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 Evidence About the FDA and for Pretrial Ruling on Whether Jury Instruction on Compliance with Applicable Codes Will be Given [DE 167] filed by the plaintiff, Rebecca Martinez, on September 30, 2021. For the following reasons, the Motion [DE 167] 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.

Any medical device must receive the approval of the Food and Drug Administration (FDA) before it can be marketed. In the instant motion, Martinez asks the court to exclude evidence of the FDA's §510(k) clearance process that resulted in the market approval of Restorelle Y. Additionally, she asks the court to make a pretrial ruling on whether a jury instruction on a provision of the Indiana Products Liability Act (IPLA) which provides for the rebuttable presumption that a product was not defective based on certain affirmative defenses will be given. The defendants oppose both requests.

Discussion

The FDA offers several different approval methods before manufacturers may market their products. The two methods relevant here are known as the "premarket approval process" and the §510(k) clearance process. Since Restorelle Y was approved for sale via the §510(k) clearance process, the court will address the premarket approval process only briefly. The

premarket approval process "requires extensive submissions by the device manufacturer and a thorough review by the FDA." ***Kaiser v. Johnson & Johnson***, 947 F.3d 996, 1003 (7th Cir. 2020). The primary focus is on the safety of the product. Though both have the same end result, approval for market sale, the §510(k) clearance process serves as an exemption to the premarket approval process and allows a product to undergo a less rigorous safety review by the FDA before being deemed marketable.

The Medical Device Amendments of 1976 (MDA) established a framework for federal regulation of medical devices. ***Kaiser***, 947 F.3d at 1003. "The MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation." ***Kaiser***, 947 F.3d at 1003. However, as stated above, there are exceptions to this. The MDA exempts from premarket review, any medical device which has been given §510(k) clearance from the FDA. ***Kaiser***, 947 F.3d at 1004. 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. However, "the FDA has promulgated a disclaimer that the §510(k) clearance does not in any way denote official approval of the device." ***Kaiser***, 947 F.3d at 1005 (internal quotations omitted); *see also* ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 322-23 (2008) (noting that devices that "enter the market through §510(k) have never been formally reviewed under the MDA for safety or efficacy") (internal quotations omitted).

In ***Kaiser***, the district court excluded §510(k) evidence, and the Seventh Circuit affirmed that decision. The Seventh Circuit stated that the introduction of the §510(k) clearance process "invit[es] the jury to draw an inference that the device was safe," when the clearance process really "speaks to equivalence, not safety." ***Kaiser***, 947 at 1018. This court agrees. Introducing

evidence of Restroelle Y's FDA clearance could cause "a confusing sideshow over the details of the §510(k) process" and mislead the jury. ***Kaiser***, 947 F.3d at 1018.

Also worth noting is that §510(k) clearance can be the product of "piggybacking," meaning that a device can be deemed substantially equivalent to a device already on the market, thereby obtaining §510(k) clearance, but that equivalent device also could have entered the market by way of §510(k) clearance. This moves a medical device "incrementally further and further away from the 'original' predicate device that the FDA actually classified." ***Kaiser***, 947 F.3d at 1005. This provides another reason to exclude this evidence in an effort to minimize confusion to the jury. *See* ***Kaiser***, 974 F.3d at 1018 (finding that while certainly relevant, "the probative value of this evidence [i]s minimal and substantially out-weighed by the risk of confusing or misleading the jury and wasting time"). As a result, evidence relating to the §510(k) clearance process of Restorelle Y will be excluded.

Next, Martinez asks the court to make a pretrial ruling on whether a jury instruction of the IPLA's rebuttable presumption will be given. The IPLA provides for a rebuttable presumption that a product that has caused physical harm is not defective, and the manufacturer is not negligent, if the product "was in conformity with the generally recognized state of the art applicable to safety of the product at the time the product was designed, manufactured, packaged, and labeled." ***Kaiser***, 947 F.3d at 1017 (*citing* **IND. CODE §34-20-5-1**). In ***Kaiser***, the Seventh Circuit affirmed the district court's decision to refuse an instruction on the presumption based on the evidence admitted at trial.

It would be premature for the court to determine whether the instruction should be given before any evidence has been introduced.[1] *See* ***Byrd v. Illinois Dept. of Public Health***, 423 F.3d

[1] The Indiana Pattern Jury Instruction on punitive damages refers to "criminal conduct." There will be no instruction referring to criminal conduct without evidence to support it.

696, 705 (7th Cir. 2005) (finding that jury instructions need not only contain correct legal statements, but also "be supported by the evidence"). Therefore, the court declines to make a finding on this issue at this time.

Based on the findings above, Martinez's Motion [DE 167] is **GRANTED in part**.

ENTERED this 16th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge