UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

REBECCA MARTINEZ,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 2:18-cv-220
	)	
COLOPLAST CORP. & COLOPLAST MANUFACTURING US, LLC,	)	
	)	
	)	
Defendants.	)	

OPINION AND ORDER

This matter is before the court on the Motion to Exclude Opinions and Testimony of Plaintiff's Expert Jimmy Mays, PH.D. [DE 175], filed by the defendants, Coloplast Corp. and Coloplast Manufacturing US, LLC, on September 30, 2021. For the following reasons, the Motion [DE 175] is **GRANTED**.

Background

Prior to 2016, the plaintiff, Rebecca Martinez, experienced a series of medical problems including multiple forms of pelvic organ prolapse (POP). After consulting with two gynecologists, Timothy Weiss and Andrew Waran, Martinez underwent surgery on March 17, 2016. Dr. Weiss performed a hysterectomy, and Dr. Waran implanted a surgical mesh manufactured by the defendants. During the same operation, Dr. Waran also implanted a sling manufactured by Ethicon to support her bladder.

The surgical mesh was made of polypropylene and had the product name of Restorelle Y. The Restorelle mesh was designated "Y" because of its shape. Because of multiple pregnancies and age, some of Martinez's internal organs were sagging and in need of additional support. The

three ends of the Y shaped mesh were sutured to different parts of the pelvic cavity and were intended to provide a sling-like support for the sagging organs.

Throughout the pleadings, the parties have drawn a distinction between a surgical mesh and a sling. Both are intended to correct POP problems in women. The Restorelle Y surgical mesh is designed to be attached to the woman's sacrum, to extend downward, and to be attached to the vagina. It is implanted under the woman's small bowel. The sling is implanted to provide support for the woman's bladder and is not attached to the surgical mesh. (See generally, ***Daubert*** Hearing, Ex. A).

Several months after the implantation, Martinez sought treatment for abdominal, vaginal, pelvic, back, and leg pain. Dr. Waran found that it was unlikely that the surgical mesh was causing the pain, but he referred her to a urogynecologist, Dr. Roger Goldberg, who agreed to perform a partial removal surgery. On September 19, 2017, Dr. Goldberg performed an exploratory laparotomy and partial excision of the mesh. The parties have used the term "explanted" to describe both the procedure and the portion of the mesh removed.

Martinez now complains that the surgical mesh was defective and has caused her additional problems. In particular, she contends that the polypropylene tends to shrink and harden in the woman's body and that this leads to inflammation, pressure on nerves, and other complications. The lawsuit raises both product liability and negligence claims.

Dr. Jimmy Mays is a chemistry professor at the University of Tennessee with over 40 years of experience working with polymer materials. He has published research as a polymer scientist in over 400 peer-reviewed publications, most involved the use of polymer characterization techniques. Dr. Mays has served as an editor and editorial advisory board member for several peer-reviewed journals about polymer science.

Martinez has named Dr. Mays as one of her general causation experts for trial. Dr. Mays' proposed testimony primarily involves his opinions about polypropylene and oxidative degradation as it relates to the mesh manufactured by the defendants. The defendants are requesting that the court exclude the testimony of Dr. Mays for several reasons. First, they allege that he is unqualified and his opinions lack a reliable basis. Second, they contend that he admitted he never tested his degradation hypotheses, did not examine the mesh at issue in this case, and could not adequately account for obvious alternative explanations. Finally, the defendants claim that Dr. Mays relied on a publication that directly contradicted his degradation hypothesis as well as on testing that he conducted on a mesh manufactured by a different company, Boston Scientific.

In her response, Martinez argues that since Dr. Mays' testimony has been permitted in other cases and that because he has conducted tests on the Boston Scientific mesh, his opinions as to the defendants' mesh are reliable.

Discussion

In ***Daubert v. Merrell Dow Pharmaceuticals, Inc.***, 509 U.S. 579 (1993), the Supreme Court interpreted **Federal Rule of Evidence 702** and imposed a gatekeeping responsibility on district court judges when expert testimony is offered. ***Daubert*** involved scientific testimony, and the lower federal courts were divided on whether the ***Daubert*** interpretation of Rule 702 applied to all expert testimony. In ***Kumho Tire Co. v. Carmichael***, 526 U.S. 137 (1999), the Supreme Court held that the gatekeeping requirement applied to all proposed expert testimony. The final case in the so-called ***Daubert*** trilogy is ***General Electric Co. v. Joiner***, 522 U.S. 136 (1997). In that case, the Supreme Court held that the abuse of discretion standard should be applied on appellate review. All three cases discussed factors that the court should consider in evaluating proposed expert testimony.

Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

In its current version, Rule 702 attempts to codify the holdings of the ***Daubert*** trilogy.

Even when there is no dispute that the proposed witness is an expert, more is required before the opinion is admissible. ***Daubert*** emphasized the need for expert testimony to meet the twin requirements of reliability and relevancy. In evaluating the proposed testimony, courts also have referred to a "fit" and an "intellectual rigor" requirement. ***Kumho Tire Co.***, 526 U.S. 137, 152; ***Harman v. EBSCO Industries, Inc.***, 758 F.3d 810, 819 (7th Cir. 2014).

The "fit" requirement is met if there is a logical connection between the expertise of the witness, the proposed opinion, and the issues at trial. The "intellectual rigor" inquiry is satisfied if the expert has applied the same diligence to both the proposed court opinion and an opinion reached in his other professional endeavors. In ***Schultz v. AKZO Nobel Paints, LLC, et al.***, 721 F.3d 426 (7th Cir. 2013), the Seventh Circuit stated:

> Although [***Daubert***] places the judge in the role of the gatekeeper for expert testimony, the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at h[is] opinion …"
>
> 721 F.3d at 431.

See also ***Kirk v. Clark Equipment Company***, 991 F.3d 865, 873 (7th Cir. 2021).

Finally, **Federal Rule of Evidence 104(a)** is the mechanism for resolving a ***Daubert*** challenge. Under **Rule 104(a)**, the court may consider any evidence which is not privileged and resolve any factual disputes. The court must determine whether the proponent of expert testimony has demonstrated by a preponderance of the evidence that the ***Daubert*** requirements have been met.

Dr. Mays undeniably is an experienced polymer scientist. But even decades of experience in the field of polymer science does not automatically render his opinions on related topics, such as polypropylene degradation, reliable. "When evaluating the reliability of expert testimony, the district court must make a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." ***Kirk***, 991 F.3d at 873. In doing so, the court looks to various factors including whether the scientific theory can be (and has been) tested and whether the theory has been subjected to peer review and publication. 991 F.3d at 873.

Dr. Mays proposes to offer the opinion that the defendants' mesh implants undergo oxidative degradation once implanted in a woman's body. He claims that this degradation occurs when the implanted mesh, containing polypropylene, interacts with the chemicals generated as a result of the human foreign body response (FBR). Therefore, the degradation leads to a breakdown of the mesh's mechanical properties and causes the type of injury and pain that Martinez complains of.

Dr. Mays has come to this opinion without testing his hypotheses on the defendants' mesh and without examining the defendants' mesh or the mesh explanted from Martinez. [DE 177-3]; *see also* ***Kirk***, 991 F.3d at 874-76 (affirming the district court's exclusion of an expert who failed to "test his design defect theory" on the product at issue and "did not view, inspect, or

operate the [product] in person," therefore the "identifiable source for [the expert's] opinion was his own speculation").

Martinez argues that Dr. Mays' testing of the Boston Scientific mesh, makes up for the fact that he has failed to test his hypotheses on the defendants' mesh. But, Dr. Mays testified that there are differences between the Boston Scientific mesh and the defendants'. Specifically, he admitted that there are different antioxidants and that different concentrations of antioxidants can affect how long it takes for the oxidative degradation process to begin. Additionally, he stated that he does not know all of the antioxidants in the defendants' mesh because he has never tested the mesh and does not know of anyone who has. [DE 177-3].

In forming reliable opinions that are admissible at trial, experts are required to "rule out any serious alternative causes." ***Kirk***, 991 F.3d at 876-77. Here, the defendants point to recent peer-reviewed literature, Thames ST, et al., *The Myth: in vivio degradation of polypropylene meshes*, INT'L UROGYNECOLOGY J 2017; 28:285-297 (Thames), that they claim "debunks" Dr. Mays' degradation hypothesis. The Thames literature states that the "cracked" surfaces on explanted polypropylene mesh, which were previously assumed to be degradation, actually are layers of biological material that were deposited on the implant. Additionally, the findings in Thames show that a properly cleaned mesh revealed no signs of chemical degradation. In response, Dr. Mays criticized that the cleaning process used by Thames, claiming it was vigorous enough to remove both biological material and the lawyer of oxidized degraded polypropylene. However, Dr. Mays did not perform any tests on an explanted mesh to verify his opinions.

New research from Thames published in 2020, directly addressed Dr. Mays' critique of Thames' cleaning process and found that no oxidized polypropylene had been removed by the cleaning process. Thames S.F., et al., *Implantation Time Has No Effect on the Morphology and Extend of Previously Reported "Degradation" of Prolene Pelvic Mesh*, FEMALE PELVIC MED

RECONSTR SURG 2020. The new study compared the surface of a cleaned, explanted mesh to a new mesh and found no differences. Thames' research has offered a plausible rebuttal to Dr. Mays' criticism, and once again, Dr. Mays did not perform any tests of his own.

Dr. Mays has had a distinguished career and obviously is an expert in his field. The hallmark of the scientific method is to test a hypothesis to verify its accuracy. Dr. Mays failed to conduct any tests either before advancing his theory on the Thames cleaning method or after the Thames article rejected his theory. It is clear that Dr. Mays did not apply the same "intellectual rigor" to his litigation opinions as he did to his 400 published articles.

The defendants also have challenged Dr. Mays' opinions on the basis that the authorities upon which he relied are actually contrary to his conclusions. Dr. Mays relied on RAUTNER, B., ET AL., *Biomaterials Science*, Chapter II 2.2 by J.M. Anderson, Academic Press, San Diego, 3d ed. 2013, in coming to his opinion that FBR continues to release oxidizing agents for the entire time that an implant remains in the body. But the Rautner text states, "while these foreign-body giant cells may persist for the limetime of the implant, it is not known if they remain activated releasing their lysosomal constituents or become quiescent," which Dr. Mays acknowledged in his deposition. [DE 177-6]. This misquote of an article relied upon as a basis for his opinions adds another reason to exclude them.

Lastly, Martinez has alleged that certain documents produced by the defendants during discovery show that they were on notice of the problems caused by the polypropylene mesh in a woman's body. At issue is whether an expert may testify to the knowledge of the defendants. Arguably, this is relevant to the claim for punitive damages.

As a general rule, a document "speaks for itself." A witness cannot testify about what a document means – that is the function of the jury. The only exception to this rule is if the document contains specific or technical information. In that case, an expert can be used to

explain those terms to the jury. In final arguments, the attorneys can argue the significance of the documents and what inferences the jury should draw from them. Therefore, neither party will be permitted to call a witness to state an opinion concerning the knowledge or state of mind of the defendants.

For the foregoing reasons, the defendants' the Motion [DE 175] is **GRANTED.**

ENTERED this 10th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge