

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

CHARLESTON DIVISION

IN RE: COLOPLAST CORP.
PELVIC SUPPORT SYSTEMS
PRODUCTS LIABILITY LITIGATION

MDL NO. 2387

THIS DOCUMENT RELATES TO:

Alechia and Billy Richardson v. Coloplast Corp.

Civil Action No. 2:16-cv-1391

MEMORANDUM OPINION & ORDER

Pending before the court is Coloplast Corp.'s Motion to Dismiss on the Pleadings [ECF No. 11]. The plaintiffs responded [ECF No. 16] and Coloplast Corp. replied [ECF No. 17] making the Motion ripe for adjudication. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 500 of which are in the Coloplast Corp. ("Coloplast") MDL, MDL 2387.

On December 13, 2010, Ms. Richardson was surgically implanted with Coloplast's Suspend-Tutoplast Processed Fascia Lata ("Fascia Lata"), a device manufactured by Coloplast to treat SUI and to reconstruct the pelvic floor. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 3]. Ms. Richardson's surgery occurred at White River

Medical Center in Batesville, Arkansas. *Id.* ¶ 11. Ms. Richardson claims that as a result of implantation of the Fascia Lata, she has experienced multiple complications. She adopts the following counts as alleged in the First Amended Master Long Form Complaint and Jury Demand (“Master Complaint”): I – negligence, II – strict liability design defect, III – strict liability manufacturing defect, IV – strict liability failure to warn, V – strict liability defective product, VI – breach of express warranty, VII – breach of implied warranty, VIII –fraudulent concealment, IX – constructive fraud, X – discovery rule and tolling, XI –negligent misrepresentation, XII – negligent infliction of emotional distress, XIII – violation of consumer protection laws, XIV – gross negligence, XV – unjust enrichment, XVI – loss of consortium, and XVII – punitive damages. *Id.* ¶ 13.

According to the Master Complaint, Coloplast “designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products,” one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23 [ECF No. 49, MDL 2387]. Coloplast admits in its Joint Master Long Form Answer and Affirmative Defenses to Plaintiffs’ First Amended Master Long Form Complaint and Jury Demand (“Master Answer”) that it “generally packaged, labeled, marketed, sold[,] and distributed” such pelvic mesh devices. Master Answer ¶ 22 [ECF No. 62, MDL 2387]. The Fascia Lata device is “dehydrated, . . . processed fascia lata from donated human tissue.” *See* Def.’s Mot. Dismiss on the Pleadings Ex. B, at 1 [ECF No. 11-2] (“Package Insert”). The Fascia Lata is preserved such that it

“retains the three-dimensional collagen structure responsible for the unidirectional, mechanical properties of the original fascia lata tissue.” *Id.*

II. Legal Standard

“[T]he Rule 12(c) judgment on the pleadings procedure primarily is addressed to . . . dispos[e] of cases on the basis of the underlying substantive merits of the parties’ claims and defenses as they are revealed in the formal pleadings.” 5C Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1367 (3d ed. 2004). A motion under 12(c) is useful when only questions of law remain. *Id.*

[A] Rule 12(c) motion is designed to provide a means of disposing of cases when the material facts are not in dispute . . . and a judgment on the merits can be achieved by focusing on the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense

Id. Rule 12(h)(2) provides that the defense of failure to state a claim upon which relief can be granted may be raised in a motion for judgment on the pleadings. Fed. R. Civ. P. 12(h)(2). If this is asserted in a Rule 12(c) motion, the district court will apply the same standards for granting the appropriate relief or denying the motion as it would have employed had the motion been brought prior to the defendant’s answer under 12(b)(6). Wright & Miller, *supra*, § 1367; see *Exec. Risk Indem., Inc. v. Charleston Area Med. Ctr., Inc.*, 681 F. Supp. 2d 694, 706 n.17 (S.D. W. Va. 2009) (“[T]he standards under Federal Rule of Civil Procedure 12(c) for a motion for judgment on the pleadings are identical to those applicable to a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss.”).

A motion to dismiss filed under Rule 12(b)(6) tests the legal sufficiency of a complaint or pleading. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A pleading must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). This standard “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570). To achieve facial plausibility, the plaintiffs must plead facts allowing the court to draw the reasonable inference that the defendant is liable, moving the claim beyond the realm of mere possibility. *Id.* Mere “labels and conclusions” or “formulaic recitation[s] of the elements of a cause of action” are insufficient. *Twombly*, 550 U.S. at 555.

III. Discussion

The plaintiffs assert that Coloplast’s Rule 12(c) Motion to Dismiss on the Pleadings is truly a Rule 56 Summary Judgment Motion because Coloplast has attached exhibits for the court’s consideration. However, when deciding a 12(c) motion, the court may consider “the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense.” Wright & Miller, *supra*, § 1367. Of Coloplast’s attached documents and the plaintiffs’ referenced evidence in their

Response, the court will only consider the package insert marked as Exhibit B to Coloplast's Motion because it is integral to the claim for relief and defense. *See* Package Insert. The package insert offers a product description and a warranty statement which are pertinent to the claims at hand—specifically the breach of warranty claims. *See id.* at 1; Am. Short Form Compl. ¶ 13. The evidence the plaintiffs put forward in their Response, the content from Coloplast's website, is not part of the content of the pleadings, an exhibit thereto, incorporated by reference in the pleadings, or central or integral to the claims. Therefore, it will not be considered. Further, Coloplast attached the Short Form Complaint as Exhibit A and the Amended Short Form Complaint as Exhibit C to its Motion. *See* Def.'s Mot. Dismiss on the Pleadings Ex. A [ECF No. 11-1]; Def.'s Mot. Dismiss on the Pleadings Ex. C [ECF No. 11-3]. This *is* a pleading and must be considered by the court, and accordingly has no transformative power. Thus, Coloplast's Motion is not a Rule 56 Summary Judgment Motion.

Next, this court applies the substantive tort law of the state where the plaintiff's implantation occurred—in this case, Arkansas. *In re: Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-760, 2016 WL 3067752, at *2 (S.D. W. Va. May 31, 2016); Am. Short Form Compl. ¶ 11. The claims are addressed below.

a. Strict Liability and Breach of Warranty (Counts II–VII)

Coloplast argues that it is immune from the plaintiffs' strict liability and warranty claims alleged in Counts II-VII by virtue of Arkansas's Public Health and Welfare Act which states:

No physician, surgeon, hospital, blood bank, tissue bank, or other person or entity who donates, obtains, prepares, transplants, injects, transfuses, or otherwise transfers or who assists or participates in obtaining, preparing, transplanting, injecting, transfusing, or transferring any tissue, organ, blood, or component thereof from one (1) or more human beings, living or dead, to another human being, shall be liable as the result of the activity, except that each such person or entity shall remain liable for negligence or willful misconduct only.

Ark. Code Ann. § 20-9-802. Arkansas’s statute specifically states that entities that participate in transferring human tissue from cadavers to another human are immune from liability beyond negligence and willful misconduct. *Id.* The language of § 20-9-802 is sufficiently broad to cover Coloplast’s actions alleged in Counts II–VII. Coloplast distributes an allograft, the Fascia Lata. Master Compl. at ¶ 22. Per its labeling, the allograft is “dehydrated, Tutoplast processed Fascia lata from donated human tissue.” Package Insert 1. By the plain words of the statute, Coloplast is immune from the plaintiffs’ strict liability claims and breach of warranties claims as alleged in Counts II–VII.

Even so, the Eighth Circuit in *Kirkendall v. Harbor Insurance Company* and the Restatement (Third) of Torts lead the court to the same conclusion—that the plaintiffs’ strict liability and breach of warranty claims must fail. *See* 887 F.2d 857 (8th Cir. 1989); Restatement (Third) of Torts § 19(c) (Am. Law Inst. 1998). In *Kirkendall* the Eight Circuit found that under § 20-9-802 “the supplying of blood . . . is a service rather than a product” so “[t]he implied warranties of the Uniform Commercial Code therefore do not apply to blood, and blood is not a ‘product’ for

purposes of imposing strict liability in tort.”¹ 887 F.2d at 859. Although the facts of *Kirkendall* only involved blood, the court sees no reason why human tissue is not subject to the same standard. *See id.* The Restatement of Torts gives even more credence to this position—that supplying human tissue is a “service” and thus not subject to products liability claims.² The Restatement (Third) of Torts elaborates on products liability law in the context of human tissue and states: “Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement.” Restatement (Third) of Torts § 19(c) (Am. Law Inst. 1998). This update clarifies that human tissue, such as the allograft in this case, is not a “product” and is consistent with the nationwide policy against applying products liability to the distribution of human tissue. *See id.* at § 19(a)–(c), cmt. c.

Additionally, on the topic of breach of warranties claims, the Fifth Circuit has elaborated:

It is axiomatic, of course, that breach of express warranty is not available as a cause of action without a sale, because the essence of warranty is a consensual agreement—express or implied—arising from contract. Without a sale under contract, there is no consensual nexus between the parties and thus no warranties may attach.

Heirs of Fruge v. Blood Servs., 506 F.2d 841, 846 (5th Cir. 1975) (citation omitted) (interpreting a statute defining tissue as a medical service and expressly exempting

¹ Even though § 20-9-802 does not specifically delineate supplying of blood to be a “service,” the Eighth Circuit construed the statute to be in accordance with the majority of jurisdictions in this regard. *See, e.g., Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226 (D. Utah 2002); *Palermo v. Lifelink Found., Inc.*, 152 So.3d 1177 (Miss. App. 2014); *Cryolife, Inc v. Super. Ct.*, 2 Cal. Rptr. 3d 396 (Cal. Ct. App. 2003).

² The term “products liability” is used in reference to both strict liability and breach of warranty claims. *See* 63 Am. Jur. 2d *Products Liability* § 625 (2010) (“An action for products liability may be brought under several theories, including . . . strict liability, and warranty.”).

contracts for the sale of human tissue from breach of warranty claims); *see also* *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226, 1227 & n.1 (D. Utah 2002) (recognizing that the analysis for breach of warranties claims is the same as strict liability); *McKee v. Miles Labs., Inc.*, 675 F. Supp. 1060, 1063 (E.D. Ky. 1987) (holding that distribution of human tissue is a service and thus outside of the purview of Kentucky’s applicable breach of warranty statute).

Finally, where the statutory language varies modestly between jurisdictions, the public policy behind blood and human tissue shield statutes remains the same as to strict liability claims. On this matter, the California Court of Appeal stated:

[L]egislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.

Cryolife, Inc. v. Super. Ct., 2 Cal. Rptr. 3d 396, 405 (Cal. Ct. App. 2003) (emphasis omitted) (quoting *Hyland Therapeutics, Inc. v. Super. Ct.*, 220 Cal. Rptr. 590, 594 (Cal. Ct. App. 1985)). Moreover, there is “a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue.” *Palermo v. Lifelink Found., Inc.*, 152 So. 3d 1177, 1181 (Miss. Ct. App. 2014). Indeed, “no court has ever applied strict liability to the distribution of human tissue.” *Condos*, 208 F. Supp. 2d at 1229; *see Palermo*, 152 So. 3d at 1181.

According to the Master Complaint, Coloplast “designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products,” one of which was an allograft, the Fascia Lata. First Am. Master

Compl. ¶¶ 22–23. Coloplast admits in its Master Answer that it “generally packaged, labeled, marketed, sold[,] and distributed” such pelvic mesh devices. Master Answer ¶ 22. Thus, it is not in dispute that Coloplast distributed the Fascia Lata allograft. Per its labeling, the allograft is “dehydrated, Tutoplast processed Fascia [L]ata from donated human tissue.” Package Insert 1. The plaintiffs do not dispute this fact either. Because there is no dispute as to whether Coloplast distributed processed human tissue, the Fascia Lata, no discovery is needed to determine whether the statute applies, as the plaintiffs suggest.³ Coloplast’s actions are plainly covered by the statute and must be considered a “service.” Public policy, precedent, and the plain language of the statute all dictate that the plaintiffs’ strict liability and breach of warranty claims must fail.

The plaintiffs further argue that discovery is needed to identify other conduct that may allow a claim for strict liability to go forward. It is well-settled law, however, that the scope of discovery may not exceed the boundaries of the complaint. *See Cuomo v. Clearing House Ass’n, LLC*, 557 U.S. 519, 531 (2009) (“Judges are trusted to prevent ‘fishing expeditions’ or an undirected rummaging through . . . records for evidence of some unknown wrongdoing.”).

³ The court acknowledges that Coloplast’s status as a commercial distributor does not change the applicability of the statute. Human tissue and blood shield statutes have been interpreted to apply to for-profit entities. *See, e.g., Coffee v. Cutter Biological*, 809 F.2d 191, 193 (2d Cir. 1987) (interpreting Connecticut’s human tissue and blood shield statute’s use of “blood bank” to include commercial manufacturers and distributors); *Cryolife*, 2 Cal. Rptr. 3d at 404 (“When the Legislature enacted section 1635.2 in 1991 as part of a regulatory scheme for tissue banks, it had to know that tissue banks are paid for their activities in connection with providing human cadaver tissue for medical use. By expressly deeming such activities to constitute a service, the Legislature must have intended a tissue bank to be immune from strict liability, just like a pharmacy.”).

Therefore, Counts II–VII of the plaintiffs’ Amended Short Form Complaint, which correspond with Counts II–VII in the Master Complaint, are **DISMISSED with prejudice**.

b. Remaining Claims (Counts I, VIII–XVII)

Coloplast argues that instead of the ordinary three-year statute of limitations for negligence claims, Arkansas’s medical malpractice two-year statute of limitations period applies because Coloplast rendered a medical service. *See* Ark. Code Ann. §§ 16-114-201, 203; *Bryan v. City of Cotter*, 344 S.W.3d 654, 656 (Ark. 2009) (“The statute of limitations period for an action based on negligence is three years.”); Def.’s Mem. Supp. Mot. Dismiss on the Pleadings 19 [ECF No. 12]. The discovery rule does not apply to Arkansas’s statute of limitations for medical malpractice actions and as a result, the plaintiffs’ claims would be time barred should this period apply. *See Humphreys v. Roche Biomed. Labs., Inc.*, 990 F.2d 1078, 1080–81 (8th Cir. 1993) (citing *Treat v. Kreutzer*, 720 S.W.2d 716 (Ark. 1986)) (applying Arkansas law). The court rejects this argument.

Arkansas’s two-year limitation period only applies to “action[s] for medical injury.” Ark. Code Ann. § 16-114-202. An “[a]ction for medical injury” is defined as “all actions against a medical care provider” *Id.* at § 16-114-201. A “[m]edical care provider” is defined as

a physician, certified registered nurse anesthetist, physician’s assistant, nurse, optometrist, chiropractor, physical therapist, dentist, podiatrist, pharmacist, veterinarian, hospital, nursing home, community mental health center, psychologist, clinic, or not-for-profit home healthcare agency licensed by the state or otherwise lawfully providing professional medical care or services, or an officer, employee or agent thereof acting

in the course and scope of employment in the providing of such medical care or medical services

§ 16-114-201. Although Coloplast does render a medical service, as explained above, tissue distributors are not included among the enumerated medical care providers in § 16-114-201. It is well-settled law that where a list of items is designated, “courts should infer that all omissions were intentional exclusions.” 2A Norman J. Singer & J.D. Shambie Singer, *Statutes and Statutory Construction* § 47:23, at 410–13 (7th ed. Supp. 2014); *see also Watkins v. Wassell*, 20 Ark. 410, 420 (1859) (“[T]he expression of one thing is sometimes the exclusion of another, and when the Legislature has enumerated a variety of cases . . . , it may be safely assumed that it was not intended to [include] cases not enumerated.”). Because tissue distributors are not included and Coloplast is not an “agent” of any of the enumerated medical care providers, the two-year medical malpractice statute of limitations does not apply. Thus, the plaintiffs’ remaining claims are not subject to the medical malpractice two-year period and instead are subject to the ordinary three-year period.

Whether or not the plaintiffs filed their Short Form Complaint within the three-year period turns on whether Arkansas allows delayed accrual in this circumstance and if so, when Ms. Richardson discovered her injury. Without delayed accrual, the plaintiffs’ claims would be plainly barred as they did not file their Short Form Complaint until five years after the date of implantation. The discovery rule has not been formally adopted in Arkansas for ordinary negligence actions subject to the three-year period. *See Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 924 (8th Cir. 1970). However, courts have allowed for delayed accrual in certain cases. *See id.*

(accumulating Arkansas cases on the matter); *see also Midwest Mut. Ins. Co. v. Ark. Nat'l Co.*, 538 S.W.2d 574, 577–78 (Ark. 1976) (allowing a delayed accrual date to account for delayed damages). The Eighth Circuit has stated: “As we construe the Arkansas cases, in the instances where there has been delay between the negligent act and the damage, the occurrence of harm marks the beginning of the period.” *Schenebeck*, 423 F.2d at 924. At this time, discovery is still needed to discern whether delayed accrual is warranted in this case and consequently, whether the plaintiffs’ claims are barred. Thus, the court will not dismiss on these grounds at this time.

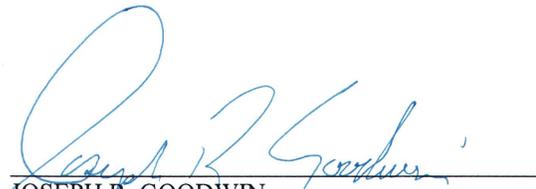
Given the plaintiffs’ Steering Committee’s impending motion to amend the Master Complaint contemplated in the plaintiffs’ Response, the nature of a short form complaint, and for reasons appearing to the court, the Motion is **DENIED** at this time as to all other claims (Counts I, VIII–XVII).

IV. Conclusion

For the reasons stated above, it is **ORDERED** that Coloplast’s Motion to Dismiss on the Pleadings [ECF No. 11] is **GRANTED in part** and **DENIED in part**. The Motion is **GRANTED** with respect to Counts II–VII and is otherwise **DENIED** at this time. Counts II–VII are **DISMISSED with prejudice**.

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

ENTER: November 22, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE