

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

SHERI SCHOLL,

Plaintiff,

v.

CIVIL ACTION NO. 2:12-cv-00738

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Summary Judgment)

Pending before the court is the defendants' Motion for Partial Summary Judgment [ECF No. 83]. As set forth below, the defendants' Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to the court by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in Ethicon, Inc. and Johnson & Johnson, Inc. ("Ethicon") MDL, MDL 2327. In an effort to efficiently and effectively manage this massive MDL, the court decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all

summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, the court ordered the plaintiffs and defendants to submit a joint list of 200 of the oldest cases in Ethicon MDL that name only Ethicon, Inc., Ethicon, LLC, and/or Johnson & Johnson, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 193, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002327, Aug. 19, 2015, *available at* <http://www.wvsc.uscourts.gov/MDL/ethicon/orders.html>. I completed this process four times and selected Mrs. Scholl’s case as a Wave 1 case.

On December 23, 2010, Mrs. Scholl was surgically implanted with the Ethicon’s TVT-Obturator (“TVT-O”) and Prosima (“Prosima”), products manufactured by Ethicon. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 4]. Mrs. Scholl’s surgery occurred at Mary Washington Hospital in Fredericksburg, Virginia. *Id.* ¶ 11. Mrs. Scholl claims that as a result of implantation of these devices she has experienced multiple complications. She brought the following claims against Ethicon: (I) negligence, (II) strict liability – manufacturing defect, (III) strict liability – failure to warn, (IV) strict liability – defective product, (V) strict liability – design defect, (VI) common law fraud, (VII) fraudulent concealment, (VIII) constructive fraud, (IX) negligent misrepresentation, (X) negligent infliction of emotional distress, (XI) breach of express warranty; (XII) breach of implied warranty, (XIII) violation of consumer protection laws, (XIV) gross negligence, (XV) unjust enrichment, (XVI) loss of

consortium¹ (XVII), punitive damages, and (XVIII) discovery rule and tolling. *Id.* ¶ 13.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise,

¹ Former plaintiff Gary Scholl’s loss-of-consortium claim (Count XVI) was previously dismissed with prejudice by stipulation. *See* Joint Stip. [ECF No. 37].

conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where Mrs. Scholl first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of

West Virginia, however, as Mrs. Scholl did in this case, the court consults the choice-of-law rules of the state where the plaintiff was implanted with the product. *See Sanchez v. Bos. Sci. Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (“For cases that originate elsewhere and are directly filed into the MDL, the court will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.”). Mrs. Scholl underwent the Prosima and TVT-O implantation surgery in Virginia. Thus, the choice-of-law principles of Virginia guide the court’s choice-of-law analysis.

Virginia adheres to the principle of *lex loci delicti* for tort actions: the place where the harm occurred provides the substantive law. *Vicente v. Obenauer*, 736 F. Supp. 679, 690 (E.D. Va. 1990); *see also Jones v. R. S. Jones & Assoc.*, 246 S.E.2d 33, 34 (Va. 1993). As stated above, Mrs. Scholl was implanted with the two products at issue in Virginia. Thus, the court applies Virginia’s substantive law to this case.

III. Analysis

Ethicon argues that it is entitled to summary judgment on all of Mrs. Scholl’s claims because her legal theories are either without evidentiary or legal support. Mem. Supp. Mot. Summ. J. 1, [ECF No. 84]. Mrs. Scholl agrees that this court should dismiss several of the counts listed in her Amended Short Form Complaint because they are not recognized by Virginia law or because Mrs. Scholl is no longer pursuing the cause of action. Pl.’s Resp. Mem. Opp. Mot. Summ. J. 1, [ECF No. 96]. Mrs. Scholl

contends that only (Count I) negligence, (Count XI) breach of express warranty, (Count XII) breach of implied warranty, (Count VI) common law fraud, (Count VII) fraudulent concealment, (Count VIII) constructive fraud, and (Count XIV) gross negligence survive the motion. *Id.*

Accordingly, Ethicon's Motion with regard to all other claims is **GRANTED**: negligent manufacturing (part of Count I); (Count II) strict liability – manufacturing defect; (Count III) strict liability – failure to warn; (Count IV) strict liability – defective product; (Count V) strict liability – design defect; (Count IX) negligent misrepresentation; (Count X) negligent infliction of emotional distress; (Count XIII) consumer protection; and (Count XV) unjust enrichment. Below, the court applies the summary judgment standard to each remaining claim.

A. Negligence (Failure to Warn) (Count I)

In Virginia, a manufacturer has a duty to warn users of known dangers posed by its products. *Micjan v. Wal-Mart Stores, Inc.*, Civil Action No. 14-855, 2016 WL 4141085, at *11 (W.D. Pa. Aug. 4, 2016). The manufacturer will be subject to liability when the manufacturer:

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Micjan, 2016 WL 4141085, at *11 (quoting *Featherall v. Firestone Tire & Rubber Co.*,

252 S.E.2d 358, 366 (Va. 1979) and Restatement (Second) of Torts § 388 (Am. Law Inst. 1965)).

Ethicon asks the court to employ the learned intermediary doctrine in considering Mrs. Scholl's failure to warn claim. Ethicon further alleges that the warnings provided were adequate as a matter of law. *Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 504 (E.D. Va. 2013), *aff'd*, 587 F. App'x 78 (4th Cir. 2014) ("Courts have routinely held warnings adequate as a matter of law when they alert a party to the very injury for which the plaintiff seeks relief.").

Virginia, like many jurisdictions, has adopted the learned intermediary doctrine. *Pfizer v. Jones*, 272 S.E.2d 43, 44 (Va. 1980). Manufacturers of prescription medical products have a duty to warn only the physician rather than the plaintiff of the risks associated with the product. *Id.* Thus, manufacturers are shielded from liability if the manufacturer adequately warned the physician. *Talley v. Danek*, 7 F. Supp. 2d 725, 730 (E.D. Va. 1998). Under this doctrine, a plaintiff must establish two elements: (1) the warning was inadequate and (2) the failure to warn affected the physician's use of the product thereby injuring the plaintiff. *Id.* Ethicon's liability on this claim depends on whether it adequately warned the implanting physician about the risks associated with its products. Mrs. Scholl presented ample evidence demonstrating genuine disputes of material fact with regard to whether an inadequate warning to her physician caused her injuries. Furthermore, the adequacy of the warning is a question of fact for the jury. *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1115 (4th Cir. 1988) (applying Virginia law).

Therefore, Ethicon's Motion for Summary Judgment on the plaintiff's negligent failure to warn claim is **DENIED**.

B. Fraud Claims

To prevail on a claim of fraud, a plaintiff must show by clear and convincing evidence both that a defendant intentionally and knowingly made a false representation or an omission of a material fact with the intent to mislead and that the plaintiff detrimentally relied upon the misrepresentation or omission. *Hitachi Credit Am. Corp. v. Signet Bank*, 166 F.3d 614, 628 (4th Cir. 1999) (applying Virginia law); *see also Van Deusen v. Snead*, 441 S.E.2d 207, 209 (Va. 1994). Constructive fraud differs in that the misrepresentation is made innocently or negligently, not with the intent to mislead. *Id.*

Ethicon argues that Mrs. Scholl cannot succeed on any of her fraud claims because she did not rely on any alleged misrepresentation by Ethicon. Def.'s Mem. 11-12. Ethicon also asserts that Mrs. Scholl's fraud claims are merely repackaged failure-to-warn claims that should fail under the learned intermediary doctrine. Reply Supp. Defs.' Mot. for Partial Summ. J. 6-7 [ECF No. 97]. Additionally, Ethicon notes that Virginia law does not allow a plaintiff to establish a fraud claim based on reliance by a third party. *Id.* at 7.

Mrs. Scholl alleges Ethicon misrepresented and concealed facts about the mesh that Dr. Josephs, her treating physician, and she relied upon. Resp. 10-11. Based on this alleged conduct, she asserts that a reasonable juror could infer that the devices' manufacturers acted with the requisite intent to deceive. *Id.*

Virginia law requires proof of reliance by the injured party, as opposed to reliance by a third party, in order to maintain an action for fraud. *Rich. Metro. Auth. v. McDevitt St. Bovis, Inc.*, 507 S.E.2d 344, 346 (Va. 1998) (noting that fraud claims require “reliance by the party misled”). Establishing the element of reliance by the injured party can be “problematic” in the medical device context because any alleged misrepresentations are typically made to the prescribing doctor or other learned intermediary. Robert E. Draim, *Va. Prac. Series Prods. Liab.* § 6:7. Mrs. Scholl never interacted with any representative of Ethicon, nor did she read or review any materials created by Ethicon. The court has not found any evidence that Mrs. Scholl “relied” on a misrepresentation by Ethicon, so this element cannot be met and must be dismissed as a matter of law.

Ethicon’s Motion regarding common law fraud (Count VI), fraudulent concealment (Count VII), and constructive fraud (Count VIII) is **GRANTED**.

C. Breach of Warranty Claims

1. Breach of Express Warranty (Count XI)

To recover for breach of warranty, a plaintiff has the burden of showing the existence of a warranty in addition to a breach. *Hitachi Credit Am. Corp.*, 166 F.3d at 624. Under Virginia’s codification of the Uniform Commercial Code, Virginia Code § 8.2-313(1), an express warranty can be created under the following circumstances:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Va. Code Ann. § 8.2-313(1). Furthermore, “formal words such as ‘warrant’ or ‘guarantee’” or “a specific intention to make a warranty” are not necessary to create an express warranty. *Id.*, § 8.2-313(2). Additionally,

Lack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods.

Va. Code Ann. § 8.2-318. The buyer does not necessarily even have to rely on the seller’s representation for those representations to form the basis of the bargain. *Daughtrey v. Ashe*, 413 S.E.2d 336, 338-40 (Va. 1992).

Ethicon focuses its argument on the fact Mrs. Scholl did not review or rely upon any information provided by Ethicon. However, “[a]ny description of the goods, other than the seller’s mere opinion about the product, constitutes part of the basis of the bargain and is therefore an express warranty. It is unnecessary that the buyer actually rely upon it.” *Martin v. Am. Med. Sys.*, 116 F.3d 102, 105 (4th Cir. 1997).

Additionally, under Virginia law, privity is not required to establish a breach of express warranty for claims made by foreseeable users of a product. *See* Va. Code Ann. § 8.2-318. Virginia case law further confirms that in the medical device context,

“privity is not required, and there is no need to show that the representations were made directly to [the plaintiff].” *Martin*, 116 F.3d at 104–5. Ethicon should have reasonably anticipated that the direct purchasers, hospitals or doctors, would not be the user of the product, and instead, it would be women like Mrs. Scholl who would ultimately be implanted with its products.

The plaintiff alleges that Ethicon misrepresented facts about the nature of the risks of its products and concealed facts by not updating the IFU when additional information compelled an updated warning. There remains a genuine dispute of fact regarding the alleged misrepresentations and whether those alleged misrepresentations support a cause of action for breach of an express warranty.

Therefore, Ethicon’s Motion on the claim for breach of express warranty for is **DENIED**.

2. Breach of Implied Warranty (Count XII)

Ethicon argues that Mrs. Scholl’s implied warranty claims overlap with her negligence claims and should be dismissed. However, as Mrs. Scholl noted in her response, Virginia law allows for both negligence and warranty claims to proceed to trial, despite being “largely identical.” *Higgins v. Forest Labs*, 48 F. Supp. 3d 878, 883-84 (W.D. Va. 2014).

a. Implied Warranty of Merchantability

In order to succeed on the implied warranty of merchantability, a plaintiff must show that the product was “unreasonably dangerous” for its ordinary use, or another foreseeable use, and that the “unreasonably dangerous condition” existed

when the product left the manufacturers' control. *Abbot*, 844 F.2d at 1114. A product can be considered "unreasonably dangerous" when it is not accompanied by adequate warnings. *Id.*

Ethicon argues that the court should dismiss this count because Mrs. Scholl cannot establish that the warnings related to the Prosima or TVT-O products were inadequate in breach of the implied warranty of merchantability. Def.'s Mem. 15. As discussed previously, Mrs. Scholl has provided sufficient evidence through the testimony and reports of her experts to create a genuine dispute of material fact as to whether the warnings were adequate.

Ethicon's motion for summary judgment for breach of implied warranty of merchantability is **DENIED**.

b. Implied Warranty of Fitness for a Particular Purpose

The implied warranty of fitness for a particular purpose arises when "the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods." Va. Code Ann. § 8.2-315. A "particular purpose" is one that is different than the ordinary purpose for which the good is generally used. *Id.*, at cmt. 2. Whether or not there is an implied warranty of fitness for a particular purpose is generally a question of fact. *Bayliner Marine Corp. v. Crow*, 509 S.E.2d 499, 503 (Va. 1999).

Ethicon contends that Mrs. Scholl has failed to allege a "particular purpose" different from their ordinary purposes for which the Prosima and TVT-O were to be

used. I agree. The record is devoid of any evidence that would permit a reasonable juror to infer that the Prosima and TVT-O were being used for anything other than their ordinary use – to treat POP and SUI, respectively.

Accordingly, Ethicon’s Motion for breach of implied warranty of fitness for a particular purpose is **GRANTED**.

D. Gross Negligence (Count XIV)

Gross negligence in Virginia requires “an unusual and marked departure from the routine performance of business activities.” *Hamilton v. Boddie-Noell Enters., Inc.*, 88 F. Supp. 3d 588, 592 (W.D. Va. 2015) (internal quotations omitted). A plaintiff must prove that the defendant acted with “an utter disregard of prudence that amounts to a complete neglect of the safety of another person that would ‘shock fair-minded persons.’” *Id.* (internal quotations omitted). Gross negligence, however, requires proof of negligence of a degree less than “willful recklessness.” *Griffin v. Shively*, 315 S.E.2d 210, 213 (1984) (citing *Ferguson v. Ferguson*, 181 S.E.2d 648, 651 (Va. 1971)). Generally, gross negligence is an issue for a jury to resolve; it only becomes a question of law when “reasonable minds could not differ.” *Id.* at 212.

Ethicon asserts that Mrs. Scholl has not met the elements of this claim, namely that she failed to present evidence of conduct that represented “an unusual and marked departure” from normal business practices. Def.’s Mem. 16.

Mrs. Scholl contends that much of Ethicon’s conduct was intentional, which is a higher standard than what is required to satisfy gross negligence. Her experts testify that Ethicon knew of the risks the mesh posed to patients and that the mesh

posed no advantage over traditional native tissue repair, but Ethicon promoted the product nonetheless. Resp. 11. For example, Mrs. Scholl asserts that Ethicon deliberately chose not to update the TVT-O IFU after becoming aware of adverse events. *See* Kohli Report 36-7 [ECF No. 96-3]. She argues that Ethicon disregarded the safety of women who may be implanted with the product in the future. Resp. 11. Mrs. Scholl also points to the allegations in Dr. Shull's expert report. Shull Report, at 2-3 [ECF No. 96-4]. She further argues that Ethicon did not exercise its regular due diligence in designing and developing the product. Resp. 11. Whether such actions are the type of conduct that would implicate liability for gross negligence is best suited for the trier of fact.

Here, genuine disputes of material fact exist with regard to whether Ethicon acted with gross negligence. Ethicon's Motion regarding the claim for gross negligence is **DENIED**.

IV. Conclusion

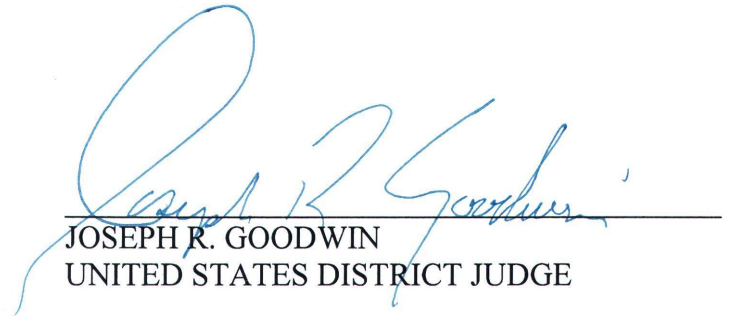
For the reasons discussed above, it is **ORDERED** that Ethicon's Partial Motion for Summary Judgment [ECF No. 84] is **GRANTED in part** and **DENIED in part**. As Mrs. Scholl has conceded these claims, Ethicon's Motion is **GRANTED** regarding the following claims: negligent manufacturing (part of Count I); (Count II) strict liability – manufacturing defect; (Count III) strict liability – failure to warn; (Count IV) strict liability – defective product; (Count V) strict liability – design defect; (Count IX) negligent misrepresentation; (Count X) negligent infliction of emotional distress; (Count XIII) consumer protection; and (Count XV) unjust enrichment.

Ethicon's Motion on the following claims is **GRANTED**: common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), and breach of implied warranty of fitness for a particular purpose (Count XII).

Ethicon's Motion on the following claims is **DENIED**: negligence (Count I), breach of express warranty (Count XI), breach of implied warranty of merchantability (Count XII), and gross negligence (Count XIV).

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 14, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE