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 Karen Becker, PHD [DE 165], filed by the plaintiff, Rebecca Martinez, on September 30, 2021. For the following reasons, the Motion [DE 165] 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. 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.

The defendants have identified Dr. Karen Becker as an expert witness to opine on medical device industry practices and the Food and Drug Administration's (FDA) regulation of medical devices. The defendants also seek to offer her testimony in response to Martinez's regulatory expert, Dr. Peggy Pence.[1]

[1] The court excluded all the proffered testimony of Dr. Peggy Pence on February 11, 2022. [DE 233].

In this motion, Martinez is requesting that the court exclude Dr. Becker's opinions regarding the FDA in general as well as its regulatory process as it pertains to labeling, adverse event reporting system, and the §510(k) clearance process. Additionally, Martinez asks that Dr. Becker's opinions regarding industry standards and the defendants' compliance with them be excluded.

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.

Martinez spends a majority of her motion arguing that Dr. Becker's testimony regarding the FDA, and its regulations and procedures, should be excluded for the possibility that it could result in prejudice, confusion, or mislead the jury. The court need not address this because it has

already excluded all evidence concerning the FDA's regulatory process, and specifically, its §510(k) clearance process.[2] [DE 239].

The only issue that remains is whether Dr. Becker's opinions regarding the defendants' compliance with industry standards and practices are admissible. Martinez argues that the opinions should be excluded because there is no authoritative basis for them in Dr. Becker's report and that they "only tie back to her FDA regulatory opinions." The defendants claim that her opinions are the product of her work as an industry consultant for the last 27 years. Additionally, Dr. Becker explained in her deposition that industry practices are "a bit different" than FDA regulatory compliance. [DE 192-1]. "[A]n example of industry practice is when you go above and beyond the regulations or you implement procedures that help you confirm with the regulations." [DE 192-1].

The court appreciates the possibility of overlap between the FDA regulations that a medical device company must follow and common industry practices. However, unlike FDA regulations, industry practices are not governed by a set of codified rules. They are established by gathering data regarding the common operations of businesses within the relevant industry. There is no question that Dr. Becker is qualified to opine on such practices, for she has worked in the medical device industry as a consultant for decades. The fact that FDA regulations and industry practices are independent of one another, coupled with Martniez's undeveloped argument that Dr. Becker's testimony be wholly excluded, the court finds that Dr. Becker's testimony on the topic of industry practices, separate and distinct from the FDA, is admissible.

[2] The Medical Device Act of 1976 (MDA) exempts from premarket review, any medical device which has been given §510(k) clearance from the FDA. ***Kaiser v. Johnson & Johnson***, 947 F.3d 996, 1004 (7th Cir. 2020). The FDA will grant such clearance if the device is "substantially equivalent" to another device already on the market. ***Kaiser***, 947 F.3d at 1004.

For the foregoing reasons, the defendants' the Motion [DE 165] is **GRANTED in part.** Dr. Becker is permitted to testify about the industry standards and practices as it pertains to the defendants' and the medical device industry in general. However, the court is refraining from expressing an opinion as to the specific testimony of Dr. Becker's that will be admissible, as it has not been provided the details of those opinions. In no event will Dr. Becker be permitted to testify beyond the bounds of her report.

ENTERED this 22nd day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge