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:

Deborah Wright v. Coloplast Corp. — Civil Action No. 2:16-cv-01562

MEMORANDUM OPINION & ORDER

Pending before the court is Coloplast Corp.'s Motion to Dismiss on the Pleadings [ECF No. 14]. The plaintiff responded [ECF No. 18] and Coloplast Corp. replied [ECF No. 19] 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 August 22, 2011, Ms. Wright 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. Short Form Compl. ¶¶ 9–10 [ECF No. 1]. Ms. Wright's surgery occurred at St. Joseph Hospital East in

Lexington, Kentucky. *Id.* ¶ 11. Ms. Wright 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, 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." Def.'s Mot. Dismiss on the Pleadings Ex. B, at 1 [ECF No. 14-2] ("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 plaintiff asserts 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 plaintiff's referenced evidence in her 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; Short Form Compl. ¶ 13. The evidence the plaintiff puts forward in her 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 to its Motion. *See* Def.'s Mot. Dismiss on the Pleadings Ex. A [ECF No. 14-1]. 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, Kentucky. *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); 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 plaintiff's strict liability and warranty claims alleged in Counts II-VII by virtue of Kentucky's blood and human tissue shield statute which states:

> The procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissues such as corneas, bones or organs for the purpose of injecting, transfusing or transplanting any of them into the human body is declared to be, for all purposes, the rendition of a service by every person participating therein and, whether or not any remuneration is paid therefor, is declared not to be a sale of such whole blood, plasma, blood products, blood derivatives or other tissues, for any purpose, subsequent to enactment of this section.

Ky. Rev. Stat. Ann. § 139.125. Where a statute such as this one clearly defines the distribution of "other human tissues" to be a service, there can be no sale of a product subject to products liability actions.[1] *See Revenue Cabinet v. Plasma All., Inc.*, 794 S.W.2d 639, 640 (Ky. Ct. App. 1990) ("The plain language of [§ 139.125] (enacted to shield entities such as appellee from products liability claims) indicates to us that plasmapheresis and the distribution of source plasma is a service, *not* a sale."). Additionally, case law applying § 139.125 mandates the same conclusion. *See, e.g.*, *McKee v. Cutter Labs., Inc.*, 866 F.2d 219, 222 (6th Cir. 1989) ("We hold that KRS 139.125, which defines a blood product transaction as the rendition of a service, bars plaintiff's strict liability claims."); *McKee v. Miles Labs., Inc.*, 675 F. Supp. 1060, 1063 (E.D. Ky. 1987) ("[T]his Court concludes that Kentucky's blood shield statute was intended to preclude the assertion of product liability claims arising out [sic] the sale of blood components. The plain and unambiguous words of the statute clearly state that supplying blood or blood derivatives is to be considered a service by every person participating therein.").

It follows that the plaintiff's warranty claims also fail for this reason. As the Fifth Circuit has explained:

> 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.

[1] 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.").

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 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); *Miles*, 675 F. Supp. at 1063 (holding that distribution of human tissue is a service and thus outside of the purview of Kentucky's applicable breach of warranty statute).

The Restatement of Torts gives even more credence to the idea that human tissue is not a "product" and thus not subject to products liability claims. 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 strict liability to the distribution of human tissue. *See id.* at § 19(a)–(c), cmt. c.

Where the statutory language varies modestly between jurisdictions, the public policy behind blood and human tissue shield statutes remains the same. 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 plaintiff does 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 plaintiff suggests.[2] Coloplast's actions are plainly covered by

[2] 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).

the statute and must be considered a "service." Public policy, precedent, and the plain language of the statute all dictate that the plaintiff's strict liability and breach of warranty claims must fail.

The plaintiff further argues 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.").

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

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

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–XV, XVII).

IV. Conclusion

For the reasons stated above, it is **ORDERED** that Coloplast's Motion for Judgment on the Pleadings [ECF No. 14] 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