UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

REBECCA MARTINEZ,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 2:18-cv-220
	)	
COLOPLAST CORP. AND COLOPLAST MANUFACTURING US, LLC,	)	
	)	
Defendants.	)	

OPINION AND ORDER

This matter is before the court on the Motion for Summary Judgment [DE 163] filed by the defendants, Coloplast Corp. and Coloplast Manufacturing US, LLC, on September 30, 2021. For the following reasons, the motion is **GRANTED in part**.

Background

The plaintiff, Rebecca Martinez, initiated this lawsuit on June 6, 2018, alleging injuries caused by an implanted surgical mesh manufactured by the defendants, Coloplast Corp. and Coloplast Manufacturing US, LLC (hereinafter collectively referred to as the defendants). Polypropylene mesh devices have been the subject of multiple lawsuits which were assigned to the judicial panel on multidistrict litigation.

Prior to 2016, 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 he 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. As a result, Martinez has filed this lawsuit against the defendants[1]. Her complaint contains one count of negligence (count VI), a strict liability design defect claim (count VII), a strict liability failure to warn claim (count VIII), a discovery rule, tolling, and fraudulent concealment claim (count IX)[2], and a claim for punitive damages (count X). The defendants have moved for summary judgment on all claims. Martinez responded in opposition on November 1, 2021, and the defendants replied on November 19, 2021.

Discussion

Pursuant to **Federal Rule of Civil Procedure 56(a)**, summary judgment is proper only if it is demonstrated that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." ***Celotex Corp. v. Catrett***, 477 U.S. 317, 322–23 (1986); ***Garofalo v. Vill. of Hazel Crest***, 754 F.3d 428, 430 (7th Cir. 2014); ***Kidwell***

[1] Coloplast Corp. and Coloplast Manufacturing US, LLC are two of six defendants originally sued in this case. The other four defendants have been dismissed.

[2] In her response to the defendants' Motion for Summary Judgment, Martinez withdrew count IX. Therefore, count IX of her Amended Complaint [DE 23] is **DISMISSED**.

v. Eisenhauer, 679 F.3d 957, 964 (7th Cir. 2012); ***Stephens v. Erickson***, 569 F.3d 779, 786 (7th Cir. 2009). A fact is material if it is outcome determinative under applicable law. The burden is upon the moving party to establish that no material facts are in genuine dispute, and any doubt as to the existence of a genuine issue must be resolved against the moving party. ***Adickes v. S.H. Kress & Co.***, 398 U.S. 144, 160 (1970); ***Stephens***, 569 F.3d at 786.

When the movant has met its burden, the opposing party cannot rely solely on the allegations in the pleadings but must "point to evidence that can be put in admissible form at trial, and that, if believed by the fact-finder, could support judgment in [her] favor." ***Marr v. Bank of America, N.A.***, 662 F.3d 963, 966 (7th Cir. 2011); *see also* ***Steen v. Myers***, 486 F.3d 1017, 1022 (7th Cir. 2007) (quoting ***Hammel v. Eau Galle Cheese Factory***, 407 F.3d 852, 859 (7th Cir. 2005) (summary judgment is "the put up or shut up moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of the events.")). The non-moving party cannot rely on conclusory allegations. ***Smith v. Shawnee Library System***, 60 F.3d 317, 320 (7th Cir. 1995). Failure to prove an essential element of the alleged activity will render other facts immaterial. ***Celotex***, 477 U.S. at 323; ***Filippo v. Lee Publications, Inc.***, 485 F. Supp. 2d 969, 972 (N.D. Ind. 2007) (the non-moving party "must do more than raise some metaphysical doubt as to the material facts; she must come forward with specific facts showing a genuine issue for trial").

In viewing the facts presented on a motion for summary judgment, a court must construe all facts in a light most favorable to the non-moving party and draw all legitimate inferences in favor of that party. ***Anderson v. Liberty Lobby, Inc***., 477 U.S. 242, 248 (1986); ***McDowell v. Vill. of Lansing***, 763 F.3d 762, 764-65 (7th Cir. 2014). The trial court must determine whether the evidence presented by the party opposed to the summary judgment is such that a reasonable

jury might find in favor of that party after a trial. ***Anderson***, 477 U.S. at 248; ***Cung Hnin v. Toa, LLC***, 751 F.3d 499, 504 (7th Cir. 2014); ***Wheeler v. Lawson***, 539 F.3d 629, 634 (7th Cir. 2008).

First, the defendants claim that Martinez cannot meet her burden of proving individual causation because her specific causation expert, Dr. Michael Margolis, cannot provide an expert opinion on the cause of her current medical problems. Simultaneously with the instant motion, the defendants filed the Motion to Exclude the Testimony and Opinions of Michael Thomas Margolis, M.D [DE 172], asking the court to exclude all of Dr. Margolis' testimony in this case. Since the court already has ruled on that motion [DE 227], and granted it in part, it will only summarize its findings briefly.

A ***Daubert*** hearing was held on the admissibility of Dr. Margolis' testimony on January 4, 2022. Dr. Margolis testified, and both parties presented arguments. The court ultimately held that Dr. Margolis' opinions relating to the design and biomedical properties of Restorelle Y were not admissible because he had not demonstrated any experience or training that would allow him to reliably testify as to how the design of Restorelle Y was defective. Additionally, the court held that his opinions relating to Martinez's future care were not admissible. However, the court found Dr. Margolis' specific causation opinions of Martinez's pain in her back, pelvis, abdomen, and during sex to be reliable and allowed those opinions to remain. Lastly, the court held that Dr. Margolis' potential testimony about the warnings associated with Restorelle Y were inadmissible because the parties agreed that Dr. Margolis was not qualified to offer testimony about them from a regulatory perspective and because Dr. Waran testified that, based on his familiarity with the product, he did not read the warnings prior to surgery. Therefore, Martinez can rely on the testimony of Dr. Margolis to substantiate some her medical claims.

Next, the defendants claim that Martinez' design defect claim fails.[3] In this diversity case, the parties are in agreement that the Indiana Products Liability Act (IPLA) applies. Under **IND. CODE § 34-20-14**, all claims against a manufacturer by a consumer come within the scope of the statute regardless of the legal theory raised in the complaint. ***Kaiser v. Johnson & Johnson***, 947 F.3d 966, 1007 (7th Cir 2020); ***Koehler by Koehler v. Wyeth Laboratories Div. of America Home Products Corp***., 1987 WL 47831, at *3 (S.D. Ind. Sept. 8, 1987); *see also* ***Dague v. Piper Aircraft Corp***., 275 Ind. 520, 528 (1981) (holding that the IPLA "expressly applies to all product liability actions sounding in tort, including those based upon the theory of negligence …"). A manufacturer is liable for a defectively designed product if the product is found to be in an unreasonably dangerous condition when it is placed into the stream of commerce. ***Kaiser***, 947 F.3d at 1007.

Indiana also has adopted **Restatement of Torts (2d) § 402A** along with Comment k of that section. ***Ortho Pharmaceutical Corp. v. Chapman***, 180 Ind. App. 33, 37 (Ind. Ct. App. 1979); ***Parks v. Danek Medical***, Inc., 1999 WL 1129706, at *6 (N.D. Ind. June 17, 1999). Section 402A is under the strict liability provisions of the Restatement. Comment k recognizes that some products are "unavoidably unsafe" and that the benefits from a potentially dangerous product being placed in the stream of commerce outweigh the risks they pose to the public. Experimental drugs are given as an example in Comment k. ***Parks v. Danek Medical***, Inc., 1999 WL 1129706, at *6 (N.D. Ind. June 17, 1999).

The defendants challenge the strict liability design defect claim in the instant motion and argue that the Restorelle Y comes within the scope of Comment k. In other words, the defendants are arguing that the strict liability portion of the IPLA bars the design defect claim,

[3] The defendants address only the strict liability design defect claim (count VII) in their Motion for Summary Judgment, waiving any argument against Martinez's design defect claim based on negligence (count VI).

conceding that the negligence claim as it relates to the design defect.

The IPLA provides a negligence, not a strict liability, standard for design defect claims. The plaintiff must

> establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions.

IND. CODE § 34-20-2-2.

See also ***Kaiser***, 947 F.3d at 1008.

The briefs are based on the assumption that Comment k applies to the design defect claim. It does not. By its terms, **Restatement §402A** outlines the elements of a strict liability claim. Because, in Indiana, a design defect claim is based on negligence, §402A and its accompanying Comments are not applicable to design defect claims. As a result, the case will proceed to trial on the issue of a defective design based on the theory of negligence and not strict liability. Therefore, count VII of the Amended Complaint [DE 23] is **DISMISSED**.

Next, the defendants challenge Martinez's failure to warn claims. Martinez has plead both a strict liability failure to warn claim as well as failure to warn based on negligence. As discussed above, Indiana does not recognize design defect claims on the basis of strict liability. Since the failure to warn can render a product defective, such a claim must be based in negligence. ***Kaiser***, 947 F.3d at 1007-08. As a result, count VIII of the Amended Complaint [DE 23] is **DISMISSED**.

The defendants argue that the warnings accompanying Restorelle Y were adequate as a matter of law and that the undisputed facts show that different warnings would not have changed the treatment decision of Dr. Waran, the implanting physician. Therefore, the defendants claim, Martinez cannot establish causation under the learned-intermediary doctrine.

Under the IPLA, a product is deemed defective if the seller does not "properly package or label the product to give reasonable warnings of danger about the product … when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." ***Kaiser***, 947 F.3d at 1015 (*citing* **IND. CODE 34-20-4-2**). When the seller of a product is a manufacturer and the consumer is a physician, Indiana's learned-intermediary doctrine governs and the manufacturer "can discharge th[e] [duty to warn] by providing the adequate warnings to physicians." ***Kaiser***, 947 F.3d at 1015; *see also* ***Ortho Pharm. Corp***., 388 N.E.2d at 548-49 (holding that "since such drugs are available only by prescription, a manufacturer's duty to warn extends only to the medical profession, and not the ultimate users"). In other words, the defendants "cannot be held liable if it [] provided the appropriate warnings" and Dr. Waran failed in his "duty to transmit the[] warnings to" Martinez. ***Parks***, 1999 WL 1129706, at *6 (*citing* ***Ortho Pharm. Corp***., 388 N.E.2d at 549); *see also* ***Phelps v. Sherwood Medical Industries***, 836 F.2d 296, 303 (7th Cir. 1987) (finding that "it was up to [the doctor], the heart surgeon who, according to the evidence, knew the risks and benefits of this kind of catheter usage, to warn [the plaintiff]").

Martinez has alleged the following injuries resulting from the implantation of Restorelle Y: pain in her back, pelvis, abdomen, and during sex, as well as urinary incontinence, urinary tract infections, and thickening of the small bowel. Martinez has argued that these complications are due to Restorelle Y eroding, causing it to shrink and contract after it was implanted. The Instruction For Use (IFU) accompanying Restorelle Y is more than one page long and contains over 80 different warnings. Included are warnings of the following adverse events that are "known to occur": "mesh erosion (e.g. vagina, urethra, bladder)", "mesh extrusion", "bladder, bowel, urethra, vagina, vessel, and/or nerve pertoration/injury", and "pain

(acute or chronic)."[4] [DE 168-3]. It also warned of additional risks including "allergic and/or foreign body reaction", "dyspareunia/partner discomfort", "palpable mesh (patient and/or partner)", "sexual dysfunction", "small bowel obstruction", "urinary tract infection", and "continued and/or worsening incontinence." [DE 168-3].

Applying the learned-intermediary doctrine to this case, it was Dr. Waran's responsibility to warn Martinez of all of the known risks and complications of Restorelle Y, including those discussed above. Dr. Waran testified to the following:

> Q: Doctor, do you agree there's no such thing as a risk free surgery?
> Waran: I agree.
> Q: Would you also agree that all pelvic floor surgeries have basic known risks?
> Waran: Yes.
> Q: And there was basically known risks to all pelvic floor surgeries back in March 2016?
> Waran: Yes.
>
> ***
>
> Q: Before you recommended TVT ABBREVO[5] to Miss Martinez – I am going to read you a list of complications and I'm going to ask if you're aware of those complications before you made the recommendation to Miss Martinez, okay?
> Waran: Okay.
> Q: Acute and chronic pain with sexual intercourse?
> Waran: Yes.
> Q: Vaginal scarring?
> Waran: Yes.
> Q: Urinary problems?
> Waran: Yes.
> Q: Urinary Frequency?
> A: Yes.
> Q: Urinary urgency?
> Waran: Yes.
> Q: Retention?
> Waran: Yes.

[4] Acute conditions are "severe and sudden in onset," whereas chronic is defined as "a long-developing syndrome …" *Acute vs. Chronic Conditions*, MEDICINEPLUS, https://medlineplus.gov/ency/imagepages/18126.htm (last visited Feb. 1, 2022). Martinez briefly argues that the defendants should have included a warning describing the risk of pain as "severe." The warnings contain the risk of "acute" pain which, by definition, encompasses the notion of "severe" pain.

[5] Restorelle Y is often referred to as TVT ABBREVO or TVT.

Q: Urinary obstruction?
Waran: Yes.
Q: Either relapse or any urinary incontinence?
Waran: Yes.
Q: What about organ damage?
A: yes.
Q: Nerve damage?
Waram: Yes.
Q: Bleeding?
Waran: Yes.
Q: Wound complication?
Waran: Yes.
Q: Inflammation?
Waran: Yes.
Q: Fistula Formation?
Waran: Yes.
Q: Neuromuscular problems?
Waran: Yes
Q: The need for additional surgery to treat a complication?
Waran: Yes.
Q: Recurrence of stress urinary incontinence or failure of the device to treat Urinary incontinence?
Waran: Yes.
Q: Foreign body response to mesh?
Waran: Yes.
Q: Erosion, exposure or extrusions of the mesh?
Waran: Yes.
Q: Contracture or shrinkage of the mesh?
Waran: Yes.
Q: Were you aware each of those problems I just described could be either acute or chronic?
Waran: Yes.
Q: And that each of those potential complications could be mild, moderate or severe?
Waran: Yes.

[Dr. Waran Dep. pg. 75-78].

When asked about whether he relied on Restorelle Y's IFU and whether he considered the associated risks before recommending that Martinez proceed with the surgery, Dr. Waran testified as follows:

> Q: Okay. Now, so you in part relied upon instruction for use for the Restorelle Y as part of your risk benefit discussion with Miss.

Martinez. Is that accurate or not?
A: Yes.

***

Q: Is it your – does that document the fact that you had a risk/benefit discussion with Miss Martinez about surgical treatment for the stress urinary incontinence?
A: Yes.
Q: Do you believe that you had a strong, robust informed discussion with Miss. Martinez?
Waran: Yes.

***

Q: Is it fair to say, Doctor, that in providing quality care to your patients you familiarize yourself with safety information before using a medical device for the first time?
Waran: Yes.
Q: And that the IFU may be one of the things you use to inform yourself but is not the only thing, correct?
Waran: Yes.

***

Q: Do you recall in relation to Miss Martinez's surgery when the last time you had read the IFU for [Restorelle Y] was?
Waran: I don't recall but probably first few times that I used the product.

***

Q: In your hands, Doctor, have you found that the benefits of the TVT for patients outweigh the potential risks?
Waran: Outweigh, yes.

***

Q: In your hands, Doctor, have you found TVT to be a safe and effective treatment for your patients?
Waran: Yes.

[Dr. Waran Dep. pg. 49, 51, 79-86].

Martinez makes unavailing arguments in support of her failure to warn claim. She claims that the defendants should not be permitted to rely upon physicians telling their patients about the design defects in Restroelle Y when they never told the implanting surgeons, like Dr. Waran, of risks including degradation and pore collapse. She states that Dr. "Waran wasn't aware of numerous risks." Although there is no evidence to support that statement, even if he was not aware of all of the risks, Dr. Waran certainly was aware of the ones relevant to this

case. He testified that he was aware of the possibility of erosion, exposure or extrusions of the mesh, as well as contracture or shrinkage of the mesh. Additionally, the IFU explicitly warned of mesh erosion or extrusion, which can lead to degradation and pore collapse.

The evidence as to the failure to warn claim is clear. There is no dispute that the Restorelle Y's IFU warned of the exact injuries that Martinez now complains of. Additionally, Dr. Waran testified that he was aware of all of the relevant risks associated with Restorelle Y prior to the surgery and had a "strong, robust informed discussion" with Martinez about them before she agreed to the surgery. Dr. Waran testified that he believed the risks associated with Restorelle Y were outweighed by the benefits and continues to use the mesh. *See* ***Parks***, 1999 WL 1129706, at *8 (holding that "because the learned-intermediary doctrine applies in this case and the undisputed evidence shows that [the doctor] was aware of the risks of pedicle screw fixation, summary judgment will be granted in favor of [the manufacturer defendant] on [the plaintiff]'s failure to warn claim"). The facts show that the defendants have fulfilled their duty to warn, as it pertains to this case, under the learned-intermediary doctrine.

The court notes that Martinez attempts to make the argument that had she known that she would have her current medical problems, she never would have consented to the surgery. It stands to reason that any patient who has had unsatisfactory results regrets having the surgery. This is not the legal standard or test for a failure to warn claim. For the reasons discussed above, Martinez's failure to warn claim is **DISMISSED**.

Finally, the defendants request that the court grant summary judgment in their favor on Martinez's punitive damages claim. Under Indiana law, "punitive damages may be awarded only if there is clear and convincing evidence that the defendant 'acted with malice, fraud, gross negligence or oppressiveness which was not the result of a mistake of fact or law, honest error

or judgment, over-zealousness, mere negligence or other human failing.'" ***Parker v. Hostetler***, 2015 WL 5177637, at *14 (N.D. Ind. Sept. 4, 2015) (*quoting* ***McLaughlin v. State Farm Mut. Auto. Ins. Co.***, 30 F.3d 861, 868 (7th Cir. 1994)). "Where the substantive law mandates a 'clear and convincing' standard of proof … the court in disposing of a summary judgment motion must consider whether a reasonable factfinder could conclude that the plaintiff had sufficient evidence to meet that burden." ***Wood v. Allstate Ins. Co.***, 2012 WL 6553000, at *4 (N.D. Ind. Dec. 14, 2012) (internal citations omitted). However, the issue of "[w]hether conduct is sufficient to justify an award of punitive damages is usually a factual question for the jury to decide." ***Parker***, 2015 WL 5177637, at *14.

The defendants' argument in favor of summary judgment on Martinez's punitive damages claim is cursory. They claim that Restorelle Y was cleared by the FDA and that placing it in the stream of commerce did not rise to the quasi-criminal state of mind required to recover an award of punitive damages in Indiana. They also noted that Dr. Margolis conceded that was within the standard of care for Dr. Waran to have implanted the mesh given Martinez's medical problems.

Since the defendants have not developed any argument challenging Martinez's negligence claim as it relates to design defect, it can be assumed that there still are genuine disputes about material facts. Deciding the viability of the punitive damages claim at this point would be premature. Therefore, Martinez's punitive damages claim will proceed to trial. *See* ***McLaughlin***, 30 F.3d at 868 (finding that where there "were substantial disputes about material facts and inferences to be drawn from circumstantial evidence," the denial of summary judgment on the plaintiff's punitive damages claim was "not erroneous").

Based on the foregoing reasons, the Motion for Summary Judgment [DE 163] is

GRANTED in part. Counts VII, VIII, and IX of the Amended Complaint [DE 23] are hereby **DISMISSED**. The claims for negligence, with the exception of failure to warn, and punitive damages remain.

ENTERED this 4th day of February, 2022.

/s/ Andrew P. Rodovich
United States Magistrate Judge