UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

MARGO ELLIS and BEAU ELLIS, Plaintiffs, v. ETHICON, INC., and JOHNSON & JOHNSON, Defendants.	CASE NO. C20-5692 BHS ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT

This matter comes before the Court on Defendants Ethicon, Inc. and Johnson & Johnson's (collectively "Defendants") supplemental motion for summary judgment. Dkt. 104. The Court has considered the briefings filed in support of and in opposition to the motion and the remainder of the file and hereby grants in part and denies in part the motion for the reasons stated herein.

I. PROCEDURAL HISTORY

On December 16, 2012, Plaintiffs Margo and Beau Ellis filed suit against Defendants in the MDL *In re Ethicon, Inc. Products Liability Litigation*, MDL No. 2327, located in the Southern District of West Virginia. Dkt. 1. On August 16, 2017, Defendants moved for partial summary judgment. Dkts. 37, 38. Plaintiffs conceded the

dismissal of several of their claims but opposed Defendants' motion as to their claim for Fraudulent Concealment. *See* Dkt. 41. The Southern District of West Virginia did not resolve the motion prior to transfer.

In July 2020, this case was transferred from the Southern District of West Virginia to this Court. Dkt. 82. The Court referred the case to the Circuit Mediation Office of the Ninth Circuit Court of Appeals, Dkt. 102, but mediation was unsuccessful. Defendants then moved for summary judgment on Plaintiffs' Washington Products Liability Act ("WPLA"), RCW 7.72, *et seq.*, claims, fraud-based claims, and loss of consortium claim on March 25, 2021. Dkt. 104. On April 19, 2021, Plaintiffs responded. Dkt. 106. On April 23, 2021, Defendants replied. Dkt. 107. On April 28, 2021, Plaintiffs filed a surreply. Dkt. 110.

II. FACTUAL BACKGROUND

Plaintiffs bring claims against Defendants arising out of Mrs. Ellis's surgical implantation of TVT—a prolene mesh implant—to treat her stress urinary incontinence. Dkt. 1; Dkt. 105-1, Second Amended Plaintiff Fact Sheet ("PFS"), at 6. Dr. Marc Mitchell performed surgery on Mrs. Ellis to implant the TVT device on January 6, 2010 in Silverlake, Washington. PFS at 6. Mrs. Ellis states that she has suffered from "chronic sharp pelvic pain" and "nerve pain/neuropathy in [her] legs and feet," as well as a "systemic immune system reaction, including all over body rash" and "vaginal discharge." *Id.* at 8. She further states that she has extremely painful intercourse and has suffered from depression and "great frustration" as a result of her inability to do many activities. *Id.* Mrs. Ellis asserts that she first had painful intercourse within the first few

months after her January 2010 surgery, that her back pain and neuropathy began shortly after, and that her pelvic pain worsened approximately four months after surgery. *Id.*

Dr. Mitchell (Mrs. Ellis's implanting surgeon) has surgically implanted approximately 400 to 500 polypropylene mesh midurethal slings, such as TVT, for the treatment of stress urinary incontinence. Dkt. 106-1, Deposition of Marc Mitchell, D.O. ("Mitchell Dep."), at 20:11–15. He was trained to use pelvic mesh implants during his residency and not by Ethicon. *Id.* at 23:5–9. However, Dr. Mitchell testified that he previously attended educational symposiums on the use of pelvic mesh implants but that he was unsure who specifically sponsored the symposiums. *Id.* at 21:13–18. Dr. Mitchell further testified that he kept himself informed on mesh products by attending professional meetings, reading medical journals such as the Journal of the American Urologic Association, and discussing urology and journals with colleagues. *See id.* at 90:16–8; 91:23–4; 93:4–10; 94:19–95:5. And he stated that if a mesh product manufacturer came out with a new product or brochure, he would look through the package insert or brochure and familiarize himself with the brochure before giving it to a patient. *Id.* at 95:6–12; 96:7–13. But Dr. Mitchell generally does not use data that comes from a mesh manufacturer to stay current on product information. *Id.* at 95:21–13.

At the time of Mrs. Ellis's surgery, Dr. Mitchell was aware of the potential risks associated with the procedure, including (but not limited to) acute and/or chronic pain with intercourse, incontinence, inflammation, organ or nerve damage, mesh erosion, exposure, or extrusion, and infection. *Id.* at 60:10–63:22; *see also* Dkt. 105-5. Plaintiffs contend that Dr. Mitchell was aware of general risks associated with TVT at the time

Mrs. Ellis's implantation but that he was unaware of certain risks that were known to Ethicon but undisclosed in either patient brochures or instructions for use. Dkt. 106 at 4. Dr. Mitchell testified though that if any additional risks were disclosed to him within any literature, such as patient brochures, he would have passed the information on to the patient. Mitchell Dep. at 104:6–14.

While Dr. Mitchell had previously read the TVT instructions for use, *see id.* at 47:11–19, he did not read the instructions for use when he performed Mrs. Ellis's surgery, *id.* at 48:2–6. He additionally testified that he believed that the TVT was the best surgical option for treating Mrs. Ellis's stress urinary incontinence at that time. *Id.* at 40:23–41:6.

Mrs. Ellis testified that she was sure that she was given a patient brochure about TVT but does not remember getting a brochure from Dr. Mitchell. Dkt. 105-6, Deposition of Margo Ellis ("Ellis Dep."), at 46:1–15. She stated that she would have read the whole brochure and that, after reading the brochure, she was aware that the implantation surgery had some associated risks. *Id.* at 46:21–47:3. Plaintiffs have thus brought claims for violations of the WPLA, for fraud, and for loss of consortium.

III. DISCUSSION

Defendants move for summary judgment on Plaintiffs' unconceded claims for Strict Liability – Failure to Warn, Strict Liability – Design Defect, Common Law Fraud, Fraudulent Concealment, Constructive Fraud, Loss of Consortium, Punitive Damages, and Discovery Rule and Tolling.

A. Summary Judgment Standard

Summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient showing on an essential element of a claim in the case on which the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). There is no genuine issue of fact for trial where the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986) (nonmoving party must present specific, significant probative evidence, not simply "some metaphysical doubt"). Conversely, a genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve the differing versions of the truth. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 253 (1986); *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The determination of the existence of a material fact is often a close question. The Court must consider the substantive evidentiary burden that the nonmoving party must meet at trial—e.g., a preponderance of the evidence in most civil cases. *Anderson*, 477 U.S. at 254; *T.W. Elec. Serv., Inc*., 809 F.2d at 630. The Court must resolve any factual issues of controversy in favor of the nonmoving party only when the facts specifically attested by that party contradict facts specifically attested by the moving party. The nonmoving party may not merely state that it will discredit the moving party's evidence

at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elec. Serv., Inc*., 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory, nonspecific statements in affidavits are not sufficient, and missing facts will not be presumed. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888–89 (1990).

B. WPLA Claims

1. Strict Liability – Failure to Warn

The WPLA permits recovery "if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was . . . not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1). To prevail on a failure to warn claim, a plaintiff must show that (1) the defendant failed to sufficiently warn, (2) the plaintiff suffered damages, and (3) the defendant's failure to sufficiently warn of the dangers was a proximate cause of the plaintiff's damages. *See, e.g.*, *Little v PPG Industries, Inc.*, 19 Wn. App. 812, 818 n.3 (1978) (approving the Restatement of Torts' recitation of the elements). However, in the context of medical failure to warn claims, the duty of the manufacturer to warn is satisfied if the manufacturer gives adequate warning to the physician who prescribes or implants the product. *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13 (1978).

Defendants argue that Plaintiffs' failure to warn claim fails because Mrs. Ellis's implanting physician—Dr. Mitchell—was aware of the specific risks and injuries Plaintiffs' expert Dr. Raybon attributes to the TVT implant, because Dr. Mitchell did not read or rely on the warnings accompanying Mrs. Ellis's implant, and because there is no

non-speculative evidence that Dr. Mitchell would have taken a different course of action if better warnings had been issued.

In order to prove causation, Plaintiffs must show that Mrs. Ellis's implanting physician was aware of the alleged inadequate warning made by Defendants. *See Cutter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9. 2020) ("Dr. Guiler testified that he did not consult these materials to obtain information about the risks of implanting the Prolift device in Jenesta and, in fact, has never relied on them for such information."). They must also show that her physician would have acted differently had he been given an adequate warning. *See Contreras v. Bos. Sci. Corp.*, No. 2:12-cv-03745, 2016 WL 1436682, at *4 (S.D.W. Va. Apr. 11, 2016) ("Here, the plaintiffs have not provided any citations to the record showing that Dr. Baker, the implanting physician, would have taken a different course of action even if she had been given an adequate warning."); *Fulgenzi v. PLIVA*, 140 F. Supp. 3d 637, 648 (N.D. Ohio 2015) ("The undisputed facts in the record establish that plaintiff's physicians did not ever read, let alone rely on, PLIVA's inadequate 2004 warning."); *Higgins v. Ethicon, Inc.*, No. 2:12-cv-01365, 2017 WL 2813144, at *3 (S.D.W. Va. Mar. 30, 2017) (granting summary judgment on a Texas law failure to warn claim because "[t]he plaintiffs have failed to present any testimonial or other evidence that Dr. Anhalt would not have used or prescribed the TVT-S to treat Ms. Higgins had he received a different warning.").

Plaintiffs argue that Defendants' labels and warnings for TVT did not contain "accurate, clear, and consistent warnings and failed to adequately describe the known risks and adverse events associated with the mesh[.]" Dkt. 106 at 11. Specifically, they

argue that the labels did not include any reference to mesh fraying, roping, or curling or to the likelihood, long-term nature, or permanence of injuries Plaintiffs assert Defendants knew at the time. *Id.* at 12 (citing, *inter alia*, Mitchell Dep. at 87:21–88:2, 98:2–9).

Dr. Mitchell did not read the IFU connected with Mrs. Ellis's implant, but he testified that he did previously read materials provided by Ethicon (the materials Plaintiffs assert are inadequate). *See* Mitchell Dep. at 47:11–22. And he further testified that he would have looked through a new product or brochure to familiarize himself with it and would have passed along any new information to the patient. *Id.* at 95:6–12; 96:7–13. This testimony does not support Defendants' assertion that Dr. Mitchell would not have read any updated package inserts. *See* Dkt. 104 at 9.

But Dr. Mitchell was aware of the risks of injuries that Mrs. Ellis asserts she suffers from. *See* Mitchell Dep. at 60:10–63:22; *see also* Dkt. 105-5. A "[medical device] manufacturer's failure to warn a prescribing physician cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved . . . ." *Wash. State Physicians Ins. Exchange & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 315 (1993). Plaintiffs cannot establish proximate cause because of Dr. Mitchell's prior knowledge of the risks of injuries.

And further, Plaintiffs have not presented any non-speculative evidence that Dr. Mitchell would have taken a different course of action if additional warnings were given to him. He testified that he would have read through a new product or brochure and passed that information along to *the patient*; his testimony was not that the new information would have altered his decision to recommend the TVT to Mrs. Ellis. This is

not a conditional statement about whether he would have taken a different course of action in recommending the TVT to Mrs. Ellis as Plaintiffs content. *Cf. Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F. Supp. 2d 1163, 1174 (W.D. Wash. 2006) (concluding that a physician's conditional statement on prescribing a pharmaceutical created a question of fact). While Dr. Mitchell testified that he would like to know "if something was unsafe for use in humans[,]" Mitchell Dep. at 100:21–22, this statement alone does not create an issue of material fact about whether Dr. Mitchell would have taken a different course of action. The evidence provided by Plaintiffs speculates as to what Dr. Mitchell would have done if he was given additional warnings. The uncontroverted evidence is simply that Dr. Mitchell would have informed Mrs. Ellis of the additional risks, not that he "would have treated the product differently and avoided the harm." *Ayers By and Through Smith v. Johnson & Johnson Baby Products Co.*, 59 Wn. App. 287, 291 (1990).

Even assuming Defendants' warnings were inadequate, Plaintiffs have not established proximate cause. Summary judgment is therefore GRANTED as to Plaintiffs' Strict Liability – Failure to Warn claim.

2. Strict Liability – Design Defect

The WPLA also allows for recovery "if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed[.]" RCW 7.72.030(1). To prevail in a WPLA claim for design defect, a plaintiff must show that (1) a manufacturer's product (2) not reasonably safe as designed

(3) caused harm to the plaintiff. *Pagnotta v. Beall Trailers of Or., Inc.*, 99 Wn. App. 28, 36 (2000). Defendants again argue that Plaintiffs cannot establish proximate causation.

Expert testimony is not always required to establish causation for a design defect claim, but "[e]xpert testimony is required to establish causation when an injury involves obscure medical factors that would require an ordinary lay person to speculate or conjecture in making a finding." *Bruns v. PACCAR, Inc.*, 77 Wn. App. 201, 214 (1995) (internal citations omitted). Such is the case here. Plaintiffs' "required expert testimony must provide proof that the defect 'more probably than not' caused [Mrs. Ellis's] injuries." *Id.* at 215.

Plaintiffs' expert here is Dr. Brian Raybon, and in support of their opposition to summary judgment, Plaintiffs filed Dr. Raybon's cases-specific Rule 26 Expert Report, Dkt. 106-5, and Dr. Raybon's supplemental affidavit, Dkt. 106-6. Defendants object to Dr. Raybon's new affidavit, arguing that the Court should exclude the affidavit under Federal Rule of Civil Procedure 37 and Federal Rule of Evidence 702. Dkt. 107 at 10–11. Plaintiffs, in turn, move to strike Defendants' request to exclude. Dkt. 110.

Defendants first argue that Dr. Raybon's affidavit should be excluded pursuant to Rule 37 because the opinions contained therein are not in his Rule 26 expert report. Rule 37 states, in part, that a party is not allowed to use information to supply evidence on a motion if that party fails to provide the information as required by Rule 26(a) unless that failure is substantially justified or is harmless. Fed. R. Civ. P. 37(c)(1). But as Plaintiffs highlight, the Court entered a new scheduling order upon transfer, and the deadline for disclosure of expert testimony is July 28, 2021. Dkt. 100. Defendants themselves bring

their supplemental motion for summary judgment in conformance with the Court's scheduling order, and it would be inconsistent to allow Defendants to bring this motion but exclude an expert's disclosure or report as untimely. The Court does acknowledge that the MDL scheduling order required expert disclosures by September 2019, *see* Dkt. 47, but the Court's current scheduling order allows for any additional discovery to be completed by September 27, 2021. To the extent that Defendants want to conduct further discovery on Dr. Raybon's affidavit, the schedule of the case will allow them to do so. The Court thus concludes that Plaintiffs' submission of Dr. Raybon's affidavit is substantially justified.

Defendants additionally argue that Dr. Raybon's affidavit should be excluded pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Defendants assert that there is "simply no factual basis for Dr. Raybon's opinion that Mrs. Ellis's injuries were caused by alleged mesh-induced 'complications[.]'" Dkt. 107 at 11. Plaintiffs assert Rule 702 and *Daubert* are satisfied because Dr. Raybon's opinions are based on his experience and his review of Dr. Rosenzweig's expert report and Mrs. Ellis's medical records. Dkt. 110 at 3. A court may consider evidence that "could be presented in an admissible form at trial." *Fraser v. Goodale*, 342 F.3d 1032, 1037 (9th Cir. 2003). Plaintiffs could present Dr. Raybon's affidavit in an admissible form if the foundation of his opinions is established. The Court will therefore consider the contents of his affidavit for the purposes of summary judgment.

In forming his opinion, Dr. Raybon reviewed the general expert report of Dr. Bruce Rosenzweig in which he identified the design defects of the Gynecare TVT device that lead to mesh-related complications (i.e., the composition and structure of the mesh used in the TVT). Dr. Raybon states in his affidavit that "it is [his] opinion, to a reasonable degree of medical certainty, that the characteristics (i.e., heavy weight, deforms, small pores, and that it degrades over time) of the old construction mechanical cut polypropylene mesh, as identified in Dr. Rosenzweig's expert report, directly caused the complications" suffered by Mrs. Ellis. Dkt. 106-6, ¶ 8. Unlike other mesh cases this Court has recently ruled on, Dr. Raybon explicitly connects Mrs. Ellis's injuries to specific design defects. *Cf. Breen v. Ethicon, Inc.*, No. C20-5595 BHS, 2021 WL 673485, at *6–7 (W.D. Wash. Feb. 22, 2021); *Rodman v. Ethicon*, No C20-6091, 2021 WL 2434521, at *5–6 (W.D. Wash. June 15, 2021).

Dr. Raybon opines, to a reasonable degree of medical certainty, that "the defect 'more probably than not' caused [Mrs. Ellis's] injuries." *Bruns*, 77 Wn. App. at 215. As such, Plaintiffs have created a genuine issue of material fact as to causation. *Cf. Lynch v. Ethicon, Inc.*, No. 2:20-cv-00217-SMJ, 2020 WL 5733184, at *2 (E.D. Wash. Sept. 24, 2020.) ("But without an expert opinion asserting a causal link between the general *design defects* identified by Dr. Veronikis and Lynch's injuries, Lynch has not established a genuine issue of material fact." (emphasis in original)).

Summary judgment is therefore DENIED as to Plaintiffs' Strict Liability – Design Defect claim.

C. Fraud-Based Claims

Plaintiffs additionally bring claims for Common Law Fraud, Fraudulent Concealment, and Constructive Fraud.

Washington has adopted the nine common law elements of fraud, and, at its core, a fraud claim requires a false representation of material fact. *See Stiley v. Block*, 130 Wn.2d 486, 505 (1996) (listing the nine elements). Defendants argue that Plaintiffs cannot identify fraudulent statements Mrs. Ellis relied upon. *See* Dkt. 104 at 13. Mrs. Ellis testified that she was sure that she was given a patient brochure about TVT but does not remember getting a brochure from Dr. Mitchell. Ellis Dep. at 46:1–15. She did state, however, that she would have read the whole brochure. *Id.* at 46:21–47:3. While Plaintiffs' expert reports may identify how Ethicon misrepresented facts about the mesh in its TVT product, Plaintiffs do not identify any *particular* fraudulent statements Mrs. Ellis relied upon. Their argument does not provide specific, significant probative evidence to create a genuine dispute of material fact. *Matsushita*, 475 U.S. at 586. Summary judgment is therefore GRANTED as to Plaintiffs' Common Law Fraud claim.

Plaintiffs' final fraud-based claims are for Fraudulent Concealment and Constructive Fraud. Both claims require a "special relationship" between the parties that gives rise to a duty to disclose. *See Giraud v. Quincy Farm & Chem.*, 102 Wn. App. 443, 452 (2000) (fraudulent concealment); *Green v. McAllister*, 103 Wn. App. 452, 467–68 (2000), *superseded by statute on other grounds*, RCW 25.05.250(2), *as recognized in McLelland v. Paxton*, 11 Wn. App. 2d 181, 221–22 (2019) (constructive fraud). Whether

a duty to disclose exists is a question of law. *Colonial Imps., Inc. v. Carlton Nw., Inc.*, 121 Wn.2d 726, 731 (1993).

Washington law establishes that "a manufacturer has a duty to warn the medical profession and not the user of its risks." *Terhune* 90 Wn.2d at 18. Plaintiffs argue that there is a special relationship between Defendants and Dr. Mitchell and that relationship is sufficient to establish their fraudulent concealment claim. Dkt. 106 at 18–19. But Plaintiffs provide no case law to support their argument that a relationship between a medical manufacturer and a medical professional can run to the patient. The Court therefore concludes, as a matter of law, that Defendants did not owe a duty of disclosure to Mrs. Ellis. Summary judgment is GRANTED as to Plaintiffs' Fraudulent Concealment and Constructive Fraud claims.

D. Remaining Claims

Defendants additionally move for summary judgment on Plaintiffs' Loss of Consortium, Punitive Damages, and Discovery Rule and Tolling claims.

Loss of consortium is typically thought of as a "loss of society, affection, assistance and conjugal fellowship, and . . . loss or impairment of sexual relations" in the marital relationship. *Ueland v. Pengo Hydra-Pull Corp.*, 103 Wn.2d 131, 132 n.1 (1984) (citing *Black's Law Dictionary* 280 (5th ed. 1979)). In Washington, a loss of consortium claim is a separate and independent claim rather than a derivative claim. *Green v. A.P.C. (Am. Pharm. Co.)*, 136 Wn.2d 87, 101 (1998). Defendants argue that Mr. Ellis's claim for loss of consortium fails because no tort has been committed against his impaired spouse, Mrs. Ellis. Dkt. 104 at 14 (quoting *Conradt v. Four Star Promotions, Inc.*, 45 Wn. App.

847, 853 (1986)). They do not present any substantive arguments for dismissing the loss of consortium claim. As the Court has denied summary judgment on Mrs. Ellis's Design Defect claim, the Court concludes that Mr. Ellis's claim for loss of consortium is still viable. Defendants' motion for summary judgment is therefore DENIED as to the loss of consortium claim.

Defendants also move for summary judgment on Plaintiffs' claims for Punitive Damages and Discovery Rule and Tolling, arguing that these are not recognized causes of action in Washington. Defendants are correct that Washington law prohibits punitive damages in a product liability action. *Laisure-Radke*, 426 F. Supp. 2d at 1174. They are also correct that the discovery rule is not its own cause of action, but rather is a doctrine that determines when a cause of action accrues. *See Green*, 136 Wn.2d at 95 (explaining the application of Washington's discovery rule). Defendants' motion for summary judgment as to Plaintiffs' Punitive Damages and Discovery Rule and Tolling claims is therefore GRANTED.

IV. ORDER

Therefore, it is hereby **ORDERED** that Defendants' supplemental motion for summary judgment, Dkt. 104, is **GRANTED in part** and **DENIED in part**.

Plaintiffs' claims for Strict Liability – Failure to Warn (Count III), Common Law Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Punitive Damages (Count XVII), and Discovery Rule and Tolling (Count XVIII) are **DISMISSED with prejudice**.

Dated this 14th day of July, 2021.

BENJAMIN H. SETTLE
United States District Judge