions and retractions. (*Id.* at 10). Dr. Pence also discusses the recommendations of the National Institute for Health and Care Excellence, which include the warning that transvaginal mesh repair "should be used with special arrangements for clinical governance, consent and audit or research." (*Id.* at 43).
>
> In contrast with *Lewis*, Dr. Pence's opinion in this case is backed by authoritative studies that recommend the performance of clinical trials and long-term follow-ups before using polypropylene mesh. Thus, her opinion on the inadequacy of BSC's pre-market testing is more than a bare declaration of her professional opinion. Accordingly, I **FIND** that Dr. Pence's methodology is reliable under *Daubert* and **DENY** BSC's motion with respect to this opinion.

Sanchez, 2014 WL 4851989, at *34. I **ADOPT** this ruling here.

3. Dr. Pence's Opinions on the Adequacy of BSC's Product Labels

Dr. Pence proffers two opinions regarding the labeling of the Obtryx. First, she states that "BSC marketed [these products] without adequate instructions for use throughout the life of these

products . . . , in particular, without adequate warnings, precautions, and information about the likelihood and extent of potential risks." (Pence Report [Docket 219-1], at 62). Second, she states that "patients implanted with the Obtryx Sling or Pinnacle mesh were prevented from . . . giving true informed consent as a result of BSC's inadequate professional and patient labeling." (*Id.* at 63). She then offers a list of warnings and risks that she believes should have been included in the products' instructions for use ("IFU") and patient brochures.

BSC asserts that these opinions should be excluded because they relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), which is irrelevant in this case and consequently unhelpful to the jury. The plaintiffs agree that whether BSC violated the FDCA is not relevant and that Dr. Pence will not offer an opinion on that issue. The plaintiffs stress, however, that Dr. Pence's testimony about labeling is relevant to the plaintiffs' failure to warn claim. To assess the validity of this claim, the jury will need to understand what information should be included in IFUs and patient brochures but was not included by BSC—the plaintiffs argue that Dr. Pence can provide such understanding to the jury. I agree that such testimony might help guide the jury in reaching a verdict on these state law claims, which consider the appropriateness of product labeling, and as such, her opinions are relevant.[8] *See, e.g.*, *Church v. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989) (explaining that in failure to warn cases, "the focus is not so much on a flawed or physical condition of the product, as on its unsafeness arising out of failure to adequately label, instruct or warn" (quoting *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (W. Va. 1979))).

[8] In *Lewis, et al. v. Ethicon, Inc.*, I concluded that Dr. Pence's opinions on product labeling would "confuse and mislead the jury" because the state law claims of failure to warn and breach of warranty no longer existed in the case. 2:12-cv-4301, 2014 WL 186872 (S.D. W. Va. Feb. 3, 2014). Here, however, the failure to warn claim is still pending, and so my conclusions in *Lewis* are inapposite on this point.

BSC adds that even if Dr. Pence's opinions on BSC's labeling practices are relevant, they lack a reliable basis. In BSC's view, Dr. Pence does not provide any authority supporting her assertion that BSC's labeling fell short of the standard of care, and instead, she simply insists that BSC "should have gone further." (Def.'s Mem. in Supp. of its Mot. to Exclude the Ops. and Test. of Peggy Pence ("BSC's Mem. re: Pence") [Docket 220], at 8 (quoting Pence Dep. [Docket 219-3], at 328:3)). In response, the plaintiffs point to Dr. Pence's reliance on medical publications and the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database as evidence that Dr. Pence supported her opinions with authority. (*See* Pence Report [Docket 219-1], at 49–50).

Again, the reasoning in *Sanchez* reflects the court's view of this issue as presented here, and I **ADOPT** the *Sanchez* ruling as quoted below:

> Indeed, Dr. Pence cites to various publications and data throughout her report. However, the information she references—literature and data on the reported complications associated with Pinnacle mesh—does not go to the heart of her opinion—that BSC failed to meet the "standard of care required of a medical device manufacturer" in its deficient labeling of its product. (*Id.* at 63). In other words, although this authority demonstrates that complications occurred, it does not provide any guidance as to whether these complications should have been included as warnings in the Pinnacle's IFU. Eliminating this peripheral information, Dr. Pence is left with *ipse dixit* sources like "the standard of care" (*id.*) and "a matter of ethics" (*id.* at 61), both of which fall short of *Daubert*'s reliability prong. *See Daubert*, 509 U.S. at 594 (explaining the importance of ascertainable "standards" to govern the expert's methodology in reaching his opinion).
>
> Dr. Pence also utilizes FDCA provisions and FDA regulations to craft criteria for the information that should be included in medical device labeling. (*See* Pence Report [Docket 118-1], at 62 n.257–59, 63 n.260–61). As explained above, this may very well be relevant to the state law claim of failure to warn. *Daubert*, however, advises courts to keep in mind the other rules of evidence when evaluating expert testimony. *See Daubert*, 509 U.S. at 595 ("Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules . . . ."). Rule 403, which permits exclusion of relevant evidence "if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury," Fed. R. Evid. 403,

> carries particular significance in *Daubert* decisions because "[e]xpert evidence can be both powerful and quite misleading." *Daubert*, 509 U.S. at 595 (internal quotations omitted). Here, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the failure-to-warn claim than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in [West Virginia], whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling materials. 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. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim") (internal quotations omitted).
>
> In sum, the only basis for Dr. Pence's opinions on the adequacy of BSC's product labeling is violation of the FDCA and FDA regulations. Such a violation, however, is not probative to the claims at issue. Moreover, asserting a violation of the FDCA is a legal conclusion, not an expert opinion. Accordingly, Dr. Pence's opinion testimony on BSC's labeling practices, both in the IFU and the patient brochure, is **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *35–36.

4. Opinion on Postmarket Vigilance

In her last opinion, Dr. Pence proffers that BSC "deviated from the standard of care by its failure to report to [the] FDA a number of adverse events that met the criteria for Medical Device Reporting, rendering the Obtryx and Pinnacle devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA." (*See* Pence Report [Docket 219-1], at 91). BSC argues that whether BSC "reported certain adverse events to the FDA is not helpful to the jury" in determining whether BSC provided adequate warnings or whether its products were defective. (*See* BSC's Mem. re: Pence [Docket 220], at 9).

For the reasons explained in *Sanchez*, I agree with BSC.

> Dr. Pence cites to FDA public health notifications, the FDA's corporate warning letter to BSC, and the FDCA's Medical Device Reporting regulations. Contrary to the plaintiffs' assertions, however, the FDCA's reporting requirements and BSC's

> alleged violation of them have minimal relevance. First, the plaintiffs have not brought any claims concerning the FDCA. Second, even if an explanation of BSC–FDA communications could shed light on the state law claims at issue, testimony on whether or not BSC complied with the FDCA would constitute an impermissible legal conclusion rather than an expert opinion. And finally, . . . opinion testimony on the labyrinth of reporting regulations within the FDCA has little probative value compared to the substantial risk of jury confusion, particularly when both parties agree that "whether, how, and when BSC communicated safety information to the FDA is irrelevant." (*See* Pls.' Resp. re: Pence [Docket 122], at 17). Accordingly, . . . I **EXCLUDE** Dr. Pence's opinions on postmarket vigilance.

Sanchez, 2014 WL 4851989, at *36.

In conclusion, Dr. Pence can testify on pre-market testing, but her other opinions on the adequacy of product labels and the reporting of adverse events to the FDA are **EXCLUDED**. As such, BSC's Motion to Exclude Peggy Pence [Docket 219] is **GRANTED IN PART** and **DENIED IN PART**.

F. Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D.

BSC moves to exclude the opinions and testimony of Thomas H. Barker, Ph.D. Dr. Barker is a biomedical engineer who seeks to opine as to the behavior of polypropylene mesh inside of the human body. (*See* Barker Report [Docket 223-1], at 1, 4–5). He bases his opinions on mechanical stress tests that he conducted on the Obtryx and Pinnacle products, his experience, scientific literature, and internal documents. (*See id.* at 3). BSC argues that Dr. Barker's opinions are unreliable and irrelevant. In particular, BSC argues that Dr. Barker's testing methodology was flawed, that his opinions are litigation driven, that he is unqualified to opine as to polypropylene and product design, and that Dr. Barker seeks to offer impermissible state of mind testimony.

I have previously reviewed the opinion testimony of Dr. Barker under *Daubert*. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *5–10 (S.D.

W. Va. Sept. 29, 2014). The parties in this case assert arguments on the admissibility of Dr. Barker's expert opinion that I addressed in *Sanchez*. To the extent that there are differences in fact or exhibits, the court does not find them sufficiently material to this case. Thus, I **ADOPT** my prior ruling on Dr. Barker as follows and thereby **GRANT** BSC's motion. I will address additional arguments raised by the parties in this case below.

1. Qualifications

BSC challenges Dr. Barker's qualifications. In *Sanchez*, I found Dr. Barker qualified to opine as to the properties of polypropylene, and I **ADOPT** the same reasoning here:

> Dr. Barker holds a Ph.D. in biomedical engineering and is currently on the faculty of a joint department within the Georgia Institute of Technology and Emory University School of Medicine. He states in his expert report that his research focuses on
>
> > the effects of mechanical forces and tissue/material mechanical properties (e.g. stiffness) on the host response. I am trained and have extensive expertise in the evaluation of biomaterial mechanical properties, biomaterial/implant design, the foreign body host response, and human tissues under repair and fibrosis, including analyses of cell/molecular biological outcomes.
>
> ([Barker Report [Docket 71-1],] at 2). He conducted postdoctoral research focusing on "exploring the mechanisms of biomaterial associated fibrosis (e.g. the foreign body response)." (*Id.*). Additionally, Dr. Barker has authored several book chapters and peer-reviewed articles on biomaterials and biomedical engineering. (*See id.*).

Sanchez, 2014 WL 4851989, at *5–6. As I note in *Sanchez*, even though Dr. Barker is qualified, I must still determine that his method is reliable. *Id.* at 6.

2. Admissibility of Opinions Based on Dr. Barker's Mechanical Testing

BSC argues that Dr. Barker's opinions based on his mechanical testing are unreliable and irrelevant. In particular, BSC argues that Dr. Barker's testing is flawed because it "1) does not replicate the published protocol he claims to have followed; 2) fails to utilize a sufficient sample

size; 3) fails to meet the standards required for publication in a peer-reviewed journal; and 4) does not replicate the physiological environment or forces experienced in the female pelvic floor." (Def. BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Thomas H. Barker, Ph.D. ("BSC's Mem. re: Barker") [Docket 224], at 5). In *Sanchez*, BSC raised the same arguments.

a. Dr. Barker Failed to Follow Published Protocols

BSC argues that Dr. Barker's failure to soak the pieces of mesh in a saline bath, contrary to published protocols, is unreliable. The Shepherd and Moalli protocols call for the use of a saline bath as part of testing to help better replicate the physiological environment of the human body. In *Sanchez*, I found that this deviation from protocols without a scientific basis rendered his method flawed:

> His only reasoning was that Georgia Tech denied him permission to submerge its equipment in saline, a "potentially corrosive" solution. (*Id.* at 197:20–198:21). The difference in the results obtained by Dr. Barker and by Drs. Shepherd and Moalli further demonstrate the unreliability of his method. Dr. Barker's tests revealed two to four times more relative elongation of the mesh than Drs. Shepherd and Moalli's tests. (*See* Shepherd, *supra*, at 617; Moalli, *supra*, at 662; Barker Report [Docket 71-1], at 21).

Sanchez, 2014 WL 4851989, at *7. Moreover, I found that the use of a saline bath to replicate the human body was particularly important because Dr. Barker seeks to opine as to the in vivo effects of mesh. *See id.*

In this case, the plaintiffs in response raise an additional argument as to this matter. They submit an exhibit that seems to refute my finding. (*See* Pls.' Ex. D [Docket 267-4]). The plaintiffs provide a portion of Dr. Barker's testimony "in a recent trial pelvic mesh trial[,] [sic]" where he explains that he did follow a published testing protocol and that he did, in fact, soak the mesh in a

saline bath for testing. (Pls.' Resp. to Def.'s Mot. to Exclude the Ops. And Test. of Dr. Barker ("Pls.' Resp. re: Barker"), [Docket 267], at 14; *see* Pls.' Ex. D [Docket 267-4], at 1073:5–12, 1073:19–1074:4). In their response, the plaintiffs also assert that "Dr. Barker pre-soaked the mesh in a saline solution to mimic the bodily fluids, just as performed by Dr. Moalli at the University of Pittsburgh." (Pls.' Resp. re: Barker [Docket 267], at 14).

However, this prior testimony is at odds with Dr. Barker's expert report and deposition in this case. In his expert report, Dr. Barker writes that, "[p]rior to this case, I have never given sworn testimony in a litigation proceeding." (Barker Report [Docket 267-1], at 3). Therefore, it is unclear when and why Dr. Barker provided the testimony that the plaintiffs attached in their Exhibit D [Docket 267-4]. Also, the plaintiffs provide very minimal information about his previous testimony. Exhibit D contains merely three pages of a transcript and contains no case name. The only identification of the case is in the plaintiffs' response, where they reference "Ex. D; pgs 1072-1074 of Albright v. BSC." (Pls.' Resp. re: Barker [Docket 267], at 14). The plaintiffs provide no citation number for "Albright v. BSC" and give no information about whether Dr. Barker conducted additional testing for *Albright* or submitted a different expert report in *Albright*.

Furthermore, the plaintiffs attached portions of Dr. Barker's deposition for this case which contradict his *Albright* testimony. In his deposition for this case, Dr. Barker testifies that he did *not* soak the mesh that he tested in a saline bath:

> Q: It goes on to say that, [t]he mesh was allowed to sit in the 37-degree Celsius saline bath for 10 minutes prior to testing. Correct?
>
> A: Correct.
>
> Q: Obviously, in your test the mesh did not sit in any 37-degree Celsius saline bath prior to testing; is that right?

A: That's correct.

(Barker Dep. [Docket 267-2], at 202:13–21). Also, in their response, the plaintiffs actually reference the fact that Dr. Barker failed to use a saline bath. (*See, e.g.*, Pls.' Resp. re: Barker [Docket 267], at 14 ("Moreover, the only reason Dr. Barker did not submerge BSC's meshes in a saline bath was because Georgia Tech . . . has a policy that forbids the submersion followed in the Moalli Protocol") (citations omitted)). As a result, the plaintiffs' argument is inconsistent and unavailing.

For the reasons stated above and in *Sanchez*, I find Dr. Barker's methodology to be unreliable.

b. Dr. Barker Failed to Use a Sufficient Sample Size

BSC next argues that Dr. Barker failed to use a sufficient sample size when he tested one piece of Obtryx mesh and 2 pieces of Pinnacle mesh. In *Sanchez*, I agreed with this argument, especially since Dr. Barker admitted that a statistical test cannot be performed on a sample size of one:

> Dr. Barker admits that having a sample size of one is "insufficient to perform statistical analysis." (Dr. Barker Dep. [Docket 71-4], at 233:17–234:5). As a result, it is difficult to predict whether his results were merely chance occurrences. Dr. Barker explains that he wanted additional materials and he would have conducted additional testing if they had been provided:
>
> > Q: In fact, a lot of the results that Dr. Moalli has published that are different than your results, don't you think you need to test another piece of Obtryx mesh to confirm or not confirm the results that you got based on your N equals 1?
> >
> > A: I would have liked to have been provided with materials, additional materials to do additional testing.

(*Id.* at 233:3-12) (objections omitted).

Sanchez, 2014 WL 4851989, at *7–8. As a result, Dr. Barker's sample size was a flaw in his method.

c. Dr. Barker's Testing Failed to Meet Peer Reviewed Standards

BSC argues that Dr. Barker's testing was flawed because it was not up to peer-reviewed standards. In *Sanchez*, I noted that Dr. Barker admits to this in his deposition testimony:

> Q: Would you agree with me that your testing that you performed on the Obtryx with an N of 1 wouldn't meet standards to be published in a peer-reviewed journal?
>
> A: I would.
>
> Q: And would you agree with me that your testing that you did on Pinnacle with an N of 2 wouldn't meet the standards to be published in a peer reviewed journal?
>
> A: I would agree.

Id. at *8 (citing Barker Dep. in *Sanchez* [Docket 71-4], at 301:20–302:5). I **ADOPT** this same reasoning here and find that this factor weighs against finding Dr. Barker's method reliable.

d. Dr. Barker's Testing Did Not Replicate In Vivo Conditions

BSC argues that Dr. Barker's method is flawed because it failed to replicate the physiological multi-directional forces in the female pelvic floor. In *Sanchez*, I agreed that Dr. Barker's uniaxial testing was unreliable to base opinions on the behavior of the mesh in vivo:

> [B]ecause Dr. Barker's method did not account for the multi-directional forces inside of the female pelvis, his opinions about the effect of the mesh once implanted in vivo are unreliable and do not survive *Daubert* scrutiny. Even Drs. Shepherd and Moalli note that their studies do not conclusively reveal the mesh's behavior in the human body. (*See* Shepherd, *supra*, at 619 (stating that "this experimental setup allows us to draw only preliminary conclusions about the various meshes"); Moalli, *supra*, at 663 (noting that "the behavior of these slings in vivo and after incorporation into host tissue may be inferred, but is not directly apparent from these studies")).

Sanchez, 2014 WL 4851989, at *9. I **ADOPT** this reasoning from *Sanchez* here, and based on the above four arguments I **FIND** Dr. Barker's method to be unreliable.

e. Plaintiffs Argue that Dr. Barker's Method Was Generally Accepted

In this case, the plaintiffs raise an additional argument as to the reliability of Dr. Barker's method. The plaintiffs contend that Dr. Barker's testing was generally accepted within the scientific community. (Pls.' Resp. re: Barker [Docket 267], at 11–12). In support, the plaintiffs point to Dr. Barker's deposition testimony, where he explains that his general method of testing material—reading relevant scientific literature, developing a testing protocol, and then conducting "cyclic tensile testing and stress deformation analyses" in accordance with the developed testing protocol—is generally accepted within his field. (Barker Dep. [Docket 267-2], at 324:7–327:16). The plaintiffs argue that general acceptance "definitively forecloses a *Daubert* challenge." (Pls.' Resp. re: Barker [Docket 267], at 12).

The trial judge must "ensur[e] that an expert's testimony . . . rests on a reliable foundation" and has "flexib[ility]" in making this assessment. *Daubert*, 509 U.S. at 594, 597. Even if cyclic tensile testing and stress deformation analyses are generally accepted in the bioengineering field, the plaintiffs' argument does not cure the fatal deficiency in Dr. Barker's method—that he failed to take measures to replicate the human body when forming and providing opinions as to the mesh's behavior in vivo. For the reasons stated above and in *Sanchez*, I find Dr. Barker's methodology to be unreliable. *See Sanchez*, 2014 WL 4851989, at *5–10.

Therefore, as I concluded in *Sanchez*, Dr. Barker's method was unreliable and his opinions based on this method are **EXCLUDED**.

3. Admissibility of Opinion Regarding the Mechanical Mismatch Between the Mesh and the Human Body

BSC challenges Dr. Barker's opinion regarding a mechanical mismatch between the mesh and the human body and the adverse in vivo effects resulting from that mismatch. BSC argues that it is unreliable. In *Sanchez*, I agreed because Dr. Barker based his calculation as to the mesh on his unreliable testing:

> [H]e based his elastic modulus calculations of the Pinnacle mesh on his methodologically flawed and unreliable testing. . . Furthermore, as explained above, Dr. Barker's testing does not replicate the forces and environment of the human body and, therefore, his opinions regarding the mesh's effects in vivo are unreliable.

Id. at *9. I **ADOPT** this reasoning here and find that Dr. Barker's opinions based on the mechanical mismatch are unreliable and, thus, **EXCLUDED**.

4. BSC Argues that Dr. Barker's Opinions are Litigation Driven

BSC also argues that "Dr. Barker's opinions are unreliable because they are litigation driven[.]" (BSC's Mem. re: Barker [Docket 224], at 2). BSC raised this same argument in *Sanchez*, and, thus, I **ADOPT** my reasoning:

> [O]therwise reliable expert testimony will be admitted even if litigation driven. Because I find Dr. Barker's opinions to be otherwise unreliable and inadmissible, I need not address this argument.

Sanchez, 2014 WL 4851989, at *9.

5. Relevancy of Dr. Barker's Opinions Based on His Testing of the Pinnacle

Dr. Barker tested both the Pinnacle and Obtryx products. The Obtryx is a product at issue in this case, but the Pinnacle device is not at issue in this case. Because I find his opinions to be unreliable, I need not address the relevancy of Dr. Barker's opinions based on his testing of the Pinnacle device. *See Daubert*, 509 U.S. at 594–95 (noting reliability and relevancy requirement for expert testimony).

6. Plaintiffs' Relevancy Argument Regarding *Lewis v. Ethicon*

In this case, the plaintiffs raise an additional argument as to the relevancy of Dr. Barker's testimony. The plaintiffs argue that "[t]he crux of Dr. Barker's opinions, and hence his role in this case, is to provide expert evidence of the precise design engineering failure in BSC's meshes." (Pls.' Resp. re: Barker [Docket 267], at 17). As a result, the plaintiffs contend that "Dr. Barker's opinions provide the precise evidence that the plaintiff in *Lewis v. Ethicon* lacked and warranted a directed verdict[,]" and that, therefore, his testimony is helpful to a jury. (*Id.* (citing *Lewis* trial transcript)).

As I explained in *Sanchez*, I find Dr. Barker's method to be unreliable, and I exclude his opinions on this basis. As a result, I do not need to address the relevancy of Dr. Barker's testimony. *See Daubert*, 509 U.S. at 594–95 (noting requirement that expert testimony be both reliable and relevant). However, I note that the portions of the *Lewis* trial transcript in which the plaintiffs cite in support of their argument refer to specific causation. (*See* Pls.' Ex. E *Lewis* Trial Tr. [Docket 267-5], at 60:5–22, 62:10–15). Dr. Barker does not offer specific causation opinions here.

7. Dr. Barker's Proposed State of Mind Testimony

BSC argues that Dr. Barker is unqualified to opine as to product design or testing and that his proposed state of mind testimony is inadmissible. In *Sanchez*, BSC made these same arguments. However, I did not reach the issue of Dr. Barker's qualifications as to product design or testing because I found his state of mind testimony to be impermissible expert testimony:

> Dr. Barker contends that "BSC designed the Pinnacle . . . to meet the specification of substantial similarity to products pre-existing on the market, rather than engage in the engineering and design process of development of a safe and effective medical product (even for one similar to a pre-existing product in the market)" and that this "is inconsistent with appropriate medical device design principles."

(Barker Report [Docket 71-1], at 4, 15). These opinions relate to the state of mind of BSC and are, thus, **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *10. I **ADOPT** this reasoning from *Sanchez* in this case.

Therefore, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. on the grounds explained above and in *Sanchez*. *See id.* at *5–10.

G. Motion to Exclude the Opinions and Testimony of Donald R. Ostergard, M.D.

As one of the five founders of the American Urogynecological Society, Dr. Ostergard is a seasoned obstetrician and gynecologist, having practiced in the field since 1970. He has also assumed several academic roles, most recently serving as a professor of obstetrics, gynecology, and women's health at the University of Louisville. The plaintiffs offer Dr. Ostergard to testify as an expert witness on the properties of polypropylene; the design of the Obtryx sling; the regulatory process of the FDA, specifically with regard to product labeling; and the motives and ethics of BSC. (*See generally* Ostergard Report [Docket 217-2]). BSC seeks to exclude Dr. Ostergard's expert opinions under *Daubert*. I address BSC's arguments in turn.

1. Dr. Ostergard's Qualifications

Although Dr. Ostergard has an impressive background as a physician, BSC argues that his medical training does not qualify him under Federal Rule of Evidence 702 to render the opinions set forth in his expert report.

a. Opinions on the Properties of Polypropylene and the Obtryx Product Design

First, Dr. Ostergard offers opinions on the "defective" qualities of the polypropylene mesh used in the Obtryx sling, such as its "impurity" and its tendency to shrink, degrade, and oxidize. (Ostergard Report [Docket 217-2], ¶ 10). BSC moves to exclude these opinions because Dr. Ostergard's clinical experience "does not qualify him to testify as to the specific chemical

composition and attributes of polypropylene." (BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Donald R. Ostergard, M.D. ("BSC's Mem. re: Ostergard") [Docket 218], at 5). In short, BSC argues that because Dr. Ostergard is not a biomaterials expert, he cannot testify about the properties of polypropylene.

I can dispose of BSC's objection by referring back to my ruling on a prior *Daubert* challenge brought against Dr. Ostergard:

> It is difficult to deride Dr. Ostergard's qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic and biologic materials in pelvic reconstruction, including polypropylene mesh. He has extracted polypropylene mesh products from patients. He has treated them for mesh-related complications. He also performed preliminary theoretical work on a new pelvic mesh device for American Medical Systems.
>
> Dr. Ostergard has conducted scanning electron microscope imaging of mesh. He is also participating in an on-going study of its degradation characteristics in conjunction with his University of Louisville colleagues. Finally, Dr. Ostergard has published, in a peer reviewed setting, on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980s. *I conclude that Dr. Ostergard's qualifications are sufficient to testify about polypropylene.*

(*Jones v. Bard, Inc., et al.*, No. 2:11-cv-00114 [Docket 391], at 6 (S.D. W. Va. Jan. 6, 2014) (footnote omitted) (emphasis added)).

Dr. Ostergard also opines about the "procedure design promoted by BSC." (Ostergard Report [Docket 217-2], ¶ 12). He concludes that insertion of the Obtryx through the vagina, a "contaminated surgical field," is "dangerous" and that the proximity of the Obtryx to various pelvic organs and vessels creates a "risk of injury." (*Id.*). BSC argues that Dr. Ostergard has no experience in designing mesh products, and consequently, he lacks the qualifications necessary to opine on alleged design defects of the Obtryx. The plaintiffs respond by pointing to Dr. Ostergard's extensive knowledge of the pelvic anatomy and pelvic reconstructive surgery.

Furthermore, the plaintiffs emphasize Dr. Ostergard's published research on polypropylene materials, as well as his experience with the development of other mesh devices.

After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products. As I explained in *Jones*, any challenge to his demonstrated expertise is "better suited for cross examination." (*Jones*, No. 2:11-cv-00114 [Docket 391], at 9).

In conclusion, I **FIND** that Dr. Ostergard is qualified to opine on the properties of polypropylene and the design of the Obtryx sling.

b. Opinions on FDA Regulatory Requirements and Product Labeling

Dr. Ostergard also comments on BSC's alleged noncompliance with FDA regulations, particularly as they relate to product labeling. BSC disputes Dr. Ostergard's qualifications to opine on these matters, asserting that his "familiarity" with the warnings on mesh implant products does not rise to the level of expertise under *Daubert*. (BSC's Mem. re: Ostergard [Docket 218], at 7). The plaintiffs, on the other hand, contend that Dr. Ostergard's experience as a urogynecological surgeon makes him "extremely well suited" to describe the information that BSC should have included on the directions for use and brochure for the Obtryx sling. (Pls.' Opp. to BSC's Mot. to Exclude Dr. Ostergard ("Pls." Resp. re: Ostergard") [Docket 286], at 8). Moreover, Dr. Ostergard has "taken a course on the FDA process" and reviewed internal BSC documents that, in the plaintiffs' view, give him the knowledge of the regulatory process needed to support his opinions.

(*Id.*).

Without more, however, Dr. Ostergard's distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance. First, Dr. Ostergard admitted that he is "not an expert in FDA regulations." (Ostergard Dep. [Docket 217-1], at 395:23–25). Second, his understanding of medical device warnings does not exceed the knowledge of physicians in general. That is, he has never drafted a device warning, and he only knows the "information that would be useful to the physician and his counseling of patients." (*Id.* at 402:15, 20–23).[9] This minimal experience with medical device warnings and FDA regulations does not satisfy the "knowledge, skill, experience, training, or education" required under Rule 702. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) ("Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process."). Accordingly, I **EXCLUDE** Dr. Ostergard's opinion testimony as it relates to product labels, the Obtryx's directions for use, and FDA compliance.

Having excluded Dr. Ostergard's FDA opinions for insufficient expertise, I do not need to consider *Daubert*'s follow-up question of whether these opinions would be helpful to the jury. My ruling in *Sanchez*, however, provides an analysis on the issue that I could easily apply here. *See Sanchez et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *35 (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

[9] The fact that Dr. Ostergard took a single online course on the FDA regulatory process—a course that is freely available to the public—does not alter my conclusion that Dr. Ostergard lacks the qualifications necessary to opine about BSC's compliance with FDA regulations.

relates to the FDCA or FDA regulations.").

2. Reliability of Dr. Ostergard's Opinions on Polypropylene

Next, BSC argues that this court should exclude Dr. Ostergard's opinions on polypropylene—that it is toxic, impure, and subject to degradation and shrinkage—because his opinions do not satisfy *Daubert*'s reliability prong. Specifically, according to BSC, these opinions are unreliable because (1) they are not generally accepted in the medical community; (2) Dr. Ostergard has not conducted testing to support these theories; and (3) Dr. Ostergard has based his opinions on selective review of scientific literature. The plaintiffs claim that BSC's objections concern the weight, not the admissibility, of Dr. Ostergard's opinions.

As an initial matter, general acceptance is merely one factor a court should consider in determining admissibility of expert testimony. *See Kumho Tire Co. v. Carmichael*, 527 U.S. 137, 151 (1999) ("[*Daubert*'s] list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged."). Here, although Dr. Ostergard's opinions conflict with the position statements of several urogynecological professional societies, he nevertheless finds support for his opinions in several peer-reviewed articles. (*See* Ostergard Report [Docket 217-2], at ¶ 10 (citing to various publications that corroborate his opinions on polypropylene mesh)). Consequently, that Dr. Ostergard belongs to the minority does not, in itself, render his opinion unreliable. Instead, I defer to the other *Daubert* factors and leave the profession's acceptance (or lack thereof) of Dr. Ostergard's opinions as a possible basis for impeachment at trial.

Further challenging the reliability of Dr. Ostergard's opinions, BSC contends that Dr. Ostergard has "conducted no testing on whether Boston Scientific mesh products in fact display

the defects he describes." (BSC's Mem. re: Ostergard [Docket 218], at 9). An expert, however, may support his opinions with resources other than the results of his scientific experimentation or testing. *See Daubert*, 509 U.S. at 592 ("Unlike an ordinary witness, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." (internal citations omitted)). In fact, "numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts." *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) (listing relevant case law). In *Jones*, I ruled that Dr. Ostergard's reliance on the analyses of others, when considered alongside his own peer-reviewed research, satisfied the reliability requirements of *Daubert*. (*See Jones*, No. 2:11-cv-00114 [Docket 391], at 8). Revisiting Dr. Ostergard's list of publications on polypropylene mesh, (*see* Ostergard Curriculum Vitae [Docket 286-2], at 24), I again conclude that Dr. Ostergard's opinions have reliable support.

Finally, BSC asserts that Dr. Ostergard has "misinterpreted" the medical articles he relied on in reaching his opinions, and as a result, his opinions are unreliable. (BSC's Mem. re: Ostergard [Docket 218], at 10). BSC's argument misplaces my role under *Daubert*. As the gatekeeper of expert testimony, I need not concern myself with the "correctness of the expert's conclusions" and should instead focus on the "soundness of his methodology." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II*"). As explained above, the review of other professionals' research can form a sound and reliable basis for an expert opinion. Here, Dr. Ostergard conducted a thorough review of others' medical research in establishing his opinions. (*See* Ostergard Curriculum Vitae [Docket 217-2], at 148–56 (providing a list of medical literature that Dr. Ostergard considered in writing his expert report)). Whether Dr. Ostergard correctly

interpreted this research has no bearing on the admissibility of his opinions. Accordingly, BSC's objection has no merit, and I **FIND** that Dr. Ostergard's opinions on the properties of polypropylene are reliable.[10]

This holding, however, does not apply to Dr. Ostergard's opinion on the carcinogenicity of polypropylene. Although the plaintiffs point to several studies connecting polypropylene to cancer, (*see* Pls.' Resp. re: Ostergard [Docket 286], at 15 n.74), none of the plaintiffs in this case has claimed that the Obtryx sling caused cancer. Thus, "[t]he mention of cancer in the context of this case . . . would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value." (*Jones*, No. 2:11-cv-00114 [Docket 391], 8 n.4). All of Dr. Ostergard's opinions on the carcinogenicity of polypropylene are **EXCLUDED**.

3. Admissibility of Dr. Ostergard's Opinions on BSC's State of Mind

BSC asserts that a majority of Dr. Ostergard's expert report consists of impermissible opinion testimony on the "intentions and motivations of Boston Scientific." (BSC's Mem. re: Ostergard [Docket 218], at 13). The plaintiffs admit that Dr. Ostergard seeks to provide insight into BSC's "intent, motives (including financial motives), or ethics" for the purpose of opining on "what information BSC *should* have known" and "*should* have done" as a manufacturer of mesh devices. (Pls.' Mem. re: Ostergard [Docket 286], at 16). In the plaintiffs' view, such opinion testimony is admissible because it is relevant to the issue of punitive damages and will help the jury understand the medical language in many of BSC's internal documents. (*Id.*).

I disagree. As I have consistently held throughout these MDL cases, the defendant's

[10] BSC also argues that Dr. Ostergard's opinions on the properties of polypropylene are irrelevant because he has not specifically applied his opinions to the plaintiffs. There is no indication in Dr. Ostergard's expert report that he is offering a specific causation opinion. If at trial, however, Dr. Ostergard attempts to transform his general causation opinion on the properties of mesh—which is certainly relevant to the question of whether mesh is defective—into a specific causation opinion, a proper objection can be brought at that time.

"knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis*, 2014 WL 186872, at *6 (citing to *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004), which ruled that "the question of intent is a classic jury question and not one for the experts"). Accordingly, Dr. Ostergard's opinions related to BSC's intent, motives, ethics, and corporate conduct—including any comments about what BSC "knew or should have known"—are **EXCLUDED**.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Dr. Ostergard [Docket 217] is **GRANTED IN PART** and **DENIED IN PART**.

H. Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D.

BSC seeks to exclude the opinions of Dr. Vladimir Iakovlev. Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. (Iakovlev Report [Docket 225-1], at 1). In his expert report, Dr. Iakovlev describes a study he participated in with Dr. Robert Bendavid beginning in 2012, "to investigate the morphological specifics of tissue before and after the inguinal hernia surgery, with and without the use of the mesh." (*Id.* at 2). Based on this study, as well as his analysis of published literature and patient records, Dr. Iakovlev concludes that complications of mesh placement in the body include: (1) pain; (2) urinary symptoms; (3) mesh hardening, deformation, and formation of nodule/mass; and (4) mucosal lesions and/or post-coital bleeding. (*Id.* at 3). BSC argues that Dr. Iakovlev's general causation opinions and "stretch test" are scientifically unreliable. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("Def.'s Mem. re: Iakovlev") [Docket 226], at 1–2). Additionally, BSC

contends that, as a pathologist, Dr. Iakovlev is unqualified to opine on mesh design, mesh deformation, and polypropylene degradation. (*Id.*). For the reasons discussed below, BSC's motion [Docket 268] is **GRANTED**.

1. Qualifications as a Pathologist

BSC argues that Dr. Iakovlev is unqualified to render opinions on mesh design, mesh deformation, and polypropylene degradation. (Def.'s Mem. re: Iakovlev [Docket 226], at 7–9). Dr. Iakovlev is a pathologist. BSC argues that because Dr. Iakovlev does not have a degree in physics, engineering, or biomaterials and only recently became familiar with the basic manufacturing principles for synthetic mesh, he is not qualified to opine on the design, deformation, and degradation of mesh explants. (*Id.*).

A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. *Edwards v. Ethicon*, No. 2:12-cv-09927, 2014 WL 3361923, at *24 (S.D. W. Va. July 8, 2014) (citation omitted). In his expert report, Dr. Iakovlev states that his "professional activities include diagnostic examination of specimens removed surgically or by biopsies from the human body, where [his] annual practice volume amounts to 5000 cases." (Iakovlev Expert Report [Docket 225-1], at 1). Dr. Iakovlev also teaches a course on anatomic pathology and cytology. (*Id.* at 29). BSC does not question Dr. Iakovlev's pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render these opinions. However, throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh. *See, e.g.*, *Sanchez*, 2014 WL 4851989, at *19–20 (discussing Dr. Richard W. Trepeta); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (discussing Dr. Bernd Klosterhalfen). In fact, in *Edwards*, I determined that Dr.

Iakovlev was qualified to render an opinion regarding polypropylene degradation based on his experience as a pathologist. *See Edwards*, 2014 WL 3361923, at *24–25. The fact that Dr. Iakovlev took the time to familiarize himself with BSC's manufacturing process in no way diminishes his qualifications. Therefore, I **FIND** that Dr. Iakovlev is qualified to testify regarding mesh design, mesh deformation, and polypropylene degradation.[11]

2. General Causation Opinions Related to Bendavid Study

Next, BSC argues that Dr. Iakovlev lacks reliable methodology for his general causation opinions related to his review of explanted mesh as part of the Bendavid study. In preparing his expert report, Dr. Iakovlev examined over 100 mesh explants, approximately twenty percent of which were polypropylene and some fraction of which were transvaginal. (Iakovlev Report [Docket 225-1], at 2; Iakovlev Dep. [Docket 225-3], at 55, 243). The explanted mesh types included woven, knitted, printed, GoreTex, combined designs of different manufacturers, and 21 samples from BSC. (Iakovlev Report [Docket 225-1], at 2; Iakovlev Dep. [Docket 225-3], at 320). BSC argues that because the study was not confined to polypropylene mesh and Dr. Iakovlev provides no information on how the mesh explants were chosen, the results are irrelevant and unreliable. The plaintiffs contend that Dr. Iakovlev's independent scientific testing is grounded in reliable methodology because he saw nerve entrapment, nerve ingrowth and degradation in 100% of the BSC explants. (Pls.' Opp. to Def.'s Mot. to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("Pls.' Opp. re: Iakovlev") [Docket 268], at 9).

Although BSC fails to cite to any testimony from Dr. Iakovlev supporting its premise, I agree that Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. (Def.'s Mem. re: Iakovlev [Docket 226], at 5–6). Dr. Iakovlev testified

[11] BSC does not object to Dr. Iakovlev's qualifications in relation to his general causation opinions or "stretch" test.

that the 21 BSC samples he examined were provided by plaintiffs' counsel. (Iakovlev Dep. [Docket 268-2], at 42). I also note, in his deposition for *Edwards*, Dr. Iakovlev further testified that he requested all available meshes for examination, but had no way of knowing what methodology the plaintiffs' lawyers employed in providing him with the number of meshes they did. (*Id.* at 157–61). Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Lewis*, 2014 WL 186872, at *8. "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594). By simply highlighting the fact that Dr. Iakovlev performed an independent analysis, the plaintiffs have not demonstrated that Dr. Iakovlev's opinions regarding pelvic mesh explants were derived using scientific methods. Therefore, Dr. Iakovlev's general causation opinions related to the Bendavid study are **EXCLUDED**.[12]

Unlike his opinions in *Edwards*, it is unclear which of Dr. Iakovlev's opinions relate to specific plaintiffs in the current litigation or whether he reviewed samples separate from the Bendavid study. In *Edwards*, I allowed Dr. Iakovlev to testify regarding Ms. Edward's mesh because his specific causation opinions did not present the same reliability concerns as his general causation opinions. 2014 WL 3361923, at *23 ("Dr. Iakovlev may not testify regarding his general conclusions about mesh because his choice of samples lacks scientific methodology. However, this is not a reason to exclude his testimony about Ms. Edward's mesh, which was made after a review of her explant."). Here, when discussing polypropylene degradation and his polarization technique, Dr. Iakovlev refers to the 21 BSC samples provided to him by plaintiffs' counsel. (Iakovlev Dep. [Docket 225-3], at 412). In his expert report, when discussing mesh design, Dr.

[12] This holding is consistent with my previous exclusion of Dr. Iakovlev's opinions regarding transvaginal mesh generally. *See Edwards*, 2014 WL 3361923, at *23.

Iakovlev states he examined a "variety" of BSC devices, but fails to indicate their source. Without more information, I must assume that Dr. Iakovlev's additional opinions are based on his general review of mesh explants as part of the Bendavid study, which I have determined to be unreliable. Therefore, I **FIND** that Dr. Iakovlev's opinions on mesh design, mesh deformation, and polypropylene degradation should also be **EXCLUDED**.[13]

3. Deformation Opinions Based on Stretch Test

BSC challenges the reliability of Dr. Iakovlev's opinions drawn from his mechanical testing of BSC slings. Dr. Iakovlev tested one sling and one Uphold. (Iakovlev Dep. [Docket 225-3], at 349). Dr. Iakovlev performed a "stretch test" on the mesh to simulate forces acting on the device in the body and confirm his hypothesis that mesh deforms after stretching forces are applied to it. (Iakovlev Report [Docket 225-1], at 7; Iakovlev Dep. [Docket 225-3], at 350). Dr. Iakovlev placed the mesh on a flat surface against a scale and secured the ends with clamps. (Iakovlev Dep. [Docket 225-3], at 345). Then, by pulling the clamps apart, he stretched the mesh to 120% of its original length. (*Id.*). Dr. Iakovlev observed permanent bowing, lengthening, and raised edges, which he opines is similar to the natural deformation that takes place inside the human body. (Iakovlev Report [Docket 225-1], at 7). Dr. Iakovlev also points out that when the clamps were released the mesh did not return to its original length and shape. (*Id.* at 7–8).

In particular, BSC makes the following arguments as to why Dr. Iakovlev's testing was methodologically flawed: (1) his testing method was not based on any testing standards and did not have a written protocol; (2) he did not regulate or measure how much force he applied to the mesh samples; (3) he set clamps on the mesh, but cannot provide measurements; (4) he intended to

[13] Even if Dr. Iakovlev's mesh design and deformation opinions were not based on an unreliable sample, they would still be inadmissible because of his subjective and conclusory approach. (*See* Iakovlev Dep. [Docket 225-3], at 330–31 (stating his opinion is based solely on touch and comparing the mesh to a sweater or scarf)).

stretch the mesh to reach 120% of the original length, but does not know how he arrived at that result or how to repeat the test; (5) he could not describe or comprehend how he controlled his test for confirmation bias; (6) he does not know whether mesh responds to stretching with clamps the same way it does when implanted in the human body, nor has he done mechanical testing on mesh in the body; (7) he cannot validate that stretching mesh on a machine replicates the behavior of mesh in the body because he only measured unilateral forces, and not forces from multiple directions or the amount of force used; and (8) he has no knowledge of any general acceptance of his methodology in the scientific community. (Def.'s Mem. re: Iakovlev [Docket 226], at 7). BSC's objections can be divided into two categories: (1) testing standards and (2) in vivo environment.

a. Testing Standards

Many of BSC's arguments incorporate Dr. Iakovlev's failure to adhere to testing standards or a written protocol.[14] In his deposition, Dr. Iakovlev states that he developed the stretch test method; however, he failed to follow a written protocol other than the brief description included in his expert report. (Iakovlev Dep. [Docket 225-3], at 345). When describing the methodology he employed, Dr. Iakovlev admits that he did not wear gloves, clean or sterilize the mesh, or use machinery to regulate the amount of force exerted. (*Id.* at 347–48). Dr. Iakovlev insists that because the criterion for the test was length rather than force, the regulation of force was irrelevant. (*Id.* at 348). Nevertheless, Dr. Iakovlev readily admits that he developed and performed the stretch test himself, without taking care to standardize his method or the results. (*Id.* at 345, 350). Additionally, Dr. Iakovlev has no knowledge of whether his methodology is generally accepted in the medical community. (*Id.* at 350). Finally, when asked how he can be sure his results were not

[14] BSC arguments 1–5, 8.

caused by the way he pulled the mesh, Dr. Iakovlev's only response is that the stretch test was a simulation, which I **FIND** insufficient to establish reliability. (*Id.* at 351–52).

b. In Vivo Environment

BSC's remaining two arguments are in regard to Dr. Iakovlev's failure to replicate an in vivo environment.[15] Although Dr. Iakovlev states that he performed the stretch test to simulate forces acting on the device in the body, BSC contends that Dr. Iakovlev has no way of knowing whether mesh responds to stretching with clamps the same way it does when implanted inside of a woman. (Def.'s Mem. re: Iakovlev [Docket 226], at 7). BSC further argues that Dr. Iakovlev's tests failed to replicate the forces in the female pelvic floor because he measured uniaxial forces, while the forces in the female pelvic floor are generally multi-directional. (*See id.*).

The mere fact that Dr. Iakovlev's study was uniaxial does not alone render his methodology unreliable; however, the fact that he did not account for multi-directional forces inside of the female pelvis weighs heavily against admissibility. Much like his response to BSC's question regarding confirmation bias, when asked about the way mesh responds inside and outside of the body, Dr. Iakovlev states that "the assumption is that if the forces are similar, the behavior will be similar. That's a limitation of all experimental studies." (Iakovlev Dep. [Docket 225-3], at 352). Dr. Iakovlev's "assumption" that the force he applied by pulling on the clamps accurately represents the forces inside the human body is hardly sufficient to survive *Daubert* scrutiny. Accordingly, I **FIND** that Dr. Iakovlev's opinions based on his "stretch test" are unreliable and thus, **EXCLUDED**.

I. Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D.

[15] BSC arguments 6-7.

Dr. Jerry Blaivas is a pelvic surgeon and urologist. The plaintiffs offer Dr. Blaivas to opine as to general and specific causation. He seeks to offer opinions regarding the complications of synthetic slings and prolapse kits, BSC's warnings to physicians and patients, the removal of slings, the safety and efficacy of pubovaginal slings using autologous fascia and native tissue prolapse repair, and BSC's awareness of complications relating to its products. (*See* Blaivas Report [Docket 239-1], at 3–4).

BSC contends that Dr. Blaivas's testimony should be excluded as unreliable. In particular, BSC makes the following arguments: (1) his opinions are not generally accepted within his field; (2) he improperly discounted contrary studies; (3) he fails to support his opinions with peer-reviewed literature; and (4) he failed to consider any studies using the Obtryx. (BSC's Mem. in Supp. of Its Mot. to Exclude the Ops. and Test. of Jerry Blaivas, M.D. ("BSC's Mem. re: Blaivas") [Docket 240], at 1–2). Also, BSC argues that Dr. Blavias's specific causation opinions as to Ms. Hendricks should be excluded because he did not perform a proper differential diagnosis. (*See id*. at 2). Finally, BSC argues that "Dr. Blaivas seeks to offer opinions that (1) constitute legal opinions, (2) fall outside the scope of his expertise; or (3) consist of speculation regarding Boston Scientific's knowledge, intent, and/or state of mind." (*Id.*).

1. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe In the Treatment of SUI

BSC challenges Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe to treat SUI. BSC makes several sub-arguments as to this point.

a. General Acceptance

First, BSC argues that the opinion "is unreliable because it is not generally accepted in the relevant medical and scientific communities and . . . conflicts with the findings of a FDA Advisory

Panel and leading urogynecological and urological organizations" of which is he a member (*Id.* at 5). BSC notes that the FDA Advisory Panel and organizations, including the American Urogynecologic Society ("AUGS") and the American Urological Association ("AUA"), have released findings and statements stating that polypropylene slings are safe and effective and are the "worldwide standard of care for the surgical treatment of stress urinary incontinence." (*Id.* at 5–6). BSC contends that Dr. Blaivas discounts these findings and statements with unfounded accusations of bias. (*See id.* at 6). Also, at his deposition, Dr. Blavias testified that the majority of physicians performing surgery to treat SUI use synthetic mesh slings and think that using polypropylene mesh slings are safe. (*See* Blaivas Dep. II [Docket 239-6], at 511:12–23).

"'General acceptance' is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence . . . ." *See Daubert*, 509 U.S. at 597. As a result, even if Dr. Blavias's opinion is not generally accepted, that factor alone does not dictate a finding of unreliability. Furthermore, as I explain above in my ruling on BSC's Motion to Exclude Plaintiffs' Experts' Opinion that Polyproylene Mid-Urethral Slings are Defective [Docket 227], BSC is seeking to challenge Dr. Blavias's conclusion rather than his methodology. *See Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). Therefore, this argument has no merit.

b. Failing to Consider Contrary Scientific Literature

Second, BSC argues that "Dr. Blaivas inexplicably dismisses and fails to consider published, peer-reviewed literature demonstrating polypropylene mid-urethral slings are safe and effective." (BSC's Mem. re: Blaivas [Docket 240], at 5). In particular, BSC contends that Dr.

Blavias discounts the Nilsson study, the Delorme study, and the Ulmsten study with unsupported allegations of bias. (*See id.* at 9–10).

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

However, contrary to BSC's contentions, Dr. Blavias provided more than mere blanket accusations of bias for discounting these studies. He *explained why* he suspected bias. Dr. Blaivas explained that Dr. Delorme was an inventor of the approach being studied and stated that "to conclude after [looking at] 32 patients by the inventor of the operation that it's safe and effective stretches credibility in my judgment." (Blaivas Dep. I [Docket 239-4], at 293:20–22; *see id.* at 292:9–294:19). Similarly, Dr. Blavias claims that the Ulmsten study was "one of the studies I

referred to that I believe to be completed and to get paid had to show a complication rate that was comparable to the last study . . . I think this study is ethically challenged." (*Id.* at 287:15–20). In regards to the Nilsson follow-up study, Dr. Blavias testified that its methodology was, in fact, problematic because "[t]wenty-one of the patients were lost to follow-up." (Blaivas Dep. II [Docket 239-6], at 392:5). He explained further:

> A: . . . All those patients that they did follow-up, no complications, no serious complications in all of their patients but one that had a minor complication, yet, there's 21 patients that they cannot account for and we are to assume that it's safe because they didn't include them. All 21 of them could have had another operation for the same thing. All 21 of them could have died from an infection from this. We don't know that. How can we possibly say that that's safe.

(*Id.* at 392:9–17). If BSC seeks to challenge Dr. Blaivas's allegations of bias as to these studies, it may do so on cross examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

c. Not Based on Scientific Literature

In another section of its memorandum, BSC argues that Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe to treat SUI is based only on his experience. (BSC's Mem. re: Blaivas [Docket 240], at 5–6). Dr. Blaivas testifies that he "remember[s] [his] opinions about the safety were not based predominantly on the medical literature." (Blaivas Dep. II [Docket 239-6], at 434:22–23). In support of its argument, BSC further cites to Dr. Blaivas's deposition testimony demonstrating that he could not identify which articles on his list he relied upon in forming this opinion and explained that "I guess I can't answer your question fairly without

looking at each article, but I do believe that I will find some." (Blaivas Dep. I [Docket 239-4], at 150:3–5; *see* BSC's Mem. re: Blaivas [Docket 250], at 12).

Dr. Blaivas's failure to recall which articles supported his opinion as to safety is an insufficient reason to find his methodology unreliable. Dr. Blaivas has extensive experience, (*see* Blaivas Report [Docket 239-1], at Ex. A (Dr. Blaivas's curriculum vitae)), has authored peer-reviewed articles on this subject (*see* Blaivas Dep. I [Docket 239-4], at 149:16–23), and considered scientific literature in forming his opinions as evidenced by his relied upon list (*see* Blaivas Report [Docket 239-1], at Ex. B). The fact that the scientific literature was not the "predominant[ ]" basis of his opinion does not thereby render it unreliable. (Blaivas Dep. II [Docket 239-6], at 434:23).

Therefore, I **FIND** that Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI is sufficiently reliable to pass *Daubert* scrutiny.

2. Failure to Base Opinion on Published, Peer-Reviewed Literature

BSC also argues that Dr. Blaivas did not base his opinions on peer-reviewed literature. (BSC's Mem. re: Blaivas [Docket 240], at 10). In support, BSC cites to portions of Dr. Blaivas's testimony where he discusses his relied upon list in another case, *Hall*. (*See id.* at 11; Blaivas Dep. I [Docket 239-4], at 105:10–11). It does not reveal that he based his opinions on experience alone:

> Q: Okay. And you said that your opinions in these matters are based upon the 36 medical literature items that you've attached, correct?
>
> A: No, I don't think I said that. What I said is that these are supporting documents for my opinions. Many, if not most of my opinions come from my own experience with patients, talking to other doctors, particularly other experts about what they're seeing and, you know, conducting courses, inviting speakers, listening to lectures, et cetera. That's where – and – and having lived through the evolution of – the evolution of slings. In fact, I think that – I think these papers were mostly chosen as the best we could

> find in the peer-review literature to support those – my opinions, but I would not at all rely on these papers to substantiate my opinions. If none of these papers existed, my opinions would be the same.

(*Id.* at 106:5–107:1) (objection omitted). This demonstrates that Dr. Blaivas at least reviewed and considered the literature on his list. These studies supported his opinions. Whether or not his conclusions exactly comport with the conclusions reached in the studies is not determinative of my *Daubert* analysis. I am to assess the reliability of Dr. Blaivas's method, not the accuracy of the conclusions that he reaches. *See Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Next, BSC challenges Dr. Blaivas's opinion that "[p]ubovaginal slings using autologous fascia are a safer alternative to synthetic slings[.]" (Blaivas Report [Docket 239-1], at 4). In support of its argument, BSC cites to Dr. Blavias's deposition testimony, where he states that "there are no head-to-head studies" comparing the two slings and that he was unable to name studies finding that pubovaginal slings are safe. (Blaivas Dep. II [Docket 239-6], at 380:25). As I explain above, I do not find this deposition testimony to be dispositive. Therefore, I **FIND** Dr. Blaivas's opinion that pubovaginal slings are safer than polypropylene slings survives *Daubert* scrutiny.

3. Dr. Blaivas's Qualifications to Opine on the Design of the Obtryx Slings or the Adequacy of Its Warnings

BSC argues that Dr. Blaivas is unqualified to opine as to the design of the Obtryx or the adequacy of its warnings. BSC challenges several opinions in Dr. Blaivas's report:

> BSC did not warn physicians and patients about the possibility of serious and life-style altering complications including, chronic, debilitating pain, dyspareunia, nerve injuries, vaginal scarring, bladder dysfunction, the need for multiple corrective surgeries, and others.

> . . .
>
> BSC did not warn physicians about the possibility that these complications could occur months, years, or decades after placement of the devices, such as the Pinnacle and Advantage.
>
> . . .
>
> BSC did not warn doctors and patients about the difficulty removing their products and the less than optimal results when excision or revision became warranted due to complications.
>
> . . .
>
> A permanent device, such as BSC Advantage and Pinnacle, should not have been designed to be placed in a surgically contaminated field . . .

(Blaivas Report [Docket 239-1], at 3–5; *see* BSC's Mem. re: Blaivas [Docket 240], at 13–14). I have previously found Dr. Blaivas qualified to testify as to the adequacy of warnings. *See Huskey, et al., v. Ethicon, Inc., et al.*, No. 2:12-cv-05201, 2014 WL 3362264, at *20 (S.D. W. Va. July 8, 2014). As I explained in *Huskey* with respect to a different product's warnings:

> [A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when the warnings were published.

Id. at 20 (citation omitted). Here, the same reasoning applies. Therefore, I **FIND** Dr. Blaivas qualified to testify as to the adequacy of the Obtryx warnings.

As for product design, BSC contends that Dr. Blaivas lacks design experience and has not implanted an Obtryx sling or BSC pelvic mesh product. (*See* BSC's Mem. re: Blaivas [Docket 240], at 13; Blaivas Dep. I [Docket 239-4], at 26:22–23 ("Q: Have you ever done an Obtryx surgery? A: Have not.")). Dr. Blaivas's experience removing SUI devices and observing

complications during the removal process does not alone render him qualified to opine as to design. Dr. Blaivas worked in developing the autologous rectus fascial sling operation. However, this experience in developing procedures does not make him an expert in the design of a medical *device*. (*See* Blaivas Report [Docket 239-1], at 1–2). As a result, Dr. Blaivas lacks the "knowledge, skill, experience, training, or education" as to product design that Federal Rule of Evidence 702 requires. Fed. R. Evid. 702. His opinions related to product design are **EXCLUDED**.

4. BSC Argues Dr. Blaivas's Opinions Are Legal Conclusions

BSC argues that Dr. Blaivas seeks to offer opinions that are legal conclusions. BSC challenges only one opinion: "Claims that make the procedure appear safer and easier to perform than it actually is are misleading." (Blaivas Report [Docket 239-1], at 4). The plaintiffs interpret this opinion as Dr. Blaivas commenting "that BSC downplayed the difficulties associated with the surgical implantation of the Obtryx device." (Pls.' Opp'n to Def. BSC's Mot. and Mem. of Law in Supp. of its Mot. to Exclude the Ops. and Test. of Jerry Blaivas, M.D. ("Pls. Resp. re: Blavias") [Docket 279], at 17). I recently explained that Dr. Blaivas's opinion on downplaying complications based on his personal experience is not an expert opinion and declined to address its admissibility. *See Huskey*, 2014 WL 3362264, at *22. Therefore, I will not address the admissibility of this testimony here.

5. BSC Argues Dr. Blaivas's Opinions Are Outside of His Expertise

BSC argues that Dr. Blaivas's opinions as to polypropylene mesh shrinkage and degradation are beyond his expertise because Dr. Blaivas admits in his deposition that he is not an expert in biomaterials and that he read and relied upon other experts' depositions in educating himself on degradation. (*See* Blaivas Dep. II [Docket 239-6], at 482:12–13 (testifying "I mean, the

biochemistry and stuff was over my head"); *id.* at 481:4–484:3). BSC also cites to Dr. Blaivas's deposition testimony which reveals that he has not performed tests on shrinkage, he has "never looked for any" studies finding that mesh shrinks asymmetrically, and he could not recall the details of a particular study on mesh shrinkage. (*See id.* at 458:12–14, 459:6–8, 465:8–466:2). In response, the plaintiffs point to Dr. Blaivas's experience removing SUI devices and personally observing degradation. (*See* Pls. Resp. re: Blaivas [Docket 279], at 14).

In *Huskey*, I found that Dr. Blaivas was unqualified to opine as to mesh shrinkage and degradation due to his failure to disclose his particular experience with these matters in his expert report. 2014 WL 3362264, at *23–24. I **ADOPT** this reasoning here. Therefore, I **FIND** that Dr. Blaivas is not qualified to opine as to these matters.

6. Dr. Blaivas's State of Mind Testimony

BSC argues that Dr. Blaivas seeks to offer state of mind testimony. (*See* BSC's Mem. re: Blaivas [Docket 240], at 17–18). As I explain above, this testimony is impermissible expert testimony. The plaintiffs concede that Dr. Blaivas will not offer state of mind testimony. (*See* Pls. Resp. re: Blaivas [Docket 279], at 17). Therefore, BSC's motion with regard to this matter is **DENIED AS MOOT**.

7. BSC Argues That Dr. Blaivas's Opinions Do Not Fit the Facts of the Case

BSC also argues that Dr. Blaivas's opinions do not fit the facts of the case because he cannot recall whether he has reviewed any studies concerning the safety and efficacy of the Obtryx. (*See* Blaivas Dep. I [Docket 239-4], at 334:20–25). Even if this is the case, Dr. Blaivas's opinions as to polypropylene mesh slings generally are still helpful to a jury here.

8. Dr. Blaivas's Specific Causation Opinions as to Ms. Hendricks

BSC challenges Dr. Blaivas's specific causation opinions as to Ms. Hendricks. Ms. Hendricks is no longer a plaintiff in this case. Therefore, BSC's motion with respect to this matter is **DENIED AS MOOT**.

9. Dr. Blaivas's References to POP and the Pinnacle

Dr. Blaivas's report contains references to POP, the Pinnacle device, and the Advantage product. (*See, e.g.*, Blaivas Report [Docket 239-1], at 3–4). In this case, the product at issue is the Obtryx which is used to treat SUI. I find that Dr. Blaivas's references to POP, the Pinnacle, and the Advantage are immaterial to my *Daubert* ruling here. Many of his opinions apply to both synthetic slings and prolapse kits and merely refer to the Pinnacle and Advantage devices as examples of such. (*See, e.g.*, *id.* at 3 (opining that "[s]ynthetic slings and prolapse kits, such as [BSC's] Pinnacle and Advantage devices, cause serious and life-style altering complications . . .")).

Therefore, BSC's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D., is **GRANTED IN PART** and **DENIED IN PART**.

J. Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE

Dr. Vredenburgh works as a consultant and researcher in the field of "human factors," providing business guidance on matters such as product warning design, injury prevention, risk management, and warning effectiveness. (*See* Vredenburgh Curriculum Vitae [Docket 241-1], at 2 (describing Dr. Vredenburgh's current consulting position)). The plaintiffs offer Dr. Vredenburgh to provide expert testimony on "BSC's management of hazards related to its transvaginal mesh products." (Pls.' Opp. to BSC's Mot. to Exclude Dr. Vredenburgh ("Pls. Mot. re: Vredenburgh") [Docket 284], at 2). In sum, Dr. Vredenburgh opines that "BSC failed to effectively control the hazards present in its transvaginal mesh products at issue in this litigation, including its design and

hazard communication (including instructions, training, and warnings) of the Obtryx." (Vredenburgh Report [Docket 241-3], at 3).

BSC's objections to this expert testimony fall into four categories: (1) Dr. Vredenburgh is not qualified to offer the opinions set forth in her report; (2) Dr. Vredenburgh's opinions are not helpful to the jury; (3) Dr. Vredenburgh did not support her opinions with reliable methodology; and (4) Dr. Vredenburgh's opinions are not proper for expert testimony because they assert legal conclusions and opine about BSC's state of mind. Because I find that Dr. Vredenburgh's opinions are improper and therefore not helpful to the jury as prescribed by Federal Rule of Evidence 702, I need not address BSC's arguments regarding Dr. Vredenburgh's qualifications and the reliability of her methods. As further explained below, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Dr. Vredenburgh [Docket 242].

1. Improper Legal Conclusions

Rule 702 provides that an expert witness may testify in the form of an opinion if his or her "specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). If, for instance, an expert's opinion "supplies the jury with no information other than the witness's view of how the verdict should read," then the testimony is essentially a legal conclusion "that is better handled by the judge and, coming from the witness, will be of little assistance to the jury." *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011). Dr. Vredenburgh's testimony collapses under this rule. Instead of simply outlining her opinion on the vital parts of a product warning, Dr. Vredenburgh's report goes a step further, concluding that BSC "failed to provide adequate instructions" and "did not include adequate warnings." (Vredenburgh Report [Docket 241-3], at 5). As I held in *In re C. R. Bard, Inc.*, "whether [the

defendant] failed to warn [is a] question[] for the jury, not for Dr. [Vredenburgh]." 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013); *see also Strong v. E. I. DuPont de Nemours Co.*, 667 F.2d 682, 686 (8th Cir. 1981) ("[T]he question of whether the lack of warnings rendered the . . . products unreasonably dangerous is not the kind of issue on which expert assistance is essential for the trier of fact. The jury was capable of drawing its own inferences from the available evidence."). Accordingly, I **EXCLUDE** Dr. Vredenburgh's opinions, as they are all based on legal conclusions.

2. Improper State of Mind Testimony

Dr. Vredenburgh's expert report also offers opinions on BSC's state of mind and corporate conduct. Specifically, Dr. Vredenburgh states that BSC: "*knew* the complication rates, yet failed to include them in the warnings and/or labeling"; "*was aware* of debilitating outcomes"; "*ignored* the numerous red flags raised by multiple agencies, publications and physicians"; used "anti-warnings" to "*deliberately misrepresent* dangerous products as safe"; and "*refused* to perform Clinical Testing to help identify risks." (Vredenburgh Report [Docket 241-3], at 10–24 (emphasis added)).

As I have previously stressed, the defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 611 (citing to *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.")). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time

immemorial." *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998). Here, opinions on BSC's alleged corporate misconduct and improper decisions are strewn throughout Dr. Vredenburgh's report, largely supported by various BSC internal documents. (*See, e.g.*, Vredenburgh Report [Docket 241-3], at 6 (citing to the depositions of BSC corporate executives)). While internal corporate documents and executives' testimony are certainly relevant in this case, such evidence "should be presented directly to the jury, not through an expert." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 628. Thus, I **EXCLUDE** Dr. Vredenburgh's opinions on BSC's state of mind, corporate knowledge, business failures, and the like.

In conclusion, Dr. Vredenburgh's expert report provides legal conclusions about whether BSC acted appropriately and opines about BSC's corporate ethics. The jury is capable of evaluating the evidence on these subjects without the help of an expert. Furthermore, the court believes her testimony as offered would mislead and confuse the jury, even if arguably adequate under *Daubert*. Therefore, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Dr. Vredenburgh [Docket 241].

K. Motion to Exclude the Opinions and Testimony of Bruce Allen Rosenzweig, M.D.

Dr. Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. The plaintiffs offer Dr. Rosenzweig as an expert witness on general causation and on specific causation for Ms. Blankenship. (*See* Rosenzweig Report on Jeanie Blankenship ("Rosenzweig Report re: Blankenship") [Docket 273-1], at 4–6 (opining that, with a reasonable degree of medical certainty, the Obtryx device implanted in Ms. Blankenship caused her injuries)). BSC attacks the reliability of Dr. Rosenzweig's specific causation opinions, as well as the general causation opinions underlying them. I address BSC's objections below, beginning with Dr.

Rosenzweig's general causation opinions.

1. General Causation Opinions

Dr. Rosenzweig's expert reports primarily focus on diagnosing the particular symptoms of Ms. Blankenship, but he supports these diagnoses with an analysis of the medical literature on polypropylene transvaginal mesh and mid-urethral slings. BSC's general causation objection arises from Dr. Rosenzweig's assessment of this literature. BSC argues that Dr. Rosenzweig "relied on inferior studies and failed to read more complete studies which came to conclusions opposite of his own," and as a result, his opinions are unreliable and incomplete. (BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Test. of Dr. Rosenzweig ("BSC's Mem. re: Rosenzweig") [Docket 252], at 6–7).

I disagree with BSC's contentions for several reasons. First, I have considered Dr. Rosenzweig as a general causation expert three times in the past, and on each occasion, I have admitted his general causation testimony on the properties of polypropylene mesh. *See Lewis et al. v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (finding that Dr. Rosenzweig is qualified to offer the opinion that vaginally implanted polypropylene mesh degrades, based on his clinical experience and his analysis of scientific literature and academic papers); *Edwards v. Ethicon, Inc.*, 2:12-cv-09972, 2014 WL 3361023, at *11 (S.D. W. Va. July 8, 2014) (same); *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *8 (S.D. W. Va. July 8, 2014) (same). BSC has not distinguished Dr. Rosenzweig's opinions in this case from the opinions I have admitted in prior MDLs.

In an attempt to discredit Dr. Rosenzweig's review of the relevant literature, BSC emphasizes Dr. Rosenzweig's failure to read the Litwiller paper, an unpublished study that

included 954 patients with the Obtryx sling. (Rosenzweig Dep. [Docket 251-2], at 139:18–140:1). But BSC has not demonstrated the relevance of this study to Dr. Rosenzweig's opinions in this case. Furthermore, BSC has not explained why Dr. Rosenzweig's unfamiliarity with this single study renders his opinion unreliable as a whole.

Without a demonstrated reason for abandoning my prior holdings, I **DENY** BSC's motion with respect to Dr. Rosenzweig's general causation opinions.

2. Specific Causation Opinions

BSC next asks this court to exclude Dr. Rosenzweig's specific causation opinions about Ms. Blankenship because Dr. Rosenzweig failed to conduct a reliable differential diagnosis. A reliable differential diagnosis requires the expert to "determin[e] the possible causes for the patient's symptoms and then eliminat[e] each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be considered is the most likely." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). Although BSC makes much of the fact that Dr. Rosenzweig does not have a physician–patient relationship with Ms. Blankenship, Fourth Circuit law provides that "a physician may reach a reliable differential diagnosis without personally performing a physical examination." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). As such, Dr. Rosenzweig's failure to physically examine Ms. Blankenship does not per se render his specific causation testimony unreliable, especially when he reached his opinions by studying the records of other physicians who examined the two women. *See Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997), *as amended* (Dec. 12, 1997), ("[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available.").

BSC argues that the court should nevertheless exclude Dr. Rosenzweig because he did not adequately consider and eliminate alternative causes for the exhibited symptoms. As explained below, I do not find this argument persuasive.

After her pelvic surgery, Ms. Blankenship developed suprapubic and pelvic pain and a delayed-onset voiding dysfunction. Dr. Rosenzweig opines that these symptoms directly resulted from the Obtryx implantation. BSC asserts that Dr. Rosenzweig has overlooked several symptoms that Ms. Blankenship experienced before her Obtryx sling surgery, including pelvic pain and dyspareunia. But Dr. Rosenzweig's report and deposition testimony confirm that Dr. Rosenzweig did in fact consider these symptoms in reaching his conclusions.

First, Dr. Rosenzweig acknowledged that Ms. Blankenship had pre-implant pelvic pain and dyspareunia. (*See* Rosenzweig Dep. [Docket 273-2], at 153:10–16 (agreeing that Ms. Blankenship complained of pelvic discomfort and pain with sex two days prior to her pelvic surgery)). He then excluded this pain as the cause of Ms. Blankenship's current problems, explaining that someone with pre-implant pain could still experience "an increase in that pain" after transvaginal mesh placement. (*Id.* at 156:16–19). Furthermore, in his expert report, Dr. Rosenzweig explicitly lists Ms. Blankenship's prior medical problems and eliminates them as possible causes of current pain:

> Ms. Blankenship did not have, or subsequently develop, any medical or historical factors which increased her risk for developing suprapubic and pelvic pain and a voiding dysfunction. Review of her medical history reveals the following: macular degeneration, urinary tract infections, and human papilloma virus. None of these factors increased the risk for voiding dysfunction. To a reasonable degree of medical certainty, there is no other reasonable cause for the suprapubic and pelvic pain and the voiding dysfunction other than the Obtryx, given Ms. Blankenship's medical history.

(Rosenzweig Report re: Blankenship [Docket 273-1], at 5).

While a more detailed account from Dr. Rosenzweig might be desired, *Daubert* does not require additional explanation at this time. *Edwards v. Ethicon, Inc.*, 2:12-cv-09972, 2014 WL 3361923, at *6 (S.D. W. Va. July 8, 2014) (admitting the specific causation opinion of Dr. Steege, even though he "did not provide a detailed explanation" as to why he ruled out alternative causes, because "he based his conclusions on accepted scientific principles and research"). Rather, any potential errors in a doctor's differential diagnosis "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony." *Westberry*, 178 F.3d at 265 (internal quotations omitted). Therefore, I **FIND** that Dr. Rosenzweig adequately considered and eliminated alternate causes of Ms. Blankenship's symptoms such that his differential diagnosis is reliable.

BSC raises two other arguments against Dr. Rosenzweig's specific causation opinion. First, BSC asserts that Dr. Rosenzweig has no scientific evidence to support his opinion that Ms. Blankenship's mesh contracted and shrunk after implantation because he did not examine Ms. Blankenship or her mesh implant. In response, the plaintiffs refer to trial testimony from another MDL trial, *Lewis, et al. v. Ethicon, Inc.*, in which I allowed Dr. Rosenzweig to offer an opinion on mesh shrinkage based on a study by Carl Gustaf Nilsson. (*See* Transcript [Docket 273-5], at 136:15–139:9). This previous trial testimony has little value here as the plaintiffs have taken it out of context. In *Lewis*, I allowed Dr. Rosenzweig to provide a *general* causation opinion that transvaginal mesh can shrink over time. *See Lewis*, 2014 WL 186872, at *20 (permitting Dr. Rosenzweig's opinion testimony that transvaginal mesh "is not suitable for its intended application . . . because it [can lead to] mesh contracture/shrinkage"). Here, however, Dr. Rosenzweig has offered a *specific* causation opinion—that Ms. Blankenship's delayed-onset

voiding dysfunction most likely stemmed from "the Obtryx sling contracting and shrinking inside her body." (Rosenzweig Report re: Blankenship [Docket 273-1], at 6). Thus, the plaintiffs' reference to the *Lewis* trial is not instructive.

Although the trial transcript provides no assistance, Dr. Rosenzweig's deposition testimony and expert report suggest a scientific connection between Ms. Blankenship's voiding dysfunction and contracture of the Obtryx that can withstand *Daubert*. According to Dr. Rosenzweig:

(1) Ms. Blankenship had abnormal urodynamic flow patterns, which indicate a voiding dysfunction caused by mesh contraction (*see* Rosenzweig Dep. [Docket 273-2], at 165:8–166:15 (explaining that "bi-peaked" flow pattern is "a sign of voiding dysfunction"));

(2) Several medical studies, including the Nilsson study, demonstrate that if "delayed-onset voiding dysfunction is diagnosed," then "sling contraction/shrinkage occurred" (Rosenzweig Report re: Blankenship [Docket 273-1], at 5); and

(3) the explant operative report reviewed by pathologist Dr. Richard Trepeta evidences that "Ms. Blankenship's body reacted to the shrinkage and contracture by developing peri-urethral scarring," which is "the foreseeable pathological response to transobturator mesh placement that shrinks and contracts" (*id.* at 6).

Dr. Rosenzweig's analysis has plenty of gaps that BSC can capitalize on during cross-examination. But *Daubert* only requires "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." *Daubert*, 509 U.S. at 592. Dr. Rosenzweig thoroughly considered Ms. Blankenship's medical history and test results in the light

of the applicable publications, thereby establishing "medical evidence as to what caused [Ms. Blankenship's] specific injuries"—that is enough to get through *Daubert*'s gate. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 201 (rejecting expert testimony that "simply failed to provide any medical evidence as to what caused [the plaintiff's] specific injuries").

Finally, BSC disputes Dr. Rosenzweig's conclusion that Ms. Blankenship's sling was cut by Dr. Lassere during Ms. Blankenship's revision surgery on July 11, 2012. Dr. Lassere testified that he "could not find the sling," and so, in BSC's view, Dr. Rosenzweig's conclusion otherwise is an *ipse dixit* opinion. (BSC's Mem. re: Rosenzweig [Docket 252], at 14). The fact that Dr. Rosenzweig's testimony counters that of Dr. Lassere does not dictate admissibility. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 533–54 (D.N.J. 2004) ("Listening to testimony and deciding whether it is contradictory is the 'quintessential jury function of determining credibility of witnesses." (internal quotations omitted)). Moreover, although Dr. Rosenzweig was not present at the revision surgery, Dr. Rosenzweig supports his conclusion with scientific methodology—he examined Ms. Blankenship's medical records and pathology reports, applied his clinical expertise to those findings, and concluded that Dr. Lassere must have cut Ms. Blankenship's sling in the revision surgery. (*See* Rosenzweig Dep. [Docket 251-2], at 158:23–159:2 (using his clinical experience to conclude that even though Dr. Lassere could not find the sling, he likely was still able to transect it); *id.* at 163:19–24 (explaining that part of "revision surgery" requires "releas[ing] the sling"); Rosenzweig Report re: Blankenship [Docket 273-1], at 6 (relying on Dr. Richard Trepeta's pathology report from Ms. Blankenship's explant to conclude that the revision surgery removed part of the Obtryx)). Therefore, BSC's objection to Dr. Rosenzweig's testimony on the revision surgery has no merit.

In sum, these final two arguments do not change my conclusion that Dr. Rosenzweig's specific causation opinions about Ms. Blankenship are reliable. Accordingly, I **DENY** BSC's motion to exclude Dr. Rosenzweig [Docket 251] and **FIND** that Dr. Rosenzweig can testify about the general causation and specific causation opinions set forth in his expert report.

L. Motion to Exclude the Opinions and Testimony of Christopher Walker, M.D.

Dr. Walker is a board certified urogynecologist whom the plaintiffs hired to physically examine Plaintiff Chris Renee Wilson. Ms. Wilson alleges that her Obtryx mesh implant has led to dyspareunia, pelvic pain, urinary incontinence, and other complications. On May 2, 2014, Dr. Walker examined Ms. Wilson and recorded his results. (*See generally* Walker Report [Docket 270-2]). The plaintiffs now offer Dr. Walker as an expert on specific causation for Ms. Wilson.

Dr. Walker opines that based on his evaluation, "the presence of a midurethral sling" has caused the problems that Ms. Wilson currently experiences. (*See* Walker Dep. [Docket 270-1], at 40:18–20; *see also* Walker Report [Docket 270-2], at 9 (concluding that Ms. Wilson has "genito-urinary mesh implant complication")). BSC objects to Dr. Walker's opinion testimony, asserting that Dr. Walker's opinions are not based on reliable facts and that Dr. Walker failed to conduct a proper differential diagnosis in reaching his conclusion. As explained below, I disagree and **DENY** BSC's Motion to Exclude the Testimony of Christopher Walker, M.D. [Docket 247].

BSC first argues that Dr. Walker "failed to rely on *any* studies and/or medical literature regarding polypropylene transvaginal mesh and mid-urethral slings, including the Obtryx, in forming his opinions," and as a result, his opinions "are not based on reliable facts or data." (BSC's Mem. in Supp. of Its Mot. to Exclude the Test. of Christopher Walker, M.D. ("BSC's Mem. re: Walker") [Docket 248], at 5). As an initial matter, Dr. Walker's deposition testimony suggests that

BSC's contention is not wholly accurate. Dr. Walker stated that although he did not rely on particular studies in preparing his report for this case, he reads peer-reviewed literature and scientific studies on midurethral slings "very, very frequently" in his clinical practice, which involves treating women with urologic dysfunction. (Walker Dep. [Docket 270-1], at 15:12–17). Dr. Walker also answered multiple questions about the American Urogynecology Society's ("AUGS") statement on the use of midurethral slings for SUI. (*See id.* at 120:21–125:15 (evaluating each paragraph of the AUGS's statement)). Additionally, he explained that in his practice, he has relied on the research of Dr. Shlomo Raz, whom he described as one of the "leading authorities" in the urogynecological field. (*Id.* at 27:8–28:7).

In any event, peer-reviewed literature is merely one tool an expert witness can use to support his or her opinion. For instance, when providing a specific causation opinion, as Dr. Walker is in this case, experts often utilize differential diagnosis, a methodology that courts have accepted under *Daubert*. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001) (confirming that a reliable differential diagnosis "provides a valid foundation for an expert opinion under Rule 702"). A reliable differential diagnosis generally involves the performance of physical examinations, the taking of medical histories, and the review of clinical tests. *Id.* While integrating scientific literature into the process might bolster the credibility of an expert's opinion, the absence of scholarly references in an expert report does not invariably exclude an otherwise reliable differential diagnosis. *See Cavallo v. Star Enter.*, 892 F. Supp. 756, 774 (E.D. Va. 1995), *aff'd in relevant part*, 100 F.3d 1150, 1159 (4th Cir. 1996) ("[I]f a person were doused with chemical X and immediately thereafter developed symptom Y, the need for published literature showing a correlation between the two may be lessened."); *see also Heller v. Shaw Indus. Inc.*, 167 F.3d 146,

154 (3d Cir. 1999) (concluding that *Daubert* does not require a physician to "rely on definitive published studies before concluding that exposure to a particular object or chemical was the most likely cause of a plaintiff's illness").

Here, Dr. Walker relied on three sources in reaching his specific causation opinion about Ms. Wilson. Prior to meeting Ms. Wilson, Dr. Walker reviewed her medical records. (Walker Dep. [Docket 270-1], at 34:17). Then, when Ms. Wilson arrived for her physical examination, Dr. Walker took her medical history. (*See* Walker Report [Docket 270-2], at 3–5 (recording Ms. Wilson's past medical history, including her gynecological, obstetric, surgical, social, and family history)). Finally, Dr. Walker performed a 2.5-hour physical examination of Ms. Wilson. (*See id.* at 6–9 (describing the physical examination and recording his findings)). Courts consistently accept this methodology as a reliable foundation for opining what illness a patient has contracted. *See, e.g.*, *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 171, 762 (3d Cir. 1994) (concluding that a physician should examine the patient or review the patient's medical records, in addition to seeking a patient's self-report of symptoms, to determine that a patient is ill and what illness the patient has contracted). Thus, Dr. Walker's alleged failure to rely on peer-reviewed literature in reaching his conclusion does not compel me to exclude his opinion.

Next, BSC argues that this court should exclude Dr. Walker's opinion because his differential diagnosis did not "properly rule out other causes" of some of Ms. Wilson's complaints. (BSC's Mem. re: Walker [Docket 248], at 8). To be admissible, an expert's differential diagnosis must, at a minimum, "take serious account of other potential causes" of the patient's symptoms. *Cooper*, 259 F.3d at 202. Here, Dr. Walker's deposition testimony verifies that he has satisfied this requirement.

In his review of Ms. Wilson's medical records and history, Dr. Walker documented all of Ms. Wilson's prior medical problems and subsequently "eliminated [them] as a pathology." (Walker Dep. [Docket 270-1], at 64:17–22). Then, in concluding that the midurethral sling was the source of Ms. Wilson's pain, Dr. Walker explained that he considered "all the other comorbidities, but at the end of the day, it didn't change [his] opinion." (*Id.* at 102:17–103:1).16 Specifically, he considered and ruled out Ms. Wilson's past history of ovarian cysts, (*id.* at 102:13–17 (explaining that he "factored [the presence of ovarian cysts] into his differential diagnosis")), and Ms. Wilson's obesity (*id.* at 86:7–11). He even considered the fact that Ms. Wilson never shared her complaints of pelvic pain with her treating physicians:

> Q: Okay. Did it strike you as unusual that she's giving you complaints in your evaluation of her while she has a lawsuit pending for certain medical complaints that she's not mentioned to any other doctors that she has seen? Does that raise a red flag in your mind?
>
> A: It didn't raise a red flag in my mind, sir, because of the amount of time I had to spend with her. . . . I spent around two and a half hours with this lady during the encounter, so I was able to unearth a lot of information from her. . . .
>
> Q: Did it -- was it important to you to note, though, that these were not complaints that she had made to any other doctors?
>
> A: I took it into consideration, but it wasn't -- it didn't change my overall impression of what was happening, sir.

(*Id.* at 61:8–62:6). In short, Dr. Walker did precisely what a differential diagnosis requires—he evaluated Ms. Wilson's medical records, took her medical history, performed a physical examination, and, accounting for other potential causes of Ms. Wilson's condition, ultimately concluded that her pain arises from mid urethral sling complications. (*Id.* at 40:13–30).

16 "Comorbidity" refers to a "coexisting" disease or condition in the same individual. Jose M. Valderas, et al., *Defining Comorbidity: Implications for Understanding Health and Health Services*, 7 Annals of Fam. Med. 357, 357 (2009).

Accordingly, I **FIND** that Dr. Walker conducted a proper differential diagnosis such that his specific causation opinion satisfies the reliability prong of *Daubert*.

BSC asks the court, in the event that it admits Dr. Walker's opinions, to limit his testimony to a specific causation opinion on Ms. Wilson. Dr. Walker's expert report does not appear to offer opinions unrelated to Ms. Wilson, and the plaintiffs agree to limit Dr. Walker's testimony accordingly. In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Dr. Walker [Docket 247] is **DENIED**.

M. Motion to Strike the Rebuttal Report of Dr. Abbas Shobeiri

Pending before the court is Defendant BSC's Motion to Strike Rebuttal Report of Dr. Abbas Shobeiri. As discussed below, BSC's Motion to Strike [Docket 400] is **GRANTED**.

1. BSC's Motion to Strike

On August 29, 2014, the plaintiff served a rebuttal expert report pursuant to Federal Rule of Civil Procedure 26(a)(2)(D)(ii) for Dr. Abbas Shobeiri specific to Jacquelyn Tyree. BSC seeks an order striking this report on the grounds that (1) it is untimely under the court's Docket Control Order and Rule 26(a)(2)(D); (2) it is not proper rebuttal evidence as defined by the Federal Rules of Civil Procedure; and (3) under Rule 37(c)(1), the delay is unjustified and prejudicial. (*See generally* Def.'s Mot. to Strike & Incorporated Mem. of Law in Supp. of Its Mot. to Strike Rebuttal Report of Dr. Abbas Shobeiri ("Def.'s Mot. Strike") [Docket 400]).

First, BSC contends that the court directed rebuttal reports be served by July 1, 2014, and the plaintiff did not serve Dr. Shobeiri's report until August 29, 2014. In the alternative, under Rule 26(a)(2)(D), BSC maintains that even in the absence of the court's order, the plaintiff was required to serve the rebuttal report on August 16, 2014, 30 days after BSC served Dr. Green's

supplemental report. In opposition, the plaintiff contends that Dr. Shobeiri's report was timely because it was filed within 30 days of Dr. Green's August 16, 2014 deposition, in which she argues Dr. Green offered new, additional opinions. (Pl.'s Resp. in Opp. to BSC's Mot. to Strike Rebuttal Report of Dr. Abbas Shobeiri ("Pl.'s Resp. Opp.") [Docket 407], at 6).

Next, BSC argues that in addition to the plaintiff's failure to meet deadlines, Dr. Shobeiri's report is not proper rebuttal evidence "intended solely to contradict or rebut evidence on the same subject matter identified by another party under paragraph (2)(B)." Fed. R. Civ. Proc. 26(a)(2)(D)(ii). BSC takes issue with the plaintiff's failure to identify what Dr. Shobeiri's report is intended to rebut. (Def.'s Mot. Strike [Docket 400], at 5). The plaintiff argues, however, that "it is irrelevant that the same evidence might also support the case in chief." (Pl.'s Resp. Opp. [Docket 407], at 7).

Finally, BSC contends that the plaintiff offers no explanation or substantial justification for the delay, and BSC will likely be prejudiced because trial is imminent. (Def.'s Mot. Strike [Docket 400], at 7). The plaintiff rejects BSC's argument by utilizing five factors courts should consider in determining whether a flawed disclosure is either substantially justified and/or harmless pursuant to *Hoyle v. Freightliner, LLC,* 65 F.3d 321 (4th Cir. 2011). (Pl.'s Resp. Opp. [Docket 407], at 9).

2. Procedural Background

The court established its initial schedule for expert disclosures on March 28, 2014. (Pretrial Order # 87 [Docket 39]). This schedule was modified several times by agreement of the parties and orders of the court. On July 23, 2014, the court issued a Second Amended Docket Control Order setting the following deadlines:

Plaintiffs' Expert Reports	May 11, 2014
Defendant's Expert Reports/Rebuttal Expert Reports	June 1, 2014
Plaintiffs' Rebuttal Expert Reports	July 1, 2014
Completion of Expert Discovery	August 1, 2014
Daubert Motions & Non-*Daubert* Dispositive Motions	August 1, 2014
Daubert-based Dispositive Motions & Motions *in Limine*	August 28, 2014

(Pretrial Order #106 [Docket 204]).

BSC met the June 1, 2014 deadline by serving its expert reports, including Dr. Green's. However, Dr. Green required additional time to complete individual medical examinations ("IME"), which took place during the week of July 13, 2014. (Pl.'s Resp. Opp. [Docket 407], at 3). Dr. Green examined Ms. Tyree on July 15, 2014, and BSC served Dr. Green's IME report on July 17, 2014. Dr. Green was deposed on July 19–20, 2014. However, the parties were unable to complete the deposition and did not discuss Ms. Tyree specifically. (*Id.*). Subsequently, the parties agreed to continue Dr. Green's deposition on August 16, 2014, and the court extended the relevant motion deadlines for Dr. Green accordingly. (*Id.*; *see also* Pretrial Order # 106 [Docket 204], at 3 (extending deadline for *Daubert* motions related to Dr. Green to August 21, 2014)). On August 16, 2014, the parties completed Dr. Green's deposition, which included a specific discussion of Ms. Tyree. (Pl.'s Resp. Opp. [Docket 407], at 3–4). On August 29, 2014, the plaintiff disclosed Dr. Shobeiri as a rebuttal expert. (Def.'s Mot. Strike [Docket 400], at 3).

3. Discussion

a. Timeliness

The plaintiff clearly missed the deadline to serve Dr. Shobeiri's rebuttal report under the Docket Control Order. However, common sense dictates that if the court extended the deadlines for Dr. Green, it likewise extended the deadlines for rebuttals to Dr. Green. *See 103 Investors I, L.P. v. Square D Co.*, 372 F.3d 1213, 1216–17 (10th Cir. 2004) ("We see no reason why the Second Amended Scheduling Order should have created a situation in which Investors' rebuttal reports would be due *prior* to the deadline for Square D's initial expert reports. Such a scenario would put Investors in the impossible situation of attempting to rebut something that it had not yet seen."). Therefore, the plaintiff was no longer bound by the Docket Control Order, and Rule 26(a)(2)(D)(ii) governed instead.

Absent a court order, disclosures must be made at least 90 days before trial or if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party, within 30 days after the other party's disclosure. Fed. R. Civ. P. 26(a)(2)(D)(ii). Here, BSC served Dr. Green's expert report on June 1, 2014. However, Dr. Green also supplemented his expert report on July 17, 2014, after personally examining Ms. Tyree. Because the plaintiff is rebutting Dr. Green's opinions specific to his examination of Ms. Tyree, the plaintiff should have served a rebuttal report on August 16, 2014, within 30 days of the supplemental report from Dr. Green. However, the plaintiff did not serve Dr. Shobeiri's rebuttal until August 29, 2014. The plaintiff instead asserts that she had 30 days from Dr. Green's deposition to serve a rebuttal because Dr. Green offered new opinions during his deposition that were not included in his supplemental report.

After thoroughly reviewing Dr. Green's original report, supplemental report, and extensive deposition testimony, I **FIND** that he did not offer any new opinions in his deposition that were not

previously discussed in his expert reports. The plaintiff takes issue with Dr. Green's deposition testimony on (1) marked scarring; (2) banding; (3) the presence of sling arms; (4) the palpability of sling arms; and (5) area of pain. (*See* Pl.'s Resp. Opp. [Docket 407], at 3–4). However, as BSC clearly lays out in its Reply [Docket 411], Dr. Green previously addressed all five of these issues in his supplemental report. (*See* Def.'s Reply in Supp. of Its Mot. to Strike Rebuttal Report of Dr. Abbas Shobeiri ("Def.'s Reply") [Docket 411], at 5; *see also* Green IME re: Tyree [Docket 400-3], at 4). In accordance with Rule 26, the plaintiff should have served Dr. Shobeiri's rebuttal report no later than August 16, 2014, 30 days after being served with Dr. Green's supplemental report. Because the plaintiff served Dr. Shobeiri's report on August 29, 2014, I **FIND** that Dr. Shobeiri's rebuttal is untimely. In light of this finding, I need not address whether it was a proper rebuttal. However, the inquiry does not end at timeliness.

b. Federal Rule of Civil Procedure 37(c)(1)

Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) . . . the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, *unless the failure was substantially justified or is harmless*." Fed. R. Civ. P. 37(c)(1) (emphasis added); *see Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011). The five factors I must consider to determine whether the failure was substantially justified or is harmless are:

> (1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party's failure to name the witness before trial; and (5) the importance of the testimony.

Id. at 329 (quoting *S. States Rack & Fixture v. Sherwin-Williams Co.*, 318 F.3d 592, 596 (4th Cir. 2003)). With the above standards in mind, I will proceed to review Dr. Shobeiri's report.

With respect to the first factor, BSC's supposed surprise at the disclosure of a rebuttal expert is unfounded. Although Dr. Shobeiri's original expert report served on June 1, 2014, included conclusions specific to Ms. Tyree, it did not include conclusions based on a physical examination. Once BSC disclosed Dr. Green's expert opinions related to the examination of Ms. Tyree, it should have expected that Ms. Tyree might choose to rebut those opinions. Nevertheless, the remaining factors weigh heavily against admissibility.

Turning to the second and third factors, the trial is currently set to begin on November 3, 2014, and I will not move it. Accordingly, allowing an improper rebuttal expert at this stage would likely prejudice BSC's ability to properly challenge Dr. Shobeiri. Under the fourth factor, the only explanation the plaintiff offers for her failure to disclose Dr. Shobeiri's rebuttal report within 30 days of Dr. Green's supplemental report is the same explanation I rejected above in regard to timeliness. The final factor to consider is the importance of the disputed evidence. The plaintiffs' expert, Dr. Margolis, opines on specific causation regarding Ms. Tyree based on a physical examination. (*See* Margolis Report [Docket 237-1], at 68–70). As discussed more fully *supra* related to Dr. Margolis, I have reserved ruling on the admissibility of Dr. Margolis's specific causation opinions at this time. Therefore, Dr. Shobeiri's report is not necessarily crucial to the plaintiff's ability to be heard on the merits of her case. In sum, applying the five-factor test, I **FIND** that the plaintiff's failure to disclose Dr. Shobeiri within 30 days of Dr. Green's supplemental report was not substantially justified and is not harmless. Accordingly, BSC's motion is **GRANTED**.

IV. Plaintiffs' *Daubert* Motions

The plaintiffs move to limit or exclude the testimony of Dr. Stephen H. Spiegelberg; Dr. Stephen F. Badylak; Dr. Gary L. Winn; Dr. Christine Brauer; Dr. Patrick Culligan; and Dr. Lonny Green.

A. Motion to Exclude the Opinions and Testimony of Stephen H. Spiegelberg, Ph.D.

The plaintiffs seek to exclude the opinions of Dr. Stephen H. Spiegelberg. Dr. Spiegelberg is a chemical engineer who has extensive experience in polymer science. In his expert report, Dr. Spiegelberg concludes that polypropylene is a safe biomaterial for use in BSC's pelvic mesh devices and polypropylene remains the state of the art for synthetic graft materials. On June 2, 2014, Dr. Spiegelberg filed a supplemental report because the deposition of Frank Zakrzewski, corporate representative for Chevron Phillips Chemical Company ("Chevron Phillips"), provides additional support for the following two opinions: (1) The Medical Application Caution in the Material Safety Data Sheet ("MSDS") for Marlex HGX-030-01 polypropylene resin has no scientific or medical basis; (2) The Advantage and Polyform meshes comprising BSC's pelvic mesh devices contain two different antioxidants; therefore, BSC mesh does not undergo oxidative degradation in vivo. (Spiegelberg Supplemental Report [Docket 215-1], at 1). The plaintiffs argue that (1) Dr. Spiegelberg's opinions regarding position statements by medical organizations; and (2) his state of mind or intent opinions related to the MSDS should be struck. (Pls.' Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Stephen H. Spiegelberg, Ph.D. ("Pls.' Mem. re: Spiegelberg") [Docket 216], at 1). I review each of these objections in turn.

1. Opinions Regarding Position Statements by Medical Organizations

The plaintiffs seek to exclude Dr. Spiegelberg's references to physician organization statements promoting the safety and efficacy of polypropylene material, including those of the

American Urogynecological Society ("AUGS") and the Society for Female Urology and Urodynamics ("SUFU"). Dr. Spiegelberg writes that "this history of safe use has been recognized by leading medical organizations for the treatment of female pelvic floor disorders." (Spiegelberg Supplemental Report [Docket 215-1], at 3).

Plaintiffs argue that Dr. Spiegelberg's characterization and use of these statements should be excluded because Dr. Spiegelberg is unqualified and lacks reliable methodology. As I indicated previously during these MDLs, position statements are not expert opinions. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *33 (S.D. W. Va. Jul. 8, 2014). Dr. Spiegelberg is not using his "scientific, technical, or other specialized knowledge" in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here and **RESERVE** this ruling for trial.

2. Opinions Related to Chevron Phillips's State of Mind or Intent

The plaintiffs also seek to exclude Dr. Spiegelberg's opinions in both his expert and supplemental report related to the MSDS created by Chevron Phillips, the company whose polypropylene BSC used in the manufacturing of POP mesh. The plaintiffs argue that these MSDS opinions are a "backdoor attempt" to opine about Chevron Phillips's state of mind or intent. (Pls.' Mem. re: Spiegelberg [Docket 216], at 7). The majority of Dr. Spiegelberg's expert report properly reviews BSC records, scientific literature, and other expert reports to come to his conclusions. Section I (Polypropylene Raw Material was Appropriate for Use in Boston Scientific's Devices), however, crosses the line into state of mind.

Although Dr. Spiegelberg's opinion, that the Medical Application Caution was not added for any scientific reason, could have been based on the analysis present throughout his report,

instead, he specifically refers to a history of "liability concerns." (Spiegelberg Report [Docket 215-13], at 40 ("Resin manufacturers, mindful of Dow Corning's lawsuits involving their supply of silicone for breast implants, are often reluctant to supply raw material for medical devices based purely on liability concerns, rather than performance concerns.")). Dr. Spiegelberg infers that Chevron Phillips added the Medical Application Caution because it was concerned with liability merely because it is his personal belief and he discovered no evidence to the contrary.

In his supplemental report, Dr. Spiegelberg reiterates his belief that Chevron Phillips "did not add the statement based on any scientific or medical *concerns* with transvaginal mesh." (Spiegelberg Supplemental Report [Docket 215-1], at 3 (emphasis added)). He bolsters this conclusion by relying on a deposition that is both vague and unclear. Dr. Spiegelberg filed a supplemental report after reviewing the deposition of Mr. Zakrzewski. While Dr. Spiegelberg states that the deposition provides additional support for his opinions, it is in fact an unreliable source. Mr. Zakrzewski clearly indicates that he has no knowledge of who wrote the MSDS or why it was written. (*See* Zakrzewski Dep. [Docket 215-14], at 45). Dr. Spiegelberg uses the deposition to unequivocally opine that there is no scientific evidence behind the MSDS; however, Mr. Zakrzewski only states that he was not aware of any scientific testing. (*Id.* at 47). Mr. Zakrzewski's statements are inconclusive and in no way enable Dr. Spiegelberg to infer that Chevron Phillips lacked a scientific basis in adding the caution.

While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—Chevron Phillips's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony

because opinions on these matters will not assist the jury. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I **FIND** that Dr. Spiegelberg's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**.

B. Motion to Exclude the Opinions and Testimony of Stephen H. Badylak, D.V.M., Ph.D., M.D.

The plaintiffs seek to exclude the opinions of Dr. Stephen H. Badylak. Dr. Badylak is a medical doctor and biomaterials expert with research experience related to polypropylene. In his expert report, Dr. Badylak concludes that (1) polypropylene mesh is an appropriate implantable material to reinforce soft tissue; (2) there is no evidence that Advantage or Polyform mesh experience any form of device failure; (3) pathologic evaluation of the mesh shows no evidence of physical fracture, deformation, failure, or polypropylene degradation; (4) BSC reasonably relied on a preclinical study in proceeding to market with the Advantage and Polyform mesh; (5) BSC's design history files are complete; (6) Type-1 polypropylene mesh is non-toxic, non-carcinogenic, and non-degradable in the body; (7) implanting the mesh transvaginally does not increase risk of infection; (8) the design and testing of the BSC devices complied with accepted industry and scientific standards; and (9) examination of two specimens is consistent with the expected

response to polypropylene material and does not evidence product defect. (Badylak Report [Docket 215-13], at 4, 8, 10–17).

On June 16, 2014, Dr. Badylak filed a supplemental report because the deposition of Frank Zakrzewski provides additional support for Dr. Badylak's opinion that the Medical Application Caution in the MSDS for the raw polypropylene material used in BSC's surgical mesh was not based upon or supported by safety concerns, scientific testing, or scientific data. (Badylak Supplemental Report [Docket 215-1], at 1).

The plaintiffs argue that (1) Dr. Badylak's opinions regarding position statements by medical organizations; and (2) his state of mind or intent opinions related to MSDS should be struck. (Pls.' Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. ("Pls.' Mem. re: Badylak") [Docket 214], at 1-2). I review these objections in turn.

1. Opinions Regarding Position Statements by Medical Organizations

The plaintiffs seek to exclude Dr. Badylak's references to physician organization statements promoting the safety and efficacy of polypropylene material, including those of AUGS and SUFU. Dr. Badylak writes that "[t]his resin has a long history of safe and effective use in the body and continues to be used today." (*Id*. at 3). He subsequently quotes the same position statement regarding polypropylene that Dr. Spiegelberg references in his testimony. As discussed more fully *supra* related to Dr. Spiegelberg's expert opinions and consistent with those findings, I will not address the admissibility of this testimony here because position statements are not expert opinions. *Huskey*, 2014 WL 3362264, at *33. I **RESERVE** these evidentiary rulings for trial.

2. Opinions Related to Chevron Phillips's Knowledge, State of Mind, and Corporate Conduct

The plaintiffs also seek to exclude Dr. Badylak's opinions in both his expert and supplemental report related to the MSDS created by Chevron Phillips, the company whose polypropylene Boston Scientific used in the manufacturing of POP mesh. The plaintiffs argue that these MSDS opinions are a "backdoor attempt" to opine about Chevron Phillips's state of mind or intent. (Pls.' Mem. re: Badylak [Docket 214], at 7). A portion of the MSDS testimony in Dr. Badylak's report, as well as all MSDS testimony in the supplemental report are almost identical to Dr. Spiegelberg's testimony. (Badylak Report [Docket 215-13], at 7 ("I have not seen any evidence to indicate the additional language was supported by safety concerns or other scientific data."); Badylak Supplemental Report [Docket 215-1], at 1, 3 ("Mr. Zakrzewski's testimony lends additional support to my opinion that the medical application statement in the MSDS for the raw polypropylene material used in Boston Scientific's surgical mesh was not based upon, nor supported by, safety concerns, scientific testing or data.")). As discussed more fully *supra* related to Dr. Spiegelberg's expert opinions and consistent with those findings, I **FIND** that Dr. Badylak's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**.

C. Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D.

The plaintiffs seek to exclude the opinions of Dr. Gary L. Winn. Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University who has approximately 30 years of experience in safety, health, and training. (Winn Report [Docket 229-1], at 1). In his expert report, Dr. Winn offers opinions with regard to the nature and purpose of Material Safety Data Sheets ("MSDS") and as to the MSDS for polypropylene used by BSC in the manufacture of its pelvic mesh products. (*Id.*). The plaintiffs

argue that the MSDS is relevant and should be admitted, but that Dr. Winn's opinions should be struck entirely because (1) he is unqualified; (2) his methodology is unreliable; and (3) his opinions are impermissible legal conclusions and factual narratives speculating about Chevron Phillips's knowledge. (Pls.' Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. ("Pls.' Mem. re: Winn") [Docket 230], at 2–3). BSC opposes all of the plaintiffs' arguments regarding Dr. Winn, but also acknowledges that "Dr. Winn's testimony and his opinions concern one thing—the MSDS." (Def.'s Mem. in Opp. to Pls.' Mot. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. ("Def.'s Mem. re: Winn") [Docket 281], at 10).

Both parties devote significant portions of their memoranda to arguing for or against the relevance of the MSDS. These arguments are not appropriate for a *Daubert* motion. Rule 702, by its plain terms, contemplates *Daubert* challenges directed at the opinions of *specific* experts, not the opinions of a collection of experts. The court must determine whether *an expert* is qualified, whether his opinions are the product of reliable methodology, and whether those opinions will be helpful to the jury. *See* Fed. R. Evid. 702. I can only conduct the required *Daubert* analysis on an individualized basis.

However, because I have determined that the MSDS is relevant, (*see* Mem. Op. & Order re: MSDS [Docket 443]), I must now examine the remaining arguments regarding the admissibility of Dr. Winn's expert opinions under *Daubert*. As BSC points out, had I excluded the MSDS, Dr. Winn's opinions would not have been necessary. (Def.'s Mem. re: Winn) [Docket-281], at 2).

In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. (Winn Report [Docket 229-1], at 3–8). Dr. Winn concludes that raw polypropylene is not

hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. (*Id.* at 8–10). Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form.[17] Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

D. Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D.

The plaintiffs seek to exclude or limit the expert opinions of Dr. Christine Brauer. Dr. Brauer is a former FDA employee and regulatory consultant who offers opinions regarding the FDA regulatory process and BSC's regulatory activities. Plaintiffs argue that Dr. Brauer's "opinion testimony regarding: (1) the FDA regulatory scheme; (2) the FDA clearance of BSC devices at issue in this litigation; (3) BSC's Directions for Use, Patient Labeling and Patient Brochures; (4) FDA MAUDE Database and MDR Reports; (5) FDA Advisory Panel Meetings; and (6) BSC's Corporate Warning Letter" should be excluded in its entirety. (Pls.' Mem. of Law in Supp. of Mot. to Exclude, or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 232], at 1–2).

I have previously reviewed the opinion testimony of Dr. Brauer under *Daubert*. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *36–37 (S.D.

[17] In fact, in another pleading, there is evidence of an agreement between BSC and its supplier indicating it was BSC's responsibility to determine the suitability of polypropylene application. (*See* Agreement [Docket 287-6], at 3–4; *see also* Winn Report [Docket 229-1], at 10).

W. Va. Sept. 29, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Sanchez* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently materially. The *Sanchez* excerpts quoted below are to explicate the conclusions the court reaches on the issue of Dr. Brauer's expert opinions:

> 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. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, 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 (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 (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); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014 [Docket 223], at 1 ("This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process . . . In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury."). Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

Sanchez, 2014 WL 4851989, at *36–37. Therefore, I **ADOPT** my prior ruling on Dr. Brauer, as stated in *Sanchez*, and **EXCLUDE** her opinions in their entirety.

E. Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D.

The plaintiffs move to limit the opinions and testimony of Patrick Culligan, M.D. Dr. Culligan is a urogynecologist. He offers eleven opinions relating to polypropylene mid-urethral slings and traditional procedures to treat SUI, the risks associated with pelvic surgeries and mesh, BSC's Obtryx device, and the Obtryx directions for use ("DFU"). (*See* Culligan Report [Docket 233-2], at 15–16). The plaintiffs challenge Dr. Culligan's opinions about the "physical properties of polypropylene, the design of the Obtryx, the Obtryx DFU, and the Obtryx patient brochure." (Pls.' Mot. to Limit the Ops. & Test. of Patrick Culligan, M.D. [Docket 233], at 2). In particular, the plaintiffs argue that he is unqualified to testify as to these matters. (*See id.*). The plaintiffs also assert that Dr. Culligan fails to provide sufficient support for his conclusions and that, therefore, his opinions should be excluded as unreliable. (*See id.*).

1. Opinions Regarding the Physical Properties of Polypropylene

In his expert report, Dr. Culligan opines that "[t]here is no evidence that Obtryx is defective or unreasonably dangerous" and "[t]he claims that polypropylene implanted in the pelvic floor degrades, significantly contracts, causes systematic infection, and/or cancer is not supported in the medical or scientific community." (Culligan Report [Docket 233-2], at 16). The plaintiffs argue that these opinions should be excluded because Dr. Culligan lacks qualifications to opine as to these matters and because the opinions are based on an unreliable method.

a. Qualifications

Dr. Culligan is an accomplished urogynecologist. (*See id.* at Ex. A (Dr. Culligan's curriculum vitae)). He has experience treating women for POP and urinary incontinence, (*see id.* at 1), and performing mesh revision surgeries once or twice a month for approximately the last ten years. (*See* Culligan Dep. [Docket 277-3], at 58:15–21). Dr. Culligan has served on university

faculties, published peer-reviewed articles concerning mesh and sling procedures, and served as a reviewer for scientific journals. (*See* Culligan Report [Docket 233-2], at 2–8). He also relied upon scientific literature in forming his opinions. (*See id.* at 1–16, Ex. B). In fact, the "[p]laintiffs do not challenge Dr. Culligan's qualifications as a urogynecologist." (*See* Pls.' Mem. of Law in Supp. of Their Mot. to Limit the Ops. & Test. of Patrick Culligan, M.D. ("Pls.' Mem. re: Culligan") [Docket 234], at 5). Instead, the plaintiffs challenge his qualifications to opine as to the properties of polypropylene.

Dr. Culligan testified that he is not an expert in materials:

> Q: And does the pore size change after implantation?
>
> A: Well, we're beginning to get into a line of questioning that would require me to be more of a materials expert, which I'm not.
>
> * * *
>
> Q: Do you know if the Obtryx sling is heated in any fashion when it's manufactured?
>
> A: I – I don't know the specifics of the manufacturing process for these. I'm not a materials or manufacturing expert.
>
> Q: And that's a good point. Maybe I should have asked that at the beginning, could have saved some time. Are you an expert in biomaterials?
>
> A: No, I'm not an expert in biomaterials.

(Culligan Dep. [Docket 233-3 & 233-4], at 57:9–15, 325:9–20) (objections omitted). However, this testimony is not dispositive. *See Huskey, et al., v. Ethicon, Inc., et al.*, No. 2:12-cv-05201, 2014 WL 3362264, at *36 (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony "Q: Okay. You're not a biomaterials expert, are you? A: Um, I'm a clinical medical expert."). I have previously found certain medical doctors qualified to

opine as to polypropylene. *See Jones v. Bard, Inc., et al.*, No. 2:11-cv-00114, [Docket 391], at 6–9 (finding Dr. Ostergard qualified to opine as to polypropylene and product design); *Huskey*. 2014 WL 3362264, at *35–37 (finding Dr. Johnson qualified to opine as to mesh degradation)). Dr. Culligan has similar types of experience as these prior experts. *See Jones*, No. 2:11-cv-00114, [Docket 391], at 1, 6–7 (noting Dr. Ostergard's performance of thousands of POP surgeries, SEM imaging of mesh, participation in an ongoing degradation study, and practice of 45 years); *Huskey*, 2014 WL 3362264, at *36 (noting Dr. Johnson's experience implanting at least 750 TVT and TVT-O devices, performance of 25–30 polypropylene sling revisions, and research on urinary incontinence treatments).

Therefore, I **FIND** that Dr. Culligan is qualified to testify as to the opinion that "[t]here is no evidence that Obtryx is defective or unreasonably dangerous" and "[t]he claims that polypropylene implanted in the pelvic floor degrades, significantly contracts, causes systematic infection, and/or cancer is not supported in the medical or scientific community." (Culligan Report [Docket 233-2], at 16).

b. Reliability

The plaintiffs also argue that Dr. Culligan's opinions regarding the physical properties of polypropylene nevertheless lack a reliable scientific foundation. (Pls.' Mem. re: Margolis [Docket 234], at 10–12). I agree.

Although Dr. Culligan is qualified to testify about polypropylene, his method is unreliable. In *Huskey*, I found that "drawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming" a similar opinion regarding degradation. *See Huskey*, 2014 WL 3362264, at *36. However, even if Dr. Culligan considered both scientific literature and

his experience, his deposition testimony reveals flaws in his method:

> Q: And does that pore size change after implantation?
>
> A: Well, we're beginning to get into a line of questioning that would require me to be more of a materials expert, which I'm not.
>
> Q: Okay.
>
> A: So – but I can give you my clinical opinion.
>
> Q: Go ahead.
>
> A: That, no I don't believe the pore size changes from any of my clinical experience with the products.
>
> Q: And what do you base that opinion on?
>
> A: My only experience with your question would have to do with removing products and just examining them grossly whenever I've had to do that.

(Culligan Dep. [Docket 233-3 & 233-4], at 57:9–58:4) (objections omitted). Dr. Culligan's opinions regarding polypropylene are general and do not relate to a particular plaintiff. Basing an opinion on "gross[ ]" examinations of products "whenever [he] had to do that" is not a reliable scientific methodology to reach these generalized conclusions. (*See id.* at 58:1–4). Dr. Culligan elaborates further:

> Q: . . . [Y]ou said you grossly examined some mesh that you've explanted. Have you ever tried to determine in any measurement form whether the shape or size of the mesh has changed significantly?
>
> A: No. It wouldn't be relevant to what I'm talking about because if I remove part of a piece of mesh, I'm removing part of that mesh and I wouldn't have any way to measure that against how that specific part that I removed was sized, you know, when it was placed. It's – it's impossible to make a before and after comparison like that.

(*Id.* at 428:16–429:6). Dr. Culligan fails to provide a sound basis for his opinions. His method is unreliable, and, therefore, his opinions as to the properties of polypropylene are **EXCLUDED**.

2. Opinions Regarding the Design of Transvaginal Mesh

Also, Dr. Culligan contends that "Boston Scientific's decision to design and market the Obtryx incorporating a Type I mesh was reasonable and appropriate." (*Id.* at 15). The plaintiffs challenge Dr. Culligan's qualifications and the reliability of this opinion.

First, the plaintiffs argue that Dr. Culligan lacks qualifications to opine as to the design of transvaginal mesh. In support, the plaintiffs point to deposition testimony of Dr. Culligan, where he admits that he is not an expert in design and where he is unable to answer questions concerning pore size, contraction, and the word "detanged," which the plaintiffs contend are "important design components." (Pls.' Mem. re: Culligan [Docket 234], at 8–9).

Dr. Culligan states that he is no expert in product design:

> Q: Okay. Are you an expert in the design of slings?
>
> A: I'm not sure quite how to answer that. I have never designed one that was manufactured, but I certainly have preferences. And as a surgeon I am certainly an expert on how to implement designs. So it's – it's – I hope you understand there's a – sort of an overlap there.
>
> Q: Let me see if I can make it easier. You're not an expert in determining the appropriate pore size, for example, for slings, are you?
>
> A: Well, as I mentioned earlier today, there tends to be a sort of a classification system for the mesh products. And the mesh products that are available tend to fall within the pore size that's thought of as the Type I mesh material. So I would not be in a position to determine the pore size of a sling. I don't manufacture slings.
>
> Q: And that goes back to the fact that you're not an expert in biomaterials; correct?
>
> A: Correct. I'm not a biomedical engineer.

(Culligan Dep. [Docket 233-3 & 233-4], at 326:17–327:24) (objections omitted). In *Jones*, I found Dr. Ostergard, also a urogynecologist, qualified to testify about product design based on his

knowledge and experience. *See Jones*, No. 2:11-cv-00114, [Docket 391], at 8–9. However, Dr. Ostergard had performed sling product design work "namely, a polytetrafluoroethylene suburethral sling in the 1980s, along with . . . design theory work for AMS[.]" *Id.* at 9. Here, Dr. Culligan admits that he lacks experience with sling design. The fact that he has design "preferences" as a practicing doctor in itself does not render him an expert in product design. (Culligan Dep. [Docket 233-3 & 233-4], at 326:23). Therefore, I **FIND** that Dr. Culligan is not qualified to opine as to product design.

As a result, I do not need to address the reliability of Dr. Culligan's opinion that "Boston Scientific's decision to design and market the Obtryx incorporating a Type I mesh was reasonable and appropriate." (Culligan Report [Docket 233-2], at 15). It is **EXCLUDED**.

3. Opinions as to the Obtryx DFU

The plaintiffs also challenge Dr. Culligan's opinion that "[t]he DFU for the Obtryx adequately warns of all potential complications" and that "[i]t is not appropriate to include rates of complications for a procedure in product labeling[.]" (*Id.* at 16). Dr. Culligan based his opinion on the adequacy of the Obtryx DFU on "carefully reading the DFU and realizing, with my knowledge of slings and their potential complications, that the DFU adequately covered them." (Culligan Dep. [Docket 233-3- & 233-4], at 259:3–10). He also notes that he based his opinion on a description for use. (*Id.* at 259:19). The plaintiffs argue that Dr. Culligan lacks qualifications to opine as to the DFU and that his opinions as to the Obtryx DFU are unreliable.

As for qualifications, Dr. Culligan has "participated in the drafting of a DFU." (*Id.* at 260:4–5). However, he testified that he hired a regulatory consultant that wrote the first draft and that he "then . . . just worked on the specific wording for that document." (*Id.* at 260:13–16). Also,

he admits that he is "not an expert in the drafting of DFUs." (*Id.* at 261:5–6). Dr. Culligan further testifies about his lack of expertise as to the inclusion of complication rates in DFUs:

> Q: In general, do directions for use include complications to your knowledge?
>
> A: I – I guess I can't really answer for all directions of use. I'm not an expert on what directions of use are supposed to include. I'm thinking about my knowledge of my own, you know, document and certainly include information about how to avoid or by the proper use implying how to avoid complications. I – you know, I'm not sure –
>
> Q: Okay. Fair enough.
>
> A: -- what you want.

(*Id.* at 305:16–306:8) (objections omitted). Dr. Culligan does not have the "knowledge, skill, experience, training, or education" to opine as to the Obtryx DFU. Fed. R. Evid. 702; *see In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 607 (S.D. W. Va. 2013) (finding Dean Altenhofen, M.D., unqualified to opine as to adequacy of warnings). Therefore, I **FIND** that Dr. Culligan is unqualified to testify as to these opinions. As a result, I need not address the plaintiffs' argument that Dr. Culligan's opinions as to the Obtryx DFU are unreliable. These opinions are **EXCLUDED**.

4. Opinions as to the Obtryx Patient Brochure

In his deposition, Dr. Culligan testified that he may offer opinions about the Obtryx Patient Brochure. (*See* Culligan Dep. [Docket 233-3& 233-4], at 148:13–18). However, he was unable to state an opinion on the Obtryx Patient Brochure in his deposition because he was not provided with a copy of it. (*See id.* at 155:15–19). Even so, Dr. Culligan included no opinions about the Obtryx Patient Brochure in his expert report. "Under Rule 26, expert reports must contain 'a complete statement of all opinions the witness will express and the basis and reasons for them.'" *Lewis v.*

Ethicon, Inc., 2:12-cv-4301, 2014 WL 186872, *17 (S. D. W. Va. Jan. 15, 2014) (citing Fed. R. Civ. P. 26(a)(2)(B)(i)). In considering the factor test set forth in *Hoyle v. Freightliner, LLC*, it does not appear that Dr. Culligan's omission was "substantially justified or harmless." *Id.* at *9–10 ("In determining whether the nondisclosure of evidence is substantially justified or harmless under Rule 37(c), a district court must consider '(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party's failure to name the witness before trial; and (5) the importance of the testimony.'") (citing *Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011)). Dr. Culligan's deposition does not even provide the specific opinion which Dr. Culligan would offer at trial regarding the brochure. Dr. Culligan's testimony as to this matter is **EXCLUDED**. Therefore, I need not address his qualifications to opine as to the Obtryx Patient Brochure or the plaintiffs' reliability argument.

5. Dr. Culligan's References to POP

In his expert report, Dr. Culligan writes about POP and the treatment of POP. (*See, e.g.*, Culligan Report [Docket 233-2], at 13). The product at issue in this case is the Obtryx to treat SUI. I do not find Dr. Culligan's references to POP and POP treatments to be material to my *Daubert* ruling here. The plaintiffs challenge his opinions that relate to the Obtryx and slings generally.

Therefore, the plaintiffs' Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D., is **GRANTED**.

F. Motion to Limit the Opinions and Testimony of Lonny Green, M.D.

In this case, BSC offers Dr. Green to testify as an expert witness on (1) common female pelvic floor disorders; (2) treatment for SUI; (3) treatment options for urge incontinence; (4)

midurethral slings as the standard of care in treatment of SUI; (5) treatment for POP; (6) risks of pelvic surgery; and (6) specific causation opinions related to the plaintiff, Ms. Hendricks. (*See generally* Green Report [Docket 354-1]). Dr. Green is a board-certified urologist and the Director of the Virginia Women's Continence Center, a division of the Virginia Women's Center, in Richmond, Virginia. (*Id.* at 1). Dr. Green "treat[s] a wide range of female pelvic floor disorders" and has "extensive experience with the device at issue in this case, the Obtryx Transobturator Mid-Urethral Sling." (*Id.*).

The plaintiffs move to limit or exclude the opinions of Dr. Green, raising three primary objections: (1) Dr. Green is not qualified to opine on the adequacy of the Obtryx Directions for Use ("DFU") and these opinions are not the product of a reliable methodology; (2) Dr. Green is not qualified to offer opinions on the significance of the FDA 510(k) clearance; and (3) Dr. Green is not qualified to offer opinions that the Obtryx does not shrink, contract, degrade, or cause systemic infections and these opinions are methodologically flawed and lack any reliable bases. (*See generally* Pls.' Mem. of Law in Supp. of their Joint Mot. to Limit the Ops. & Test. of Lonny Green, M.D. ("Pls.' Mem. re: Green") [Docket 355]). I review these objections in turn.

1. Obtryx DFU

a. Qualifications

First, the plaintiffs argue that Dr. Green is not qualified to offer opinions on the Obtryx DFU because he has never written a DFU and could not describe the general requirements for a DFU during his deposition. (Pls.' Mem. re: Green [Docket 355], at 5). BSC contends that Dr. Green need not be a warnings or regulatory expert "to offer competent, helpful testimony on the subject of what risks [BSC] should have warned against for the Obtryx." (Mem. in Opp. to Pls.'

Mot. to Limit the Ops. & Test. of Dr. Lonny Green, M.D. ("Def.'s Mem. re: Green") [Docket 361], at 2–3).

Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

In his expert report, Dr. Green discusses the risks of pelvic surgery and states that "[a]ll of the aforementioned potential complications are adequately warned of in the [DFU] for the Obtryx sling." (Green Report [Docket 354-1], at 16–18). Dr. Green fails to address the significance of complications he has not seen in his practice, and which are not warned of in the DFU. In his deposition, Dr. Green admits he has never drafted a DFU for a medical device or pharmaceutical. (Green Dep. [Docket 354-3], at 532). Although Dr. Green indicates he has "expertise" in the process of writing patient handouts warning against drug complications, his experience appears to be limited to his review and distribution of these handouts, rather than contribution to the drafting. (*Id.*). Accordingly, I **FIND** that Dr. Green is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU should be **EXCLUDED**.

2. FDA 510(k) Clearance

Second, the plaintiffs object to Dr. Green's opinions and testimony regarding the FDA because he is not an expert on the 510(k) clearance process. (Pls.' Mem. re: Green [Docket 355], at 7). However, I need not reach the second issue in light of BSC's statement that it does not intend to elicit testimony from Dr. Green on the 510(k) clearance process. (Def.'s Mem. re: Green [Docket 361], at 5–6). Furthermore, even if Dr. Green does attempt to offer testimony on the FDA 510(k) clearance process, his testimony will be inadmissible for two reasons. First, these opinions were not present in his expert report. Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Second, as discussed more fully *supra* related to Dr. Brauer's expert opinions and consistent with those findings, the parties may not present evidence regarding the FDA 510(k) clearance process.

3. Mesh Shrinkage, Degradation, & Infections

a. Qualifications

Lastly, the plaintiffs argue that Dr. Green is not qualified to opine that the Obtryx does not shrink, contract, degrade, or cause systemic infections because he is not a pathologist and "has never looked at any mesh (explanted from a patient or otherwise) under a microscope." (Pls.' Mem. re: Green [Docket 355], at 9). I disagree. Simply because Dr. Green has not personally performed pathology research on polypropylene explants does not necessarily render him unqualified under Rule 702 to offer opinions on the suitability of the Obtryx device. An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Dr. Green has performed almost 3,000 sling procedures, and his clinical practice has "largely focused on the treatment of female urinary incontinence" over the last twenty years. (Green Report [Docket 354-1], at 1; Green Dep. [Docket 361-3], at 390). Further, Dr. Green cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective. I therefore **FIND** that Dr. Green is qualified to offer the opinion that the Obtryx mesh does not shrink, contract, degrade, or cause systemic infections.

b. Reliability

The plaintiffs also argue that Dr. Green "has not utilized any method – let alone a reliable method – to reach the conclusions outlined in his report." (Pls.' Mem. re: Green [Docket 355], at 10). Dr. Green plans to testify that he has not seen "evidence of polypropylene degradation,

systemic infection, or other unexpected reactions" and that "[t]he Obtryx has proven to be safe and efficacious for the treatment of female SUI." (Green Report [Docket 354-1], at 15). District courts have "considerable leeway" in applying *Daubert's* reliability factors. *Kumho Tire*, 526 U.S. at 152. Here, Dr. Green's opinion is partially based on the fact that he has observed minimal complications in his clinical practice. Obviously, this type of opinion is not subject to testing or peer review. Additionally, Dr. Green explains that his "clinical experience with the Obtryx is on par with the findings in [the] studies" he cites throughout his expert report. Therefore, I **FIND** Dr. Green's clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion.

In conclusion, (1) Dr. Green's DFU opinions are excluded; (2) BSC has conceded that Dr. Green will refrain from testifying about the FDA 510(k) clearance process; and (3) Dr. Green's opinions on the suitability of the Obtryx are not excluded under *Daubert*. Accordingly, the plaintiffs' Motion to Limit the Opinions and Testimony of Lonny Green, M.D. [Docket 335] is **GRANTED IN PART** and **DENIED IN PART**.

V. Effect of *Daubert* Rulings

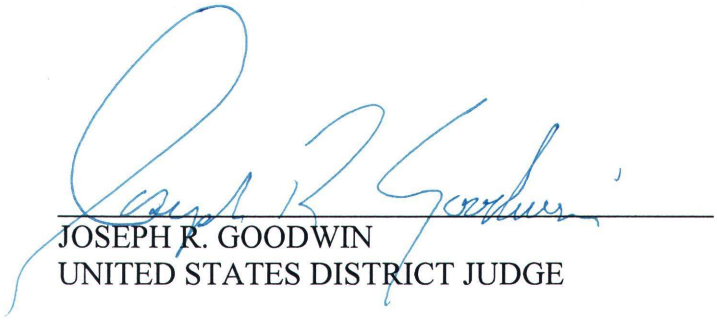
I emphasize that my rulings *excluding* expert opinions under Rule 702 and *Daubert* are dispositive of their admissibility in these cases, but my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VI. Conclusion

To reiterate: The defendant's motion with respect to Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 227] is **DENIED**. The defendant's motion with respect to Dr. Margolis [Docket 237] is **GRANTED IN PART** and **DENIED IN PART** and **RESERVED IN PART**. The defendant's motion with respect to Dr. Trepeta [Docket 235] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Drs. Mays and Gido [Docket 221] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Pence [219] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Barker [Docket 223] is **GRANTED**. The defendant's motion with respect to Dr. Ostergard [Docket 217] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Iakovlev [Docket 225] is **GRANTED**. The defendant's motion with respect to Dr. Blaivas [Docket 239] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Vredenburgh [Docket 241] is **GRANTED**. The defendant's motion with respect to Dr. Rosenzweig [Docket 251] is **DENIED**. The defendant's motion with respect to Dr. Walker [Docket 247] is **DENIED**. The defendant's motion to strike the rebuttal report of Dr. Shobeiri [Docket 400] is **GRANTED**. The plaintiffs' motion with respect to Dr. Spiegelberg [Docket 215] is **RESERVED IN PART** and **GRANTED IN PART**. The plaintiffs' motion with respect to Dr. Badylak [Docket 213] is **RESERVED IN PART** and **GRANTED IN PART**. The plaintiffs' motion with respect to Dr. Winn [Docket 229] is **GRANTED**. The plaintiffs' motion with respect to Dr. Brauer [Docket 231] is **GRANTED**. The plaintiffs' motion with respect to Dr. Culligan [Docket 233] is **GRANTED**. The plaintiffs' motion with respect to Dr. Green [Docket 354] is **GRANTED IN PART** and **DENIED IN PART**.

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

ENTER: October 29, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE