UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

TRACIE SYLVESTER, ET AL.,	)	**CASE NO. 1:19CV2658**
	)	
Plaintiff,	)	**JUDGE CHRISTOPHER A. BOYKO**
	)	
vs.	)	
	)	
ETHICON, INC., ET AL.,	)	**OPINION AND ORDER**
	)	
Defendant.	)	

CHRISTOPHER A. BOYKO, J:

This matter is before the Court on Defendants' Motion for Partial Summary Judgment. (ECF # 36). For the following reasons, the Court grants, in part, and denies, in part, Defendants' Motion.

Plaintiffs Tracie Sylvester and Antonio May, the spouse of Sylvester, allege Sylvester was suffering from stress urinary incontinence and pelvic organ prolapse when she had Defendants' TVT pelvic mesh implanted at University Hospital's Bedford Medical Center in 2010. After implantation of the mesh, Sylvester began to experience pain, numbness, dyspareunia and recurrent urinary incontinence caused by the allegedly defective TVT pelvic mesh. Sylvester underwent a mesh revision procedure in 2012 in Cleveland to alleviate her symptoms.

Plaintiffs' First Amended Complaint ("FAC") alleges claims for: (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; (XII) Violation of Consumer Protection Laws; (XIV) Gross Negligence; (XV) Unjust Enrichment; (XVI) Loss of Consortium; (XVII) Punitive Damages; and (XVIII) Discovery Rule and Tolling against Defendants Ethicon, Inc. and Johnson & Johnson, makers of the TVT pelvic mesh.

Defendants' Motion for Partial Summary Judgment

According to Defendants, most of Plaintiffs' claims are abrogated by the Ohio Product Liability Act ("OPLA"). Furthermore, Counts II, III and IV must be dismissed because Plaintiffs have failed to produce sufficient evidence of a manufacturing defect or failure to warn. Defendants seek judgment on Plaintiffs' claims under Counts I-IV and VI-XV.

Defendants argue Ohio law applies as Plaintiffs were Ohio residents and both the initial implantation and subsequent revision were performed in Ohio. Ohio Revised Code ("O.R.C.") § 2307.71(A)(13) applies to all claims seeking to recover compensatory damages from a manufacturer or supplier for death, physical injury, emotional distress or physical damage to property. In 2005, the OPLA was amended to abrogate all common law product liability claims or causes of action. Accordingly, Defendants contend Plaintiffs' claims for Negligence, Common Law Fraud, Fraudulent Concealment and Constructive Fraud, Negligent Misrepresentation; Negligent Infliction of Emotional Distress; Breach of

Express Warranty; Breach of Implied Warranty, Gross Negligence and Unjust Enrichment are all abrogated by the OPLA.

Furthermore, Defendants move for partial summary judgment on Plaintiffs' Defective Manufacturing claim, alleging it requires expert testimony. Because Plaintiffs have offered no expert testimony that the TVT pelvic mesh was defectively made, Defendants are entitled to summary judgment.

Defendants further allege that Plaintiffs lack evidence demonstrating that the implanting physician would not have treated with the TVT mesh if he had received different warnings from Defendants, therefore, Defendants contend they are entitled to summary judgment on Plaintiffs' Failure to Warn claim.

Lastly, Defendants argue Ohio does not recognize a Strict Liability Manufacturing Defect claim.

Plaintiffs' Response

Plaintiffs concede their claims for Strict Liability – Manufacturing Defect; Strict Liability – Failure to Warn; Strict Liability – Defective Product; Breach of Implied Warranty and Violation of Consumer Protection Laws should be dismissed and they do not oppose summary judgment for Defendants on these claims. Therefore, the Court grants summary judgment for Defendants on these claims.

Plaintiffs oppose Defendants' Motion for Partial Summary Judgment on Counts I, VI-VIII, X, XI, XIV and XV because they assert the OPLA does not abrogate these claims. According to Plaintiffs, the OPLA describes specific conduct to which it applies and these claims, as asserted in Plaintiffs' First Amended Master Complaint, do not fall within the

OPLA's description, therefore, they are not preempted.

LAW AND ANALYSIS

Standard of Review

Rule 56(a) of the Federal Rules of Civil Procedure provides that the Court shall grant summary judgment 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. Pro. 56(a). In asserting that a material fact can or cannot be genuinely disputed, a party must support that assertion by either citing to materials contained in the record or show that the materials cited to do or do not create a genuine issue or material fact. Fed. R. Civ. Pro. 56(c)(1). In its consideration of a motion for summary judgment, the Court need only consider those materials cited in the motion. Fed. R. Civ. Pro. 56(c)(3). The trial court is not required to search the entire record to establish that a genuine issue of material fact exists. *Tucker v. Tennessee,* 539 F.3d 526, 531 (6th.Cir. 2008) (citing *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th. Cir. 1989). Further, "if a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c)," the court may determine that that fact is undisputed. Fed. R. Civ. Pro. 56(e)(2).

The OPLA

The OPLA defines a product liability claim as "a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> (c) Any failure of that product to conform to any relevant representation or warranty."

Ohio Rev. Code Ann. § 2307.71 (West).

Defendants argue that all Plaintiffs' Ohio common law claims are abrogated by the OPLA, pursuant to O.R.C. §2307.71(B).

Under Ohio law, "prior to 2005, three common law theories of recovery existed in Ohio product liability litigation: (1) breach of contract based on either express or implied warranty; (2) strict liability/implied warranty in tort; and (3) negligence." *Quill v. Albert M. Higley Co.*, 2014 Ohio 5821, ¶ 35, 26 N.E.3d 1187, 1194–95, citing *Temple v. Wean United, Inc.*, 50 Ohio St.2d 317, 320, 364 N.E.2d 267 (1977). In 1997, the Ohio Supreme Court in *Carrel v. Allied Products Corp.*, 78 Ohio St.3d 284, 677 N.E.2d 795 (1997), held that the version of the OPLA in effect at that time lacked sufficiently strong language abrogating common law causes of action arising from product liability injuries.

In response to *Carrel*, the Ohio General Assembly, in 2005, amended the OPLA to include Section 2307.71(B), which states as follows: "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." The General Assembly stated that the 2005 amendment was: " Intended to supersede the holding of the Ohio Supreme Court in *Carrel v. Allied Products Corp.* that the common-law product liability cause of action of negligent design survives the enactment of the Ohio Product Liability Act, sections 2307.71 to 2307.80 of the Revised Code, and to abrogate all

common law product liability causes of action." *Quill*, at 1194–95. "Likewise, both the Sixth Circuit Court of Appeals and the Northern District of Ohio have acknowledged that the OPLA expressly abolished all common law product liability claims." *Meta v. Target Corp.*, 74 F. Supp. 3d 858, 861 (N.D. Ohio 2015) citing *Krumpelbeck v. Breg, Inc.*, 491 Fed.Appx. 713, 715 (6th Cir.Ohio 2012); *Germain v. Teva Pharms., USA, Inc.*, 2014 U.S.App. LEXIS 12111, *86–88 (6th Cir.2014).

Negligence, Negligent Misrepresentation, Negligent Infliction of Emotional Distress, Breach of Express Warranty and Gross Negligence

The OPLA includes "within its definition of "product liability claims" those based upon "[a]ny warning or instruction, or lack of warning or instruction, associated with th[e] product." *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 921 (N.D. Ohio 2009), O.R.C § 2307.71(A)(13)(b). Therefore, the Court must determine whether each of Plaintiffs' common law claims constitute product liability claims abrogated by the OPLA. Courts considering the OPLA's preemption of common law causes of action have determined that the OPLA bars the following claims: *Nationwide Agribusiness Ins. Co. v. CNH America LLC*, 1:12-CV-01430, 2014 WL 2520502 (N.D. Ohio June 4, 2014)(common law claims of breach of warranty and strict liability are preempted by the OPLA); *Mitchell v. Proctor & Gamble*, 2:09-CV-426, 2010 WL 728222, 3 (S.D. Ohio Mar. 1, 2010)("The OPLA has been held to abrogate claims for strict products liability."); *McConnell v. Cosco, Inc.*, 238 F.Supp.2d 970, 974-76 (S.D. Ohio 2003) (Strict products liability claims in Ohio are governed by the OPLA). *See Saraney v. TAP Pharm. Prods.*, No. 1:04-CV-02026, 2007 U.S. Dist. LEXIS 3113, 2007 WL 148845 (S.D. Ohio January 16, 2007) (negligence claim is preempted by the OPLA); *Miller v.*

ALZA Corp., 759 F.Supp.2d 929, 943-44 (S.D. Ohio 2010)(common law claims of negligence, breach of express warranty and breach of implied warranty are abrogated by the OPLA); *Paugh v. R.J. Reynolds Tobacco Co.*, 834 F.Supp. 228, 230 (N.D. Ohio 1993) (allegations that there was negligence in how cigarettes were "tested, researched, sold, and promoted" fell under OPLA).

For a negligence claim to be abrogated by the OPLA, the claim must concern the factors described in O.R.C. 2307.71(A)(13).

Plaintiffs' FAC Master Complaint alleges the following negligent acts by Defendants:

> a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs:
>
> b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> d. Failing to use reasonable care in inspecting the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> e. Failing to use reasonable care in training its employees and health care providers related to the use of the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public as set forth herein of risks associated with the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> g. Failing to use reasonable care in marketing and promoting the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;
>
> h. In negligently and carelessly promoting the use of the Pelvic Mesh Products

to physicians who had not received sufficient training to master the techniques necessary for implantation of the device into the Plaintiffs;

i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing or selling the Pelvic Mesh Products, and;

j. In the case of the Prolift System, failing to use reasonable care in seeking and obtaining FDA clearance prior to marketing and selling the device for implantation into the human body.

In addition to the above, Plaintiffs further alleged Defendants acted negligently when they:

Failed to conduct post-market vigilance, or surveillance, by:

a. Monitoring or acting on findings in the scientific and medical literature; and

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for defendants' Pelvic Mesh Products.

Lastly, Plaintiffs Master Complaint alleges Defendants were negligent when they:

Failed to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

a. Failed to report MDRs (Medical Device [adverse event] Reports); and

b. Failed to investigate reports of serious adverse events.

The parties do not discuss in any meaningful detail the specific allegations of Plaintiffs' FAC but only discuss in general terms what claims are abrogated under the OPLA while relying on Plaintiffs' Short Form Complaint. However, the Court must consider the allegations to determine whether they state a product liability claim under § 2307.71(A(13).

The Court finds all Plaintiffs' claims for Negligence and Gross Negligence are abrogated as they concern the design, formulation, construction, creation, assembly, rebuilding, testing marketing, failure to warn or instruct except Plaintiffs' claims that

Defendants negligently failed to train their employees and healthcare providers related to the use of the Products, failed to monitor or act on findings in the scientific and medical literature and failed to monitor or investigate and evaluate reports from the FDA.

Plaintiffs' Negligent Misrepresentation claim is also abrogated by the OPLA because Plaintiffs allege Defendants negligently misrepresented that the pelvic mesh was adequately tested and found to be safe, misrepresented the risk of adverse side effects, compared favorably to older generations of similar products, had been sufficiently tested and had adequate warnings. All these allegations go to testing, marketing and warnings on the product which fall under the OPLA's product liability parameters. Therefore, the Court grants summary judgment for Defendants' on Plaintiffs' Negligent Misrepresentation claim.

Likewise, the Court grants summary judgment to Defendants on Plaintiffs' Negligent Infliction of Emotional Distress claim as it is also abrogated by the OPLA, which bars common law product liability claims seeking damages for emotional distress. "... [T]he OPLA defines a product liability claim as a claim seeking compensatory damages for "death, physical injury to person, emotional distress, or physical damage to property other than the product in question * * *." *Caterpillar Fin. Servs. Corp. v. Harold Tatman & Son's Ents., Inc.*, 2015-Ohio-4884, ¶ 32, 50 N.E.3d 955, 966 citing O. R.C. § 2307.71(A)(13).

Plaintiffs Negligent Infliction claim seeks compensatory damages arising out of Defendants' careless and negligent manufacture, design, developments, testing, labeling, marketing and selling of the pelvic mesh. Therefore, it too is abrogated as a product liability common law claim by the OPLA and Defendants are entitled to summary judgment on the claim.

Insofar as Plaintiffs' FAC alleges a common law Breach of Express Warranty claim it too is abrogated by the OPLA. "The OPLA unequivocally encompasses claims based on the failure of a product "to conform to any relevant representation or warranty." *Nationwide Agribusiness Ins. Co. v. CNH Am. LLC*, No. 1:12-CV-01430, 2014 WL 2520502, at *12 (N.D. Ohio June 4, 2014) quoting O.R.C. § 2307.71(A)(13)(c). Here, Plaintiffs' Breach of Express Warranty claim alleges the pelvic mesh was not fit for use by consumers nor was it of merchantable quality. These claims are expressly abrogated by the OPLA. However, Plaintiffs' FAC alleges, "Defendants' breaches constitute violations of common law principles and the statutory provisions of the Plaintiffs' respective states." (Plaintiffs FAC. Para. 185). Courts in this District have determined that UCC warranty claims are not abrogated by virtue of O.R.C. § 2307.71(B). See *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) see also *Miles v. Raymond Corp.* 612 F. Supp.2d (N.D. Ohio 2009).

Therefore, the Court finds Plaintiffs' Breach of Express Warranty claim is barred by the OPLA insofar as it is brought under Ohio common law. However, because Plaintiffs' FAC alleges it is also brought under Ohio statutory law, such a claim is not barred by the OPLA.

Fraud, Fraudulent Concealment, Constructive Fraud

While Plaintiffs' Negligent Misrepresentation product liability claim is barred by the OPLA, fraud is not. See *Stratford* v. *SmithKline Beecham Corp.*, No. 2:07CV639, 2008 WL 2491965, at *8 (S.D. Ohio June 17, 2008), (" claims of active misrepresentation are not necessarily abrogated by the OPLA because they may implicate the more general duty not to deceive, rather than the duty to warn."). *Stratford* listed the following cases as holding a

fraud claim was not abrogated by the OPLA:

> *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343 (6th Cir.2000) (fraud claims are based on the general duty not to deceive); *see Chamberlain*, 1999 U.S. Dist. LEXIS 2263, 1999 WL 33994451 (complaint for fraud that was grounded on allegations of breach of a general common law duty not to deceive rather than on allegations that the product did not conform to defendant's representations or warranties is not displaced by the OPLA); *Hollar v. Philip Morris Inc.*, 43 F.Supp.2d 794, 808 (N.D.Ohio 1998) (common law fraud claim is based primarily on defendant's breach of its alleged duty not to deceive and is not limited to a product liability claim).

Here, Plaintiffs' FAC claims for Fraud, Fraudulent Concealment and Constructive Fraud allege Defendants knowingly and falsely represented that the pelvic mesh products were tested and found to be safe and effective and fraudulently concealed from Plaintiffs, physicians and the medical community that the products were unsafe and defective. Thus, caselaw holds, and this Court finds, that Plaintiffs' Fraud, Fraudulent Concealment and Constructive Fraud claims, insofar as they state that Defendants actively misrepresented the safety and effectiveness of the pelvic mesh with knowledge that their representations were false, are not abrogated by the OPLA. However, Plaintiffs' Fraud and Fraudulent Concealment and Constructive Fraud claims are preempted insofar as they allege fraud in failing to adequately warn of the risks and dangers of the pelvic mesh.

Unjust Enrichment

The Court finds Plaintiffs' Unjust Enrichment claim is also abrogated because it alleges Plaintiffs purchased the pelvic mesh to treat Sylvester's stress urinary incontinence and pelvic organ prolapse but did not receive the safe and effective medical devise for which they paid. This claim implicates the pelvic mesh's failure to conform to a relevant representation and/or its marketing. Thus, it is a product liability claim abrogated by the

OPLA.

Therefore, for the foregoing reasons, the Court GRANTS summary judgment for Defendants on Plaintiffs' claims on Counts II, III, IV, IX, X, XII, XIII, XIV and XV. The Court grants, in part, Defendants' Motion for Summary Judgment on Count I, VI, VII, VIII and XI as discussed above. The Court denies Defendants' Motion on all other claims.

IT IS SO ORDERED.

Dated: March 19, 2020

/s/Christopher A. Boyko
CHRISTOPHER A. BOYKO
Senior United States District Judge