UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

JOY PERRY *et al.*,

Plaintiff,

v.

Case No. 2:20-cv-6592
JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Elizabeth P. Deavers

ETHICON, INC., *et al.*,

Defendants.

OPINION AND ORDER

This matter arises on Defendant Johnson & Johnson and Defendant Ethicon, Inc.'s (Collectively, "Ethicon") Motion to Sever Plaintiffs' Claims (the "Motion to Sever") (ECF No. 9) and Motion for Partial Dismissal of Plaintiffs' First Amended Complaint for Failure to State a Claim (the "Motion to Dismiss") (ECF No. 17). Ethicon's Motion to Sever seeks to sever the claims of former-plaintiff Joy Perry from those of Plaintiffs Bernadette and Shane Smith (Collectively, "Plaintiffs"). (*See* ECF Nos. 9.) Ms. Perry's claims, however, have since been dismissed. (ECF No. 27.)

Accordingly, Ethicon's Motion to Sever is **DENIED AS MOOT**. (ECF No. 9.) Moreover, the foregoing reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Ethicon's Motion to Dismiss. (ECF No. 17.)

I. BACKGROUND

A. Factual Background

Plaintiff Bernadette Smith ("Ms. Smith") and her spouse, Shane Smith, have brought a thirteen-count complaint against Ethicon for injuries that directly and/or indirectly arose from Ms. Smith's use of Ethicon's Gynecare TVT-Secur pelvic mesh product (the "TVT-S" or "TVT-S

device"). (Pl.'s First Am. Compl., ECF No. 10.) Plaintiffs' allegations, taken as true, are as follows:

Since 1996, Ethicon has manufactured, marketed, and distributed an assortment of TVT-S products, including the device implanted in Ms. Smith. (*Id.* at ¶ 33.) These devices are specifically intended to treat stress urinary incontinence ("SUI"). (*Id.*) To that end, the devices are "permanently implanted to reinforce the weakened vaginal wall to support the urethra to treat urinary incontinence." (*Id.* at ¶ 27.)

On February 16, 2007, Dr. James H. Nelson, III ("Dr. Nelson") surgically implanted Ms. Smith with a TVT-S device to treat her SUI. (*Id.* at ¶¶ 5, 16.) Subsequently, Ms. Smith "developed . . . mesh implant complications necessitating removal [of the TVT-S device], difficulty voiding, worsening mixed incontinence, recurrent urinary tract infections, dyspareunia, frequency, nocturia, pelvic pain, and infections." (*Id.* at ¶ 6.)

Like "[m]ost TVT-S pelvic mesh products[,]" the TVT-S implanted in Ms. Smith contained mesh that was "made from polypropylene, a type of plastic." (*Id.* at ¶¶ 16-17, 27.) Over the years, mounting scientific evidence has demonstrated that polypropylene is "biologically incompatible with human tissue" and thereby prone to eliciting an immune response (*i.e.*, a "host defense response") in its users which degrades both the mesh and the pelvic tissue it affronts. (*Id.* at ¶¶ 29-30.) This response has also been known to cause "biomechanical" issues with the device, such as "shrinkage or contraction of the mesh," which, in turn, causes "chronic inflammation of the pelvic tissue . . . nerve entrapment, further inflammation, chronic infectious response and chronic pain," as well as "new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation." (*Id.* ¶ 30.)

After Ms. Smith's surgery—namely, in 2008 and 2011—the Food and Drug Administration ("FDA") issued warnings regarding physical complications arising from pelvic mesh products like the TVT-S. (*Id.* at ¶¶ 40-42.) The FDA's 2011 warning, in particular, noted that "serious complications" associated with transvaginal mesh devices that used the "same mesh" as the TVT-S, including "[m]esh contraction (shrinkage) . . . associate[d] with vaginal shortening, vaginal tightening and vaginal pain." (*Id.* at ¶ 43.)

B. Plaintiffs' Claims

Plaintiffs allege that, from the moment Ethicon brought its TVT-S line of products to market, it (1) has known (or, alternatively, should have known) of the devices' propensity to cause the aforementioned complications and (2) actively represented otherwise to consumers. (*Id.* at ¶¶ 35, 55-74, 115.) They assert that these representations, in tandem with the device's own defectiveness, caused Ms. Smith to "sustain permanent injury," resulting in significant mental and physical pain; ongoing medical treatment; and "financial or economic loss, including but not limited to, obligations for medical services and expenses, lost income, and other damages." (*Id.* at ¶¶ 94, 101, 106, 125, 137, 146, 191.)

Accordingly, Plaintiffs now bring the following claims: Strict Liability – Failure to Conform to Representations (Count I); Strict Liability – Design Defect (Count II); Strict Liability – Manufacturing Defect (Count III); Strict Liability – Failure to Warn (Count IV); Breach of Express Warranty (Count V); Breach of Implied Warranty (Count VI); Fraudulent Concealment (Count VII); Constructive Fraud (Count VIII); Common Law Fraud (Count IX); Negligent Pharmaco-Vigilance (Count X); Unjust Enrichment (Count XI); Loss of Consortium (Count XII); and Punitive Damages (Count XIII). (*Id.* at ¶¶ 82 – 217.)

Ethicon now moves, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss all of Plaintiffs' claims other than Count IV and V.[1] (Def.'s Mot., ECF No. 17.)

II. STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 677–78 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Furthermore, "[a]lthough for purposes of a motion to dismiss [a court] must take all the factual allegations in the complaint as true, [it][is] not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* at 677–79 (quoting *Twombly*, 550 U.S. at 55) (internal quotations omitted).

III. ANALYSIS

Ethicon, in the main, argues that all of Plaintiffs' common law claims—namely, Counts VI-IX and Count XI—are abrogated by the Ohio Products Liability Act (the "OPLA"), Ohio Rev. Code §§ 2307.71-80 and/or duplicative of their OPLA claims. (ECF Nos. 17-1, 23.) Even if that is not the case, Ethicon argues that those claims, as well as Plaintiffs' OPLA claims (namely, Counts I-III) are insufficiently pled. (*Id.*)

A. Governing Law

A federal district court sitting in diversity must apply the choice-of-law rules of the forum

[1] Ethicon expressly acknowledges that its Motion to Dismiss does not apply to Count IV. It does not make the same acknowledgement for Count V (Breach of Express Warranty). Nevertheless, Ethicon does not address Count V in its Motion to Dismiss.

state. *State Farm Mut. Auto. Ins. Co. v. Norcold, Inc.*, 849 F.3d 328, 331 (6th Cir. 2017). Here, given Plaintiffs' Ohio residency, there is no dispute that Ohio's substantive law applies. (*See* ECF Nos. 17-1, 19.)

B. OPLA Abrogation and "Economic Loss"

In Ohio, all "product liability claims" must be brought pursuant to the OPLA. *See* R.C. § 2307.71(B). This includes "product liability claims" involving an "[e]thical medical device" such as the TVT-S.[2] *See* R.C. § 2307.72(A)(5).

Under the OPLA, a "product liability claim" constitutes any

> 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.

R.C. § 2307.71(A)(13).

All common law "product liability claims" are explicitly abrogated by the OPLA. R.C. § 2307.71(B). Courts consider a common law claim to constitute a "product liability claim"—and, thus, to be abrogated by the OPLA—when "[t]he actionable conduct that forms the basis" of that claim is "the same conduct that the OPLA defines as giving rise to a 'product liability claim.'" *Mitchell v. Procter & Gamble*, No. 2:09-cv-426, 2010 WL 728222, at *4 (S.D. Ohio Mar. 1, 2010).

[2] Under the OPLA, an "[e]thical medical device" includes any medical device that is prescribed, dispensed, or implanted by a physician or any other person who is legally authorized to prescribe, dispense, or implant a medical device and that is regulated under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. 301-392, as amended. There is no dispute that the TVT-S falls within the ambit of this definition.

The abrogation inquiry is also shaped by the type of relief a claim pursues. Claims that otherwise fall within the ambit of the OPLA, for instance, are not considered "product liability claims" if they do not pursue "compensatory damages" for "Harm" that arises from a codified product defect. *See* R.C. § 2307.71(A)(7) (defining "Harm" as "death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question"); *WEL Companies, Inc. v. Haldex Brake Products Co.*, 467 F. Supp. 3d 545, 559 (S.D. Ohio 2020) ("In order for common law claims to survive, courts require the damages sought to be outside those that the OPLA allows."); *Great Northern Ins. Co. v. BMW of N. Am. LLC*, 84 F. Supp. 3d 630, 647 (2015) (noting that the OPLA does not classify a claim for economic damages as a "product liability claim"). This includes product-based claims that exclusively seek to recover a plaintiff's "economic loss." *See* R.C. § 2307.71(2) (defining "Economic loss" as any "direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product").

1. Duplication (Counts VI-XI)

Plaintiffs assert numerous claims under the OPLA and, alternatively, at common law. These include: Count VI (Breach of Implied Warranty), Count VII (Fraudulent Concealment); Count VIII (Constructive Fraud); Count IX (Common Law Fraud); Count X (Negligent Pharmaco-Vigiliance); and Count XI (Unjust Enrichment). Plaintiffs contend that, outside of their claim for unjust enrichment, the "essence" of these claims are "actionable" under the OPLA's "Failure to Warn" (R.C. § 2307.76) or "Failure to Conform" (R.C. § 2307.77) provisions. (*See* Pl.'s Resp., ECF No. 19 at PageID #222) (citation omitted). If that is true, it is unclear how, if at all, these claims are distinguishable from the failure to conform and failure to warn claims that Plaintiffs

have already brought (*i.e.*, Counts I and IV, which, as discussed *infra*, may proceed).[3] Accordingly, to the extent Counts VI-XI pursue the same conduct, theories of liability, and damages as Counts I and IV, they are duplicative—and, thus, subject to dismissal.

However, as discussed below, to the extent these claims are brought under a different theory of liability (*i.e.*, Ethicon's breach of the "general duty not to deceive") or solely pursue "economic loss," they may proceed, so long as they are sufficiently pled. *See Sylvester v. Ethicon*, *Inc.*, No. 1:19-cv-2658, 2020 WL 1308738, at *5 (S.D. Ohio Mar. 19, 2020) (noting that claims of active misrepresentation may not be abrogated by the OPLA) (citation omitted); *Great Northern Ins. Co.*, 84 F.Supp. 3d at 649.

2. Plaintiffs' Alternative, Common Law Claims for "Economic Loss"

Generally, "Ohio courts are divided as to how to evaluate an action that alleges both a common law [tort] claim seeking economic losses and an OPLA claim seeking compensatory damages." *Simpson v. Johnson & Johnson*, No. 5:20-cv-1237, 2020 WL 5629092, at *5 (N.D. Ohio Sept. 21, 2020). As Plaintiffs note, "[s]ome courts"—including this one—allow both claims to "proceed alternatively to one another," even though they both "arise from the same set of facts."[4]

[3] Count I, for example, alleges that Ethicon breached its duty to "accurately and truthfully represent to the medical and healthcare community, Plaintiffs, the FDA, and the public, that the TVT-S pelvic mesh products had not been adequately tested and found to be safe and effective for the treatment of incontinence" partly because it "knew" that the device was unsafe. (Compl., ECF No. 10 at ¶¶ 58, 69, 91-92.) Accordingly, to the extent Counts VI-XI on this theory of liability, pursue the same compensatory damages, and are brought under the same provision of the OPLA, they are subsumed by Count I.

[4] The underlying rationale for this principle, as originally set forth in *Huffman v. Electrolux Home Prods., Inc.*, derives from the fact that the OPLA does not permit plaintiffs to recover "economic" damages unless and until they are awarded compensatory relief. But not all defective product claims are created equal. One injured by a defective product may have a "relatively certain" claim for "economic loss," but a less certain claim for compensatory damages. To preclude those plaintiffs from bringing both claims in the same suit, as the *Huffman* court recognized, would effectively turn their "recovery of economic loss damages into a gamble." That is, it would require them to "choose" to either (1) forego any chance of obtaining compensatory relief (*i.e.*, by solely pursuing a common law "economic loss" claim) or (2) deliberately reduce the "certainty" of their "economic loss" recovery by solely bringing an OPLA claim. The law of Ohio, in the words of the *Huffman* court, "does not support circumscribing a plaintiff's right to the remedy of economic loss damages." *Id.* at 881. Nor do Federal Rules of Civil Procedure 8(d)(2)-(3), which "explicitly allow parties to assert inconsistent alternative theories." *Id.* Accordingly, in the absence of any "good argument as to

See Dates v. Ethicon, Inc., No. 2:20-cv-1287, 2020 WL 3265537, at *2 (S.D. Ohio June 17, 2020); *WEL Companies, Inc.*, 467 F. Supp. 3d at 559; *Great Northern Ins. Co.*, 84 F. Supp. 3d at 649.

Here, Plaintiffs argue that, insofar as Counts VI-IX (1) are brought at common law and (2) solely seek to recover their "economic loss," they are not abrogated by the OPLA—and, thus, may be brought in the alternative to their OPLA claims. Ethicon, however, contends that Plaintiffs have not suffered any "economic loss" at all. This is so, it argues, because all of Plaintiffs' alleged "economic" losses derive from the TVT-S device. (*See* Def.'s Reply, ECF No. 23 at PageID #270-71) (arguing that "because [Plaintiffs'] common law claims for economic damages are intertwined with their claim[s] for personal injuries," all of their common-law claims "fall under," and are thus abrogated by, the OPLA). To that end, Ethicon argues that Plaintiffs' alternative claims are abrogated by the OPLA—and, thus, may not be brought in the alternative.

Ethicon's characterization of Plaintiffs' alleged scope of economic loss, however, is far too narrow. As Ethicon notes, "economic loss" under the OPLA "typically encompass[es] the change in value of a defective product or the indirect losses sustained as a result of a defective product such as the value of production time lost and resulting lost profits." *Darwish v. Ethicon, Inc.*, No. 1:20 CV 1606, 2020 WL 7129582, at *3 (N.D. Ohio Dec. 4, 2020) (quoting *Dates*, 2020 WL 3265537, at *2). Here, Plaintiffs' allegations, read favorably, demonstrate that Ms. Smith paid to have a product that (1) was intended to "reinforce" human tissue and (2) began to destruct *upon contact with human tissue* implanted in her body. It is, in that light, certainly plausible that the value she paid for the device was more than the value of the product she received. That is an economic loss. *See Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624, 634

why" the claims "should be mutually exclusive," they are permitted to be brought simultaneously and in the alternative. *Dates v. Ethicon*, *Inc.*, No. 2:20-cv-1287, 2020 WL 3265537, at *2 (S.D. Ohio June 17, 2020).

(Ohio 1989) (stating that defects in the product itself which reduced the product's value constituted economic damages).

The Court need not define all of the potential forms of Plaintiffs' economic losses. At this juncture, the mere fact that Plaintiffs have alleged some economic loss is enough.[5] Accordingly, insofar as Plaintiffs' common law claims are (1) sufficiently stated (2) pled in the alternative and (3) brought solely in pursuit of "economic loss," they may proceed.

C. Plaintiffs' Common Law Claims (Counts VI-XI)

1. Breach of Implied Warranty of Fitness for Ordinary, Intended Purpose (Count VI)

Plaintiffs assert their breach of implied warranty claim is separately cognizable under contract law and therefore not preempted by the Ohio Product Liability Act ("OPLA"). Alternatively, they argue that, to the extent the claim *is* abrogated by the OPLA, they may assert it in the alternative to recover their economic loss.

i. Plaintiffs' UCC Implied Warranty Claim is Insufficiently Pled

Ethicon argues that Count VI cannot be brought separately as a contract claim because "Plaintiffs have not alleged privity and have not sufficiently pled an applicable exception to the privity requirement in order to maintain a UCC implied warranty claim." Plaintiffs disagree. They argue, specifically, that they *have* sufficiently demonstrated contractual privity because their allegations, taken as true, demonstrate that Ms. Smith was a "third-party beneficiary" to the sale of the TVT-S device.

As a threshold matter, the Court agrees with Plaintiff's general contention that an Ohio UCC breach of implied warranty claim may be brought independently against a defendant-

[5] Indeed, as Ethicon even points out, several courts facing similar claims have assumed for purposes of dismissal that an economic loss has occurred. *See Darwish v. Ethicon, Inc*., 2020 WL 7129582, at *3 (N.D. Ohio Dec. 4, 2020); *Dates,* 2020 WL 3265537, at *2

manufacturer in a products liability suit. *See Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 924 (N.D. Ohio 2009) (holding the same). Claims under the OPLA and Ohio UCC are based on "separately identifiable statutory duties imposed by law." *Id.* Thus, the mere fact an Ohio UCC implied warranty claim implicates a defective product does not mean it cannot proceed on its own. That much is clear.

What is less clear is whether a secondary purchaser like Ms. Smith can establish contractual privity—a requirement under Ohio law—as an "intended third-party beneficiary." *See Curl v. Volkswagen of Am., Inc.*, 114 Ohio St.3d 266, 2007-Ohio-3609, 871 N.E.2d 1141, ¶ 28. Plaintiffs cite our sister court's decision in *Miles* to support the proposition that she can. *See Miles*, 612 F. Supp. 2d at 924-26. But *Miles*, as Defendants note, is not quite as helpful as Plaintiffs suggest.

Miles involved a forklift accident that ultimately resulted in the death of a Wooster Brush Company ("Wooster Brush") employee. *Id.* at 916-17. The administrator of that employee's estate, individually and behalf of the decedent, sued Raymond Corporation ("Raymond"), the forklift's manufacturer, on a breach of implied warranty claim asserted under both the common law and the Ohio UCC. *Id.* Raymond, akin to Ethicon here, argued that the latter claim could not proceed, given that Wooster Brush (rather than the decedent herself) was the only party who had a direct contractual relationship with Raymond. *Id.* at 924-26.

The *Miles* court, for purposes of dismissal, disagreed. *Id.* It first recognized that that Ohio's caselaw came out both ways on the issue of whether, in the "absence of a direct contractual relationship," a consumer could cognizably constitute a "third-party beneficiary" under the Ohio UCC.[6] *Id.* at 925-26; *compare Bobb Forest Prods., Inc. v. Morbark Indus. Inc.*, 783 N.E.2d 560,

[6] In *Curl*, the Ohio Supreme Court has construed "privity" to exist "only between immediate links in the distribution chan." *Curl v. Volkswagen of Am., Inc.*, 114 Ohio St.3d 266, 2007-Ohio-3609, 871 N.E.2d 1141, ¶ 32. Nevertheless, the *Curl* court did not dismiss the idea that exceptions to this general principle exist. *See id.* at ¶ 33 (acknowledging,

576, ¶¶ 58-61 (Ohio Ct. App. 2002) (holding that consumers may qualify as third-party beneficiaries for purposes of asserting an implied warranty claim under the Ohio UCC), *with Bruns v. Cooper Indus., Inc.*, 78 Ohio App.3d 428, 432, 605 N.E.2d 396 (1992) (holding that a direct contractual relationship between buyer and seller is a requirement to assert a breach of warranty claim under the UCC). Nevertheless, given the stage of the proceedings, the court declined to "wade into" the merit of the plaintiff's position, and simply assumed, for purposes of dismissal, that a "seller's" implied warranties could, in at least some instances, extend to the employees of a corporate "buyer." *Id.* at 925, n. 11. Based on that assumption, the court found that the plaintiffs' allegations arguably demonstrated that the decedent constituted an "intended third-party beneficiary" of Raymond's sale of the forklift to Wooster Brush. *Id.* at 925-26. ("Plaintiffs allege that Wooster Brush informed Raymond of the specific dimensions of the area in which it intended to use the forklift and made inquiries about its safety and fitness for use in this application. These allegations put Raymond on adequate notice of Plaintiffs' third-party beneficiary theory since Wooster Brush, as a corporation, can act only through its employees.").

Here, however, Plaintiffs do not offer any facts from which this Court can plausibly infer that Ethicon knew (or was "on adequate notice") that Ms. Smith was the intended recipient of the TVT-S device at issue. *See id.* at 925; *Bobb Forest Prod., Inc.* at ¶ 60 (holding that the plaintiff was an intended third-party beneficiary of a contract of sale for a sawmill because, *inter alia*, the sawmill's seller "knew that it was manufacturing the sawmill for [the plaintiff's] ultimate use and [the buyer] purchased the sawmill from [the seller] only after he knew that [the plaintiff] would purchase it from him"). They do not allege, for instance, that the principal "buyer" of the product—Ms. Smith's implanting hospital or physician—informed (or even suggested to) Ethicon that the TVT-

but declining to find, that certain agency principles can establish contractual privity in the absence of a contractual relationship). Moreover, it did not address the viability of the "third-party beneficiary" doctrine at all. *Id.*

S was for Ms. Smith's benefit, or that Ethicon tailored the device for Ms. Smith's use. Plaintiffs solely allege that Ms. Smith was an "intended third-party beneficiary of Ethicon's TVT-S, through assumption of the contract between Defendants and Ms. Smith's implanting physician or hospital . . . for the purchase of the TVT-S product." (Compl., ECF No. 10 at ¶ 145) (cleaned up). This conclusory assertion, absent more, is not enough.[7]

Accordingly, to the extent Plaintiffs bring Count VI under the Ohio UCC, their claim is **DISMISSED**.

ii. Plaintiffs' Common Law Implied Warranty Claim May Proceed in the Alternative

Plaintiffs contend that, regardless of the existence of privity, and pursuant to the "economic loss" doctrine discussed above, they may bring Count VI under common law tort theory. To the extent Plaintiffs' claim is (1) sufficiently pled; (2) solely seeks to recover Plaintiffs' "economic loss[;]" and (3) is pled in the alternative, the Court agrees. *See Great Northern Ins. Co.*, 84 F. Supp. 3d at 649.

Remote purchasers need not prove the existence of contractual privity to pursue a breach of implied warranty claim that sounds in tort. *Risner v. Regal Marine Indus., Inc.*, 8 F. Supp. 3d 959, 995 (S.D. Ohio 2014). To prevail on this claim, Plaintiffs must ultimately prove (1) that the TVT-S device contained a defect that made it unfit for its ordinary, intended use; (2) that this defect existed at the time the product left Ethicon's possession; and (3) that this defect proximately caused Plaintiffs' economic injuries. *See Wotring Towing v. Ford Motor Co.*, No. 2:16-cv-1193, 2017 WL 2378003, at *2 (S.D. Ohio May 31, 2017).

[7] Nor is the fact that Ethicon—a mass producer of TVT-S devices—generally knew that the TVT-S would be used on an individual *like* Ms. Smith (*i.e.*, individuals with SUI). *Bobb Forest Prods.* at ¶ 61 (construing the fact that seller "did not mass produce sawmills" to demonstrate its knowledge that the sawmill it ultimately sold was for the plaintiff's use).

Here, Plaintiffs easily satisfy all three of these elements. Plaintiffs allege—and Defendants agree—that the ordinary, intended use of the TVT-S device was to treat urinary incontinence, and that Ms. Smith had the TVT-S device implanted to treat such a condition. Plaintiffs also plausibly allege (1) that the TVT-S device implanted in Ms. Smith was not actually "fit" to treat her incontinence because it contained material (*i.e.*, polypropylene mesh) that eroded within her body; (2) that said defect existed at the time the device left Ethicon's possession; and (3) that, due to its erosion, the TVT-S device caused Ms. Smith to incur "economic loss." (Compl., ECF No. 10 at ¶¶ 6, 27-32, 138-46.) These facts, taken as true, are enough to sufficiently make out a common law claim for breach of implied warranty.

To that extent, Ethicon's Motion to Dismiss is **DENIED** as to Count VI.

2. Fraud-Based Claims (Counts VII-IX)

i. Plaintiffs' Fraud-Based Claims May Stand Alone if Sufficiently Pled

Plaintiffs contend that, to the extent their fraud-based claims (Counts VII-IX) are based on Ethicon's active misrepresentation of the TVT-S' safety and efficacy—as opposed to its "failure to warn" of the device's dangerousness—those claims may be brought independently. (*See* Pl.'s Resp., ECF No. 19 at PageID #223-24.) The Court agrees.

As this Court recognized in *Stratford*:

> [C]laims 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. *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* v. *Am. Tobacco Co.*, 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).

Stratford v. SmithKline Beecham Corp., No. 2:07-cv-639, 2008 WL 2491965, at *1 (S.D. Ohio); *see also Sylvester*, 2020 WL 1308738, at *5.

Here, Count VII (Fraudulent Concealment), Count VII (Constructive Fraud), and Count IX (Common Law Fraud) all, in some form, allege that Ethicon "knowingly and falsely represented" that its TVT-S devices were "tested and found to be safe and effective," and that, in so doing, Ethicon "fraudulently concealed" contrary information from (1) Plaintiffs, (2) the physicians and hospitals that purchased the TVT-S device, (3) and the medical community as a whole. To the extent these claims seek to hold Ethicon liable for "actively misrepresent[ing] the safety and effectiveness of the pelvic mesh with knowledge that their representations was false," they may, in light of the above, proceed independently. *Sylvester*, 2020 WL 1308738, at *5. However, to the extent these claims solely "allege fraud in failing to adequately warn on the risks and dangers" of the TVT-S device, they are (1) abrogated by the OPLA and (2) duplicative of Plaintiffs' failure to warn claim (Count IV). *See id.*

With this in mind, the Court now turns to the sufficiency of the pleadings.

ii. Plaintiffs' Fraud-Based Claims Fail for Lack of Particularity

Ethicon asserts that all of Plaintiffs' fraud-based claims are insufficiently pled because they do not meet the heightened particularity requirement set forth in Federal Rule of Civil Procedure 9(b).

Claims sounding in fraud are, indeed, "subject to heightened pleading requirements." *In re Porsche Cars*, *Inc.*, 880 F. Supp. 2d at 814. Specifically, they must identify the circumstances surrounding the defendant's alleged misrepresentations—namely, as Defendants note, their "time, place, and content." Fed. R. Civ. P. 9(b); *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008). These requirements are to be construed with respect to "Rule 9(b)'s broad

purpose of ensuring that a defendant is provided with at least the minimum degree of detail necessary to begin a competent defense." *U.S. ex rel. SNAPP, Inc.*, 532 F.3d at 504. They are also, as Plaintiffs observe, to be relaxed in specific instances, such as when, in the absence of discovery, "the information required for a plaintiff to achieve particularity is held exclusively by the opposing party." *In re Porsche*, 880 F. Supp. 2d at 814 (citation omitted).

Here, Plaintiffs allege that, from the moment Ethicon took its TVT-S device to market in 1996, it was aware of the fact that its mesh material was biologically incompatible with human tissue—and, thus, prone to causing health complications when implanted in the human body. (Compl., ECF No. 10 at ¶¶ 55, 71.) Plaintiffs allege that, to keep the product commercially viable, and "[d]espite this knowledge," Ethicon (1) marketed the device as "safe and effective" to downstream consumers (*i.e.*, hospitals, physicians, and their patients) through various unnamed representatives and "written materials"; and (2) conducted certain TVT-S "training programs" which intentionally misled attending physicians into believing that proper surgical technique could "minimize or eliminate" any device-related health risks. (*Id.* at ¶¶ 55, 71-74, 115-126, 129, 147-177.) At least some of this messaging, Plaintiffs assert, found its way to Dr. Nelson, Ms. Smith's implanting surgeon and/or Ms. Smith. (*Id.* at ¶¶ 147-77.) Plaintiffs contend that both Dr. Nelson and/or Ms. Smith justifiably relied on this information to select the TVT-S device as a means of resolving Ms. Smith's incontinence, ultimately leading to Ms. Smith's stated injuries. (*Id.* at ¶¶ 71, 87, 156.)

These allegations are arguably sufficient under Rule 9(b) to the extent they specify the content of Ethicon's alleged misrepresentations (*e.g.*, that the TVT-S device was "safe and effective"). They are insufficient, however, insofar as they do not identify how or when this misinformation was conveyed to Dr. Nelson and/or Ms. Smith. Ethicon cannot properly respond

to Plaintiffs' contention that "Plaintiffs and/or their implanting physicians justifiably relied on [Ethicon's] misrepresentations" if it does not know when or how those alleged misrepresentations were made. *See U.S. ex rel. SNAPP, Inc.*, 532 F.3d at 504 (citation omitted). Simply stating that, since 1996, Ethicon permeated the market with TVT-S-related misinformation through "key opinion leaders, agents, employees, representatives, designees, or any other person acting on behalf of Defendants" and/or various "written materials" is not enough.[8]

That, however, does not mean that those claims must be dismissed with prejudice. Plaintiffs have requested leave to cure the deficiencies in their Complaint pursuant to Federal Rule of Civil Procedure 15(a). (*See* Pl.'s Resp., ECF No. 19 at PageID #234.) As Plaintiffs note, "[t]he thrust of Rule 15 is to reinforce the principle that cases should be tried on their merits rather than the technicalities of pleadings." *Brewington v. Bos. Sci. Corp.*, No. 2:17-cv-1082, 2018 WL 2088007, at *1 (S.D. Ohio May 4, 2018) (quoting *Tefft v. Seward*, 689 F.2d 637, 639 (6th Cir. 1982)). To that end, and in light of their partial sufficiency, Plaintiffs' request for leave is **GRANTED** with respect to their fraud-based claims (Counts VII-IX). Plaintiffs shall have **FOURTEEN DAYS** from the date of this Opinion and Order to file a new amended complaint which comports with Rule 9(b). In the meantime, however, Plaintiffs' fraud-based claims (Counts VII-IX) are **DISMISSED WITHOUT PREJUDICE**.

3. Negligent Pharmaco-Vigilance (Count X)

Plaintiffs have brought one count of "Negligent Pharmaco-Vigilance" (Count X) against Ethicon for breaching its "ongoing duty to [Ms. Smith] and [her] physician to monitor safety data and testing on their TVT-S pharmaceutical product," as well as its "duty to inform physicians (including [Ms. Smith's]), regulatory agencies (including the FDA), and the public of the risks,

[8] This information, by its very nature, is not in the exclusive possession of Ethicon; thus, there is no cause for this Court to "relax" its enforcement of Rule 9(b). *See In re Porsche*, 880 F. Supp. 2d at 814.

adverse events, and contraindications of the TVT-S device which came to, or should have come to, Defendants' attention." (Compl., ECF No. 10 at ¶¶ 181-82).

Ethicon asserts that this claim must be dismissed because it "has never been a recognized cause of action under Ohio common law," and, even if it has, it is "abrogated by the OPLA." The Court agrees. Plaintiffs do not cite—and this Court has not identified—any Ohio caselaw recognizing a specific common law cause of action for "negligent pharmaco-vigilance." *See Stratford*, 2008 WL 2491965, at*6, n.3. Thus, if the claim is to be brought at all, it must have a statutory basis. *Id.* at *6. Here, Plaintiffs, as noted, claim that basis to be the OPLA's "post-marketing warning or instruction" provision. *See* R.C. § 2307.76(A)(2)(a)-(b). To that end, and as discussed, this claim is subsumed by Plaintiffs' failure to warn claim (Count IV).

Accordingly, Count X is **DISMISSED**.

4. Unjust Enrichment (Count XI)

i. Count XI May Proceed in the Alternative

Count XI of Plaintiffs' Complaint alleges that Ethicon unjustly enriched itself by deceiving Ms. Smith into purchasing a TVT-S device which, contrary to Ethicon's representations otherwise, was not "safe and effective." (Compl., ECF No. 10 at ¶¶ 193-204). Ethicon argues that Plaintiff's unjust enrichment claim should be dismissed because the thrust of their lawsuit sounds in tort, and a "claim for unjust enrichment is legally irrelevant in a tort-based product liability suit." (*See* Def.'s Mot., ECF No. 17-1 at PageID #211) (citing *Hosbrook v. Ethicon, Inc.*, No. 3:20-cv-88, 2020 WL 5214644, at *8 n. 7 (S.D. Ohio Sept. 1, 2020)).

To prevail on their claim for unjust enrichment, Plaintiffs must prove (1) that a benefit was conferred upon Ethicon; (2) that Ethicon had knowledge of this benefit; and (3) Ethicon retained this benefit "under circumstances where it would be unjust to do so without payment." *Salameh v.*

Doumet, 2019-Ohio-5391, 151 N.E.3d 83, ¶ 65 (5th Dist.). Here, Plaintiffs allege that (1) Ms. Smith directly or indirectly (*i.e.*, via her implanting hospital) paid for the TVT-S device, thus conferring a benefit unto Ethicon; (2) Ethicon accepted and retained this payment knowing that the device paid for was "not safe and effective[;]" and (3) the device implanted in Ms. Smith, in actuality, was not "safe and effective." (Compl., ECF No. 10 at ¶¶ 198-203.) Plaintiffs assert that, given these circumstances, "it would be unjust or inequitable" for Ethicon to keep Ms. Smith's money.

Undoubtedly, part of Plaintiffs' claim "implicates the pelvic mesh's failure to conform to a relevant representation and/or its marketing." *Sylvester*, 2020 WL 1308738, at *6. And, indeed, Plaintiffs point out that their theory of liability hinges on the idea that "a benefit was not conferred *because* the device was defective." (Pl.'s Resp., ECF No. 19 at PageID #233) (quoting *Kuchenberger v. Johnson & Johnson*, No. 19-61712-CIV-MORENO, 2019 WL 4416079, at *4 (S.D. Fla. Sept. 16, 2019) (emphasis added)). To that extent—as well as in light of the fact that Plaintiffs request "compensatory damages"—Count XI constitutes a "product liability claim," and, therefore, is abrogated by the OPLA. *See Sylvester*, 2020 WL 108738, at *6. However, to the extent Plaintiffs bring Count XI as an equitable claim, it may proceed in the event all of their other legal remedies fail. *See Chapman v. Tristar Prods, Inc.*, No. 1:16-cv-1114, 2017 WL 1433259, at *11 (citation omitted) ("Additionally, 'the equitable claim of unjust enrichment fails when a legal remedy is available.'").

Accordingly, Ethicon's Motion to Dismiss is **DENIED** as to Count XI.

D. Plaintiffs' OPLA Claims

Plaintiffs bring Counts I-IV of their Complaint "under the common law, Section 402A of the Restatement of Torts (Second) and pursuant to O.R.C. 2307.77." (Compl., ECF No. ¶ 90.)

These claims, as noted, include: (1) "Strict Liability – Failure to Conform to Representations" (Count I); (2) "Strict Liability – Design Defect" (Count II); and (3) "Strict Liability – Manufacturing Defect" (Count III); and (4) "Strict Liability – Failure to Warn" (Count IV). Ethicon argues that all but Count IV are insufficiently pled.

Before addressing Ethicon's arguments, several things are of note. *First*, to the extent Counts I-IV are brought "under the common law," they are, as discussed above, abrogated by the OPLA. These claims may only be brought pursuant to R.C. § 2307.71-.79. *Second*, of Counts I-IV, only Count I is brought with reference to its applicable OPLA provision (R.C. § 2307.77). "Claims that are authorized by the OPLA should be pled with reference to [their] applicable provision of the OPLA." *Mitchell*, 2010 WL 728222, at *3 (dismissing plaintiffs product liability claims without prejudice and granting leave for plaintiffs to amend those claims to be brought with reference to their applicable OPLA provision); *Stratford*, 2008 WL 2491965, at *5 (same) (citing *Delahunt v. Cytodyne Tech.*, 241 F. Supp. 2d 827, 844 (S.D. Ohio 2003)). Ethicon, however, does not seek dismissal on this ground. Thus, the Court will—as Ethicon does—assume that these claims have been brought under their applicable OPLA provision, and, to the extent Ethicon addresses their sufficiency with respect to those provisions, evaluate them accordingly. Nevertheless, Plaintiffs are **DIRECTED** to reform Counts II-IV to be pled with reference to their enabling OPLA provisions by filing a new amended complaint **WITHIN FOURTEEN DAYS** of the date of this Opinion and Order. Should Plaintiffs fail to do so, they risk dismissal of these claims.

With the above in mind, the Court turns to Ethicon's arguments.

1. Strict Liability Failure to Conform (Count I)

To prevail on Count I, Plaintiffs must ultimately prove (1) that Ethicon "made a representation of material fact concerning the character or quality" of the TVT-S device; (2) that the device "did not conform" to this representation; (3) that Ms. Smith "justifiably relied" on said representation; and (4) that "this reliance was the direct and proximate cause" of Ms. Smith's injuries. *Saraney v. TAP Pharmaceutical Prod., Inc.*, No. 1:04-cv-02026, 2007 WL 148845, at *7 (N.D. Ohio Jan. 16, 2007)). Ethicon contends that Plaintiffs "have not identified any specific misrepresentation made to them by the Defendants, let alone one on which they relied, or that [said misrepresentation] was the proximate cause of their injuries"—and, thus, that Count I must be dismissed.

Ethicon's argument appears to presume that the same heightened pleading standard that applies to Plaintiffs' fraud-based claims applies to Plaintiffs' failure to warn claim. That is not the case. Section 2307.77—and, therefore, the facial sufficiency of Count I—does not turn on an allegation of "fraud or mistake." *See* R.C. § 2307.77 ("A product may be defective because it did not conform to a representation *even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation*.") (emphasis added). Ethicon provides no legal argument otherwise.

Thus, by default, Federal Rule of Civil Procedure 8(a)(2) applies. That means that Plaintiffs' must only provide "a short and plain statement" of their claim which, taken as true, "plausibly" shows that they are entitled to relief. Fed. R. Civ. P. 8(a)(2); *Iqbal*, 556 U.S. 662. As discussed at length, Plaintiffs have alleged (1) that Ethicon marketed its TVT-S device to Ms. Smith and her implanting physician as "safe and effective" (despite knowing otherwise); (2) that the device, due to its use of polypropylene mesh, was definitively *not* "safe and effective[;]"and

(3) that, absent any cause to do otherwise, Ms. Smith and/or her implanting physician relied on this representation, ultimately leading to Ms. Smith's stated injuries. These factual allegations, taken as true, sufficiently state a claim pursuant to R.C. § 2307.77.

Accordingly, Ethicon's Motion to Dismiss is **DENIED** as to Count I.

2. Strict Liability Design Defect (Count II)

To prevail on their Strict Liability Design Defect claim (Count II), Plaintiffs must ultimately prove (1) that the TVT-S implanted in Ms. Smith was "manufactured and sold" by Ethicon; (2) that this device was defective in design; (3) that this defect "existed at the time the product left" Ethicon's possession; (4) that the defect was the "direct and proximate cause" of Ms. Smith's injuries; and (5) that a "safer alternative design" existed. *See* R.C. § 2307.73(A)(1) (defining the evidentiary elements of a design defect claim for "compensatory damages"); *Simko v. CMI Terex Corp.*, No. 1:09CV757, 2010 WL 1161843, at *2 (N.D. Ohio Feb. 1, 2010). Ethicon argues that Plaintiffs' design defect claim is insufficiently pled to the extent that (1) Plaintiffs only offer "conclusory assertions" that the design of the TVT-S device was prone to causing physical complications in its users "without explaining how the design gave them any such propensity" and (2) even if Plaintiffs have sufficiently alleged a design defect, they have pled "no facts whatsoever that would plausibly link their injuries to the alleged defect(s)." The Court disagrees on both counts.

Plaintiffs allege a horde of specific reasons as to why the TVT-S device was prone to causing the physical complications that Ms. Smith allegedly suffered—namely, that it contained mesh material (polypropylene) that was "biologically incompatible" with human tissue. (Compl., ECF No. 10 at ¶¶ 29-32.) That, among others, is one very clear reason Plaintiffs give for the TVT-

S' "propensity" to cause physical complications. Accordingly, Ethicon's first argument is not well taken.

Ethicon's second argument—that Plaintiffs have not "plausibly linked" the device's defectiveness to their injuries—fares no better. Plaintiffs note, specifically, that polypropylene is prone to eliciting a "host defense response" in a woman's pelvis which "promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response[,] chronic pain . . . new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic dysfunction," and other "hyper-inflammatory responses." (*Id.* at ¶¶ 30-31.) Plaintiffs also (quite obviously) allege that Ms. Smith had the TVT-S *implanted in her pelvis*, and that, sometime after, she suffered the same general injuries often associated with polypropylene mesh. (*Id.* at ¶¶ 6, 16, 55.) These factual allegations, at this stage, are enough to "plausibly link" Plaintiffs' injuries to the TVT-S device.

Outside of these arguments, Ethicon offers no persuasive reason as to why Plaintiffs' design defect claim fails. Accordingly, Ethicon's Motion to Dismiss is **DENIED** as to Count II.

3. Strict Liability Manufacturing Defect (Count III)

To prevail on a manufacturing defect claim, Plaintiffs must ultimately prove that (1) the TVT-S device "was defective in manufacture or construction; (2) the effective aspect of the product was a proximate cause" of Ms. Smith's injuries; and (3) Ethicon "manufactured the actual product in question." *Smitley v. Nissan N. Am., Inc.*, No. 2:09-cv-148, at *2 (S.D. Ohio Aug. 2, 2010) (citing R.C. § 2307.73). A product "is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units

manufactured to the same design specifications, formula, or performance standards." R.C. § 2307.74.

Ethicon contends that Plaintiffs' manufacturing defect claim is insufficient to the extent that it does not explain how the TVT-S device implanted in Ms. Smith deviated from its manufacturing specifications. Plaintiffs, in response, argue (1) that their allegation that the TVT-S device "deviated in some material way" from its manufacturing specifications "is enough at this stage to give rise to a plausible inference" that the TVT-S device implanted in Ms. Smith "contained manufacturing defects[;]" and (2) that their claim "can be proven by developing the evidence to show" that the product did not work as intended after it left Ethicon's possession.

Ethicon's argument carries the day. Plaintiffs have not explained how, if at all, the TVT-S device implanted in Ms. Smith differed from Ethicon's design "specifications or standards" or other TVT-S devices manufactured to the "same specifications . . . or performance standards." R.C. § 2307.74. Indeed, the bulwark of Plaintiffs' complaint rests on the allegation that "[m]ost TVT-S pelvic mesh products are comprised" of the same "biologically incompatible" polypropylene mesh. (Compl., ECF No. 10 at ¶¶ 27, 29-32.)

Accordingly, because Plaintiffs have not sufficiently pled the existence of a manufacturing defect, Count III is **DISMISSED**.

E. Other Claims

Ethicon asserts that, because Plaintiffs' Loss of Consortium (Count XII) and Punitive Damages (Count XIII) claims are "derivative of Plaintiffs' primary causes of action," they must be dismissed. Plaintiffs' "primary causes of action," as discussed, may proceed. Thus, Ethicon's Motion to Dismiss is **DENIED** as to Counts XII and XIII.

IV. CONCLUSION

For the foregoing reasons, the Court **DENIES AS MOOT** Ethicon's Motion to Sever (ECF No. 9) and **GRANTS IN PART** and **DENIES IN PART** Ethicon's Motion to Dismiss (ECF No. 17). Specifically, the Court holds as follows:

- Count III (Strict Liability - Manufacturing Defect) and Count X (Negligent Pharmaco-Vigilance) of Plaintiffs' Complaint are **DISMISSED**.
- Counts VII-IX of Plaintiffs' Complaint are **DISMISSED WITHOUT PREJUDICE**. The Court, for good cause, **GRANTS** Plaintiffs leave to amend their Complaint with **FOURTEEN DAYS** of this Opinion and Order to bring their fraud-based allegations into compliance with Federal Rule of Procedure 9(b).
- Count VI (Breach of Implied Warranty) and Count XI (Unjust Enrichment) may proceed in the alternative as specified above. Otherwise, they are abrogated by the OPLA.

IT IS SO ORDERED.

3/29/2022
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE