WO

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Amanda McBroom,
Plaintiff,
v.
Ethicon, Inc.; and Johnsons & Johnson,
Defendants.

No. CV-20-02127-PHX-DGC

ORDER

This products liability action involves pelvic mesh devices manufactured and sold by Defendants Ethicon, Inc. and Johnson & Johnson to treat stress urinary incontinence and pelvic organ prolapse. Plaintiff Amanda McBroom received implants of Defendants' devices and claims they are defective and have caused her serious injury. Plaintiff filed suit in 2015 as part of a multidistrict litigation ("MDL") proceeding in the Southern District of West Virginia. Doc. 1; *see In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va. 2012). The case was transferred to this Court on November 4, 2020. Docs. 41, 56.

Defendants have filed a motion for partial summary judgment that is fully briefed (Docs. 30, 31, 35, 38), and oral argument will not aid the Court's decision, *see* Fed. R. Civ. P. 78(b); LRCiv 7.2(f). For reasons set forth below, the Court will grant the motion in part and deny it in part.[1]

[1] The parties have filed motions to exclude expert witnesses. Docs. 32, 79, 80. The Court will address those motions in a separate order.

I. Background.

Plaintiff was implanted with Defendants' Gynecare Prolift and TVT Secur pelvic mesh devices on April 26, 2007. Doc. 1 ¶¶ 8-10 (short form complaint); Doc. 30-1 at 3 (plaintiff fact sheet). Dr. Scott Crawford performed the surgical procedure at Banner Good Samaritan Medical Center in Phoenix, Arizona. Doc. 1 ¶¶ 10-12. Plaintiff claims that she began experiencing adverse symptoms from the Prolift and TVT Secur devices in 2011. Doc. 30-1 at 4.

Plaintiff brought this action in 2015, asserting a host of state law claims and seeking compensatory and punitive damages. Doc. 1; *see McBroom v. Ethicon, Inc.*, No. 2:15-cv-03043 (S.D. W. Va. Mar. 13, 2015). Specifically, Plaintiff asserts the following claims under Arizona law: negligence and gross negligence (Counts I and XIV); strict liability manufacturing defect, failure to warn, defective product, and design defect (Counts II-V); common law fraud, fraudulent concealment, and constructive fraud (Counts VI-VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express and implied warranty (Counts XI and XII); violation of consumer protection laws (Count XIII); unjust enrichment (Count XV); and punitive damages (Count XVII). Doc. 1 ¶ 13.[2]

Defendants move for summary judgment on all claims except design defect and punitive damages (Counts V and XVII). Docs. 30 at 1-2, 31 at 4-14. Plaintiff does not oppose summary judgment on the claims for manufacturing defect (Count II), defective product (Count IV), fraud (Counts VI-VIII), negligent misrepresentation (Count IX), breach of warranty (Counts XI and XII), consumer protection violations (Count XIII), gross negligence (Count XIV), and unjust enrichment (Count XV). *See* Doc. 35. The

[2] The parties agree that Arizona law governs Plaintiff's claims because Arizona is where she resides, received the implants, and suffered her alleged injuries. Docs. 31 at 3-4, 35 at 2; *see also In re Ethicon, Inc.*, No. 2:12-MD-02327, 2014 WL 346717, at *7 (S.D. W. Va. Jan. 30, 2014) ("As this is a direct-filed case, the choice of law that applies is the place where the plaintiff was implanted with the product."). The Court also agrees. *See Barraza v. C. R. Bard Inc.*, 322 F.R.D. 369, 383 (D. Ariz. 2017) (Arizona follows the "most significant relationship" test of the Restatement (Second) of Conflict of Laws, which considers the place where the injury occurred, the place where the conduct causing the injury occurred, and the residence of the parties).

Court will grant summary judgment on those claims. *See* Fed. R. Civ. P. 56(a), (e)(3); *Madding v. Ethicon, Inc.*, No. 2:12-CV-02512, 2017 WL 2624546, at *2 (S.D. W. Va. June 16, 2017) (granting summary judgment on conceded claims); *Paseka v. Ethicon Inc.*, No. CV-20-00100-PHX-SRB, 2020 WL 8175427, at *3 (D. Ariz. Nov. 9, 2020) (granting summary judgment on unopposed claims). As explained more fully below, the Court will also grant summary judgment on the failure to warn claim (Count III) and the negligence and negligent infliction of emotional distress claims (Counts I and X) to the extent they are based on an alleged failure to warn.

II. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor – "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson*, 477 U.S. at 255.

III. Strict Liability Failure to Warn Claim (Count III).

There are three types of defects in strict products liability actions in Arizona: manufacturing defects, design defects, and informational defects in instructions and warnings. *See Sw. Pet Prods., Inc. v. Koch Indus., Inc.*, 273 F. Supp. 2d 1041, 1051 (D. Ariz. 2003) (citing *Piper v. Bear Med. Sys., Inc.*, 883 P.2d 407 (Ariz. Ct. App. 1993)). To

establish a failure to warn claim, the plaintiff must show, among other things, that the defendant had a duty to warn. *See id.* (citing *Gosewisch v. Am. Honda Motor Co.*, 737 P.2d 376 (1987)). Manufacturers generally have a duty to warn consumers of foreseeable risks of harm from using their products. *See Watts v. Medicis Pharms. Corp.*, 365 P.3d 944, 949 (Ariz. 2016). In cases involving medical devices, however, Arizona applies the "learned intermediary" doctrine. *See id.*; *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018) ("*Watts* adopted the Restatement (Third) of Torts provision [in § 6(d)] that sets forth the [doctrine] for prescription drug and medical device manufacturers."); *Paseka*, 2020 WL 8175427, at *3 ("There is no doubt that the [doctrine] applies to medical device manufacturers like Defendants.") (citing *Conklin*, 431 P.3d at 577-78)); *Baca v. Johnson & Johnson*, No. CV-20-01036-PHX-DJH, 2020 WL 6450294, at *3 (D. Ariz. Nov. 2, 2020) ("This case involves a medical device sold by a manufacturer to a health-care provider for use by a patient, and the Court, therefore, finds that the learned intermediary doctrine applies."). Under this doctrine, "a manufacturer satisfies its duty to warn end users by giving appropriate warnings to the specialized class of [intermediaries] who may prescribe or administer the product." *Conklin*, 431 P.3d at 577 (quoting *Watts*, 365 P.3d at 947). "[T]he intermediary (often a treating physician) 'assumes the duty to pass the necessary warnings on to the end users.'" *Id.* (quoting *Watts*, 365 P.3d at 948).[3]

To prevail on a failure to warn claim, the plaintiff also must show that the missing warning made the product defective and unreasonably dangerous, the warning was missing when the product left the defendant's hands, and the failure to warn proximately caused the plaintiff's injuries. *See Sw. Pet Prods.*, 273 F. Supp. 2d at 1051; *Paseka*, 2020 WL 8175427, at *4; *Baca*, 2020 WL 6450294, at *3.

Defendants argue that Plaintiff cannot establish causation because Dr. Crawford was aware of the risks posed by the Prolift and TVT Secur devices before Plaintiff's surgery

---

[3] Plaintiff does not recall Dr. Crawford giving her any written information about the Prolift and TVT Secur devices before her surgery, and did not otherwise rely on Defendants' product information in making her decision to have the surgery. *See* Doc. 31 at 2, ¶ 4 (citing Doc. 30-2 at 7-10).

and there is no evidence that a different warning would have altered his decision to implant the devices. Docs. 31 at 5-6, 38 at 2-3. The Court agrees.[4]

"The proximate cause of an injury is that which, in a natural and continuous sequence, unbroken by any efficient intervening cause, produces an injury, and without which the injury would not have occurred." *Paseka*, 2020 WL 8175427, at *4 (quoting *McMurty v. Weatherford Hotel, Inc.*, 293 P.3d 520, 532 (Ariz. Ct. App. 2013)). To establish proximate cause in a failure to warn claim, the plaintiff "must submit evidence that the medical outcome would have been different had the manufacturer provided different warnings to the physician." *Id.* (citing *D'Agnese v. Novartis Pharms. Corp.*, 952 F. Supp. 2d 880, 891 (D. Ariz. 2013)).

Plaintiff claims that the Prolift and TVT Secur devices caused her to suffer the following injuries: pelvic pain, dyspareunia (painful intercourse), continued urinary issues, recurrent bleeding, infection, bowel problems, vaginal mesh erosion, posterior mesh bunching, and pelvic floor muscle tightness and spasm. *See* Doc. 31 at 2, ¶ 3 (citing Docs. 30-1 at 4, 30-2 at 4-6); Doc. 35 at 2-3 (citing Doc. 35-1 ¶¶ 50-56). Dr. Crawford testified at his deposition that, before Plaintiff's surgery in 2007, he was aware of the following risks from pelvic mesh devices: bleeding, infection, inflammation, scarring, pelvic pain, painful intercourse, organ and nerve damage, recurrent urinary issues, neuromuscular problems, tissue contraction and shrinkage, and mesh erosion and extrusion. Doc. 30-3 at 4-7; *see also* Doc. 35-2 at 85 ("So in 2007, I feel I was adequately informed and aware of risks associated with mesh. So those would be then as – even years later, such complications as pain, scarring, infection, bleeding, failure to correct the problem, and possibly dysfunction – increased dysfunction of prolapse or the symptomatology. Extrusion and erosion[.]").

---

[4] Defendants contend that a manufacturer has no duty to warn of risks generally known by those to be warned and that an alleged failure to warn of known risks is not considered an informational defect. *Id.* at 4 (citations omitted). But Defendants do not develop these arguments or seek summary judgment based on a lack of duty or defect.

Plaintiff contends that "while Dr. Crawford was *generally* aware of risks of the product, he was unaware of the extent, frequency, and severity of the risks." Doc. 35 at 4 (emphasis in original).[5] But Plaintiff presents no evidence that Defendants' products had higher risks or that, had Defendants warned Dr. Crawford about the alleged higher risks, he would have shared this information with Plaintiff or would have decided not to implant the Prolift and TVT Secur devices. Plaintiff notes that Dr. Crawford testified that the frequency and severity of risks can influence his informed consent with the patient and his decision whether to use a product. Doc. 35 at 4 (citing Doc. 35-2 at 120-21). But he did not testify that he would have shared warnings about increased risks with Plaintiff, or that the warnings would have altered his decision to implant the Prolift and TVT Secur devices in Plaintiff. When asked whether he would have passed on a warning about increased risks to his patients, Dr. Crawford testified:

> Well, again, it's a given that I've already discussed [the risks] with them. Independently would have I have said that the manufacturer says that it happens more than I'm saying it happens. I don't know that I would have gone into that or not. It's all theoretical. It depends on the data, the study, the numbers. How that was determined, so on and so forth.

Doc. 35-2 at 119-20.[6] The mere theoretical possibility that a warning about increased risks may have influenced Dr. Crawford's informed consent process or his decision to use the Prolift and TVT Secur devices is not sufficient to create a triable issue on causation. *See Hanson v. Boston Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D. W. Va. Apr. 12, 2016) (causation evidence was insufficient where it "require[d] a reasonable juror

---

[5] Defendants note that Plaintiff cites no Arizona law requiring a medical device manufacturer to provide incidence, severity, or frequency rates concerning a particular adverse event. Doc. 38 at 3. The Court need not address this issue given that Plaintiff has failed to create a triable issue on causation.

[6] Plaintiff's counsel do not provide any specific numbers or data about increased risks in their briefing, nor did they present such information to Dr. Crawford in his deposition. And Dr. Crawford was not asked whether warnings about increased risks would have altered his decision to implant the Prolift and TVT Secur devices in Plaintiff. *See* Doc. 35-2. Dr. Crawford believed that he was "adequately informed of the risks" associated with the Prolift and TVT Secure devices before he implanted them in Plaintiff, and that the devices were "safe and effective treatment options" for his patients. Doc. 30-3 at 12-14.

to speculate, based only on mere *possibility*, that [the doctor] would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus") (emphasis in original); *see also Russell v. Ethicon, Inc.*, No. 4:20-CV-00405, 2020 WL 5993774, at *6 (M.D. Pa. Oct. 9, 2020) ("Plaintiff's attempt to salvage her claim by pointing to some equivocation in Dr. Minassian's answer is unavailing. Plaintiff argues that the mere fact that Dr. Minassian did not remember whether he had read the IFU creates a genuine dispute of material fact. It does not.").[7]

Because Plaintiff presents no evidence that Dr. Crawford would have acted differently in the face of different warnings by Defendants, she has failed to create a triable issue on causation. *See Gosewisch*, 737 P.2d at 380 ("Because of the absence of [relevant] testimony, the jury would have been forced to speculate whether the alleged informational defect was a proximate cause of Gosewisch's injury."); *D'Agnese*, 952 F. Supp. 2d at 892 ("Plaintiffs' claims . . . fail because Plaintiffs have offered no evidence that warnings to Dr. Curley would have changed his decision to prescribe Aredia to Mr. D'Agnese in 1996."); *see also Lankston v. Ethicon, Inc.*, No. 2:12-CV-00755, 2016 WL 5843723, at *4 (S.D.W. Va. Oct. 4, 2016) ("The doctor did not testify that he would have changed his mind with adequate warning. Thus, the court finds that the plaintiff is unable to prove that Ms. Lankston's treating physician would have refrained from prescribing the TVT-S had he received adequate warnings."); *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 3586404, at *9 (D. Ariz. July 26, 2018) ("Plaintiffs argue at length that Bard's warnings for the G2X were inadequate, but present no evidence . . . from which a reasonable inference can be drawn that an adequate warning would have altered Dr. Henry's decision to use a G2X filter."); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("Absent proof that a more complete or explicit warning

[7] Dr. Crawford also testified that while he relied on manufacturers to provide accurate information about their products, it was not his habit to review instructions for use before each surgery because he "knew everything already from either experience or didactic information." *See* Docs. 30-3 at 10, 35-2 at 99-100. Plaintiff presents no evidence that he reviewed Defendants' instructions for use or product brochures before her surgery.

would have prevented Kurer's use of Loestrin, she cannot establish that [the] alleged failure to warn was the proximate cause of her injuries.").[8]

The Court will grant summary judgment on the strict liability failure to warn claim in Count III. *See Celotex*, 477 U.S. at 322 (summary judgment is appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 184-85 (D. Ariz. 1999) (granting summary judgment on a failure to warn claim where the plaintiff failed to show that her doctor would not have used a medical device if alternative warnings had been given); *Lim v. Ethicon*, Inc., No. 3:20-CV-780-KHJ-LGI, 2021 WL 612399, at *6 (S.D. Miss. Feb. 12, 2021) (granting summary judgment where the doctor "relied on his own knowledge and training in Lim's treatment" and the defendants' "warnings would not have altered his decision" to implant a TVT-O device); *Heide v. Ethicon*, Inc., No. 4:20CV160, 2020 WL 1322835, at *5 (N.D. Ohio Mar. 20, 2020) (granting summary judgment where, "despite suggesting that the implanting physician was not aware of the product's defects, Plaintiff has not presented evidence suggesting that he would have acted differently if he had been aware of the potential risks or had been given an adequate warning").

---

[8] While Plaintiff is entitled to a "heeding presumption," Defendants have rebutted the presumption because Dr. Crawford's testimony would permit a jury reasonably to infer that he would not have heeded a warning about increased risks. *See Golonka v. Gen. Motors Corp.*, 65 P.3d 956, 968-69 (Ariz. Ct. App. 2003); *Paseka*, 2020 WL 8175427, at *5 (the heeding presumption "shifts the burden of production, but not the burden of persuasion"). Plaintiff presents no countering evidence to create a triable issue as to whether such a warning would have caused Dr. Crawford to act differently. *See Paseka*, 2020 WL 8175427, at *5 ("Having rebutted the presumption, it was not Defendants' burden to 'negate the element of causation' as Plaintiff suggests. Instead, given Dr. Stratford's testimony [that he did not read the instructions for use], it was Plaintiff's burden to produce evidence that Defendants' failure to warn proximately caused Plaintiff's injuries.") (citations omitted); *Gosewisch*, 737 P.2d at 380 ("[E]ven with the benefit of [a heeding] presumption, Gosewisch would not have proved that the alleged failure to warn was a proximate cause of his injury" because "there was evidence that even if a suitable warning had been provided, Gosewisch would have ignored it."); *see also Feuerstein v. Home Depot, U.S.A., Inc.*, No. 2:12-CV-01062 JWS, 2014 WL 2557122, at *6 (D. Ariz. June 6, 2014) ("[The] evidence would permit a reasonable juror to conclude that Feuerstein would not have heeded a specific warning about using the ladder on decking material. Plaintiffs have not pointed to any countering evidence to create a genuine issue of fact as to whether Feuerstein would have considered a warning regarding the use of the AL-22 on Trex decking.").

IV. Remaining Negligence Claims (Counts I and X).

Defendants argue that summary judgment is warranted on Plaintiff's negligence claims to the extent they are based on an alleged failure to warn. Doc. 31 at 8; *see Paseka*, 2020 WL 8175427, at *4 (a plaintiff in Arizona must show that the defective condition is the proximate cause of her injury "under negligence or strict liability"); *Hull v. Ethicon, Inc.*, No. 3:20-cv-00038-JMS-DML, 2020 WL 1154577, at *9 (S.D. Ind. Mar. 10, 2020) ("Because Ms. Hull has not identified record evidence that Dr. Basinski would have changed her recommendation for the TVT-S surgery had Defendants warned her of additional risks, Ms. Hull's negligence claim based on a failure to warn theory fails as a matter of law[.]"); *Kelly v. Ethicon, Inc.*, No. 20-CV-2036-CJW-MAR, 2020 WL 6120155, at *6 (N.D. Iowa Oct. 16, 2020) ("[T]he Court granted summary judgment on plaintiff's negligent failure to warn claim because there was no evidence of proximate causation. Specifically, under the learned intermediary doctrine, the Court found that plaintiff had not shown that different warnings by defendants would have changed Dr. Bremner's decision to use the TVT implant or how he explained the risks to plaintiff."); *Nix v. Ethicon*, Inc., No. 1:19-CV-04896-SCJ, 2020 WL 5525172, at *3 (N.D. Ga. Sept. 14, 2020) (granting summary judgment on negligent failure to warn claim where the evidence did not show that "different or additional warnings from Defendants would have changed Dr. Meadows' decision to prescribe and implant the TVT-O device").

Plaintiff does not oppose summary judgment on this ground, but notes that the negligence and negligent infliction of emotional distress claims (Counts I and X) are also based on a negligent design theory, which involves a separate series of facts. Doc. 35 at 1. The Court will grant summary judgment on the negligence claims to the extent they are based on an alleged failure to warn, for reasons stated above. The Court will deny summary judgment to the extent the claims are based on an alleged negligent design.

Defendants further argue that the negligent infliction of emotional distress claim fails in its entirety because Plaintiff cannot show "extreme and outrageous conduct." Doc. 31 at 8. Such a showing is required for intentional infliction of emotional distress,

but not for negligent infliction of emotional distress. *See Ford v. Revlon, Inc.*, 734 P.2d 580, 585 (Ariz. 1987) (intentional infliction) (citing Restatement (Second) of Torts § 46 cmt. b (1965)); *Castillo v. City of Tempe*, No. CV-12-02225-PHX-ROS, 2014 WL 11505911, at *6 (D. Ariz. Sept. 18, 2014) (discussing the two torts); *Snyder v. Banner Health*, No. 1 CA-CV 13-0630, 2014 WL 4980382, at *4 (Ariz. Ct. App. Oct. 7, 2014) ("A claim for negligent infliction of emotional distress requires proof that a defendant's conduct caused the plaintiff to suffer emotional distress that manifested itself as physical injury from either witnessing an injury to a closely related person or suffering a threat to her own personal security.") (citing *Keck v. Jackson*, 593 P.2d 668, 669-70 (Ariz. 1979)); *Quinn v. Turner*, 745 P.2d 972, 973 (Ariz. Ct. App. 1987)); Rev. Ariz. Jury Instr. (Civil) 6th, Negligence 9 (requiring the plaintiff to show that the defendant's negligence created an unreasonable risk of bodily harm and was a cause of emotional distress to the plaintiff). The Court accordingly will grant summary judgment on Plaintiff's negligent infliction claim only to the extent it is based on an alleged failure to warn.

IT IS ORDERED that Defendants' motion for partial summary judgment (Doc. 30) is **granted in part and denied in part**. The motion is granted with respect to Plaintiff's claims for strict liability manufacturing defect, failure to warn, and defective product (Counts II-IV); common law fraud, fraudulent concealment, and constructive fraud (Counts VI-VIII); negligent misrepresentation (Count IX); breach of express and implied warranty (Counts XI and XII); violation of consumer protection laws (Count XIII), gross negligence (Counts XIV); and unjust enrichment (Count XV); and with respect to the claims for negligence and negligent infliction of emotional distress (Counts I and X) to the extent they are based on an alleged failure to warn. The motion is denied with respect to the negligence and negligent infliction claims to the extent they are based on negligent

design. These negligence claims, along with the claims for strict liability design defect (Count V) and punitive damages (Count XVII), remain for trial.[9]

DATED this 4th of March, 2021.

David G. Campbell
Senior United States District Judge

[9] Plaintiff does not assert a loss of consortium claim (Count XVI) in her short form complaint. *See* Doc. 1 ¶ 13. While Plaintiff asserts a "discovery rule and tolling" claim (Count XVIII), the discovery rule and tolling doctrine are not independent claims for relief in Arizona, and Defendants do not argue that Plaintiff's claims are time-barred. *See* Doc. 31; *McGill v. Nat'l Specialty Ins. Co.*, No. CV12-01671-PHX-DGC, 2013 WL 331256, at *6 (D. Ariz. Jan. 29, 2013) ("Under Arizona law, 'the discovery rule tolls limitations until the plaintiff possess[es] a minimum knowledge sufficient to recognize that a wrong occurred and caused injury.'") (citation omitted). Thus, the "discovery rule and tolling" claim will not be an issue for trial.