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 and Memorandum in Support of Motion to Exclude Opinions and Testimony of Emily Cole, M.D. [DE 181] filed by the plaintiff, Rebecca Martinez, on September 30, 2021. For the following reasons, the Motion [DE 181] is **GRANTED in part**.

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.

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

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 various organs.

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 mesh device was causing the pain, but referred her to 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.

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.

The defendants have retained Emily Cole, M.D., a urologist and surgeon who specializes in female pelvic health, as a general causation expert. Martinez is challenging Dr. Cole's proposed testimony regarding the design of the defendants' mesh for several reasons including that Dr. Cole did not review any Coloplast documents related to product design and safety of the mesh, that she has no knowledge of the design process, that she is unaware of key literature on the safety of the mesh, and that she relies on personal complication rates that cannot be objectively verified. Therefore, Martinez is requesting that the court limit Dr. Cole's testimony to her own personal clinical experience working with and implanting mesh devices, whether she is comfortable recommending mesh implantation to her patients, risks that she perceives from using the mesh, and what she has found in literature regarding mesh outcomes and whether those findings are consistent with her own clinical experience.[1]

[1] Martinez cites to ***Bayless v. Bos. Sci.***, 2020 WL 10058191, at *6 (M.D. Fla. Dec. 7, 2020), where the court excluded Dr. Cole's testimony as to the design of the mesh device but allowed her to testify regarding her personal clinical

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.

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:
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> (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.

Daubert emphasized the need for expert testimony to meet the twin requirements of reliability and relevancy. In evaluating the proposed testimony, courts have referred to a "fit" and "intellectual rigor" requirement. ***Kumho Tire Co.***, 526 U.S. 137, 152; ***Harman v. EBSCO***

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experience working with and implanting mesh devices. Martinez asks that the court "so limit her opinions" here too. [DE 206 at pg. 2].

Industries, Inc., 758 F.3d 810, 819 (7th Cir. 2014). Even when there is no dispute that the proposed witness is an expert, more is required before the opinion is admissible.

The "fit" requirement is met if there is a valid 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 standard to both the proposed court opinion and an opinion reached in her other professional endeavors.

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*** requirement have been met.

In the instant motion, Martinez primarily challenges the admissibility of Dr. Cole's testimony regarding the design of Restorelle Y, as detailed above. In support of her argument, Martinez points to Dr. Cole's deposition testimony in which she admitted that she has not reviewed any of the defendants' internal company documents, that she is not an expert in the design of medical devices, and that she was unaware of the key mesh characteristics of Restorelle Y.

The defendants state in their response that Martinez "has confounded a question and created a straw man by attacking Dr. Cole's qualifications for issues that she has ***not*** offered to opine on, namely the Restorelle [Y]'s design or development process." [DE 186 at pg. 6]. They claim that Martinez's "repeated attacks" on Dr. Cole's lack of design experience "is simply misplaced because her opinion is not being offered for that 'specific question,'" and they do not

"contend that [her] opinions have any foundation in the process to design or develop Restorelle [Y] … because her opinion is wholly unrelated to that topic." [DE 186 at pg. 7].

Dr. Cole is clearly an experienced female pelvic health surgeon. She has performed over 1,500 pelvic floor surgeries in the last ten years, with five involving Restorelle Y. She currently serves as the Chief Urologist and Director of the Female Pelvic Health Center at Sharp Ress-Stealy Medical Group where she maintains an active surgical practice that specializes in using mesh implants to treat female POP and urinary incontinence conditions.

Based on her decades of clinical experience, Dr. Cole is competent to testify as to what she has personally experienced and observed. Certainly, a surgeon who has performed over a thousand pelvic floor surgeries, some involving mesh implants, would be qualified to testify regarding the benefits and risks that she has observed in her patients. Therefore, in her proposed testimony, she has applied the same standards to her court opinions and opinions reached in her other professional endeavors.

Since Martinez is only challenging Dr. Cole's proffered testimony regarding the design of the mesh, and the defendants have stated that they are not offering her as an expert witness regarding Restorelle Y's design, the court finds there is no dispute to resolve. Dr. Cole will not testify as to the design and development process of Restorelle Y.

Based on the findings above, Martinez's Motion [DE 181] is **GRANTED in part**. Dr. Cole's testimony will not be permitted as to the design and development of Restorelle Y, but will be permitted to testify as to her personal experience with polypropylene mesh, including Restorelle Y.

ENTERED this 14th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge