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

CHARLESTON DIVISION

ROSEANNE SANCHEZ, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05762

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

The following motions are pending before the court: (1) Defendant's Motion to Exclude Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 92]; (2) Defendant's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 58]; (3) Defendant's Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. [Docket 86]; (4) Defendant's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 98]; (5) Defendant's Motion to Exclude the Testimony of Dr. Mark Slack [Docket 115]; (6) Defendant's Motion to Exclude the Testimony of Dr. Peggy Pence [Docket 117]; (7) Defendant's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 71]; and (8) Plaintiffs' Motion to Exclude or Limit Testimony of Christine Brauer, Ph.D. [Docket 113].

For the reasons explained below, the defendant's motion with respect to Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 92] is **DENIED**. The defendant's motions with respect to Dr. Barker [Docket 71] and Dr. Slack

[Docket 115] are **GRANTED**. The defendant's motion with respect to Dr. Margolis [Docket 58] is **GRANTED IN PART** and **DENIED IN PART** and **RESERVED IN PART**. The defendant's motions with respect to Dr. Trepeta [Docket 86], Drs. Mays and Gido [Docket 98], and Dr. Pence [Docket 117] are **GRANTED IN PART** and **DENIED IN PART**. The plaintiffs' motion with respect to Dr. Brauer [Docket 113] is **GRANTED**.

I. Background

This 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, plaintiff Roseanne Sanchez was surgically implanted with two products manufactured by defendant Boston Scientific Corporation ("BSC"): the Pinnacle Pelvic Floor Repair Kit (the "Pinnacle") to treat pelvic organ prolapse and the Advantage Fit Transvaginal Mid-Urethral Sling System (the "Advantage") to treat stress urinary incontinence. (*See* Pls.' Mem. in Supp. of Pls.' Mot. for Partial Summ. J. [Docket 63], at 1).[1] The plaintiffs allege that as a result of implantation of the Pinnacle, Ms. Sanchez experienced several complications, including vaginal discharge, painful intercourse, bleeding, pelvic pain, and cramping. (*See id.*). Their complaint alleges the following causes of action: 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; loss of consortium; fraudulent

[1] Plaintiffs' counsel have stated that they are not pursuing any claims in connection with the Advantage product. (*See* Pls.' Opposition to BSC's Mot. to Exclude Pls.' Experts' Op. that Polypropylene Mid-Urethral Slings are Defective [Docket 112], at 6 n.13).

concealment; and punitive damages. (*See* Compl. [Docket 1]).[2] 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) 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.[3] 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

[2] The claims for manufacturing defect in strict liability, breach of express and implied warranties, and fraudulent concealment have been dismissed. (*See* Mem. Op. and Order (Mots. For Summ. J. on Substantive Claims and Punitive Damages) [Docket 134], at 25).

[3] 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.

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 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).

III. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the opinion testimony of Dr. Thomas Barker, Dr. Michael Margolis, Dr. Richard W. Trepeta, Drs. Jimmy Mays and Samuel Gido, Dr. Mark Slack, and Dr. Peggy Pence. BSC also seeks to preclude the plaintiffs' experts from opining on the alleged defects of polypropylene mid-urethral slings. Before I review these motions, I begin by addressing three of BSC's arguments that apply to many of its *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.

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

BSC moves to preclude the plaintiffs' experts from opining that polypropylene mid-urethral slings are defective. BSC argues that I should grant its motion because these opinions (1) are not generally accepted by the scientific community, (2) have not been tested or subjected to peer review, and (3) run contrary to the published medical literature establishing the safety and

efficacy of these products. In particular, BSC contends that the FDA Advisory Committee, the American Urogynecologic Society ("AUS"), and the American Urological Association ("AUA") have concluded that these products are safe and effective. BSC further asserts that the plaintiffs' experts cannot point to a single peer-reviewed clinical study demonstrating that polypropylene slings are unsafe or less effective than alternative procedures.

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. Accordingly, BSC's Motion to Exclude Plaintiffs' Experts' Opinion That Polypropylene Mid-urethral Slings Are Defective [Docket 92] is **DENIED**.

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

Dr. Thomas Barker is a professor of biomedical engineering at the Georgia Institute of Technology. (*See* Barker Report [Docket 71-1], at 1). Dr. Barker conducted a series of mechanical tests on the Pinnacle product and found that BSC meshes deform under stress. (*See id.* at 5). Based on these test results, he opines that the deformation of the mesh "foreseeably" leads to harmful in vivo effects, including scarring, erosion, and tissue damage. (*See id.* at 5). Dr.

Barker also opines that the polypropylene mesh used in the Pinnacle device degrades after implantation in the human body due to a mechanical mismatch with the surrounding tissue. (*See id.*, at 4). Finally, Dr. Barker comments on BSC's design process and maintains that BSC failed to adequately test the Pinnacle device prior to marketing it. (*See id.* at 4, 10–15).

BSC moves to exclude Dr. Barker entirely. BSC contends that Dr. Barker is unqualified to offer opinions regarding the properties of polypropylene and BSC's product design or testing. BSC also argues that Dr. Barker's opinions based on his mechanical testing and his opinions regarding the mechanical mismatch between the mesh and the human body are unreliable and irrelevant. BSC further contends that his opinions are litigation driven and unreliable as a result. Finally, BSC argues that Dr. Barker's opinions regarding BSC's product design or testing are impermissible expert testimony because they pertain to BSC's state of mind.

1. Qualifications

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.

(*Id.* 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.*).

I do not doubt Dr. Barker's qualifications in the field of biomedical engineering. However, I need not address them because I find Dr. Barker's opinions to be unreliable. Even if an expert is highly qualified, an analysis of the reliability of that expert's methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence "do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (Goodwin, J.) (excluding opinions of a "very qualified" expert because the basis for the testimony was unreliable). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert*, 509 U.S. at 590.

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

BSC challenges the reliability of Dr. Barker's opinions drawn from his mechanical testing of the Pinnacle product and the Obtryx Transobturator Sling, another BSC mesh product. Dr. Barker tested one piece of Obtryx mesh and two pieces of Pinnacle mesh. (*See* Barker Report [Docket 71-1], at 22). He tested the mesh pieces by cutting strips of the mesh from pristine products and attaching them to clamps. (*See id.* at 22–24). The clamps then stretched the mesh, applying various amounts of pressure. (*See id.* at 24). Dr. Barker then documented the pore sizes of the mesh at each respective strain load. (*See id.*). Based on his test results, Dr. Barker concludes that "the material within BSC Pinnacle and Obtryx surgical implants clearly deforms under physiologically relevant forces exhibited during normal activity." (*Id.* at 34). He explains that deformation leads to smaller effective pore sizes and, thus, reduces tissue ingrowth. (*Id.*). Moreover, Dr. Barker opines that deformation and reduced pore sizes have the "foreseeable

biomedical effect of increased tissue reaction, scar formation, infection, and erosion of the material into or through surrounding tissues." (*Id.*).

BSC argues that Dr. Barker's opinions based on this testing should be excluded as unreliable because his method was flawed. In particular, BSC makes four arguments as to why Dr. Barker's testing was methodologically flawed: (1) his methodology did not follow published protocols; (2) he failed to use a sufficient sample size; (3) his methodology failed to meet peer-reviewed standards; and (4) his tests did not replicate an in vivo environment. As I will explain below, these four factors render Dr. Barker's opinions based on his testing unreliable.

a. Dr. Barker's Methodology Did Not Follow Published Protocols

First, BSC argues that Dr. Barker's opinions are unreliable because he failed to follow the published testing protocols by Drs. Shepherd and Moalli. (*See* Shepherd, JP et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes For Pelvic Organ Prolapse*, 23 Int'l Urogynecology Journal 613, 613 (2012) [Docket 71-2]; Moalli et al., *Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT*, 19 Int'l Urogynecology Journal 655, 655 (2008) [Docket 71-3]). Contrary to the published protocols, Dr. Barker did not conduct his testing in a saline bath, which was designed to help replicate the physiological environment of the human body. (*See* Barker Dep. [Docket 71-4], at 197:20–199:11).

Dr. Barker's failure to conduct his testing in a saline bath is the fatal flaw in his methodology, particularly where Dr. Barker altered the protocols of peer-reviewed studies without a scientific basis for doing so. 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).

Moreover, the use of a saline bath seems to be a particularly pertinent feature to the design of these mechanical tests. Drs. Shepherd and Moalli recognize that, ideally, tests should be done in vivo to learn about the mesh's behavior when inside of the human body. (*See* Shepherd, *supra*, at 619 (stating that "[f]urther research will need to correlate how those differences in biomechanical performance in the lab affect clinical outcomes"); Moalli, *supra*, at 663 (noting that "the next logical step to the current study is the implementation of rigorous in vivo studies to determine how the textile and tensile properties of polypropylene slings relate to tissue behavior, efficacy, patient morbidity, and patient satisfaction")). Dr. Barker seeks to opine about the effects of the mesh inside of the human body, yet Dr. Barker's study did not even attempt to replicate a physiological environment with the use of a saline bath. As a result, Dr. Barker's method is unreliable.

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

Next, BSC argues that Dr. Barker's methodology was flawed because he failed to use a sufficient sample size. He tested one piece of Obtryx mesh and two pieces of Pinnacle mesh. (*See* Barker Report [Docket 71-1], at 22). 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 233:2–12) (objections omitted). Dr. Barker similarly testified about his sample size of two for the Pinnacle:

> Q: Now, with regard to the Pinnacle device, you had N equals 2, right?
>
> A: That's correct.
>
> Q: Okay. Did you do anything to determine the statistical confidence levels with regard to the testing that you performed on the two pieces of Pinnacle mesh?
>
> A: You cannot likewise perform a statistical test on an N of 2. A minimum is a minimum of 3.

(*Id.* at 236:11-20). Dr. Barker's testing of merely one or two samples lacks reliability.

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

Next, BSC argues that Dr. Barker's methodology failed to meet peer reviewed standards. 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 301:20–302:5). Although peer review and publication is only one factor in the *Daubert* analysis and is not dispositive, Dr. Barker's admission sheds light on the flaws in his method.

d. Dr. Barker's Methodology Did Not Replicate an In Vivo Environment

BSC contends that Dr. Barker's methodology was flawed because it did not replicate an in vivo environment. As I explained above, Dr. Barker's failure to use a saline bath to help create a physiological environment contributes to the unreliability of his opinions. Here, BSC further argues that Dr. Barker's tests failed to replicate the forces in the female pelvic floor. Dr. Barker's testing was uniaxial, while the forces in the female pelvic floor and the human body generally are multi-directional. (*Id.* at 187:20–188:16).

The mere fact that Dr. Barker's study was uniaxial does not alone render his methodology unreliable. Drs. Shepherd and Moalli's studies were also not precisely demonstrative of the forces in the female pelvic floor, and the authors recognize this limitation. (*See* Shepherd, *supra*, at 619 (stating that "[i]t is important to note that this testing was done ex vivo and in a single dimension"); Moalli, *supra*, at 662 (noting that, "[i]n this paper, we maintain that before studying the impact of slings on tissue behavior in vivo and clinical outcome, physicians should have a good working knowledge of the textile and biomechanical properties of different slings ex vivo").

However, because 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")).

Therefore, Dr. Barker's opinions based on his mechanical testing are unreliable and, thus, **EXCLUDED**.

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

Next, BSC argues that Dr. Barker's opinions on the mechanical mismatch between the vaginal tissue and BSC mesh are unreliable. Through his mechanical testing, Dr. Barker calculated an "elastic moduli" of the Pinnacle and compared it to a "reported elastic modulus" of vaginal tissue. (Barker Report [Docket 71-1], at 17–18). From this comparison, Dr. Barker concludes that the mesh would be stiffer than the vaginal tissue once implanted in the human body. (*Id.*). He opines that this mechanical mismatch "would be destructive to the tissue likely leading to inflammation and pain." (*Id.* at 18).

Dr. Barker is educated and experienced in the field of biocompatibility. (*See* Barker CV [Docket 89-4], at 1). He even says that, based on the elastic modulus he used, "it would be expected by anyone skilled in the art of biomechanical engineering that the relative movement between the Pinnacle . . . and their interacting tissues would be destructive to the tissue likely leading to inflammation and pain." (Barker Report [Docket 71-1, at 18). However, he based his elastic modulus calculations of the Pinnacle mesh on his methodologically flawed and unreliable testing. He also has not done "any cellular experiments to determine mismatch effects" or any specific testing to determine whether the material mismatch is significant between vaginal tissue and BSC mesh. (Barker Dep. [Docket 71-4], at 179:16–182:24). 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.

Focusing on these "principles and methodology," I conclude that Dr. Barker's opinions on the mechanical mismatch between the BSC meshes and vaginal tissue are unreliable and, thus, **EXCLUDED**. *Daubert*, 509 U.S. at 595.

4. BSC's Argument that Dr. Barker's Opinions Are Litigation Driven

BSC also argues that "Dr. Barker's opinions are unreliable because they are litigation driven and they fail to meet the standards he would apply in his professional work outside of litigation." (BSC's Mot. to Exclude the Ops. & Testimony of Thomas H. Barker, Ph.D. [Docket 71], at 2). As I explained above, otherwise 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.

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

The product at issue in this case is the Pinnacle. However, Dr. Barker tested both Pinnacle and Obtryx products. 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 Obtryx device. *See Daubert*, 509 U.S. at 594–95 (noting requirement that expert testimony be both reliable and relevant).

6. Admissibility of Opinions Regarding BSC's Product Testing or Design

Finally, BSC argues that Dr. Barker's opinions about BSC's product testing or design should be excluded because they relate to BSC's state of mind or corporate intent. As I noted above, expert testimony about a defendant company's state of mind is impermissible.

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**.

Therefore, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D., is **GRANTED**.

C. Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

Dr. Margolis is a pelvic floor surgeon and urogynecologist with experience performing surgeries to treat SUI, POP, and patients' complications from prior gynecologic surgeries. (*See* Margolis Report [Docket 58-1], at 1–4). He removes an average of two sling or mesh systems each week. (*See id.* at 3). Dr. Margolis bases his opinions on his personal experience and his review of scientific literature, depositions, and BSC corporate documents. (*See id.* at 5). He also examined Ms. Sanchez and issued a case-specific report. (*See Patient Specific Findings: Mrs. Rosanne Sanchez* in Margolis Report [Docket 58-1]). The plaintiffs offer Dr. Margolis "as both a generic and case specific expert, to opine regarding the following: (1) Stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") surgery can be performed without synthetic, polypropylene mesh; (2) complications resulting from transvaginal implantation of the Boston Scientific SUI and POP mesh; (3) complications resulting from implantation of the Boston Scientific Pinnacle into the body of Rosanne Sanchez[;] (4) past and future damages suffered by Ms. Sanchez due to complication from the Pinnacle device[;] and (5) the reasonableness of the treatment Ms. Sanchez requires." (Pls.' Resp. & Mem. of Law in Opp'n to Mot. to Exclude Michael Thomas Margolis, M.D. ("Pls.' Resp. re: Margolis") [Docket 73], at 1–2).

In particular, Dr. Margolis opines that "[s]ynthetic mesh devices can cause severe, life altering complications including chronic pelvic pain, dyspareunia, nerve injuries, and erosion" and that surgical procedures not using mesh are available to treat POP and SUI with "success

rates equal and superior to synthetic mesh repairs." (Margolis Report [Docket 58-1], at 5). He further contends that BSC should not have designed its slings for implantation in the vagina because the vagina is a "surgically contaminated field" and contains infection-inducing bacteria. (*Id.*). Also, Dr. Margolis opines that the mesh removal process requires several operations. (*Id.*).

BSC moves to exclude certain testimony of Dr. Margolis. Although Dr. Margolis has experience performing surgeries, serving on university faculties, writing peer-reviewed publications, and testifying at an FDA hearing "on the serious issue of complications of transvaginal synthetic mesh placement[,]" BSC argues that his method was unreliable and that his opinions based on this method are irrelevant. (*Id.* at 1–4; *see In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) ("Just because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of the case.'" (citing Fed. R. Evid. 702))).

According to BSC, Dr. Margolis's method was unreliable because he did not consider studies that were contrary to his opinions and because he failed to provide any scientific basis for his other opinions and bases them on personal experience and *ipse dixit* alone. Also, BSC contends that Dr. Margolis's opinions regarding Ms. Sanchez should be excluded because none of his opinions rely on a study involving the BSC Pinnacle, the product at issue in this case. Finally, BSC argues that "Dr. Margolis purports to offer a number of opinions that 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." (BSC's Mot. To Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 58], at 2).

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

Dr. Margolis opines as to the safety and efficacy of polypropylene mid-urethral slings and the complication rates in women with polypropylene mesh. BSC contends that these opinions are unreliable because Dr. Margolis did not consider contrary literature.

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. Admissibility of Opinion that Polypropylene Mid-Urethral Slings Are Not Safe and Effective for the Treatment of SUI

First, BSC contends that Dr. Margolis's opinion that polypropylene slings are not safe and effective for the treatment of SUI is unreliable because Dr. Margolis ignored peer-reviewed literature indicating otherwise.

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).

In response, the plaintiffs contend that Dr. Margolis could not explain his rejection of the *Nilsson* study because he is "bound by the confidentiality order entered by this Court in Ethicon" and because of the "work product privilege related to his role in the Ethicon litigation" (Pls.' Resp. re: Margolis [Docket 73], at 9; *see* Margolis Dep. [Docket 132-2], at 204:7–205:24).

Even if this is so, I am unable to accept the reliability of Dr. Margolis's methodology at

his word. If Dr. Margolis cannot explain the basis of his opinion, I am simply unable to conclude that his opinion is reliable. Accordingly, Dr. Margolis's opinion that polypropylene slings are unsafe and not effective for the treatment of SUI is **EXCLUDED**.

As I noted above, the product at issue in this case is the Pinnacle, which is used to treat POP. In contrast, polypropylene mid-urethral slings treat SUI. Because I exclude Dr. Margolis's opinion on the basis of reliability, I need not address the relevancy of his opinion concerning only polypropylene slings in this Pinnacle POP case.

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

BSC argues that Dr. Margolis failed to consider studies reporting lower complication rates of pain in women with polypropylene mesh and slings than he opines. Dr. Margolis contends that it is "[v]ery common" for polypropylene mesh and slings to "result in pain." (*Id.* at 237:24–238:6). He contends that "[m]ore than 50 percent" of women with a SUI or POP device experience pain, even though he admits that his expert report only discusses studies that found "40 percent vulvar pain rates." (*Id.* at 237:24-238:14). Also, Dr. Margolis gives no scientific basis for disagreeing with studies that find lower rates of pain in women:

> 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.

(*Id.* at 239:2–13). Without further explanation for his disagreement with these studies, Dr. Margolis's method is unreliable. Therefore, Dr. Margolis's opinions regarding the complication rates of pain in women with polypropylene mesh and slings are **EXCLUDED**.

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

BSC argues that Dr. Margolis's general opinions, that complications in women with polypropylene mesh products are high, should be excluded as unreliable. BSC points to several phrases that Dr. Margolis states in his report and deposition that indicate his opinion on high complication rates. (*See* BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Testimony of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 59], at 8 (quoting "'high complication rates;' 'plethora of complications;' 'tidal wave of complications;' 'extremely high rates,' '[infection] is common in mesh patients'"). BSC contends that Dr. Margolis disregards literature revealing single digit complication rates without sufficient explanation. Dr. Margolis discounts these studies by alleging that the complications are underreported, that the studies are inaccurate, and that the data is possibly fabricated:

> Q: All of the studies of slings that indicate that the complication rates are in the low single digits, you would disagree with those as well?
>
> A: I do. I think they're under reported.
>
> . . .
>
> Q: . . . Explain to me how the complications in the studies are under reported?
>
> A: I don't believe those numbers are accurate. There are more complications than are reported in those studies, for whatever reason.
>
> Q: You don't know why?
>
> A: I don't know why, and I'm not going to accuse anyone of fraud or blah, blah, blah. Not going to do that.

Q: You just believe that those studies that show low single-digit complication rates are just wrong and you don't know why?

A: They're inaccurate. I believe they're incorrect.

Q: Would you offer – do you have the same belief with regard to studies of polypropylene devices used to treat pelvic organ prolapse that have low single-digit complication rates?

A: I do.

Q: Do you think those are also inaccurate?

A: I do.

. . .

Q: Are you offering an opinion that there is fabricated data regarding polypropylene mesh?

A: It is quite possible. You've had access to my opinions for a long time. It shouldn't surprise you.

(Margolis Dep. [Docket 132-2], at 240:5–8, 241:12–242:7, 243:9–13). These conclusory statements without further explanation are insufficient to survive *Daubert* scrutiny.

In making its argument, BSC particularly focuses on the unreliability of Dr. Margolis's claims as to the dyspareunia rates in patients undergoing POP mesh surgery. In his report, Dr. Margolis cited a 2012 study that found a dyspareunia complication rate of 6.2% to 24.4%. (*See* Margolis Report [Docket 58-1], at 16–17). However, at his deposition, Dr. Margolis testified that he believed the dyspareunia rate was closer to 25%. (*See* Margolis Dep. [Docket 132-2], 255:24–256:2, 256:23–257:1, 258:7–259:9). 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." (*Id.* 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). As a result, Dr. Margolis's methodology and opinions relating to the general complication rates in women with polypropylene mesh are unreliable and, thus, **EXCLUDED**.

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

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions. BSC contends that he based these opinions on his personal experience alone.

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

In his report, Dr. Margolis opines that "[t]here is a lack of sound scientific evidence supporting clinical benefits as it relates to POP and/or SUI polypropylene mesh" and that "[a]t the time the Boston Scientific transvaginal mesh products were introduced, there was no credible scientific evidence that supported utilization of a transvaginally placed polypropylene mesh." (Margolis Report [Docket 58-1], at 7, 17). BSC argues that Dr. Margolis has no basis for this opinion because he contradicted himself during his deposition. Dr. Margolis testified at his deposition that there were studies supporting the use of polypropylene and such studies were available when BSC released its transvaginal mesh products. (*See* Margolis Dep. [Docket 132-2], at 227:14–22, 274:1–6, 275:14–19). In response, the plaintiffs disagree with BSC's allegation and state that his testimony was consistent. According to the plaintiffs, Dr. Margolis never opined that there was *no* data, just no *credible* data.

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. Therefore, I **EXCLUDE** Dr. Margolis's opinions on a lack of scientific evidence.

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

Dr. Margolis opines that "[t]here are a host of traditional surgical procedures available for the treatment of prolapse and incontinence that have success rates equal and superior to mesh repairs[.]" (Margolis Report [Docket 58-1], at 8). BSC challenges Dr. Margolis's opinion as to the Burch procedure. In his report, Dr. Margolis noted that "[t]here is ample evidence in the literature that the Burch procedure is an excellent operative procedure for stress incontinence treatment." (Margolis Report [Docket 58-1], at 9). BSC seeks to exclude Dr. Margolis's opinion that the Burch procedure is more effective than polypropylene mesh slings because Dr. Margolis failed to identify any "head-to-head studies" supporting this conclusion. (Margolis Dep. [Docket 132-1], at 137:6–15).

Even so, 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).

Dr. Margolis's failure to identify a comparison study raises concern as to the reliability of his opinions. However, unlike some of his other opinions, Dr. Margolis's conclusions are based on several peer-reviewed studies that show high success rates for the Burch procedure. His opinion is sufficiently reliable for *Daubert*.

However, *Daubert* requires expert testimony to be both reliable and relevant. *Daubert*, 509 U.S. at 597 ("[T]he Rules of Evidence—especially Rule 702—do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). At issue in this case is the Pinnacle device to treat POP. Therefore, Dr.

Margolis's opinion that the Burch procedure is more effective than polypropylene mid-urethral slings in the treatment of SUI is irrelevant to Ms. Sanchez's claims. As a result, Dr. Margolis's opinion as to this matter is **EXCLUDED.**

c. Admissibility of Opinion that the Xenform Slings are More Effective than Polypropylene Slings

Dr. Margolis uses Xenform slings, which are slings made of pig skin, (*see* Margolis Dep. [132-1], at 97:15–24), or "fetal bovine graft." (Margolis Report [Docket 58-1], at 4). Dr. Margolis testified that his complication rate for the Xenform sling was less than 4% and that Xenform slings were a safe and effective option for treating SUI. (*See* Margolis Dep. [132-1], at 120:14–21, 133:8–12). BSC argues that Dr. Margolis' opinion should be excluded because he did not provide a sufficient explanation of the comparison of the complication rates of Xenform versus polypropylene and because Dr. Margolis could not point to a study involving Xenform slings. In response, the plaintiffs argue that Dr. Margolis's experience of having "personally performed over a 1000 urethral sling implantation procedures using autgraft, allograft or xenograft" and "extensive explantation of synthetic polypropylene vaginal mesh systems" renders his opinion reliable. (Pls.' Resp. re: Margolis [Docket 73], at 14, 15).

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. As a result, his opinion is **EXCLUDED**.

Because Dr. Margolis's method is unreliable, I need not address whether his opinion on the effectiveness of Xenform and polypropylene slings in the treatment of SUI is relevant to Ms. Sanchez's claims concerning the Pinnacle product for the treatment of POP.

d. Admissibility of Opinion That the Infection Rate of Polypropylene Mesh Is Up to 100%

Dr. Margolis opines in his report that "[s]everal studies have shown significant bacterial colonization and infection of polypropylene mesh." (Margolis Report [Docket 58-1], at 16). When asked about mesh infection rates during his deposition, Dr. Margolis testified that they are "anywhere from 10 to a hundred percent" and later testified that they range from 0% to 100% (Margolis Dep. [Docket 132-2], at 177:14, 293:1–8). BSC points out that Dr. Margolis has twice given a slide presentation to doctors which cites to a study finding infection rates of 0% to 8%. (*See id.* at 290:16–295:10). As a result, BSC contends that Dr. Margolis's claim that infection rates can be up to 100% is unreliable.

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. As a result, Dr. Margolis's opinion as to infection rates is **EXCLUDED**.

e. Admissibility of Opinion That the Complication Rate of Urethral Obstruction is Greater than Ten Percent with Polypropylene Mid-Urethral Slings

BSC argues that Dr. Margolis's opinion about the complication rate of urethral obstruction is unreliable. Dr. Margolis opines that polypropylene mid-urethral slings cause urethral obstruction in more than 10% of patients but could not point to scientific studies in support of his opinion:

> 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 132-2], at 262:6–16). The plaintiffs do not respond to this argument. Without a scientific basis, Dr. Margolis's opinion is unreliable. Therefore, Dr. Margolis's opinion that the complication rate of urethral obstruction is greater than 10% is **EXCLUDED**.

Due to this reliability determination, I need not address the relevancy of Dr. Margolis's opinions concerning the urethral obstruction complication rate for polypropylene mid-urethral slings in the treatment of SUI. As I mention above, this case concerns the Pinnacle product for the treatment of POP.

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

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. The plaintiffs do not specifically respond to this argument.

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**.

3. BSC Argues that Dr. Margolis Did Not Reliably Apply His Methodology to Ms. Sanchez's Case

BSC argues that "Dr. Margolis'[s] case-specific opinions regarding *Sanchez* . . . should also be excluded because he has not reliably applied his methodology to the facts of the case." (BSC's Mem. re: Margolis [Docket 59], at 2; *see id.* at 16–17). I do not have sufficient information to rule on this matter at this time. Therefore, I **RESERVE** my ruling until trial.

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

BSC argues that Dr. Margolis's opinions concerning the following topics fall outside the scope of his qualifications: "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design and development, and marketing." (*Id.* at 17). In their response, the plaintiffs concede that Dr. Margolis will not be offering these opinions at trial. (*See* Pls.' Resp. re: Margolis [Docket 73], at 19–20). Accordingly, this aspect of BSC's motion is **DENIED as moot**.

5. BSC Argues that Dr. Margolis Offers Impermissible Expert Opinions As To BSC's State of Mind

BSC argues that Dr. Margolis seeks to offer testimony as to BSC's state of mind, knowledge, and intent during product development. For example, BSC notes that, in his expert report, Dr. Margolis states that "Boston Scientific is aware of adverse event reports related to both erosion and pain." (Margolis Report, [Docket 58-1], at 14). As I explain above, 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.

In their response, the plaintiffs concede that Dr. Margolis will not be offering these opinions at trial. (See Pls.' Resp. re: Margolis [Docket 73], at 19–20). Therefore, this aspect of BSC's motion is **DENIED as moot**.

Therefore, BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D., is **GRANTED IN PART** and **DENIED IN PART** and **RESERVED IN PART**.

D. 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 86-1]) and on the specific pathology of Plaintiff Roseanne Sanchez (*see generally* Trepeta Specific Report [Docket 86-2]). 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 86-1], 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 [Docket 87] ("BSC's Mem. re: Trepeta")). I review these objections in turn.

1. Dr. Trepeta's Qualifications

To testify as an expert, a witness must be "qualified . . . by knowledge, skill, experience, training or education." Fed. R. Evid. 702. Although Dr. Trepeta has an impressive background in medicine, BSC argues that his medical training does not qualify him under Rule 702 to render the opinions he sets forth in his expert reports.

a. Properties of Polypropylene Mesh

First, BSC objects to Dr. Trepeta's opinion testimony on the 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 86-1], 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 86-3], at 89:22–90:2). 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 90:16–22).

In making this 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 110-4], 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.

b. The Human Clinical Response to Polypropylene Mesh

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta 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 86-1], 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 86-3], at 101:19–21). 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.

Again, 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 id.* 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.[4] Therefore, I **DENY** BSC's motion on this point.

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

As stated previously, an expert's opinion is admissible if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). BSC raises several objections to the reliability and relevancy of Dr. Trepeta's opinion testimony, and I address each of these objections below.

a. *Inconsistency of Opinion*

Dr. Trepeta's general report describes the pathology of vaginal mesh implantation as a disease that is categorized into three primary states: acute, sub-acute, and chronic. (*See* Trepeta General Report [Docket 86-1], at 4). Each state has identifying characteristics and symptoms. (*See id.* at 4–5). BSC argues that Dr. Trepeta's general report seems to describe these states as pathological reactions "specific to [surgical implantation of the] Pinnacle products," whereas his deposition testimony implies that this categorical assessment can be applied to many different types of surgery. (*See* BSC's Mem. re: Trepeta [Docket 87], at 9). Thus, in BSC's view, Dr. Trepeta's testimony in his general report is inconsistent with his deposition testimony and therefore unhelpful to the jury. The plaintiffs deny the existence of a contradiction in Dr. Trepeta's proffered opinion.

[4] I reached the same conclusions when considering a *Daubert* challenges to Dr. Klosterhalfen in *In re C. R. Bard*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) ("Bard argues that Dr. Klosterhalfen is not qualified to opine on causation, and that the basis for his opinions is unreliable. Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on this issue [of causation]."), and Dr. Zheng in *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (ruling that Dr. Zheng, a pathologist, is qualified "to tell the jury the clinical reasons why patients such as Mrs. Huskey require excision of [their mesh devices]").

I will not evaluate the uniformity of Dr. Trepeta's report and his deposition testimony because the existence of an inconsistent expert opinion does not mandate the exclusion of the expert under *Daubert*. *See, e.g.*, *McReynolds v. Sodexho Marriott Servs., Inc.*, 349 F. Supp. 2d 30, 40 (D.D.C. 2004) (explaining that contradictions between the expert's depositions and declarations "go to credibility, rather than *Daubert*'s standard of admissibility"). Accordingly, BSC's motion is **DENIED** in this regard.

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

BSC next 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. (*See* Trepeta Dep. [Docket 86-3], at 62:10–21). 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." (*See* Trepeta General Report [Docket 86-1], 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. (*See 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).

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 87], at 10–11). 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**.

c. Litigation Driven Opinions

Third, BSC argues Dr. Trepeta's opinions are unreliable because they are litigation-driven. Specifically, BSC asserts that Dr. Trepeta's "regurgitation of literature outside of his area of expertise" was for the sole purpose of understanding mesh complications and "driven only by preparation to testify in these matters." (BSC's Mem. re: Trepeta [Docket 87], at 13). Here, Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Trepeta Report [Docket 86-1], 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 110-4], at 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.

d. Dr. Trepeta's Specific Causation Opinion

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

> symptoms of pain, discharge, infection, dyspareunia, mesh exposure, resulting diagnoses, and medical treatment for vaginal and pelvic floor complications are all directly attributable to the implantation of polypropylene surgical mesh in the Pinnacle Pelvic Floor repair surgical mesh used on January 15, 2010. . . . My personal experience as a pathologist, with special training and focus on the pathology of the vagina, as well as my knowledge and training, has shown complications directly as [the] effect of tissue response to polypropylene implant such as [that] received by Ms. Sanchez.

(Trepeta Specific Report [Docket 86-2], at 4). He adds that the complications associated with the human body's pathologic response to the implantation of polypropylene mesh were present in Ms. Sanchez's medical records. (*See id.*). BSC argues that Dr. Trepeta's specific causation

opinion is unreliable because: (1) his general causation opinion is unreliable; (2) he did not personally examine Ms. Sanchez, her pathology reports, or pathology specimens related to Ms. Sanchez; 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 is not determinative because Dr. Trepeta testified that he often gives pathologic opinions without examining patient specimens or pathology reports. (*See* Trepeta Dep. [Docket 110-4], at 37:11–38:9). So long as an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," he does not necessarily have to perform a physical examination of the patient to offer an expert opinion. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Here, Dr. Trepeta reached his diagnosis of Ms. Sanchez by using the same methodology that he would apply when doing his job as a clinical pathologist. That is, he reviewed clinical findings provided to him by clinicians and then provided diagnostic advice. (Trepeta Dep. [Docket 110-4], at 38:5–9). Thus, Dr. Trepeta's failure to examine Ms. Sanchez's pathology reports or specimens does not automatically render his specific causation opinion unreliable.

Although BSC's first two arguments are unpersuasive, its criticism of Dr. Trepeta's differential diagnosis carries significant weight. Differential diagnosis requires the testifying 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 excluded is the most likely." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). BSC maintains that Dr. Trepeta failed to eliminate other possible

causes of Ms. Sanchez's complications, as required for a reliable differential diagnosis. Indeed, in parts of his deposition testimony, Dr. Trepeta stated that he did not consider alternative causes for many of Ms. Sanchez's symptoms:

> Q: Did you consider UTIs as being the cause for the infections in Ms. Sanchez?
>
> . . .
>
> A: No, because the infection I believe she's experiencing is a result of the -- or producing the discharge. And I don't generally associate a vaginal discharge with a UTI.
>
> Q: The dyspareunia that she was experiencing, did you consider any other alternative causes for that post mesh implantation?
>
> A: No, ma'am.
>
> Q: As to the scar formation that you say that she had had post mesh implantation, did you rule out other causes for the scar formation that you said she had?
>
> . . .
>
> A: No. I believe everything pointed to the mesh insertion because the ulcerations that she's experiencing are all related to mesh exposure. I was not able to identify in the report that she had an ulceration that was not associated with mesh exposure.

(*See* Trepeta Dep. [Docket 86-3], at 253:4–23). Conversely, the plaintiffs cite to Dr. Trepeta's testimony that he ruled out alternative causes for Ms. Sanchez's current symptoms:

> Q: You agree that Ms. Sanchez was having pain from multiple ailments prior to her vaginal mesh implant.
>
> A: Yes, ma'am.
>
> Q. Were you able to rule out these conditions as an alternative cause of her pain postimplantation?
>
> A: In part, yes, ma'am. And if we go back to the history . . . she's experiencing symptoms which directly appear to correlate with the mesh and not something that was related to her other symptoms prior to the mesh insertion.

(Trepeta Dep. [Docket 110-4], at 261:18–262:11).

This vague, conclusory answer, however, is insufficient for *Daubert*'s reliability prong. Differential diagnosis must take "*serious account* of other potential causes" to be regarded as a reliable basis for a specific causation opinion. *Cooper*, 259 F.3d at 202 (emphasis added). Here, Dr. Trepeta did not consider alternative causes for some of Ms. Sanchez's most pervasive symptoms, including dyspareunia and scarring, and he simply inferred without any scientific basis or reasoning that her symptoms "appear to correlate with the mesh." A "wholly conclusory finding" that lacks "any valid scientific method" cannot maintain a differential diagnosis. *Id.* at 200. Accordingly, I **GRANT** BSC's motion on this matter and **EXCLUDE** Dr. Trepeta's opinions on specific causation.

In conclusion, Dr. Trepeta's general causation opinions are admitted, 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 opinion testimony about Ms. Sanchez is also excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [Docket 86] is **GRANTED IN PART** and **DENIED IN PART**.

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

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 Expert Report [Docket 98-1], 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 both the Pinnacle and Obtryx products. (*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 Pinnacle and Obtryx meshes shows clear sign of oxidative degradation; and (3) the Pinnacle and Obtryx are thus defective and not suitable to serve as permanent implants. (*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.

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. & Testimony of Jimmy W. Mays, Ph.D. & Samuel P. Gido, Ph.D ("BSC's Mem. re: Mays & Gido") [Docket 100], 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 Pinnacle and Obtryx explants, I will briefly discuss their testing procedures and results. Drs. Mays and Gido received exemplars of Pinnacle and Obtryx products on September 24, 2013. (Mays & Gido Expert Report [Docket 98-1], 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 Pinnacle and Obtryx mesh explants from Steelgate, a repository for explanted transvaginal mesh. (Aff. of Jennifer Black [Docket 117-7], ¶¶ 5–6, 12). Ms. Black identified the available BSC Obtryx and

Pinnacle 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 98-1], 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 99-1], 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			

(*Id.* at 19). However, Dr. Mays did not include the protocol or results of the TGA or the 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. (*Id.* at 49–50).

b. Reliability

With respect to the reliability of Drs. Mays and Gido's testing, BSC makes several specific arguments. As I explain below, I **FIND** that these opinions are unreliable because Drs. Mays and Gido (1) failed to control for error or bias and (2) did not establish or adhere to testing protocols.

i. Lack of Control for Error or Bias

BSC argues that Drs. Mays and Gido's test results are unreliable because plaintiffs' counsel selected the samples and they do not explain the selection process. Citing *Lewis*, BSC contends that there are "no assurances that [the expert] – or plaintiffs' counsel – did not opportunistically choose samples while ignoring others that might have weakened or disproved his theories." *Lewis, et al. v. Ethicon, Inc.*, No. 2:12-cv-04301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014).

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).

BSC also faults Drs. Mays and Gido for failing to calculate the statistical significance of their samples or calculate the rate of error on their tests. For example, 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

BSC also argues that Drs. Mays and Gido failed to adhere to or establish a consistent testing protocol. This failure is extremely prevalent throughout the depositions, and therefore, I will only discuss a few specific examples.

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**.

2. Expert Opinions Not Based on Testing[5]

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 Testimony of Pls.' Expert ("Pls.' Mem. Opp'n") [Docket 111], at 4).[6] The plaintiffs contend that both the expert report and depositions support this explanation; however, they conveniently choose to cite only Dr. Mays's deposition to support their proposition. (*See* Pls.' Mem. Opp'n [Docket 111], at 4–5; *see also* Mays Dep. [Docket 115], at 65 ("I believe all of my conclusions are ones that one could reach simply by looking at 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

[5] 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)).

[6] 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.

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 99-2], 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 111-5], at 65; Gido Dep. [Docket 99-2], 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 99-2], 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

The plaintiffs argue 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, the plaintiffs contend 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 100], at 15). 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 the plaintiffs take 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.

Finally, the plaintiffs argue 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, 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.

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 Expert Report [Docket 98-1], 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 Expert Report [Docket 98-1], 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 Pinnacle and Obtryx are suitable to serve as permanent implants, but his opinions cannot be phrased as legal

conclusions. Therefore, these statements are **EXCLUDED**.

F. Motion to Exclude the Testimony of Dr. Mark Slack

Defendant seeks to limit the opinions of Dr. Mark Slack. Dr. Slack is a consultant gynecologist and practicing urogynecologist in the United Kingdom. (Slack Expert Report [Docket 116-1], at 1). Eighty-five percent of his daily practice involves dealing with the management of prolapse and incontinence. (*Id.*). Dr. Slack opines on the following topics as they relate to BSC's mesh products: (1) pelvic floor anatomy and pelvic floor dysfunction; (2) research and testing necessary for marketing and launch; (3) directions for use ("DFU"); and (4) physician training. (*Id.* at 5). The defendant does not challenge Dr. Slack's opinions regarding pelvic floor anatomy and pelvic floor dysfunction. The defendant seeks to exclude Dr. Slack's opinions on the remaining three topics because he is unqualified and fails to offer any reliable basis for his opinions. (Def.'s Mem. of Law in Supp. of its Mot. to Limit the Ops. & Testimony of Mark Slack, M.D. ("Def.'s Mem. Supp.") [Docket 116], at 1-2). Additionally, the defendant contends that Dr. Slack's report largely consists of improper expert testimony including: (1) narrative testimony; (2) conclusory statements regarding BSC's state of mind; and (3) improper legal conclusions. (*Id*. at 2). As discussed below, Dr. Slack's opinions should be excluded to the extent challenge and, accordingly, BSC's motion to limit his opinions is **GRANTED**.

1. Narrative, State of Mind, & Legal Conclusions

Much of Dr. Slack's export report is a narrative review of corporate documents and his opinions are riddled with improper testimony regarding BSC's state of mind and legal conclusions. (*See, e.g.*, Slack Expert Report [Docket 116-1], at 13 ("Boston Scientific had an obligation to critically evaluate all of the potential complications and their consequences, in order to adequately warn physicians and patients. Boston Scientific did not satisfy their

obligation by failing to study the grave consequences of attempting to treat mesh complications, and did not recognize or admit that the devices might introduce too much risk and should be studied before being marketed."); *id.* at 16 ("Boston Scientific recognized the problems created by not having clinical data supporting the use of its products."); *id.* at 19 ("In March 2007, the Boston Scientific clinical affairs department knew that if a woman suffered erosion or exposure of mesh the consequences could be severe including the need for follow up invasive surgery. This potential significant risk, with the root cause being the mesh itself, was foreseen by Boston Scientific before marketing a single Pinnacle device."); *id.* at 20 ("It appears that as early as 2003, Boston Scientific knew that there could be problems with the polypropylene mesh."); *id.* at 21 ("Boston Scientific was aware of the significant role physician training has with respect to patient safety."); *id.* at 22 ("Boston Scientific knew prior to the time these products were placed on the open market that surgeon technique could impact surgical outcome."); *id.* at 23 ("It was Boston Scientific's goal to create a standardized, reproducible surgical technique."). In fact, an entire section of Dr. Slack's report is about how BSC possessed the same knowledge as the scientific community regarding the safety and efficacy of pelvic floor products before introducing their product into the market. (*Id.* at 10-12).

Dr. Slack also opines on what course of action BSC should have taken; however, the majority of Dr. Slack's opinion simply recites what BSC did or did not do. *See In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 209) ("An expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on the record of evidence."). As I previously discussed, expert opinions on BSC's knowledge, state of mind, and legal conclusions are not appropriate subjects of expert testimony. Therefore, these opinions are **EXCLUDED**.

Although Dr. Slack's impermissible state of mind opinions permeate his entire expert report, I will also briefly address the remainder of the defendant's specific objections based on reliability.

2. Product Design & Testing

The defendant seeks to exclude Dr. Slack's opinions on product testing and design because they lack a reliable basis, and he is not qualified to make them. (*Id.* at 4). Dr. Slack opines that "Boston Scientific did not establish a systematic approach in the development, design and evaluation of the pelvic floor support devices." (Slack Expert Report [Docket 1161], at 12). More specifically he argues that BSC "did not satisfy their obligation" because they did not conduct proper clinical trials. (*Id.* at 13). Dr. Slack bases these opinions on his experience and training, and points out some issues that testing might have revealed. (*See id.* (identifying graft tension, maintenance of graft orientation, shrinkage tendencies, deformation of mesh, potential nerve and blood vessel injuries, histological indicators of immune and inflammatory reactions, impact on sexual function, and bladder and bowel function)). However, Dr. Slack fails to provide a scientific basis for his opinion, including any particular regulation or authority that requires such testing. Dr. Slack's cursory review of the record, identification of risks, and confusing history of other BSC products evidence nothing more than an unsupported personal opinion. Accordingly, I **FIND** that Dr. Slack's opinions related to product design and testing should be **EXCLUDED**. As I **FIND** that Dr. Slack's opinions are unreliable, I need not address whether he is qualified to make them.

3. Directions for Use

The defendant seeks to exclude Dr. Slack's opinions on product labeling, specifically the adequacy of the risk information contained in BSC's DFUs. (Def.'s Mem. Supp. [Docket 116], at

7). Again, the defendant argues THAT Dr. Slack's opinions lack a reliable basis, and he is unqualified to make them. In his expert report, Dr. Slack lists seven pieces of information that BSC did not include in its product DFUs. (Slack Expert Report [Docket 116-1], at 17-18). Although Dr. Slack provides a general definition of what a DFU is, he cites no other authority supporting or explaining why certain information is required. Without any indication of the principles or methods used to establish these seven factors, I cannot reasonably assess reliability. Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief. Additionally, in his deposition, Dr. Slack admits that the DFU he previously drafted for Prosima failed to include some of the same information as the BSC DFU, further illustrating his lack of a consistent methodology. (Slack Dep. [Docket 124-1], at 451-54). Accordingly, I **FIND** that Dr. Slack's opinions related to DFUs should be **EXCLUDED**. As I **FIND** that Dr. Slack's opinions are unreliable, I need not address whether he is qualified to make them.

4. Physician Training

The defendant seeks to exclude Dr. Slack's opinions on physician training because he lacks a reliable basis. (Def.'s Mem. Supp. [Docket 116], at 9). Dr. Slack opines that BSC training programs did not meet the standards necessary to teach complex procedures utilizing the mesh based kits. (Slack Expert Report [Docket 116-1], at 21-22). The majority of this section of Dr. Slack's report is simply a narrative review of corporate documents, which is not helpful to the jury. Additionally, where Dr. Slack briefly comments on the quality of training, he is primarily focusing on the competence of other physicians, which is irrelevant and will not assist the jury in determining the issues in this case. *See id.* at 21 ("When targeting physicians for training Boston Scientific should have invited only *qualified* surgeons as described above to train

on mesh based kits.") (emphasis added)). Accordingly, I FIND that Dr. Slack's opinions related to physician training should be **EXCLUDED**.

G. 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 118-1], 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 and Pinnacle products prior to placing them on the market; (2) the Obtryx and Pinnacle products were inadequately labeled; (3) patients could not adequately consent to the surgical implantation of the Obtryx and Pinnacle due to the misbranding of these products; and (4) BSC failed to meet the postmarket vigilance standard of care for these products, leading to further misbranding. BSC seeks to exclude Dr. Pence's testimony in its entirety, raising objections to Dr. Pence's qualifications as an expert and the reliability of her opinions.

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 on the development of medical products 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*.

I disagree. 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 Pinnacle. 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, as I ruled in *Lewis*, 2014 WL 186872, at *17–19, 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. Having found that Dr. Pence is qualified to offer these opinions, I next address whether her opinions are relevant and reliable.

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

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 118-1], 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*, Dr. Pence gave a similar opinion. 2014 WL 186872, at *18–19. 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. *See id.* at 18. Without a reliable foundation, I excluded Dr. Pence's opinion as unreliable. *See 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 ("Pls.' Resp. re: Pence") [Docket 122], at 5).

I agree with the plaintiffs—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.

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

Dr. Pence proffers two opinions regarding the labeling of the Pinnacle. 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 118-1], 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.[7] *See, e.g., Finn v. G. D. Searle & Co.*, 677 P.2d 1147, 1152 (Cal. 1984) (discussing California's product liability law and explaining that for a failure-to-warn claim, an adequate warning "informs a consumer (or, in the case of prescription drugs, the physician) of potential risks or side effects which may follow the foreseeable use of the product").[8]

BSC adds that even if Dr. Pence's opinions on BSC's labeling practices are relevant, they lack a reliable basis. Dr. Pence states that BSC's labeling fell short of the standard of care, but in BSC's view, she does not provide any authority supporting this assertion and instead insists simply that BSC "should have gone further." (Def.'s Mem. in Supp. of its Mot. to Exclude Peggy Pence [Docket 118] ("BSC's Mem. re: Pence"), at 8 (quoting Pence Dep. II [Docket 118-3], at 300:3–16)). 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 118-1], at 49–50).

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

[7] 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.

[8] In their memorandum, the plaintiffs cite to Florida law to support the relevance of Dr. Pence's testimony on labeling, but as I have previously ruled, California law applies to the plaintiffs' failure to warn claims. (*See* Mem. Op. Ord. (Mots. for Summ. J. on Substantive Claims & Punitive Damages) [Docket 134], at 3).

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 California, 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**.

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 118-1], at 91). BSC argues that this opinion is not helpful to a jury because whether BSC "reported adverse events to the FDA has no bearing" on whether BSC provided adequate warnings or whether its products were defective. (*See* BSC's Mem. re: Pence [Docket 118], at 9).

For the reasons explained in the above section, 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 has 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, as explained above, 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, as in *Lewis*, I **EXCLUDE** Dr. Pence's opinions on postmarket vigilance. *See Lewis*, 2014 WL 186872, at *19 (excluding Dr. Pence's opinion on the defendant's failure to report adverse events to the FDA because (1) the plaintiffs had not brought any claims based on the FDCA, and (2) the opinions will confuse and mislead the jury).

IV. Plaintiffs' *Daubert* Motions

The plaintiffs seek exclude the opinion testimony of Dr. Christine Brauer.

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

Plaintiffs seek to exclude or limit the testimony 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 114], at 2).

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.

V. Conclusion

For the reasons stated above, the defendant's motion with respect to Plaintiffs' Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 92] is **DENIED**. The defendant's motions with respect to Dr. Barker [Docket 71] and Dr. Slack [Docket 115] are **GRANTED**. The defendant's motion with respect to Dr. Margolis [Docket 58] is **GRANTED IN PART** and **DENIED IN PART** and **RESERVED IN PART**. The defendant's motions with respect to Dr. Trepeta [Docket 86], Drs. Mays and Gido [Docket 98], and Dr. Pence [Docket 117] are **GRANTED IN PART** and **DENIED IN PART**. The plaintiffs' motion with respect to Dr. Brauer [Docket 113] is **GRANTED**.

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

ENTER: September 29, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE