

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF ARKANSAS  
CENTRAL DIVISION**

**MARIBETH FULLER, *ET AL.***

**PLAINTIFFS**

**VS.**

**4:20-CV-00800-BRW**

**ETHICON INC, *ET AL.***

**DEFENDANTS**

**ORDER**

Pending are Defendants' Motion for Partial Summary Judgment (Doc. No. 29) and Motion to Exclude the Testimony of Dr. Michael Thomas Margolis (Doc. No. 34). Plaintiffs have responded to both motions.<sup>1</sup> For the reasons set out below, the Motion for Partial Summary Judgment (Doc. No. 29) is GRANTED IN PART and DENIED IN PART, and the Motion to Exclude the Testimony of Dr. Michael Thomas Margolis (Doc. No. 34) is DENIED.

**I. BACKGROUND**

Defendants manufacture and sell a medical device called TVT-O.<sup>2</sup> On November 1, 2006, Plaintiff Maribeth Fuller was implanted with a TVT-O to treat stress urinary incontinence.<sup>3</sup> Plaintiffs allege that she suffers from pain, infections, dyspareunia, and incontinence because of the TVT-O. Plaintiffs assert claims for failure to warn, design defect, manufacturing defect, defective product, negligence, fraud, consumer protection claims, unjust enrichment, and breach of warranty.<sup>4</sup>

---

<sup>1</sup>Doc. Nos. 33, 35.

<sup>2</sup>Transvaginal Tension Free Vaginal Tape-Obturator.

<sup>3</sup>Doc. No. 7.

<sup>4</sup>Doc. Nos. 1.

Defendants seek summary judgment on all claims except for design defect and loss of consortium.<sup>5</sup> They also assert that Dr. Margolis's opinions should be excluded.

## **II. DISCUSSION**

### **A. Motion for Summary Judgment**

Summary judgment is appropriate only when there is no genuine issue of material fact, so that the dispute may be decided on purely legal grounds.<sup>6</sup> The Supreme Court has established guidelines to assist trial courts in determining whether this standard has been met:

The inquiry performed is the threshold inquiry of determining whether there is the need for a trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.<sup>7</sup>

The Court of Appeals for the Eighth Circuit has cautioned that summary judgment is an extreme remedy that should be granted only when the movant has established a right to the judgment beyond controversy.<sup>8</sup> Nevertheless, summary judgment promotes judicial economy by preventing trial when no genuine issue of fact remains.<sup>9</sup> A court must view the facts in the light most favorable to the party opposing the motion.<sup>10</sup> The Eighth Circuit has also set out the burden of the parties in connection with a summary judgment motion:

[T]he burden on the party moving for summary judgment is only to demonstrate, *i.e.*, “[to point] out to the District Court,” that the record does not disclose a genuine dispute on a material fact. It is enough for the movant to bring up the fact that the

---

<sup>5</sup>Doc. No. 30. However, a loss-of-consortium claim is not marked in the short-form complaint.

<sup>6</sup>*Holloway v. Lockhart*, 813 F.2d 874 (8th Cir. 1987); Fed. R. Civ. P. 56.

<sup>7</sup>*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

<sup>8</sup>*Inland Oil & Transport Co. v. United States*, 600 F.2d 725, 727 (8th Cir. 1979).

<sup>9</sup>*Id.* at 728.

<sup>10</sup>*Id.* at 727-28.

record does not contain such an issue and to identify that part of the record which bears out his assertion. Once this is done, his burden is discharged, and, if the record in fact bears out the claim that no genuine dispute exists on any material fact, it is then the respondent's burden to set forth affirmative evidence, specific facts, showing that there is a genuine dispute on that issue. If the respondent fails to carry that burden, summary judgment should be granted.<sup>11</sup>

Only disputes over facts that may affect the outcome of the suit under governing law will properly preclude the entry of summary judgment.<sup>12</sup>

## **1. Conceded or Withdrawn Claims**

Defendants assert that several causes of action are either not recognized under Arkansas law or not supported by the record. Plaintiffs conceded some causes of action and agreed to withdraw others. Accordingly, the following are DISMISSED: Strict Liability – Manufacturing Defect (Count II); Strict Liability – Defective Product (Count IV); Fraud (Count VI); Fraudulent Concealment (Count VII); Constructive Fraud (Count VIII); Negligent Misrepresentation (Count IX); Negligent Infliction of Emotional Distress (Count X); Breach Of Warranty (Count XI And Count XII); and Consumer Fraud (Count XIII).

## **2. Failure to Warn (Count III)**

The parties agree that, because this case involves a medical device, Defendants had a duty to warn the doctor, not the patient.<sup>13</sup> To succeed, Plaintiffs must establish:

---

<sup>11</sup>*Counts v. MK-Ferguson Co.*, 862 F.2d 1338, 1339 (8th Cir. 1988) (quoting *City of Mt. Pleasant v. Associated Elec. Coop.*, 838 F.2d 268, 273-74 (8th Cir. 1988) (citations omitted)).

<sup>12</sup>*Anderson*, 477 U.S. at 248.

<sup>13</sup>*Sharp v. Ethicon, Inc.*, No. 2:20-CV-2028, 2020 WL 1434566, at \*3 (W.D. Ark. Mar. 24, 2020) (quoting *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (“Arkansas law also acknowledges that one of the exceptions to a manufacturer’s duty to warn is ‘the learned intermediary rule, which assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects.’”).

(1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) *that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury*. Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.<sup>14</sup>

Defendants argue that Plaintiff's failure to warn claims fails because Plaintiff's surgeon, Dr. Diaz, did not read the TVT-O "instructions for use package insert" before implanting it.<sup>15</sup> However, that is not quite what he said. Dr. Diaz testified that he does not read the insert before every procedure and that he did not read it before Plaintiff's procedure. However, he has "glanced at one or two of those packets in passing."<sup>16</sup> Dr. Diaz later attempted to clarify that the only reason he would have looked at the packet was because he was "waiting for the case to start and . . . had nothing else to look at."<sup>17</sup> He also testified that he relies on his skills and training to implant the device, not the instructions provided by Defendants, and has not and would not read the instructions for use to refresh his memory.<sup>18</sup>

There is a fact dispute regarding Dr. Diaz's reliance on the packet insert. The fact that he did not read the insert before this particular surgery does not change the fact that he may have relied on the information that he read in the past. Additionally, Dr. Diaz testified that if Defendants' "sales representative had informed him of a risk or complication associated with the TVT-O that he was unaware of, he would have included that risk or complication in his informed

---

<sup>14</sup>*Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (emphasis in original).

<sup>15</sup>Doc. No. 30-1, Diaz (10/25/18) Dep. at pp. 47-48.

<sup>16</sup>*Id.* at p. 48.

<sup>17</sup>*Id.* at pp. 56-57.

<sup>18</sup>*Id.* at p. 57.

consent discussion with his patients.”<sup>19</sup> This issue along with several others raised by Defendants – *e.g.* what risks Dr. Diaz was aware of and whether he would have changed his treating decision with a different warning – are all issues for the jury. Accordingly, summary judgment is DENIED.

### **3. Arkansas Product Liability Act (APLA)**

Defendants argue that “all of Plaintiffs’ negligence-based claims arise from personal injuries arising from the ‘manufacture, constructions, design . . . assembly . . . warning, marketing . . . and labeling of TVT-O.’”<sup>20</sup> According to Defendants, because Plaintiffs’ “negligence claims are based on the same series of facts as their strict liability claims, they are subsumed by and merged into a single claim under the APLA.”<sup>21</sup> Defendants’ position is contrary to Arkansas law.<sup>22</sup> Accordingly, summary judgment is DENIED as to the Negligence (Count I) and Gross Negligence (Count XIV) claims.

### **4. Unjust Enrichment (Count XV)**

Defendants assert that “Plaintiffs cannot prevail on a claim of unjust enrichment, because they cannot show that the device’s labeling was false or misleading.”<sup>23</sup> Whether the label was misleading is an issue for the jury. Summary judgment is DENIED.

---

<sup>19</sup>*Id.* at p. 58.

<sup>20</sup>Doc. No. 30.

<sup>21</sup>*Id.*

<sup>22</sup>*Singleton v. Arkansas Hous. Authorities Prop. & Cas. Self-Insured Fund, Inc.*, No. 4:15-CV-205-KGB, 2018 WL 1588022, at \*4 (E.D. Ark. Mar. 31, 2018), *aff’d*, 934 F.3d 830 (8th Cir. 2019) (“Negligence and strict liability are not mutually exclusive claims. More than one theory of liability is permissible in a products liability claim.”) (citing *Nationwide Rentals Co. v. Carter*, 765 S.W.2d 931, 933 (Ark. 1989); *W.M. Bashlin Company v. Smith*, 643 S.W.2d 526, 529 (Ark. 1982)).

<sup>23</sup>Doc. No. 30.

## **B. *Daubert* Motion**

Defendants seek to exclude Plaintiffs' expert, Dr. Michael Thomas Margolis. Defendants assert that "Dr. Margolis' so-called case-specific report consists mostly of general causation opinions" but that he "has been disclosed solely as a case-specific expert in this case, not as a general expert."<sup>24</sup> What is the issue exactly? Presumably Defendants have deposed (or will depose) Dr. Margolis regarding his report. If Dr. Margolis's report consists primarily of general causation opinions, then there is no surprise to Defendants. To the extent that Defendants believe Dr. Margolis's report is not adequately catered to Plaintiffs' case, this might well be fodder for cross-examination.

Defendants assert that Dr. Margolis's opinions regarding the adequacy of the warnings is irrelevant because Dr. Diaz did not read the warning. Again, that is not quite what Dr. Diaz said. How closely Dr. Diaz read the warning and how much it or other warnings would have affected his decisions are issues for the jury to decide.

## **CONCLUSION**

For the reasons set out above, Defendants' Motion for Partial Summary Judgment (Doc. No. 29) is GRANTED IN PART and DENIED IN PART.

The following causes of action are DISMISSED: Strict Liability – Manufacturing Defect (Count II); Strict Liability – Defective Product (Count IV); Fraud (Count VI); Fraudulent Concealment (Count VII); Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX); Negligent Infliction of Emotional Distress (Count X); Breach Of Warranty (Count XI And Count XII); and Consumer Fraud (Count XIII).

---

<sup>24</sup>Doc. No. 34.

Summary judgment is DENIED as to the claims for:, Negligence (Count I); Strict Liability – Failure to Warn (Count III); Strict Liability – Design Defect (Count V); Unjust Enrichment (Count XV); and Gross Negligence (Count XIV).

I note that Defendants assert that they are not seeking summary judgment on Plaintiffs' loss-of-consortium claim. However, Plaintiffs' short-form complaint does not assert a claim for loss of consortium. It is unclear to me whether this is an accidental omission. Accordingly, Plaintiffs must forthwith clarify whether they are perusing this claim. If so, an amended complaint must be filed (at which time Plaintiffs should also removed all the claims dismissed as a result of this Order). If not, an email to opposing counsel and me is sufficient.

The Motion to Exclude the Testimony of Dr. Michael Thomas Margolis (Doc. No. 34) is DENIED.

IT IS SO ORDERED this 17th day of July, 2020.

Billy Roy Wilson  
UNITED STATES DISTRICT JUDGE