UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

SARAH BERGMAN, KEN BERGMAN, PATRICIA BUDNIK, and ANTHONY BUDNIK,

Plaintiffs,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

Civil No. 20-2693 (JRT/HB)

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANTS' MOTION FOR PARTIAL DISMISSAL

Andrew Feldman and Jacob A. Flint, **FLINT LAW FIRM LLC**, 222 East Park Street, Suite 500, P.O. Box 189, Edwardsville, IL 62034; and David E. Scouton, **THIBODEAU JOHNSON & FERIANCEK PLLP**, 302 West Superior Street, Suite 800, Duluth, MN 55802, for plaintiffs.

Tracy J. Van Steenburgh and Brandie L. Morgenroth, **NILAN JOHNSON LEWIS PA**, 250 Marquette Avenue South, Suite 800, Minneapolis, MN 55401, for defendants.

Plaintiffs brought a products liability action asserting myriad claims against Defendants Johnson & Johnson and Ethicon for injuries allegedly caused by Defendants' pelvic mesh products. Defendants have moved to dismiss, in part, Plaintiffs' First Amended Complaint ("FAC"), arguing that all claims except those premised on failure to warn are either insufficiently pleaded or not cognizable. Because Plaintiffs have failed to include foundational factual allegations and because most of their claims are not

recognized under Minnesota law, the Court will grant Defendants' Motion for Partial Dismissal and dismiss all claims except for Plaintiffs' failure to warn claims and the derivative claim for loss of consortium.

BACKGROUND

I. FACTUAL BACKGROUND

On November 17, 2003, Sarah Bergman had a procedure to implant pelvic mesh products. (FAC ¶ 2, Mar. 19, 2021, Docket No. 18.) She subsequently developed complications arising from the implanted pelvic mesh products, which required implant removal and allegedly led to urinary tract infections, pelvic pressure and pain, dyspareunia, incomplete voiding, urgency, frequency, and nocturia. (*Id*. ¶ 3.)

On May 7, 2008, Patricia Budnik had a procedure to implant a pelvic mesh product. (*Id.* ¶ 6.) She subsequently developed complications arising from the pelvic mesh, which necessitated removal and allegedly led to complications, including pelvic pain, bleeding, urinary tract infections, and dyspareunia. (*Id.* ¶ 7.)

Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson ("J&J"). (*Id.* ¶ 11.) Ethicon is part of J&J's Ethicon Franchise business unit, which was charged with the design, development, marketing, and distribution of pelvic mesh products. (*Id.* ¶ 10.) Surgical mesh has been used to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI") since the 1990s. (*Id.* ¶ 26.) Defendants manufactured three pelvic mesh products—TVT, Gynemesh PS, and Prolift—

for women suffering from POP and SUI. (*Id.* ¶ 28.) Defendants' pelvic mesh products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh or collagen. (*Id.* ¶ 29.) The FDA cleared the first pelvic mesh products for use in treatment of POP in 2002, including Gynemesh PS and Prolift, and Defendants obtained FDA approval of their products at various times thereafter. (*Id.* ¶ 37.) However, the approval process did not require Defendants to prove the safety or efficacy of the products, so a safety review was never conducted. (*Id.* ¶ 37.)

Defendants marketed the pelvic mesh products to the medical community and directly to patients as safe, effective, and minimally invasive, (*id.* ¶ 38), but Plaintiffs allege that, at all relevant times, Defendants were aware of or had actual knowledge that polypropylene mesh is biologically incompatible with human tissue and promotes an immune response that contributes to adverse reactions, (*id.* ¶¶ 31–32.) Plaintiffs allege that Defendants withheld or misrepresented this information to Plaintiffs and withheld known information that collagen causes hyper-inflammatory responses, pain, and a hardening of bodily tissue. (*Id.* ¶¶ 31–34.)

On October 20, 2008, the FDA issued a Public Health Notification describing more than 1000 complaints or adverse events related to TVT, Gynemesh PS, and Prolift products over the course of three years. (*Id.* ¶ 43.) The FDA issued a new warning and publication regarding serious complications on July 31, 2011, stating that complications associated with use of pelvic mesh for POP treatment are not rare and that benefits of

using the products did not outweigh the risks. (*Id.* ¶¶ 45–50.) On April 16, 2019, the FDA ordered all POP device manufacturers to stop selling and distributing POP products. (*Id.* ¶ 57.) Plaintiffs allege that the risks associated with SUI repair are the same as for POP repair even though the data is less developed. (*Id.* ¶ 54.)

Plaintiffs allege that Defendants knew or should have known the pelvic mesh products unreasonably exposed patients to risk of serious harm while conferring no benefit over feasible alternatives, (*id.* ¶ 58), yet suppressed this information and failed to inform the FDA, health care providers, and patients, thus actively misleading the public, (*id.* ¶ 62.) Plaintiffs also allege that Defendants failed to adequately test the products and failed to design a safe procedure for removal of the pelvic mesh products, and that an alternative design and procedures exist. (*Id.* ¶¶ 63–65.)

II. PROCEDURAL HISTORY

Plaintiffs initiated this action on December 30, 2020, (Compl., Dec. 30, 2020, Docket No. 1), and filed the operative First Amended Complaint on March 19, 2021. Plaintiffs justify the joinder of their claims pursuant to Federal Rule of Civil Procedure 20, on grounds that they were injured in the same transaction, occurrence, or series of transactions or occurrences because they were both implanted with the same pelvic mesh products. (*Id.* ¶¶ 16–18.) Plaintiffs also contend that the similarities of their claims and the fact that general discovery has concluded in the related multidistrict litigation outweigh any case-specific differences between Plaintiffs. (*Id.* ¶ 20.)

Plaintiffs assert fourteen claims: negligence (Count I); strict liability – design defect (Count II); strict liability – manufacturing defect (Count III); gross negligence (Count IV); negligent infliction of emotional distress (Count V); strict liability – failure to warn (Count VI); breach of warranty (Count VII); fraudulent concealment (Count VIII); constructive fraud (Count IX); common law fraud (Count X); negligent misrepresentation (Count XI); unjust enrichment (Count XII); loss of consortium (Count XIII); and punitive damages (Count XIV). (*Id.* ¶¶ 83–291.)

On April 16, 2021, Defendants filed a Motion for Partial Dismissal, excluding the failure to warn claim (Count VI) and other claims that are premised on a failure to warn.[1] (Mot. Partial Dismiss, Apr. 16, 2021, Docket No. 22.)

DISCUSSION

I. STANDARD OF REVIEW

In reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court considers all facts alleged in the complaint as true to determine if the complaint states a "claim to relief that is plausible on its face." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to

[1] Earlier, Defendants filed a Motion to Dismiss in regard to the initial complaint. (Mot. Dismiss, Mar. 12, 2021, Docket No. 13.) As this Motion lost effect once Plaintiffs filed the FAC, the Court will deny it as moot.

draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Although the Court accepts the complaint's factual allegations as true and construes the complaint in a light most favorable to the plaintiff, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986). In other words, a complaint "does not need detailed factual allegations" but must include more "than labels and conclusions, and a formulaic recitation of the elements" to meet the plausibility standard. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

II. ANALYSIS

Defendants have moved to dismiss all counts except those claims predicated on a failure to warn theory. Failure to warn allegations are included in Counts I and VI, for negligence and strict liability, respectively. Count VI, for strict liability failure to warn, survives the Motion in full. Count I for negligence survives the Motion only insofar as Plaintiffs have alleged a negligent failure to warn; the other types of negligence encompassed in that claim—design defect and manufacturing defect—will be dismissed. Because Defendants have not moved to dismiss the failure to warn claims, the claim for loss of consortium will also survive the Motion, as it is related to the failure to warn claims. *See Kaplan v. Mayo Clinic*, 947 F. Supp. 2d 1001, 1011 (D. Minn. 2013). The Court will dismiss the remaining claims for failure to state a claim pursuant to Rule 12(b)(6), as explained below.

A. Strict Liability – Design Defect

To prevail on a strict liability design defect claim under Minnesota law, a plaintiff must prove (1) the products were in a defective condition unreasonably dangerous for their intended use; (2) the defect existed when the product left the manufacturer's control; and (3) the defect was the proximate cause of the injury sustained. *Green Plains Otter Tail, LLC v. Pro-Envtl., Inc.*, 953 F. 3d 541, 545–46 (8th Cir. 2020). The parties dispute whether Plaintiffs have sufficiently alleged the third element in regard to both causation and injury.

The FAC lacks basic details about Plaintiffs' alleged injuries, such as when their injuries were discovered, or locations or dates about the revision procedures that Plaintiffs allegedly underwent to address the injuries. Plaintiffs have alleged numerous design defects, but those defect allegations are not accompanied by allegations regarding how any of the defects caused the alleged injuries. As such, the allegations in the FAC are insufficiently sparse because the FAC lacks factual allegations specific to Plaintiffs and their alleged injuries. *Accord Dolan v. Boston Sci. Corp.*, No. 20-1827, 2021 WL 698777, at *2 (D. Minn. Feb. 23, 2021).

Plaintiffs contend that their claims could proceed under a theory of res ipsa loquitor, which permits plaintiffs to prove products liability claims based on circumstantial evidence when it can be inferred that a plaintiff would not have been injured absent a defect in the product. *See Holkestad v. Coca-Cola Bottling Co. of Minn., Inc.*, 180 N.W.2d

860, 865–66 (Minn. 1970). However, the FAC deficiencies are not limited to allegations about the product defects, but rather lack detail even regarding Plaintiffs' injuries—information that Plaintiffs should have access to themselves. The FAC merely rattles off a number of conditions the Plaintiffs developed at unspecified times and of unspecified severity, without any details about the treatment sought or any other facts that support an inference that Plaintiffs were injured because of Defendant's pelvic mesh products. As such, the Court finds that res ipsa loquitor cannot salvage Plaintiffs' design defect claim and will grant Defendants' Motion as to Count II.

B. Strict Liability – Manufacturing Defect

A manufacturing defect claim comprises the same three elements as a design defect claim, but the defect arises from a discrepancy between the design and the actual manufactured product, whereas in design defect cases the product is in the condition intended by the manufacturer but the chosen design is defective. *See, e.g.*, *Bilotta v. Kelley Co., Inc.*, 346 N.W.2d 616, 622 (Minn. 1984). Plaintiffs have not alleged how the products they received deviated from a correctly-manufactured version of Defendants' pelvic mesh products—or even that they deviated at all. Manufacturing defect claims depend on a "manufacturing flaw—some deviation from a flawless product—that renders a product unreasonably dangerous." *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1147 (D. Minn. 2011). Plaintiffs have alleged that the product was unreasonably dangerous, but have not alleged a deviation from a flawless version. Thus, they fail to

state a claim for manufacturing defect, and the Court will grant Defendants' Motion as to Count III.

C. Negligence Claims

As stated at the outset, the failure to warn aspect of Count I for negligence is not subject to Defendants' Motion and will not be dismissed. However, Count I also includes negligence-based design defect and manufacturing defect theories. Under Minnesota law, "the distinction between theories of strict liability and negligence is typically insignificant." *Id.* at 1146. Although strict liability imposes liability without proof of negligence, "in many cases proof of a defect may simply be a substitute word for negligence." *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (1971). Because Plaintiffs have failed to sufficiently allege causation and injury for strict liability design defect, their negligent design defect claim likewise fails to state a claim. Further, their failure to allege a manufacturing flaw for the strict liability manufacturing defect claim is equally fatal to the negligent manufacturing defect claim. The Court will therefore grant Defendants' Motion as to Count I insofar as it is premised on negligent design and manufacturing defect theories.

Plaintiffs have pleaded several other negligence-based claims, none of which are sufficient to state a claim on which relief can be granted. First, Count IV for gross negligence will be dismissed because under Minnesota law, "a claim for gross negligence is not recognized as a distinct cause of action, separate from a cause of action from

ordinary negligence." *See Doub v. Life Time Fitness, Inc.*, No. A17-0322, 2017 WL 4341814, at *4 (Minn. Ct. App. Oct. 2, 2017); *see also Peet v. Roth Hotel Co*., 253 N.W. 546, 548 (Minn. 1934) ("The doctrine that there are three degrees of negligence—slight, ordinary, and gross—does not prevail in this state.").

Second, Plaintiffs' claim for negligent infliction of emotional distress ("NIED") requires proving negligence plus three elements: that a plaintiff "(1) was within the zone of danger of physical impact created by the defendant's negligence; (2) reasonably feared for their own safety; and (3) consequently suffered severe emotional distress with attendant physical manifestations." *Engler v. Illinois Farmers Ins. Co.*, 706 N.W. 2d 764, 767 (Minn. 2005) (cleaned up). Under Minnesota law, the zone of danger test for NIED requires that a plaintiff was clearly in grave personal peril for some defined period of time, a standard which products liability cases such as this one are hard-pressed to satisfy. *See Masepohl v. Am. Tobacco Co.*, 974 F. Supp. 1245, 1252 (D. Minn. 1997). Plaintiffs have not pleaded factual allegations supporting an inference that they were in a zone of danger related to the pelvic mesh products. Additionally, emotional distress must meet a high standard to qualify as severe under the NIED elements. *See, e.g.*, *Hubbard v. United Press Int'l Inc.*, 330 N.W.2d 428, 440 (Minn. 1983). Plaintiffs' allegations about their emotional distress lack specificity and are conclusory and merely consistent with liability for NIED. The Court therefore finds that Plaintiffs have failed to state a claim for NIED and will grant Defendants' Motion as to Count V.

Third, Plaintiffs have alleged liability for negligent misrepresentation. Negligent misrepresentation claims are subject to the pleading standard of Rule 9(b), which requires a plaintiff to plead "such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). The FAC is devoid of nearly any specifics about the "who, what, where, why, and how" of the alleged misrepresentation and it therefore falls short of the heightened pleading requirements under Rule 9(b). *See id.*; *see also BJC Health Sys. v. Columbia Cas. Co.*, 478 F.3d 908, 917 (8th Cir. 2007) ("Conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule."). Moreover, Minnesota courts have not recognized negligent misrepresentation as a viable theory of recovery for physical harm, instead suggesting that negligent misrepresentation is limited to commercial or business transactions resulting in pecuniary damages. *See Forslund*, 2010 WL 3905854, at *6. As such, the Court finds that Plaintiffs have not stated a claim for negligent misrepresentation under Minnesota law and will therefore grant Defendants' Motion as to Count XI.

D. Fraud

Plaintiffs assert three other fraud-based claims—fraudulent concealment (Count VIII), constructive fraud (Count IX), common law fraud (Count X)—all of which also must

be pleaded with particularity. *See Tuttle v. Lorillard Tobacco Co.*, 118 F. Supp. 2d 954, 963 (D. Minn. 2000) (stating that heightened pleading requirements under Rule 9(b) apply when the gravamen of the complaint is fraud). However, in some cases, the standard might be relaxed: "[w]hen the facts constituting the fraud are peculiarly within the opposing party's knowledge . . . such allegations may be pleaded on information and belief. Claims pleaded on information and belief are sufficient under Rule 9(b) if they are accompanied by a statement of the facts on which the belief is based." *Select Comfort Corp. V. Sleep Better Store, LLC*, 796 F. Supp. 2d 981, 985 (D. Minn. June 17, 2011) (quotation and citations omitted).

Plaintiffs assert that a relaxed standard should be applied in this case because information about the alleged fraud was within Defendants' exclusive control, it occurred over an extended period of time, and it consisted of numerous acts. Yet, Plaintiffs admit that they "have substantial prediscovery evidence—much of which was obtained from the discovery already concluded in the underlying [multidistrict litigation]." (Mem. Opp. Mot. Partial Dismissal at 13, Apr. 28, 2021, Docket No.26.) Even if there are some details about the nature of the fraud that Plaintiffs should not be expected to know at this point, the FAC lacks specifics about the "who, what, where, why, and how" of the Defendants' alleged fraud as it relates to the Plaintiffs injuries, despite Plaintiffs admittedly being privy to pre-discovery evidence, and Plaintiffs' allegations that the misrepresentations were made to them, their physicians, and the public at large. Thus, it cannot plausibly be said

that the facts are "peculiarly within the opposing party's knowledge," and Plaintiffs have not sufficiently pleaded their fraud claims in light of the circumstances. The Court will therefore grant Defendants' Motion as to Counts VIII–X.

E. Breach of Warranty

Plaintiffs represent that their warranty claim is based on breach of both express and implied warranties. Under Minnesota law, however, claims for breach of implied warranty are preempted by strict liability claims where personal injuries are at issue. *Masepohl*, 974 F. Supp. at 1253. The Court therefore only decides whether Plaintiffs have adequately pleaded their claim for breach of express warranty.

To establish such a claim, "the plaintiff ordinarily must establish that the seller made an express, affirmative promise about the qualities of the product." *Leedahl v. Rayco Mfg., Inc.*, No. 06-310, 2006 WL 1662959, at *4 (D. Minn. May 15, 2006) (citations omitted). Additionally, Minnesota statute provides that a breach of warranty claim must be brought within four years of when the action has accrued. Minn. Stat. § 336.2-725(1). "A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." *Id.* § 336.2-725(2).

Plaintiffs had the pelvic mesh implanted more than four years before initiation of this action: Bergman underwent her procedure in 2003 and Budnik in 2008, and the action

is deemed initiated as of February 23, 2017.[2] Plaintiffs argue that Defendants warranted future performance such that the statute of limitations should be tolled. However, Plaintiffs have not alleged any specifics about Defendants' express warranties such as the format, timing, or language used. Without more specific allegations of what Defendants warranted to Plaintiffs, the Court cannot toll the statute of limitations or conclude that Plaintiffs have pleaded factual allegations above a conclusory level. The Court therefore finds that Plaintiffs have failed to state a claim for breach of express warranty and will grant Defendants' Motion as to Count VII.

F. Unjust Enrichment

Plaintiffs assert a claim of unjust enrichment in the alternative to legal remedies sought. In Minnesota, courts allow simultaneous pleading of legal claims and unjust enrichment claims under Rule 8(d), *see, e.g.*, *Daigle v. Ford Motor Co.*, 713 F. Supp. 2d 822, 828 (D. Minn. 2010), but unjust enrichment is limited to claims premised on "an implied or quasi-contract in which the defendant received a benefit of value that unjustly enriched the defendant in a manner that is illegal or unlawful," *Caldas v. Affordable Granite & Stone, Inc.*, 820 N.W.2d 826, 838 (Minn. 2012). Plaintiffs have not pleaded

[2] The action was initiated on December 30, 2020, but Defendants state that "pursuant to a private agreement between the parties, their suit is deemed filed as of February 23, 2017." (Mem. Supp. Mot. Partial Dismiss at 12, Apr. 16, 2021, Docket No. 23.)

allegations that sound in quasi-contract, but only in tort. As such, the Court will deny the claim for unjust enrichment and will grant Defendants' Motion as to Count XII.

G. Punitive Damages

Minnesota law provides that punitive damages are available "upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others." Minn. Stat. § 549.20, subd. 1(a). Punitive damages are a derivative claim like loss of consortium, *see Hern v. Bankers Life Cas. Co.*, 133 F. Supp. 2d 1130, 1139 (D. Minn. 2001), but Defendants seek dismissal of the punitive damages claim in full because Plaintiffs have violated the procedural requirements to seek punitive damages under Minnesota law.

Minnesota Statutes § 549.191 provides that a complaint must not seek punitive damages; instead, a party must later move to amend the pleadings to claim punitive damages, which a court shall grant if it finds prima facie evidence in support of the motion. Minn. Stat. § 549.191. The relationship between § 549.191 and Federal Rule of Civil Procedure 15, which provides that a court should freely give leave to amend when proposed claims are plausible, has recently evolved in the District of Minnesota, specifically as to whether § 549.191's prima facie standard or Rule 15's plausibility standard applies. *See, e.g.*, *Shank v. Carleton Coll.*, 329 F.R.D. 610, 612 (D. Minn. 2019). As there is no motion to amend or proposed amended complaint at issue in the present matter, the issue of which standard the Court would apply to determine whether a

plaintiff may seek punitive damages is irrelevant. Plaintiffs have never filed a motion to amend; they have improperly included punitive damages from the outset. *See Clancy v. Vacationaire Ests., Inc.*, No. 18-2249, 2019 WL 955113, at *11 (D. Minn. Feb. 27, 2019). The Court therefore grants Defendants' Motion with respect to punitive damages at this time. Should Plaintiffs later file a motion for leave to amend to add a punitive damages claim, the Court will examine the sufficiency of the allegations and support for punitive damages then.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Dismiss [Docket No. 13] is **DENIED as moot**;
2. Defendants' Motion for Partial Dismissal [Docket No. 22] is **GRANTED, in part, as follows**:
    a. Count I Negligence is **DISMISSED without prejudice** with respect to design defect and manufacturing defect, but **NOT DISMISSED** with respect to failure to warn;
    b. Count II Strict Liability – Design Defect is **DISMISSED without prejudice**;
    c. Count III Strict Liability – Manufacturing Defect is **DISMISSED without prejudice**;
    d. Count IV Gross Negligence is **DISMISSED without prejudice**;

e. Count V Negligent Infliction of Emotional Distress is **DISMISSED without prejudice**;

f. Count VI Strict Liability – Failure to Warn is **NOT DISMISSED**;

g. Count VII Breach of Warranty is **DISMISSED without prejudice**;

h. Count VIII Fraudulent Concealment is **DISMISSED without prejudice**;

i. Count IX Constructive Fraud is **DISMISSED without prejudice**;

j. Count X Common Law Fraud is **DISMISSED without prejudice**;

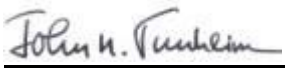
k. Count XI Negligent Misrepresentation is **DISMISSED without prejudice**;

l. Count XII Unjust Enrichment is **DISMISSED without prejudice**;

m. Count XIII Loss of Consortium is **NOT DISMISSED**; and

n. Count XIV Punitive Damages is **DISMISSED without prejudice**.

DATED: August 13, 2021
at Minneapolis, Minnesota.



JOHN R. TUNHEIM
Chief Judge
United States District Court