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

**CHARLESTON DIVISION**

**DEBRA WISE, et al.,**

**Plaintiffs,**

**v.** **CIVIL ACTION NO. 2:12-cv-01378**

**C. R. BARD, INC.,**

**Defendant.**

**MEMORANDUM OPINION AND ORDER**
**(*Daubert* Motions)**

The following motions have been brought by the defendant, C. R. Bard, Inc. ("Bard"): (1) Motion to Exclude or Limit Certain Opinions and Testimony by Donald R. Ostergard, M.D. [Docket 113]; (2) Motion to Exclude the Opinions and Testimony of Bernd Klosterhalfen, M.D. [Docket 134]; (3) Motion to Exclude or Limit Certain Opinions and Testimony by Anthony Brennan, Ph.D. [Docket 150]; (4) Motion to Exclude Certain Opinions and Testimony of Colleen Fitzgerald, M.D. [Docket 158]; and (5) Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Brian Raybon [Docket 177].

The following motions have been brought by the plaintiffs, Debra and Ronald Wise: (1) Motion to Exclude Opinions and Testimony of Christine T. Wood, Ph.D. [Docket 123]; (2) Motion to Exclude Opinions and Testimony of Marta Villaraga, Ph.D. [Docket 142]; (4) Motion to Exclude Certain General Opinions and Testimony of Matthew Clark, M.D. [Docket 176]; (5) Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Laura Bigby [Docket 187]; (6) Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Roger Darois [Docket 188]; (7) Motion to Exclude Certain

Opinions and Testimony of Bard's Non-Retained Corporate Expert Adam Silver [Docket 189]; and (8) Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Scott Britton [Docket 190].

For the reasons set forth below, the following motions brought by Bard are **GRANTED in part** and **DENIED in part**: Motion to Exclude or Limit Certain Opinions and Testimony by Donald R. Ostergard, M.D. [Docket 113]; Motion to Exclude the Opinions and Testimony of Bernd Klosterhalfen, M.D. [Docket 134]; Motion to Exclude or Limit Certain Opinions and Testimony by Anthony Brennan, Ph.D. [Docket 150]; and Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Brian Raybon [Docket 177]. Bard's Motion to Exclude Certain Opinions and Testimony of Colleen Fitzgerald, M.D. [Docket 158] is **DENIED**.

The following motions brought by the plaintiffs are **GRANTED in part** and **DENIED in part**: Motion to Exclude Opinions and Testimony of Marta Villaraga, Ph.D. [Docket 142]; Motion to Exclude Certain General Opinions and Testimony of Matthew Clark, M.D. [Docket 176]; Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Laura Bigby [Docket 187]; and Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Scott Britton [Docket 190]. The following motions brought by plaintiffs are **GRANTED**: Motion to Exclude Opinions and Testimony of Christine T. Wood, Ph.D. [Docket 123]; (2) (4) Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Roger Darois [Docket 188]; and Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Adam Silver [Docket 189].

## I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 10,000 of which are in the Bard MDL, MDL 2187. In this particular case, the plaintiff, Debra Wise, was surgically implanted with the Avaulta Plus Anterior Support System and the Avaulta Plus Posterior Support System (collectively "Avaulta"), mesh products manufactured by Bard to treat POP. (*See* Short Form Compl. [Docket 1], at 2).[1] The plaintiff received her surgery in West Virginia. (*Id.* at 4). The plaintiff claims that as a result of implantation of the Avaulta products, she has experienced multiple complications, including vaginal spasms, damage to her ureter, vagina, and rectum, kidney reflux, urinary tract infections, chronic constipation, dyspareunia (pain during sexual intercourse), lower pelvic pain, incontinence, and kidney stones. (*See* Pl. Fact Sheet [Docket 102-9], at 7). The plaintiff alleges negligence, strict liability for design defect, strict liability for manufacturing defect, strict liability for failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (Short Form Compl. [Docket 1], at 4).[2] Additionally, the plaintiff's husband, Ronald Wise, alleges loss of consortium. (*Id.*). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

## II. Legal Standard

[1] The present case is part of Wave 1 of the Bard MDL, MDL 2187. (Pretrial Order # 118 (Docket Control Order for Selection and Discovery of 200 Cases) [Docket 15]). Because the parties agree that the Southern District of West Virginia is the proper venue, I set this case for trial in the Southern District. (*See* Am. Joint Submission, MDL 2187 [Docket 1004], at 8; *see also* Order [Docket 63]).

[2] By Memorandum Opinion and Order entered on February 5, 2015, I granted Bard's Motion for Summary Judgment with respect to the plaintiffs' claims of strict liability for manufacturing defect and breach of warranty. (*See* Mem. Op. & Order (Def.'s Mot. for Summ. J.) [Docket 224]).

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

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

[3] With more than 70,000 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 and the arguments of counsel.

*Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

*Daubert* mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

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

With respect to relevancy, *Daubert* further explains:

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

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

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

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

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

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

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

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

Before I review these motions, I begin by addressing two arguments that apply to many of the parties' *Daubert* objections. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g.*, *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").

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

## III. The Defendant's *Daubert* Motions

In this case, the defendant seeks to limit or exclude the expert opinions of Donald R.

Ostergard, M.D., Bernd Klosterhalfen, M.D., Anthony Brennan, Ph.D., Colleen Fitzgerald, M.D., and Dr. Brian Raybon.

### A. Motion to Exclude or Limit Certain Opinions and Testimony by Donald R. Ostergard, M.D.

As one of the five founders of the American Urogynecological Society, Dr. Ostergard is a seasoned obstetrician, gynecologist, and urogynecologist, having practiced in the field for over fifty years. (Ostergard Report [Docket 113-1], at 3). He has published hundreds of peer-reviewed articles on the topic of urogynecology and has performed thousands of pelvic surgeries. (*Id.* at 4). The plaintiffs offer Dr. Ostergard to testify as an expert witness in this case on the adequacy of the warnings Bard provided to physicians; the design of the Avaulta; the feasibility of safer alternative designs; the need for clinical trials; and the adequacy of physician training. (*See generally id.*). Bard seeks to exclude several of Dr. Ostergard's expert opinions under *Daubert.* I address Bard's arguments in turn.

#### 1. Opinions on Bard's State of Mind

First, Bard contends that Dr. Ostergard "is not qualified to give, and has no basis for, opinions on Bard's state of mind and should not be permitted to offer narrative testimony as to Bard's knowledge, motives or corporate conduct." (Bard's Mem. in Supp. of Its Mot. to Exclude or Limit Certain Ops. & Test. by Donald R. Ostergard, M.D. ("Mem. in Supp. re: Ostergard") [Docket 114], at 4). Specifically, Bard objects to Dr. Ostergard's opinions about what Bard knew or intended. In response, the plaintiffs contend that the court should allow Dr. Ostergard's statements about what Bard knew because they "are not Dr. Ostergard's opinions [and] are instead the evidentiary and factual predicate for his opinions." (Pls.' Resp. in Opp. to Bard's Mot. to Exclude the Ops. & Test. by Donald Ostergard, M.D. ("Resp. re: Ostergard") [Docket 186], at 6). As I explained above, expert opinions on Bard's knowledge or state of mind are not

helpful to the jury. To the extent Dr. Ostergard's opinions touch on these matters, they are **EXCLUDED**. Again, I will not go through his report sentence-by-sentence in addressing this objection, and I instead rely on counsel to tailor Dr. Ostergard's testimony at trial as necessary.

**2. Opinions Regarding FDA Regulatory Requirements and Product Labeling**

Bard next objects to Dr. Ostergard's opinions about "the purpose of FDA labeling requirements and the ways in which Bard allegedly failed to fulfill those requirements." (Mem. in Supp. re: Ostergard [Docket 114], at 7). In Bard's view, Dr. Ostergard lacks the qualifications necessary under *Daubert* to render these opinions, given that Dr. Ostergard's only experience with product labeling is his "review" of numerous Instructions for Use (IFU) for mesh products. (*Id.*). The plaintiffs concede that they will not offer Dr. Ostergard as an expert on the regulatory requirements for product labels and warnings. Instead, they offer Dr. Ostergard to opine on "the extent to which any inaccuracies or omissions [in Bard's labeling and warnings] could either deprive a reader or mislead a reader as to the risks and benefits of the product at the time the labeling was published." (Resp. re: Ostergard [Docket 186], 10–11). The plaintiffs argue that as a urologist, Dr. Ostergard is qualified to testify about these matters.

I agree with the plaintiffs. While I have found Dr. Ostergard unqualified to opine on FDA regulations and whether a product label satisfies those regulations, *see Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *36–37 (S.D. W. Va. Oct. 17, 2014), the plaintiffs have confirmed that Dr. Ostergard will not testify on these topics. Rather, as indicated by his expert report, Dr. Ostergard will testify about the risks he perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding

Dr. Blaivas, a urologist, as qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings. . . ." (internal quotations and brackets omitted)). Relying on the plaintiffs' assurance that Dr. Ostergard's testimony will be limited to an evaluation of Bard's warnings based on his knowledge of and clinical experience with the risks of pelvic mesh products—and not on FDA requirements or regulations—Bard's motion on this point is **DENIED**.[4]

**3. Opinions Regarding Polypropylene**

Dr. Ostergard offers several opinions about the characteristics of polypropylene, including that it has carcinogenic effects and that it is, among other things, "incompatible with oxidizing agents"; "inherently impure"; and prone to flaking, fissuring, and shrinking. (Mem. in Supp. re: Ostergard [Docket 114], at 9 (quoting Dr. Ostergard's expert report)). Bard argues that (1) Dr. Ostergard is not qualified to render these opinions, and (2) the opinions have no reliable, scientific basis. Accordingly, Bard asks the court to exclude these opinions in their entirety.

I can dispose of Bard's argument regarding Dr. Ostergard's qualifications by referring to my previous ruling on this matter:

> It is difficult to deride Dr. Ostergard's qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic

[4] I note that some portions of Dr. Ostergard's expert report seem to go a step further than comparing the risks of the product to the content of the label. For instance, Dr. Ostergard opines that the purported omissions in the Avaulta IFU "rendered [the device] not reasonably safe." (Ostergard Report [Docket 113-1], at 11). This opinion invades the province of the jury by stating a legal conclusion and will not be accepted at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding an expert witness "from using legal terms of art" and "giv[ing] legal conclusions, such as, but not limited to, the conclusions that the [product] was 'defective,' 'unreasonably dangerous,' or was the 'proximate cause' of [the plaintiff's] injury").

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

*Tyree*, 2014 WL 5320566, at *35–36. I **ADOPT** this ruling here.

With respect to reliability, Bard raises several very specific challenges to Dr. Ostergard's opinions on the characteristics of polypropylene. I have addressed these objections before and concluded that Dr. Ostergard's reliance on the research and peer-reviewed work of others, when considered alongside his own peer-reviewed research, satisfied the reliability requirements of *Daubert*. *See id.*; (*see also Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114 [Docket 391], at 7–8). I do not find Dr. Ostergard's report in this case materially different from these prior cases—his opinions continue to arise from the peer-reviewed research of others, (*see* Ostergard Report [Docket 113-1], at 24–26 (citing various medical journals to support his opinions on the bacterial colonization, shrinkage, and degradation of polypropylene)), in addition to his own research (*see* Ostergard Curriculum Vitae [Docket 186-1], at 29 (listing works authored by Dr. Ostergard related to pelvic mesh morphology, among other things)), and his own experience and training as a urogynecologist, (*see id.* at 26 (explaining the difficulty of explanting polypropylene)). Given that Dr. Ostergard's opinions rest upon "good grounds, based on what is known," *Daubert*, 509 U.S. at 590, they must be "tested by the adversary process." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). That is, to the extent that Bard finds Dr. Ostergard's opinions to be incorrectly generalized or otherwise lacking, it may attack them via cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of

contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). For these reasons, I **FIND** Dr. Ostergard's opinions sufficiently reliable, and I **DENY** Bard's motion to exclude on this point.[5]

This holding, however, does not apply to Dr. Ostergard's opinion on the carcinogenicity of polypropylene. Ms. Wise has not claimed that the Avaulta caused cancer, and as such, the mention of cancer in the context of this case would, at a minimum, offend Federal Rule of Evidence 702 and confuse the jury on a matter with scant probative value. All of Dr. Ostergard's opinions on a connection between polypropylene and cancer are therefore **EXCLUDED**, and Bard's motion on this topic is **GRANTED**.

**4. Opinions Regarding Product Design**

Lastly, Bard contends that the court should exclude Dr. Ostergard's opinions on the design of the Avaulta because "he has no meaningful experience in product design." (Mem. in Supp. re: Ostergard [Docket 114], at 14). I held oppositely in *Tyree*, relying on Dr. Ostergard's demonstrated experience and training with pelvic mesh products. 2014 WL 5320566, at *36 ("[Dr. Ostergard] has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products."). That this ruling was in the context of an SUI product, rather than a POP product

[5] Bard debates whether the articles written by Dr. Ostergard deserve the label of "peer-reviewed." (*See* Reply in Supp. of Its Mot. to Limit the Ops. of Dr. Ostergard [Docket 210], at 7–9 (arguing that Dr. Ostergard's articles on polypropylene mesh do not qualify as peer-reviewed articles)). Of the 141 peer-reviewed articles listed on Dr. Ostergard's curriculum vitae, Bard raises this objection as to 6 of them. Rather than delving into each article and attempting to define what counts as a peer-reviewed article, I accept the articles as peer-reviewed on the basis that the publishing journals—*International Urogynecology Journal* and *Obstetrics and Gynecology*—clarify that all articles submitted are peer-reviewed. *See* Am. Coll. of Obstetrics & Gynecologists, *A Guide to Writing for* Obstetrics & Gynecology, 2 (4th ed.), *available at* http://edmgr.ovid.com/ong/accounts /guidetowriting.pdf ("All submissions to *Obstetrics & Gynecology* are reviewed by experts in the relevant subject areas."); Int'l Urogynecology J., *Instructions for Authors*, 1 (Jan. 2015), *available at* http://www.springer.com/medicine /gynecology/journal/192 (accepting original articles, reviews, and editorials, but stating that "[a]ll manuscripts are subject to peer review").

such as the Avaulta, is inapposite—Dr. Ostergard's education, training, and experience encompass all areas of pelvic anatomy and pelvic reconstruction surgery. Moreover, Dr. Ostergard has previously served as an expert witness in a pelvic mesh trial involving the Avaulta Plus. In *Scott v. C. R. Bard, Inc.*, Dr. Ostergard testified as to the deficiencies in the Avaulta Plus, and on appeal, the court found his testimony as determinative in upholding the plaintiff's negligent design claim. 231 Cal. App. 4th 763, 779 (2014) (concluding that although Dr. Ostergard had never implanted the Avaulta Plus, "he was familiar with the design of various transvaginal mesh kits and was an expert in the field of urogynecology," and from his testimony, "the jury could decide whether Bard acted as a reasonably careful medical device manufacturer when it designed Avaulta Plus"). The state court's admission of Dr. Ostergard as an expert on the Avaulta Plus product reinforces his qualifications. *See, e.g., Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 785 (4th Cir. 1998) (affirming the admission of the expert testimony based, in part, on the fact that the expert's opinion "ha[d] been admitted by at least one other district court"). For these reasons, I **FIND** that Dr. Ostergard is qualified to testify about the design of the Avaulta.

In sum, Bard's Motion to Exclude or Limit Certain Opinions and Testimony by Donald R. Ostergard [Docket 113] is **GRANTED in part** and **DENIED in part**.[6]

**B. Motion to Exclude the Opinions and Testimony of Bernd Klosterhalfen, M.D.**

Bard seeks to exclude certain opinions of Dr. Bernd Klosterhalfen. Dr. Klosterhalfen is a pathologist who has "devoted much of [his] career to the study of the body's responses to implanted devices, and how the design of those devices influences biocompatibility." (Klosterhalfen Report [Docket 134-1], at 2). Bard moves to exclude the following opinions

[6] The specific causation opinions set forth in Dr. Ostergard's report and challenged by Bard's motion do not apply to the case at bar, and as such, I do not address them here.

offered by Dr. Klosterhalfen: (1) surface degradation of polypropylene; (2) Bard's state of mind; (3) opinions based on personal data pools; and (4) opinions not offered in Rule 26(f) report. This is not the first time I have reviewed *Daubert* challenges to Dr. Klosterhalfen's opinions on these topics, and my findings today remain largely consistent with past decisions.

**1. Surface Degradation**

First, Bard argues that Dr. Klosterhalfen's opinions with regard to polypropylene degradation do not fit the facts of the case because he has not seen any degradation on the plaintiff's explant. Dr. Klosterhalfen relies on sufficient and reliable bases in forming his opinion that polypropylene degrades and the effects of such degradation *generally*. However, there does not appear to be any connection between his surface degradation opinions and Ms. Wise specifically. (*See* Bard's Mem. of Law in Supp. of Mot. to Exclude the Ops. of Bernd Klosterhalfen, M.D. [Docket 135], at 3 (citing deposition testimony where Dr. Klosterhalfen stated he had not seen surface degradation on any of the eleven explants he reviewed, including Ms. Wise)). Therefore, I **FIND** that Dr. Klosterhalfen's opinions are limited to polypropylene degradation and the effects of such degradation generally.

**2. State of Mind**

Next, Bard contends that Dr. Klosterhalfen should not be permitted to opine as to Bard's state of mind. The plaintiffs appear to partially concede that Dr. Klosterhalfen will not offer opinions as to Bard's state of mind. Regardless, I have repeatedly held that a party's knowledge and state of mind are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. Accordingly, Bard's motion with regard to state of mind is **GRANTED**, and these opinions are **EXCLUDED**.

**3. Data Pools**

Next, Bard argues that Dr. Klosterhalfen should be precluded from relying on his personal database because it has not been produced and is unreliable. In response, the plaintiffs contend that, consistent with this court's previous findings, Dr. Klosterhalfen's reliance on his personal database is part of his knowledge and experience. In *In re C. R. Bard, Inc.*, I allowed Dr. Klosterhalfen to rely on his personal database in forming his expert opinions. *See* 948 F. Supp. 2d 589, 622 (S.D. W. Va. 2013). However, I also noted that Bard failed to timely move to compel the production of the explant database. *Id.* Here, Bard timely moved to compel. (Mot. to Compel, MDL 2187 [Docket 1355]). Magistrate Judge Eifert has indicated from the bench that she is not inclined to allow Bard access to the raw data in Dr. Klosterhalfen's database, and she intends to enter an order to that effect. I agree with Judge Eifert that granting Bard's request would quickly devolve into a mini-trial on Dr. Klosterhalfen. Through Bard's Motion to Compel, this issue has developed, and I now **FIND** that without a fully synthesized representation of Dr. Klosterhalfen's database, specific reliance on that database is unreliable. Accordingly, Bard's motion with regard to Dr. Klosterhalfen's personal database is **GRANTED**, and these opinions are **EXCLUDED**.

**4. Opinions Not in Rule 26(f) Report**

Last, Bard contends that Dr. Klosterhalfen should be precluded from offering opinions that are not in his Rule 26(f) report, as well as opinions he agreed not to offer during his deposition. The plaintiffs concede that Dr. Klosterhalfen will not offer opinions on subjects for which he testified he is not an expert. Accordingly, Bard's motion with regard to these opinions is **DENIED as moot**.

For the reasons above, Bard's motion with respect to Dr. Klosterhalfen [Docket 134] is **GRANTED in part** and **DENIED in part**.

**C. Motion to Exclude or Limit Certain Opinions and Testimony by Anthony Brennan,**

**Ph.D.**

Bard seeks to exclude certain opinions of Anthony B. Brennan, Ph.D. Dr. Brennan is a biomedical engineer who has "evaluated and continue[s] to evaluate numerous explants to determine behavior in the human body." (Brennan Report [Docket 150-1], at 4). Bard moves to exclude Dr. Brennan's opinions and conclusions concerning: (1) polypropylene or mesh, their degradation, or their material characteristics; (2) SEM, EDS, FTIR, HPLC data and results and any opinions related to or relying upon those results or reports; (3) GPC, DSC, and TGA data and results and any opinions related to or relying upon those results or reports; (4) data, testing, or examination performed on explants "cleaned" of tissue by Dr. Brennan, Dr. Garth Wilkes, or Polymer Solutions; (5) effects the Bard mesh products have on the human body or medical injuries or conditions they may cause, including inflammation; (6) pore size of the Bard mesh products or Bard's measurement thereof; (7) Dr. Brennan's pore size measurements of the Bard mesh products; (8) MSDS of any kind, including of raw material of the Bard mesh products; and (9) biocompatibility of the Bard mesh products and testing or standards thereof. (Bard's Mem. of Law in Supp. of Mot. to Exclude or Limit Certain Ops. and Test. of Anthony Brennan, Ph.D. ("Bard's Mem. re: Brennan" [Docket 168], at 2–3). Broadly, Bard offers five arguments in support of excluding Dr. Brennan's opinions. I proceed to address each in turn.

**1. Effect of Mesh on the Body—Inflammation & Degradation[7]**

First, Bard argues that Dr. Brennan is not "competent" to testify regarding the effects of Bard's mesh products on the plaintiff or the human body because he lacks the proper medical education or background. (*Id.* at 4). Dr. Brennan's expert report notes that he is "knowledgeable about a number of chemical fields including polymeric biomaterials, polymeric materials . . . physical and chemical aging of polymers and nanocomposites and the design,

[7] Bard's first two arguments with regard to inflammation and degradation can be disposed of together.

manufacturing, testing, clinical evaluation and distribution of medical devices for both short-term and long-term implantation." (Brennan Report [Docket 150-1], at 4). Clearly, as a biomedical engineer, Dr. Brennan has extensive education and experience in biomaterials generally—which includes polymers—as well as knowledge of how these materials respond when implanted in the human body. Accordingly, I **FIND** that Dr. Brennan is qualified to offer opinions on the effect of polypropylene mesh on the human body.

Bard also contends that Dr. Brennan's inflammation opinions are unreliable because he did not review any medical records, pathology slides, or histology slides of the plaintiff. (Bard's Mem. re: Brennan [Docket 168], at 6). However, the plaintiffs concede that Dr. Brennan is not offering any specific causation opinions in this case. Therefore, Dr. Brennan's failure to examine individual records or slides does not affect the reliability of his opinions. In discussing inflammation and degradation, Dr. Brennan cites multiple peer-reviewed articles and refers to his own testing of explant samples. Accordingly, I **FIND** Dr. Brennan's opinions on the effect of polypropylene mesh on the human body sufficiently reliable under *Daubert*. I **DENY** Bard's motion on this point.

**2. Polymer Solutions Testing**

Next, Bard argues that Dr. Brennan's opinions based on testing performed by Polymer Solutions should be excluded because he lacked the qualifications to perform the testing himself and the cleaning methodology was inadequate. (*Id.* at 10). Bard's first argument with regard to the testing performed by Polymer Solutions is misplaced. Dr. Brennan collaborated with Dr. Wilkes and Polymer Solutions—an accredited laboratory—to conduct the testing at issue. (Pls.' Resp. in Opp. to Bard's Mot. to Exclude or Limit Certain Ops. and Test. of Anthony Brennan, Ph.D. ("Pls.' Resp. re: Brennan") [Docket 184], at 9). Dr. Brennan provided written protocols for the testing, and both doctors were often present to direct and oversee what took place in the

laboratory. (*Id.* at 9–10). The fact that a third-party laboratory physically performed the testing is not sufficient to prohibit Dr. Brennan from relying on such testing. In fact, the plaintiffs point out that Bard's expert, Dr. Reitman, engaged in a similar practice. (*See* Reitman Dep. [Docket 145-3], at 27–28 (describing a "collaborative process" for evaluating explants)). Furthermore, in his deposition, Dr. Brennan explicitly stated that he has conducted similar testing on his own before. (*See* Brennan Dep. [Docket 150-1], at 191 ("I've done extensive FTIR testing on my own for years.")). Accordingly, I **FIND** that Dr. Brennan properly relied on the testing performed by Polymer Solutions.

Bard also contends that the cleaning methodology employed by Polymer Solutions was inadequate, invalidating the testing entirely. Dr. Brennan, Dr. Wilkes, and Polymer Solutions developed a cleaning protocol based on literature, experience, and other scientific information. (Pl.'s Resp. re: Brennan [Docket 184], at 14). In his deposition, Dr. Brennan explained that some remaining tissue would not affect his ability to observe degradation and that such an occurrence is to be expected. (*See* Brennan Dep. [Docket 150-1], at 164–65 ("I can clearly see the degradation on the sample. So the tissue isn't an issue at this point.")). Based on Dr. Brennan's testimony, I am satisfied that the cleaning methodology was sufficiently reliable under *Daubert*. Accordingly, I **FIND** that Dr. Brennan's opinions based on the testing performed by Polymer Solutions should not be excluded, and I **DENY** Bard's motion on this issue.

**3. Pore Size**

Next, Bard argues that Dr. Brennan is unqualified to perform pore size testing and that his methodology is not representative of conditions in the human body. (Bard's Mem. re: Brennan [Docket 168], at 15). I previously reviewed Dr. Brennan's qualifications and the reliability of his pore size opinions under *Daubert*. *See Bard*, 948 F. Supp. 2d at 638–39. The

parties in this case assert the same arguments; therefore, my reasoning and conclusions from *In re C. R. Bard, Inc.* govern. In *Bard*, I ruled as follows:

> After review of Dr. Brennan's report and deposition testimony, and the parties' arguments, I **FIND** that to the extent Dr. Brennan relies on his tensile testing to render opinions related to how mesh performs inside the female pelvis, such opinions should be excluded; these opinions would not assist the jury because the tensile testing is not intended to represent how mesh performs inside the female pelvis. However, opinions derived from tensile testing regarding the effect of stress on the mesh are admissible. I further **FIND** that Dr. Brennan is qualified to testify as to pore size, and that his opinions are based on reliable principles and methodology and properly applies to the facts of the case.

948 F. Supp. 2d 589, 639 (S.D. W. Va. 2013). Accordingly, I **ADOPT** my prior ruling on Dr. Brennan, as stated in *Bard* and **FIND** that he is qualified to opine on pore size and that his opinions are reliable, with the exception of his opinions related to how mesh performs inside the female pelvis based on tensile testing. Thus, I **DENY in part** and **GRANT in part** Bard's motion to exclude this opinion.

**4. MSDS and Biocompatibility**

Last, Bard contends that Dr. Brennan's MSDS and biocompatibility opinions are "unreliable and contradictory." (Bard's Mem. re: Brennan [Docket 168], at 18). It is unclear to me how this argument is any different from Bard's arguments with regard to Dr. Brennan's other opinions on polypropylene. I have already determined that Dr. Brennan is qualified to opine on polypropylene generally, as well as polypropylene degradation, and that his opinions are reliable. I see no reason to depart from those findings merely because Bard opposes Dr. Brennan's references to the MSDS and biocompatibility. Furthermore, "[l]istening to testimony and deciding whether it is contradictory is the quintessential jury function of determining credibility of witnesses." *Crowley v. Chait*, 322 F. Supp. 2d 530, 553–54 (D.N.J. 2004) (internal quotation

omitted)). Accordingly, I **FIND** that Dr. Brennan is permitted to offer opinions that include references to the MSDS and biocompatibility testing.

To summarize, Bard's Motion to Exclude Certain Opinions and Testimony by Anthony Brennan, Ph.D. [Docket 150] is **DENIED in part** and **GRANTED in part**.

**D. Motion to Exclude Certain Opinions and Testimony of Colleen Fitzgerald, M.D.**

Bard seeks to exclude certain opinions of Dr. Colleen Fitzgerald. Dr. Fitzgerald is a licensed and board-certified physical medicine and rehabilitation medical doctor who specializes in women's pelvic and musculoskeletal rehabilitation, chronic pelvic pain, pelvic floor muscle disorders, and pregnancy-related musculoskeletal disorders. (Fitzgerald Report [Docket 158-1], at 2). Bard moves to exclude the following opinions offered by Dr. Fitzgerald: (1) mesh implantation should be avoided; (2) mental health of plaintiffs, including depression diagnoses; (3) specific causation that the Bard mesh products caused incontinence and pain in the plaintiffs; and (4) permanence of the alleged injuries. I will address each contested opinion in turn.

**1. Avoiding Mesh Implantation**

First, Bard argues that Dr. Fitzgerald's opinion that mesh implantation should be avoided is inadmissible. The plaintiffs concede that they do not intend to have Dr. Fitzgerald offer any opinions at trial regarding the propriety of mesh implantation generally. Therefore, Bard's motion with regard to avoiding mesh implantation is **DENIED as moot**.

**2. Plaintiff's Mental Health**

Next, Bard contends that Dr. Fitzgerald is unqualified to opine that the plaintiff's pain is aggravating her depression and that such opinion will not assist the jury. However, the plaintiffs explain that the opinion Bard challenges applies only to plaintiff Lynda Barner, not Ms. Wise. (*See* Pls.' Resp. in Opp. to Bard's Mot. to Exclude or Limit Ops. and Test. of Colleen Fitzgerald, M.D. [Docket 183], at 3–4). Dr. Fitzgerald's independent medical examination of Ms. Wise

makes no mention of depression. Accordingly, Bard's motion with regard to the plaintiff's mental health is **DENIED as moot**.

**3. Specific Causation**

First, Bard argues that Dr. Fitzgerald is unqualified to offer opinions related to incontinence. This challenge is completely unfounded, given that Dr. Fitzgerald's entire clinical practice is dedicated to understanding, diagnosing, and treating female pelvic pain, as well as pelvic pain-related complications. (*See* Fitzgerald Report [Docket 158-1], at 184). Furthermore, she has published and presented multiple times on incontinence and the connection between pelvic pain and incontinence. *See, e.g.*, Colleen M. Fitzgerald, et al., *The Association Between Pelvic Girdle Pain and Urinary Incontinence Among Pregnant Women in the Second Trimester*, 117 Int'l J. Gynecology & Obstetrics 248 (2012). Accordingly, Bard's motion with regard to incontinence is **DENIED**.

Bard also contends that Dr. Fitzgerald's specific causation opinions are unreliable because she failed to perform a proper differential diagnosis or conduct testing. In the beginning of her report, applicable to all six plaintiffs she examined, Dr. Fitzgerald describes the differential diagnosis process she used in arriving at her opinions in these cases. (*See* Fitzgerald Report [Docket 158-1], at 186–87). Furthermore, in Ms. Wise's case specific report, Dr. Fitzgerald includes a section ruling out other causes of pain, such as endometriosis and kidney stones. (*See id.* at 275). Additionally, I agree with the plaintiffs that Dr. Fitzgerald's failure to perform quantitative sensory testing goes to the weight of her opinions, not their admissibility. In preparing her case specific report, Dr. Fitzgerald reviewed Ms. Wise's extensive medical history and records, as well as performed a physical examination. I **FIND** her methodology sufficiently reliable under *Daubert*. Accordingly, Bard's motion with regard to specific causation is **DENIED**.

#### 4. Permanent Injuries

Last, Bard argues that Dr. Fitzgerald's opinions regarding permanent injuries are unreliable because she fails to account for contrary scientific literature. The only specific "contrary" literature Bard cites is an article entitled "Managing Vaginal Mesh Exposure/Erosions" by Dr. Willy Davila, which acknowledges the risks associated with transvaginal mesh. Bard contends that Dr. Fitzgerald "merely dismisses" Dr. Davila's conclusion that mesh complications can usually be managed successfully without providing any explanation. (Bard's Mem. of Law in Supp. of Its Mot. to Exclude or Limit Ops. and Test. of Colleen Fitzgerald, M.D. [Docket 159], at 13). After reviewing Dr. Fitzgerald's report and deposition testimony, I find Bard's argument without merit. Dr. Fitzgerald reviewed the Davila article in preparation for this case and cites it in her report. (Fitzgerald Report [Docket 158-1], at 210). Furthermore, during her deposition, Dr. Fitzgerald is the one who brings up the Davila article, explaining that she agrees with some portions of the article and disagrees with others. Although Dr. Fitzgerald admits that she has not performed research to support her partial disagreement with Dr. Davila, she states that her opinion is based on other research she has seen, her clinical experience, her scientific review of the literature, and her evidence-based practice. (Fitzgerald Dep. [Docket 158-1], at 96–97). If Bard disagrees with Dr. Fitzgerald's ultimate conclusion that mesh complications usually cannot be managed successfully, it is free to examine that issue further at trial on cross-examination. Accordingly, Bard's motion with regard to permanent injuries is **DENIED**.

In sum, Bard's Motion to Exclude Certain Opinions and Testimony of Colleen Fitzgerald, M.D. [Docket 158] is **DENIED**.

### E. Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Brian Raybon

Dr. Raybon is a board certified physician in obstetrics and gynecology, specializing in female pelvic and reconstructive surgery since 1998. (Raybon Report [Docket 177-1], at 3). He has testified as an expert at two previous MDL trials, *Cisson v. C. R. Bard, Inc.* and *Eghnayem et al. v. Boston Scientific Corp.*, and the plaintiffs again offer him as an expert here. Bard raises several objections to his expert opinions, and after applying *Daubert*, I **DENY in part** and **GRANT in part** Bard's Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Brian Raybon [Docket 177].

**1. Opinions on Bard's State of Mind and Opinions That State a Legal Conclusion**

Bard first challenges Dr. Raybon's opinions that go to Bard's intent, motive, state of mind, and corporate ethics, as well as Dr. Raybon's opinions that state a legal standard or legal conclusion. These opinions are generally inadmissible, and to the extent Dr. Raybon's opinions touch on these matters, they are **EXCLUDED**. Again, I will not go through his report sentence-by-sentence in addressing this objection and instead rely on counsel to tailor Dr. Raybon's testimony at trial as necessary.

**2. Opinions Regarding Physician Training**

Dr. Raybon also opines that Bard's physician training program "was inadequate and resulted in Bard's 'certification' of numerous physicians who were undertrained and who lacked the experience, skills and expertise necessary to properly perform the implantation of these products." (Raybon Report [Docket 177-1]). Bard raises several objections to these opinions. First, Bard argues that Dr. Raybon's criticism of the physician training program is "a dramatic shift" from his opinion in previous cases, thereby "throw[ing] Dr. Raybon's testimony about physician training into question." (Mem. of Law in Supp. of Mot. to Exclude or Limit Certain Ops. & Test. of Dr. Brian Raybon ("Mem. in Supp. re: Raybon") [Docket 177], at 6). Alleged

inconsistencies in a witness's testimony "go to credibility, rather than *Daubert*'s standard of admissibility." *McReynolds v. Sodexho Marriott Servs., Inc.*, 349 F. Supp. 2d 30, 40 (D.D.C. 2004). Accordingly, the proper forum for hashing out whether Dr. Raybon's current opinions contradict his previous opinions is cross-examination, not motions practice, and I will not exclude Dr. Raybon as an expert on this basis. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 553–54 (D.N.J. 2004) ("Listening to testimony and deciding whether it is contradictory is the quintessential jury function of determining credibility of witnesses." (internal quotation omitted)).

Bard's next argument, however, leads the court towards exclusion. Bard argues that because Dr. Raybon's opinions on physician training depend on the competence of other physicians, it should be excluded under *Daubert* as irrelevant. Relevance under *Daubert* depends on whether "a valid scientific connection" exists between the expert's testimony and the facts or issues of the case, *Daubert*, 509 U.S. at 591–92, and here, I cannot detect such a connection. Whether Bard admitted into its training programs certain physicians who Dr. Raybon considers as "undertrained" says little about the design of the Avaulta or the adequacy of its warnings. *See, e.g.*, *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *32 (S.D. W. Va. Sept. 29, 2014) (excluding an expert's opinion on physician training because it "primarily focus[es] on the competence of other physicians, which is irrelevant and will not assist the jury in determining the issues in this case"). Therefore, I **EXCLUDE** Dr. Raybon's opinions on physician training as irrelevant, and Bard's motion on this point is **GRANTED**.[8]

### 3. Opinions on Product Labeling and Warnings

[8] The plaintiffs assert that Dr. Raybon's opinion on physician training is relevant to retort Bard's "blame the doctor" defense, which the plaintiffs assume Bard will pursue at trial. I am not persuaded by this argument, however, because Ms. Wise's implanting physician, Dr. Mitchell Nutt, did not attend Bard's training sessions. Therefore, Dr. Raybon's opinions on the training sessions and the skills of the physicians in attendance do not fit the facts of this case, as required for admission under *Daubert*.

Bard also objects to Dr. Raybon's opinion that Bard failed to provide adequate warnings to physicians about the Avaulta in that the IFU minimized or wholly did not mention certain complications. Bard asserts that Dr. Raybon lacks the qualifications necessary to render this opinion, given that he is not an expert in product labeling. The plaintiffs respond that Raybon's experience as Bard's Key Opinion Leader qualifies him "to render an opinion regarding the IFU's completeness, accuracy, and the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits are or were at the time the labeling was published." (Pl.'s Resp. to Def.'s Mot. to Exclude the Opinions of Dr. Brian Raybon ("Pl.'s Resp. re: Raybon") [Docket 179], at 15).

In addressing this objection, I refer to my ruling in this order on Dr. Ostergard, where I have concluded that although Dr. Ostergard is not qualified to opine on FDA regulations and whether a product label satisfies those regulations, he is qualified to evaluate Bard's warnings based on his knowledge of and experience with the risks of the Avaulta. *Supra* at 10. I reach the same conclusion with respect to Dr. Raybon. Dr. Raybon has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the Avaulta poses to patients and then opine that the Avaulta IFU did not convey those risks. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings. . . ." (internal quotations

and brackets omitted)). To the extent that Dr. Raybon's opinions fit within this comparison, they are not excluded at this time, and Bard's motion on this issue is **DENIED**.[9]

**4. Opinions on Product Design**

Next, Bard objects to Dr. Raybon's opinions about the design of the Avaulta, including the characteristics of polypropylene and the insertion method of the device, on the basis that Dr. Raybon is unqualified to render these opinions and that the opinions lack a reliable basis. With respect to the former argument, I disagree. Dr. Raybon has extensive experience with POP and the use of mesh as a form of treatment. (*See* Raybon Report [Docket 177-1], at 3 (stating that Dr. Raybon has performed over 1,000 POP surgeries, and in approximately half of the surgeries, he used some form of synthetic mesh)). Moreover, he has direct experience with the Avaulta products as a consultant for Bard. In this role, Dr. Raybon tested the Avaulta products on cadavers and taught training courses on the use and implantation of the Avaulta. This knowledge of and experience with POP devices and, more specifically, Avaulta products, qualifies him to opine on the design of the Avaulta and the polypropylene used to construct it. *See* Fed. R. Evid. 702 (stating that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education"); *see also, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (ruling that a urogynecologist was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders").

[9] As is the case with Dr. Ostergard, some portions of Dr. Raybon's expert report seem to go a step further than comparing the risks of the product to the content of the label. For instance, Dr. Raybon opines that the purported omissions in the Avaulta IFU "rendered [the device] not reasonably safe." (Raybon Report [Docket 177-1], at 8). This opinion invades the province of the jury by stating a legal conclusion and will not be accepted at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding an expert witness "from using legal terms of art" and "giv[ing] legal conclusions, such as, but not limited to, the conclusions that the [product] was 'defective,' 'unreasonably dangerous,' or was the 'proximate cause' of [the plaintiff's] injury").

With respect to the reliability prong of *Daubert*, Bard disputes the basis for eight of Dr. Raybon's opinions on the design of the Avaulta. In general, Bard criticizes Dr. Raybon's significant reliance on internal corporate documents in reaching his conclusions and his inability during deposition to cite peer-reviewed literature to support his opinions. First, though an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions. *See, e.g.*, *Sanchez*, 2014 WL 4851989, at *4 (holding that an expert "may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions"); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1368 (M.D. Ga. 2010) ("[T]he experts' reliance on the journal articles and [the defendant's] internal documents does not diminish the weight that the Court gives to the experts' opinions, assuming that the opinions are otherwise sufficiently reliable."). For the most part, Dr. Raybon has properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct. Furthermore, many of the internal documents relied upon by Dr. Raybon could stand alone as medical research and literature. For these reasons, I do not consider Dr. Raybon's reliance on corporate documents as problematic.

In addition, given that Dr. Raybon has demonstrated in his report that his opinions have literary support, I decline to exclude his opinions on the grounds that he was unable to recall the literature during his deposition. (*See, e.g.*, Raybon Report [Docket 177-1], at 10–11 (supporting his opinion on polypropylene pore size with several written works)). At trial, Bard can certainly expound upon any errors or inconsistencies that it extracted during Dr. Raybon's deposition. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking

shaky but admissible evidence."). But because Dr. Raybon has undeniable experience on this subject matter and has substantiated his opinion with testable, peer-reviewed literature, I must open the gates to his testimony.[10] Bard's motion on this point is therefore **DENIED**.

**5. General Causation Opinions**

Additionally, Bard argues that the court should exclude Dr. Raybon's opinions on the complications he has seen in patients implanted with the Avaulta because they rest on unverified and "wildly extrapolate[ed]" estimates of a complication rate. (*See* Mem. in Supp. re: Raybon [Docket 177], at 18–19 (asking the court to exclude testimony "about the number of Avaulta devices Dr. Raybon has explanted, his complication rates with the Avaulta, and his comparative complication rates with non-mesh prolapse repair procedures")). In response, the plaintiffs maintain that Bard has mischaracterized Dr. Raybon's testimony and that Dr. Raybon "does not purport to offer any opinion regarding any 'complication rate.'" (Resp. re: Raybon [Docket 179], at 18). Bard has subsequently accepted this clarification, agreeing that Dr. Raybon can "describe the types of complications he has seen with the Avaulta and how they are treated," so long as he does not rely on "self-described 'wild guesses' about his anecdotal Avaulta complication rates." (Def.'s Reply in Supp. of Its Mot. to Exclude or Limit Certain Ops. & Test. of Brian Raybon, M.D. [Docket 211], at 9).

[10] Dr. Raybon's expert report mirrors—nearly word-for-word—the expert report of Dr. Ostergard.(*Compare* Raybon Report [Docket 177-1], *with* Ostergard Report [Docket 113-1]). From this, I deduce that plaintiffs' counsel had heavy involvement in the drafting process. And while Federal Rule of Civil Procedure 26 allows counsel to aid in preparing an expert's report, the final report must be signed by the witness and must "be written in a manner that reflects the testimony to be given by the witness." Fed. R. Civ. P. 26(a)(2)(B) advisory committee notes. There is no indication that Drs. Ostergard and Raybon did not have sufficient involvement in preparing their respective expert reports, and consequently, I do not feel obligated to exclude either opinion as violations of Rule 26. *But see In re Jackson Nat'l Life Ins. Co. Premium Litig.*, No. 96-md-1122, 2000 WL 33654070, at *1 (W.D. Mich. Feb. 8, 2000) (excluding an expert's testimony because the "undeniable substantial similarities" between his report and the report of another expert "demonstrate[s] that counsel's participation so exceeded the bounds of legitimate 'assistance' as to negate the possibility that [the expert] actually prepared his own report within the meaning of Rule 26(a)(2)"). That said, this situation provides ground for Bard's cross-examination of both witnesses, as well as an objection under Federal Rule of Evidence 403, which allows the court to exclude cumulative evidence.

I agree that if Dr. Raybon's opinion is limited in this way, it survives *Daubert*'s scrutiny. That is, Dr. Raybon may testify about the complications he has observed in patients implanted with the Avaulta (without referring to complication rates), but, as I explained in *Eghnayem, et al. v. Boston Scientific Corp.*, he lacks the qualifications to infer conclusions from these observations as to the etiology of complications associated with a pelvic mesh device:

> Federal Rule of Evidence 702 allows a witness to provide expert testimony only to the extent that the testimony draws from the expert's knowledge and expertise. Fed. R. Evid. 702 advisory committee notes. . . . Dr. Raybon's opinion testimony [] goes beyond his experience with pelvic mesh. He is not a specialist in the etiology of pelvic and vaginal pain, and his awareness of any relationship between nerve trauma and mesh products is limited to his experience in diagnosing fifteen to twenty post-implantation patients. Accordingly, Dr. Raybon's knowledge, though extensive with respect to the mechanics of pelvic surgery, does not qualify him to opine on the cause of nerve trauma in the pelvis. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

No. 2:13-cv-07965, 2014 WL 5320566, at *35 (S.D. W. Va. Oct. 27, 2014). This holding equally applies to this case. To the extent that Dr. Raybon's opinions go beyond his observations and into an assessment of the general causal relationship between pelvic pain (or other complications) and the Avaulta, they are **EXCLUDED**.

**6. Opinions Regarding Product Testing and Clinical Trials**

Bard next objects to Dr. Raybon's opinions on Bard's purported failures with respect to the funding and performance of clinical trials on the Avaulta. According to Bard, Dr. Raybon does not have the expertise necessary to opine on the premarket tests a manufacturer should conduct, and furthermore, Dr. Raybon's opinions on this matter "are based on pure speculation." (Mem. in Supp. re: Raybon [Docket 177], at 19–20). I agree that Dr. Raybon is not qualified to testify about what testing Bard should or should not have conducted prior to placing the Avaulta on the market. There is no indication in Dr. Raybon's expert report or otherwise that he has any

experience with or knowledge about the appropriate testing a medical device manufacturer should undertake. His experience as a pelvic surgeon does not qualify him to speak on this matter, *see, e.g.*, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014) (excluding the opinions of Drs. Blaivas and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing), nor does his experience with training others on how to use the Avaulta, a role that did not require him to participate in clinical testing or clinical trials.

Because Dr. Raybon has no demonstrated training in, knowledge of, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Rule 702 and cannot be admitted. *See* Fed. R. Evid. 702 (stating that an expert must be qualified . . . by knowledge, skill, experience, training, or education"). Bard's motion, therefore, is **GRANTED**.

**7. Specific Causation Opinions**

Dr. Raybon has also provided a specific causation opinion for Ms. Wise, wherein he opines that the cause of Ms. Wise's chronic pelvic pain, lower back pain, and dyspareunia "direct[ly] result [from] the implanted Avaulta prolapse mesh products produced by C. R. Bard." (Raybon Report [Docket 177-1], at 54–55). Bard asks this court to exclude Dr. Raybon's opinions specific to Ms. Wise on the grounds that they do not "fit" the facts of her case. (Mem. in Supp. re: Raybon [Docket 177], at 20).

The requirement that an expert's testimony "fits" the facts of the case ensures that his testimony will aid the jury. *Daubert*, 509 U.S. at 591. Put simply, there must be a "valid scientific connection" between the offered testimony and the issues presented in the case. *Id.* at 591–92. Here, such a connection exists. After reviewing the medical records of Ms. Wise and

applying a differential diagnosis to her symptoms, Dr. Raybon concludes that her chronic pelvic pain, low back pain, and dyspareunia resulted from implantation of the Avaulta. (*See* Raybon Report [Docket 117-1], at 50–55). This opinion relates to one of the fundamental disputes in this case—whether the design of the Avaulta caused Ms. Wise's injuries—and is therefore helpful to the jury. *See, e.g.*, *Daubert*, 509 U.S. at 591 (explaining that for expert testimony to be relevant, it must "aid the jury in resolving a factual dispute" (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985))). Accordingly, I find no error in the fit of Dr. Raybon's specific causation opinion, and I **DENY** Bard's motion on this matter.[11]

To summarize, Dr. Raybon's opinions are excluded in part, as set forth in this order, and so, Bard's Motion to Exclude or Limit the Opinions and Testimony Dr. Brian Raybon [Docket 177] is **GRANTED in part** and **DENIED in part**.

## IV. The Plaintiffs' *Daubert* Motions

In this case, the plaintiffs seek to limit or exclude the expert opinions of Christine T. Wood, Ph.D., Marta Villaraga, Ph.D., Maureen Reitman, SC.D, and Matthew Clark M.D.

### A. Motion to Exclude Opinions and Testimony of Christine T. Wood, Ph.D.

The plaintiffs seek to exclude the opinions and testimony of Christine T. Wood, Ph.D. Dr. Wood has her Ph.D. in experimental psychology and is a human factors expert. Her opinions focus on the adequacy of the Avaulta's warnings, including whether Bard adequately identified potential adverse events and whether Bard was justified in failing to include the MSDS medical

[11] Bard also argues that Dr. Raybon's specific causation opinions are excludable because they arise from inadmissible general causation opinions. (Mem. in Supp. re: Raybon [Docket 177], at 20 ("[B]ecause Dr. Raybon's general causation opinions are not based on reliable methodology and principles, his specific causation opinions should also be excluded.")). I disagree. While Dr. Raybon partially relies on his general causation opinions in opining about Ms. Wise's condition, he also bases his conclusions on an interpretation of her medical records. Review of a patient's medical records can substantiate a specific causation opinion. *See, e.g.*, *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) ("[A] physician may reach a reliable differential diagnosis without personally performing a physical examination."). As such, because Dr. Raybon's specific causation opinions come from a source apart from his general causation opinions, I reject Bard's argument.

application caution in the IFU. Bard contends that "[w]hat a human factors expert like Dr. Wood brings to bear in this situation is a scientific understanding of how humans react to and process warnings and, therefore, how best to configure warnings." (Def. Bard's Mem. of Law in Opp'n to Pls.' Mot. to Exclude Ops. & Test. of Christine T. Wood, Ph.D. ("Bard's Resp. re: Wood") [Docket 196], at 6).

I **FIND** that Dr. Wood's testimony lacks an adequate reliable foundation. Her opinions are not the product of reliable testing and methods. Dr. Wood's testimony would not be helpful to a jury. Therefore, her opinions are **EXCLUDED**. The plaintiffs' motion concerning Dr. Wood is **GRANTED**.

**B. Motion to Exclude Opinions and Testimony of Marta Villaraga, Ph.D.**

The plaintiffs seek to exclude certain opinions and testimony of Marta Villarraga, Ph.D. Dr. Villarraga is a biomedical engineer that works for Exponent, Inc.

**1. Preparation of Expert Report**

As a preliminary matter, the plaintiffs discuss the preparation of Dr. Villarraga's expert report. They contend that multiple Exponent employees assisted in the research and writing of it and argue that "Exponent's holistic 'team' approach to expert report preparation warrants close scrutiny of Bard's proposed Exponent experts' testimony." (Pls.' Mot. to Exclude Ops. & Test. of Marta Villarraga, Ph.D. & Br. in Supp. [Docket 142], at *6). According to the plaintiffs, this team method "renders [Dr. Villarraga's] entire report suspect from the outset." (*Id.*). Even having made these arguments, the plaintiffs never contend that this method of report preparation is a basis to exclude Dr. Villarraga's opinions entirely. Thus, I need not address such a contention under *Daubert* standards.

**2. Allegedly Non-Expert Lawyer Arguments**

Next, the plaintiffs argue that much of Dr. Villarraga's report contains alleged expert opinions which are, in reality, arguments that the lawyers can make. As such, they state that such opinions should be excluded. I have previously analyzed opinions of Dr. Villarraga in another case, and I rule consistently here. "To the extent that the [Dr. Villarraga] purport[s] to simply make arguments that Bard's lawyer's may make, such testimony is not expert opinion and should be excluded. Simply pointing out inconsistencies does not require any 'scientific, technical, or other specialized knowledge.'" *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 644 (S.D. W. Va. June 4, 2013) (citing Fed. R. Evid. 702). However, Dr. Villarraga's "attacks on the plaintiffs' experts' scientific basis for their opinions and their alleged failure to take into account certain testing and clinical experience are admissible." *Id.* Therefore, I **EXCLUDE** Dr. Villarraga's opinions to the extent that they "simply make arguments that Bard's lawyer's may make." *Id.*

**3. Factual Narratives**

The plaintiffs allege that Dr. Villarraga's report contains factual narratives that are improper expert testimony. I incorporate my prior decision concerning this matter here:

> I **FIND** that *Liberty Medica Corp. v. Vivendi Universal, S.A.* provides the appropriate solution to the situation at hand. 874 F. Supp. 2d 169, 174 (S.D.N.Y. 2012). The Southern District of New York in *Liberty Media* held:
>
> > [The expert] will not be permitted to exhaustively recount all of the facts of the case. . . . [The expert] will not be permitted to recount the entire history of Vivendi through the class period. Rather, [the expert] must draw on the facts only as necessary—and in as concise a manner as possible—to support his opinion . . . which is based on his experience in corporate valuations. I decline to parse [the expert]'s report paragraph-by-paragraph to determine where the report turns from expert analysis to factual narrative. Rather, I trust plaintiff's counsel will exercise discretion in allocating trial time and will only present the facts necessary to support [the expert]'s opinion. In the event plaintiffs' counsel fails to exercise appropriate discretion, I will cut off any lengthy factual narrative.

> *Id.* Accordingly, the plaintiffs' motion to exclude factual narratives by the Exponent Experts is **GRANTED in part** to the extent that they may not seek to offer factual narratives, but **DENIED in part** to the extent that they may present the bases for their expert opinions in this case.

*In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 646. I adopt my reasoning above and, thus, **DENY in part** and **GRANT in part** the plaintiff's motion as to this matter.

**4. Opinions Regarding Biocompatibility Testing and Benchtop Testing**

The plaintiffs argue that Dr. Villarraga's opinions related to Bard's biocompatibility testing and Bard's benchtop testing are unreliable. First, the plaintiffs argue that any opinion based on Bard's biocompatibility testing under ISO 10993 is unreliable. They point out that, for the Avaulta, Bard relied on past biocompatibility testing of another product, the Spermatex, and that Bard conducted lab tests for the Avaulta on only animals and no living humans. If the plaintiffs would like to challenge Dr. Villarraga's opinions in regard to these facts, I **FIND** that cross-examination is the proper vehicle, rather than a *Daubert* motion. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

In addition, the plaintiffs argue that Dr. Villarraga's opinions based on benchtop testing are unreliable. Benchtop testing includes mechanical tests, such as tensile testing. Due to this testing's failure to replicate an in vivo environment, I have previously found it to be an unreliable basis for opinions concerning the behavior of mesh in the human body. *See Tyree, et al. v. Boston Scientific Corp.*, 2014 WL 5320566, No. 2:12-cv-08633, at *29–33 (S.D. W. Va. Oct. 17, 2014) (Dr. Barker); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 639 (S.D. W. Va. 2013) (Dr. Brennan). I rule accordingly here. Therefore, I **EXCLUDE** Dr. Villarraga's testimony to the extent that her opinions based on benchtop testing relate to the mesh's behavior in vivo.

To summarize, I **GRANT in part** and **DENY in part** the plaintiffs' motion concerning Dr. Villarraga [Docket 142] consistent with my reasoning above.

### C. Motion to Exclude Certain General Opinions and Testimony of Matthew Clark, M.D.

The plaintiffs seek to exclude certain general opinions and testimony of Matthew Clark, M.D. Dr. Clark is a urogynecologist. The plaintiffs argue that Dr. Clark should be precluded from offering opinions on mesh shrinkage, polypropylene degradation, and the polypropylene MSDS. Bard has filed a response that, at times, presents confusing and somewhat circular arguments. Under my discretion as the trial judge, I will address such arguments under the *Daubert* standards as I see fit.

#### 1. Bard's Contention that General Opinions Not at Issue

As a preliminary matter, Bard in its response claims that mesh shrinkage, degradation, and the MSDS are not implicated in Ms. Wise's case "because no witness has offered an opinion that Ms. Wise's implant, or the tissue around it, contracted or that there was any evidence of degradation" and because Dr. Nutt, Ms. Wise's implanting physician, "testified that he did not need this kind of document [meaning the MSDS] to make an informed choice about the treatment for Ms. Wise or to obtain Ms. Wise's informed consent." (Def. Bard's Resp. in Opp'n to Pls.' Mot. to Exclude Certain General Ops. & Test. of Matthew Clark, M.D. ("Bard's Resp. re: Clark") [Docket 208], at 1). As a result, Bard presents the court with the following argument:

> So to the extent Plaintiffs seek to exclude *all* opinions about shrinkage/contraction, degradation, and the MSDS from the *Wise* case, including those offered by Plaintiffs' experts, Bard agrees. These issues are not implicated in *Wise*, and it would be a waste of judicial and other resources to spend time on them.
>
> To the extent these issues are permitted in this case, then Dr. Clark should be permitted to talk about them. . . .

(*Id.*) (emphasis in original). This is not a proper argument for a *Daubert* motion. *Daubert* motions must be directed at a particular expert and may not be used to wholesale exclude opinions on a given subject. I decline to entertain such an argument by Bard here.

**2. Opinions Regarding Mesh Shrinkage**

Next, the plaintiffs argue that Dr. Clark's opinions regarding mesh shrinkage should be excluded because his methodology was unreliable. In particular, they allege that he based his opinions merely on personal experience and little scientific literature.

In response, Bard contends that the plaintiffs have misinterpreted Dr. Clark and have challenged an opinion that Dr. Clark, in fact, does not give. According to Bard, the term "mesh shrinkage" has two different interpretations—(1) that the mesh itself shrinks, and (2) that the tissue surrounding the mesh contracts, which then causes the mesh itself to shrink in size. In their motion, the plaintiffs challenge Dr. Clark's "opinion that contraction of tissue around implanted mesh (often referred to as mesh shrinkage) does not occur." (Pls.' Mot. to Exclude Certain General Ops. & Test. of Matthew Clark, M.D. & Brief in Supp. [Docket 176], at 2). However, in its response, Bard contends that "Dr. Clark *agrees* that tissue contracts" but, instead, merely "does not believe . . . that the *mesh itself* shrinks." (Bard's Resp. re: Clark [Docket 208], at 3) (emphasis in original). Therefore, since the parties appear to be in agreement on this issue, I **DENY as moot** the plaintiff's motion with respect to this matter.

In its response, Bard also responds to the plaintiffs' reliability arguments concerning Dr. Clark. However, because the language quoted above renders an analysis of the reliability of Dr. Clark's method unwarranted and unnecessary, I need not reach the merits of such arguments. If the plaintiffs do, in fact, challenge Dr. Clark's opinion that the mesh itself does not shrink, this simply should have been made clearer in their motion.

### 3. Opinions on Degradation of Polypropylene

The plaintiffs also challenge Dr. Clark's opinion that polypropylene mesh does not degrade in the human body. In particular, they take issue with the following statement from Dr. Clark's expert report:

> [A]lthough I have reviewed the medical application caution language included in the Marlex HGX-030-01 MSDS, I am not aware of any medical literature or scientific information to support the theory PP is not suitable for permanent implant in humans or that it degrades as a result of either oxygen or peroxides in the body or intraoperative contact, however minimal, with Betadine.

(Clark Report [Docket 176-1], at 33) ("PP" meaning polypropylene). In sum, the plaintiffs argue that this opinion is unreliable because some of Dr. Clark's reliance materials and multiple scientific studies refute his conclusion.

The plaintiffs' arguments here do not assist me in my *Daubert* analysis. I am to determine whether the *methodology* used by Dr. Clark in developing his opinions was reliable. The plaintiffs, instead, focus their arguments on why Dr. Clark's ultimate conclusion—that degradation does not occur—is wrong according to other sources. However, under *Daubert*, the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). If the plaintiffs wish to challenge the content of Dr. Clark's conclusion regarding degradation, they may do so on cross-examination.

Moreover, the plaintiffs' argument that Dr. Clark is unreliable because he failed to account for this contrary literature is unavailing. In arguing this, the plaintiffs refer to parts of my *Daubert* opinion in *Tyree* concerning Dr. Margolis. *See Tyree, et al. v. Boston Scientific Corp.*,2014 WL 5320566, No. 2:12-cv-08633, at *7 (S.D. W. Va. Oct. 17, 2014). In *Tyree*, the

challenging party cited to particular portions of Dr. Margolis's deposition testimony where he was asked about specific studies contrary to his opinion and, then, dismissed them in a conclusory manner without scientific basis. Here, the plaintiffs point to no such testimony. The mere statement in Dr. Clark's report that he is "not aware of any medical literature or scientific information to support the theory that PP . . . degrades" is hardly equivalent, especially in light of his relied-upon list that the plaintiffs have, in fact, failed to attach to their motion. (*See* Clark Relied-Upon List [Docket 208-1], at 355-65).

Therefore, the plaintiffs' motion with respect to this matter is **DENIED**.

**4. Opinions Regarding the MSDS**

In addition, the plaintiffs seek to exclude Dr. Clark's opinions on the polypropylene MSDS. They take issue with the following passage of Dr. Clark's report:

> PP is composed of raw materials that are extruded in the thin filaments woven into the final mesh product. Because the resin is altered in the process of manufacturing, my focus as a surgeon has been on the biocompatibility of the final product rather than the raw material. In particular, I have never asked a manufacturer of medical devices for information regarding the substance of an MSDS, which I understand is regulated by the Occupational Safety & Health Administration (OSHA) and used to ensure workplace safety where raw materials are being used. Nor would I expect a manufacturer to provide me with the MSDS, which has proven to be misleading and harmful in understanding the properties of the manufactured device. Prior to being shown the MSDS listed in my reliance list, I had never before examined an MSDS in the course of my practice.

(Clark Report [Docket 176-1], at 33). In particular, the plaintiffs challenge his opinions that the MSDS is a workplace safety regulation merely applying to raw materials and that he does not use MSDSs in his medical practice.

In *Tyree*, I stated the following in excluding the testimony of a proffered safety, health, and training expert:

> Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue

> of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form.

*Tyree*, 2014 WL 5320566, at *63. To the extent that Dr. Clark's opinions are a mere general discussion of MSDSs, those opinions are accordingly **EXCLUDED**. The plaintiffs' motion is **GRANTED** to the extent that Dr. Clark's opinions run counter to my ruling above in *Tyree*.

The plaintiffs also argue that his statement, "I had never before examined an MSDS in the course of my practice[,]" is unhelpful to a jury and irrelevant. (Clark Report [Docket 176-1], at 33). I agree with the plaintiffs that this is not an expert opinion. Dr. Clark is merely stating what *he* does in *his* practice. Thus, I need not address its relevancy under *Daubert*. In its response, Bard contends that Dr. Clark instead "generally opines that physicians do not typically rely on MSDS for raw materials used in medical devices" and that this is the "standard practice in the medical community." (Bard's Resp. re: Clark [Docket 208], at 12, 13). However, I do not read the above contested sentence to disclose such an opinion. I will not address the admissibility of this non-expert testimony here.

In conclusion, the plaintiffs motion to exclude certain general opinions of Dr. Clark [Docket 176] is **DENIED in part**, and **GRANTED in part**.

**D. Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Laura Bigby**

The plaintiffs seek to exclude certain opinions of Bard's non-retained corporate expert Laura Bigby. Ms. Bigby is Former Director of Research and Development, Bard Urological Division ("BUD"). Bard's disclosure provides: "Ms. Bigby may provide expert witness testimony regarding the design and development of Bard's Avaulta Plus . . . their characteristics,

and the appropriateness of the testing and evaluation of these products." (Pls.' Mot. to Exclude Certain Ops. and Test. of Bard's Non-Retained Corp. Expert Laura Bigby and Br. in Supp. ("Pls.' Mot. re: Bigby") [Docket 187], at 2).

**1. Biocompatibility Testing**

First, the plaintiffs argue that Ms. Bigby should be precluded from offering any opinions based on Bard's biocompatibility testing or bench testing because it is unreliable. The plaintiffs explain that Bard did not in fact perform biocompatibility testing on the Avaulta, but instead relied on biocompatibility testing of similar products. (*Id.* at 4). The plaintiffs have also filed a motion *in limine* making practically identical arguments. In *Cisson v. C. R. Bard, Inc.*, I allowed Bard's non-retained corporate expert Roger Darois to testify with regard to biocompatibility testing over the plaintiffs' objection. (*See* Cisson Trial Tr. [Docket 191-2], at 161–63). My opinion on the relevance of such testing has not changed. If the plaintiffs are concerned that the jury is under the impression Bard performed biocompatibility testing on the Avaulta, and not just on similar products, they are free to address that issue at trial on cross-examination. Accordingly, the plaintiffs' motion with regard to biocompatibility testing is **DENIED**.

**2. MSDS**

The plaintiffs also argue that Ms. Bigby should be precluded from offering "patently improper" testimony about the MSDS. (Pls.' Mot. re: Bigby [Docket 187], at 10). In particular, the plaintiffs oppose testimony that the Medical Application Caution was added to the Marlex MSDS solely to shield Chevron Phillips from liability, and not for scientific reasons. I have repeatedly held that while an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—Chevron Phillips's knowledge, state of mind, alleged bad acts, failures to

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

The plaintiffs' motion with respect to Ms. Bigby [Docket 187] is **GRANTED in part** and **DENIED in part**.

**E. Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Roger Darois**

The plaintiffs seek to exclude certain opinions of Bard's non-retained corporate expert Roger Darois. Mr. Darois is Vice President of Research and Advanced Technologies, Davol. The plaintiffs argue that Mr. Darois should be precluded from offering "patently improper" testimony about the MSDS. (Pls.' Mot. to Exclude Certain Ops. and Test. of Bard's Non-Retained Corp. Expert Roger Darois and Br. in Supp. [Docket 188], at 2). As with Ms. Bigby's expert opinions and consistent with those findings, I **FIND** that Mr. Darois's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**, and therefore, the plaintiffs' motion with respect to Mr. Darois [Docket 188] is **GRANTED**.

**F. Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained**

**Corporate Expert Adam Silver**

The plaintiffs seek to exclude certain opinions of Bard's non-retained corporate expert Adam Silver. Mr. Silver is Vice President of Marketing. The plaintiffs argue that Mr. Silver should be precluded from offering "patently improper" testimony about the MSDS. (Pls.' Mot. to Exclude Certain Ops. and Test. of Bard's Non-Retained Corp. Expert Adam Silver and Br. in Supp. [Docket 189], at 2). As with Ms. Bigby's expert opinions and consistent with those findings, I **FIND** that Mr. Silver's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**, and therefore, the plaintiffs' motion with respect to Mr. Silver [Docket 189] is **GRANTED**.

**G. Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Scott Britton**

The plaintiffs seek to exclude certain opinions of Bard's non-retained corporate expert Scott Britton. Mr. Britton is Former Vice President of Research and Development, BUD. The plaintiffs argue that Mr. Britton should be precluded from offering any opinions based on Bard's biocompatibility testing or bench testing because it is unreliable. The plaintiffs also argue that Mr. Britton should be precluded from offering "patently improper" testimony about the MSDS. In particular, the plaintiffs oppose testimony that the Medical Application Caution was added to the Marlex MSDS solely to shield Chevron Phillips from liability, and not for scientific reasons. As with Ms. Bigby's expert opinions and consistent with those findings, I **DENY** the plaintiffs' motion with regard to biocompatibility testing and **FIND** that Mr. Britton's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**. Therefore, the plaintiffs' motion with respect to Mr. Britton [Docket 190] is **DENIED in part** and **GRANTED in part**.

**V. Conclusion**

For the reasons set forth above, For the reasons set forth below, the following motions brought by Bard are **GRANTED in part** and **DENIED in part**: Motion to Exclude or Limit Certain Opinions and Testimony by Donald R. Ostergard, M.D. [Docket 113]; Motion to Exclude the Opinions and Testimony of Bernd Klosterhalfen, M.D. [Docket 134]; Motion to Exclude or Limit Certain Opinions and Testimony by Anthony Brennan, Ph.D. [Docket 150]; and Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Brian Raybon [Docket 177]. Bard's Motion to Exclude Certain Opinions and Testimony of Colleen Fitzgerald, M.D. [Docket 158] is **DENIED**.

The following motions brought by the plaintiffs are **GRANTED in part** and **DENIED in part**: Motion to Exclude Opinions and Testimony of Marta Villaraga, Ph.D. [Docket 142]; Motion to Exclude Certain General Opinions and Testimony of Matthew Clark, M.D. [Docket 176]; Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Laura Bigby [Docket 187]; and Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Scott Britton [Docket 190]. The following motions brought by plaintiffs are **GRANTED**: Motion to Exclude Opinions and Testimony of Christine T. Wood, Ph.D. [Docket 123]; (2) (4) Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Roger Darois [Docket 188]; and Motion to Exclude Certain Opinions and Testimony of Bard's Non-Retained Corporate Expert Adam Silver [Docket 189].The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 7, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE