

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

CHARLESTON DIVISION

CAROLYN JONES,

Plaintiffs,

v.

CIVIL ACTION NO. 2:11-cv-00114

C. R. BARD, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is the motion by Defendant C. R. Bard, Inc. (“Bard”), to limit the opinions and testimony of Donald R. Ostergard, M.D., pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its line [Docket 370]. I **GRANT** in part and **DENY** in part the motion.

I. Background

This action is one of many thousands consolidated here by the Judicial Panel on Multidistrict Litigation. It is a bellwether case currently set for trial on Friday, January 10, 2014. The plaintiff, Carolyn Jones, alleges injuries suffered as the result of an implanted Avaulta product. She relies upon a number of expert opinions. One opinion is offered by Dr. Ostergard. His qualifications are summarized as follows:

1. He has been actively involved in the practice of Obstetrics, Gynecology, and Urogynecology for 45 years.
2. He is board certified in Obstetrics and Gynecology in both California and Kentucky.
3. He presently serves in a teaching capacity at the University of Louisville Medical School.

4. He is one of the pioneers in his field and jointly responsible with four colleagues in forming the American Urogynecological Society. (*See also* Pl.’s Resp. at 2 (“He was the first to establish a urogynecological fellowship training program, the first to publish textbooks in urogynecology, and the first to offer postgraduate preceptorships in urogynecology, among many other significant ‘firsts’ in his career.”)).

Dr. Ostergard has reviewed Ms. Jones’ medical records. He has also studied her deposition testimony, along with a host of materials prepared by (1) fellow physicians who have treated her, and (2) other peers who offer opinions on the defense side. Dr. Ostergard’s views are summarized below:

1. The Avaulta product at issue in this case is not suited for the treatment of pelvic organ prolapse.
2. The polypropylene mesh used in the Avaulta product is defective in multiple ways, including the following:
 - a. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them.
 - b. Polypropylene is impure.
 - c. Polypropylene mesh is not inert. It is susceptible to flaking and fissuring. It degrades and releases toxic compounds.
 - d. Polypropylene mesh shrinks in the body.
 - e. The large polypropylene surface area promotes wicking of fluids and bacteria and is a "bacterial super highway." (citation omitted).
 - f. It is a potential carcinogen.

Dr. Ostergard also offers specific causation opinions about the Avaulta product and Ms. Jones’ various maladies. He opines that the Avaulta product implanted in her has caused irritative lower urinary tract symptoms, promoted infections and bacterial growth, and ultimately eroded and degraded in a detrimental way.

Bard seems unimpressed with Dr. Ostergard’s credentials. It calls him “a historical relic” and protests that “the field he helped . . . create has far surpassed him.” (Def.’s Reply at 1

(stating also that, “[o]ffering Dr. Ostergard as an expert in today’s field of female pelvic medicine and reconstructive surgery is like offering Chief Justice John James Marshall as an expert in electronic filing”).

Bard asserts that Dr. Ostergard should be excluded as a witness because (1) he is unqualified to render opinions concerning polypropylene, which opinions also lack reliability and a suitable fit with this case, (2) he is unqualified to render opinions regarding product design, which opinions also lack reliability, and (3) his specific causation opinions are based upon his failure to consider portions of her medical history and possible alternative causes for her symptomology.¹

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 is (1) “based upon sufficient facts or data,” (2) “the product of reliable principles and methods,” and (3) the principles and methods have been “reliably applied . . . to the facts of the case.” Fed. R. Evid. 702. A two-part test governs admissibility of expert testimony. The evidence is admitted if “it rests on a reliable foundation and is relevant[.]” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. He must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc., Inc.*, 137 F.3d 780, 784 (4th Cir. 1998).

¹ Bard also asks me to prohibit Dr. Ostergard from offering opinions about its intentions and motivations. Ms. Jones disavows trial use of those opinions. They are plainly inadmissible.

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

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include “(1) whether the particular scientific theory can ‘be (and has been) tested’; (2) whether the theory ‘has been subjected to peer review 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 (citing *Kumho* for the proposition "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.

Id. at 591-92 (internal citations omitted).

Finally is the subject of 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. Analysis

A. Polypropylene Opinions

First, Bard challenges Dr. Ostergard’s qualifications to hold forth about polypropylene. It notes that he is not board certified in Female Pelvic Medicine and Reconstructive Surgery.² Bard also says he is neither a biomaterials nor a design expert. Dr. Ostergard has never been trained in the constituents of polypropylene. He has studied neither its tensile strength nor flexibility. Bard states he has also never examined its contraction or shrinkage rates. Lacking these qualifications, Bard wants Dr. Ostergard barred from opining about the chemical makeup of polypropylene and its behavior in the body.

It is difficult to deride Dr. Ostergard’s qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic and biologic materials in pelvic reconstruction, including polypropylene mesh. He has extracted polypropylene mesh products from patients. He has treated them for mesh-related complications. He also performed preliminary theoretical work on a new pelvic mesh device for American Medical Systems.

Dr. Ostergard has conducted scanning electron microscope imaging of mesh. He is also participating in an on-going study of its degradation characteristics in conjunction with his University of Louisville colleagues. Finally, Dr. Ostergard has published, in a peer reviewed

² The plaintiff asserts that this specialty was unavailable until June 2013. She also notes that Dr. Ostergard will not sit for the exam as he no longer has his own private practice.

setting, on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980s.³ I conclude that Dr. Ostergard's qualifications are sufficient to testify about polypropylene.

Aside from his qualifications, however, Bard next asserts that Dr. Ostergard lacks sufficient facts or data to support his polypropylene views. They charge him with relying upon articles he has not read and a Material Safety Data Sheet ("MSDS") omitted from his expert report. Bard's very specific challenges also critique his putative failure to (1) conduct tests to confirm his polypropylene-impurity opinions, and (2) his unsubstantiated assertion that the material contains fifteen compounds that leach into the body. Bard also makes much of the fact that he has not studied the Avaulta product manufacturing process but concedes that processes of that type affect the raw polypropylene used.

It appears undisputed that Dr. Ostergard has testified to reviewing published, peer-reviewed studies relating to polypropylene implants. Dr. Ostergard's qualifications, and his review of this literature, carries significant weight. While Bard asserts that Ms. Jones "is wrong in arguing that reading research conducted by others is an adequate basis for an expert opinion," (Def.'s Reply at 5), the law is otherwise. *See* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has *been made aware of* or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.") (emphasis added); *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) ("Likewise, numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts for purposes of Rule of Evidence 703.");

³ Bard criticizes the depth and breadth of some of the articles published by Dr. Ostergard. In the main, those pieces seem to be reasoned, footnoted, analyses in some of the leading journals in the field.

Ratliff v. Schiber Truck Co., 150 F.3d 949, 955 (8th Cir.1998); *see also Gussack Realty Co. v. Xerox Corp.*, 224 F.3d 85, 94, 95 (2d Cir. 2000); Charles B. Gibbons, *Federal Trial Objections* § E90 (4th ed. elec. 2013). Apart from studying the analyses of others, Dr. Ostergard has conducted his own research in the area, with at least some instances of peer review. (See Pl.’s Resp. at 9 n.6 (listing articles)). *See Daubert*, 509 U.S. at 594 (“[S]ubmission to the scrutiny of the scientific community is a component of ‘good science,’ in part because it increases the likelihood that substantive flaws in methodology will be detected.”).

So the data challenge, like the qualifications challenge, must fail.⁴ While Bard appears to have abundant fuel for the engine of cross examination, it lacks a sufficient basis to stop Dr. Ostergard at the gate on the subject of polypropylene.

B. Product Design Opinions

Bard next challenges Dr. Ostergard’s Avaulta product design opinions. It repeats the same two challenges above, saying he is unqualified in the area and has relied upon insufficient facts or data. Specifically, Bard asserts that Dr. Ostergard should not be talking about pore size and related matters when he has no bio- or materials-engineering experience. It adds that he has never implanted an Avaulta product nor conducted any laboratory testing on the device. (Def.’s

⁴ The same is true of Bard’s final polypropylene challenge. It asserts that Dr. Ostergard’s opinions do not sufficiently fit the facts of this case. With one exception, the fit is imperfect but certainly not the type of square peg that would cause an adversary to invoke Rule 702. That exception relates to Dr. Ostergard’s musings respecting a cancer/polypropylene link.

Dr. Ostergard asserts that he has researched the link between cancer and polypropylene. He has presented that research to the *International Urogynecology Journal*. The resulting peer review process has tracked the piece for publication. While there are additionally other peer-reviewed, published medical journal articles discussing the link between the chronic inflammatory response to polypropylene and other synthetic mesh implants and cancer, the opinion does not fit the facts here. The mention of cancer in the context of this case, where Ms. Jones shows no signs of it, would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value. There will be no mention of the cancer opinion at trial.

Mem. in Supp. at 11 (“His lack of experience with product design and the Avaulta Plus make him unqualified to offer an opinion about its design.”)).

Ms. Jones observes that “Bard has presented testimony from three different urogynecologists -- none of whom, Plaintiff submits, are even arguably as qualified as Dr. Ostergard -- to tout the design of this product.” (Pl.’s Resp. at 11). She appends a host of other reasons why Dr. Ostergard should not be stopped at the gate on product design. First, she again touts his (1) extensive academic and medical research, and (2) his publications in recognized journals respecting mesh infirmities. She also points to other product design work he has performed, namely, a polytetrafluoroethylene suburethral sling in the 1980s, along with the design theory work for AMS that was discussed earlier.

I conclude that Bard’s two challenges on product design fall short. Dr. Ostergard has sufficient scientific knowledge and experience to permit his design testimony on the Avaulta product. The challenges to his expertise and data bank in this area are better suited for cross examination.

C. Specific Causation Opinions

Bard next challenges Dr. Ostergard’s views, among others, that Ms. Jones’ Avaulta product caused the appearance of irritative lower urinary tract symptoms, an intense chronic inflammatory reaction, bilateral leg pain, and problems with the obturator nerve. It asserts that the opinions are inadmissible for several reasons. First, it contends that the bulk of these opinions are based on Dr. Ostergard’s generalized views about polypropylene and product design. Second, they assert that the opinions lack a sufficient basis in fact or data because Dr. Ostergard had incomplete medical records when he advanced the opinions and will not retreat

from them when confronted with new evidence. (*See* Def.'s Mem. in Supp. at 15 ("Only months after writing his report did he review Plaintiff's records going back to 2001. Although the older records contradict his report in several ways, they did not change his opinion about the source of Plaintiff's pain and other medical concerns.")). This second challenge appears coupled with a differential diagnosis challenge. Third, Bard asserts that Dr. Ostergard lacks the qualifications and data needed to offer an opinion on the plaintiff's orthopedic and pain symptoms.

The first argument fails. I am permitting Dr. Ostergard to testify generally from a causation perspective on polypropylene and product design in the areas indicated. His specific causation testimony is thus not excludable for lack of a general causation predicate.

The second argument meets the same fate. If Dr. Ostergard undertook an incomplete review of Ms. Jones' medical history, cross examination might considerably dampen his assistance to her.⁵ An incomplete review of this type, however, would rarely erect a *Daubert* bar. That is especially so where, as here, Dr. Ostergard has refined his opinions in light of reviewing the missing medical records. The matter of a sufficient differential diagnosis is a bit closer. In light of Ms. Jones' significant medical history, one might expect more substantial rigor to have been applied on the point. On balance, however, I cannot conclude that the diagnostic opinions offered by Dr. Ostergard, and apparently based on his substantial clinical and theoretical experience, are unscientific and barred as a matter of law.⁶

⁵ For example, Ms. Jones has a prior history of irritative lower urinary tract symptoms. Dr. Ostergard believes that the Avaulta product caused it. Bard asserts he was unaware that the condition pre-dated implantation.

⁶ I conclude likewise concerning Bard's complaint that Dr. Ostergard lacks the experience and training necessary to testify about the plaintiff's orthopedic and pain complaints.

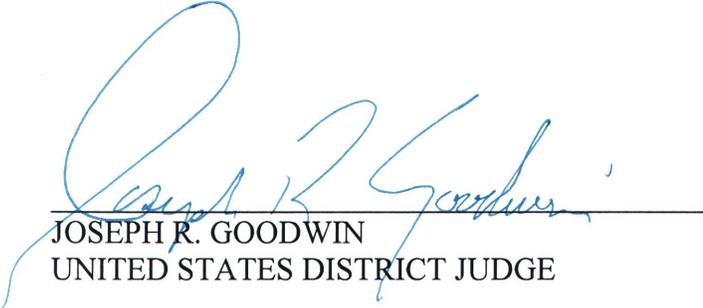
IV. Conclusion

Bard elsewhere in its briefing picks around the edges of Dr. Ostergard's opinions. Those additional criticisms are met not with exclusion but with cross examination and competing evidence. Bard has also raised some matters for the first time in its reply brief. I have no occasion to reach those.

Having considered the entirety of the challenge to Dr. Ostergard, I **GRANT** the motion to limit his testimony as it relates to the subject of cancer and Bard's intentions and motives. I **DENY** the residue of Bard's challenges.

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

ENTER: January 6, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE