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

**CHARLESTON DIVISION**

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

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THIS DOCUMENT RELATES TO CIVIL ACTION NUMBERS:

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| Cisson, et al. v. C. R. Bard, Inc. | 2:11-cv-00195 |
| Queen, et al. v. C. R. Bard, Inc. | 2:11-cv-00012 |
| Rizzo, et al. v. C. R. Bard, Inc. | 2:10-cv-01224 |
| Jones v. C. R. Bard, Inc. | 2:11-cv-00114 |

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

Pending before the court are C. R. Bard, Inc. ("Bard")'s *Daubert* motions:[1] Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Denniz Zolnoun, M.D., M.P.H. [Docket 91]; Defendant C. R. Bard, Inc.'s Motion to Exclude the Testimony and Opinions of Dean Altenhofen, M.D. [Docket 94]; Defendant C. R. Bard, Inc.'s Motion to Exclude the Opinions and Testimony of Timothy J. Loving, Ph.D. and Janell L. Carroll, Ph.D. [Docket 100]; Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Dr. Bob Shull, M.D. [Docket 98]; Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Plaintiffs' Treating Physicians [Docket 103]; Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Dr. Bernd Klosterhalfen, M.D. [Docket 108]; Defendant C. R. Bard,

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[1] In the four bellwether cases noted above, Bard has filed identical *Daubert* motions in all bellwether cases, with *Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114 containing one additional motion regarding Dr. Lentnek. Except where specifically noted, all docket numbers refer to filings in *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, because that is the first case set for trial. However, my rulings apply to the identical motions filed in all bellwether cases.

Inc.'s Motion to Limit the Opinions and Testimony of Lennox Hoyte, M.D. [Docket 110]; Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of David A. Kessler, M.D. [Docket 113]; Defendant C. R. Bard, Inc.'s Motion to Exclude the Opinions and Testimony of Ahmed El-Ghannam, Ph.D. [Docket 130]; Defendant C. R. Bard, Inc.'s Motion to Exclude the Opinions and Testimony of Anthony B. Brennan, Ph.D. [Docket 127]; Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Arnold Lentnek, M.D. [Docket 105];[2] and Defendant C. R. Bard, Inc.'s Motion to Limit the Opinions and Testimony of Julia E. Babensee, Ph.D. [Docket 154]. Also pending before the court is Plaintiffs' Motion to Exclude Opinions and Testimony of Marta Villarraga, Ph.D. and Maureen Reitman, Sc.D. and Brief in Support [Docket 250].

As set forth below, Bard's motions with respect to Dr. Zolnoun [Docket 91], Dr. Altenhofen [Docket 94], Dr. Loving and Dr. Carroll [Docket 100] and Dr. Shull [Docket 98] are **GRANTED**, Bard's motions with respect to the treating physicians [Docket 103], Dr. Klosterhalfen [Docket 108], Dr. Hoyte [Docket 110], Dr. Kessler [Docket 113], Dr. El-Ghannam [Docket 130], Dr. Brennan [Docket 127], Dr. Lentnek (*Jones* [Docket 105]), and Dr. Babensee [Docket 154] are **GRANTED in part** and **DENIED in part**, and the plaintiffs' motion [Docket 250] is **GRANTED in part** and **DENIED in part**.

## I. Background

These cases are four of several thousand assigned to me by the Judicial Panel on Multidistrict Litigation and currently set for trial pursuant to Pretrial Order # 32.[3] These MDLs involve use of transvaginal surgical mesh to treat pelvic organ prolapse or stress urinary

[2] This motion is filed only with respect to the bellwether plaintiff Carolyn Jones, and the docket number refers to *Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114.

[3] Originally, there was a fifth case, *Smith v. C. R. Bard*, No. 2:10-cv-01355, which was terminated on February 22, 2013 pursuant to a Stipulation of Dismissal/Order.

incontinence. The four bellwether cases involve implantation of one or more products, but only the pelvic organ prolapse products are at issue. The plaintiffs in these cases allege injuries suffered as a result of Avaulta products implanted in Ms. Cisson, Ms. Queen, Ms. Rizzo, and Ms. Jones. The Complaints allege the following causes of action: 1) negligence; 2) strict liability – design defect; 3) strict liability – manufacturing defect; 4) strict liability – failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) loss of consortium; and 8) punitive damages. (*See, e.g.*, Compl. [Docket 1]). The plaintiffs, as well as Bard, have retained many experts to render opinions regarding the elements of these causes of action. The instant motions involve the parties' efforts to exclude or limit the opinions and testimony of many of these experts.

## II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all

scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous 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 (alteration in original)); *see also Maryland Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

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

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject

of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

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

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

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

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

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

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

> why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

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

## III. Bard's *Daubert* Motions

Bard seeks to exclude or limit the testimony of a total of twelve sets of expert witnesses. The testimony of eleven of these experts relate to all four bellwether plaintiffs: Denniz Zolnoun, Dean Altenhofen, Timothy J. Loving and Jannell L. Caroll, Bob Shull, the treating physicians, Bernd Klosterhalfen, Lennox Hoyte, David A. Kessler, Ahmed El-Ghannam, Anthony B. Brennan, and Julia E. Babensee. The testimony of the twelfth expert witness, Arnold Lentnek, relates only to plaintiff Carolyn Jones. Bard's motions as to each of these experts will be discussed below.

### A. *Denniz Zolnoun, M.D., M.P.H.*

The plaintiffs offer Dr. Zolnoun to opine on the general and specific causation of pain in the plaintiffs by the Avaulta mesh products. Bard argues that Dr. Zolnoun's opinions are classic *ipse dixit* opinions, unsupported by any testing or reliable methodology. As discussed below, Dr. Zolnoun's opinions should be excluded in their entirety and accordingly, Bard's motion to exclude her opinions is **GRANTED**.

#### i. *General Causation Opinions*

Dr. Zolnoun sets forth two general causation opinions regarding "mechanisms by which transvaginal mesh procedures cause nerve injury and neuropathic pain." (Zolnoun Report [Docket 91-2], at 3). The first is "a direct insult to a nerve in the pelvis by the trocars used to place the mesh or the arms of the mesh as they are pulled through the transobturator and ischiorectal spaces." (*Id.*). The second is "caused by the well-established contraction and retraction of the mesh over time, resulting in entrapment of nerves in scar and fibrosis." (*Id.*).

Bard argues that Dr. Zolnoun's general causation opinions are inadmissible because they are not supported by any reliable basis or methodology. The plaintiffs respond by first arguing that general causation is not in dispute and therefore a *Daubert* inquiry is unnecessary, citing *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005). In *McClain*, the Eleventh Circuit noted that:

> [T]oxic tort cases usually come in two broad categories: first, those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue, and second, those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges.

*Id.* The court then listed several examples: "asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; and cigarette smoke, which causes cancer." *Id.*; *see also* n.5 ("There is rarely a reason for a court to consider opinions that medical doctors routinely and widely recognize as true, like cigarette smoking causes lung cancer and heart disease, too much alcohol causes cirrhosis to the liver, and that the ingestion of sufficient amounts of arsenic causes death."). The court based this idea on *Kumho Tire*, noting that a "trial court does not need to waste time with a *Daubert* hearing where the reliability of an expert's methods is properly taken for granted . . . ." *Id.* at 1239 n.5 (internal quotation marks omitted).

Bard contends that Dr. Zolnoun's general causation opinions are very much in dispute among the medical community. I agree. The plaintiffs cite to a number of internal Bard documents and a FDA white paper, none of which Dr. Zolnoun either cited or reviewed. While these documents may certainly suggest that Dr. Zolnoun's general causation opinions are true, it does not appear from these documents that the medical community generally recognizes them as true to the same extent that the medical community recognizes that cigarette smoke causes cancer.

The plaintiffs then argue that Dr. Zolnoun's general causation opinions are based upon a reliable basis and methodology because she "properly relies on her clinical experience and relevant, peer-reviewed literature to establish" these opinions. (Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude Certain Testimony from Pls.' Proposed Expert Witness Dr. Denniz Zolnoun, M.D., M.P.H. [Docket 157], at 7). I disagree. A review of Dr. Zolnoun's lengthy deposition transcript shows that her opinions are simply *ipse dixit* opinions.

For example, with respect to Dr. Zolnoun's first general causation opinion—that the trocars and the arms of the mesh cause a direct insult to nerves in the pelvis—Dr. Zolnoun first testified that it was not the trocars that cause nerve injury, but the mesh arms:

> Q. But you agree in any patient it's impossible for you to say whether your opinion is that the symptoms are caused by the mesh itself or by the mesh procedure, correct?
>
> A. . . . I could say with reasonable degree of medical certainty that [it] is not caused primarily by the needle, but it is the track of the mesh and the contractures that are associated with the mesh.

(Zolnoun Dep. vol. I [Docket 91-3], at 183:7-183:15). With respect to the mesh arms, Dr. Zolnoun then testified:

> Q. What did you do to arrive at this opinion that the mesh arms are sharp and have the ability to damage or cut nerves as they are pulled with the trocars?
>
> A. I mean, it's obvious. I mean, I've seen the propylene mesh. Avaulta mesh is not something I've personally touched, but propylene, polypropylene mesh comes in a variety of shapes and fashions and, with notable exception of Gore-Tex, all their edges are very sharp and they're rigid. . . .
>
> . . .
>
> Q. Do you have any basis for your opinion that the mesh arms are sharp and can serrate nerves as they are pulled through by the trocars that we haven't talked about?
>
> A. Other than the fact that I've been dealing with this for six years and I had to take care of the pain, feel them come through the vagina, and looking at

the biomechanics of how they rotate the vagina. Empirical evidence based on my experience, that's the only construct I could present.

Q. Are you relying on any scientific literature as a basis for your opinion that the mesh arms are sharp and can serrate or tear nerves as they are pulled through the tissue by the trocars?

A. I mean, it's obvious. Those propylene meshes are very rigid and that my finger on a glove catches, I'm really sorry, but I don't understand how to prove this. . . . I'm not sure what scientific proof you're mentioning, but these are just daily observation[s] of what the mesh eroding feels like.

(*Id.* at 185:13-185:21; 188:16-189:16). Finally, Dr. Zolnoun admits that the only mesh she has touched is mesh that has been implanted for some time:

Q. And do you agree that you've never touched an Avaulta mesh, Avaulta Solo, Avaulta Plus when it was just coming out of the package?

A. . . . [N]o, I haven't. But I do know how they feel because I touch a lot of them as they are eroding out of the upper vagina, lower vagina, pararectal space.

Q. But you've never touched one before it was inserted into someone's body?

A. No.

. . .

Q. This mesh eroding that you're talking about feeling with your glove, is that mesh that has been in place for a long period of time?

A. Sometimes two years, sometimes six months . . .

(*Id.* at 186:16-187:2; 189:17-189:20). Dr. Zolnoun's first general causation opinion is therefore based on nothing more than her personal, unscientific observation and opinion that "it's obvious" that mesh arms are sharp and can serrate or tear nerves. This is the type of "subjective, conclusory approach that cannot reasonably be assessed for reliability" and that Rule 702 is designed to exclude. Fed. R. Evid. 702 advisory committee's note.

Dr. Zolnoun's second general causation opinion—that mesh causes nerve injury by the contraction and retraction of the mesh over time, resulting in entrapment of nerves in scar and fibrosis—is similarly lacking in any reliable basis and methodology and is simply an *ipse dixit* opinion. For example, she testified:

> As you stated, I'm not an expert in mesh and traction and contraction. So I cannot possibly be an expert in amount of scarring because of mesh because that's not what I do. But if you ask me as a pain person, then this contraction happens, it's obvious. Scarring happens and it happens differently in different setting in different context.

(Zolnoun Dep. vol. II [Docket 91-4], at 255:11-255:17). Accordingly, I **FIND** that Dr. Zolnoun's general causation opinions should be excluded.

**ii. *Specific Causation Opinions***

Dr. Zolnoun's specific causation opinions are based on her general causation opinions. In other words, her opinion as to each bellwether plaintiff is that the plaintiff suffered nerve injuries through one or both of the general causation mechanisms discussed *supra*. Because I found that Dr. Zolnoun's general causation opinions are not based on reliable methodology and principles, her specific causation opinions—based on her general causation opinions—should also be excluded. *See, e.g.*, *In re Bausch & Lomb Inc. Contact Lens Solution Prods. Liab. Litig*, MDL No. 1785, 2010 WL 1727807, at *2 (D.S.C. Apr. 26, 2010) ("[E]stablishing general causation is

an essential prerequisite to proving specific causation").[4] Thus, I **FIND** that Dr. Zolnoun's specific causation opinions also should be excluded.

**B.** ***Dean Altenhofen, M.D.***

According to the plaintiffs, Dr. Altenhofen will opine on:

> (i) his general experience with higher complications and injuries sustained by his patients following his implantation of certain Bard pelvic mesh products over a three-year period compared with the complication rates reflected in the published scientific literature, (ii) his opinion that the IFUs did not adequately disclose to him all the risks known by Bard when the Avaulta products were launched, (iii) the Avaulta training he personally received from Bard, and (iv) the erosion rate communicated to him by a Bard sales representative during the time Defendant was touting the alleged success rate of its pelvic mesh products.

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[4] A review of Dr. Zolnoun's specific causation opinions leads to the same result because they are based upon the logical fallacy of *post hoc ergo propter hoc*. For example, Dr. Zolnoun testified:

> Q. And this technique of bedside sensory testing does not tell you what caused the nerve damage that you believe that you identified through using this clinical examination, does it?
>
> A. This technique doesn't tell me – I just want to make sure I understand here. Does the technique tell me what caused it? I don't think that is a question that could be asked because cause is the index event. *So cause and effect is surgery, pain.* The technique doesn't tell me the mechanism completely, yes, but *the cause is obvious. Some patients didn't have pain, they had pain after surgery. Some of them had different kind of pain and they develop completely new kind of pain after surgery. So the cause was – is obvious.* But mechanism, the exam alludes to plausible mechanism, but doesn't tell me – confirms that that's exactly the mechanism.
>
> Q. So I just want to make sure I understand. What you're saying is that if a patient develops new pain after surgery, then it's your belief that the surgery caused the pain?
>
> A. The procedure was associated with the pain. *No procedure, no pain. So the event was the anteceding event.*

(Zolnoun Dep. vol. II [Docket 91-4], at 265:16-266:14) (emphasis added). In short, her specific causation opinion is based on the idea that because each bellwether plaintiff suffered pain after the mesh surgery, then the mesh must have caused the pain. A review of Dr. Zolnoun's expert report and deposition reveals that the bedside sensory testing she conducted is designed only to find the *location and nature* of the pain, not the *cause*, and that she did not perform a reliable differential diagnosis. Again, this is the type of "subjective, conclusory approach that cannot reasonably be assessed for reliability" that Rule 702 is designed to exclude. Fed. R. Evid. 702 advisory committee's note.

(Pls.' Resp. in Opp'n to Def. Bard's Mot. to Exclude the Testimony & Ops. of Dean Altenhofen, M.D. [Docket 149], at 3). Bard argues that Dr. Altenhofen's opinions regarding complication rates and injuries are not based on reliable methodology, and that his opinions regarding Bard's IFUs, Avaulta training, and statements by Bard sales representatives are irrelevant to the facts of the bellwether plaintiffs. As discussed below, Dr. Altenhofen's opinions should be excluded in their entirety and accordingly, Bard's motion to exclude his opinions is **GRANTED**.

**i. *Complication Rate Opinion***

Dr. Altenhofen opines that from 2006 until 2009, he implanted Avaulta mesh products into a number of his patients. Of the patients that received Avaulta mesh products, some suffered complications and injuries that Dr. Altenhofen opines were caused by the mesh products. Using simple division—the number of patients implanted with Avaulta mesh products divided by the number of patients that suffered complications—Dr. Altenhofen arrives at his complication rate. According to the plaintiffs, "Dr. Altenhofen's opinion based on his clinical experience is straightforward: these Avaulta products had more severe, repeated, and unusual complications than the published complications rates in the scientific literature specific to pelvic floor mesh products." (*Id.* at 7).

The fundamental problem with Dr. Altenhofen's complication rate opinion is that it has no basis in any reliable methodology. Importantly, Dr. Altenhofen's complication rate itself has changed throughout the course of his involvement in this litigation. His initial expert report indicated that he implanted Avaulta mesh products in 68 of his patients, and of those 68 patients, 16 suffered complications from the mesh products—a complication rate of 23.53%. (Altenhofen Report [Docket 94-2], at 2). Interestingly, despite a mathematical complication rate of 23.53%,

Dr. Altenhofen's initial expert report also noted that "[m]ore than 30% of my patients developed injuries and complications that required repair and revision." (*Id.* at 3).

During his deposition, Dr. Altenhofen corrected his initial expert report, testifying that he had 18 patients, not 16, who suffered complications—a complication rate of 26.47%:

> Q. Okay. Now, your report refers to 16 of the 68 patients in which you implanted an Avaulta product as having some sort of complication, correct?
>
> A. Correct. Yes.
>
> Q. But would you count for me how many patients' records are in Exhibit 7?
>
> A. There's 17 individual patients in this booklet.
>
> Q. I guess what I'm trying to get at is what is the correct number, 16, 17, or 18?
>
> A. All right. So there's one, two, three, four, five, six, seven eight – there's 18. I'm sorry, there's 18 in this booklet here.
>
> Q. Why does your report only refer to 16?
>
> A. Maybe a miscalculation or a count here. There's one – may have been a mistake when we were counting up the numbers here. And then when we went down, they wanted specifics on here, so it could have been an oversight.

(Altenhofen Dep. [Docket 94-4], at 135:17-136:11; *see also* Revised Altenhofen Report [Docket 94-3], at 2).

Most recently, the plaintiffs submitted an errata sheet for Dr. Altenhofen's deposition, which further alters Dr. Altenhofen's complication rate. (*See* Errata Sheet [Docket 149-1], at 6-7). For example, several of the 18 patients were ultimately determined not to have an Avaulta implant, two patient records were determined to be the same patient, and another patient had subsequent revision surgeries but her medical device implant record could not be located. (*See id.*). Considering the errata sheet and as calculated by Bard, 65 patients were implanted with

Avaulta products, 14 of which experienced complications, resulting in a complication rate of 21.54%. Further complicating matters, Dr. Altenhofen also provided, in the errata sheet, 21 additional implant records between March 1, 2007 and November 15, 2007 evidencing other implantations of Avaulta mesh products, without any explanation as to their relevance.

In sum, it is clear that Dr. Altenhofen's methodology of producing his complication rate is unreliable, resulting in multiple changes to his expert report on this issue. Accordingly, I **FIND** that Dr. Altenhofen's complication rate opinion should be excluded.

#### ii. *Opinions Regarding IFUs, Training, and Marketing*

Dr. Altenhofen's other opinions are either outside of his expertise, irrelevant, or outside the realm of appropriate expert testimony. Dr. Altenhofen seeks to opine on the adequacy of Bard's IFUs and training, as well as Bard's sales representative's statements regarding the erosion rate and other complications, pain, and reoperation rates. However, he is simply not qualified to render opinions on the adequacy of warnings, as he has no "knowledge, skill, experience, training, or education" in this particular area. Fed. R. Evid. 702. To the extent that Dr. Altenhofen might opine on Bard's knowledge, motive, or intent based on corporate documents, such opinions are not properly the subject of expert testimony because these are lay matters. Accordingly, I **FIND** that Dr. Altenhofen's remaining opinions should be excluded.

### C. *Timothy J. Loving, Ph.D. and Janell L. Carroll, Ph.D., C.S.E.*

The plaintiffs offer Dr. Loving and Dr. Carroll (collectively referred to as the "Relationship Experts") to opine on the plaintiffs' damages. According to the plaintiffs, "Dr. Janell L. Carroll will offer opinions about the impact of the bellwether plaintiffs' loss in terms of body image, self-esteem, confidence, sexual drive and the ability to maintain an affectionate sexual relationship," and "Dr. Timothy J. Loving will offer opinions about the impact of the

bellwether plaintiffs' loss in terms of how and why the quality of their intimate relationships has changed, and what affect [sic] that has in terms of self-concept, connections and pain experienced as a result." (Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude the Ops. & Testimony from Pls.' Proposed Expert Witnesses Dr. Loving & Dr. Carroll [Docket 150], at 1-3).

Bard argues that the Relationship Experts are not qualified to render opinions regarding the bellwether plaintiffs or their conditions, and that the opinions of the Relationship Experts would not assist the jury because:

> (1) Plaintiffs can themselves describe how their lives have changed without the need for expert testimony, (2) the subject matter of the Relationship Experts' opinions are understandable to the average juror, (3) Dr. Carroll relies on inadmissible hearsay to draw improper comparisons, and (4) Dr. Loving attempts to vouch for Plaintiffs' stories.

(Def. Bard's Reply Mem. of Law in Supp. of Mot. to Exclude the Ops. & Testimony of Timothy J. Loving, Ph.D. & Jannell L. Carroll, Ph.D. [Docket 170], at 5 n.5). As discussed below, the Relationship Experts' opinions should be excluded in their entirety and accordingly, Bard's motion to exclude their opinions is **GRANTED**.

#### i. *Opinions that Would not Assist the Jury – Unnecessary for Subject Matter*

Expert testimony which "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness" is properly excluded. *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011). Parts of the Relationship Experts' expert reports merely state what the plaintiffs told them. (*See, e.g.*, Loving Report [Docket 100-2], at 6-8; Carroll Report [Docket 100-1], at 2, 4-8). Such testimony is better presented directly to the jury via the bellwether plaintiffs themselves.

To the extent that the Relationship Experts reliably apply scientific literature to the facts presented to them by the plaintiffs, however, expert testimony on this issue is unnecessary

because it is understandable to the average juror. To the extent that the bellwether plaintiffs may be uncomfortable speaking to the jury about the personal issues and the impact that these issues have had on their relationships and lives, the average juror will also understand. For example, Dr. Loving explains the concept of "scripts" in the context of the Queen plaintiffs:

> People hold scripts, or expectations, for how social situations are supposed to progress across a wide variety of settings. . . . People hold sexual scripts as well, and they tend to be quite powerful in terms of how much they guide people's expectations of sexual behavior. . . . Importantly, once we have a script for specific social situations, it is very difficult to deviate from those scripts. Thus, it's no surprise that Wanda and Greg Queen see no point in even beginning the process of their (and most peoples') sexual intimacy scripts: it's just too frustrating and unfulfilling to not be able to play out that script.

(Loving Report [Docket 100-2], at 15-16; *see also* Loving Dep. [Docket 100-3], at 201:19-202:2). However, this discussion of "scripts" follows from what the Queens told Dr. Loving: "They both commented that there's 'no point' in touching, or kissing, or rubbing somebody's shoulders when you know it can't go anywhere else." (Loving Report [Docket 100-2], at 15). While an average juror may not necessarily fully understand the psychological concept of scripts, the idea that there is "no point" in certain acts of affection when it cannot lead to sex is something that can both be explained by the Queens themselves and understood by the average juror. The Relationship Experts' depositions and reports are replete with these kinds of opinions. Accordingly, I **FIND** that the Relationship Experts' opinions related to the impact of the plaintiffs' loss in terms of their intimate relationships should be excluded.

#### ii. *Opinions that Would Not Assist the Jury – Not Applied to the Facts of the Case*

Several of the Relationship Experts' opinions are also appropriately excluded because they are not applied to the facts of the case. For example, Dr. Carroll seeks to explain to the jury that:

> Without professional testimony the jury might look at a plaintiff and tie "sexuality with attractive body types". Intimacy, love, expressions of sexuality come in all body types. It is a mistake to assume sexuality is not important to women of all body shapes and ages. It is important to all, not just those who may be on magazine covers.

(Carroll Report [Docket 100-1], at 17). However, Dr. Carroll testified that she has never met or seen the plaintiffs that she spoke with, that the plaintiffs' appearances had never been described to her, and that she only had knowledge of a plaintiff's physical experience if that plaintiff offered such information. (Carroll Dep. [Docket 100-5], at 33:2-35:12). Regardless of whether Dr. Carroll's opinion is true as a general matter, and regardless of whether the bellwether plaintiffs do or do not have the "attractive body types" described by her, Dr. Carroll has simply not applied this stated principle "to the facts of the case." Fed. R. Evid. 702.

Dr. Loving's testimony regarding how personal relationships affect morbidity and mortality—the "life expectancy" testimony that Bard takes issue with—also suffers from a similar defect. For example, Dr. Loving testified:

> Q. Okay. Well, in term – your point here – and now that I'm talking about it, I might as well keep going. Your point is that lack of physical intimacy and lack of physical touch is the reason why these women or people would have reduced life expectancy?
>
> A. My point is, right, when you look at large data sets and you look at – and other types of studies, individuals who experience a lack of physical intimacy and given what we know about the effects of physical touch on morbidity as well as long-term health outcomes, that those – those deficits, if you will, would lead to a reduction in life expectancy, but I'm not – I'm not proposing a specific amount for a specific individual.

(Loving Dep. [Docket 100-3], at 102:8-102:20). Dr. Loving's "life expectancy" opinion is effectively that because the plaintiffs engage in less physical intimacy subsequent to the mesh-related complications than they engaged in prior to the complications, there will be some reduction of life expectancy for the plaintiffs. Regardless of whether Dr. Loving's opinion is true

as a general matter, however, this general opinion has not been applied "to the facts of the case" such that it would assist the jury. Fed. R. Evid. 702. Accordingly, I **FIND** that such opinions should be excluded.

#### iii. *Causation Opinions*

Parts of the Relationship Experts' reports allude to discussions of causation. (*See, e.g.*, Carroll Report [Docket 100-1], at 2) ("Based on my expertise, the implantation of the vaginal mesh product significantly contributed to all of these losses."). As noted previously, it appears that the plaintiffs offer the Relationship Experts solely on the issue of damages. To the extent that the Relationship Experts were offered to opine as to causation, they have not shown that they are qualified to render such opinions, nor have they offered any basis—much less a reliable one—for these opinions. Accordingly, I **FIND** that any causation opinions by Dr. Loving or Dr. Carroll should be excluded.

### D. *Bob Shull, M.D.*

According to the plaintiffs, "Dr. Shull holds the opinion that the transvaginal implantation of Bard's Avaulta Solo and Plus products are inappropriate for use in women for a variety [of] reasons . . . ." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Expert Opinions & Testimony of Dr. Bob Shull [Docket 151], at 2-3). Dr. Shull's expert report, however, suggests that he is offering opinions on much more than just the issue of whether transvaginal implantation of the Avaulta products are inappropriate. For example, his expert report includes, but is not limited to, discussions as to: (1) whether proper and sufficient clinical trials were conducted; (2) whether there was a scientific basis for the use of an armed, transvaginally placed polypropylene mesh; (3) whether Bard knew about potential problems with the use of

polypropylene in the vagina; (4) whether Bard informed doctors of safety concerns, and; (5) whether Bard acted irresponsibly in the recruitment, training, and monitoring of surgeons.

Bard takes issue with several categories of opinions that are set forth in Dr. Shull's expert report: (1) opinions related to Bard's knowledge, state of mind, alleged bad acts or failures to act, and corporate conduct and ethics; (2) opinions related to product warnings; (3) opinions related to product design, testing, and materials; and (4) opinions related to product marketing and training. As discussed below, Dr. Shull's opinions as to these issues should be excluded and accordingly, Bard's motion to exclude his opinions is **GRANTED**.

**i. *Opinions Related to Bard's Knowledge, State of Mind, Alleged Bad Acts, Failures to Act, and Corporate Conduct and Ethics***

A significant portion of the first forty pages of Dr. Shull's expert report discusses Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics. Dr. Shull opines, for example, that "Bard, in fact, recognized the problems created by not having clinical data supporting the use of the Avaulta products." (Shull Report [Docket 98-2], at 4). He then opines that "[p]atient safety . . . should have been the highest priority for Bard, not the 'first to be cut.' It is also unethical for a company to withhold relevant clinical information from physicians . . . ." (*Id.* at 5; s*ee also, e.g.*, *id.* at 10) ("Bard also knew that the amount of mesh – the 'mesh load' – and the material characteristics . . . would be an issue with their products."); (*id*. at 10-11) ("Bard justified the development of mesh kits based on the inaccurate perception of high recurrence rates when traditional reconstructive procedures using native tissue repair were performed."); (*id.* at 14) ("Bard documents show that the company recognized the need to have large pores (3-5mm) to avoid contraction and what is described as 'scar plate formation.'"); (*id.*) ("I see no evidence that Bard . . . addressed the question of synthetic material surface area used as a function of risks and benefits."); (*id.* at 14-15) ("Bard . . . documents demonstrate [that it

was] aware of shrinkage and contraction when tissue comes in contact with the polypropylene and xenograft materials.").

Similar statements are pervasive throughout the first forty pages of Dr. Shull's expert report. For example, Section II is titled "Bard did not inform doctors of safety concerns," Section III is titled "Bard acted irresponsibly in the recruitment, training, and monitoring of surgeons," Section IV is titled "Bard sales representatives appear to be giving medical advice, both in the operating room and in the management of complications," and Section V is titled "Bard seems to lack concern for the individual woman's health and safety, focusing instead simply on sales." (*See id.* at 24-40).

While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I **FIND** that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

### ii. *Opinions Related to Product Warnings*

Dr. Shull opines that Bard failed to inform doctors of safety concerns related to the Avaulta mesh products. (Shull Report [Docket 98-2], at 24-29). However, Dr. Shull does not provide a reliable basis for his opinions of what Bard should have done with respect to its warnings. For example, Dr. Shull's expert report opines:

> Bard knew that pain could be a significant postoperative problem when these products are utilized in vaginal surgery, and yet it is not even mentioned in Avaulta 510(K) applications, labeling, or physician and patient education materials. . . . Pain as a result of the trocar placed armed mesh kits is often life-altering and can be permanent. Bard . . . should have investigated and resolved a complication of this magnitude prior to marketing a permanent implanted medical device.

(*Id.* at 26). Strikingly absent from this discussion is any *basis* for Dr. Shull's opinion of what Bard "should have" done. This is likely the result of Dr. Shull's lack of expertise in the specific area of warnings and labels for medical devices:

> Q. . . . But would you agree that you are not an expert in developing warnings and labels for medical devices?
>
> A. I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area.

(Shull Dep. vol. I [Docket 98-3], at 115:1-115:7; *see also id.* at 64:12-64:16 (no familiarity with federal regulations regarding IFUs); Shull Dep. vol. II [Docket 98-4], at 348:11-350:25 (no familiarity with whether FDA or other manufacturers' IFUs include supporting data)). Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process. To the extent that Dr. Shull seeks to opine that surgeons did not receive adequate warnings from Bard, he is similarly unqualified to do so. Accordingly, I **FIND** that Dr. Shull's opinions related to Avaulta product warnings should be excluded.

### iii. *Opinions Related to Product Design, Testing, and Materials*

With respect to Dr. Shull's opinions related to product design, testing, and materials, Bard argues that (1) Dr. Shull lacks qualifications to render opinions on such issues; (2) Dr. Shull's opinions on such issues are not based on sufficient data and are unreliable; and (3) Dr. Shull's opinions on such issues will not assist the jury.

Dr. Shull is qualified to render opinions on such issues. A witness may be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Shull's extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on such issues, notwithstanding his lack of expertise in the particular areas of product design or biomaterials.

However, Dr. Shull's opinions on the issues of product design, testing, and materials have no reliable basis. A review of Dr. Shull's expert report reveals that his opinions are largely based on (1) his personal experiences and observations and (2) internal Bard documents. For example, he testified:

> Q. Your opinions as to what may have occurred with the mesh implanted in these women, whose records you reviewed, those opinions are based only on the medical records and the depositions, perhaps, of the treating physicians, correct?
>
> A. No, that isn't correct.
>
> Q. What else is it –
>
> A. My – my conclusions are based on my professional experience, my professional education, my examination of women who have had complications of surgery, my interviews with them, with their spouses, my examination of them, my operating on them, in addition to the information provided in these records. So, otherwise, you would be presuming I'm making – drawing a conclusion disassociated with anything else in my background of knowledge and experience, and that isn't true.

(Shull Dep. vol. I [Docket 98-3], at 196:15-197:8). Dr. Shull further states that "the source of my words for describing [that mesh can saw into tissue] are based in large part on a clinical practice of managing women who have similar symptoms and physical findings." (Shull Dep. vol. II [Docket 98-4], at 227:22-227:25). "[A] bold statement of the experts' qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard." *In re Bausch & Lomb, Inc.*, 2009 WL 2750462, at *10 (quoting *Doe 2 v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006)).

With respect to his "sawing effect" opinion, Dr. Shull relies on his experience and one specific observation, and Dr. Shull testified that he "can't say that [the mesh] actually sawed into the [tissue]" in that case. (Shull Dep. vol. II [Docket 98-4], at 229:10-229:14). The plaintiffs appear to use Dr. Shull's qualifications as a means for arguing that his opinions are reliable. Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

Dr. Shull's deposition testimony also reveals that his opinions have not been applied "to the facts of the case." Fed. R. Evid. 702. For example, with respect to whether Avaulta products shrink, Dr. Shull testified:

> Q. You're basing that on a document you read that was furnished to you by the Plaintiffs' attorneys, correct?
>
> A. That's accurate.
>
> Q. You've done no independent assessment of that?
>
> A. I have not tested any Avaulta product.

Q. And you're not qualified to test Avaulta products to determine their rate of shrinkage, if any, are you?

A. I would say my only qualification and testing of products *in general, not specifically Avaulta,* would be seeing women who have had mesh products implanted and examining them and learning about the characteristics of their exam after they've had a product implanted.

. . .

I have not seen an Avaulta explant that I saw before it was implanted and observed it, made any measurements, and then measured it again after it had been explanted.

(Shull Dep. vol. I [Docket 98-3], at 172:6-173:5) (emphasis added). With respect to several other opinions, such as the ability of mesh to saw into tissue, Dr. Shull testified:

Q. Now . . . you say that you have observed in your practice banding of the arms and bunching of the central mesh piece with these devices?

A. That's accurate.

Q. Have you seen that specifically with regard to the Bard product?

A. I cannot answer that. I've seen it in women who have had mesh placed for the treatment of pelvic organ prolapse. In some circumstances I do not know the name of the device and I cannot tell you specifically that I have seen that with a Bard product.

. . .

Q. Do you have any specific evidence that the arms or the mesh sawed into the tissue of any of these individual Bellwether Plaintiffs?

A. No.

. . .

Q. Have you seen any evidence of mesh becoming hard and embrittled with regard to vaginal mesh products?

A. Yes.

Q. Have you made that specific observation with regard to a Bard Avaulta product?

A. I do not know that for a fact.

(Shull Dep. vol. II [Docket 98-4], at 229:15-230:3; 232:24-233:3; 233:15-233:22). Without any application to the facts of the case (Avaulta products), Dr. Shull's opinions on these matters will not assist the jury.[5] Accordingly, I **FIND** that Dr. Shull's opinions related to product design, testing, and materials should be excluded.

**iv. *Opinions Related to Product Marketing and Training***

With respect to marketing, Dr. Shull admitted that he is not qualified to render opinions on such matters. (Shull Dep. vol. I [Docket 98-3], at 116:5-116:10). A review of Dr. Shull's expert report also reveals that his opinion on Bard's marketing is an effort to show that Bard acted improperly in its marketing. (*See* Shull Report [Docket 98-2], at 29-31). As I have previously ruled, such expert "opinions" regarding Bard's motives, intent or state of mind should be excluded because they are not properly the subject of expert testimony.

Finally, with respect to training, Dr. Shull's opinion will not assist the jury because it is not applied to the facts of the case. While Dr. Shull opines that Bard indiscriminately marketed its Avaulta products to all physicians, including inexperienced and unqualified physicians, he testified at his deposition:

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[5] To the extent that the plaintiffs cite *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-00837, 2012 WL 524442, at *6 (S.D. W. Va. 2012), Bard is correct in pointing out that the opinion at issue in *Hershberger* was derived from the doctor's "personal observations during the course of treating [the patient]." Even if Dr. Shull made a personal observation of "sawing" with respect to any Avaulta products, because it was not in his role as treating physician of any of the bellwether plaintiffs, his opinion is expert testimony subject to a *Daubert* challenge.

Additionally, the plaintiffs argue that "Dr. Shull's testimony regarding mesh shrinkage, and the sawing effect of its mesh arms . . . are not merely matters of opinion, but rather are verifiable facts." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Expert Opinions & Testimony of Dr. Bob Shull [Docket 151], at 17). In support, the plaintiffs cite various Bard internal documents on this issue. (*Id.* at 17-19). As previously held, Dr. Shull may not present expert opinion on Bard's alleged knowledge. Further, assuming *arguendo* that the plaintiffs are correct, there is no reason why the plaintiffs require an expert to opine on these "verifiable facts." Rather, such factual issues are properly presented as non-expert evidence and testimony for the jury to consider.

> Q. Do you have an opinion as to whether the surgeons who performed the implant surgery on the Bellwether Plaintiffs whether they were qualified and capable of performing surgery in the pelvic floor area?
>
> A. By looking at the preoperative assessment, the operative notes, and the follow-up, it appears that all of the surgeons are conscientious, described things in ways that are understandable, and describe their operative interventions and their subsequent evaluation of patients.
>
> Q. So it's not the case in your view in any of these cases where Bard trained or provided the product to a surgeon that was just not qualified?
>
> A. I don't see that in the three patients for whom I've reviewed the records.

(Shull Dep. vol. II [Docket 98-4], at 358:2-358:19). He further testified that he had "no specific information" as to whether he was aware of any instance where an unqualified and incapable physician was brought to a Bard training program. (*Id.* at 358:20-359:3). Accordingly, I **FIND** that Dr. Shull's opinions related to product marketing and training should be excluded.

**E. *The Plaintiffs' Treating Physicians***

As a preliminary matter, Bard argues that the plaintiffs never submitted a written Rule 26(a)(2)(B) report for the treating physicians and therefore, they may not present any expert opinions. Bard's substantive *Daubert* arguments attack the treating physicians' qualifications to opine on certain matters, and the relevancy and reliability of their opinions. In particular, Bard seeks to exclude:

> (1) testimony as to the existence of a product defect or inadequate design, including the biomechanical properties of mesh; (2) testimony as to those alleged defects causing injury; (3) testimony regarding other patients and complications that the bellwether plaintiff they were treating did not experience; and (4) testimony on topics that do not fall within the scope of their practice, such as marketing practices, adverse event reporting, and corporate conduct, intent, and duties.

(Def. Bard's Mot. to Limit the Opinions & Testimony of Pls.' Treating Physicians [Docket 103], at 2; *see also* Def. Bard's Mem. of Law in Supp. of Mot. to Limit the Expert Opinions &

Testimony of Pls.' Treating Physicians [Docket 104], at 4). As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

**i. *Federal Rule of Civil Procedure 26(a)(2)(B)***

Pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), an expert witness must provide a written report if he or she "is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony." Fed. R. Civ. P. 26(a)(2)(B). In Pretrial Order # 48, this court found that "[w]hile treating physicians and surgeons are typically highly trained and educated, and offer opinions concerning their care and treatment of their patients, they do not automatically qualify as 'expert witnesses' who must write a report and make Rule 26(a)(2)(B) disclosures." (Pretrial Order # 48, Case No. 2:10-md-02187 [Docket 290], at 4). This court held that "[a]bsent evidence that a plaintiff's treating physician or surgeon is retained or specially employed to provide expert testimony, a Rule 26(a)(2)(B) written report will not be required." (*Id.* at 5).

The inquiry is whether the treating physician's testimony addresses knowledge gained and opinions formed during the course of treatment, or whether the treating physician seeks to offer opinions which address information outside the scope of treatment. *See Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817, 824-26 (9th Cir. 2011) (discussing and joining the Sixth, Seventh, and Eighth Circuits in holding that "a treating physician is only exempt from Rule 26(a)(2)(B)'s written report requirement to the extent that his opinions were formed during the course of treatment."); *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-00837, 2012 WL 524442, at *6-7 (S.D. W. Va. Feb. 15, 2012) (analyzing whether an attending

surgeon's testimony was that of a treating physician or an expert witness).[6]

The plaintiffs do not make clear whether they are offering any expert opinions through the treating physicians. On one hand, the plaintiffs argue that the treating physicians "are not retained experts, and their examination of these plaintiffs was for purposes of treatment, not for purposes of providing testimony in these cases." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to

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[6] In footnote 3 of their response, the plaintiffs appear to argue that Rule 26(a)(2)(C), rather than 26(a)(2)(B), applies to the treating physicians in this case. In 2010, Rule 26 was amended to add subsection (C), which states:

> (C) *Witnesses Who Do Not Provide a Written Report*. Unless otherwise stipulated or ordered by the court, if the witness is not required to provide a written report, this disclosure must state:
>
> > (i) the subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705; and
> >
> > (ii) a summary of the facts and opinions to which the witness is expected to testify.

Fed. R. Civ. P. 26(a)(2)(C). According to the Advisory Committee Notes, this amendment seeks to "resolve[] a tension that has sometimes prompted courts to require reports under Rule 26(a)(2)(B) even from witnesses exempted from the report requirement." Advisory Committee's Notes on 2010 Amendments on Fed. R. Civ. P. 26. "Frequent examples include physicians or other health care professionals and employees of a party who do not regularly provide expert testimony." *Id.*

Case law since the 2010 Amendments continue to "adhere to traditional tests for determining when a Treating Physician is considered to be a full-blown expert and when he is considered to be more akin to a percipient witness with professional expertise." *Kondragunta v. Ace Doran Hauling & Rigging Co.*, No. 1:11-cv-01094-JEC, 2013 WL 1189493, at *10 (N.D. Ga. Mar. 21, 2013). In *Kondragunta*, Judge Carnes engaged in an exhaustive analysis of post-amendment case law and held, consistent with the traditional test, that:

> [I]f a physician's opinion regarding causation or any other matter was formed and based on observations made during the course of treatment, then no Subsection B report is required, albeit the Subsection C report discussed above will be required. If, however, the physician's opinion was based on facts gathered outside the course of treatment, or if the physician's testimony will involve the use of hypotheticals, then a full subsection B report will be required.

*Id.* at *12 (internal citations omitted); *see also Hershberger*, 2012 WL 524442, at *6-7 (analyzing whether an attending surgeon's testimony was that of a treating physician or an expert witness); *but see Kristensen ex rel. Kristensen v. Spotnitz*, No. 3:09-CV-00084, 2011 WL 5320686, at *4 (W.D. Va. June 3, 2011) (questioning the continued viability of prior case law requiring Rule 26(a)(2)(B) reports from treating physicians called upon to opine on information learned outside the course of treatment). This court will apply the traditional test to determine whether a Rule 26(a)(2)(B) written report is required for the plaintiffs' treating physicians.

Limit the Expert Ops. & Testimony of Pls.' Treating Physicians [Docket 146], at 3) [hereinafter Pls.' Resp. re: Treating Physicians]. On the other hand, the plaintiffs argue that the treating physicians are qualified to testify as to the design of the Avaulta products. (*See id.* at 7-13). The treating physicians are, of course, able to testify as to opinions formed during the course of treatment.

To the extent that the treating physicians offer opinions formed outside the course of treatment, I **FIND** that even if the plaintiffs violated Rule 26(a)(2)(B) by not submitting expert reports, such violations were substantially justified or harmless under Fed. R. Civ. P. 37(c)(1). *See Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011) (discussing the five-factor test for determining whether nondisclosure is substantially justified or harmless). There was no surprise to Bard because the treating physicians' depositions were before the deadline for expert reports and Bard had ample notice of any expert opinions that the treating physicians intended to offer. Further, allowing the testimony would not disrupt the trial, and the plaintiffs properly relied upon Pretrial Order # 48 in their decision not to submit expert reports for the treating physicians. Thus, I will not exclude the testimony of the plaintiffs' treating physicians simply because they did not produce expert reports.

**ii.** ***Bard's Daubert Challenges to the Treating Physicians' Testimony***

I now turn to Bard's *Daubert* challenges to the treating physicians' testimony. Bard seeks to preclude opinions regarding:

> (1) physicians testifying as to the existence of a product defect or inadequate design, including the biomechanical properties of mesh; (2) physicians testifying as to those alleged defects causing injury; (3) physicians' testimony regarding other patients and complications that the bellwether plaintiff they were treating did not experience; and (4) physicians' testimony on topics that do not fall within the scope of their practice, such as marketing practices, adverse event reporting, and corporate conduct, intent, and duties.

(Def. Bard's Mem. of Law in Supp. of Mot. to Limit the Expert Ops. & Testimony of Pls.' Treating Physicians [Docket 104], at 4). The plaintiffs provide a lengthy summary of the treating physicians' qualifications. (*See* Pls.' Resp. re: Treating Physicians [Docket 146], at 7-13). Even assuming that the treating physicians are qualified to offer the expert opinions that they seek to offer in this case, the plaintiffs have not shown any indicia of reliability underlying these opinions. *See* Fed. R. Evid. 702 (requiring expert testimony to be "the product of reliable principles and methods").

In sum, I **FIND** that (1) causation opinions, if formed in the course of treatment of the bellwether plaintiffs, and (2) fact testimony related to the learned intermediary issue, specifically, whether the treating physicians would have used the Avaulta products if they were given the warnings that the plaintiffs contend should have been given, should not be excluded. These opinions fall within the realm of proper testimony from treating physicians. I further **FIND** that (1) expert opinions, if any, on product design, (2) testimony regarding other patients and complications unrelated to the bellwether plaintiffs treated by the physician, and (3) other opinions formed outside of the treating physicians' care and treatment of the bellwether plaintiffs should be excluded. These latter opinions are fraught with reliability and relevancy issues.

**F. *Bernd Klosterhalfen, M.D.***

Dr. Klosterhalfen's expert report states that his opinions concern "1) the products, 2) the human body's reaction to the products, and 3) the significant problems the products cause and have caused women implanted with these products." (Klosterhalfen Report [Docket 108-1], at 1). Specifically, he offers opinions related to: (1) the qualifications that a surgeon should have to use Avaulta products; (2) product design and materials; (3) polypropylene degradation; (4) curling

and folding of the mesh in addition to scarification and chronic inflammatory response; and (5) other complications resulting from use of the mesh. (*See generally id.*).

Bard seeks to exclude Dr. Klosterhalfen's opinions on the following issues:

> (1) surgical technique and the requisite qualifications of surgeons to use Avaulta products; (2) the marketing of Avaulta to doctors; (3) the design of the Avaulta products, including an opinion on something called "effective pore size," a term that only one of his colleagues uses; (4) "surface degradation" in Avaulta products; (5) Bard's state of mind; and (6) medical causation related to the named Plaintiffs.

(Def. Bard's Mem. of Law in Supp. of Mot. to Limit the Ops. & Testimony of Dr. Bernd Klosterhalfen, M.D. [Docket 116], at 1) [hereinafter Bard's Mem. re: Klosterhalfen]. Bard also seeks to preclude Dr. Klosterhalfen from relying on his database of explanted mesh products and tissue samples in any of his opinions. As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

**i. *Opinions Related to Surgeon Qualifications***

Bard argues that Dr. Klosterhalfen seeks to opine that: (1) "the surgeon must be very experienced and well trained to even attempt" the usage of Avaulta products and that (2) "[d]ue to the complexity of the mesh design . . . even the very experienced pelvic floor surgeons experience complications with Avaulta products." (*Id.* at 3). Bard argues that Dr. Klosterhalfen, as a pathologist, is not qualified to opine on these issues. Dr. Klosterhalfen testified, for example:

> Q. . . . Can you tell us what your experience is with respect to mesh used in pelvic floor reconstruction other than being a co-author to the DePrest article?
>
> A. So no, I'm – you want to say I'm – basically, it's not a field I should talk about. That's not true. You see, I have – if we talk about clinical studies, I agree I'm not the expert. If we talk about operation procedures, I agree I am not the expert. But – but I am the only one who has 500 explants. And you must know, and now we will come with evidence levels of studies, do you know what a pathologist is doing? And this is our basic work. . . . What we do is we collect samples, we observe, we investigate. We have

> subgroups. And, of course, in prolapse repair, I'm the expert if you talk about the histology and the pathology of these meshes because there's nobody else who has this data pool.

(Klosterhalfen Dep. vol. I [Docket 108-2], at 74:10-75:7). He further testified:

> Q. . . . So with respect to pelvic organ prolapse repair surgery, I think we've already agreed you are not a surgeon, correct?
>
> A. Yeah.
>
> Q. You have never performed this procedure, correct?
>
> A. Yeah. But I have –
>
> Q. Is that right?
>
> A. Yes, that's true.
>
> . . .
>
> Q. So you have never attempted to perform pelvic organ prolapse repair with any of the Avaulta products, correct?
>
> A. No.

(*Id.* at 76:21-77:4; 79:13-79:16). Bard argues that because Dr. Klosterhalfen admitted he was not an expert on surgical procedures or clinical studies, is not a surgeon, and has never performed or attempted to perform a pelvic organ prolapse repair with an Avaulta (or any other) product, he is not qualified to offer an expert opinion on surgical techniques.

The plaintiffs respond by arguing that Dr. Klosterhalfen is qualified "based on his experiences, discussions and observations of the procedures being performed, and his extensive research in this specific subject area." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Ops. & Testimony of Dr. Bernd Klosterhalfen, M.D. [Docket 156], at 3) [hereinafter Pls.' Resp. re: Klosterhalfen]. For example, Dr. Klosterhalfen testified that:

> Q. Okay. Going to your report, you mention that with pelvic utilization of polypropylene mesh constructed with arms and implanted transvaginally,

such as Avaulta biosynthetic (Classic), Avaulta Solo, and Avaulta Plus, the surgeon must be very experienced and well trained to even attempt its usage. That's in your report, correct?

. . .

A. Yeah, that's true. You see, basically, as an opinion leader in that field, I have seen a lot of these operations, and I have made wet labs, and I've discussed, of course, to representatives and to professionals in this field. And I know that this operation is highly complicated. And so I know a little bit more than the pathology.

. . .

Q. Maybe we can shortcut some of this. Are you going to be offering an opinion about the procedure itself of doing pelvic floor reconstruction?

A. I'm offering my opinion – well, the statement that I've heard and have spoken to surgeons saying that this is a complicated operation. And that I have seen operations during congresses and during wet labs, and you can see that it's – for a normal surgeon who never have done it, it's highly complicated because you're working blind.

(Klosterhalfen Dep. vol. I [Docket 108-2], at 75:16-76:10; 78:13-78:24). After review of Dr. Klosterhalfen's qualifications and deposition testimony, I **FIND** that Dr. Klosterhalfen is qualified to offer his expert opinions on surgeon qualifications. A witness may be qualified as an expert by "knowledge, skill, experience, training, or education," and Dr. Klosterhalfen has shown that he is qualified by his knowledge. Fed. R. Evid. 702.

**ii.** ***Opinions Related to Product Design***

Dr. Klosterhalfen offers design opinions relating to (1) the complexity of the mesh design and (2) the necessary pore size of the meshes. Bard argues that Dr. Klosterhalfen is not qualified to offer opinions related to product design and that his opinions have no factual foundation. Bard takes particular issue with Dr. Klosterhalfen's "effective pore size" opinion, arguing that it has no scientific basis, that "it is also questionable how strongly it is received among the few who study the concept," and that it is irrelevant (Bard's Mem. re: Klosterhalfen [Docket 116], at 6).

The plaintiffs spend the bulk of their response arguing that (1) Dr. Klosterhalfen is qualified to testify on these issues and that (2) Dr. Klosterhalfen provides a sufficient and reliable basis for his opinion on effective pore size. (*See* Pls.' Resp. re: Klosterhalfen [Docket 156], at 3-11). The record shows that Dr. Klosterhalfen is qualified to offer such opinions. Again, a witness may be qualified as an expert by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Klosterhalfen has significant experience analyzing mesh explants, and more importantly, in the consulting and designing of mesh products. Bard's attempts to limit Dr. Klosterhalfen's consulting and design experience are unconvincing.

An expert's opinions must be based on reliable principles and methods applied to the facts of the case. Fed. R. Evid. 702. Dr. Klosterhalfen's opinions related to pore size are properly applied to the facts of this case. He saw Bard's calculations of the pore size for the Avaulta products and opined that they were inadequate. (*See* Klosterhalfen Report [Docket 108-1], at 3).[7] Turning to the sufficiency and reliability of Dr. Klosterhalfen's basis for his pore size opinions, it is important to note the difference between his opinions on *pore size* and *effective pore size*. Dr. Klosterhalfen opines that Avaulta mesh products should have a pore size of 3 millimeters or greater (before implantation) and an "effective pore size" of at least 1 millimeter (after implantation). (Klosterhalfen Report [Docket 108-1], at 3). These appear to be two separate, but related opinions.[8] Bard does not appear to contest Dr. Klosterhalfen's opinion regarding pore size, and this opinion is amply supported by scientific literature. With respect to *effective* pore

[7] Bard also seeks to exclude Dr. Klosterhalfen's opinion regarding "the complexity of the mesh design." (Klosterhalfen Report [Docket 108-1], at 2). It is unclear what opinions Dr. Klosterhalfen seeks to render in this regard, but in any case, he has not provided any basis for rendering any opinions regarding the "complexities" of the Avaulta mesh design beyond pore size.

[8] In essence, a mesh product with a pore size of 3 millimeters or greater prior to implantation would have an effective pore size of 1 millimeter or greater after implantation.

size, the analysis is more difficult. For example, Dr. Klosterhalfen testified regarding a 2011 article provided by the plaintiffs:

> Q. . . . Now, what does macroporosity mean?
>
> A. I think, basically, he – in that case, he describes the pore size, basically. So he's talking about large pore concept.
>
> Q. Okay. And the millimeter range is constituted of all relative large pores existing between the columns of stitches. The knitting pattern controls the size, shape, and density of such large pores. The macroporosity has an even more important impact on the mesh integration because insufficient pore size will generate the mesh fibrotic encapsulation, which will bridge between the mesh yarns and then be responsible for the mesh shrinkage and potential pain or discomfort during tissue contraction. Then he refers to figures 25.2 and 25.3 illustrate the encapsulation mechanism according different mesh pore sizes. From this study and others, it sounds that the cutoff in pore size to limit the risk of fibrous capsule formation and subsequent shrinkage is around 1.5 – 1 to 1.5 millimeters. Several teams showed that macroporosity was the key factor to control fibrosis. In that – is that confirmatory or not confirmatory of your opinions that you have rendered in regard to effective pore size and the importance of effective pore size?
>
> MR. BROWN: Objection, there's no reference in there to effective pore size.
>
> A. Yeah, it's a little bit – little bit tricky, but all together I think it confirms our concept, but the problem here is whether he's talking about effective pore size or just the pore size. But what is clearly coming out, that they recognize the importance of the pore – of the pore for the tissue integration, especially here with what is very nice in that group because, as I say, they are pretty good. He's talking about the knitting pattern which controls the size and the shape and density of that large pore, *so he is little bit talking about effective pore size.*

(Klosterhalfen Dep. vol. II [Docket 108-4], at 634:6-635:24) (emphasis added). Dr. Klosterhalfen further noted that the author "describes what we mean with effective pore size. So what he's talking about, that the pore must be stable even if you have mechanical stress on the mesh, and that's pretty nice true." (*Id.* at 636:17-636:21). Additionally, the parties agree that Dr. Muhl published a study on effective pore size. Bard's attempts to discredit the article ignore the

plaintiffs' argument that Dr. Muhl's study was peer-reviewed and published in a peer-reviewed publication.[9] Accordingly, I **FIND** that Dr. Klosterhalfen's expert opinions related to product design should not be excluded.

### iii. *Opinions Related to Bard's Marketing Practices and State of Mind*

As discussed more fully *supra* related to Dr. Shull's expert opinions and consistent with those findings, I **FIND** that Dr. Klosterhalfen's opinions related to Bard's marketing practices and state of mind should be excluded.[10]

### iv. *Opinions Related to Surface Degradation*

Dr. Klosterhalfen offers his expert opinion relating to surface degradation of meshes, which plays a role in a "chronic inflammatory process that is long term and induces scarification, contraction of tissues, pain, and infection, both clinical and subclinical." (Klosterhalfen Report [Docket 108-1], at 4-5). Bard argues that this opinion should be excluded because (1) Dr. Klosterhalfen based this opinion on a series of scanning electron micrographs (SEMs) that "lack the necessary foundation to support an admissible opinion," (2) this opinion is based on "shaky science at best, making it inherently unreliable," and (3) he made several admissions, including that "he did not see any evidence of surface degradation on the explants of any of the bellwether Plaintiffs." (Bard's Mem. re: Klosterhalfen [Docket 116], at 8-9).

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[9] Bard places too much reliance on its argument that the concept of effective pore size is not generally accepted in the scientific community. Although general acceptance is one factor to consider under *Daubert*, it does not end the inquiry. *See Crisp*, 324 F.3d at 266 (considering general acceptance in the relevant scientific or expert community as one of five factors).

[10] The plaintiffs argue that this is not a *Daubert* issue, but rather an issue to be presented in a motion *in limine*. I disagree. Under Federal Rule of Evidence 702, an expert may testify in the form of an opinion only if it will assist the jury. *See* Fed. R. Evid. 702. For example, Dr. Klosterhalfen offers the opinion that "[i]t was inappropriate to sell the Avaulta meshes for utilization by every surgeon who practices as an urologist or gynecologist." (Klosterhalfen Report [Docket 108-1], at 2). These types of opinions are not properly the subject of expert testimony and therefore, I will exclude them via a *Daubert* ruling.

Again, an expert's opinions must be based on reliable principles and methods applied "to the facts of the case." Fed. R. Evid. 702. Dr. Klosterhalfen testified:

> Q. With respect to the women we're calling bellwether plaintiffs, you reviewed pathology for four because one did not have any, right?
>
> A. That's true, yes.
>
> Q. And did you see any evidence of surface degradation on the explants of any of the bellwether plaintiffs?
>
> A. No, you can't with this methodology what I'm doing. In most cases the fiber is gone after processing the tissue for that staining.

(Klosterhalfen Dep. vol. II [Docket 108-4], at 600:12-600:21). Accordingly, Dr. Klosterhalfen's opinion on this issue is not applied "to the facts of the case" as required by Rule 702. Accordingly, I **FIND** that Dr. Klosterhalfen's expert opinions related to surface degradation should be excluded.

**v. *Opinions Related to Medical Causation***

Dr. Klosterhalfen opines that the Avaulta meshes are a proximate cause of the pain, contraction, and other problems that the bellwether plaintiffs experience. Bard argues that Dr. Klosterhalfen is not qualified to opine on causation, and that the basis for his opinions is unreliable. Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on this issue. Additionally, Dr. Klosterhalfen's basis is effectively that because he reviews a large number of explants and has seen patterns that can observed in nearly all of them, that the patterns are a general result of the procedure or of the mesh. For example, he testified:

> Q. And so you disagreed with the – so you believe the mesh in each instance was responsible for the complication listed?
>
> A. The mesh as its own pathology. I cannot say – I cannot – I cannot say in each instance, of course. But here, you find general rules, how these meshes behave in the body. I'm absolutely agree it's possible that you have a special patient with a special situation, why he got an infection in

> this mesh, okay. But what you see here, that you have always patterns which you can observe in nearly all of these implants, and there must be a general behavior of these meshes in this special location. For instance, look, the erosion mostly you'll find at one place in the vagina. Why is that? If you find 90 percent or 80 percent or the majority of the erosion at one place, there must be something very particular, huh?

(Klosterhalfen Dep. vol. I [Docket 108-2], at 138:8-139:1). Furthermore, Dr. Klosterhalfen effectively rules out other potential causes by discussing the randomization in his data:

> Q. And your data pool does not take into account the other medical conditions that may have led to infection, for example, correct?
>
> A. Oh, yeah, but you – but, basically, you sell these products not for healthy people, yeah? You know that these people have diabetes, that they have obesity, that they have hypertension, which all promotes infection. That you have to know. So – but basically, if you got a special level, and if you have 500 tissue samples, these data are randomized. You cannot say that this lady – this special lady has this infection because she has diabetes, especially if all of the 500 implants or explants show all the same.

(*Id.* at 136:5-136:18). Finally, Dr. Klosterhalfen testified regarding his review of the pathology slides of the bellwether plaintiffs Ms. Jones, Ms. Queen, and Ms. Cisson:

> A. Basically, the meshes show all what here was addressed and before. They show the scar tissue formation, they show this wrinkling, they show entrapped nerves. And, basically, I think in that location the meshes play a major role for the complaints of these women, yeah.

(Klosterhalfen Dep. vol. II [Docket 108-4], at 641:17-641:22). In short, Dr. Klosterhalfen has demonstrated a sufficient and reliable basis for his causation opinions. Accordingly, I **FIND** that Dr. Klosterhalfen's expert opinions related to causation should not be excluded.

#### vi. *Dr. Klosterhalfen's Reliance on his Personal Database*

Dr. Klosterhalfen relied on a personal database of explanted devices and tissue samples in forming his opinions. Bard argues that any opinion based on this database should be excluded because Dr. Klosterhalfen has not disclosed this data, the data is unreliable, and the data is irrelevant. I disagree. At his deposition in January and February of 2013 in Europe, Dr.

Klosterhalfen declined to produce his personal explant database because of German privacy laws. He explained that the explants were the property of the patient and each patient's consent was required for disclosure. (Klosterhalfen Dep. vol. I [Docket 108-2], at 23:17-23:25). Instead, he produced a chart in German and English about the patient, the explant and certain findings including the patient's date of birth, characteristics of the mesh such as pore and weight, and brand of the product if known, date of implant, the primary indication, the patient's subjective complaints, objective complaints, the explant date and other findings. Despite its apparent dissatisfaction with Dr. Klosterhalfen's chart, Bard *did not* timely move to compel the production of the explant database.

Dr. Klosterhalfen's reliance on this personal database, created over years for purposes unrelated to this litigation, is part of his knowledge and experience that he may base his opinions on under Federal Rule of Evidence 703. Accordingly, I **FIND** that Dr. Klosterhalfen's reliance on his personal database does not render his opinions unreliable.

**G. *Lennox Hoyte, M.D.***

Dr. Hoyte offers opinions related to: (1) Bard's marketing of the products to inadequately trained surgeons; (2) product design and biomechanics of Avaulta mesh,[11] and; (3) causation.

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[11] As stated by the plaintiffs:

> Dr. Hoyte holds the opinion that the transvaginal implantation of Bard's Avaulta Solo, Plus and Biosynthetic Prolapse Organ repair systems is problematic for a variety [of] reasons: the blind placement of the mesh arms cut muscle tissue and may damage nerves; the side to side fixation of the mesh arms in combination with the known tendency of polypropylene mesh to shrink creates non-anatomic mechanical stresses on the pelvic muscles causing pain; the static nature of the mesh restricts the functional mobility of the pelvic floor organs and restricts the natural movements of the vagina during defecation, urination and intercourse causing pain during these activities; and the transvaginal placement of the mesh exposes the mesh to the "clean-contaminated" vaginal microbian environment presenting an opportunity for the mesh to be contaminated.

(Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Expert Ops. & Testimony of Dr. Lennox Hoyte [Docket 147], at 2).

Bard takes issues with all of these opinions. As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

**i.** ***Opinions Related to Biomechanics, Biomechanical Analysis, and Product Design***

Bard argues that (1) Dr. Hoyte is not qualified to render opinions in these areas; (2) Dr. Hoyte's opinions are unreliable; and (3) Dr. Hoyte's opinions will not assist the jury.

**a.** ***Qualifications – Biomechanics and Biomechanical Analysis***

Bard argues that Dr. Hoyte is not qualified to opine on biomechanics because he is "not a biomedical engineer, biomaterial engineer, or biomaterials expert. He has never designed any products containing mesh. He is not an expert in biomaterials or biomechanics. He is not a physicist. He is not a radiologist or neuroradiologist and is not qualified to render opinions based on radiologic images." (Def. Bard's Mem. of Law in Supp. of its Mot. to Limit the Ops. & Testimony of Lennox Hoyte, M.D. [Docket 117], at 5) [hereinafter Bard's Mem. re: Hoyte]. In short, Bard focuses on what Dr. Hoyte is not. Dr. Hoyte, however, has two engineering degrees – a Bachelor of Science in electrical engineering from Worcester Polytechnic and a Master of Science in electrical engineering and computer science from Massachusetts Institute of Technology. (Hoyte Curriculum Vitae [Docket 110-3], at 2; *see also* Hoyte Dep. vol. I [Docket 110-1], at 194:24-195:6). He practiced as an engineer for twelve years. (Hoyte Dep. vol. I [Docket 110-1], at 195:7-195:13). A review of his deposition testimony also reveals that he is amply qualified; for example, he testified:

> Q. And then since you became a physician and after medical school – and, of course, we will go through your C.V., you went through your residency and your Fellowship, you stopped practicing as an engineer on a day to day basis?
>
> A. Not correct.

Q. Explain.

A. Actually part of my research activity as a resident, a Fellow, and ongoing has been biomechanical analysis of tissues in the pelvic floor. I have been studying the pelvic floor from an engineering perspective since 1993.

. . .

Q. And then I will pull out your resume and look at it while we're talking. But since becoming a doctor you spend your professional time as a physician, correct?

A. I'm a physician researcher, and my research area involves biomechanical analysis of pelvic floor structures.

Q. Okay.

A. One of the earliest works that I did was actually this 3D reconstruction based on MR-based data. And this was published as – reported on as early as 1999. And I have been doing biomechanical analysis as a researcher in an ongoing way. So no, I haven't stopped. You can't stop being an engineer.

(*Id.* at 195:17-197:2). The plaintiffs also argue that "[a]t least a quarter of his publications involve three dimensional mapping of women with prolapse issues." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Expert Ops. & Testimony of Dr. Lennox Hoyte [Docket 147], at 5) [hereinafter Pls.' Resp. re: Hoyte]. With respect to his qualifications to render opinions based on radiologic images, Bard itself addressed Dr. Hoyte's qualifications to serve as a preceptor when it stated that he "is one of the leaders in pelvic MRI data in the world." (Preceptor Qualification Form [Docket 147-1], at 1). Dr. Hoyte also has extensive experience in the interpretation of MRIs; for example, he testified:

Q. So there is an official interpretation that is conducted by the radiologists, by the Board certified radiologists or neuroradiologists, and then you say you utilize those images and reports and do your own, from your standpoint, is that what you are saying?

A. As a surgeon and an anatomist required to correct pelvic floor disorders, I have to personally interpret the images myself because my surgery, my

surgical intervention, my clinical intervention depends on my impressions that I see from interpreting the images.

Q. Okay.

A. So while I'm not a radiologist in the sense of a radiologist looking for tumors, for cancer, for abnormal radiologic – traditional radiologic structures, I'm looking very specifically the structural information contained in that MRI, and in that area I'm very much an expert.

(Hoyte Dep. vol. I [Docket 110-1], at 52:16-53:9).

While Dr. Hoyte is not a radiologist, he has significant experience interpreting MRIs. Furthermore, his research experience in the field of biomechanics involving the pelvic floor makes him amply qualified. In sum, Dr. Hoyte is qualified "by knowledge, skill, experience, training, or education" to opine as to biomechanics and biomechnical analysis. Fed. R. Evid. 702. Accordingly, I **FIND** that Dr. Hoyte is qualified to offer his expert opinions on biomechanics and biomechanical analysis.

**b.** ***Qualifications – Product Design***

Bard argues that Dr. Hoyte is not qualified to opine on the design of Avaulta mesh because he has no training or experience using Avaulta products. Bard heavily emphasizes that Dr. Hoyte "never implanted an Avaulta device transvaginally in a live patient." (Bard's Mem. re: Hoyte [Docket 117], at 5) (emphasis omitted). An expert witness may be qualified by "*knowledge*, skill, experience, training, or education." Fed. R. Evid. 702 (emphasis added). From a review of Dr. Hoyte's testimony, he clearly has knowledge of Avaulta products and the design of Avaulta products. While he may not have experience *implanting* an Avaulta device, he has *explanted* Avaulta devices, and personally observed other physicians implanting an Avaulta device. Bard itself sought out Dr. Hoyte's services as a preceptor:

A. Well, let's see. I think in the Boston time I think they were referring to me as a potential surgeon that they could recruit as somebody that would be a Bard implanter who –

. . .

A. . . . They were complimentary about myself and my skills as a surgeon and my abilities and my reputation and things like that and is going to be great, when he comes to Tampa you guys can recruit him –

Q. Okay.

A. --and make him be a Bard preceptor, he's good for us, you know, those kinds of things is what I –

(Hoyte Dep. vol. II [Docket 110-2], at 520:9-520:12; 521:18-522:1). In sum, it is clear that Dr. Hoyte is qualified "by knowledge, skill, experience, training, or education" to opine as to the design of Avaulta mesh products.[12] Fed. R. Evid. 702. Accordingly, I **FIND** that Dr. Hoyte is qualified to offer his expert opinions on the design of the Avaulta mesh products.

**c. *Reliability – Biomechanical Analysis and Opinion***

Bard takes issue with Dr. Hoyte's biomechanical analysis "using a mesh-free method and creat[ing] a variety of graphics, purported computer simulation videos and 3-D models of a pelvis." (Bard's Mem. re: Hoyte [Docket 117], at 6). Bard argues that (1) Dr. Hoyte selected the MRI of a non-bellwether plaintiff as a model for his graphics, videos, and 3-D models, without

[12] Bard's cited authorities are unpersuasive. *See, e.g., Khoury v. Philips Med. Sys.*, 614 F.3d 888, 893 (8th Cir. 2010). In *Khoury*, the Eighth Circuit found that a doctor was unqualified to opine on the design of laboratories or of monitor banks and radiation shields because the doctor was an ergonomist and otherwise had "no training, education, or experience" in the design of medical laboratories or of monitor banks and radiation shields. *Id. Khoury* did not deal with a lack of first-hand experience with a particular product; rather, it dealt with a lack of training, education, or experience in the design of the entire class of products. *Khoury*'s holding would not preclude in and of itself, for example, the testimony of a doctor who had some training, education, or experience in the design of laboratories or of monitor banks and radiation shields to opine on the *specific* laboratories or monitor banks and radiation shields that were at issue in that case. In other words, it was not the doctor's lack of first-hand experience with the Cath Lab 5 or the BH5000 product, but his lack of experience with *any* laboratories or monitor banks or radiation shields, that caused him to be unqualified.

ensuring that it was representative of the four bellwether plaintiffs and (2) Dr. Hoyte made no allowance for any variation amongst pelvic floors in women.

It is worth keeping in mind, at the outset, the opinion that Dr. Hoyte seeks to offer based on his biomechanical analysis: "where the anterior Avaulta mesh kit would be placed in a female pelvis and what happens to the mesh and the surrounding structures during the normal dynamic operation of the pelvis from various activities." (Pls.' Resp. re: Hoyte [Docket 147], at 10). Dr. Hoyte's methodology in his biomechanical analysis appears to be reliable and grounded in scientific basis. For example, he testified:

> A. I have used an insert here to attach to the pelvic sidewall to show how the vagina is actually attached. This is based on a peer-reviewed, anatomically agreed upon understanding in living women of how the pelvis and the vagina relate to each other. . . . Based on our understanding of the past ten years, some work by Dr. Delancey, myself, and others, demonstrated the living anatomy in the female pelvis, and it is now agreed upon from peer-reviewed data that this is actually the shape of the vagina in the pelvis.

(Hoyte Dep. vol. I [Docket 110-1], at 84:16-85:10). Dr. Hoyte relied upon peer-reviewed literature to determine that his model is a representative pelvic floor, and his reconstruction of it is also based upon peer-reviewed literature. (*See id.* at 63:24-64:4). Bard argues that Dr. Hoyte's model is not representative of the pelvises of any of the bellwether plaintiffs, or even the individual whose MRI he used to base his model. However, Dr. Hoyte's model is designed to be *generally* representative of the female pelvis. It is Dr. Hoyte's opinion that in "a woman's pelvic floor, invariably the structures that you will find there and the relationships between the structures are pretty uniform." (*See* Hoyte Dep. [Docket 110-1], at 64:10-64:16). I **FIND** that Dr. Hoyte's biomechanical analysis and opinions are sufficiently reliable to withstand a *Daubert* challenge.

**d. *Reliability – Product Design***

The plaintiffs failed to respond to Bard's arguments regarding the reliability of Dr. Hoyte's opinions on this issue. While Dr. Hoyte may be qualified to opine on the design of the Avaulta products, such qualifications, without more, do not form a reliable basis for the expert's opinions. Dr. Hoyte's expert report, however, suggests that he relied not only on his knowledge and experience, but also on scientific literature. (*See, e.g.*, Hoyte Report [Docket 110-3], at 4-5) ("The same is recognized in the scientific literature."). Accordingly, I **FIND** that Dr. Hoyte's product design opinions are sufficiently reliable.

**e. *Relevance***

The plaintiffs also failed to respond to Bard's arguments regarding the relevance of Dr. Hoyte's opinions on the issues of biomechanics and product design. However, Dr. Hoyte's opinions on the biomechanics and product design of the Avaulta mesh are relevant to the issues of product defect, notwithstanding the lack of a specific application to the bellwether plaintiffs. For example, the question of whether a product is defectively designed does not have to relate to whether it was defectively designed as implemented in a particular patient. Accordingly, I **FIND** that Dr. Hoyte's opinions related to biomechanics and product design of the Avaulta mesh are relevant and would assist the jury.

**ii. *Opinions Related to Specific Causation***

Bard's reply to the plaintiffs' response argues that on March 28, 2013, the plaintiffs filed a supplemental report for Dr. Hoyte's opinions, which include "brand-new, never previously-disclosed specific causation opinions." (Def. Bard's Reply in Supp. of its Mot. to Limit the Ops. & Testimony of Lennox Hoyte, M.D. [Docket 171], at 12). Bard argues that I should not

consider the supplemental report. The plaintiffs argue that Dr. Hoyte did, in fact, offer a specific causation opinion in his first report.

Federal Rule of Civil Procedure 26(e) governs the supplementing of disclosures. A disclosure must be supplemented or corrected "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). Dr. Hoyte's original expert report was submitted pursuant to the October 15, 2012 deadline. Six months later, and a week after Bard filed its *Daubert* challenges to Dr. Hoyte's opinions, the plaintiffs submitted the supplemental report.

Dr. Hoyte's original expert report offers two opinions related to causation. First, he states:

> To a reasonable degree of medical and scientific certainty, it is my professional medical opinion that the design defects and/or actions caused by the design defects cause and contribute to the pain experienced by women with transvaginal Avaulta mesh implants.

(Hoyte Report [Docket 110-3], at 6). Next, he states:

> I can state with reasonable medical certainty that what is being shown in the graphics is representative of what is experienced by the women who have difficulties with the Avaulta products. After reviewing the medical records, including operative reports and follow-up evaluations of Ms. Queen, Ms. Cisson, Ms. Jones, Ms. Rizzo, Ms. Smith, I can say with reasonable medical certainty that the symptoms experienced by these 5 women are consistent with the findings demonstrated by these MRI derived simulation graphics, and also consistent with my clinical experience with the many women whom I have treated for transvaginal mesh related complications.

(*Id.* at 9). I **FIND** that Dr. Hoyte offers specific causation opinions in his original expert report, and that his supplemental report clarifies the basis for the specific causation opinions that he

originally offered. Accordingly, I will consider the supplemental report and Bard's substantive *Daubert* challenges to Dr. Hoyte's opinions.[13]

Bard argues that Dr. Hoyte is not qualified to offer opinions on specific causation and that his specific causation opinions are unreliable. As an urogynecologist with significant experience with pelvic repair and Avaulta products, Dr. Hoyte has personally examined hundreds of patients with mesh complications. As a result, Dr. Hoyte is qualified to offer specific causation opinions. In addition, Dr. Hoyte has reviewed the bellwether plaintiffs' medical records and has performed a sufficiently reliable differential diagnosis to support his specific causation opinions.[14] Accordingly, I **FIND** that Dr. Hoyte's specific causation opinions should not be excluded under *Daubert*.

#### iii. *Opinions Related to Bard's Marketing Practices*

As discussed more fully *supra* related to Dr. Shull's expert opinions and consistent with those findings, I **FIND** that Dr. Hoyte's opinions regarding Bard's marketing of the Avaulta products are not an appropriate subject of expert testimony and will not assist the jury.

### H. *David A. Kessler, M.D.*

Dr. Kessler's lengthy report of almost 200 pages seeks to offer a total of ten expert opinions:

a. Bard . . . had responsibility for the safety of their Avaulta products.
b. FDA regulations and state tort liability operate independently.

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[13] This ruling is limited very narrowly to the circumstances surrounding and the contents of Dr. Hoyte's expert reports. The parties are specifically admonished that this ruling does not invite the parties to indiscriminately file supplemental expert reports under the guise of clarifying the basis for an earlier opinion.

[14] Dr. Hoyte rules out any fault by the surgeon in his supplemental report. Moreover, Dr. Hoyte effectively rules out other possibilities by suggesting that, to a reasonable degree of medical certainty, the complications experienced by the bellwether plaintiffs are so consistent with those that Dr. Hoyte has observed and experienced that nothing other than the mesh could be the cause.

c. A device company has a responsibility, independent of what the FDA directs it to do, to alert physicians and patients to risks that are known to the company.
d. Bard knew there were safety issues with their Avaulta Products and should have investigated these risks in humans before marketing.
e. Bard stated their Avaulta Products were new and revolutionary. These products had different technological characteristics and raised safety questions, yet Bard claimed to FDA these products were substantially equivalent. Substantially equivalent devices cannot pose new safety or technological characteristics.
f. Bard failed to adequately disclose adverse risks associated with their products to physicians.
g. Bard withheld material information from FDA, physicians, and patients.
h. Bard inappropriately promoted its products.
i. Bard failed to objectively evaluate and take action concerning potential problems.
j. Bard's Avaulta Products were not "reasonably safe" and should not have been marketed.

(Kessler Report [Docket 113-2], at 8-9). Bard argues that Dr. Kessler's report "contains innumerable opinions that go far beyond the regulation of medical devices and the permissible scope for regulatory expert testimony." (Def. Bard's Mem. of Law in Supp. of its Mot. to Limit the Ops. & Testimony of David A. Kessler, M.D. [Docket 114], at 1) [hereinafter Bard's Mem. re: Kessler]. Bard moves to exclude the following opinions of Dr. Kessler:

> (1) legal opinions and legal standards regarding, *inter alia*, the state law duties applicable to Bard and the interplay between state law product liability law and federal regulations; (2) opinions regarding Bard's knowledge, motivation, state of mind, corporate conduct, or intent; (3) opinions regarding the safety of Bard's Avaulta devices and whether the devices were reasonably safe; (4) opinions regarding the design, manufacturing, and testing of Bard's Avaulta devices; (5) opinions regarding the adequacy of the warnings and labeling that Bard provided for its Avaulta devices; (6) opinions regarding the risks demonstrated for pelvic mesh in scientific and medical literature; (7) medical opinions, including those relating to causation, injuries, or other issues relating to specific plaintiffs; (8) opinions regarding "safety signals" for Bard's Avaulta devices; and (9) opinions regarding whether Bard allegedly violated FDA regulations or otherwise acted inappropriately in its 510(k) submissions, its disclosures to the FDA, its promotion of its products, and its post-marketing activities.

(*Id.* at 3-4). I will consider each of these arguments in turn. As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

**i. *Opinions Related to Bard and Others' Knowledge, Intent, or Motives***

Bard argues that "Dr. Kessler spends the majority of his voluminous Report summarizing and selectively quoting from internal corporate emails, literature in Bard's possession, deposition testimony of corporate employees, and internal company documents" without presenting any expert analysis of these facts. (*Id.* at 5) (internal citations omitted). Bard also argues that Dr. Kessler "also intertwines his own speculative views about the supposed knowledge and intent of Bard." (*Id.* at 6).

Dr. Kessler's expert report is replete with such types of expert opinions. For example, it appears that the entirety of Section VI of his report opines on what Bard knew and when Bard knew it. The plaintiffs argue that "[t]his is classic use of expert testimony to establish what was known and knowable to a defendant, and when it was known or knowable." (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Limit the Expert Ops. & Testimony of David A. Kessler, M.D. [Docket 152], at 8) [hereinafter Pls.' Resp. re: Kessler]. As discussed previously, however, while an expert may rely on these materials as part of the basis for their opinions, Bard's knowledge, intent, or motives are simply not appropriate subjects for expert testimony. The documents and testimony should be presented directly to the jury, not through an expert. To the extent that Dr. Kessler opines on Bard's knowledge, intent, or motives, such conclusions are factual inferences for the jury to determine, not for an expert to opine. Accordingly, I **FIND** that Dr. Kessler may not offer expert testimony on Bard's knowledge, intent, or motives.

### ii. *Opinions that are Impermissible Legal Conclusions*

In the Fourth Circuit, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Dr. Kessler's expert report seeks to draw various legal conclusions, which is properly the jury's role. For example, Section IX is entitled "Bard *failed to adequately disclose* adverse risks associated with their products," and subsection D states that "Bard *failed to warn on its label* . . . ." (Kessler Report [Docket 113-2], at 108, 120) (emphasis added). Section XVI is entitled "Bard's Avaulta products *were 'not reasonably safe*.'" (*Id.* at 170) (emphasis added). Such statements draw legal conclusions from facts. The questions of whether Bard's Avaulta products were not reasonably safe, for example, or whether Bard failed to warn, are questions for the jury, not for Dr. Kessler.

That is not to say that Dr. Kessler is precluded from offering expert testimony related to the FDA 510(k) framework and process, Bard's actions taken with respect to this framework and process, and form an expert opinion that embraces an ultimate issue, to the extent that it may be relevant and assist the jury. Under Federal Rule of Evidence 704, "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). The Fourth Circuit has explained that the "role of the district court . . . is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion." *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002). "The best way to determine whether opinion testimony contains legal conclusions, 'is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.'" *Id.* (quoting *Torres v. Cnty. of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)). Thus, Dr. Kessler may not offer an expert opinion that, for example, Bard's Avaulta products

were "not reasonably safe" or that Bard "failed to warn." Dr. Kessler may, however, offer a more general expert opinion, using terms that do not have a separate, distinct, and specialized meaning in the law.

Dr. Kessler's expert report also seeks to state legal standards, which is properly the court's role. The court will instruct the jury on Bard's duties and obligations under state law. Similarly, to the extent that the court finds it relevant, the interplay between FDA regulations and state tort liability is also the type of instruction that the jury will receive from the court. Accordingly, I **FIND** that Dr. Kessler may not offer expert opinions that state legal standards.

#### iii. *Opinions Relating to Bard's Disclosures to the FDA*

Bard argues that *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001) precludes the admission of Dr. Kessler's opinions regarding certain information that he believes Bard should have provided to the FDA. In short, *Buckman* held that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348. The plaintiffs argue that there are no such claims here, and therefore *Buckman* is inapplicable. I agree.

Nevertheless, the question remains as to the relevancy of Dr. Kessler's opinions to the instant case. As noted above, Dr. Kessler may not testify that Bard violated FDA regulations—such testimony would be drawing legal conclusions. However, Dr. Kessler may testify, for example, that Bard did not disclose certain information to the FDA that Dr. Kessler, as a former Commissioner of the FDA, would have found pertinent. These opinions are relevant to the instant matter because evidence of Bard's "efforts to manipulate the regulatory process" may be relevant to the state law claims at issue. *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006). Accordingly, I **FIND** that Dr. Kessler may offer

expert opinions related to Bard's disclosures to the FDA, as long as his opinions do not impermissibly draw legal conclusions.

**iv. *Opinions Relating to Product Design, Testing, and Labeling***

Bard argues that while Dr. Kessler "may be qualified to testify about federal regulation of medical devices," he is not qualified to offer any medical opinions or opinions on the design, testing or labeling of the Avaulta products. (Bard's Mem. re: Kessler [Docket 114], at 11-16). Bard argues that Dr. Kessler is not an expert in any of these areas because: (1) he has no expertise implanting or using pelvic mesh products; (2) he is not an engineer, biomedical engineer, biomaterial engineer, or pathologist, and; (3) he is not an expert on the products, has no expertise as to what risk information or instructions would be appropriate for a urogynecologist performing a mesh implantation procedure, and has no experience drafting medical device warnings.

Federal Rule of Evidence 702 notes that a witness may be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Rule 703 further notes that experts may base their opinions on facts or data that they have "been made aware of or personally observed." Fed. R. Evid. 703. Through his experience as Commissioner of the FDA, Dr. Kessler has obtained expertise regarding these matters. For example, he testified:

> Q. You're not a biomaterials expert, are you?
>
> A. I am certainly have – with regard to these issues as they interact with the regulatory process, I have expertise. And have dealt with some of the most complex biomaterials issues, as I'm sure you're well aware, I mean, over the – you know, while at FDA. And so I – you know, I – I do – but in the context of the regulatory environment.
>
> . . .
>
> Q. Outside of regulatory, do you have any expertise in biomaterial analysis?

> A. As – as – as you would have in – in training, both medical and scientific training. And I've – again, so I certainly have expertise that exceeds, I mean, through medical and scientific training, but I've – you know, again, people – there should be – there should be biomaterials experts. My – my usefulness is how biomaterials can interact with the regulatory process –

(Kessler Dep. [Docket 113-1], at 176:22-177:4; 178:11-178:20). In sum, as long as Dr. Kessler's expert opinions on product design, testing, and labeling are given in the context of the FDA regulatory process, I **FIND** that he is qualified to offer such opinions The reliability of such opinions is another issue, however, as discussed below.

#### v. *Reliability of Dr. Kessler's Opinions Relating to Product Safety, Design, Testing and Labeling, and Bard's Promotion of its Products, Safety Signals, and Post-Marketing Activities*

Bard attacks the reliability of Dr. Kessler's opinions, arguing that "his Report is entirely devoid of an independent, objective, and scientifically valid method in reaching his opinions." (Bard's Mem. re: Kessler [Docket 114], at 17). A review of Dr. Kessler's lengthy report reveals that some of his expert opinions are sufficiently reliable, while others are not. Taking, for example, Section VII, Dr. Kessler first states that "[t]o be substantially equivalent, a device cannot raise new questions about safety and effectiveness." (Kessler Report [Docket 113-2], at 80). Dr. Kessler then discussed the differences between the Avaulta products and their predicate products, and relied upon Bard documents, testimony, and scientific literature in Bard's possession in forming his opinions that the Avaulta devices do, in fact, raise new questions about safety and effectiveness.[15] Dr. Kessler's opinions regarding the adequacy of product labeling and warnings and safety signals similarly appear to be reliable with references to medical publications and documentation of risks and adverse events. Accordingly, I **FIND** that Dr.

[15] Dr. Kessler's report refers several times to "scientific literature in Bard's possession." (*See, e.g.*, Kessler Report [Docket 113-2], at 90).

Kessler's opinions related to product safety, design and labeling and warnings are sufficiently reliable to be admissible.

In contrast, Dr. Kessler's opinion that Bard needed to conduct human clinical trials is an example of an opinion that is not reliable. In essence, Dr. Kessler summarized the reasons for conducting human clinical trials, identified risks of the mesh products, and concluded on these bases that Bard should have conducted clinical trials. This opinion is based on his personal opinion, rather than any reliable basis.[16] Dr. Kessler's opinions related to Bard's promotion of its products and post-marketing activities should similarly be excluded. Accordingly, I **FIND** that Dr. Kessler's opinions related to human clinical trials and Bard's promotion of its products and post-marketing activities should be excluded.

#### vi. *Opinions Related to Specific Causation*

Both parties agree that Dr. Kessler will not provide any opinions related to specific causation. Additionally, to the extent that Dr. Kessler opines on issues of general causation, I **FIND** that such opinions should be excluded. Dr. Kessler, as a regulatory expert, is not qualified to render opinions "on the risks of injury and damage caused by Bard's Avaulta products." (Pls.' Resp. re: Kessler [Docket 152], at 13).

### I. *Ahmed El-Ghannam, Ph.D.*

Dr. El-Ghannam is a biomaterials and bioengineering expert retained by the plaintiffs primarily to offer opinions on the design of the Avaulta mesh products, particularly on the issue of polypropylene degradation. Bard identifies four sets of Dr. El-Ghannam's opinions that it challenges: (1) specific causation; (2) design defects; (3) manufacturing processes; and (4) the adequacy of Bard's FDA qualifying tests. Bard argues that Dr. El-Ghannam is not qualified to

[16] At times, it appears that the plaintiffs conflate qualification with reliability. Certainly, Dr. Kessler is *qualified* as former Commissioner of the FDA to offer expert opinions on testing; however, his opinions must still be grounded in reliable methodology and principles. Fed. R. Evid. 702.

render any of the opinions that he seeks to offer and that his foundations are unreliable. As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

**i. *Opinions Related to Specific Causation***

Bard argues that Dr. El-Ghannam may not testify as to specific causation. I agree. It appears that Dr. El-Ghannam is qualified by virtue of his education, experience and training as a biomedical engineer to testify as to causation—how the Avaulta mesh "affects the biological system." (El-Ghannam Dep. vol. II [Docket 130-3], at 323:21). Nothing in his expert report, however, suggests that he is offering an opinion that any of the particular bellwether plaintiffs was injured by the Avaulta mesh that was implanted in them. (*See generally* El-Ghannam Report [Docket 130-1]). Rather, it seems that Dr. El-Ghannam opines that the degradation of polypropylene is one of the causes for the product's failure inside the body generally. Moreover, while the plaintiffs argue that Dr. El-Ghannam is "qualified to testify regarding specific injury causation," that section of their response argues that Dr. El-Ghannam is qualified to testify as to causation and makes no argument regarding *specific* causation.[17] (Pls.' Resp. in Opp'n to Def. Bard's Mot. to Exclude the Ops. & Testimony of Ahmed El-Ghannam, Ph.D. [Docket 166], at 4) [hereinafter Pls.' Resp. re: El-Ghannam]. Accordingly, I **FIND** that Dr. El-Ghannam may not offer any expert opinions as to specific causation.

[17] The plaintiffs cite and quote *Thorpe v. Davol, Inc.*, MDL No. 07-1842ML, 2011 WL 470613, at *25 (D.R.I. Feb. 4, 2011) to support this argument. The basis for Dr. El-Ghannam's conclusion here and Dr. Ducheyne's conclusion in *Thorpe* appear to differ. For example, in *Thorpe*, Dr. Ducheyne personally observed the plaintiff's explanted product and explained in detail how he arrived at the conclusion that it broke. Here, at most, Dr. El-Ghannam has only tested and analyzed explanted mesh from "certain of these bellwether Plaintiffs." (Pls.' Resp. re: El-Ghannam [Docket 166], at 5). Perhaps in part because Dr. El-Ghannam did not intend to offer specific causation opinions in this case, he does not seem to have a sufficiently reliable basis for doing so.

### ii. *Opinions Related to Design Defects*

Dr. El-Ghannam seeks to render opinions regarding the degradation of polypropylene pelvic mesh. Bard first argues that Dr. El-Ghannam is not qualified to opine on the degradation of the specific material at issue, polypropylene. Dr. El-Ghannam is certainly qualified in the field of biomaterials and biomedical engineering – he is educated and his professional experience has focused in this field. For example, he testified that:

> Q. You're not an expert in the design of surgical mesh, are you?
>
> A. I'm an expert in biomaterials, and a surgical mesh an implant material. So I am – I know how to analyze the composition and structure, I know what is required for a material to be biocompatible, I know what is the effect of persisting conditions on the structure of the material, I know what parameters would affect the properties of the material, whether these parameters are related to the persisting conditions or the environment during service inside the patient. So I know biomaterials and whatever related to the behavior of the material or the response to this material when it is implanted into the body.

(El-Ghannam Dep. vol. II [Docket 130-3], at 343:23-344:13). Moreover, he testified:

> A. . . . I wanted to emphasize again here one important point. The surgical mesh is used as an implant inside the patient, and as I said earlier whether it's a surgical mesh or it is a titanium implant or it is a ceramic material, as long as this material is going to be inserted into the body, it has to be biocompatible. So the biocompatibility is a preliminary test that's not related what kind of materials or what is the physical shape of this material should be.

(*Id.* at 345:1-345:11). Finally, he testified:

> Q. What do you consider your subspecialty to be?
>
> A. I'm a biomaterialist.
>
> Q. And have you had additional training in biomaterials beyond your medical degree, biomedical engineering degree?
>
> A. That's – that's what I am.
>
> Q. Okay.

A. I'm a biomaterialist. I do evaluation of biomaterials, I do development of new biomaterials or modify biomaterials, study them.

Q. Other than your work on this litigation, what other implantable medical devices have you worked on?

A. That's all my career. That's what I do for living.

(El-Ghannam Dep. vol. I [Docket 130-3], at 232:7-232:22). Bard points out that Dr. El-Ghannam's history in biomaterials has concentrated in the bioceramic area. (*Id.* at 232:23-233:12). However, testimony also revealed that he has some experience with polymeric material:

Q. You have not conducted, outside of litigation, biomaterials testing on medical devices made of polymeric material; is that correct?

A. As I indicated early on, I included polymethylmethacrylate as a carrier for antibiotics in my study to compare it with the ceramic.

Q. As a control?

A. As a control, yes.

Q. Right. But other than that, nothing else?

A. There was a student who got her Master thesis in working with polylactic acid, polyglycolic acid, and bioceramic composites. So we mixed the polymer with the ceramic and then studied the response to this composite.

Q. And that was your student?

A. One of my students, yes.

(*Id.* at 233:13-234:3). I have some concerns about Dr. El-Ghannam's qualifications to testify specifically as to the properties of polypropylene. However, in sum, Dr. El-Ghannam has extensive education and experience in biomaterials generally—which include polymers—and particularly as it relates to materials implanted in the human body. Accordingly, I **FIND** that Dr. El-Ghannam has demonstrated sufficient knowledge of the area of polypropylene to qualify him to offer opinions on design defects.

Next, Bard argues that Dr. El-Ghannam's design defect opinions are unreliable because his scanning electron microscopy ("SEM"), Fourier transform infrared spectroscopy ("FTIR") and Gel Permeation Chromatography ("GPC") testing lacked methodology and was unreliable. Bard makes arguments regarding Dr. El-Ghannam's "[u]nreliable record keeping" and note taking, his "lack of testing protocols," his "[u]nreliable handling of mesh samples," his "[u]nreliable tissue culture immersion and bleach testing," and his "[u]nreliable removal of biologics and contaminants on explant samples." (Def. Bard's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Testimony of Ahmed El-Ghannam, Ph.D. [Docket 131], at 8-12) [hereinafter Bard's Mem. re: El-Ghannam]. Essentially, Bard contends that while the tests themselves are ordinarily reliable, Dr. El-Ghannam conducted the tests in an unreliable manner and therefore, his opinions derived from the tests should be excluded. The plaintiffs respond by merely citing to Dr. El-Ghannam's Supplemental Rule 26 Report, which purports to address "in detail each of the critiques of his testing by Bard's experts, including his alleged improper cleaning and handling of the mesh samples." (Pls' Resp. re: El-Ghannam [Docket 166], at 9 n.10).

Dr. El-Ghannam's supplemental report does not address all of the methodology issues Bard presented. Upon review of his deposition testimony, I have some concerns about the reliability of the methodology that he used. First, for example, Dr. El-Ghannam did not appear to follow any written protocols in conducting his tests:

> Q. When you did the tissue culture medium testing, were you following any kind of a written protocol?
>
> A. No.
>
> Q. Did you write out the protocol that you were following as you did it?
>
> A. I did. I didn't bring that with me. I will send that to you.

(El-Ghannam Dep. vol. I [Docket 130-3], at 142:2-142:9). However, he had previously testified:

> Q. What is the literature you're relying on to establish that it's appropriate to use a tissue culture medium to evaluate the potential degradation of a polymer?
>
> A. This is the common test that all research groups who work on developing new materials or studying modifications of materials or biomaterials will do. And this is also in – so it's very common in the literature. It's very common also in the books.
>
> . . .
>
> A. . . . If you go to the literature, it's – that's what every bioengineer is doing, to evaluate the response or the interaction between the material and tissue fluids. In my – in my own research, that's what I do. And for my Ph.D., that's what I did. For – for people who work with wide variety of material, this is A, B, C biomaterials evaluation.

(*Id.* at 122:15-123:16). Additionally, his supplemental report notes that he has been using SEM and FTIR testing since 1984. (El-Ghannam Supplemental Report [Docket 130-2], at 1).

Second, Dr. El-Ghannam's handling of the pristine mesh samples is of some concern. For example, his supplemental report states: "[t]he pristine implant is taken from the box so it does not have any biological contaminants." (*Id.* at 28). More specifically, "[t]he pristine Avaulta polypropylene samples were taken from the original Bard packages to the FTIR machine for analysis without any treatment." (*Id.*). During deposition, however, he testified:

> Q. First of all, how do you cut the sample?
>
> A. With a scissor.
>
> Q. Just the scissors on your desk?
>
> A. Just a scissor on the lab, yes. Scissor that I get from the lab.
>
> . . .
>
> Q. . . . So you go into your office. Do you take the scissors back with you?

A. Well, the scissors are everywhere.

(El-Ghannam Dep. vol. I [Docket 130-3], at 24:9-24:13; 27:17-27:19). While this in and of itself may not necessarily indicate that the mesh samples were contaminated, it is certainly *possible* that Dr. El-Ghannam's use of nothing more than "a good pair of scissors"—with no indication that the scissors were cleaned or sterilized prior to use—could have contaminated the pristine mesh samples on their way to being tested. (*Id.* at 24:19).

Third, Dr. El-Ghannam used bleach to clean tissue from the explants, and immersed the pristine implants to test any effect that bleach may have had on the polypropylene:

> A. The goal for immersing the pristine implant in the bleach is to mimic the same immersion treatment that I do for the explants that has tissues. So when I immersed the samples that has tissues in the bleach to remove the tissues, I also wanted to see what would happen to the pristine if it were to be immersed in the same solution.

(*Id.* at 150:20-151:7). Dr. El-Ghannam was unable to point to any part of his report where he compared the pristine implants without bleach to the pristine implants with bleach, however:

> Q. Can you show me in the report where there's a comparison from the pristine implants to the pristine implants treated with bleach?
>
> A. The only part that I found is that on page 2 where I see in the second paragraph under the title, Scanning Electron Microscope, on line number 3, I just reported here, other pristine samples were also immersed in the bleach, NaOCI, and analyzed by SEM. See Exhibit 14, photomicrographs. The details of my analyses are described below. And I really did not see part of the discussion after that about the comparison.
>
> Q. You did not?
>
> A. I did not.

(*Id.* at 176:12-176:25).

When Dr. El-Ghannam used bleach to clean tissue from the explants, the method he used to evaluate whether material was left behind was simply by "eyeballing" it:

Q. Do you do anything further at that point to ensure that all the tissue is removed from the mesh other than the eyeball evaluation that you've done after it comes out of the incubator?

A. I do scanning electron microscope analysis.

Q. Before that, is there any other test or step you take to ensure that there's no tissue remaining?

A. No, I don't.

(*Id.* at 206:20-207:4). In short, while Dr. El-Ghannam adamantly believes that questions about possible artifacts in his analysis have no basis, the above examples make clear that there is *some* basis for questioning his methodology in conducting the SEM and FTIR testing. Dr. El-Ghannam's methodology is certainly not flawless. However, I **FIND** that it is minimally satisfactory to pass a *Daubert* challenge, and is more properly tested at trial during cross-examination and the testimony of counter experts.

Finally, although Bard spends another several pages arguing that "Dr. El-Ghannam's degradation opinions are flawed and unreliable," its remaining arguments are based on his ultimate conclusions. (Bard's Mem. re: El-Ghannam [Docket 131], at 12). For example, Bard argues that Dr. El-Ghannam's "images are instead evidence of foreign materials," (*Id.* at 13), and that certain conclusions are "simply and demonstrably inaccurate." (*Id.*). In short, experts can disagree on their opinions and conclusions, as long as they are based on reliable principles and methods. Fed. R. Evid. 702. I **FIND** that Dr. El-Ghannam's testing methodology is sufficiently reliable for his design defect opinion to pass a *Daubert* challenge.

**iii. *Opinions Related to Manufacturing Process***

Bard argues that Dr. El-Ghannam is not qualified to opine on the manufacturing process, and that his opinions are unreliable and nothing more than *ipse dixit* opinions. After review of Dr. El-Ghannam's deposition testimony and his supplemental report, it appears that he is

qualified—and his opinions are reliable—to an extent. With respect to the heating process, Dr. El-Ghannam has explained adequately and with sufficiently reliable basis in his deposition testimony and supplemental report, the effects of subjecting the polypropylene material in the Avaulta mesh to the heat during the manufacturing process. (*See generally* El-Ghannam Supplemental Report [Docket 130-2]). However, with respect to the knitting process, Dr. El-Ghannam testified, in part:

> Q. How are these – can you – do you understand how the knitting process works for these implants?
>
> A. I have an idea, but really I'm not a textile engineer.
>
> Q. Okay. So you're not – textile engineering is not an area of your expertise?
>
> A. No, it's not.
>
> Q. And you've not carefully reviewed the manufacturing documents to see and understand how the knitting process is conducted, correct?
>
> A. Correct.

(El-Ghannam Dep. vol. I [Docket 130-3], at 272:16-273:2). Accordingly, I **FIND** that Dr. El-Ghannam may opine on the manufacturing process as it relates to temperature, but not as it relates to the knitting process of the mesh.

#### iv. *Opinions Related to the Adequacy of Bard's FDA Qualifying Tests*

Because the plaintiffs do not intend for Dr. El-Ghannam to testify regarding the sufficiency of Bard's 510(k) testing, such opinions are excluded. With respect to the "stiffness" measurements set forth in Dr. El-Ghannam's Rule 26 report at pages 26-27, Dr. El-Ghannam does not appear to provide any reliable basis supporting this opinion. Dr. El-Ghannam states that "[t]his is a further defect with this mesh as the variation of the degree of stiffness would result in improper transduction of the mechanical signal between the components of the same mesh." (El-

Ghannam Report [Docket 130-1], at 26). The plaintiffs do not point to any basis from scientific literature or otherwise for Dr. El-Ghannam's opinion on this issue. Accordingly, I **FIND** that Dr. El-Ghannam may not opine on the "stiffness" measurements regarding Avaulta mesh.

### J. *Anthony B. Brennan, Ph.D.*

Dr. Brennan is a biomaterials and biomedical engineering expert retained by the plaintiffs primarily to offer opinions on the design of the Avaulta mesh products. Bard notes three particular areas that Dr. Brennan criticizes: "(1) the biocompatibility and stability of the Avaulta mesh products; (2) the pore size of the Avaulta products; and (3) Bard's measurements of the pore size and failure to test the 'effective pore size' dimensions under load." (Def. Bard's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Testimony of Anthony B. Brennan, Ph.D. [Docket 128], at 1) [hereinafter Bard's Mem. re: Brennan]. Bard argues that Dr. Brennan is not qualified to render any of his opinions and that his opinions are neither reliable nor relevant. At the outset, I note that Bard's arguments as to the admissibility of Dr. Brennan's opinions are substantially similar to, and based in part, on its arguments as to the admissibility of Dr. El-Ghannam's opinions.

#### i. *Qualifications*

Bard argues that Dr. Brennan lacks the qualifications to testify as to polypropylene surgical mesh. Bard's arguments here are nearly identical to its arguments against Dr. El-Ghannam's qualifications. *See supra*, Section I. Here, Dr. Brennan also clearly has extensive education and experience in biomaterials generally. His expert report notes that he is "knowledgeable about a number of chemical fields including polymeric biomaterials, polymeric materials . . . [and] physical and chemical aging of polymers and nanocomposites." (Brennan Report [Docket 127-1], at 2). In sum, he appears even more qualified than Dr. El-Ghannam in

this particular subject. Accordingly, I **FIND** that Dr. Brennan is qualified to offer opinions on the design of the Avaulta mesh.[18]

**ii. *Reliability of Opinions Related to Degradation and Molecular Weight***

Next, Bard argues that Dr. Brennan's opinions are unreliable because he did not review sufficient data and his opinions were "predicated upon Dr. El-Ghannam's scientifically unreliable and inadmissible images and findings." (Bard's Mem. re: Brennan [Docket 128], at 6). As previously discussed, I ruled that Dr. El-Ghannam's opinions are based on sufficiently reliable methodology to pass a *Daubert* challenge. Moreover, after reviewing Dr. Brennan's expert report, cited literature and deposition testimony, I **FIND** that Dr. Brennan relies on sufficient and reliable scientific literature.[19] For example, while Bard takes issue with Dr. Brennan's reliance on literature produced by plaintiffs' counsel, Dr. Brennan testified that he requested additional literature:

> Q. So the medical literature that you reviewed in order to prepare your expert report was literature that is provided to you by the plaintiffs' lawyers, right?

---

[18] Bard argues that Dr. Brennan admitted he was not an expert on the design of pelvic mesh, citing his deposition testimony:

> Q. You are not an expert in the design of pelvic mesh, is that correct?
>
> A. Correct.

(Brennan Dep. vol. I [Docket 127-2], at 67:20-67:22). Dr. Brennan's expert report discusses his opinion that "[f]rom a biomechanical viewpoint, the Avaulta mesh products and female pelvic tissue are not compatible. The Avaulta mesh fibers degrade after implantation into women. . . ." (Brennan Report [Docket 127-1], at 2-3). While it may be obvious to one trained in the legal profession that Dr. Brennan is opining on issues related to the design of the Avaulta mesh products because he is opining on the materials from which the Avaulta mesh products are designed, it is also somewhat obvious that Dr. Brennan believes there is a difference between being an expert in "the design of pelvic mesh" and being an expert that is qualified to testify regarding the material properties and characteristics and the biocompatibility of the mesh.

[19] Disagreements in the literature or conclusion do not preclude an expert from testifying, as long as the expert's testimony "will help the trier of fact" and is "based on sufficient facts or data" and the "product of reliable principles and methods" that are applied "to the facts of the case." Fed. R. Evid. 702.

A. Not exactly.

Q. Okay. What is the "not exactly" part of that statement?

A. Because a lot of the literature, I – I pull and ask them to get for me.

Q. Okay.

A. So they provide it, but it's because I have asked for it directly, you know, by reviewing the literature.

. . .

A. And so I asked them to bring me literature, and then I asked them for literature on subjects that I wanted to look at.

(Brennan Dep. vol. I [Docket 127-2], at 98:4-99:10). It is also clear that, in forming his opinions, Dr. Brennan relied on more than just Dr. El-Ghannam's data and opinions. Dr. Brennan did, of course, review the data from Dr. El-Ghannam's testing and consider the data; however, he did so in the process of reaching his own independent conclusions and opinions.[20] Accordingly, I **FIND**

[20] Dr. Brennan testified:

Q. Did you see evidence of artifacts or contamination in the SEM images that you reviewed?

A. There were some indications of material build-up on the polypropylene fibers for some of the explants. I think I – I included that in my expert report that there was.

Q. And what – you said there were indications of material build-up on the polypropylene fibers in some explants. Were you able to determine what those materials were?

A. No. I did not go in and look at them in detail. I think it's important that – it's – I don't know how to say this in this setting. But I try to teach my students to be careful they don't get caught up in the wrong information that's facing them. And on those fibers that I included that had some extra material on the surface they had such substantial cracking and degradation in the surface that it becomes almost a nonissue what the additional material might be on that surface.

(Brennan Dep. vol. II [Docket 127-2], at 268:16-269:11).

that Dr. Brennan's opinions regarding degradation and molecular weight are based on sufficient and reliable facts and data.

#### iii. *Reliability of Opinion Related to Oxidation*

Bard argues that Dr. Brennan's assertion that polypropylene fibers degrade in the human body through the oxidative process is unreliable and flawed because (1) it is derived from Dr. El-Ghannam's data and (2) it ignores a fundamental scientific principle that "[o]xidative degradation of polypropylene materials leads to discoloration or browning." (Bard's Mem. re: Brennan [Docket 128], at 11-12). I have already addressed above Bard's arguments regarding Dr. Brennan's use of Dr. El-Ghannam's data. With respect to the fundamental scientific principle that Bard argues, I note that the Exponent Report states: "Oxidative degradation of polypropylene materials *can* lead to discoloration (e.g., browning)." (Exponent Report [Docket 127-4], at 148) (emphasis added). The fact that oxidation can lead to discoloration does not mean that it necessarily will. Accordingly, I **FIND** that Dr. Brennan's opinion regarding oxidation is not unreliable.

#### iv. *Reliability and Relevance of Opinions Derived from Tensile Testing and Pore Size Measuring*

Bard argues that Dr. Brennan's tensile testing is irrelevant to the instant matters because it is not applied "to the facts of the case." Fed. R. Evid. 702. Dr. Brennan did his tensile testing in an attempt to replicate Bard's testing: "I tried to discern what Bard had done, and that is what this test in Figure 6 was about was trying to replicate that." (Brennan Dep. vol. I [Docket 127-2], at 185:13-185:16). Bard also argues that Dr. Brennan's opinions concerning inadequate pore size should be excluded. According to his report, Dr. Brennan seeks to offer three different opinions regarding pore size, which appear to rely, in part, on his tensile testing:

> [1] Bard incorrectly measured and misrepresented the size of Avaulta mesh pores at rest and did not consider smaller pores when making measurements. [2] Bard did not test the most important aspect of the pores, which is the effective dimension under load. Deformation of the mesh product during and after implantation decreases the size of the pores. [3] The pore sizes did not allow for adequate tissue ingrowth and caused excessive scarring and encapsulation of the Avaulta mesh product.

(Brennan Report [Docket 127-1], at 3). 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 applied to the facts of the case.

### K. *Arnold L. Lentnek, M.D., FACP*[21]

Dr. Lentnek's expert report sets forth several opinions. First, he opines that "Carolyn Jones developed repetitive vaginal erosions with exposure and ultimately partial extrusion of the prosthesis" approximately fifteen months after implantation of Bard Avaulta products. (Lentnek Report [Docket 105-2], at 4). Next, he offers the opinion that the "pattern of local irritation associated with formation of granulation tissue and ultimately with partial extrusion" was not the result of infection, but is "typical of a submucosally implanted foreign body that fails to become incorporated within the submucosal stoma." (*Id.* at 4-5). Bard does not take issue with Dr. Lentnek's opinion that Ms. Jones's inflammation was not the result of infection, but rather the presence of a foreign body. (*See* Def. Bard's Mem. of Law in Supp. of its Mot. to Limit the Ops.

[21] Dr. Lentnek's opinions are offered only for one bellwether plaintiff, Carolyn Jones. Accordingly, all citations to the docket in this section are to the *Jones* case.

& Testimony of Arnold Lentnek, M.D. [Docket 106], at 1) [hereinafter Bard's Mem. re: Lentnek]. Bard does, however, take issue with Dr. Lentnek's remaining opinions. First, Bard takes issue with opinions related to the material used in the Avaulta mesh products:

> Such objects, due either to fiber pattern, fiber pore size or chemical composition, do not permit the in-growth of fibrous tissue through the material and instead become surrounded by a fibrous capsule around the material. They thus fail to become firmly anchored within the submucosal tissues. This failure of fibrous in-growth and consequent incorporation into the soft tissue permits the object to shift slightly with normal body movement. Over time this constant shifting results in local tissue inflammation and ultimately in erosion through the adjacent mucosa.

(Lentnek Report [Docket 105-2], at 5) (emphasis in original). Bard also takes issue with Dr. Lentnek's opinions related to causation: "To a reasonable degree of medical probability, this failure of fibrous in-growth and soft tissue incorporation resulted in local irritation and ultimately in extrusion of both the Align sling as well as the anterior and posterior vaginal mesh." (*Id.*). Finally, Bard argues that Dr. Lentnek has no basis for offering any opinion on the risk of future erosions or need for additional surgeries. (*See id.*) ("Ms. Jones remains at increased risk of developing future instances of vaginal erosion with . . . the need for additional surgical procedures."). As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

#### i. *Opinions Related to Materials*

Bard argues that Dr. Lentnek is not qualified to testify about the specific material used in the Avaulta products, that his opinions are not reliable, and that he abandoned this opinion during deposition. With respect to qualifications, Bard argues that Dr. Lentnek is not qualified to render the opinion that the Avaulta products "due either to fiber pattern, fiber pore size, or chemical composition, do not permit the in-growth of fibrous tissue through the material . . ." and that the lack of such in-growth "permits the [mesh product] to shift slightly with normal body movement," which ultimately "results in local tissue inflammation and ultimately in

erosion through the adjacent mucosa." (Bard's Mem. re: Lentnek [Docket 106], at 6) (emphasis in original). Bard argues that Dr. Lentnek is not an expert in biomaterials and biomechanics and has no specialized training, knowledge or experience in "any of the relevant medical specialties" such as urogynecology. (*Id.*). I agree in part.

Dr. Lentnek testified, for example:

> Q. And the assignment you were hired, retained as an expert for your expertise in infectious disease; is that correct?
>
> A. Yes. Well, infectious disease and my knowledge of the potential inflammatory properties of implanted prosthetic devices, yes.
>
> Q. Let's talk about that for a little bit. What type of experience do you have in that area, sir?
>
> A. Well, in my practice we routinely see individuals who have had various materials implanted in their body, be it prosthetic joints, prosthetic cardiac valves, or prosthetic mesh as in the case here, and that forms a considerable portion of the practice.
>
> . . .
>
> Q. What are the reasons why [the prosthesis] may not take?
>
> A. They can be mal-positioned and therefore can be in a position where they cause local irritation and ultimately rejection. There can be mechanical and/or chemical properties to which the body will react and therefore reject material; they can become infected, and therefore, again the body will react to not only the bacteria but to the material as well and reject them. . . .

(Lentnek Dep. [Docket 105-1], at 12:12-12:25; 13:5-13:14). I **FIND** that Dr. Lentnek is qualified, based on his role as an infectious disease specialist, regarding the causes of infection and inflammation. His role includes the determination of *why* inflammation exists, and his knowledge and experience include pelvic repair mesh devices. (*See, e.g.*, Lentnek Dep. [Docket 105-1], at 53:16-54:6). However, I also **FIND** that Dr. Lentnek is not qualified to testify specifically that the failure of fibrous in-growth was the result of "fiber pattern, fiber pore size or

chemical composition" because this opinion exceeds the scope of his qualifications. (Lentnek Report [Docket 105-2], at 5).[22]

**ii. *Opinion on Future Erosions and Need for Additional Surgeries***

Bard argues that Dr. Lentnek's opinion that the plaintiff "remains at an increased risk of developing future instances of vaginal erosion with . . . the need for additional surgical procedures" should be excluded. (Bard's Mem. re: Lentnek [Docket 106], at 12). Bard, again, argues that Dr. Lentnek is not qualified to render this opinion and that this opinion is not based on sufficient facts or data. I disagree. Dr. Lentnek testified:

> A. I have had individuals routinely who have had perivaginal and pelvic inflammatory conditions, including infection. I have treated those individuals. And I have read about and see both short and long-term complications of that condition. So I think I can offer an informed judgment about what condition she is prone to develop. I don't know that she absolutely will develop those conditions but I do know what kind of conditions she is susceptible to.

(Lentnek Dep. [Docket 105-1], at 108:20-109:4). As a result of Dr. Lentnek's experience in his area of expertise, he has gained the knowledge and experience to qualify him to testify as to the risk of future erosions and the need for additional surgical procedures due to the residual tape and mesh left in place inside the plaintiff. Additionally, based on his review of the plaintiff's medical history and his own experience and knowledge, Dr. Lentnek appears to have relied upon sufficient facts or data to reach this opinion. Accordingly, I **FIND** that Dr. Lentnek may offer the opinion that the plaintiff "remains at increased risk of developing future instances of vaginal

[22] I therefore do not reach Bard's argument regarding the reliability or abandonment of this opinion. Without the specific testimony regarding fiber pattern, pore size, or chemical composition, Dr. Lentnek's opinion on this issue is limited to the opinion that the plaintiff's inflammation was caused by the Avaulta mesh and his understanding, without referring to the design or materials of the mesh, of how and why the plaintiff's inflammation was caused by the mesh. A review of Dr. Lentnek's curriculum vitae and deposition testimony reveals that he is qualified to render opinions on these matters and that he has relied upon sufficient bases.

erosion with . . . the need for additional surgical procedures." (Lentnek Report [Docket 105-2], at 5).

### L. *Julia E. Babensee, Ph.D.*

Dr. Babensee's expert report sets forth her primary opinion that "the most concerning aspect of the Avaulta devices is their lack of biocompatibility." (Babensee Report [Docket 155-4], at 4). Dr. Babensee's opinion regarding lack of biocompatibility is broken up into several different factors, including an incompatibility between the polypropylene mesh and the pelvic tissue and polypropylene degradation *in vivo* through oxidation. (*See generally id.* at 6-9). Dr. Babensee also opines on causation. (*See, e.g.*, *id.* at 9) ("Cumulatively, it is my opinion that the host responses to the Avaulta devices demonstrated by Queen, Cisson, Jones, and Smith are similar and consistent with that observed in the majority of other similarly implanted women."). Bard argues for the exclusion of Dr. Babensee's opinions related to polypropylene, including its degradation, and for the exclusion of her opinions related to causation. Finally, Bard argues that Dr. Babensee testified to an opinion regarding porosity during her first deposition which she did not disclose in her Rule 26 expert report, and therefore the opinion should be excluded. Bard attacks both Dr. Babensee's qualifications and her methodology. As discussed below, Bard's motion is **GRANTED in part** and **DENIED in part**.

#### i. *Qualifications – Polypropylene*

Bard argues that Dr. Babensee is not qualified to render opinions related to polypropylene or the theory of its degradation. Bard's arguments here are similar to its arguments regarding Dr. El-Ghannam and Dr. Brennan's qualifications. *See supra*, Sections I & J. In short, Bard argues that Dr. Babensee's education was in chemical engineering and applied chemistry, she has no background or experience with polypropylene outside of litigation, and she has no experience

with medical devices outside of litigation. (*See* Def. Bard's Mem. of Law in Supp. of its Mot. to Limit the Ops. & Testimony of Julia E. Babensee, Ph.D. [Docket 155], at 3-6) [hereinafter Bard's Mem. re: Babensee].

A review of Dr. Babensee's curriculum vitae and deposition testimony reveals that while her education was in chemical engineering and applied chemistry, her postdoctoral work and research have focused in the area of biomaterials and biomedical engineering. (*See, e.g.*, Babensee Curriculum Vitae [Docket 155-3]). One of her areas of research is host responses to implantable biomaterials, and she has previously studied implantable materials generally. (*See* Babensee Dep. vol. I [Docket 155-1], at 105:20-107:12). In short, while Dr. Babensee may not have background or experience in the specific area of polypropylene or with medical devices specifically, she is qualified to testify as to the host response to the Avaulta mesh products because of her general background and experience in the area of studying implantable materials in the human body and studying the effects thereof. Moreover, because she studies the interaction between implanted materials and human tissue, she necessarily has experience studying what happens to the implanted materials and human tissue. Accordingly, she is qualified to testify as to the theory of degradation in polypropylene. In sum, I **FIND** that Dr. Babensee is qualified to render opinions related to polypropylene.

**ii.** ***Opinions Related to Degradation***

Bard argues that Dr. Babensee's opinions rely on (1) her histological observations and (2) Dr. El-Ghannam's testing, and that both are unreliable. Bard contends that Dr. Babensee's histology observations are unreliable because (a) in some instances, there was a delay between her observation of a slide and the creation of a photomicrograph of the slide and (b) her methodology for analyzing and documenting her slide observations exhibit "grave

inconsistencies." (Bard's Mem. re: Babensee [Docket 155], at 14). Bard then contends that "all of [Dr. Babensee's] purported opinions rely upon the unscientific and unreliable testing of Dr. Ahmed El-Ghannam, Ph.D." and that she was unaware of the methodology Dr. El-Ghannam employed to create the SEMs. (*Id.* at 15). The plaintiffs have responded to each of these points. In sum, it appears that Dr. Babensee's histology analysis is based on sufficiently reliable methodology. She explained the methodology of how she received or prepared the slides, what she did when she went through each slide and the notes that she took. (*See generally* Babensee Dep. vol. I [Docket 155-1], at 226-243). The notes and charts are imperfect, but Dr. Babensee testified:

> Q. So Exhibit 11, just so when we all leave here we understand this, has representative histological observations, but you did not intend to nor did you provide observations on every slide?
>
> A. Only because they were the same as what was already written here.

(*Id.* at 246:25-247:6). She also testified that even though she did not specifically write about every slide, she looked at them all. (*Id.* at 246:17-246:24). With respect to her degradation opinions, although she did review Dr. El-Ghannam's SEMs, she did so in combination with her review of peer-reviewed literature to reach her own independent conclusions and opinions. She also testified that the SEMs were not a problem to her because "the end product is representative of what I would expect SEMs to look like of – of this kind of mesh material." (*Id.* at 219:16-219:18). Accordingly, I **FIND** that Dr. Babensee's testimony related to polypropylene and specifically, degradation of polypropylene, is admissible.

### iii. *Opinions Related to Specific Causation*

Bard first argues that Dr. Babensee is not qualified to render causation opinions. A review of Dr. Babensee's expert report, curriculum vitae and deposition testimony reveals that she is qualified to render causation opinions in this matter based on her experience in pathology.

Bard then argues that Dr. Babensee's causation opinion is not relevant and will not assist the jury. Dr. Babensee's expert report offers the opinion that "the host responses to the Avaulta devices demonstrated by Queen, Cisson, Jones, and Smith are similar and consistent with that observed in the majority of other similarly implanted women." (Babensee Report [Docket 155-4], at 9) (emphasis added). She further opines that:

> It is my opinion that if an Avaulta device has been implanted in a woman, and the woman develops complaints such as pain, dyspareunia, infection, vaginal shortening, scarification and urinary and defecatory dysfunction, that more likely than not, to a reasonable degree of scientific probability, the Avaulta device(s) is a contributing factor of the problems.

(*Id.*). Her deposition testimony is very similar:

> Q. Now, whether you can specifically identify in the Plaintiffs whether they have these specific conditions, you just don't know, do you?
>
> A. But as a group the common – these complaints are common amongst any, you know, combination of these are common amongst the Plaintiffs.
>
> Q. Okay.
>
> A. And what's common is the implantation of the mesh.

(Babensee Dep. vol. I [Docket 155-1], at 186:15-186:25; *see also id.* at 201:1-201:7). Dr. Babensee's conclusion, based on her expertise in pathology, is that the bellwether plaintiffs demonstrate the same type of responses that are seen in women implanted with these products generally. I **FIND** that this opinion is relevant and will be helpful to the jury. However, Dr. Babensee's causation opinion will be limited to that which she set forth in her expert report.

### iv. *Opinions Related to Porosity*

Bard argues that Dr. Babensee did not provide her opinion on the pore size of the Avaulta products in her expert report, but did so for the first time at her deposition. The plaintiffs respond that Dr. Babensee's expert report discussed encapsulation of the mesh, which is the result of small pore size. However, Dr. Babensee testified:

> Q. So what you're saying is this binder that has the handwritten note Porosity on it and the addition materials that came to us, I think, earlier this week with an amended Exhibit 5, which we'll mark in a little while, *references or relates to an additional opinion*?
>
> A. Yes.
>
> Q. And tell me what that opinion is.
>
> A. That the porosity of the mesh is – is smaller than what is recommended to provide a more appropriate host response for the implants.
>
> . . .
>
> Q. Yeah, we'll talk more about that when we get to – into the, you know, the actual opinions. But I think what you're saying is Exhibit 3, although, you signed off on it on October 12th, 2012, *does not contain this additional opinion about porosity, correct*?
>
> A. Correct.
>
> Q. And that's something that you – and you haven't done an amended complaint? I mean, an amended report?
>
> A. No, no.
>
> Q. You haven't written anything about that, correct?
>
> A. No.

(*Id.* at 30:9-31:13) (emphasis added). The plaintiffs' arguments therefore directly contradict Dr. Babensee's testimony. Accordingly, I find that Dr. Babensee's porosity opinion is a new opinion,

not discussed in her Rule 26 expert report. Because this is a new opinion, and no supplemental report has been filed, I **FIND** that Dr. Babensee's porosity opinion should be excluded.

## IV. The Plaintiffs' *Daubert* Motion

The plaintiffs filed a single *Daubert* motion seeking to exclude certain opinions and testimony of Maureen Reitman, Sc.D. and Marta Villarraga, Ph.D. (the "Exponent Experts"). The Exponent Experts filed a 202-page joint expert report (the "Exponent Report") seeking to opine on a variety of matters. (*See* Exponent Report [Docket 127-4], at 191-92). The plaintiffs argue that certain opinions should be excluded because the Exponent Experts (1) offer lawyer arguments that are not expert opinions; (2) are not qualified to opine on or criticize Dr. Hoyte's biomechanical analysis based on 3-D models; (4) offer general factual narratives that are not expert opinions; (5) selectively removed data from the results of their FTIR testing; and (6) never presented or discussed SEM opinions.[23]

### A. *Allegedly Non-Expert Lawyer Arguments*

The plaintiffs argue that much of "the Exponent Report is largely nothing more than what Bard's lawyers can argue at the trial of this case." (Pls.' Mot. to Exclude Ops. & Testimony of Marta Villarraga, Ph.D. & Maureen Reitman, Sc.D. & Brief in Supp. [Docket 250], at 5) [hereinafter Pls.' Mot. re: Exponent Experts]. The plaintiffs point to: (1) arguments regarding the plaintiffs' experts' degradation testimony; (2) testimony pointing out alleged inconsistencies in the plaintiffs' experts' reports; (3) statements that the plaintiffs' experts have no scientific basis for their opinions; (4) criticisms of the plaintiffs' experts' failure to take into account certain aspects of Bard's testing and clinical experience; and (5) criticisms of the plaintiffs' experts' causation opinions.

[23] The plaintiffs lead by arguing that the Exponent Experts are "professional expert witnesses/consultants" that should be subject to a more rigorous *Daubert* analysis. (Pls.' Mot. re: Exponent Experts [Docket 250], at 4).

To the extent that the Exponent Experts purport to simply make arguments that Bard's lawyers 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." Fed. R. Evid. 702. For example, the Exponent Experts' contention that "if we . . . assume that the alleged degradation is as pervasive as the plaintiffs' experts suggest, then one would expect clinical observations to reveal the patient population to consistently exhibit degraded meshes and encounter the same types of complications as the plaintiffs" is a fancy way of stating a simple logical inference: if the problem is as bad as the plaintiffs contend, then more (or all) patients should be experiencing the problem. (Exponent Report [Docket 127-4], at 152).

Additionally, the Exponent Experts' attack the plaintiffs' experts' causation opinions by noting that (1) "successful clinical outcomes have been reported for patients following the use of Avaulta products" and (2) the post-operative pain experienced by the bellwether plaintiffs "are not unique to patients undergoing vaginal repair with polypropylene meshes." (*Id.* at 166). To the extent that the Exponent Experts simply rely on these bases for their opinions—such as Section 5.3.3 of the Exponent Report—such opinions should be excluded as they are more appropriately lawyer arguments that the jury can understand without the assistance of the experts. (*See id.* at 166).[24]

However, the Exponent Experts' 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. As the Third Circuit explained in *United States v. Mitchell*:

> On the one hand, the court must exclude some evidence as a gatekeeper, by preventing opinion testimony that does not meet the requirements of qualification,

[24] In contrast, in Section 5.3.4 the Exponent Experts discuss and apply scientific literature to support their opinion that infections suffered by the bellwether plaintiffs may not be related to the Avaulta products. The experts would assist the jury in understanding the application and discussion of this scientific literature.

> reliability and fit from reaching the jury. But on the other hand, the court is *only* a gatekeeper, and a gatekeeper alone does not protect the castle; as we have explained, a party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination.

365 F.3d 215, 245 (3d Cir. 2004) (internal citations and quotation marks omitted); *see also Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (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"). Thus, in addition to attacking the substance of an expert's opinions, a counter-expert may also opine on the unreliability of the data on which an expert's opinions is based. These types of opinions also necessarily require some "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Accordingly, the plaintiffs' motion to exclude the Exponent Experts' "non-expert opinions" is **GRANTED in part** and **DENIED in part** as discussed above.

### B. *Criticisms of Dr. Hoyte's 3-D Modeling*

The plaintiffs argue that neither of the Exponent Experts is qualified to render any opinions regarding Dr. Hoyte's MRI modeling. (*See* Exponent Report [Docket 127-4], at 179-84). A review of Dr. Hoyte's MRI modeling reveals that a "finite element analysis" was conducted on his 3-D models, and a review of Dr. Villarraga's curriculum vitae and the Exponent Report reveals that Dr. Villarraga is qualified to opine on the subject of finite element analyses. For example, Dr. Villarraga has published papers in which she conducted a finite element analysis. (*See* Vilarraga Curriculum Vitae [Docket 258-4], at 3). She has also taught graduate and undergraduate courses on the subject of finite element analysis. (*See* Exponent Report [Docket 127-4], at 17). Finally, Dr. Villarraga's experience "includes analysis of devices used in . . . urogynecological . . . surgery). (*Id.* at 16). In sum, Dr. Villarraga is qualified to

render opinions regarding Dr. Hoyte's MRI modeling. Accordingly, the plaintiffs' motion to exclude the Exponent Experts' opinions regarding Dr. Hoyte's 3-D modeling is **DENIED** with respect to Dr. Villarraga. However, because Bard has not made any attempt to argue that Dr. Reitman is qualified to render opinions regarding Dr. Hoyte's 3-D modeling, the plaintiffs' motion to exclude on this issue is **GRANTED** with respect to Dr. Reitman.

### C. *Factual Narratives*

The plaintiffs argue that the Exponent Experts may not offer "general factual narratives based on information about which they have no first hand knowledge, and about which the jury is capable of understanding and drawing their own conclusions." (Pls.' Mot. re: Exponent Experts [Docket 250], at 11). First, experts may form opinions by relying on facts that they have "been made aware of," as long as "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. Accordingly, they do not need first-hand knowledge but may be supplied this information. Additionally, the plaintiffs do not contend that experts in the field do not reasonably rely on these kinds of facts or data.

I **FIND** that *Liberty Media 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 plaintiffs' 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.

**D. *Opinions Based on FTIR Test Data***

The plaintiffs argue that Dr. Reitman conducted FTIR testing on explanted mesh material, but removed a portion of the test results. Dr. Reitman was asked at her deposition:

> Q. Why is there a gap?
>
> A. We blanked out the background signals. So there is—in that region, that's where you'll pick up moisture and carbon dioxide from the air. So it's a noise element. And so we will – we will look at the full spectra, and there's very few materials that have an actual signal in there, and we know it's noise, so we simply just blank it as opposed to artificially making it straight.

(Reitman Dep. [Docket 250-2], at 264:22-265:5). Bard argues that Dr. Reitman employed a "conventional approach and standard analysis" when she blanked out the supposed noise. (Def. Bard's Mem. of Law in Opp'n to Pls.' Mot. to Exclude the Ops. & Testimony of Dr. Marta L. Villarraga, Ph.D. & Dr. Maureen T. F. Reitman, Sc.D. [Docket 258], at 18). Bard also argues that "Dr. Reitman used her vast education, training, and experience to determine what information was simply irrelevant 'noise' that could be 'blanked out.'" (*Id.*).

This "blanking out" is problematic. On one hand, if it was simply irrelevant noise, then there should have been no problem in submitting the full results of the testing; the plaintiffs' experts could analyze the test results and agree that it was irrelevant noise. On the other hand, if it was something more than irrelevant noise, then Dr. Reitman has blanked out relevant information that may have called her opinions into doubt and supported the plaintiffs' theories. In short, the problem is that regardless of whether the "blanked out" portion of the test results

was noise or not, and regardless of Dr. Reitman's explanation of why it was blanked out, Dr. Reitman's selective presentation of the test results raises substantial doubt about the reliability of her methodology. Accordingly, the plaintiffs' motion to exclude Dr. Reitman and Dr. Villarraga's opinions based on the FTIR testing is **GRANTED**.

### E. *Opinions Based on SEM Images*

The plaintiffs argue that the Exponent Experts offered only a "bare conclusion" and "no opinion or expert analysis regarding any SEM images of unimplanted Avaulta mesh." (Pls.' Mot. re: Exponent Experts [Docket 250], at 17). The plaintiffs thus argue that the Exponent Experts should be precluded from "offering any SEM imaging of unimplanted mesh, or from offering any opinion regarding any SEM imaging of unimplanted mesh beyond that stated on page 152 of the Exponent Report." (*Id.* at 18).

A review of the Exponent Report and the supplemental report reveals that the Exponent Experts analyzed Dr. El-Ghannam's SEM images and conducted their own SEM testing. Their analysis of Dr. El-Ghannam's SEM imaging is admissible, and I have also ruled that the supplemental report is admissible. Accordingly, the plaintiffs' motion to exclude the Exponent Experts' opinions based on SEM images is **DENIED**.

## V. Effect of *Daubert* Rulings

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

## VI. Conclusion

### A. *Cisson, 2:11-cv-00195*

For the reasons discussed above, it is **ORDERED** that in *Cisson* (2:11-cv-00195), Bard's motions with respect to Dr. Zolnoun [Docket 91], Dr. Altenhofen [Docket 94], Dr. Loving and Dr. Carroll [Docket 100] and Dr. Shull [Docket 98] are **GRANTED**, and Bard's motions with respect to the treating physicians [Docket 103], Dr. Klosterhalfen [Docket 108], Dr. Hoyte [Docket 110], Dr. Kessler [Docket 113], Dr. El-Ghannam [Docket 130], Dr. Brennan [Docket 127], and Dr. Babensee [Docket 154] are **GRANTED in part** and **DENIED in part**. It is further **ORDERED** that the plaintiffs' motion [Docket 250] is **GRANTED in part** and **DENIED in part**. The Clerk is instructed to file a copy of this Memorandum Opinion and Order in *Cisson*.

### B. *Queen, 2:11-cv-00012*

For the reasons discussed above, it is **ORDERED** that in *Queen* (2:11-cv-00012), Bard's motions with respect to Dr. Zolnoun [Docket 95], Dr. Altenhofen [Docket 98], Dr. Loving and Dr. Carroll [Docket 104] and Dr. Shull [Docket 101] are **GRANTED**, and Bard's motions with respect to the treating physicians [Docket 107], Dr. Klosterhalfen [Docket 110], Dr. Hoyte [Docket 114], Dr. Kessler [Docket 117], Dr. El-Ghannam [Docket 132], Dr. Brennan [Docket 129], and Dr. Babensee [Docket 154] are **GRANTED in part** and **DENIED in part**. It is further **ORDERED** that the plaintiffs' motion [Docket 254] is **GRANTED in part** and **DENIED in part**. The Clerk is instructed to file a copy of this Memorandum Opinion and Order in *Queen*.

### C. *Rizzo, 2:10-cv-01224*

For the reasons discussed above, it is **ORDERED** that in *Rizzo* (2:10-cv-01224), Bard's motions with respect to Dr. Zolnoun [Docket 122], Dr. Altenhofen [Docket 125], Dr. Loving and Dr. Carroll [Docket 130] and Dr. Shull [Docket 129] are **GRANTED**, and Bard's motions with

respect to the treating physicians [Docket 134], Dr. Klosterhalfen [Docket 137], Dr. Hoyte [Docket 141], Dr. Kessler [Docket 144], Dr. El-Ghannam [Docket 159], Dr. Brennan [Docket 156], and Dr. Babensee [Docket 181] are **GRANTED in part** and **DENIED in part**. It is further **ORDERED** that the plaintiffs' motion [Docket 276] is **GRANTED in part** and **DENIED in part**. The Clerk is instructed to file a copy of this Memorandum Opinion and Order in *Rizzo*.

**D. *Jones, 2:11-cv-00114***

For the reasons discussed above, it is **ORDERED** that in *Jones* (2:11-cv-00114), Bard's motions with respect to Dr. Zolnoun [Docket 102], Dr. Altenhofen [Docket 108], Dr. Loving and Dr. Carroll [Docket 114] and Dr. Shull [Docket 111] are **GRANTED**, and Bard's motions with respect to the treating physicians [Docket 117], Dr. Klosterhalfen [Docket 121], Dr. Hoyte [Docket 124], Dr. Kessler [Docket 127], Dr. El-Ghannam [Docket 142], Dr. Brennan [Docket 139], Dr. Lentnek [Docket 105], and Dr. Babensee [Docket 165] are **GRANTED in part** and **DENIED in part**. It is further **ORDERED** that the plaintiffs' motion [Docket 261] is **GRANTED in part** and **DENIED in part**. The Clerk is instructed to file a copy of this Memorandum Opinion and Order in *Jones*.

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

ENTER: June 4, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE