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

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are the defendants' (1) Motion to Limit the Testimony of Bruce Rosenzweig, M.D. [Docket 149]; (2) Motion to Limit the Testimony of Prof. Dr. Med. Bernd Klosterhalfen [Docket 152]; (3) Motion to Exclude Opinion Testimony of John F. Steege, M.D. [Docket 155]; (4) Motion to Exclude Certain Opinions of Jerry G. Blaivas, M.D. [Docket 157]; (5) Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher, Ph.D. [Docket 181]; (6) Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., P.E. [Docket 183]; and (7) Motion to Exclude the Opinions and Testimony of Dr. Abhay Pandit, Ph.D. [Docket 185]; and the plaintiffs' (1) Motion to Exclude the Opinions and Testimony of Michael Greenberg, M.D., M.P.H. [Docket 165]; (2) Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, M.D. [Docket 167]; (3) Motion to Exclude the Opinions and Testimony of Harry Johnson, Jr., M.D. [Docket 169]; (4) Motion to Exclude the Opinions and Testimony of Daniel J.

Sexton, M.D. [Docket 171]; and (5) Motion to Exclude the Opinions and Testimony of Wenxin Zheng, M.D. [Docket 175].

For the reasons explained below, the defendants' motions with respect to Dr. Rosenzweig [Docket 149], Dr. Dunn [Docket 183], Dr. Steege [Docket 155], and Dr. Pandit [Docket 185] are **GRANTED in part** and **DENIED in part**. The defendants' motion with respect to Dr. Klosterhalfen [Docket 152] is **DENIED in part** and **RESERVED in part**. The defendants' motion with respect to Dr. Blaivas [Docket 157] is **GRANTED in part** and **DENIED in part** and **RESERVED in part**. The defendants' motion with respect to Dr. Guelcher [Docket 181] is **DENIED**. The plaintiffs' motion with respect to Dr. Greenberg [Docket 165] is **GRANTED**. The plaintiffs' motions with respect to Dr. Pramudji [Docket 167] and Dr. Zheng [Docket 175] are **GRANTED in part** and **DENIED in part**. The plaintiffs' motions with respect to Dr. Sexton [Docket 171] and Dr. Johnson [Docket 169] are **DENIED.**

I. Background

This case is one of more than 60,000 in seven MDLs that have been assigned to me by the Judicial Panel on Multidistrict Litigation. This case involves surgical mesh products manufactured and sold by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, "Ethicon"), to treat female stress urinary incontinence. The device at issue is Ethicon's Gynecare TVT Obturator ("TVT-O"), which was implanted in the plaintiff, Ms. Huskey. The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra. The parties have brought several *Daubert* challenges to proposed experts.

II. Legal Standards

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient

facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper.[1] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). 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 overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review

[1] 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.

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* also 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).

III. Ethicon's *Daubert* Motions

Ethicon seeks to limit or exclude the testimony of Dr. Bruce Rosenzweig, Dr. Bernd Klosterhalfen, Dr. Scott Guelcher, Dr. Russell Dunn, Dr. Abhay Pandit, Dr. John F. Steege, and Dr. Jerry G. Blaivas. I will address each proposed expert in turn.

Before I begin, I will address two arguments that apply to many of Ethicon's *Daubert* motions. First, as I have repeated throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function to determine Ethicon's state of mind, or whether Ethicon acted reasonably. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872, at *6, 21 (S.D. W. Va. Jan. 15, 2014). While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her

opinions—assuming the opinions are otherwise admissible—Ethicon'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. Similarly, "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 will not repeatedly parse the expert reports and depositions of each expert in relation to this same objection. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Second, Ethicon repeatedly argues that expert opinions relating to polypropylene do not apply to the Prolene mesh used in the TVT-O. Ethicon states that experts testifying about polypropylene fail "to account for the important chemical differences between generic polypropylene and PROLENE, which is an isotactic form of polypropylene that has been treated with two proprietary antioxidants." (*See* Defs.' Mem. of Law in Supp. of Mot. to Exclude the Test. and Ops. of Dr. Scott Guelcher, Ph.D. [Docket 182], at 4). This appears to be an argument wholly conceived by lawyers, unfounded in science. The experts in this case, including Ethicon's experts, testify as to "polypropylene" and its propensities. This is a strong indication that Ethicon's argument is disingenuous. For example, Dr. Michael Greenberg, an Ethicon expert, writes in his report that "polypropylene is a safe biomaterial with an extensive history of use inside the human body." (Greenberg Report [Docket 211-4], at 14). Another Ethicon expert, Dr. Harry Johnson writes that "[p]olypropylene is the most used material for pelvic floor repair." (Johnson Report [Docket 212-2], at 24). Further, Dr. Christina Pramudji writes in support of Ethicon that "[p]olypropylene material is safe and effective as a surgical implant." (Pramudji Report [Docket 209-5], at 25). It is clear that the experts in this case do not consider Prolene to be different from polypropylene for the purposes of their opinions in this case. Therefore, to the extent that Ethicon

contends that an expert's opinions are unreliable or unhelpful because they do not account for the "important chemical differences" between polypropylene and Prolene, this argument is rejected.

A. Dr. Bruce Rosenzweig

Dr. Rosenzweig is a urogynecologist and professor of obstetrics and gynecology. He offers several different opinions, each of which Ethicon contends is improper: (1) opinions regarding the sufficiency of warnings set out in the TVT-O Instructions for Use ("IFU") and other promotional materials, (2) opinions that Ethicon failed to provide adequate training, (3) opinions that the TVT-O causes an increased risk of infection, (4) opinions that the TVT-O degrades in vivo and is subject to fraying and particle loss, and (5) opinions regarding mesh shrinkage or contracture. I will address each opinion in turn.

1. Opinions Related to Sufficiency of Warnings on the IFU and Promotional Materials

Dr. Rosenzweig opines that the TVT-O's IFU was inadequate, that Ethicon failed to inform patients and physicians about particular risks of the TVT-O, and that the TVT-O's marketing materials were inaccurate or incomplete. (*See* Rosenzweig Report [Docket 201-1], at 3). Ethicon first argues generally that Dr. Rosenzweig is not qualified to testify about product warnings because he has not drafted an IFU. While it is true that Dr. Rosenzweig has not personally drafted an IFU, Dr. Rosenzweig's testimony reveals that he has consulted on product warnings in the past:

Q. Have you ever prepared IFUs?

A. Well, I did work with Gish Biomedical to get the information that they needed to put in the amnioinfusion catheter IFU.

Q. Did you actually draft the IFU?

A. No, I did not. I worked as a consultant on that.

Q. Have you ever drafted an IFU?

A. No, I have not.

Q. Have you ever drafted a patient brochure?

A. I worked on the amnioinfusion catheter brochures, yes.

(Rosenzweig Dep. [Docket 149-3], at 53:17-54:4). Dr. Rosenzweig also testified that he served on another company's scientific advisory committee that worked on similar documents. (*See id.* at 54:10-12). In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the device." (Rosenzweig Report [Docket 201-1], at 55). Further, as a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT-O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-O's IFU. I therefore **FIND** that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials.[2]

Finding Dr. Rosenzweig qualified to opine generally about the TVT-O's warnings and marketing materials, I now turn to Ethicon's specific objections in relation to particular product warning opinions.

a. Cancer

The plaintiffs state that Dr. Rosenzweig will not testify about cancer. (*See* Pls.' Resp. to Defs.' Mot. to Limit the Test. of Bruce Rosenzweig, M.D. ("Pls.' Resp.") [Docket 200], at 6). Accordingly, Ethicon's motion on this subject is **DENIED as moot**.

[2] Ethicon argues that my decision in the *In re C. R. Bard* MDL to preclude Dr. Bob Shull from testifying about product warnings should control here. *See In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). But there, Dr. Shull *admitted* that he had not developed product warnings, had no experience in that area, and did not hold himself out as an expert in product warnings. *See id.* Dr. Rosenzweig has made no similar admissions. Therefore, my holdings regarding Dr. Shull are inapposite.

b. Cytotoxicity

Dr. Rosenzweig states in his expert report that an internal Ethicon document suggested that polypropylene mesh was cytotoxic. (*See* Rosenzweig Report [Docket 201-1], at 105). Cytotoxicity refers to a material's potential to cause cell death. Dr. Rosenzweig writes that Ethicon failed to undertake testing "to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use." (*Id.* at 105-06). He then opines that Ethicon failed to act as a "reasonably prudent medical device manufacturer" because it "failed to inform physicians and their patients about the risk of its mesh being cytotoxic[]." (*Id.* at 106).

According to Ethicon, cytotoxicity testing "does not represent in vivo testing, and toxicological experience is required to extrapolate the results to humans." (Mem. in Supp. of Mot. to Limit the Test. of Bruce Rosenzweig, M.D. ("Defs.' Mem.") [Docket 150], at 6). Ethicon therefore argues that this testimony exceeds Dr. Rosenzweig's qualifications because he does not have toxicological experience, and he admits that he has never conducted toxicity or cytotoxicity testing of mesh. (*See* Rosenzweig Dep. [Docket 149-3], at 222:4-6). Ethicon also argues that this testimony is unreliable because the internal Ethicon study cited by Dr. Rosenzweig states that "this clinical data provides important evidence that the cytotoxicity of the [polypropylene] mesh observed in vitro does not translate into any clinical significance or adverse patient outcomes." (Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device [Docket 149-8], at 2).

I **FIND** that Dr. Rosenzweig is qualified to offer the opinion that Ethicon failed to inform physicians about the risk that the TVT-O is cytotoxic. Although Dr. Rosenzweig is not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants. (*See* Rosenzweig Aff. [Docket 201-4] ¶ 4). He also stated that he has removed mesh implants, including the TVT, as a result of cytotoxicity. (*See id.*).

I further **FIND** that this opinion is sufficiently reliable. Dr. Rosenzweig relies on an internal Ethicon finding that the mesh used in the TVT-O was cytotoxic. Further, Dr. Rosenzweig states that the potential for cytotoxicity is important information that physicians need to know. (*See* Rosenzweig Report [Docket 201-1], at 106). To the extent that Ethicon believes cytotoxicity is not clinically significant, it may cross examine Dr. Rosenzweig on that issue. Therefore, Ethicon's motion with respect to Dr. Rosenzweig's opinions about the failure to warn about cytotoxicity is **DENIED**.

However, I **FIND** that Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, Dr. Rosenzweig's testimony that Ethicon failed to appropriately test for cytotoxicity is **EXCLUDED**.

c. TVT-O Appropriateness for Certain Populations

Dr. Rosenzweig will also testify that "Ethicon promoted the TVT-O as a 'reproducible' technique that was appropriate for all patients," when in fact it was less efficacious for certain types of women, including obese women, older women, active women, diabetics, smokers, Asian women, and African-American women. (Rosenzweig Report [Docket 201-1], at 77-80). He claims that Ethicon should have warned physicians of risks to these different populations. In support, he simply reviews deposition testimony and internal documents of Ethicon employees expressing concerns about the TVT-O's adaptability to different populations. For instance, Dr. Rosenzweig quotes deposition testimony of Ethicon's Medical Director to show that "obese patients do not fare well with these devices." (*Id.* at 77). He also reviews a document wherein the inventor of the TVT-O stated that the TVT-O was inappropriate for treatment in younger, active women. (*See id.*

at 78).

As the plaintiffs concede, much of this opinion is not relevant to Ms. Huskey's case and should be excluded. (*See* Pls.' Resp. [Docket 200], at 8-9). The only part that is relevant is the TVT-O's appropriateness for younger, active women, a category into which Ms. Huskey falls. But it is not helpful to the jury to have Dr. Rosenzweig read a document explaining what the inventor of the TVT-O thought about this. The jury is capable of reading that document itself. *See In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008); Fed. R. Evid. 702 ("the expert's scientific, technical, or other specialized knowledge" must "help the trier of fact to understand the evidence"). Therefore, Dr. Rosenzweig's opinion that Ethicon should have warned that the TVT-O could be more dangerous for certain populations is **EXCLUDED**.

d. Adverse Event Reporting

Dr. Rosenzweig opines that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate, and misleading." (Rosenzweig Report [Docket 201-1], at 98). Ethicon argues that Dr. Rosenzweig is unqualified to offer this opinion, and it is unreliable. The plaintiffs concede that Dr. Rosenzweig will not offer this opinion at trial. (Pls.' Resp. [Docket 200], at 9-10). Therefore, this aspect of Ethicon's motion is **DENIED as moot**.

2. Failure to Provide Adequate Training

Dr. Rosenzweig opines that Ethicon "failed to provide adequate training" to physicians regarding the use of the TVT-O. (Rosenzweig Report [Docket 201-1], at 3). However, instead of commenting on the quality of training, Dr. Rosenzweig reviews corporate documents showing that Ethicon cut funding for professional trainings which Dr. Rosenzweig says "contrasted" with Ethicon's corporate credo. (*See* Rosenzweig Report [Docket 201-1], at 74-77). Not only is this

opinion simply a narrative review of corporate documents, which is not helpful to the jury, but it is unreliable because Dr. Rosenzweig fails to describe the basis for his opinion that Ethicon's training was inadequate. Therefore, this opinion is **EXCLUDED**.

3. Infections

Dr. Rosenzweig opines that the TVT-O mesh and implantation procedure carry an increased risk of infection. (*See id.* at 26). Ethicon argues that this opinion is not helpful to the jury because Ms. Huskey has not suffered from a mesh-related infection. However, the plaintiffs clearly indicated on their Plaintiff Fact Sheet that Ms. Huskey suffered from an infection. (*See* Pl. Fact Sheet [Docket 161-2], at 6). Further, Dr. Siddique, who partially explanted Ms. Huskey's mesh, testified that Ms. Huskey's eroded mesh caused an infection. (*See* Siddique Dep. [Docket 227-2], at 41:2-14). He also testified that Ms. Huskey suffered from chronic inflammation caused by a chronic infection of the eroded mesh. (*See* Siddique Dep. [Docket 201], at 63:8-11). Therefore, contrary to Ethicon's arguments, infections are a fact in issue in this case, and Ethicon's motion, as presented on this issue, is **DENIED**.

4. Degradation and Fraying

Dr. Rosenzweig will testify that the TVT-O is defective because its mesh degrades in vivo and is subject to fraying and particle loss. (*See* Rosenzweig Report [Docket 201-1], 11-20, 34-46). Further, Dr. Rosenzweig will testify that Ms. Huskey's mesh degraded, frayed, and lost particles.

Ethicon first argues that Dr. Rosenzweig is unqualified to offer these opinions because he does not have a background in polymer chemistry, has never studied biomaterials, and has never done any bench or lab research regarding polypropylene. I disagree. As I stated in relation to *Lewis v. Johnson & Johnson*,

> Simply because Dr. Rosenzweig has not personally performed pathology research on polypropylene explants does not necessarily render him unqualified under Rule 702 to offer opinions regarding the suitability of the TVT device for implantation. An expert may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an expert opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).
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> Dr. Rosenzweig has performed over a thousand pelvic floor surgical procedures, and over 200 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. Dr. Rosenzweig testified that as early as 2004 or 2005, he determined, as a result of explanting mesh products, that polypropylene degrades in the human body. Further, he cites dozens of studies and academic papers in his expert report to support his opinion that vaginally implanted polypropylene mesh degrades. I therefore **FIND** that Dr. Rosenzweig is qualified to offer the opinion that the TVT is not suitable for permanent implantation to treat stress urinary incontinence.

In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2:12-MD-02327, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (internal citations and quotation marks omitted). I **ADOPT** that holding here.

With respect to Dr. Rosenzweig's general causation opinions that the mesh used in the TVT-O degrades, frays, and loses particles, Ethicon contends that these opinions are not helpful to the jury. According to Ethicon, "neither Dr. Rosenzweig nor any of Plaintiffs' other experts can reliably testify (1) that the mesh in Ms. Huskey's TVT-O device *actually* degraded, frayed, or lost particles, or (2) that any such degradation, fraying, or particle loss proximately caused Ms. Huskey's injuries." (Defs.' Mem. [Docket 150], at 13). Ethicon is incorrect that Dr. Rosenzweig's *general causation* testimony—that the TVT-O mesh can degrade, fray, or lose particles—should be excluded under Rule 702 simply because the plaintiffs might fail to carry their burden as to *specific causation*—that Ms. Huskey was injured by the TVT-O mesh. If Ethicon believes the

plaintiffs ultimately fail to carry their burden, they are free to make that argument at trial.[3]

With respect to Dr. Rosenzweig's specific causation opinions, Ethicon contends that they are unreliable because none of the plaintiffs' experts tested Ms. Huskey's explanted mesh. The parties agree that Ms. Huskey's mesh was discarded by the hospital before the parties had an opportunity to test it. Therefore, Ethicon argues that there is no way to test any of Dr. Rosenzweig's opinions about Ms. Huskey's mesh. *See Daubert*, 509 U.S. 579, 593 (1993) ("[A] key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.").

I **FIND** that Dr. Rosenzweig's specific causation testimony on degradation, fraying, and particle loss is not sufficiently reliable under Rule 702.[4] Although he has not examined Ms. Huskey's mesh, he formed his opinion by conducting an examination of Ms. Huskey and determining that the tissues surrounding the remaining mesh were tender. (*See* Rosenzweig Dep. [Docket 149-2], at 281:25-282:5; 283:16-22). He stated that "[w]hen I examine her, I feel a very tender band along the left side of the vagina. That could represent mesh that's frayed, pieces of mesh that are still there, or a scar plate that formed when – before it was excised." (Rosenzweig Dep. [Docket 201-9], at 255:7-11). He agreed that tenderness during an examination can result from "numerous things," including degradation. (Rosenzweig Dep. [Docket 149-2], at 282:7-9). He then stated that of his more than 200 explant surgeries, it is "not [] infrequent" that he sees actual degradation on the explanted mesh. (Rosenzweig Dep. [Docket 201-9], at 275:15-276:14). Based on that experience, and his "work in seeing mesh degradation," he opined that Ms. Huskey's

[3] My holding here also applies to Ethicon's argument that I should exclude as unhelpful Dr. Rosenzweig's general causation opinions that the TVT-O mesh shrinks and contracts in vivo. (*See* Defs.' Mem. [Docket 150], at 19).

[4] Because I exclude Dr. Rosenzweig's specific causation opinions for being unreliable, I do not discuss whether they should also be excluded under Federal Rule of Civil Procedure 37(c) as a result of Dr. Rosenzweig's failure to disclose these opinions in his expert report.

remaining mesh is "more likely than not undergoing degradation." (*Id.* at 276:16-277:3). Finally, when counsel suggested that he was essentially guessing whether Ms. Huskey's mesh had degraded, he stated that "I'm using my experience, my medical knowledge, to make an opinion with a reasonable degree of medical certainty." (Rosenzweig Dep. [Docket 149-2], at 283:12-14).

That is not enough to indicate that his opinions are reliable. In addition to the fact that Dr. Rosenzweig has not seen or tested Ms. Huskey's mesh, he does not explain how tenderness indicates that Ms. Huskey's mesh has degraded. Nor does he attempt to rule out the other potential causes for tenderness that he identified, even though he admits there could be "numerous" others. (Rosenzweig Dep. [Docket 149-2], at 282:7); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) ("[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.").

Quite simply, Dr. Rosenzweig is using other explants to draw an inference about Ms. Huskey's explant. But he does not say precisely how often he finds degradation on explants. He simply states that such a finding is "not [] infrequent." (Rosenzweig Dep. [Docket 201-9], at 275-76). Without proper indicia of reliability, Dr. Rosenzweig's specific causation theories regarding degradation, fraying, and particle loss are **EXCLUDED**. This result does not, as the plaintiffs suggest, unfairly punish them for a missing piece of evidence over which they had no control. Rule 702 and *Daubert* are clear that an expert's testimony must be based on "reliable principles and methods." Fed. R. Evid. 702. That is not present here.

B. Dr. Bernd Klosterhalfen

Dr. Klosterhalfen offers general causation opinions related to infection, degradation, particle loss, shrinkage, and effective porosity of the TVT-O mesh. This is not the first time I have

reviewed *Daubert* challenges to Dr. Klosterhalfen's opinions on these topics. *See In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 617-22 (S.D. W. Va. 2013); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872, at *10-11 (S.D. W. Va. Jan. 15, 2014). Wisely wanting to avoid rehashing old arguments, most of Ethicon's motion argues that Dr. Klosterhalfen's opinions are not helpful to the jury in this case because (1) Ms. Huskey did not develop an infection in this case, and (2) the plaintiffs cannot link degradation, particle loss, shrinkage, or effective porosity to Ms. Huskey's injuries. (*See* Mem. in Supp. of Mot. to Limit Test. of Prof. Dr. Med. Bernd Klosterhalfen [Docket 154], at 3, 5, 11-12). First, as I have already explained, there is evidence that Ms. Huskey developed an infection in connection with her TVT-O implant. Second, simply because Dr. Klosterhalfen's opinions are limited to general causation does not mean they are not helpful to the jury. If Ethicon believes the plaintiffs cannot establish that the TVT-O caused Ms. Huskey's injuries, it can address this issue at trial.

Ethicon also challenges the reliability of two of Dr. Klosterhalfen's opinions: those based on degradation and those based on effective porosity. Ethicon argues that Dr. Klosterhalfen's testimony about surface degradation should be excluded because Dr. Klosterhalfen "cannot reliably testify that degradation has any clinical significance." (*Id.* at 9). The plaintiffs failed to respond to this argument. Without a full expert report,[5] I am unable to determine the full scope of Dr. Klosterhalfen's opinions and their foundation. Therefore, I **RESERVE** for trial my ruling on Dr. Klosterhalfen's degradation opinions.

Ethicon also argues that Dr. Klosterhalfen's testimony about effective porosity is

[5] As in *In re C. R. Bard* and *Lewis v. Johnson & Johnson*, the plaintiffs have again failed to provide a full expert report for Dr. Klosterhalfen. Although they have repeatedly argued that Dr. Klosterhalfen is a "percipient fact witness" under no obligation to provide a report, many of his opinions appear to go beyond his status as a fact witness. I previously found that such a failure is harmless under Federal Rule of Civil Procedure 37(c). *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-4301, 2014 WL 186872, at *10 (S.D. W. Va. Jan. 15, 2014). Despite this prior holding, I will not tolerate continued violations of the plaintiffs' obligation to provide a full expert report under Rule 26. The plaintiffs are advised to provide a more thorough expert report for Dr. Klosterhalfen in future cases.

unreliable because in his deposition, "Plaintiffs failed to elicit any testimony that Dr. Klosterhalfen was familiar with the details of" the studies on which those opinions are based. (*Id.* at 12). But an expert witness is not required to be familiar with the particular details of the studies on which he bases his opinion, as long as an expert in that particular field reasonably relies on the opinions contained in those studies. *See* Fed. R. Evid. 703; *Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 9 (1st Cir. 2001) ("[W]hen an expert relies on the opinion of another, such reliance goes to the weight, not to the admissibility of the expert's opinion."). Ethicon also argues that Dr. Klosterhalfen's opinions are not reliable because they have not been "validated." The plaintiffs fail to respond to this argument, and without an expert report, I again cannot determine the precise bases for these opinions. I therefore also **RESERVE** this ruling for trial.

Accordingly, Ethicon's motion to exclude Dr. Klosterhalfen is **DENIED in part** with the caveat that I **RESERVE RULING**on the admissibility of Dr. Klosterhalfen's degradation and effective porosity opinions.

C. Dr. Scott Guelcher

Dr. Guelcher holds a Ph.D. in chemical engineering and a post-doctoral degree in biomedical engineering. He is currently a professor of chemical and biomolecular engineering. He offers the following opinions in this case: (1) the human body "does not stop responding" to mesh until it is removed entirely, (2) the "dynamic environment where these meshes are implanted coupled with the chronic response of the body leads to polymer instability, embrittlement, structural degradation and other changes," (3) it is not possible to guarantee that the TVT-O will perform its intended function after implantation, and (4) the TVT-O mesh is not inert and can change after implantation, which may lead to adverse events for the patient. (Guelcher Report [Docket 203-1], at 3).

Ethicon first argues that Dr. Guelcher's general causation testimony is not helpful to the jury because the plaintiffs cannot prove specific causation and because no expert can say that degradation is clinically significant. As I have already explained, general causation opinions are helpful to the jury and fit the facts of this case regardless of whether the plaintiffs may ultimately fail to carry their burden to show that Ms. Huskey was harmed by her TVT-O implant.

Second, Ethicon argues that Dr. Guelcher's opinions are unreliable and unhelpful because they relate only to generic polypropylene, not Prolene mesh. This argument, too, has already been rejected. Therefore, Ethicon's motion to exclude Dr. Guelcher is **DENIED**.

D. Dr. Russell Dunn

Dr. Dunn holds a Ph.D. in chemical engineering and consults on chemical and polymer process and product design issues. (*See* Dunn Report [Docket 202-1], at 1). He will opine that Ethicon's risk assessment process for the TVT-O was inadequate and that the TVT-O is defective. (*See id.* at 4). Dr. Dunn also filed a rebuttal report challenging the opinions of several of Ethicon's experts. Ethicon challenges Dr. Dunn's risk assessment opinion, his opinion at his deposition that polyvinylidene fluoride, or PVDF, is a safer alternative design, and his rebuttal of Ethicon's experts.

1. Risk Assessment Opinions

Dr. Dunn offers opinions regarding Ethicon's risk assessment process—which he calls "Failure Mode & Effects Analysis"—during the design of the TVT-O. He opines that Ethicon's "design documents did not contemplate several [Failure Mode & Effects Analysis] issues and that Ethicon did not have an adequate quality system in place" with respect to Prolene. (Dunn Report [Docket 202-1], at 15). He contends that Ethicon's risk assessment processes failed to account for "polypropylene's inherent tendency to oxidize." (*Id.*). Ethicon argues that this opinion is not

helpful to the jury because Dr. Dunn fails to articulate any effect a different quality control process would have had on the TVT-O's design. (*See* Mem. in Supp. of Defs.' Mot. to Exclude the Test. and Ops. of Dr. Russell Dunn, Ph.D., P.E. ("Defs.' Mem.") [Docket 184], at 14). Ethicon frames the issue incorrectly. An expert's testimony must help the jury to "understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is **DENIED**.

2. Safer Alternative Designs

Although his expert report does not contain any opinions about safer alternative designs, Dr. Dunn testified in his deposition that mesh using PVDF would be a safer alternative design for the TVT-O. (*See* Dunn Dep. [Docket 183-3], at 123:8-20). Ethicon argues that any opinions related to safer alternative designs should be excluded because Dr. Dunn did not disclose them in his expert report pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), and because they are unreliable. The plaintiffs did not respond to this argument. Accordingly, Dr. Dunn's opinions regarding safer alternative designs are **EXCLUDED**.

3. Rebuttal Report

Dr. Dunn rebuts the opinions of Ethicon's experts, Dr. Kevin Ong, Dr. Shelby Thames, and Timothy Ulatowski. Specifically, he criticizes the conclusions that these experts draw about the Ethicon canine study and Prolene's vulnerability to oxidation. (*See* Dunn Rebuttal Report [Docket 202-2], at 1-2). Ethicon contends that this rebuttal report is unreliable because it is not supported by scientific literature. (*See* Defs.' Mem. [Docket 184], at 17).

Despite Ethicon's objection, I **FIND** that Dr. Dunn's rebuttal report has sufficient indicia of reliability. His rebuttal report simply criticizes the methods Ethicon's experts used to come to

their conclusions. Dr. Dunn writes that the Ethicon canine study failed "to recount its materials and methods of reproducibility" and used "a control group that does not comport with the implanted Prolene samples." (Dunn Rebuttal Report [Docket 202-2], at 1). He contends that Ethicon's experts ignored polypropylene's propensity to degrade, despite the use of antioxidants. (*See id.*). He cites several scientific studies for his opinions and states that the sources relied on by Ethicon's experts "favor specific data while ignoring others[.]" (*Id.*). Therefore, Ethicon's motion on this issue is **DENIED**.

E. Dr. Abhay Pandit

Dr. Pandit is a biomedical engineer. He plans to testify that the TVT-O was defectively designed and that Ethicon failed to adequately test the TVT-O. Ethicon moves to preclude Dr. Pandit's testimony in its entirety.

1. Leaching Chemicals

Dr. Pandit opines that the TVT-O is defective because, among other things, when polypropylene degrades in vivo, "chemicals are produced that leach into the surrounding tissues." (Pandit Report [Docket 207-1], at 6). He states that Ethicon failed to perform appropriate tests for "these chemicals and their effects." (*Id.*). Ethicon argues that these opinions are unreliable. Dr. Pandit cites no scientific support for these opinions, and he was unable to name which particular chemicals are produced:

> Q. Do you have an opinion, to a reasonable degree of scientific certainty, that when oxidation occurs breaking the chemical bonds, that chemicals are produced that leach into the surrounding tissues?
>
> A. Yeah.
>
> Q. What chemicals?
>
> A. I'm not so sure which ones they are.

(Pandit Dep. [Docket 185-3], at 162:15-22). It is clear from this exchange that Dr. Pandit's opinions on chemical leaching and Ethicon's failure to test for such leaching are not reliable. Therefore, these opinions are **EXCLUDED**.

2. Failure to Test

Dr. Pandit claims that Ethicon failed to adequately test the TVT-O. For instance, he states that pre-clinical testing was inadequate; Prolene mesh was not tested for shrinkage, degradation, or stiffening; the "inside-out approach" for surgical implantation was not tested appropriately; and the trocar design was not tested appropriately. (Pandit Report [Docket 207-1], at 1-2). Ethicon contends that Dr. Pandit is not qualified to offer these opinions because he failed to identify any specific experience, training, or education in designing or testing implantable devices. In his expert report, Dr. Pandit simply states, without elaboration, that he "has extensive experience in the design and testing of implantable medical devices, including surgical mesh." (*Id.* at 1). The plaintiffs failed to attach Dr. Pandit's curriculum vitae to his expert report, so I am unable to verify this statement. When asked about this statement at his deposition, Dr. Pandit's response was vague:

> Q. What experience do you have in the design and testing of surgical mesh used for the treatment of stress urinary incontinence specifically?
>
> A. So my experience in testing of implantables is a very fundamental approach of looking at host responses in the body. So I'm an expert in host responses. I design material for host response to understand what the host response is. And the approach I take is, you know, is looking at the principles involved in how one does the studies for the intended applications. So in the context of surgical meshes, I would have had implanted surgical meshes in quite a few projects before, and looking at what the host response is.

(*See* Pandit Dep. [Docket 185-2], at 24:14-25:5). He also stated that he has "used polypropylene several times" in the last 22 years in "multiple situations in the body." (*Id.* at 25:16-17, 24-25).

In light of Dr. Pandit's vague explanations and plaintiffs' counsels' failure to attach Dr. Pandit's curriculum vitae, I am unable to determine what precise qualifications he has to opine about designing or testing implantable medical devices. Therefore, the plaintiffs failed to carry their burden to demonstrate that Dr. Pandit should be permitted to testify on this issue, and Dr. Pandit's opinions regarding testing are **EXCLUDED**. *See Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) ("As in all questions of admissibility, the proffering party must come forward with evidence from which the court can determine that the proffered testimony is properly admissible.").

3. Safer Alternative Designs

Although he did not discuss safer alternative designs in his expert report, Dr. Pandit testified in his deposition that Ethicon should have used materials other than Prolene in the TVT-O. Ethicon contends that these opinions should be excluded because they were not contained in his expert report and because they are unreliable.

Whether or not these opinions should be excluded for failing to appear in Dr. Pandit's expert report, they are unreliable. Dr. Pandit refused to say which particular materials would be suitable as an alternative design:

> Q. Can you tell me today what modified synthetic materials that you have described that may have these additives or changes that may be appropriate for the use in the treatment of stress urinary incontinence?
>
> A. Yes. One other ideas could be, I don't want to give Ethicon ideas on what they should be doing.
>
> Q. Sorry, you're going to have to.
>
> A. I mean I'm giving our IP to them, telling them what they should be doing in terms of constructs.

(Pandit Dep. [Docket 185-2], at 38:8-19). The plaintiffs state that "Dr. Pandit identified PVDF and relied upon Ethicon documents which compare the mechanical properties and in vivo reactivity of polypropylene and PVDF." (Pls.' Resp. to Defs.' Mot. to Exclude the Test. and Ops. of Dr. Abhay Pandit, Ph.D. [Docket 207], at 19). But the plaintiffs do not cite to any portion of Dr. Pandit's expert report or deposition for this statement. Without an explanation from Dr. Pandit about which particular materials would be suitable alternative designs, these opinions are unreliable and are **EXCLUDED**.

4. Laser Cutting Mesh

In his deposition, Dr. Pandit stated that the TVT-O was defective because it uses laser-cut mesh. (*See* Pandit Dep. [Docket 185-2], at 69:16-22; 99:3-101:17). He also claimed that Ethicon failed to test the effects of laser cutting. (*See id.* at 99:10-12). He opines that "laser treatment does damage [to] polymer structures" and that antioxidants are lost as a result of laser cutting. (*Id.* at 99:20-21; 100:4-10). However, Dr. Pandit admitted that he could "absolutely not" testify to a reasonable degree of medical certainty that laser-cut mesh is safer than mechanically cut mesh. (*Id.* at 100:21). Therefore, this opinion is unreliable and is **EXCLUDED**.

5. Cancer

The plaintiffs state that Dr. Pandit will not opine about the TVT-O's potential to cause cancer. (*See* Pls.' Resp. [Docket 207], at 17). Ethicon's motion on this issue is accordingly **DENIED as moot**.

F. Dr. John F. Steege

Dr. Steege is an obstetrician and gynecologist. He teaches and studies the etiology or "causes" of chronic pelvic pain, vaginal pain, and sexual pain. (*See* Steege Report [Docket 210-3], at 1). In his expert report, Dr. Steege discusses the etiology of problems associated with using

mesh in gynecologic surgery. (*See id.* at 2-11). In addition, Dr. Steege opines that the TVT-O IFU failed to reflect potential mesh-related complications. (*See id.* at 11-12). Finally, Dr. Steege provides an assessment of Ms. Huskey's current medical condition. (*See id.* at 12-18).

Ethicon moves to exclude Dr. Steege's opinions entirely. Ethicon argues that Dr. Steege's general opinions regarding mesh complications exceed the scope of his qualifications and do not fit this case because he cannot connect his general criticisms of the TVT-O to Ms. Huskey's alleged injuries. In addition, Ethicon argues that Dr. Steege's specific causation opinions are unreliable because: (1) Ms. Huskey did not disclose her prior history of chronic pelvic pain to Dr. Steege, and (2) Dr. Steege did not conduct a proper differential diagnosis to rule out alternative causes of Ms. Huskey's chronic pelvic pain. Finally, Ethicon claims that Dr. Steege's opinions regarding the TVT-O IFU are unreliable because he did not review the IFU before completing his written expert report.

1. General Causation Opinions

In his report, Dr. Steege provides several opinions regarding alleged problems associated with surgically implanted mesh, including "[c]hronic inflammation of native tissue surrounding the mesh"; "[s]hrinkage and deformation of mesh"; "[d]irect trauma to nerves, incurred during the mesh implantation or explanation process"; "[n]erve irritation, distortion, and entrapment in the mesh and the surrounding fibrosis"; "[m]esh-related neuropathy"; and "[a]lteration of the function of surrounding organs due to any or all of" the above-described mechanisms. (Steege Report [Docket 210-3], at 2).

Ethicon contends that Dr. Steege is unqualified to offer these general causation opinions because he has never performed a TVT, TVT-O, or mesh-related procedure to treat SUI (*see* Steege Dep. [Docket 210-2], at 113:14-114:2); he has not taught any courses or conducted any

studies regarding the TVT-O implantation procedure (*see id.* at 136:17-137:16); and he has not handled explanted mesh, examined the biomechanical properties of mesh, or performed degradation testing of mesh (*see id.* at 156:16-19, 242:17-21).

After reviewing Dr. Steege's report and curriculum vitae, I **FIND** that Dr. Steege is qualified to opine on the etiology of problems associated with the implantation of mesh products in gynecologic surgery. An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Steege is a renowned teacher and physician who specializes in the etiology of chronic pelvic pain, vaginal pain, and sexual pain. He is the Director of the Division of Laparoscopy and Pelvic Pain at the University of North Carolina at Chapel Hill and a professor of obstetrics and gynecology. (*See* Steege Report [Docket 210-3], at 1). He has published a textbook and several book chapters and scientific papers on chronic pelvic pain. (*See* Steege CV [Docket 210-1], at 3-13). In 2009, as part of the American College of Obstetrics and Gynecology's "Clinical Expert Series," Dr. Steege discussed the relationship between mesh and the occurrence of new dyspareunia. (*Evaluation and Treatment of Dyspareunia*, 113 Obstetrics & Gynecology: Clinical Expert Series 1124, 1133 (2009) [Docket 210-3]). He concluded that:

> [m]ultiple studies of mesh placement in pelvic support surgeries demonstrate that new dyspareunia after surgery is substantially more common with these techniques compared with those that do not use mesh material. It would seem, therefore, that complications after mesh placement deserve much more detailed study and that the use of mesh should be a last resort, rather than the first procedure done.

(*Id.*). In addition, Dr. Steege has treated 15-20 patients who complained of pain after being

implanted with a mesh product. (*See* Steege Dep. [Docket 210-2], at 153-56).

Ethicon also argues that Dr. Steege's general causation opinions do not fit the facts of this case and are therefore unhelpful. Ethicon contends that because Dr. Steege has not examined Ms. Huskey's explanted mesh, he cannot connect his general causation opinions to Ms. Huskey's injuries. I have already rejected this argument and thus **FIND** that Dr. Steege's general causation opinions are helpful.

2. Specific Causation Opinions

Dr. Steege provides a case-specific assessment of Ms. Huskey. After reviewing Ms. Huskey's medical history and conducting a physical, abdominal, and gynecological examination, Dr. Steege concludes that "more likely than not her current dyspareunia and daily pain is in response to the initial mesh placement and multiple mesh excisional procedures required in an attempt to treat and manage her symptoms." (Steege Report [Docket 210-3], at 17). He also testified to a "reasonable degree of medical certainty" that "Mrs. Huskey's pelvic and vaginal pain are caused by the Ethicon TVT-O polypropylene sling[.]" (Steege Dep. [Docket 210-2], at 318:13-18). Ethicon contends that these specific causation opinions are unreliable because Ms. Huskey did not disclose to Dr. Steege her prior history of chronic pelvic pain, and because Dr. Steege did not conduct a proper differential diagnosis. For the reasons that follow, I reject Ethicon's arguments.

a. Ms. Huskey's Prior Medical History

Ethicon claims that Dr. Steege did not have sufficient facts to formulate a reliable opinion because Ms. Huskey did not inform Dr. Steege that she had chronic pelvic pain prior to her TVT-O implantation. "It is generally held that relevant testimony from a qualified expert may be received if and only if he is in possession of such facts as would enable him to express a reasonably accurate

conclusion as distinguished from mere conjecture." *Horton v. W. T. Grant Co.*, 537 F.2d 1215, 1218 (4th Cir. 1976). According to Ethicon, this prior history of chronic pain suggests that the TVT-O is not the primary cause of Ms. Huskey's current pain symptoms.

Ethicon references Ms. Huskey's December 2010 emergency room visit as evidence of her prior history of chronic pelvic pain. On December 13, 2010, Ms. Huskey visited the Decatur Memorial Hospital Emergency Room due to abdominal pain. (*See* Emergency Triage Notes [Docket 230-1]). According to the emergency room triage notes, Ms. Huskey complained of an "acute worsening of chronic left lower quadrant pain[.]" (*Id.* at 2). A subsequent colonoscopy suggested that diverticulitis was a possible source of Ms. Huskey's December 2010 pain. (*See* Steege Report [Docket 210-3], at 12).

Ethicon claims that Ms. Huskey did not inform Dr. Steege that she had chronic pelvic pain prior to her TVT-O implantation. Contrary to Ethicon's assertions, Dr. Steege does reference the December 2010 incident in his expert report. (*See id.*). In addition, Dr. Steege testified that he was aware of this incident but did not consider it to be related to Ms. Huskey's current symptoms:

> Q: Did Ms. Huskey have pelvic pain at any point before her TVT-O?
>
> A. According to her history with us, she did—she did not really. *She had that episode of left quadrant pain that was really rather separate from subsequent events.*
>
> . . .
>
> Q. Did Mrs. Huskey report to you that she had chronic abdominal pain at any point prior to her TO implantation?
>
> A. We discussed the episode of the left lower quadrant pain that she had. She did not describe it as chronic.
>
> . . .
>
> Q. Did Mrs. Huskey report to you that she had any type of history of pelvic pain before her TVT-O?

A. I think we covered that.

Q. Oh, I did?

A. Yeah.

Q. She didn't report that to you?

A. No.

(Steege Dep. [Docket 210-2], at 253:2-17, 258:1-8 (emphasis added)). Because Dr. Steege was aware of Ms. Huskey's prior pelvic pain, I **FIND** that he had the facts necessary to render a sufficiently reliable opinion regarding the cause of Ms. Huskey's current symptoms.

b. Differential Diagnosis

Ethicon also maintains that Dr. Steege failed to perform a proper differential diagnosis to rule out other possible causes of Ms. Huskey's chronic pelvic pain. In particular, Ethicon contends that Dr. Steege did not conduct a sufficient examination to rule out endometriosis as an alternative cause of Ms. Huskey's condition. Ethicon also claims that Dr. Steege did not explain the methodology he used to form his specific causation opinion.

In his report, Dr. Steege acknowledges several alternative causes of Ms. Huskey's pain. (*See* Steege Report [Docket 210-3], at 16-17). He also reviewed Ms. Huskey's medical history and conducted a musculoskeletal, abdominal, and gynecological examination. (*Id.* at 16). He described the examination procedures and their results. (*Id.*). He then concluded as follows:

> There is likely a neuropathic component to [Ms. Huskey's] pain, although we could not document a single nerve injury. The clinical diagnosis of a direct nerve injury is made when there are signs of motor weakness and/or sensory loss, however the diagnosis of nerve entrapment from progressive scarring in the pelvis is more challenging. This is because it is the nature for cutaneous sensory dermatomes to overlap and, as many of the nerves in the pelvis do not have motor innervation, it is difficult to differentiate between them. Also, some nerves with both sensory and motor function can be damaged even if there is no loss in motor function. Despite some mild hyperalgesia, she also had a normal neurosensory exam. Regardless,

> more likely than not her current dyspareunia and daily pain is in response to the initial mesh placement and multiple mesh excisional procedures required in an attempt to treat and manage her symptoms. These conclusions are based on my knowledge of pelvic neuroanatomy, the inflammatory response of tissue to foreign bodies, and my professional opinion. These opinions are supported by well-established scientific principles accepted by the medical community and published in the scientific literature. In reaching these conclusions, I was able to rule out other causes of her pelvic pain and sexual pain, including, but not limited to, her back condition, her history of back surgery, her sacro-iliac dysfunction, her history of pelvic surgery, and diverticulitis.

(*Id.* at 17).

Although Dr. Steege did not provide a detailed explanation as to why he ruled out these alternative causes, he bases his conclusions on accepted scientific principles and research. In addition, he reviewed Ms. Huskey's medical history and conducted three diagnostic examinations to determine the cause of Ms. Huskey's pain. Although he did not clearly connect these scientific studies and examinations to his opinion, it cannot be said that he provided "*no* explanation" as to why he ruled out alternative causes. *See, e.g.*, *Heller v. Shaw Indus.*, 167 F.3d 146, 156 (3d Cir. 1999) ("Dr. Papano did not offer detailed explanations for why he concluded that these were not the causes of plaintiff's illness, but his responses [during cross-examination], grounded in the alleged temporal relationship, the results of Todd's testing showing a reduction in VOCs when the carpet was removed, and Heller's medical history and physical examination, certainly are more than '*no* explanation.'"). Accordingly, I **FIND** that Dr. Steege used a sufficiently reliable methodology to ascertain the cause of Ms. Huskey's chronic pelvic pain.

Ethicon also argues that Dr. Steege failed to conduct a sufficient examination to exclude endometriosis as a source of Ms. Huskey's chronic pelvic pain. In his deposition, Dr. Steege testified that "I would [] comment that neither patient we're dealing with [including Ms. Huskey] had endometriosis for the record." (Steege Dep. [Docket 210-2], at 161:20-21). Dr. Steege testified

that endometriosis is a common health problem for women. (*See id.* at 161:10-19). He also conceded that endometriosis can cause chronic pelvic and lower back pain. (*See id.* at 161-62:15-8). Dr. Steege testified that endometriosis can be diagnosed with a physical examination, but that the condition is often diagnosed by reviewing the patient's history and conducting a diagnostic laparoscopy:

> Q. And how is endometriosis usually diagnosed?
>
> A. Sometimes by physical examination, more often by history combined with usually a diagnostic laparoscopy.
>
> Q. Say again. A laparoscopic?
>
> A. Diagnostic laparoscopy.
>
> Q. This is an area I'm not versed in too well, so can you tell me what is a diagnostic laparoscopy.
>
> A. That's—I'm also puzzled as to why it's germane to this because it kind of isn't.
>
> . . .
>
> Q. How do you determine whether or not a patient has endometriosis?
>
> A. By taking a history and physical exam in detail and those where it's clinically relevant a high index of suspicion and do a laparoscopy. Typically the person who comes to see me, though, has already had the diagnosis made because they've had four laparoscopies, some of which they didn't need. So I don't need another one.
>
> Q. So would you say then a majority of your patients who have—who come to you, they've already had a laparoscopy?
>
> A. Majority being over half, I would say that's probably true.
>
> Q. Has Mrs. Huskey ever had a prior laparotomy?
>
> A. I don't believe she had, but then to save you some breath, I've seen very few 54-year-olds with endometriosis, okay? We can cut to the quick a little bit.

(*Id.* at 9-10:16-1, 170-71:13-4).

Dr. Steege further testified that "I would say that the decision to do a laparoscopy is based on the totality of the history and physical exam to see if there's enough evidence to support the possibility. You certainly do not laparoscope every patient with pelvic pain." (*Id.* at 164:1-6). In addition, during his deposition, Dr. Steege referred to a study indicating that physicians relying on a patient's history and physical examination correctly diagnosed endometriosis eighty percent of the time. (*See id.* at 164-65:9-21). In Ms. Huskey's case, although he conducted a physical examination of Ms. Huskey, Dr. Steege did not conduct a diagnostic laparoscopy to determine whether she had endometriosis. (*See id.* at 10:16-18; *see also* Steege Report [Docket 210-3], at 16). However, he noted that it was unlikely that a fifty-four year old with a hysterectomy could have endometriosis. (*See* Steege Dep. [Docket 210-2], at 187:18-23, 322:14-19).

"[A] physician need not conduct every possible test to rule out all possible causes of a patient's illness, 'so long as he or she employed sufficient diagnostic techniques to have good grounds for his or her conclusion.'" *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 761 (3d Cir. 1994)). Here, although Dr. Steege did not conduct a laparoscopy, he did conduct a physical examination and reviewed Ms. Huskey's history, which Dr. Steege demonstrated is a reliable means of diagnosing endometriosis. Accordingly, I **FIND** that Dr. Steege used a reliable methodology to exclude endometriosis as a possible source of Ms. Huskey's chronic pelvic pain.

3. IFU Opinions

Dr. Steege opines that the TVT-O IFU did not accurately reflect the potential complications of implanting the TVT-O, such as chronic pelvic pain, vaginal pain, dyspareunia, persistent leg and groin pain, partner pain, vaginal scarring, shrinkage, degradation, chronic foreign body response, and removal difficulty. (*See* Steege Report [Docket 210-3], at 11-12).

Ethicon claims that these opinions are unreliable because he did not review the IFU before completing his expert report.

During his deposition, Dr. Steege testified that he did not review the TVT-O IFU until after he had completed his expert report:

> Q. When did you review that TVT-IFU, before or after you issued your report?
>
> A. After.
>
> Q. And so the IFU for TVT-O did not have a role in the formulation of your opinions that you issued in your report in this case, correct?
>
> A. They have a role in my general testimony about the case but not in the report. I didn't have them for the report.
>
> Q. The opinions that you formed in this case you formed those before reviewing the TVT-O IFU, correct?
>
> A. The report opinions, yes, correct.
>
> Q. And those opinions were not only formed but reduced to writing even before you reviewed the TVT-O IFU, correct?
>
> A. You know, to be honest I don't remember if I reviewed it before or not, you know, it's all—this is a large pile of information so I can't tell you what data I reviewed, each individual piece. And I also reviewed the IFUS from a number of different products that—and they're all generally pretty much the same. So which of those I read—reviewed before or after, I couldn't tell you.

(Steege Dep. [Docket 210-2], at 112-13:6-4). Clearly, Dr. Steege did not have sufficient facts or data if he did not even review the TVT-O IFU in formulating his opinions. Accordingly, Dr. Steege's opinions concerning the TVT-O IFU are **EXCLUDED**.

G. Dr. Jerry G. Blaivas

Dr. Blaivas is a urologist and one of the pioneers of sling surgery for women with sphincter incontinence. (*See* Blaivas Report [Docket 214-1], at 1). He has extensive experience treating

patients with complications related to synthetic sling surgery. (*See id.* at 2-3). Ethicon seeks to exclude parts of Dr. Blaivas's testimony because they exceed his qualifications, are unhelpful to the jury, or are not set out in his expert report. I will address Ethicon's arguments in turn.

1. Opinions Related to Product Warnings

Dr. Blaivas opines that Ethicon failed to warn physicians about particular complications with the TVT-O. For example, Dr. Blaivas states in his report that:

> 6. *Ethicon should have warned physicians and patients about the possibility of serious and life-style altering complications* (e.g. 9, 21-33). Ethicon knew or should have known about the potential for serious complications from mesh slings, such as the Gynecare TVT-O, *because of the known experience with Mersilene, Marlex and silastic slings that were performed during the last three decades of the 20th century, and more recently the Protegen and Mentor ObTape slings.*
>
> . . .
>
> 11. *Ethicon did not warn doctors and patients about the chronic and lifestyle altering nature of the complications associated with its products . . .*
>
> 12. *Ethicon did not warn doctors and patients about the difficulty removing their products . . .* and the poor or less than optimal results when excision or revision becomes warranted due to complications.
>
> . . .
>
> 16. From a scientific and ethical perspective, *Ethicon should have had a high index of suspicion relating to the product defects based on previous experience with predicate products. . . . Since many of these complications occurred many months or years after the original surgery, Ethicon should have taken appropriate measures to investigate this and also warn physicians and patients about the possibility of these late-onset complications.* At the very least there should have been a simple statement about the possibility that such complications could arise in the future after months, years, or even decades and that the technique is new, so long term studies are not yet available to determine the ultimate safety and efficacy. The many serious complications that I have seen and that occurred with the two plaintiffs discussed in this report do not appear in any study.

. . .

> 25. The TVT-O IFUs state that "animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." *Despite literature to the contrary, Ethicon never changed the IFU to reflect: 1) the inflammatory response is persistent and not transient; 2) the mesh creates dense scar tissue not a "thin layer of tissue"; and 3) the material is, in fact, subject to degradation*[.]
>
> . . .
>
> 32. I have reviewed the Material Safety Data Sheet for the polypropylene used in the Gynecare TVT-O medical device. . . . Ethicon IFUs do not include the toxic and carcinogenic warnings contained in the MSDSs. Ethicon marketing materials for doctors and patients do not include the toxic and carcinogenic warnings contained in the MSDSs.
>
> . . .
>
> *Ethicon did not adequately warn doctors and patients about the kind of complications experienced by Mrs. Huskey . . . .*

(Blaivas Report [Docket 214-1], at 7-13 (emphasis added)).[6]

Ethicon first challenges Dr. Blaivas's qualifications to give these opinions because Ethicon argues that Dr. Blaivas is not an expert on product warnings. But Dr. Blaivas need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warning and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when

[6] Ethicon argues that some of this testimony is inadmissible evidence of Ethicon's corporate knowledge or state of mind. As I previously stated, I will not parse expert reports in relation to this objection. However, the parties are cautioned that experts must offer opinions that utilize their "scientific technical, or other specialized knowledge[.]" Fed. R. Evid. 702.

the warnings were published. *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000). I therefore **FIND** that Dr. Blaivas is qualified to render opinions about the adequacy of the TVT-O's IFU.

Ethicon also maintains that these opinions are unhelpful. First, Ethicon argues that testimony about warnings is irrelevant because there is no evidence that Ms. Huskey's implanting physician relied on the warnings or that she would have changed her decision to implant the device if given "adequate" warnings. I rejected this argument in my opinion ruling on Ethicon's summary judgment motion, entered today. Second, Ethicon contends that any opinions about its alleged failure to warn about infections are irrelevant because there is no evidence that Ms. Huskey suffered from a mesh-related infection. However, Ms. Huskey clearly indicated on her Plaintiff Fact Sheet that she had an infection. (*See* Pl. Fact Sheet [Docket 161-2], at 6). In addition, Dr. Siddique, Ms. Huskey's explanting physician, testified that his operative report noted a "chronically infected space with woody edematous tissue." (Siddique Dep. [Docket 214-6], at 33:20-25). Therefore, contrary to Ethicon's arguments, infections are a fact in issue in this case.

2. Opinions Relating to Complications

Ethicon argues that several of Dr. Blaivas's opinions concerning mesh-related complications should be excluded because they are unreliable or irrelevant.

a. Alleged Under-Reporting of Mesh Complications

Dr. Blaivas opines that "[m]esh complications are significantly under-reported." (Blaivas Report [Docket 214-1], at 7). Ethicon argues that this opinion is unreliable because it is based on Dr. Blaivas's personal conversations with other physicians, but Dr. Blaivas could not identify which particular doctors had discussed this issue with him. (*See* Blaivas Dep. [Docket 214-2], at 108-10).

Dr. Blaivas did not rely *solely* on personal conversations with other physicians. He also relied on peer-reviewed studies, including two studies that compared independent reports of complications to the complications reported in the peer-reviewed literature. (*See* Blaivas Report [Docket 214-1], at 7). In the first study, the authors compared mesh-related complications reported in the scientific literature to complications reported to the Manufacturer and User Facility Device Experience ("MAUDE") database. (*See* Donna Y. Yeng et al., *Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-Reported?* 52 J. Urology 46, 46 (2007) [Docket 157-9]). In particular, the authors reviewed twenty-eight scientific studies involving the TVT, SPARC, Uratape, Monarc, Obtape, SAFYRE, and I-Stop mesh slings. (*See id.* at 47). Out of the 11,806 patients reviewed, only 86 had reported complications. (*See id.*). The MAUDE database, however, revealed a total of 928 reported complications (700 TVT, 66 SPARC, 1 TVT-O, 149 ObTape, and 12 Monarc slings). (*See id.*). The study ultimately concluded that "[a]lthough rare, major complications of midurethral slings are more common than appear in the literature." (*Id.* at 46). In another study, researchers analyzed Medicare claims from 1999-2001 and concluded that the "complication rates within 1 year after sling surgery among Medicare beneficiaries were found to be higher than those reported in the clinical literature." (Anger et al., *Complications of Sling Surgery Among Female Medicare Beneficiaries*, 109 Obstetrics & Gynecology 707, 707 (2007) [Docket 157-10]).

Ethicon incorrectly asserts that these studies are irrelevant because they did not review the TVT-O specifically. Dr. Blaivas's opinion is that "mesh complications" are under-reported. Such an opinion is clearly supported by these studies. For these reasons, I reject Ethicon's arguments and **FIND** that this opinion is sufficiently reliable.

b. Increasing Frequency of Mesh Complications

In his report, Dr. Blaivas opines that "[i]n the future, there will be an increasing number of patients who have failed initial treatments and an increasing number of 'mesh cripples[.]'" (Blaivas Report [Docket 214-1], at 4). Ethicon argues that this opinion is irrelevant to Ms. Huskey's claims. I agree. Whether future patients may face increasing rates of mesh-related complications will not help the jury decide the issues in this case. Accordingly, this opinion is **EXCLUDED**.

c. Other Physicians's Knowledge

In his report, Dr. Blaivas states that "[i]n the academic circles in which I travel, this and other serious mesh complications were already well known and many of us educators included warnings in our lectures about the use of mesh for the surgical treatment of stress incontinence." (Blaivas Report [Docket 214-1], at 8). Ethicon argues that Dr. Blaivas "is not in a position to provide a reliable assessment concerning what [physicians] knew or did not know." (Mem. in Supp. of Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. ("Defs.' Mem.") [Docket 158], at 9). I disagree. As a urologist, Dr. Blaivas is certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product and warning about its potential risks.

d. Ethicon's Alleged Downplaying of Complications

Dr. Blaivas writes that Ethicon downplayed mesh-related complications. For example, Dr. Blaivas stated in his report that "Ethicon's marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons. . . ." (Blaivas Report [Docket 214-1], at 7). However, according to Dr. Blaivas's first-hand experience and discussion with other physicians, complications can occur "even in experienced hands and when proper surgical technique is used." (*Id.*). In addition, Dr. Blaivas

stated that during lectures, "industry representatives would challenge our opinions and data about mesh complication and literally attempt to trivialize them," and that he "witnessed company representatives first hand downplaying these complications in public at post graduate seminars . . . ." (*Id.* at 8-9).

These statements are not expert opinions. Dr. Blaivas is not using his "scientific, technical, or other specialized knowledge" in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here.

e. Complication Rates

Ethicon argues Dr. Blaivas's opinions regarding complication rates should be excluded because they were not included in his report and because his opinions are unreliable. I **FIND** that Dr. Blaivas's opinions on complication rates are unreliable. In discussing complication rates, Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate:

> A: I mean, just to be fair, I mean, I haven't said you should never use it. I mean, look, my contention is that this information should be available not just to the experts but to the implanting doctors worldwide and to the patients.
>
> And I can't tell you if it's 1 percent or 9 percent. I can't tell you that it's going to—I hope it doesn't, maybe after ten years it will be 20 percent, or maybe some of them will get better. I don't know. All I can tell you right now is that it's very clear to me that these kinds of things happen, at the very least, in the single digit percent rate.

(Blaivas Dep. [Docket 214-2], at 189:11-190-4). In light of this testimony, Dr. Blaivas's opinions regarding complication rates are **EXCLUDED**.

3. Opinions Regarding the Increased Incidence of Complications Related to the Transobturator Approach

Dr. Blaivas opines that the transobturator approach used to implant the TVT-O "increases

the risk of nerve injury, leg pain, chronic pain, dyspareunia, and vaginal scarring/banding." (Blaivas Report [Docket 214-1], at 5). Dr. Blaivas does not cite any medical literature to support this statement, but rather cites Ethicon's internal documents. Ethicon contends that these opinions are unreliable because a physician would not utilize internal company documents to form an opinion about medical device complications. *See* Fed. R. Evid. 703 (allowing experts to rely on inadmissible evidence that is of the kind that is *reasonably* relied on by experts in the field).

Rule 703 addresses the circumstances in which an expert may rely on inadmissible evidence to formulate an opinion. "However, the question whether the expert is relying on a *sufficient* basis of information—whether admissible information or not—is governed by the requirements of Rule 702." Fed. R. Evid. 702, advisory committee's note. In other words, whether an expert may rely on particular information is a different question from whether an expert's opinion has a reliable basis. Therefore, I **FIND** that Dr. Blaivas's opinions are not unreliable simply because he relied on internal Ethicon documents.

4. Opinions Relating to Mesh Shrinkage and Degradation

Dr. Blaivas provides several opinions on mesh shrinkage and degradation. He opines that "mesh shrinks unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time." (Blaivas Report [Docket 214-1], at 9). In addition, he opines that "polypropylene degrades in vivo," "resulting in stiffening of the mesh, perpetuation of the inflammatory response, creation of a nidus for bacteria and other organisms, and the production of unknown and potentially toxic chemicals." (*Id.*).

Ethicon argues that Dr. Blaivas is unqualified to opine about these topics because he is not a "bio/polymer" chemist and has no background in polymer science. (*See* Defs.' Mem. [Docket 158], at 12). The plaintiffs contend that Dr. Blaivas has "personally experienced" degradation and

shrinkage in his patients. (Pls. Opp. to Def. Ethicon's Mot. and Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Jerry Blaivas, M.D. ("Pls.' Resp.") [Docket 214], at 16). But this particular experience is not set out in Dr. Blaivas's expert report. Further, the citation to Dr. Blaivas's deposition provided by the plaintiffs does not relate to degradation. Rather, it relates to Dr. Blaivas's experience with pubovaginal autologous slings. (*See id.* (citing Blaivas Dep. [Docket 214-3], at 347:17-21, 350:14-353:11)). I am unable to locate any reference whatsoever to degradation in Dr. Blaivas's deposition.

The plaintiffs also indicate that Dr. Blaivas cited several scientific studies to support his opinions. But whether an expert's opinions are supported by scientific literature is an issue of reliability, not his qualifications. Here, in light of his lack of experience with mesh degradation or shrinkage, I **FIND** that Dr. Blaivas is unqualified to opine about these topics, and these opinions are **EXCLUDED**.

5. Opinions Related to Product Marketing

Ethicon challenges Dr. Blaivas's statement that "synthetic slings were revived, reinvented and promoted by industry through pervasive advertising and inducements to physicians to perform such surgeries." (Blaivas Report [Docket 214-1], at 2). Dr. Blaivas cites no authority for this position. Moreover, as Ethicon correctly notes, Dr. Blaivas has no expertise in marketing and therefore is unqualified to make such a broad statement. Accordingly, this opinion is **EXCLUDED**.

6. Hypothetical Clinical Testing

Dr. Blaivas opines that "[a]ppropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, including the Gynecare TVT-O." (*Id.* at 8). Dr. Blaivas suggests that Ethicon should have conducted "long-term

clinical trials or at least monitor[ed] complications through a registry." (*Id.*). Ethicon argues that Dr. Blaivas's opinions are speculative because he "did not perform any of these hypothetical 'unbiased test[s],' and he does not identify any third-party unbiased testing in support of his conclusions." (Defs.' Mem. [Docket 158], at 15).

Notwithstanding Ethicon's reliability challenge, I **FIND** that Dr. Blaivas is not qualified to render opinions relating to the product testing. There is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, this opinion is **EXCLUDED**.

7. The Competence of Other Physicians in the TVT-O Procedure

Dr. Blaivas states in his report that:

> Claims that make the procedure sound as if it is safer and easier to perform than it actually is are misleading. See above. The goal was sound – a simple, safe, efficacious, outpatient procedure that required minimal surgical skills and could be mastered by surgeons with little training. But the truth is very different. The fact is, it is not so easy to learn these techniques and the ergonomics of the trocars is such that it is easy to misguide them and end up in the wrong place. *Because the company so trivialized the learning curve and potential complications, many surgeons with inadequate skill and experience perform these surgeries.*

(Blaivas Report [Docket 214-1], at 10 (emphasis added)).

Ethicon argues that this opinion is irrelevant. I agree. Testimony regarding the competence of other physicians will not assist the jury in determining the issues in this case. Accordingly, this opinion is **EXCLUDED**.

8. Alternative Procedures

Dr. Blaivas opines that Ms. Huskey would not have suffered complications if an alternative procedure, such as implantation of a pubovaginal fascial sling, had been used. (*See* Blaivas Report [Docket 214-1], at 13). Dr. Blaivas writes that pubovaginal slings "using autologous fascia are as

effective as synthetic slings" and "are safer than synthetic slings." (*See id.* at 7-8). Ethicon asserts that these conclusions are unreliable because they are not supported by the literature Dr. Blaivas cites. In particular, Ethicon contends that the primary study cited by Dr. Blaivas deals with "intrinsic sphincter deficiency," not stress urinary incontinence. (Defs.' Mem. [Docket 158], at 17).

It is not clear to me whether this study, *Pubovaginal Fascial Sling for the Treatment of All Types of Stress Urinary Incontinence: Surgical Technique and Long-Term Outcome*, which was authored in part by Dr. Blaivas, applies to stress urinary incontinence or sphincteric incontinence. Despite the study's title, it states that "[t]his article provides an update on the surgical technique and long-term outcome of the full-length autologous rectus fascial sling in the treatment of women with *sphincteric incontinence*." (*See* Blaivas et al., *Pubovaginal Fascial Sling for the Treatment of All Types of Stress Urinary Incontinence: Surgical Technique and Long-Term Outcome* [Docket 263-2], at 7 (emphasis added)). Yet, the study also appears to state that it advocates for the use of autologous fascial slings, "[n]o matter what the type" of incontinence. (*Id.* at 14). At the end of the study, in the section titled "References," it cites to several other articles that, by their titles, appear to deal with all types of stress urinary incontinence. (*See id.* at 15 (citing Chaikin et al., *Pubovaginal Fascial Sling for All Types of Stress Urinary Incontinence: Long-Term Analysis*, 160 J. Urology 1312 (1998); Cross et al., *Our Experience with Pubovaginal Slings in Patients with Stress Urinary Incontinence*, 159 J. Urology 1195 (1998)).

Although Ethicon argued in its moving brief that Dr. Blaivas's study applied only to sphincteric incontinence (*see* Defs.' Mem. [Docket 158], at 17), the plaintiffs failed to address this argument in their response (*see* Pls.' Resp. [Docket 214], at 19-20). The plaintiffs again failed to address this argument after I ordered additional briefing on the reliability of Dr. Blaivas's opinions

about pubovaginal slings. (*See* Notice of Supp. Facts and Test. Relating to Defs.' Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. [Docket 263-1], at 2-3). Accordingly, I **RESERVE** ruling on the reliability of Dr. Blaivas's opinions about pubovaginal slings using autologous fascia until trial. I will conduct a hearing on this issue before Dr. Blaivas is called to testify.

IV. Plaintiffs' Daubert Motions

I now turn to the plaintiffs' *Daubert* challenges against Ethicon's expert witnesses. The plaintiffs seek to exclude Dr. Michael Greenberg, Dr. Christina Pramudji, Dr. Daniel J. Sexton, Dr. Wenxin Zheng, and Dr. Harry Johnson.

A. Dr. Michael Greenberg

Dr. Greenberg is a board-certified medical toxicologist. He plans to testify that polypropylene mesh is safe for its intended use and that it does not cause cancer, systemic disease, or toxicological harm in humans. (*See* Greenberg Report [Docket 211-4], at 14-15). The plaintiffs move to exclude Dr. Greenberg's opinions as irrelevant and exceeding his qualifications. For the reasons discussed below, Dr. Greenberg is **EXCLUDED** as an expert in this case.

1. Cancer, Systemic Disease, Toxicological Harms

The plaintiffs argue that Dr. Greenberg's opinions relating to polypropylene's propensity to cause cancer, systemic disease, or toxicological harm are irrelevant to this case and unhelpful to the jury. Ethicon asserts that Dr. Greenberg should be permitted to testify about these topics because Ethicon cannot anticipate whether the plaintiffs' experts will opine on them. The plaintiffs concede that they are not claiming that the TVT-O caused cancer, systemic disease, or toxicological harm. (*See* Reply. Mem. in Supp. of Pls.' Mot. to Exclude the Ops. and Test. of Michael Greenberg, M.D., M.P.H. [Docket 229], at 1 ("Plaintiffs do not, and never have, claimed that the TVT-O caused any of those three injuries in Mrs. Huskey.")). No party's experts will be

permitted to testify about irrelevant subjects such as these. Accordingly, Dr. Greenberg's opinions about cancer, systemic disease, and toxicological harms are **EXCLUDED**.

2. "Biocompatibility" and Degradation Opinions

Dr. Greenberg seeks to testify that "[b]iocompatibility testing of polypropylene mesh has been conducted and has concluded that the materials used in [polypropylene] mesh are safe as clinically intended." (Greenberg Report [Docket 211-4], at 15). He further states that the "accessories" used for mesh implantation "have also undergone biocompatibility testing and [have been] determined to be safe as clinically intended." (*Id.*). The plaintiffs believe that Dr. Greenberg is unqualified to offer these opinions because he is not an expert in biocompatibility. Dr. Greenberg admitted as much in his deposition:

> Q. Have you ever testified about the biocompatibility of a medical device before?
>
> A. Not that I can recall.
>
> Q. And would you agree with me that you're not qualified as a biomaterials expert in this case, correct?
>
> A. I am not a biomaterials expert.
>
> …
>
> Q. What is the current working definition of biocompatibility that biomaterial experts use?
>
> A. I would have to ask a biomaterials expert that question. I don't know the answer to that.

(Greenberg Dep. [Docket 166-2], at 125:13-22; 139:25-140:5). Accordingly I **FIND** that Dr. Greenberg is not qualified to offer biocompatibility opinions.

The plaintiffs also challenge Dr. Greenberg's qualifications to offer opinions related to degradation and the reliability of those opinions. Dr. Greenberg reviews several studies that claim

to show that polypropylene degrades in vivo. (*See* Greenberg Report [Docket 211-4], at 41-46). He points out methodological flaws in each of these studies, and then concludes that there "is no evidence that any of the medical complaints offered by Plaintiff Jo Beth Huskey are due to degradation of pelvic mesh or due to any alleged toxicity related to implanted pelvic mesh." (Greenberg Report [Docket 211-4], at 15).

Dr. Greenberg's background in toxicology does not qualify him to render opinions about polypropylene degradation. He is not a biochemist or polymer scientist. Even if Dr. Greenberg were qualified, his opinions on degradation are not reliable. In his deposition, he could not explain the basis for his degradation opinions:

> Q. Do you believe that polypropylene can be degraded as a result of metabolites produced by phagocytic cells during the body's inflammatory reaction to mesh?
>
> A. Not to any clinically important extent.
>
> Q. Why do you say that?
>
> A. *Because that's what I believe*.

(Greenberg Dep. [Docket 166-2], at 129:22-130:7 (emphasis added)).

Ethicon's briefing confirms that Dr. Greenberg's opinions about biocompatibility and degradation are unreliable and exceed his qualifications. For instance, Ethicon contends that the plaintiffs' motion is a "straw man" that misconstrues the scope of Dr. Greenberg's opinions. (Defs.' Resp. in Opp. to Pls.' Mot. to Exclude the Ops. and Test. of Michael Greenberg, M.D., M.P.H. ("Greenberg Resp.") [Docket 211], at 4). Ethicon states that, as a board-certified medical toxicologist, Dr. Greenberg is qualified to opine that the TVT-O does not cause cancer, systemic disease, or toxicological harm, and therefore that polypropylene is biocompatible and does not degrade:

> Dr. Greenberg is . . . generally qualified, by his training, education, and experience, to opine about whether polypropylene implants such as TVT-O can cause cancer, systemic disease, or other toxicological harms. . . . Dr. Greenberg's opinions concerning degradation and biocompatibility are necessary corollaries of this conclusion: *if polypropylene implants do not cause cancer, systemic disease, or other toxicological harms in humans, then polypropylene implants are biocompatible and do not degrade (if at all) in any medically or toxicologically significant way*.

(*Id.* at 6 (emphasis added)). This recitation by Ethicon shows that Dr. Greenberg's conclusion that polypropylene is biocompatible and does not degrade is *ipse dixit*. Accordingly, these opinions are **EXCLUDED**.

3. FDA Regulatory Reliance Materials

The plaintiffs further challenge Dr. Greenberg's review of the TVT-O regulatory history. This review includes a discussion about the FDA's approval of polypropylene sutures as safe and effective. (*See* Greenberg Report [Docket 211-4], at 19-21). Ethicon argues that this discussion is relevant to his opinions about cancer, systemic disease, and toxicological harms and that "it is reasonable for a toxicologist to rely upon data concerning Prolene's safety and efficacy in assessing the toxicological effects of polypropylene implants." (Greenberg Resp. [Docket 211], at 8). As I have already discussed, cancer, systemic disease, and toxicological harms are not at issue in this case. Therefore, any testimony related to these topics and the materials or information used in forming opinions on these topics is not helpful to the jury. Therefore, these opinions are **EXCLUDED**.

B. Dr. Christina Pramudji

Dr. Pramudji is a board-certified urologist specializing in pelvic floor medicine and reconstructive surgery. The plaintiffs' *Daubert* challenges against Dr. Pramudji concern two areas: (1) polypropylene degradation in vivo, and (2) alternative causes to Ms. Huskey's injuries. Ethicon

subsequently withdrew Dr. Pramudji as an expert on chemical degradation of polypropylene, but reserves the right to call Dr. Pramudji to testify whether she has observed degradation in her clinical practice. (*See* Notice of Withdrawal of Certain Expert Ops. of Dr. Christina Pramudji and Dr. Wenxin Zheng [Docket 267]).

1. Degradation Opinions

Dr. Pramudji plans to testify that she has "not seen evidence of mesh degradation in [her] clinical practice." (Pramudji Report [Docket 205-5], at 2). First, the plaintiffs argue that this opinion exceeds Dr. Pramudji's qualifications because she lacks experience, knowledge, training, or education in the "chemical properties" of polypropylene mesh. (Mem. in Supp. of Pls.' Mot. to Exclude Certain Opinions and Test. of Christina Pramudji, M.D. [Docket 168], at 4). But Dr. Pramudji need not be qualified to such a specific degree. As a physician specializing in pelvic floor medicine, she has performed 1,500 to 2,000 mesh implant surgeries, including 700 involving the TVT-O. (*See* Pramudji Dep. [Docket 209-1], at 55, 115). She has also performed 10 to 20 complete mesh explants and 50 to 60 mesh revisions or partial explants. (*See id.* at 54). Further, Dr. Pramudji has examined meshes she has removed from patients, as well as 10 to 20 images of polypropylene mesh provided by pathologists. (*See id.* at 140). I therefore **FIND** that Dr. Pramudji is qualified by her medical experience to testify whether she has observed mesh degradation in her clinical practice.

Second, the plaintiffs challenge the reliability of this opinion. District courts have "considerable leeway" in applying *Daubert*'s reliability factors. *Kumho Tire*, 526 U.S. at 152 (1999). Here, Dr. Pramudji's opinion is limited to the fact that she has not observed degradation in her clinical practice. Obviously this type of opinion is not subject to testing or peer-review.

Therefore, I **FIND** that drawing on her own clinical experience is a sufficiently reliable method of forming this particular opinion.

2. Alternative Causes of Ms. Huskey's Injuries

Dr. Pramudji also plans to opine about several alternative causes of Ms. Huskey's injuries. In "attacking the differential diagnosis performed by the plaintiff's expert, the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions." *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 838 (S.D. W. Va. 2011) (quoting *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 808 (3rd Cir. 1997)). In her deposition and expert report, Dr. Pramudji stated that several ailments other than the TVT-O could be causing Ms. Huskey's chronic pain. The plaintiffs challenge several of those potential alternative causes as unreliable: interstitial cystitis, endometriosis, diverticulosis, emotional stress, and two prior back surgeries. I will address them each in turn. However, I emphasize that to the extent the plaintiffs believe Dr. Pramudji's alternative diagnoses are incorrect, that is a topic for cross-examination.

a. Interstitial Cystitis

Although Ms. Huskey has not been diagnosed with interstitial cystitis (*see* Pramudji Dep. [Docket 209-1], at 229:18-24), Dr. Pramudji contends that it could be a cause of Ms. Huskey's pelvic pain. She explained that Ms. Huskey has "pain with bladder filling . . . and there's not too many things that cause that. But interstitial cystitis is the main thing that causes that." (*Id.* at 212:11-16). She further explained her potential diagnosis of interstitial cystitis:

> A. And it's a diagnosis of symptoms, basically. Pain with bladder filling, urgency, frequency. She doesn't really have as much urgency/frequency now, so it's a diagnosis that I would kind of watch a patient and see, maybe try some local treatments with some bladder instillations to calm down the bladder with local anesthetic; something, you know, not too invasive to try to see if that gives her relief.

> But that said, you know, if she does have interstitial cystitis, that would definitely cause this chronic pelvic pain, that deep central pain that she's described to me and to others, and oftentimes, that goes hand-in-hand with levator spasm, where they both kind of interplay with each other.

(*Id.* at 212:18-213:10). This testimony appears to be nothing more than speculation. Dr. Pramudji admits that she would "kind of watch a patient" to determine whether she has interstitial cystitis. After her examination of Ms. Huskey, Dr. Pramudji wrote that Ms. Huskey had "possible chronic interstitial cystitis," and that Ms. Huskey "needs to be evaluated by a urologist for this condition." (Pramudji IME Rep. [Docket 209-6], at 5). These statements indicate that Dr. Pramudji's possible diagnosis of interstitial cystitis is unreliable and is **EXCLUDED**.

b. Endometriosis

Dr. Pramudji maintains that Ms. Huskey's pelvic pain is a possible symptom of endometriosis. (*See* Pramudji Dep. [Docket 209-1], at 209:5-12). However, Dr. Pramudji conceded that it "doesn't sound like endometriosis but it's something that would be on a long differential diagnosis list." (*Id.* at 206:12-15). Further, Dr. Pramudji agreed that it was "a good indication" that Ms. Huskey did not have endometriosis because her medical records did not reflect any problems with her endometrial tissue at the time of her hysterectomy. (*Id.* at 209:20-210:4). Dr. Pramudji then acknowledged that she was not "aware of any reports in the medical literature or any reports elsewhere of endometriosis developing for the first time after a hysterectomy was performed[.]" (*Id.* at 210:6-11). Ethicon does not offer any response or argue that Dr. Pramudji's opinion on endometriosis is reliable. Accordingly, this opinion is **EXCLUDED**.

c. Diverticulosis

Dr. Pramudji contends that Ms. Huskey's diagnosed diverticulosis is a contributing cause to her muscle spasms, which cause chronic pelvic pain. (*See* Pramudji Dep. [Docket 209-1], at 197:18-198:15). The plaintiffs argue that this opinion is unreliable speculation because Ms. Huskey's diverticulosis is under control. However, Ms. Huskey's medical records reflect that she experienced a "flare-up" of her diverticulosis in 2012 or 2013. (*See* Pramudji Dep. [Docket 209-1], at 200). Dr. Pramudji testified that diverticulosis can flare up as a result of Ms. Huskey's chronic constipation. (*See id.* at 201:1-10). Further, Dr. Pramudji stated that Ms. Huskey doesn't keep her chronic constipation "managed very well at all times." (*Id.* at 201:9). Because Dr. Pramudji is able to explain the basis for her medical opinion that diverticulosis is a contributing cause of Ms. Huskey's pain, I **FIND** that her opinion contains sufficient indicia of reliability.

d. Emotional Stress

Dr. Pramudji opines that Ms. Huskey's pelvic pain is at least exacerbated by stress. (*See* Pramudji Dep. [Docket 209-1], at 186:10-187:11). The plaintiffs argue that this opinion is "pure speculation" because no medical record "contains notation of stress levels in relation to physical pain; nor does any medical record contain notation of physical health concerns specifically as related to stress levels." (Mem. in Supp. of Pls.' Mot. to Exclude Certain Ops. and Test. of Christina Pramudji, M.D. [Docket 168], at 9). While Dr. Pramudji might base her opinions outside of documents in the medical record, such as her own examination of Ms. Huskey, Dr. Pramudji's opinion here appears to be speculation:

> Q. Okay. What's the cause of that muscle spasm?
>
> A. That muscle spasm, I suspect it's related to the SI joint issue that she has causing pelvic tilt. She wears a belt all the time. She has a slightly abnormal gait. I don't know if that goes back to the motor vehicle accident she was in. And I think just the overall upregulation in her pelvic area, I think the stress, that's where she's carrying her stress that she's under. You know, it's like

> some people carry it in their neck muscles where they'll get a tight neck or a headache, some people carry it in their pelvic floor muscles, that's where their stress will manifest, and she's a very stressed person. Seemed somewhat depressed, in my opinion. And so I think that's exacerbating it, not causing it but exacerbating it.

(Pramudji Dep. [Docket 209-1], at 186:10-187:5). There is no explanation as to how Dr. Pramudji knows that Ms. Huskey "carries" her stress in her pelvic area. Dr. Pramudji is simply guessing and providing nothing more than "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589. Accordingly, I **FIND** that this opinion is unreliable, and it is **EXCLUDED**.

e. Two Prior Back Surgeries

Finally, the plaintiffs seek to exclude as unreliable Dr. Pramudji's opinion that prior back surgeries contribute to Ms. Huskey's pain. Dr. Pramudji admits that this opinion is not made to a reasonable degree of medical certainty:

> Q. Okay. Do you believe that the back surgery that she had in 1997 and 2000 has any correlation or any connection to the pelvic pain that she's currently experiencing?
>
> A. I'm not -- I'm not sure about that. It's a possible etiology. I think her pain is multifactorial. It's hard to really dissect it out completely.
>
> Q. Okay, so hard to dissect out. But would you agree with me that you can't say to a reasonable degree of medical certainty that the back surgery in 1997 is causally related to her current pelvic pain issues?
>
> A. I can't say that it's not either.
>
> Q. Okay. But I'm asking if you can say that it is.
>
> A. I can't say one way or another.
>
> Q. Can't say one way or the other, okay.
>
> A. No.

(Pramudji Dep. [Docket 209-1], at 194:17-195:16). Not only is her opinion speculation, but it is not helpful to the jury because it is not made to a reasonable degree of medical certainty. Further, Dr. Pramudji admits that Ms. Huskey's back surgeries are not among the possible causes of her muscle spasms that cause her pelvic pain:

> Q. So am I correct in saying that your opinion is that there's not a single cause to the muscle spasm that she was experiencing, but there are multiple causes that working in connection with each other are causing this muscle spasm that she's having? Is that right?
>
> A. Correct, uh-huh.
>
> Q. And then that muscle spasm that she's having is the source of most of her both dyspareunia and chronic pelvic pain that she's currently having?
>
> A. Correct.
>
> Q. Okay. And you gave me then a list of the issues or a list of the conditions that you believe were all working in conjunction with each other to cause this levator muscle spasm?
>
> A. Correct.
>
> Q. Is that right?
>
> A. Yes.
>
> Q. Okay. So what's not on that list is the back surgery from '97 to 2000. Is that right?
>
> A. Uh-huh.

(*Id.* at 198:3-199:3). For these reasons, I **FIND** that Dr. Pramudji's opinion that Ms. Huskey's prior back surgeries contribute to her pelvic pain is unreliable, and it is **EXCLUDED**.

C. Daniel J. Sexton

Dr. Sexton is an infectious disease specialist. The plaintiffs challenge his opinions that (1) Ms. Huskey did not experience an infection from the TVT-O, and (2) that incidences of infection using the TVT-O are low.

1. Opinions about Ms. Huskey's Infections

The plaintiffs' main challenge is that Dr. Sexton's opinions about infections are unhelpful because they "relate to post-operative surgical site infections (SSIs)—which Ms. Huskey does not claim she incurred." (Mem. of Law in Supp. of Pls.' Mot. to Exclude the Ops. and Test. of Daniel J. Sexton, M.D. ("Pls.' Mem.") [Docket 172], at 4).

Dr. Sexton will testify in various ways that Ms. Huskey did not experience an infection from her TVT-O implant. The plaintiffs argue that these opinions are unhelpful because Dr. Sexton defines "infection" very narrowly. He states that "[i]n order to speak sensibly about infection issues . . . it is important to understand the definition of what is and is not an infection[.]" (Sexton General Report [Docket 208-1], at 13). He then provides a definition of "post-operative surgical site infection" taken from the Centers for Disease Control and Prevention and its National Healthcare Safety Network. He states that post-operative surgical site infections "can be superficial (incisional), deep (below fascial planes) or in the organ space (i.e. in anatomical spaces below the incision where they usually manifest as a discrete abscess)." (*Id.*). Dr. Sexton then states that he will confine his opinions to this definition: "My discussion and analysis will utilize the CDC/NHSN definitions for postoperative surgical site infections discussed previously that are widely and nearly universally used by experts and researchers throughout the United States and the world." (Sexton General Report [Docket 208-1], at 16). Further, when reviewing Ms. Huskey's medical records, Dr. Sexton states that Ms. Huskey did not experience an infection under the

"standard CDC criteria for a surgical site infection." (Sexton Huskey Report [Docket 208-2], at 13).

The plaintiffs maintain that Dr. Sexton's opinions are inapplicable because Ms. Huskey has not experienced a surgical site infection; rather, her "infection is related to the body's reaction to the TVT-O mesh itself." (Reply Mem. in Supp. of Pls.' Mot. to Exclude the Ops. and Test. of Daniel J. Sexton, M.D. [Docket 235], at 4). In other words, they argue that Dr. Sexton opines about a type of injury that Ms. Huskey does not claim to have experienced. The plaintiffs thus seek to exclude Dr. Sexton's infection opinions because they will not help the jury determine a fact in issue. *See* Fed. R. Evid. 702. The plaintiffs offer a different definition of "infection," taken from Dorland's Medical Dictionary, which they say is applicable to this case:

> Invasion and multiplication of microorganisms or parasites in body tissues; it may be clinically inapparent (*subclinical* infection) or remain localized with cellular injury due to competitive metabolism, toxins, intracellular replication, or antigen-antibody reaction. Infections remain localized, subclinical, and temporary if the body's defense mechanisms are effective. However, they may persist, become symptomatic, and spread by extension to become acute, subacute, or chronic disease states. A local infection may also become systematic when the microorganisms gain access to the lymphatic system or the bloodstream.

(Pls.' Mem. [Docket 172], at 5 (emphasis added)).

Despite Dr. Sexton's express language purportedly limiting his opinions to "post-operative surgical site infections," he offers opinions related to "subclinical" infections, which fall within the plaintiffs' proposed definition. For instance, he opines that there is no "convincing clinical data" that transvaginal mesh results in "sub-clinical" infections. (Sexton General Report [Docket 208-1], at 23). He stated the same in his deposition:

> Q. Dr. Sexton, as part of your evaluation of this case, did you review Ms. Huskey's medical records?
>
> A. I did.

Q. Did you find any support for the proposition that Ms. Huskey suffered from a subclinical infection?

A. No. She had an erosion.

(Sexton Dep. [Docket 208-3], at 201:24-202:5). Because subclinical infections undisputedly relate to the plaintiffs' claims, Dr. Sexton's opinions are helpful.

In any event, assuming Dr. Sexton's definition for "infection" excludes the plaintiffs' alleged injury, his opinions remain helpful to the jury. Whether or not Ms. Huskey suffered an infection is precisely a fact in issue. Dr. Sexton's definition of infection is "widely and nearly universally" utilized by other experts. Dr. Sexton, a qualified expert on infections, should be permitted to give his expert opinion that Ms. Huskey did not experience an infection. To the extent that the plaintiffs believe Dr. Sexton's opinions improperly exclude the *precise* type of infection they allege, they are free to bring this out on cross-examination. Accordingly, I **FIND** that Dr. Sexton's opinions about Ms. Huskey's infections are helpful and should not be excluded.

2. Rates of Mesh-Related Infection Associated with TVT-O

Next the plaintiffs challenge Dr. Sexton's opinions about the rate of mesh-related infections associated with the TVT-O. Dr. Sexton's expert report states that the rate of surgical infections, urinary tract infections, and vaginal yeast infections associated with the TVT-O is "low" and "equivalent to or lower than the comparable rate for the prior gold standard treatment for SUI, the Burch colposuspension." (Sexton General Report [Docket 208-1], at 5).

The plaintiffs first argue that Dr. Sexton is not qualified to render these opinions because he has little experience with transvaginal mesh; he is not a urologist, gynecologist, or urogynecologist; and he has never implanted a pelvic mesh device. (*See* Pls.' Mem. [Docket 172], at 6). I disagree. Dr. Sexton need not be an implanting surgeon to opine about infections associated

with the TVT-O. Dr. Sexton is highly qualified to offer infection opinions. He is a board-certified infectious disease specialist and a professor at Duke University's Department of Medicine and the Division of Infectious Diseases. (*See* Sexton General Report [Docket 208-1], at 2). He is the author of over 200 "articles, editorials, and letters" on infectious diseases in peer-reviewed journals. (*See id.* at 2-3). He has written more than 50 book chapters, presented scientific papers, and lectured on infectious diseases. (*See id.* at 3).

Further, these opinions are reliable. Dr. Sexton cites nearly a dozen academic studies to explain that the risk of infection following implantation of the TVT-O is low. (*See, e.g.*, Sexton General Report [Docket 208-1], at 17-23 (citing Paraiso 2004, Ward 2002, Martinez-Fornes 2009, El-Barky 205, Valpas 2003, Cheng 2010, Neuman 2012, Liapis 2002, Laurikainen 2014). He explains how the data and findings in each one of these studies supports his opinions.

I therefore **FIND** that Dr. Sexton's opinions about the rates of mesh-related infections associated with the TVT-O should not be excluded.

3. Physician Organization Statements and Guidelines

Finally, the plaintiffs seek to exclude Dr. Sexton's references to physician organization statements and guidelines promoting the safety and efficacy of the TVT-O, including those of the American Urogynecologic Society, the American Urological Association, the European Association of Urology, and the United Kingdom's National Institute for Health Care & Excellence. (*See* Sexton General Report [Docket 208-1], at 8-10). Dr. Sexton writes that these organizations "recognize that the use of synthetic mid-urethral slings is the current standard treatment for SUI[.]" (Sexton General Report [Docket 208-1], at 8).

These statements are not expert opinions. Dr. Sexton is not using his "scientific, technical, or other specialized knowledge" in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here.

D. Dr. Wenxin Zheng

Dr. Zheng is a pathologist offered to testify that the TVT-O is biocompatible. He states that polypropylene mesh "elicits an expected inflammatory response" that is mild to minimal and that the TVT-O's pores are large enough to allow "appropriate tissue integration and to allow the body's immune response to minimize potential infection." (Zheng Report [Docket 176-1], at 9).

1. Qualifications for Particular Opinions

The plaintiffs argue that eleven separate opinions proffered at deposition exceed Dr. Zheng's qualifications as a pathologist. (*See* Pls.' Mem. of Law in Supp. of Their Mot. to Exclude the Ops. and Test. of Wenxin Zheng, M.D. ("Pls.' Mem.") [Docket 176], at 3). Ethicon conceded that Dr. Zheng will not opine on several of these topics.[7] Accordingly, the plaintiffs' motion is **DENIED as moot** with respect to the following opinions: (1) whether heavy or light-weight mesh is preferable, (2) whether complications for mesh devices were underreported by manufacturers including Ethicon, (3) the causes of mesh erosion and whether the TVT-O causes erosion, (4) electron microscopy, (5) opinions requiring expertise of a materials expert, an expert on medical devices, or a biomedical engineer, (6) opinions related specifically to Ms. Huskey's pathology, (7) the surgical standard of care for Ms. Huskey's procedures and precise details of surgical techniques, and (8) that the TVT-O is the gold standard for treatment of SUI.

I will address the three remaining statements individually. First, the plaintiffs argue that Dr. Zheng is not qualified to tell the jury the "clinical reasons why patients such as Mrs. Huskey

[7] I note that Ethicon's concessions are limited to the precise statements identified in the plaintiffs' motions. Therefore, this ruling does not exclude testimony outside the literal scope of these statements.

require excision of their Ethicon mesh medical devices." (*Id.* at 2). I disagree. Dr. Zheng has examined over one hundred explanted meshes. (*See* Zheng Dep. [Docket 176-2], at 24:4-10). I therefore **FIND** that he is qualified to testify from a pathologist's perspective why patients require excisions.

Second, the plaintiffs argue that Dr. Zheng is not qualified to testify whether transvaginal mesh devices can cause pain. The plaintiffs point to the following testimony, which is vague and contradictory:

> Q. So you're telling me that as a pathologist you are not able to tell whether a patient is having pain and you receive a mesh specimen, whether it's related to the pain or not?
>
> A. Correct. But let me add something. But if the histological evidence or pathological evidence is obvious, then that can be consistent with the clinical symptoms such as pain. If there's no, you know, evidence to support, then usually there's no linkage between the finding—pathological finding and the clinical pain.

(Zheng Dep. [Docket 176-2], at 46:17-47:1). Although Dr. Zheng contradicts himself, he does admit that he is not able to tell from a mesh sample whether a patient is experiencing pain. Further, Ethicon does not point to anything in the record indicating that he is qualified to testify whether transvaginal mesh devices cause pain. For these reasons, I **FIND** that Dr. Zheng is not qualified to opine whether transvaginal mesh devices cause pain, and such opinions are **EXCLUDED**.

Third, the plaintiffs contend that Dr. Zheng is not qualified to opine about "the impact of patients' hypersensitive responses to Ethicon's mesh devices." (Pls.' Mem. [Docket 176], at 3). I cannot determine from the parties' briefing or Dr. Zheng's deposition testimony precisely what the plaintiffs seek to exclude or why they believe Dr. Zheng is unqualified. Therefore, the plaintiffs' motion on this issue is **DENIED**.

2. Reliability of Particular Opinions

Finally, the plaintiffs move to exclude several opinions as unreliable. The plaintiffs state that

> Dr. Zheng acknowledged in his deposition that the human vagina is a non-sterile environment. *Yet, the Zheng Report does not countenance that devices implanted there are not suitable to that environment and could potentially cause serious infections in women implanted with them such as Mrs. Huskey*. . . .
>
> Likewise lacking are Dr. Zheng's opinions regarding whether the TVT-O device's lack of elasticity caused Mrs. Huskey's symptoms. Dr. Zheng testified that the vagina needs to maintain elasticity to preserve vital function. However, *nowhere in his report does he acknowledge that devices implanted in the vagina also need to maintain elasticity.*

(Pls.' Mem. [Docket 176], at 4 (emphasis added)). These are not proper challenges to Dr. Zheng's methodology. In reality, they are disputes with the conclusions Dr. Zheng reached. The plaintiffs' motion on these issues is **DENIED**.

The plaintiffs also challenge the reliability of Dr. Zheng's opinion that as many as fifty percent of women seeking transvaginal mesh revisions do so "for legal purposes" to advance claims. (Zheng Dep. [Docket 176-2], at 25:19-25). Ethicon does not respond to this argument. This opinion is clearly unreliable and unhelpful, and it is **EXCLUDED**.

E. Dr. Harry Johnson

Dr. Harry Johnson is an obstetrician and gynecologist who specializes in female urinary incontinence and pelvic organ prolapse. (*See* Johnson Report [Docket 212-2], at 1). Dr. Johnson opines that the scientific literature does not indicate that Prolene mesh degrades in the body. In addition, Dr. Johnson opines that if mesh does degrade in vivo, the literature does not demonstrate that it has any clinical significance. Specifically, Dr. Johnson states that:

> In this section [of the TVT IFU], Ethicon reports that animal studies have shown minimal inflammatory reaction in tissues and stimulates the disposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, that is incorporating the mesh into the adjacent tissue. This is important to me as there will

> be no persistent or acute inflammatory response affecting the vagina and bladder in the patient. This is consistent with what I have seen in my practice and in the literature. I have seen no persistent inflammatory responses that have clinically affected any of my patients. Ethicon also states that the mesh is not subject to degradation, meaning that it is a permanent mesh and will not change in character over time. There is no data on Prolene mesh indicating that it degrades in the body. There are no studies in the literature showing degradation of mesh that is of any clinical significance. In my experience and review of the available medical literature, serious complications of TVT are very uncommon. The major intraoperative complications are very rare for midurethral slings like TVT. There is no procedure or device that has a better benefit risk ratio than TVT for SUI. As such, it developed into the gold standard procedure for treatment of SUI 5-6 years after introduction and has remained the gold standard procedure for the last 10 years.

(Johnson Report [Docket 212-2], at 20).[8] During his deposition, Dr. Johnson testified that he has "never seen any evidence that particle loss has any clinical significance in patients." (Johnson Dep. [Docket 212-1], at 162:1-6). The plaintiffs argue that Dr. Johnson is not qualified to opine on mesh degradation and particle loss and that his opinions on this subject are unreliable.

The plaintiffs contend that Dr. Johnson is unqualified to opine about polypropylene because he is not a biomaterials expert. (*See* Johnson Dep. [Docket 212-1], at 162:14-16 ("Q: Okay. You're not a biomaterials expert, are you? A: Um, I'm a clinical medical expert.")). The plaintiffs also point to testimony showing that Dr. Johnson is unfamiliar with the chemical composition of polypropylene. (*See* Johnson Dep. [Docket 170-3], at 162:17-163:1, 164:8-165:1).[9]

However, as I stated in relation to Dr. Rosenzweig's opinion on degradation, an expert "need not be precisely informed about all details of the issues raised in order to offer an [expert]

[8] It appears that Dr. Johnson's opinions apply equally to the TVT and the TVT-O IFU. (*See* Johnson Report [Docket 212-2], at 20-21).

[9] The plaintiffs' counsel initially attached a rough draft of this deposition transcript to their motion, stating that they would supplement the record with the final transcript at the court's request. This is not a request the court should have to make. In the future, counsel should supplement the record with final drafts as soon as they become available, without prompting from the court.

opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Simply because Dr. Johnson cannot describe the chemical properties of polypropylene does not render him unqualified to testify that he has not experienced mesh degradation in his practice.

Dr. Johnson has implanted at least 750 TVT or TVT-O devices, treated patients with mesh-related complications, and has performed 25-30 revisions of polypropylene slings. (*See* Johnson Dep. [Docket 236-1], at 71:21-72:19). Dr. Johnson is also the co-principal investigator and founding member of the Urinary Incontinence Treatment Network ("UITN"), which was established by the National Institute of Diabetes, Digestive and Kidney Diseases in 2000. (*See* Johnson Report [Docket 212-2], at 1). Under the direction of the National Institute of Health, the UITN has conducted several randomized, surgical trials comparing different treatments for urinary incontinence including fascial slings, Burch colposuspension, and midurethral synthetic slings, including the TVT, TVT-O, and Monarc slings. (*See id.* at 2). Accordingly, I **FIND** that Dr. Johnson's research and clinical experience qualifies him to render opinions regarding the lack of mesh degradation and particle loss.

With respect to reliability, the plaintiffs contend that Dr. Johnson is simply speculating that polypropylene does not degrade or lose particles because he has not seen degradation or particle loss in his practice. They also contend that Dr. Johnson failed to support his opinion with scientific literature. I disagree.

Dr. Johnson writes that "[t]here are no studies in the literature showing degradation of mesh that is of any clinical significance." (*Id.* at 20). He bases this opinion on his review of scientific literature as well as his clinical experience. (*See id.*; Johnson Dep. [Docket 170-3], at 163 ("Again, I've never seen any evidence of degradation in a patient. I'm not sure that has any clinical significance.")). Although Dr. Johnson's opinion is not subject to testing and it is not supported by

peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance, district courts have "considerable leeway" in applying *Daubert*'s reliability factors. *Kumho Tire*, 526 U.S. at 152 (1999). Here, Dr. Johnson offers an opinion about the lack of evidence of clinically significant degradation based on his clinical experience and his review of the scientific literature. This type of opinion is obviously not subject to testing or peer-review. Therefore, drawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming this particular opinion. *See DeKeyser v. Thyssenkrupp Waupaca, Inc.*, 747 F. Supp. 2d 1043, 1050 (E.D. Wis. 2010).

The plaintiffs also contend that Dr. Johnson's opinion is unreliable because he did not review internal Ethicon documents that refute his conclusion. (*See* Reply Mem. in Supp. of Pls.' Mot. to Exclude Certain Ops. and Test. of Harry Johnson Jr., M.D. [Docket 236], at 4). But here, Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility. For these reasons, I **FIND** that Dr. Johnson's opinion about degradation is sufficiently reliable.

V. Conclusion

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

I am particularly concerned about cumulative testimony. For instance, the plaintiffs offer at least five experts to opine on degradation, three experts on the insufficiency of Ethicon's warnings, and three experts on safer alternative designs. The defendants offer three experts on degradation.

The parties will not be permitted to call all of these experts at trial, and they should plan accordingly.

For the reasons stated above, Ethicon's motions with respect to Dr. Rosenzweig [Docket 149], Dr. Dunn [Docket 183], Dr. Steege [Docket 155], and Dr. Pandit [Docket 185] are **GRANTED in part** and **DENIED in part**. Ethicon's motion with respect to Dr. Klosterhalfen [Docket 152] is **DENIED in part** and **RESERVED in part**. Ethicon's motion with respect to Dr. Blaivas [Docket 157] is **GRANTED in part** and **DENIED in part** and **RESERVED in part**. Ethicon's motion with respect to Dr. Guelcher [Docket 181] is **DENIED**. The plaintiffs' motion with respect to Dr. Greenberg [Docket 165] is **GRANTED**. The plaintiffs' motions with respect to Dr. Pramudji [Docket 167] and Dr. Zheng [Docket 175] are **GRANTED in part** and **DENIED in part**. The plaintiffs' motions with respect to Dr. Sexton [Docket 171] and Dr. Johnson [Docket 169] are **DENIED.**

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

ENTER: July 8, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE