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 Benny Dean Freeman, PH.D, P.E. [DE 166], filed by the plaintiff, Rebecca Martinez, on September 30, 2021. For the following reasons, the Motion [DE 166] 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 polymer chemist, Dr. Benny Dean Freeman, as an expert witness in this case. Dr. Freeman opines that the defendants' surgical mesh implants are suitable for permanent implantation, and he bases his opinion, in part, on International Organization for Standardization (ISO) 10993 testing, the worldwide standard for determining biocompatibility.

In this motion, Martinez is requesting that the court exclude Dr. Freeman's opinion that polypropylene is suitable for permanent human implant because he bases his findings on unreliable methodology. She claims that the unreliable methodology consists of the Food and Drug Administration's (FDA) regulations, in which he has no expertise, and the results from the ISO test conducted on the defendants' mesh. Martinez contends that Dr. Freeman "can report on ISO 10993 test results," but she argues that "he does not have a reliable methodology to use that test to support his opinion[] [that] polypropylene will not degrade for the lifetime of the woman." [DE 202 at pg. 4].

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.

As an initial matter, Martinez spends a majority of her motion arguing that Dr. Freeman is not an FDA expert, so he is not qualified to opine on FDA regulations or the ISO test of the mesh as it relates to the §510(k) clearance process.[1] The court need not address this because it already has excluded all evidence concerning the FDA's §510(k) clearance process. [DE 239]. However, there is a difference between a test required by the FDA and the scientific method by which that test is conducted. Martinez has not challenged the actual biocompatibility test which was performed to meet the FDA requirements. Therefore, Dr. Freeman may testify that the test was conducted and the results as he interprets them. The reason why the test was conducted, to obtain §510(k) clearance, is irrelevant as it pertains to this case.

Next, Martinez has stated that she is not requesting that the following opinions of Dr. Freeman be excluded: polypropylene is not subject to oxidative degradation, polypropylene does not degrade, the defendants did biocompatibility testing of its mesh under the ISO, or how polypropylene's properties are influenced by a biological environment. She further indicates that Dr. Freeman "can report on [the] ISO test results." However, Martinez is challenging his opinion that the mesh will not degrade during the lifetime of the woman because, she claims, the ISO test results, upon which he relies, do not support it. She states that the test only established degradation as it relates to the "shelf life" of the mesh and not as to the oxidation of the mesh while in the body. Therefore, the ISO test results cannot be a reliable basis for his finding.

The defendants respond by stating that the ISO results are not the only basis for Dr. Freeman's opinion regarding the degradation, or lack thereof, of the mesh during the lifetime of the patient. The defendants state that Dr. Freeman and his laboratory at the University of Texas

[1] 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.

"regularly perform many of the underlying analytical type tests of the ISO 10993 standard on polymers like polypropylene." [DE 184 at pg. 8] (internal quotations omitted). Specifically, "Dr. Freeman actually looks to the data from the testing of the finished polypropylene yarn that is knitted into [the defendants'] surgical mesh implants." [DE 184 at pg. 8]. The defendants claim that "these tests and data include a leachable analysis on whether any substances (like the antioxidants) would leach out of the yarn (also referred to as 'fibers') and into the body over the lifetime of the patient." [DE 184 at pg. 9]. Lastly, the defendants state that Dr. Freeman's opinion also is based on relevant literature.

There is no dispute that Dr. Freeman is an experienced polymer scientist with an expertise in that field. As mentioned above, Martinez has represented that she does not object to several of Dr. Freeman's opinions including his opinion that polypropylene does not degrade. However, she takes issue with him stating that polypropylene does not degrade in the woman's body for the lifetime of the implant because the ISO testing cannot reveal that. The court finds Martinez's argument unpersuasive. Dr. Freeman's opinion regarding the lack of degradation of the defendants' mesh, for the lifetime of it, is based on more than just the ISO test results. Dr. Freeman has conducted various additional tests to support his opinion, as well as relying on literature in the field. As a result, Dr. Freeman is qualified to offer this opinion that polypropylene mesh does not degrade during the lifetime of the woman. Any challenge to his methodology affects the weight, not the admissibility, of his opinion.

For the foregoing reasons, the defendants' the Motion [DE 166] is **GRANTED in part.**

ENTERED this 17th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge