UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO Carolyn Lewis, et al. v. Ethicon, Inc., et al. Case No. 2:12-cv-4301	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are defendants Ethicon, Inc. and Johnson & Johnson, Inc.'s (collectively "Ethicon") Motion to Limit the Opinions and Testimony of Prof. Dr. Med. Uwe Klinge [Docket 132]; Motion to Preclude or, in the Alternative, Motion to Limit Testimony of Prof. Dr. Med. Bernd Klosterhalfen [Docket 134]; Motion to Exclude Sherry A. Latham and Frank D. Tinari, Ph.D. [Docket 136]; Motion to Exclude the Opinions and Testimony of Dr. Thomas Mühl [Docket 137]; Motion to Exclude Nicholas Jewell [Docket 139]; Motion to Exclude Certain Opinions of Michael Thomas Margolis, M.D. [Docket 142]; Motion to Exclude Peggy Pence, Ph.D. [Docket 144]; Motion to Exclude Bruce Rosenzweig, M.D. [Docket 152]; and Motion to Exclude Cheryl D. Blume, Ph.D. [Docket 169]. Also pending before the court is Plaintiff Carolyn Lewis's Motion to Exclude Kevin Ong, Ph.D. from Testifying as an Expert Witness [Docket 146].

As set forth below, Ethicon's motions with respect to Dr. Pence [Docket 144] and Dr. Blume [Docket 169] are **GRANTED**. Ethicon's motions with respect to Dr. Klinge [Docket 132], Dr. Klosterhalfen [Docket 134], Ms. Latham and Dr. Tinari [Docket 136], Dr. Jewell [Docket 139], Dr. Margolis [Docket 142], and Dr. Rosenzweig [Docket 152] are **GRANTED in part** and **DENIED in part**. Ethicon's motion with respect to Dr. Mühl [Docket 137] is **DENIED**. The plaintiffs' motion with respect to Dr. Ong [Docket 146] is **DENIED**.

I. Background

This case is one of over 40,000 assigned to me by the Judicial Panel on Multidistrict Litigation. This case arises out of injuries allegedly sustained from the implantation of a pelvic mesh product, Ethicon's Gynecare TVT ("TVT"), to treat stress urinary incontinence. The complaint alleges the following causes of action: 1) negligence; 2) strict liability—design defect; 3) strict liability—manufacturing defect; 4) strict liability—failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) loss of consortium; and 8) punitive damages. (*See* Compl. [Docket 1]). The plaintiffs, as well as Ethicon, have retained experts to render opinions regarding the elements of these causes of action. The instant motions involve the parties' efforts to exclude or limit the opinions and testimony of many of these experts.

II. Legal Standard

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." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. 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 Maryland 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 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).

III. The Defendants' *Daubert* Motions

Ethicon seeks to limit or exclude the testimony of Dr. Thomas Mühl, Dr. Uwe Klinge, Dr. Bernd Klosterhalfen, Sherry A. Latham, Dr. Frank D. Tinari, Dr. Nicholas Jewell, Dr. Michael Thomas Margolis, Dr. Peggy Pence, Dr. Bruce Rosenzweig, and Dr. Cheryl D. Blume. I address each proposed expert in turn.

A. Dr. Thomas Mühl

Ethicon challenges Dr. Mühl's opinions regarding "effective porosity." For the reasons stated below, Ethicon's motion [Docket 137] is **DENIED**.

Dr. Mühl holds a Ph.D. in electrical engineering and, along with Dr. Uwe Klinge, developed a concept called "effective porosity," which is defined as a percentage of the area of mesh that has a pore size of greater than one millimeter in all directions. (Mühl Report [Docket 137-1], at 2). The effective porosity threshold is based on the theory that pores should be at least one millimeter in all directions in order to (1) prevent "fibrotic bridging" (the merging of granuloma across pores that prevents tissue from filling the pores) and (2) permit tissue ingrowth. (*See* Mühl Report [Docket 137-1], at 2). Dr. Mühl uses the test to determine that Ethicon's TVT has an effective porosity of 0.0%. (Mühl Report [Docket 137-1], at 8-9).

Under the *Daubert* analysis, I must determine that an expert witness is qualified to offer his or her opinions, and that his or her opinions are both relevant—helpful to the jury to understand a fact in issue—and reliable—methodologically sound. Ethicon does not argue that Dr. Mühl is unqualified to render these opinions or that his opinions are unhelpful. Rather, Ethicon argues that Dr. Mühl's opinions are unreliable because they are not generally accepted, they do not take into account the range of forces exerted on mesh *in vivo*, the one millimeter measurement is arbitrary, and Ethicon's competitor partially financed the development of the theory. (*See generally* Defs.' Mem. of Law in Supp. of Mot. to Limit the Ops. and Test. of Prof. Dr. Thomas Mühl [Docket 138] ("Defs.' Mem. re: Mühl")). Ethicon brings these challenges to the same opinions held by Drs. Klinge and Klosterhalfen. Therefore, the analysis that follows applies equally to the effective porosity opinions of Drs. Mühl, Klinge, and Klosterhalfen.

First, Ethicon argues that Dr. Mühl's opinions are not reliable because they are not generally accepted. The concept of effective porosity is apparently adopted only in articles authored by Drs. Mühl and Klinge, and it is used only by a single manufacturer, FEG Textiltechnik ("FEG"), a company affiliated with Drs. Mühl and Klinge. But general acceptance is merely one factor a court should consider in determining admissibility of expert testimony. A court should consider numerous factors, none of which is dispositive, in determining whether an expert's methods pass muster under *Daubert*. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003). In addition to general acceptance, a court should consider whether an expert's theories have been "subjected to peer review and publication." *Daubert*, 509 U.S. at 593. Dr. Mühl's effective porosity theories are published in several peer-reviewed articles. (*See, e.g.*, Mühl Dep. [Docket 161-6], at 244:14-245:19; Klinge Report [Docket 132-1], at 18 (citing Mühl T. et al., *New Objective Measurement to Characterize the Porosity of Textile Implants*, J. Biomed. Mater. Res. Part B: Applied Biomaterials 176-183 (2007)), *id.* (citing J. Otto et al., *Elongation of Textile Pelvic Floor Implants Under Load is Related to Complete Loss of Effective Porosity, thereby Favoring Incorporation of Scar Plates*, J. Biomed. Mater. Res. Part A 1-6 (2013))).

Second, Ethicon argues that these opinions are unreliable because Drs. Mühl and Klinge have contradicted themselves in the past by stating that pores measuring less than one millimeter can be effective. (*See* Defs.' Mem. re: Mühl [Docket 138], at 8). An expert's contradictory prior statements may indicate that the expert's methods are unreliable, but that is not necessarily dispositive. The relevant inquiry is whether the proffered opinions are sufficiently reliable under *Daubert*. Dr. Klinge explained in his deposition that they adopted the one millimeter parameters in reliance on the Conze study and his research with Dr. Bernd Klosterhalfen. (*See* Klinge Dep. [Docket 161-10], at 376:14-377:16; 663:13-664:3). With support from a peer-reviewed publication, I am not convinced that opinions regarding the one millimeter parameters are unreliable.

Third, Ethicon suggests that the methods for testing effective porosity are unreliable because they were developed for FEG, a direct competitor of Ethicon. But as Ethicon admits, "a proffered expert witness's financial interest often goes to the weight rather than the admissibility of testimony." (Defs.' Mem. re: Mühl [Docket 138], at 7). "[I]t is well-settled that an expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." *Grant Thornton, LLP v. F.D.I.C.*, 297 F. Supp. 2d 880, 884 (S.D.W. Va. 2004) (Faber, J.). Ethicon is free to highlight this conflict of interest on cross-examination.

Fourth, Ethicon contends that even if I permit Dr. Mühl to testify about his effective porosity opinions, I should still prohibit his opinions regarding "effective porosity under strain" because they fail to take into account the wide range of physical forces exerted on implanted mesh. (*See* Defs.' Mem. re: Mühl [Docket 138], at 9-11). In order to test the TVT mesh's effective porosity while subjected to the mechanical forces of the human body, Dr. Mühl applied uniaxial forces (pulling from one side) between a range of 102 grams and 1,000 grams to the mesh. Ethicon argues that, in the human body, meshes are subject to forces from multiple directions simultaneously and that the actual forces to which urethral slings are subjected are estimated to be less than 50 grams. (*See* Defs.' Mem. re: Mühl [Docket 138], at 10). The plaintiffs retort that Ethicon used the same uniaxial loads to test its own products. (*See, e.g.*, Mühl Report [Docket 137-1], at 6 ("Ethicon's manner of applying uniaxial loads to Ethicon mesh to determine the behavior of mesh is strikingly similar to our test method.")). Further, Dr. Klinge explained that because slings are only one centimeter wide, any force attempting to make a sling wider will be very small (*see* Klinge Dep. [Docket 161-10], at 483:7-9), and the downward forces exerted on the sling by the pelvic floor will create a largely uniaxial strain (*id.* at 482:22-438:5). Finally, Dr. Mühl's expert report cites a published study employing similar uniaxial tensile testing methods to analyze Ethicon slings. (*See* Mühl Report [Docket 137-1], at 6).

Lastly, Ethicon argues that Dr. Mühl impermissibly relied on unreliable medical opinions of Dr. Klinge, but Ethicon does not point to any specific statements or opinions that it challenges. (*See* Defs.' Mem. re: Mühl [Docket 138], at 11). In any event, I address Ethicon's challenges to Dr. Klinge below.

Ethicon's arguments do not convince me that Dr. Mühl's opinions regarding effective porosity are unreliable. I therefore **FIND** that Dr. Mühl's opinions regarding effective porosity are not excluded.

B. Dr. Uwe Klinge

Ethicon moves to bar Dr. Klinge from testifying about (1) Ethicon's knowledge and state of mind, (2) the TVT product's propensity to cause secondary infections, (3) degradation and fraying of the TVT mesh, (4) porosity and pore deformation, (5) an alternative design, and (6) an analysis of a collection of TVT mesh explants. As discussed below, Ethicon's motion [Docket 132] is **GRANTED in part** and **DENIED in part**.

i. Opinions Related to the Ethicon's Knowledge, State of Mind, and Corporate Conduct

Throughout his expert report, Dr. Klinge discusses Ethicon's knowledge, state of mind, and corporate conduct. (*See, e.g.*, Klinge Report [Docket 132-1], at 10 ("Ethicon employees have testified that Ethicon knew before launch of its pelvic meshes . . . that in some women, there would be a severe FBR [foreign body reaction] and chronic life-altering inflammatory reaction . . . ."); *id.* ("As evidenced in countless pages of deposition testimony of Ethicon employees and internal Ethicon documents, Ethicon was aware that meshes with lighter weight and larger pores . . . lessened the risk of injury to patients."); Klinge Report [Docket 132-2], at

38 ("Internal documents reveal that there was knowledge of not only the degradative effects of polypropylene in surgical mesh but also that Ethicon's PVDF mesh, Pronova, was more elastic and demonstrated less degradation than polypropylene."); *id.* at 50 ("Ethicon was aware of the formation of biofilms on its transvaginally-placed meshes as noted by the TVM Group, the surgeons who [were the] inventors of Ethicon's prolapse repair kit, Prolift."); Klinge Report [Docket 132-3], at 54 ("Ethicon was aware of the difficulties in defining the biomechanical requirements of the human pelvis."); *id.* at 64 ("Ethicon knew the importance of a pelvic mesh that was stretchable in all directions . . . ."); *id.* at 88 ("Ethicon was aware of the challenges and uncertainties of designing a safe mesh for the pelvic floor . . . .")). Dr. Klinge also opines on what course of action Ethicon should have taken, stating "a reasonable mesh manufacturer should be less concerned about how its mesh design compares to its competition, and less concerned about telling a 'nice story' to physicians to justify selling 'inferior' meshes and more concerned with how its product affects the patients in which it will be permanently implanted." (*Id.* at 48-49).

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

ii. Secondary Infections

Dr. Klinge opines that Ethicon's product is "susceptible to an increased risk of secondary, mesh-related infections . . . ." (Klinge Report [Docket 132-1], at 4). Ethicon argues that Ms. Lewis did not suffer from a secondary, mesh-related infection, and therefore that Dr. Klinge's opinions on the product's associated risk of developing such infections are irrelevant. (*See* Defs.' Mem. of Law in Supp. of Mot. to Limit the Op. and Test. of Prof. Dr. Med. Uwe Klinge [Docket 133] ("Defs.' Mem. re: Klinge"), at 9). The plaintiffs retort that "[e]ven if Ms. Lewis has not yet had an infection due to her mesh implant, Dr. Klinge has testified that she is at an increased risk of infection over the course of the remainder of her life." (*See* Pls.' Resp. in Opp. To Defs.' Mot. to Limit the Op. and Test. of Prof. Dr. Med. Uwe Klinge [Docket 160], at 9).

An expert witness will be permitted to testify if his or her "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or *to determine a fact in issue*[.]" Fed. R. Evid. 702 (emphasis added). In his deposition, Dr. Klinge testified that "there can be some infections manifesting after two years, 50 years, with a foreign body with an implant." But his opinions appear to be limited to cases where the mesh remains in the body. (*See* Klinge Dep. [Docket 160-3], at 282:19-283:2 ("[I]f you're 80 years old, the lifelong risk [of developing an infection] fortunately is small, is shorter, but if you're 20 years old and you expect that this implant has to work there for another 70 years, of course, the risk is higher to experience an infection than in the old patient.")). Dr. Klinge does not offer opinions on secondary infections where the mesh has been explanted, as is the case with Ms. Lewis. Dr. Klinge's opinions regarding secondary infections therefore do not fit the facts of this case, and they are **EXCLUDED**.

iii. Degradation and Fraying of Polypropylene Mesh

Dr. Klinge opines that the TVT device is defective because it degrades *in vivo* and is subject to fraying and particle loss. (*See* Klinge Report [Docket 132-1], at 4). Ethicon argues that these opinions should be excluded because Dr. Klinge cannot tie degradation, fraying, or particle loss to any particular clinical complication,[1] and his methods are unreliable.

First, Ethicon ignores Dr. Klinge's statements that clearly ascribe particular complications to degradation, fraying, and particle loss. For instance, he states that "such oxidation and degradation, depending upon the severity, can [create] an enhanced inflammatory tissue response due to increased surface area as well as the lack of a smooth surface coming into contact with the tissue." (Klinge Report [Docket 132-2], at 37). Second, Dr. Klinge's opinions are based, at least in part, on peer-reviewed, published literature. (*See* Klinge Report [Docket 132-2], at 33 (citing studies by Williams et al., Liebert et al., and Oswald et al.)). I therefore **FIND** that Dr. Klinge is permitted to testify generally about polypropylene's tendency to degrade, fray, or lose particles and its effect on the human body.[2]

iv. Effective Porosity and Pore Deformation

Dr. Klinge opines that after implantation, the effective porosity of the TVT mesh is insufficient, and that "[u]nder minimal strain, the TVT mesh pores deform and collapse thereby increasing the risk of injury to patients in which it is implanted . . . ." (Klinge Report [Docket

[1] Ethicon also argues that these opinions should be excluded as irrelevant because the plaintiffs' design defect claims are preempted insofar as they are based on the composition of the Prolene Mesh. Ethicon's argument is fully set out in a motion for partial summary judgment [Docket 128], and I address it in my Memorandum Opinion and Order (Motion in Limine No. 1, Summary Judgment Motions on 510(k) Issue).

[2] Although Ethicon asserts that Dr. Klinge's specific causation opinion should be excluded, he offers none on this topic in his report.

132-2], at 2). These opinions are similar to those held by Dr. Thomas Mühl, and the parties brief these opinions in relation to Dr. Mühl's expert report. Therefore, for the reasons discussed in relation to Dr. Mühl, I **FIND** that Dr. Klinge is permitted to testify about effective porosity and pore deformation.

v. PVDF Alternative Design

Dr. Klinge intends to testify that mesh made of polyvinylidene fluoride, or PVDF, was a feasible alternative design to Ethicon's TVT. (*See* Klinge Report [Docket 132-3], at 84-88). Ethicon argues that this opinion is unreliable because it is based on Drs. Klinge's and Mühl's effective porosity studies. However, in his expert report, Dr. Klinge cites several academic articles and studies for the propositions that PVDF does not degrade like polypropylene and that PVDF meshes show little signs of surface cracking, inflammation, or scar formation after implantation. (*See, e.g.*, Klinge Report [Docket 132-3], at 86 (citing Klink, C. et al., *Comparison of Long-Term Biocompatibility of PVDF and PP Meshes*, Journal of Investigative Surgery 24:292-299 (2011); Silva, R. et al., *Degradation Studies of Some Polymeric Biomaterials: Polypropylene (PP) and Polyvinylidene Difouride (PVDF)*, Material Science Forum 593-543 (2007); Klinge, U. et al., *PVDF as a New Polymer for the Construction of Surgical Meshes*, Biomaterials 23:3487-3493 (2002)). Therefore, I **FIND** Dr. Klinge's opinions regarding a PVDF alternative design should not be excluded as unreliable.

vi. Opinions Related to Analysis of Pelvic Mesh Explants

Dr. Klinge bases various opinions on his analysis of a collection of TVT mesh explants at the Institute for Pathology, Düren. (*See* Klinge Report [Docket 132-3], at 69). Ethicon argues that Dr. Klinge should not be permitted to testify about his analysis of the explants because he is unqualified and his opinions are unreliable.

Ethicon believes Dr. Klinge is unqualified to offer opinions about his analysis of the explants because he is not a pathologist. (*See* Defs.' Mem. re: Klinge [Docket 133], at 19). Experts may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Klinge's practice focuses on hernia repair, and he has implanted and studied the Prolene mesh used in the TVT many times. (*See* Klinge Report [Docket 132-1], at 5-6). He is the author or co-author of "over 100" peer-reviewed publications which involve hernia and/or surgical mesh.

I need not decide whether Dr. Klinge is qualified to offer opinions regarding his examination of explants because his opinions are unreliable. Dr. Klinge states that he examined 485 explants from the mesh collection at the Institute for Pathology, Düren. Of the 485 meshes examined, Dr. Klinge reports that "a severe fibrosis was seen in > 60% of the TVT-devices . . . . Erosion was seen in 20% of the TVT samples . . . ." (Klinge Report [Docket 132-3], at 69). But Dr. Klinge does not state how he selected these particular explants, or whether 485 is a large sample size of the Institute's collection. He also offers opinions derived from an analysis of 22 explanted TVT and TVT-O samples. (*See* Klinge Report [Docket 132-3], at 69 ("All sections showed an intense and chronic foreign body reaction with an inflammatory infiltrate close to the polymer fibers . . . .")). Again, Dr. Klinge does not explain how he selected these 22 particular samples. There are no assurances that Dr. Klinge—or plaintiffs' counsel—did not opportunistically choose samples while ignoring others that might have weakened or disproved his theories. In short, there are no indications that Dr. Klinge's analyses of the mesh implants were controlled for error or bias. In *Daubert*, the Supreme Court stated that the "court ordinarily should consider the potential rate of error." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993). Without any explanation of the method for selecting the explants or the potential error rate in the conclusions drawn from the explants, Dr. Klinge's opinions are simply unreliable and are **EXCLUDED**.

C. Dr. Bernd Klosterhalfen

Ethicon brings two separate challenges to Dr. Klosterhalfen's testimony. First, Ethicon argues that Dr. Klosterhalfen should not be permitted to testify because the plaintiffs failed to submit a complete expert report pursuant to Federal Rule of Civil Procedure 26(a)(2). Second, Ethicon argues that, even if Dr. Klosterhalfen is permitted to testify, his opinions fail to satisfy the *Daubert* reliability and relevancy requirements. For the reasons discussed below, Ethicon's motion [Docket 134] is **GRANTED in part** and **DENIED in part**.

i. Expert Reports under Rule 26(a)(2)

According to Ethicon, the plaintiffs have failed to submit a sufficient expert report for Dr. Klosterhalfen, thus rendering him unable to testify. Under Rule 26, "a party must disclose to the other parties the identity of any witness it may use at trial . . . ." Fed. R. Civ. P. 26(a)(2)(A). In addition to disclosing the identity of a witness, when "the witness is one retained or specially employed to provide expert testimony," a party must provide a written report regarding the witness. Fed. R. Civ. P. 26(a)(2)(B). That report must contain, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" *Id.* "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c).

Ethicon argues that the plaintiffs have not provided a report that meets the requirements of Rule 26(a)(2)(A). The plaintiffs provided a report on October 14, 2013, in response to which Ethicon moved for an order compelling the plaintiffs to supplement their disclosures. Magistrate

Judge Eifert agreed with Ethicon and ordered the plaintiffs to supplement this report. (*See* Order [Docket 97]). Ethicon claims that the supplemented report is insufficient and that Dr. Klosterhalfen should be barred from testifying.

The plaintiffs argue that Dr. Klosterhalfen is a percipient fact witness, not a retained expert, and therefore he is not required to submit a detailed expert report pursuant to Rule 26(a)(2)(B). Dr. Klosterhalfen consulted for Ethicon from 1998 to 2011. During that time, Ethicon asked Dr. Klosterhalfen to analyze explanted pelvic mesh samples. Dr. Klosterhalfen also discussed with Ethicon potential changes to Ethicon's mesh. (*See* Defs.' Mem. of Law in Supp. of Their Mot. to Preclude or, in the Alterative, Mot. to Limit Test. of Prof. Dr. Med. Bernd Klosterhalfen [Docket 135] ("Defs.' Mem. re: Klosterhalfen"), at 8).

Where an expert is also a percipient fact witness, courts distinguish between "a percipient witness who happens to be an expert and an expert who without prior knowledge of the facts giving rise to litigation is recruited to provide expert opinion testimony." *Downey v. Bob's Disc. Furniture Holdings, Inc.*, 633 F.3d 1, 6 (1st Cir. 2011). "The distinguishing characteristic between expert opinions that require a report and those that do not is whether the opinion is based on information the expert witness acquired through percipient observations or whether, as in the case of retained experts, the opinion is based on information provided by others or in a manner other than by being a percipient witness to the events in issue." *U.S. v. Sierra Pac. Indus.*, CIV S-09-2445 KJM EF, 2011 WL 2119078, at *4 (E.D. Cal. May 26, 2011).

Ethicon argues that a number of Dr. Klosterhalfen's opinions go beyond his relationship with Ethicon and therefore require a detailed expert report. Ethicon contends that Dr. Klosterhalfen's opinions are based in part on a polypropylene degradation study he conducted with Dr. Klinge, as well as Dr. Klosterhalfen's collection of explanted meshes that he maintained outside his relationship with Ethicon. Regardless of whether the plaintiffs violated Rule 26(a)(2)(B), the violation was harmless. In determining whether the nondisclosure of evidence is substantially justified or harmless under Rule 37(c), a district court must consider

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

Hoyle v. Freightliner, LLC, 650 F.3d 321, 329 (4th Cir. 2011). There is no risk that Ethicon will be surprised by Dr. Klosterhalfen's testimony. Dr. Klosterhalfen's deposition and his expert testimony recently given at trial in *Cisson v. C.R. Bard*, No. 2:11-cv-195, provide Ethicon with full disclosure of Dr. Klosterhalfen's opinions and their basis. Further, Dr. Klosterhalfen's testimony will not disrupt the trial. Thus, I will not exclude Dr. Klosterhalfen's testimony under Rule 37(c).

ii. Opinions Regarding Secondary Infections

Dr. Klosterhalfen's expert report states that Ethicon "knew that biofilm formation due to bacteria adherence led to secondary, potential mesh-related infections" (Klosterhalfen Report [Docket 134-1], ¶ 10) and that he told Ethicon "that in virtually 100% of [the meshes listed in an explant report] he found a secondary, mesh-related infection." (*Id.* ¶ 6). Ethicon argues that these opinions are improper because they are unhelpful and irrelevant. I agree. As I previously discussed, an expert's opinions on Ethicon's knowledge or state of mind are not helpful to the jury. *See* Fed. R. Evid. 702. Further, secondary infections are not "a fact in issue" in this case. *Id.* Three separate physicians, Dr. Zimmern, Dr. Sexton, and Dr. Zheng, testified that Ms. Lewis did not suffer from a secondary infection. (*See* Zimmern Dep. [Docket 134-12], at 42:4-6; Sexton Rep. [Docket 134-13], at 4; Zheng Rep. [Docket 134-15], at 8). The plaintiffs do not dispute this testimony. Therefore Dr. Klosterhalfen's opinions relating to secondary infections are **EXCLUDED**.

iii. Opinions Related to Polypropylene's Propensity to Degrade

Dr. Klosterhalfen opines that polypropylene "is not inert and degrades in vivo over time." (Klosterhalfen Report [Docket 134-1], ¶ 14). This degradation, he contends, "adds to a chronic inflammatory process that is long term and induces scarification, contraction of the tissues, pain, and infection, both clinical and subclinical." (*Id.*)

Ethicon first argues that these opinions are irrelevant because Dr. Klosterhalfen "cannot say with any probability that degradation caused Mrs. Lewis' injuries." (Defs.' Mem. re: Klosterhalfen [Docket 135], at 15). It is true that none of Dr. Klosterhalfen's opinions directly address Ms. Lewis's particular injuries. Therefore, I **FIND** that Dr. Klosterhalfen's testimony is limited to opinions regarding polypropylene degradation and its effects *generally*.

Second, Ethicon argues that these opinions are unreliable because they are not generally accepted or supported by the scientific literature. Dr. Klosterhalfen's deposition testimony, although vague, appears to show the opposite:

> Q: What evidence do you have that any degradation in the polypropylene mesh adds to a chronic inflammatory process?
>
> A: Well, you'll see what happens is this degradation that you have of flaking or shaving of small particles of the surface of the polypropylene's fiber, *and in literature*, *there are a couple of studies* and especially what I told you in the hip prosthesis where different groups, including a group I participated in, I don't know when, 2004 or 2005, I don't remember, with some orthopedic surgeons from the Essen University where you can see that small particles of phagotypes and activate macrophages, and interesting in *these studies* is that the activation of the cells is independent from the material used.

(Klosterhalfen Dep. [Docket 134-7], at 438:4-21 (emphasis added)). Dr. Klosterhalfen also testified that other studies, which he could not name, and his personal experience examining tissue samples support his opinions. (*See id.* at 443:13-444:21). I am not able to determine the *specific* bases for Dr. Klosterhalfen's opinions because his expert report does not elaborate. Based on the record before me, I cannot determine whether Dr. Klosterhalfen's opinions are sufficiently reliable. Therefore, I reserve this ruling for trial.

iv. Opinions Related to Effective Porosity

Dr. Klosterhalfen's expert report states that "to avoid bridging fibrosis and shrinkage, a polypropylene mesh product . . . must have class 'A' pores with pore size of 3 millimeters in all directions or greater and an effective pore size greater than 1 millimeter in all directions after tissue integration." (Klosterhalfen Report [Docket 134-1], ¶ 13). Ethicon challenges these opinions by incorporating by reference its arguments against Dr. Mühl's effective porosity opinions. Therefore, for the same reasons discussed above in relation to Dr. Mühl, I **FIND** that Dr. Klosterhalfen's testimony regarding effective porosity should not be excluded.

D. Sherry A. Latham

Ethicon moves to exclude Ms. Latham's opinions in their entirety. For the reasons discussed below, Ethicon's motion [Docket 136] is **GRANTED in part** and **DENIED in part**.

Ms. Latham is a certified life care planner and a registered nurse. Her expert report sets forth detailed opinions on future projected care—a "life care plan"—for Ms. Lewis. The life care plan discusses and provides expected costs for "reasonable and necessary goods and services related to the impairments associated with [Ms. Lewis's] complications associated with her vaginal mesh." (Latham Report [Docket 136-1], at 12).

Ms. Latham's report provides a comprehensive summary of services that she opines that Ms. Lewis will require. For example, Ms. Latham projects that Ms. Lewis and her husband will require psychological and sexual therapy evaluations followed by psychological and sexual therapy treatment sessions for the next twenty-four years. (*See id.* at 117). Ms. Latham also projects that Ms. Lewis will require various medical supplies; drugs, such as Ambien, Citalopram, Hydrocodone, and Valium; and specific surgical procedures, such as Botox injections to the bladder, Coaptite injections to the bladder and sphincter, and "future mesh related surgery interventions for incontinence." (*Id.* at 117-18). Ms. Latham originally opined that Ms. Lewis will need an ATV with a rifle mount and a truck ramp for the ATV, (*id.* at 31), but she has since removed this item from her amended report.

Ethicon argues that Ms. Latham's life care plan is outside the scope of her expertise and lacks medical foundation. To be admissible, Ms. Latham's opinions and life care plan must be based on "reliable principles and methods" reliably applied to the facts of this case. Fed. R. Evid. 702. Because much of Ms. Latham's life care plan describes particular medical procedures and services, there must be a medical foundation for her recommendations. In other words, a doctor or medical expert must opine to a reasonable degree of medical certainty that the items listed in the life care plan are necessary. Ms. Latham herself admits that "ideally" she bases life care plans on "medical foundation" provided by a "medical doctor." (Latham Dep. [Docket 136-2], at 105:12-21). Yet at her deposition, Ms. Latham admitted that "the entire life care plan [for Ms. Lewis] is pending medical foundation." (*Id.* at 225:18-19). Ms. Latham stated that no healthcare provider recommended the particular services set out in the life care plan. (*Id.* at 220-227).

In response, the plaintiffs argue that Ms. Latham's report is in fact supported by Dr. Zimmern, who explanted Ms. Lewis' TVT mesh, and Dr. Margolis. The plaintiffs point to the following portion of Dr. Zimmern's deposition, arguing that it supports Ms. Latham's recommendations for counseling, physical therapy, and pain treatment:

Q: Let’s talk about what the future holds in terms of what she needs for therapy. As she heals from this procedure, would you recommend therapy for her?

A. Well, if she’s fine, I mean, if she has minimal incontinence, can resume sexual activity, the pain is gone, she needs nothing else.

Q. Okay. Have you had patients that have had problems resuming sexual relations after a long period of time or not?

A. We have.

Q. Have you recommended counseling for those patients?

A. Well, they can have counseling, they can have physical therapy, they can have, you know, treatment to help with the pain, yeah.

Q. Is that something you would recommend for her?

A. If that becomes the case, yes.

Q. And much of this depends on your future visits with her?

A. That’s correct.

Q. Is there any way to tell the jury whether Ms. Lewis is going to need future procedures following this explant?

A. I don't have a crystal ball, I’m sorry. I can't answer that, no.

Q. I understand that you have –

A. I hope in my heart that she won’t, but if she does, you know, there are options to manage her complaints. Because we do see those things happening, but, you know.

Q. What do you see happening with patients such as this? And I guess I refer you to--

A. Yeah, all the risks that we discussed with her. So persistent pain, persistent dyspareunia, continued incontinence, infection.

Q. So the potential exists for continued chronic pain or continued dyspareunia?

A. Correct.

(Zimmern Dep. [Docket 136-4], at 140:2-141:16). This testimony does not provide a reliable medical foundation for Ms. Latham's expert report. Rather than providing an opinion to a reasonable degree of medical certainty, Dr. Zimmern merely states that there is "potential" for continued chronic pain and continued dyspareunia.

On the other hand, Dr. Margolis's expert report does provide a medical foundation for *some* of Ms. Latham's life care plan items. Dr. Margolis states in his report that the following treatments are reasonably medically certain: (1) follow-up visits at two weeks, six weeks, and then as needed, (2) prescription pain medication, "typically Vicodin, 30-40 pills," (3) antibiotics to prevent urinary tract infection, and (4) physical therapy to "break up scarring in her vagina . . . and to strengthen her pelvic floor muscles." (Margolis Report [Docket 143-2], at 10). Although Dr. Margolis, a paid expert, seems to contradict Dr. Zimmern, a treating physician, Dr. Margolis's opinions are sufficiently reliable. He bases his opinions on his examination of Ms. Lewis and his knowledge and experience as a pelvic surgeon and urogynecologist with experience implanting and removing sling systems. Therefore Ms. Latham's cost projections related to Dr. Margolis's specific recommendations do not lack a medical foundation. I **FIND** that only Ms. Latham's recommendations that are very specifically grounded in Dr. Margolis's medical opinions are not excluded, and that the residue of her opinions is **EXCLUDED**.

E. Frank D. Tinari, Ph.D.

Ethicon moves to exclude Dr. Tinari's opinions in their entirety. For the reasons discussed below, Ethicon's motion [Docket 136] is **GRANTED in part** and **DENIED in part**.

Dr. Tinari, an economist, provides opinions regarding the total cost of lifetime care for Ms. Lewis, discounted to present value. He bases his expert report entirely on the life care plan provided by Ms. Latham. (*See* Tinari Report [Docket 136-6], at 3). As I discussed above, many opinions of Ms. Latham are excluded because they lack medical foundation and are therefore unreliable. Accordingly, Mr. Tinari's opinions, which are based on Ms. Latham's life care plan, are also unreliable. Thus Mr. Tinari's opinions are **EXCLUDED** where they are based on items in Ms. Latham's report that are also excluded.

F. Nicholas Jewell, Ph.D.

Ethicon seeks to exclude Dr. Jewell's testimony entirely. For the reasons stated below, Ethicon's motion [Docket 139] is **GRANTED in part** and **DENIED in part**.

Dr. Jewell is a biostatistician and professor at the University of California, Berkeley. Dr. Jewell examines the methodology and scientific validity of certain studies regarding the safety and efficacy of the TVT. Quoting from the plaintiffs' brief, the studies are as follows:

> 1. *Ulmsten Studies*: Beginning in 1996, Professor Ulmsten published a series of papers, including the initial proof of concept studies used to create the [TVT] and submitted for marketing authorization;
>
> 2. *Ward-Hilton Studies*: In 2002, [] Drs. Ward and Hilton published the first in a series of papers comparing TVT to Burch colposuspension. This constituted the largest randomized comparator study and was sponsored by Ethicon;
>
> 3. *TVT World Registry*: In 2011, Ethicon created and sponsored the TVT World Registry, the largest registry tracking the safety of its devices;
>
> 4. *Nilsson Studies*: In 2013, the last publication of the case series by Professor Nilsson was published. For more than 17 years, Ethicon has repeatedly relied upon this series of studies to support its claim that long-term clinical evidence proves TVT has a 97% success rate, and its claim that TVT is the "gold standard."

(Pls.' Resp. in Opp. to Defs.' Mot. to Exclude Nicholas P. Jewell [Docket 162] ("Pls.' Mem. re: Jewell"), at 4-5). Many of Ethicon's experts rely on these studies. (*See id.* at 5-6 (citing five Ethicon experts who relied on the studies)). Dr. Jewell opines that these studies contained methodological flaws, "systematically overstate the effectiveness of TVT," and therefore do not "provide an adequate basis for determining the safety or efficacy of TVT." (Jewell Report [Docket 139-7], at 3).

Ethicon first argues that Dr. Jewell's opinions are unreliable because he focuses on a limited number of studies while ignoring the rest of the scientific literature. (*See* Defs.' Mem. in Supp. of Mot. to Exclude Dr. Nicholas P. Jewell [Docket 140] ("Defs.' Mem. re: Jewell"), at 13). From Ethicon's brief:

> [Dr.] Jewell does not assess the TVT studies from an epidemiological perspective nor does he engage in a systematic review of the literature. Instead, what [Dr.] Jewell seeks to do is to raise questions about the validity of only five cherry-picked data sets (out of more than a hundred) while simultaneously purposefully ignoring the other information available. This is not the methodology of epidemiology . . . .

(*See* Defs.' Mem. re: Jewell [Docket 140], at 13). The plaintiffs retort that Dr. Jewell was not tasked with opining on the overall safety and efficacy of the TVT, but with examining the methodology of the studies that Ethicon intends to introduce. (*See* Pls.' Mem. re: Jewell [Docket 162], 4). I agree with the plaintiffs. Ethicon will proffer at least some of these studies to show that the TVT was safe and effective and therefore not defectively designed. The plaintiffs intend to use Dr. Jewell to point out problems with these studies. This type of evidence is "classic rebuttal expert testimony." *In re Silicone Gel Breast Implants Products Liab. Litig.*, 318 F. Supp. 2d 879, 898 (C.D. Cal. 2004) (where defendants proffered fifteen studies concluding that silicone breast implants do not cause cancer, plaintiff's expert testified that the studies reached no conclusions about cancer). Of course, Ethicon is free to proffer or discuss additional studies, beyond those analyzed by Dr. Jewell, which it contends support the safety and efficacy of the TVT.

Second, Ethicon contends that Dr. Jewell's opinions are unhelpful because, while Dr. Jewell criticizes the methodology used in the studies he examined, he cannot quantify the impact of the alleged methodological failures on the outcomes of the studies. (*See* Defs.' Mem. re: Jewell [Docket 140], at 14). For example, when asked what impact a financial conflict of interest had on the Ulmsten studies, Dr. Jewell replied that "I, of course, have no specific information for any—for this specific study that I'm aware of." (Jewell Dep. [Docket 139-8], at 76:12-14). But Dr. Jewell's inability to precisely quantify the effect of particular methodological errors or biases does not render his opinions unhelpful. He identifies several specific problems with each set of studies and then posits that the evidence in the studies "is insufficient to support widespread use [of the TVT] in general patients . . . ." (Jewell Report [Docket 139-7], at 18). For example, he opines that the Nilsson and Ulmsten studies "suffer from statistically unsound study design (lack of comparator, lack of well-defined inclusion/exclusion criteria, unblinded enrollment, etc.), conduct (e.g., unblended outcome assessment, biased data capture, unblinded determination of home visitation, alterations of study endpoints) and reporting of the results (improper statistical analysis, incomplete or altered reporting of adverse events)." (Jewell Report [Docket 139-7], at 19). Dr. Jewell similarly points out specific flaws in the methodology of the other studies. His opinions are therefore sufficiently helpful to the jury in evaluating the weight of Ethicon's evidence that these particular studies support the safety and efficacy of the TVT.

Third, Ethicon believes that Dr. Jewell's testimony should be excluded under Federal Rule of Evidence 403 because it will confuse and mislead the jury. I disagree. The jury should be permitted to understand the strengths and weaknesses of the evidence.

Finally, Ethicon briefly argues that if I permit Dr. Jewell to testify, I should limit the following opinions: (1) Ethicon deceived the FDA, (2) Dr. Ulmsten intentionally structured his studies to report better outcomes, (3) the Ulmsten and Nilsson studies did not use a comparator arm, (4) surgeons and investigators were not blinded, (5) study results were not reported on a center-by-center basis, (6) information contained in device brochures was improper, and (7) a clinician reading the Tincello 2011 article would be misled. (*See* Defs.' Mem. re: Jewell [Docket 140], at 18-19). Ethicon argues that these opinions are inadmissible because Dr. Jewell is not qualified to render them (opinion 2), they are based on improper methodology (opinions 3-5), and they are not helpful (opinions 1, 6-7). (*See id.*). The plaintiffs failed to respond to any of these arguments. I agree with Ethicon's arguments, and these opinions are **EXCLUDED**.

G. Dr. Michael Thomas Margolis

Dr. Margolis is a pelvic surgeon and a urogynecologist with experience implanting and removing sling systems. He also examined Ms. Lewis after her TVT device was removed. Ethicon argues that parts of his planned testimony either exceed his qualifications, are unhelpful to the jury, or are not set out in his expert report. For the reasons stated below, Ethicon's motion [Docket 142] is **GRANTED in part** and **DENIED in part**.

i. Ethicon's Knowledge and State of Mind

Dr. Margolis offers numerous opinions regarding Ethicon's state of mind and its knowledge of risks associated with the TVT. (*See, e.g.,* Margolis Report [Docket 142-2] at 5 ("Ethicon knew of these risks . . . ."), *id.* at 6 ("Ethicon possessed evidence that the risk of vaginal scarring was greater than disclosed . . . ."), *id.* at 11 ("Ethicon failed to disclose risk information available to Ethicon in its TVT Instructions for Use."). As I previously discussed, expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury. *See* Fed. R. Evid. 702. Further, Dr. Margolis is qualified as a physician; he is not qualified by "knowledge, skill, experience, training or education" to opine on Ethicon's state of mind or knowledge. *Id.* Therefore these opinions are **EXCLUDED**.

ii. Opinions Related to the Failure to Warn

Dr. Margolis opines that Ethicon failed to warn either Ms. Lewis or her implanting physician about risks associated with the TVT. (*See* Margolis Report [Docket 142-2], at 5 ("Because Ethicon knew of these risks, they should have been put in the IFU"), *id.* at 6 ("Mrs. Lewis suffered injuries that were not disclosed to her by Ethicon"), *id.* at 11 ("Ethicon failed to disclose risk information"); Margolis Supp. Report [Docket 142-3], at 3 ("[T]o a reasonable degree of medical certainty, Ethicon failed to act appropriately in informing physicians and their patients about these known risks."). Dr. Margolis also opines that the lack of these warnings caused Ms. Lewis's injuries. (*See* Margolis Report [Docket 142-2], at 6 ("Mrs. Lewis was unable to make a fully informed decision about having the TVT implanted. . . . [T]he inadequate disclosure of these risks were a substantial factor and/or cause [of] Mrs. Lewis' injuries.").

Ethicon argues that Dr. Margolis should be barred from testifying about the sufficiency of warnings that accompanied the TVT because the warnings are not a fact in issue. I agree. I granted summary judgment to Ethicon on the plaintiffs' failure to warn claims. Therefore, Dr. Margolis's opinions on the TVT's warnings are no longer relevant to a fact in issue and they are **EXCLUDED**.

iii. Historical Commentary

Ethicon argues that the following statements are merely a historical narrative of the evidence and are therefore unhelpful to the jury. I quote directly from Ethicon's brief:

- "Ms. Lewis's implanting physician, Muriel Boreham, testified that she was unaware of many of the risks listed below prior to the time she implanted Ms. Lewis' TVT" (Expert Report, p. 5);

- ". . . Ethicon did not have any procedure or Professional Education program to teach doctors how to properly remove TVT mesh slings when known complications occurred" (id. at 6);

- Inadmissible hearsay that "[Manufacturers of polypropylene resin stated that it should not be used in the human body" (id.); and

- Inadmissible hearsay testimony about alleged complaints made by patients to Ethicon's Associate Medical Director (Supp. Report, p. 2).

(Mem. in Supp. of Mot. to Exclude Certain Ops. of Michael Thomas Margolis, M.D. [Docket 143], at 8-9). It is true that "[a]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on the record of evidence." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). But that is not the case here. These statements provide the factual basis for Dr. Margolis's opinions and are therefore helpful for the jury to understand Dr. Margolis's opinions. Further, if Ethicon contends that certain statements are inadmissible hearsay, it may object to them at trial. A *Daubert* motion is not the proper method of excluding hearsay. Therefore, these opinions are not excluded.

iv. Opinions Related to Product Marketing

Dr. Margolis briefly states that the growing population of postmenopausal women "provides an attractive target for marketing campaigns by device manufacturers seeking to capture a high market share . . . ." (Margolis Report [Docket 142-2], at 4). Although Dr. Margolis cites two peer-reviewed journal articles for his claim, Ethicon rightly argues that marketing is not Dr. Margolis's field of expertise. Further, as I have previously ruled, to the extent that this opinion reflects Ethicon's motives, intent, or state of mind, it is not properly the subject of expert testimony. Accordingly, these opinions are **EXCLUDED**.

v. Opinions Regarding Increased Use of Synthetic Slings

Dr. Margolis's expert report states that "[i]ndications for synthetic sling procedures became liberalized due to several factors." (Margolis Report [Docket 142-2], at 5). Ethicon takes issue with one factor in particular: Dr. Margolis's opinion that "[s]lings pay more to physicians than the more time-consuming Burch procedure." (Margolis Report [Docket 142-2], at 5). This opinion does not appear to be reliable. Dr. Margolis stated that he based this statement on information he obtained from his "payer," and that he does not have any general information to support it. (*See* Margolis Dep. [Docket 142-4], at 143:16). Further, Dr. Margolis is not an expert on medical device payment practices. Therefore, this opinion is **EXCLUDED**.

vi. Opinions Not Expressed in the Expert Report

Ethicon states that Dr. Margolis expressed opinions in his deposition that are not present in his expert report. (*See, e.g.*, Margolis Dep. [Docket 142-5], at 82:16-23 (traditional Burch procedure is the "gold standard"), 91:18-92:2 (TVT should be pulled from the market), 116:9-118:21 (midurethral synthetic slings should be pulled from the market)). Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Thus, these opinions are **EXCLUDED**.

Ethicon argues that Dr. Margolis also failed to discuss the TVT's effectiveness in his expert report. This is not true. His entire expert report focuses on the effectiveness of the TVT with respect to Ms. Lewis. (*See, e.g.*, Margolis Report [Docket 142-2], at 11 ("Carolyn Lewis developed numerous complications set forth above as a result of the TVT device being implanted into her body.")). Further, Dr. Margolis is qualified to comment on the effectiveness of the TVT. He has explanted over 200 mesh slings, including the TVT device. (Margolis Report [Docket 142-2], at 3). He has additionally observed "numerous" sling and mesh procedures involving TVT products and studied "textbooks, publications, IFU[]s (including those from J&J/Ethicon for the TVTs), surgical videos, cadaver dissections and countless operative reports . . . ." (Margolis Report [Docket 142-2], at 4). I therefore **FIND** that Dr. Margolis's opinions related to the effectiveness of Ethicon's TVT should not be excluded.

H. Peggy Pence, Ph.D.

Dr. Pence is a toxicologist with significant knowledge and experience with the FDA's regulatory processes. She has "reviewed or contributed substantially to the development of product labeling, including not only adverse reaction content but also contraindications and warnings, nonclinical toxicology and clinical studies information, and product use instructions." (Pence Report [Docket 144-3], at 4). Dr. Pence offers four separate opinions: (1) Ethicon failed to conduct appropriate testing of the TVT device, (2) the TVT system was misbranded due to a failure to warn, (3) the TVT system was misbranded as a result of false and misleading labeling, and (4) the TVT system was misbranded due to Ethicon's failure to meet the postmarket vigilance standard of care and manage risk. Ethicon seeks to exclude Dr. Pence's testimony in its entirety. For the reasons stated below, Ethicon's motion [Docket 144] is **GRANTED**.

i. Opinions Related to Ethicon's Failure to Conduct Appropriate Testing

Dr. Pence's first opinion is that Ethicon

> failed to perform testing that was critical to learning the long-term safety for the TVT permanent implant. Ethicon fell below the standard of care required of a reasonably prudent medical device manufacturer. Moreover, Ethicon failed to comply with its own credo, specifically, that the company's first responsibility is to the doctors and patients who use Ethicon's products.

(Pence Report [Docket 144-3], at 53). To arrive at this conclusion, Dr. Pence "principally looked at 510(k) applications, the documentation in Ethicon's 510(k) and related files, and the FDA's searchable 510(k) database." (Pence Report [Docket 144-3], at 39). Dr. Pence then analyzes particular risks associated with the TVT and implies that Ethicon should have performed certain tests. (*See, e.g.*, Pence Report [Docket 144-3], at 47 ("I reviewed no evidence of any studies conducted to determine long-term whether the fraying and the particles lost inside the body might cause deleterious effects."), *id.* at 51 ("Dr. Robinson testified that he was not aware of any long-term study undertaken by Ethicon to determine whether or not the TVT mesh is clinically cytotoxic in women.”)).

Ethicon argues that Dr. Pence is not qualified to offer this opinion because she is not a biomedical engineer or a doctor, and she has no experience or training designing products or treating urinary incontinence. (*See* Mem. in Supp. of Mot. to Exclude Peggy Pence [Docket 145], at 3). I disagree. While it is true that Dr. Pence is not a doctor or biomedical engineer, she has more than forty years of experience in the research and development of pharmaceuticals and medical devices. (*See* Pence Report [Docket 144-3], at 1). She founded and presides over a company that provides “advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials design and conduct, and regulatory matters involving the U.S. Food and Drug Administration (FDA) . . . .” (Pence Report [Docket 144-3], at 1). Dr. Pence has “designed clinical trials for diseases of the female genital system and [has] been involved in both preclinical and/or clinical testing of novel medical devices and biologics for wound healing applications, including both deep wounds and surgical incisions.” (Pence Report [Docket 144-3], at 1). This experience is relevant to her opinion that Ethicon failed to act as a reasonably prudent manufacturer in testing the TVT, and she is therefore qualified to testify by her “knowledge, skill, experience, training, or education[.]” Fed. R. Evid. 702.

Although Dr. Pence is qualified to offer her opinion that Ethicon failed to conduct appropriate tests of the TVT, she must still exercise sound methodology in arriving at that opinion. Ethicon argues Dr. Pence’s opinion is unreliable because it is merely *ipse dixit*, unsupported by any particular regulations or authorities. (*See* Mem. in Supp. of Mot. to Exclude Peggy Pence [Docket 145], at 4). I agree. As stated above, Dr. Pence analyzes a number of risks with the TVT and then states that particular tests were not conducted to investigate those risks. However, Dr. Pence does not explain the bases for her opinion that Ethicon's testing was inadequate. She points to nothing requiring such testing. She does not point to other manufacturers' testing practices. She simply notes that the tests were not done, and then declares that "in my professional opinion" Ethicon failed to adequately test. Without citing Dr. Pence's report, the plaintiffs argue that

> [t]hrough her experience developing drugs and devices and bringing them to market, Dr. Pence is able to inform the jury that the practice within the medical device industry is to consider what is known about the product and its components and predicates, to look at the existing medical literature regarding the product or similar products, and to assess what additional information needs to be obtained through testing to determine if the product is safe for its intended use.

(Pls.' Resp. in Opp. To Ethicon's Mot. to Exclude Peggy Pence [Docket 166], at 23). This broad statement does not convince me that Dr. Pence's analysis is based on a reliable methodology "reliably applied . . . to the facts of the case." Fed. R. Evid. 702. Accordingly, Dr. Pence's opinion that Ethicon failed to conduct appropriate testing of the TVT device is **EXCLUDED**.

ii. Opinions Related to FDA Regulatory Process

Dr. Pence's last three opinions largely involve FDA regulations and requirements. For instance, her second opinion is that Ethicon violated Section 502 of the Food, Drug and Cosmetic Act ("FDCA") because its IFU was inadequate. ((Pence Report [Docket 144-3], at 84). Her third opinion is that Ethicon violated section 301(a) of the FDCA by utilizing "promotional labeling that was false and misleading" and failing to "reveal material facts." (Pence Report [Docket 144-3], at 89). Her fourth opinion is that "Ethicon deviated from the standard of care by its failure to report to the FDA a number of adverse events and malfunctions that met the criteria for Medical Device Reporting, rendering the TVT devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA." (Pence Report [Docket 144-3], at 109).

These opinions are **EXCLUDED** because they are not helpful to the jury. First, whether Ethicon violated particular sections of the FDCA or failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702. The plaintiffs have not brought any claims based on Ethicon's violations of the FDCA. Second, to the extent that these opinions relate to either the plaintiffs' failure to warn claims or their breach of warranties claims, they are also not helpful to the jury and they will confuse and mislead the jury. As discussed in my Memorandum Opinion and Order (Motions for Summary Judgment), those claims are no longer pending.

I. Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a urogynecologist and professor of obstetrics and gynecology. He offers several different opinions, each of which Ethicon contends are improper: (1) the TVT mesh is not suitable for permanent implantation to treat SUI, (2) the TVT's IFU was inadequate, (3) Ethicon did not disclose in the IFU particular characteristics of the TVT that render it unsuitable for permanent implantation, (4) Ethicon failed to adequately explain to physicians how to properly "tension" the TVT, (5) Ethicon did not warn physicians or patients about the polypropylene Manufacturer Safety Data Sheet admonition against using polypropylene for permanent implantation in the human body, (6) Ethicon did not properly inform physicians and patients that polypropylene mesh is cytotoxic, (7) the TVT promotional materials were inaccurate and failed to reveal material facts about complications and conflicts of interest, and (8) patient brochures overstated the benefits of the TVT and understated the risks. (*See* Rosenzweig Report [Docket 152-2], at 3). Ethicon seeks to exclude Dr. Rosenzweig because it argues that he is not qualified and his opinions are unreliable and unhelpful. For the reasons discussed below, Ethicon's motion [Docket 152] is **GRANTED in part** and **DENIED in part**.

i. Opinions Related to Ethicon's Failure to Warn

Most of Dr. Rosenzweig's opinions relate to the plaintiffs' failure to warn claims. (*See, e.g.*, Rosenzweig Report [Docket 152-2], at 3 ("Ethicon's Disclosures of Adverse Reactions and mesh complications in its TVT Instructions for Use ('IFU') were inadequate . . . . Ethicon did not disclose information to physicians in its IFUs regarding characteristics of polypropylene . . . .)). In fact, the plaintiffs admit that "[t]he only testimony offered by Dr. Rosenzweig that is not focused on the TVT's warnings is his opinion that the TVT mesh is not suitable for its intended use." (Mem. in Opp. To Defs.' Mot. to Exclude Bruce Rosenzweig, M.D. from Testifying as an Expert Witness [Docket 164], at 6).

An expert opinion must "help the trier of fact to understand the evidence or to determine a fact in issue[.]" Fed. R. Evid. 702. I granted summary judgment to Ethicon on the plaintiffs' failure to warn claims. Therefore Dr. Rosenzweig's opinions that relate to warnings, the IFU, TVT promotional materials, or patient brochures are **EXCLUDED**.

ii. Opinion That TVT Mesh Not Suitable for Its Intended Use

As the plaintiffs admit, the only opinion offered by Dr. Rosenzweig that is not related to the TVT's warnings is his opinion that the TVT "is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, and loss of pore size with tension[.]" (Rosenzweig Report [Docket 152-2], at 3).

Ethicon argues that this opinion exceeds Dr. Rosenzweig's qualifications because he "has never performed any pathological analysis on a removed TVT or implant" and "he has never performed any research or development with respect to polypropylene at all." (Mem. in Supp. of Mot. to Exclude Bruce Rosenzweig, M.D. [Docket 153] ("Defs.' Mem. re; Rosenzweig"), at 4). I disagree. 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).

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." (Rosenzweig Report [Docket 152-2], at 2). 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. (Rosenzweig Dep. [Docket 164-2], at 57:25-58:13). Further, he cites dozens of studies and academic papers in his expert report to support his opinion that vaginally implanted polypropylene mesh degrades. (*See* Rosenzweig Report [Docket 152-2], at 12-21). 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.

iii. Ethicon's corporate knowledge and state of mind

Ethicon complains that Dr. Rosenzweig's opinions are riddled with improper testimony regarding Ethicon's corporate knowledge and state of mind. (*See, e.g.*, *id.* at 18 ("Ethicon knew degradation of its mesh could occur."); *id.* at 35 ("Ethicon . . . knew . . . that the TVT mesh would rope, curl and become deformed when under tension")). As I have previously discussed, these opinions do not assist the jury. Accordingly, they are **EXCLUDED**.

iv. Legal opinions

Dr. Rosenzweig's expert report repeatedly states that "Ethicon failed to act as a reasonable and prudent medical device manufacturer." (*Id.* at 13, 20-21, 23, 26, 30, 32, 39, 53, 54, 58, 64). These statements draw legal conclusions from the facts. In the Fourth Circuit, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Whether Ethicon failed to act as a reasonable and prudent medical device manufacturer is a question for the jury. To be clear, Dr. Rosenzweig may offer opinions that, as a physician, he does not believe the TVT is suitable for treatment of stress urinary incontinence, but his opinions cannot be phrased as legal conclusions. Therefore, these statements are **EXCLUDED**.

v. Narrative testimony

Ethicon argues that much of Dr. Rosenzweig's expert report is a summary of company documents, exhibits, and websites. Ethicon does not point to any particular documents or exhibits from which it believes Dr. Roesnzweig improperly testifies. Ethicon is primarily concerned with Dr. Rosenzweig's reliance on internet materials for background information on stress urinary incontinence. For instance, Dr. Rosenzweig cites to FDA.gov and WebMD.com in his section titled "Background and Treatment Options for Stress Urinary Incontinence." (*See* Rosenzweig Report [Docket 152-2], at 4-5). Ethicon contends that "experts in the field of urogynecology [do not] rely on such layperson websites in their practice." (Defs.' Mem. re; Rosenzweig [Docket 153], at 17). That may be true. Nonetheless, Dr. Rosenzweig's reliance on these materials is simply to provide background information related to stress urinary incontinence, which is helpful to the jury to understand the plaintiffs' design defect claims. His opinions relevant to the plaintiffs' causes of action, namely that the TVT is defectively designed, are not based on these sources. Therefore, I **FIND** that Dr. Rosenzweig's reliance on websites is not improper.

J. Cheryl D. Blume, Ph.D.

Dr. Blume is offered as an expert on medical device and pharmaceutical regulatory requirements. She proffers three main opinions: (1) "Ethicon inadequately disclosed the safety risks associated with the TVT device to both healthcare professionals and their patients at the time of and following its launch," and (2) "Ethicon's promotion of the TVT device to physicians and patients was . . . improper because they promoted the product in a manner that overstated the benefits and understated the risks so that physicians and patients were not provided proper information to fully address the risks and benefits of TVT implantation," and (3) "Ethicon's postmarketing surveillance and quality assurance activities underestimated the risks of the TVT . . . ." (Blume Report [Docket 169-1], ¶¶ 15-17). Ethicon moves to exclude Dr. Blume's testimony in its entirety. For the reasons discussed below, Ethicon's motion [Docket 169] is **GRANTED**.

Ethicon first argues that Dr. Blume is unqualified to proffer her opinions because she is not a medical doctor, she has not worked directly with implanted mesh, she was not involved in the regulation of the TVT device, and she is unfamiliar with treatments for stress urinary incontinence. (*See* Mem. in Supp. of Mot. to Exclude Cheryl D. Blume, Ph.D. [Docket 170], at 3-4).

I need not decide whether Dr. Blume is qualified because her opinions do not relate to facts in issue. Each of Dr. Blume's proffered opinions relates to the plaintiffs' failure to warn or breach of warranty claims, which are no longer pending. Therefore, these opinions are **EXCLUDED** because they do not "help the trier of fact to understand the evidence or to determine a fact in issue[.]" Fed. R. Evid. 702.

IV. The Plaintiff's *Daubert* Motions

The plaintiffs have moved to exclude only Dr. Kevin Ong.

A. Kevin Ong, Ph.D.

Dr. Ong is a mechanical engineer specializing in the field of biomedical engineering. He provides consulting for, among other things, medical device product design, development, preclinical testing, failure and risk analysis, and regulatory approval. (*See* Ong Report [Docket 154-2], at 8). Dr. Ong opines that there is no evidence "that the alleged degradation of Ms. Lewis' mesh had any clinically relevant effects on mechanical properties of the mesh itself, such as stiffness, elasticity, and resistance to break." (*See id.* at 30). Dr. Ong further contends that "[s]ynthetic meshes, including polypropylene meshes, cause a mild inflammatory response for tissue in-growth to occur. The extent of inflammatory response is related to patient-specific factors including repair site location, previous medical history, and tissue quality." (*Id.*). The plaintiffs argue that Dr. Ong should be excluded because his opinions are based on unreliable methods and they go beyond Dr. Ong's qualifications and expertise. For the reasons stated below, the plaintiff's motion [Docket 146] is **DENIED**.

i. Medical opinions

As stated above, Dr. Ong is a mechanical engineer with significant expertise with medical devices. Yet Dr. Ong offers several medical opinions. He concludes that "[s]ynthetic meshes, including polypropylene meshes, cause a mild inflammatory response for tissue in-growth to occur. The extent of inflammatory response is related to patient-specific factors including repair site location, previous medical history, and tissue quality." (*See* Ong Report [Docket 154-2], at 30). Further, in section 3.2 of his report, he opines that "there is no recognized link between infection, the TVT mesh products, and Ms. Lewis' complaints." (*See id.* at 28). Dr. Ong is qualified to render these opinions. As a biomedical engineer, Dr. Ong is required to understand how materials interact with the body. He has examined "hundreds" of explanted meshes. (Ong Dep. [Docket 158-8], at 96:14-16). He has also taken courses in foreign body response and tissue inflammation. (Id. at 87:5-19). I **FIND** that Dr. Ong is qualified by his "knowledge, skill, experience, training, or education" to offer these opinions. Fed. R. Evid. 702.

ii. Opinions Related to Degradation of Polypropylene

The majority of Dr. Ong's report is devoted to his examination and testing of Ms. Lewis's explanted TVT mesh. From this testing, Dr. Ong draws the conclusion that "there is no reliable scientific evidence of physical degradation of the polypropylene mesh surface. The alleged degradation is an artifact from biological matter on the fiber surface, while any observed inflammatory effect can be associated with the normal healing process." (Ong Report [Docket 154-2], at 27).

In order to reach the conclusion that Ms. Lewis's mesh did not exhibit evidence of physical degradation of the polypropylene surface, Dr. Ong developed a twenty-step test whereby he soaked the explanted mesh in a series of chemicals. These chemicals removed the mesh's cracked outer layer. Dr. Ong maintains that this outer layer consisted entirely of biological material, although he did not chemically test the removed material. (*See* Ong Dep.

[Docket 154-1], at 71:13-23). After the mesh was "cleaned" (the outer layer was removed), Dr. Ong examined the remaining mesh and determined that the polypropylene "remained intact":

> Regions of cracked material similar to the coating or shell illustrated in Dr. Jordi's SEM images, and described by him as degraded polypropylene, were initially observed. Chemical processing removed the gross tissue, and in some areas revealed fibers with clean, smooth surfaces. Successive soaking of the explant sample in the reagents moved portions of the surface coating or shell. There was no evidence of gradient-type, ductile damage. Instead, the clean and smooth exposed regions in the explant that became further visible after the chemical processing steps, had the appearance of exemplar fibers coated with a layer of different material. The exemplar sample was also not visibly affected by the treatments, further demonstrating the chemical resistance of polypropylene.

(Ong Report [Docket 154-2], at 21-22).

The plaintiffs argue that Dr. Ong's conclusion that Ms. Lewis's mesh had not degraded is unreliable because Dr. Ong did not test the outer materials he removed from the explant. Dr. Ong admits that, as an expert witness for the C. R. Bard MDL, he did test the materials removed from explanted mesh. (*See* Ong Dep. [Docket 154-1], at 72:6-19). In this case, however, testing the removed material was not "the scope of [his] involvement in this matter." (*Id.* at 72:18-19).

The fact that he failed to test the removed material in this case does not render his methods unreliable. Dr. Ong states that he visually inspected the removed material and determined that it was biological material. Further, after removing the outer layer, Dr. Ong observed that the mesh was intact with "clean and smooth" surfaces that showed "no evidence of gradient-type, ductile damage." (Ong Report [Docket 154-2], at 22). Whether or not he chemically tested the removed material, Dr. Ong observed that the mesh was fully intact. If the mesh explant was fully intact, the removed materials could not have contained portions of the polypropylene. Although Dr. Ong's methods appear to provide strong ammunition for cross-examination, I **FIND** that they should not be excluded as unreliable pursuant to *Daubert*.

V. Conclusion

As set out above, Ethicon's motions with respect to Dr. Pence [Docket 144] and Dr. Blume [Docket 169] are **GRANTED**. Ethicon's motions with respect to Dr. Klinge [Docket 132], Dr. Klosterhalfen [Docket 134], Ms. Latham and Dr. Tinari [Docket 136], Dr. Jewell [Docket 139], Dr. Margolis [Docket 142], and Dr. Rosenzweig [Docket 152] are **GRANTED in part** and **DENIED in part**. Ethicon's motion with respect to Dr. Mühl [Docket 137] is **DENIED**. The plaintiffs' motion with respect to Dr. Ong [Docket 146] is **DENIED**.

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

ENTER: January 15, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE