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 the Opinions and Testimony of Plaintiff's Regulatory Expert Peggy Pence, PH.D. [DE 169], filed by the defendants, Coloplast Corp. and Coloplast Manufacturing US, LLC, on September 30, 2021. For the following reasons, the Motion [DE 169] 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. Peggy Pence holds degrees in microbiology, toxicology, and pharmacology. She spent the beginning of her career working for various companies where her work was focused on pharmaceuticals, or biotechnology-derived products. Dr. Pence has run her own consulting company, where she is the sole employee, for more than 25 years. Shortly after starting her own business, she began working with medical devices, writing clinical reports, performing audits, and designing and running clinical studies. Dr. Pence stated that she began working as an expert witness for plaintiffs in product liability cases in 2008. In 2018, Dr. Pence reported that approximately 100% of her work was as a plaintiff's expert in product liability litigation.

Martinez has named Dr. Pence as her regulatory expert for trial. Dr. Pence's proposed testimony is based on the defendants' testing, labeling, and post-market surveillance of its pelvic mesh devices, as well as testimony about industry standards.

The defendants request that the court fully exclude Dr. Pence from testifying as she is not qualified due to her lack of education, experience, or specified knowledge about the regulation of medical devices, specifically the defendants' mesh. Additionally, the defendants claim that her only experience with pelvic mesh devices is as a paid expert in products liability litigation.

Martinez's argument in support of Dr. Pence's qualifications consists entirely of citations to cases in other districts where Dr. Pence was permitted to testify on regulatory topics, including pelvic mesh devices.

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 her 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 her 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.

Cases which present novel technical or scientific questions frequently are filed, and the courtroom must be receptive to credible efforts to solve those problems. An expert in the field

should be permitted to do research and testing in an effort to find a plausible solution. The court should be receptive to that opinion. Another individual with impressive credentials in a different field also may do research and form an opinion at the request of a party to the litigation. The court should view that opinion with skepticism. Someone who attempts to expand her knowledge in a particular area should qualify as an expert under **Rule 702**. Someone who attempts to gain knowledge solely for the purpose of litigation should not be considered an expert for purposes of **Rule 702**.

Dr. Pence has impressive credentials and decades of experience in product development. However, her experience in product development is primarily related to pharmaceutical products. She did not begin working with medical device products until she started her own consulting business. As it relates to pelvic mesh devices, she testified that she has no training in chemical engineering or polymer science. [DE 198-1]. Additionally, she never has performed biocompatibility testing to evaluate a pelvic mesh device, has no experience with POP, has never worked on a clinical trial for a pelvic mesh device, has never prepared an instruction for use (IFU) for any medical device, and has never engaged in any research with respect to pelvic mesh devices, let alone the defendants' mesh at issue in this case. [DE 198-1]. Lastly, she never has conducted post marketing surveillance for a pelvic mesh device. [DE 198-1].

In addition to not having direct experience with pelvic mesh products, Dr. Pence has seven publications listed in her professional summary, the most recent being published in 1992. None of the publications has any connection to conducting clinical trials for medical devices or post marketing surveillance for medical products.

The proposed testimony of Dr. Pence lacks the "fit" requirement of ***Daubert*** and **Rule 702**. There is no logical connection between her expertise, the issues in the case, and her opinions. By her own admission, she has had no clinical experience with pelvic mesh devices and has not

engaged in research regarding them. Rather, her only experience with pelvic mesh devices is testifying as a paid expert witness in products liability litigation.

Martinez's argument that Dr. Pence's testimony has been admitted in other cases is not persuasive. In fact, this court has made it clear, in its February 4, 2022, Order [DE 225], that every case must be decided on its own merits. With all due respect to the learned judges in those other cases, their decisions are not binding on this court.

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 169] is **GRANTED.**

ENTERED this 11th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge