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

CHARLESTON DIVISION

DEBRA WISE, et al.,

Plaintiffs,

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

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Dr. Reitman *Daubert* Motion)

Pending before the court is the plaintiffs' Motion to Exclude Opinions and Testimony of Maureen Reitman, Sc.D. [Docket 145]. For the reasons set forth below, I **RESERVE** my ruling on this motion for trial.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 10,000 of which are in the Bard MDL, MDL 2187. In this particular case, the plaintiff, Debra Wise, was surgically implanted with the Avaulta Plus Anterior Support System and the Avaulta Plus Posterior Support System (collectively "Avaulta"), mesh products manufactured by Bard to treat POP. (*See* Short Form Compl. [Docket 1], at 2).[1] The plaintiff received her surgery in West Virginia. (*Id.* at 4). The plaintiff claims that

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

as a result of implantation of the Avaulta products, she has experienced multiple complications, including vaginal spasms, damage to her ureter, vagina, and rectum, kidney reflux, urinary tract infections, chronic constipation, dyspareunia (pain during sexual intercourse), lower pelvic pain, incontinence, and kidney stones. (*See* Pl. Fact Sheet [Docket 102-9], at 7). The plaintiff alleges negligence, strict liability for design defect, strict liability for manufacturing defect, strict liability for failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (Short Form Compl. [Docket 1], at 4).[2] Additionally, the plaintiff's husband, Ronald Wise, alleges loss of consortium. (*Id.*). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motion involves the plaintiffs' effort to exclude or limit an expert's opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

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

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

however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[3] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

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

[3] With more than 70,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

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

With respect to relevancy, *Daubert* further explains:

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

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted). I now turn to the instant motion.

III. Discussion

The plaintiffs seek to exclude the opinions and testimony of Maureen Reitman, Sc.D. Dr. Reitman is Corporate Vice President and Director of the Polymer Science and Materials Chemistry Practice at Exponent, Inc. She opines that polypropylene does not degrade and bases this opinion on scanning electronic microscopy ("SEM"), Fourier Transform Infrared Spectroscopy ("FTIR"), and Thermal Gravimetric Analysis ("TGA") testing performed on polypropylene samples at Exponent and on an "anti-oxidant" analysis of polypropylene pellets

conducted by an outside laboratory. In particular, she contends that the cracked or rough surface one may observe on polypropylene explants is not evidence of degradation caused by oxidation—rather, it is a biologic crust or layer the forms on the polypropylene that can be removed with special cleaning.

In its response, Bard frequently cites to a deposition of Dr. Reitman taken *after* the plaintiffs' motion was filed. Bard additionally discusses new tests conducted by Dr. Reitman and a new testing protocol that she produced. In their reply, the plaintiffs argue that any new information should be stricken from the record.

Given the current state of the pleadings before me, I find it necessary to defer ruling on this motion until trial. The deposition testimony and motion practice with Dr. Reitman have been inconsistent, and the court believes that it is in the best interest of justice to decide the issue of reliability after hearing a foundation of reliable principles and methods at trial.

IV. Conclusion

For the reasons set forth above, I **RESERVE** my ruling on the plaintiffs' Motion to Exclude Opinions and Testimony of Maureen Reitman, Sc.D. [Docket 145] for trial. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 11, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE