UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DEBRA RICHMOND-PROHASKA, Plaintiff, v. ETHICON, INC., Defendant.	CASE NO. C23-0210JLR ORDER

I. INTRODUCTION

Before the court is Defendant Ethicon, Inc.'s ("Ethicon") motion to dismiss Plaintiff Debra Richmond-Prohaska's second amended complaint. (Mot. (Dkt. # 20); Reply (Dkt. # 23); *see* 2d Am. Compl. (Dkt. # 17).) Ms. Richmond-Prohaska opposes Ethicon's motion to dismiss. (Resp. (Dkt. # 22).) The court has considered the motion, the parties' submissions, the relevant portions of the record, and the governing law.

//

//

Being fully advised,[1] the court GRANTS in part and DENIES in part Ethicon's motion to dismiss.

II. BACKGROUND

On May 4, 2010, Ms. Richmond-Prohaska "underwent a transvaginal tape sling with cystoscopy, anterior repair, and posterior repair with Elevate Apical and Posterior System with IntePro Lite mesh." (2d Am. Compl. ¶ 2.) During this procedure, which took place "relative to her pre-operative diagnosis for stress incontinent [sic] and vaginal prolapse," Ms. Richmond-Prohaska was implanted with Ethicon's "Gynecare TVT transvaginal mesh, product number 810041B, Lot. No. 3389734."[2] (*Id.* ¶¶ 3-4.) On the same date, another mesh was also implanted that was manufactured by a non-party to this case. (*Id.* ¶ 5.) By May 2020, Ms. Richmond-Prohaska was experiencing discomfort and "underwent a pelvic examination that revealed a less than 1cm [sic] ring of vaginal sling mesh extrusion from the pelvic region." (*Id.* ¶ 6.) On May 27, 2020, Ms. Richmond-Prohaska underwent revision surgery, "which involved revision of the mesh and cystoscopy; and trimmed the extrusion." (*Id.* ¶ 7.) She alleges that "as a direct and proximate cause of having [Ethicon's] Gynemesh implanted, [she has] suffered extensive

[1] Neither party has requested oral argument (*see* Mot. at 1; Resp. at 1) and the court finds that oral argument would not be helpful to its resolution of the motion, *see* Local Rules W.D. Wash. LCR 7(b)(4).

[2] The parties refer to this product as "Gynecare TVT," "TVT," "Gynemesh," and "the Pelvic Mesh Product." (*See, e.g.*, 2d Am. Compl. ¶ 11 (stating that it refers to Gynecare TVT as the "Pelvic Mesh Product"); *id.* ¶ 102 (referring to "Defendant's Pelvic Mesh Product, Gynemesh"); *see generally* Mot. (referring to Ethicon's product as "TVT").) For consistency, the court refers to the product as "Gynecare TVT" except when quoting Ms. Richmond-Prohaska's second amended complaint.

physical injury and has accrued economic loss, including but not limited to obligations for medical care." (*Id.* ¶ 8.) Specifically, Ms. Richmond-Prohaska alleges that she has experienced "dyspareunia, extrusion, inability to engage in sexual relations, and pain or general discomfort" after being implanted with Gynecare TVT. (*Id.* ¶¶ 55-56.)

Ms. Richmond-Prohaska alleges that Ethicon knew that there were multiple defects in the design and manufacture of Gynecare TVT—for example, that its product contains harmful materials—and knew that these defects led to injuries in many women in whom the mesh was implanted. (*See generally id.* ¶¶ 17-100.) Nevertheless, according to Ms. Richmond-Prohaska, Ethicon aggressively marketed Gynecare TVT and insisted that it was safe and effective for treatment of incontinence and prolapse. (*Id.*) Ms. Richmond-Prohaska further alleges that Ethicon misrepresented the safety of Gynecare TVT and failed to provide adequate warnings of its defects, risks, and dangers. (*Id.*)

Ms. Richmond-Prohaska filed the instant action on February 16, 2023. (Compl. (Dkt. # 1).) She amended her complaint on April 18, 2023. (Am. Compl. (Dkt. # 7).) On June 15, 2023, Ethicon and former Defendant Ethicon, LLC (together, "Defendants") moved to dismiss the amended complaint. (1st MTD (Dkt. # 13).) On June 29, 2023, the parties stipulated to strike Defendants' first motion to dismiss; to dismiss Ethicon, LLC from this action; and to allow Ms. Richmond-Prohaska to file a second amended complaint. (*See* Dkt. ## 15-16 (stipulated motions); Dkt. ## 18-19 (orders granting stipulated motions).)

Ms. Richmond-Prohaska filed her second amended complaint on June 29, 2023. (2d Am. Compl.) She alleges design defect, manufacturing defect, and failure to warn claims under Washington's Product Liability Act ("WPLA"), ch. 7.72 RCW. (*Id.* ¶¶ 101-37.) Ethicon filed this motion to dismiss Ms. Richmond-Prohaska's second amended complaint on July 19, 2023. (Mot.)

III. ANALYSIS

The court sets forth the standard of review before turning to Ethicon's motion to dismiss.

A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal when a complaint "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Under this standard, the court construes the allegations in the light most favorable to the nonmoving party, *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005), and asks whether the claim contains "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, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court need not accept as true legal conclusions, "formulaic recitation[s] of the legal elements of a cause of action," *Chavez v. United States*, 683 F.3d 1102, 1008 (9th Cir. 2012), or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences," *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). "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." *Iqbal*, 556 U.S. at 678.

B. Motion to Dismiss

The WPLA is the exclusive remedy for product liability claims in Washington and "creates a single cause of action for product-related harm with specified statutory requirements for proof." *Kirkland v. Emhart Glass S.A.*, 805 F. Supp. 2d 1072, 1076 (W.D. Wash. 2011) (first citing *Washington Water Power Co. v. Graybar Elec. Co.*, 774 P.2d 1199, 1203 (Wash. 1989); and then citing *Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 858 P.2d 1054, 1066 (Wash. 1993)). The WPLA distinguishes between and imposes different standards of liability on product manufacturers and product sellers for harm caused by defective products. *See* RCW 7.72.030-.040. Under the WPLA, a manufacturer is subject to liability "if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1). A manufacturer is also subject to liability "if the claimant's harm was proximately caused by the fact that the product . . . deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line." RCW 7.72.030(2)(a).

Ethicon argues that the court must dismiss (1) all of Ms. Richmond-Prohaska's WPLA claims because she has not plausibly alleged the causation element of those claims and (2) Ms. Richmond-Prohaska's manufacturing defect claim because she has not

alleged that the Gynecare TVT that caused her injuries deviated in some way from its design specification. (Mot. at 4-7.) The court considers each argument in turn.

1. Causation

Ethicon moves the court to dismiss all three of Ms. Richmond-Prohaska's claims because she "has not alleged with any detail how [Ethicon's] conduct caused her nondescript injuries." (Mot. at 4.) Specifically, according to Ethicon, Ms. Richmond-Prohaska "does not even specify what injuries she claims to be attributable to her [Gynecare] TVT (as opposed to the other mesh device), much less link her injuries with any 'defect' in the product or its warnings." (*Id.*; *see also id.* at 4-5 ("And although she alleges she underwent a 'revision of the mesh,' she does not even specify ***which of her two mesh devices***." (quoting 2d Am. Compl. ¶ 7) (emphasis in original)); Reply at 2 (arguing that Ms. Richmond-Prohaska "merely alleges that [she] experienced complications from 'mesh' that was implanted in her without alleging *which mesh*") (emphasis in original).)

The court is not persuaded. The second amended complaint contains over 100 paragraphs of allegations discussing Gynecare TVT, and Ms. Richmond-Prohaska expressly alleges that she suffered injuries "as a direct and proximate result of having Defendant Ethicon's Gynemesh implanted." (2d Am. Compl. ¶ 8; *see also id.* ¶¶ 55-56 (listing types of injuries suffered by women who have been implanted with Gynecare TVT and alleging that Ms. Richmond-Prohaska has experienced several of them). The court concludes that Ms. Richmond-Prohaska has pleaded sufficient factual content to support the reasonable inference that she is referring to Ethicon's Gynecare TVT in her

allegations regarding injuries caused by "the mesh." *See Iqbal*, 556 U.S. at 678. Ethicon's motion to dismiss based on causation is, therefore, denied.

2. Manufacturing Defect

Second, Ethicon contends that the court must dismiss Ms. Richmond-Prohaska's manufacturing defect claim because she "fails to identify any deviation of her TVT mesh from Ethicon's design specification." (Mot. at 5-7.)

Under the WPLA, a manufacturing defect claim requires a showing "that the product deviated in some material way from the design specifications of the manufacturer or deviated in some material way from otherwise identical units of the same product line." *Hernandez v. Johnson & Johnson*, No. 4:20-CV-05136-SMJ, 2021 WL 320612, at *4 (E.D. Wash. Jan. 8, 2021) (citing RCW 7.72.030). "Whereas design defects and warning defects apply to the entire product line, a manufacturing defect is found where the particular product that injured the plaintiff contained a 'flaw,' departing from the specifications for the product line as a whole." 16A Wash. Prac., Tort Law and Practice § 17.11 (5th ed.) (citing *Bylsma v. Burger King Corp.*, 293 P.3d 1168 (Wash. 2013)).

Ethicon relies primarily on *Harju v. Johnson & Johnson*, No. C20-6258BHS-JRC, 2021 WL 3929232 (W.D. Wash. Sept. 2, 2021), in which the court dismissed a similar pelvic mesh manufacturing defect claim. In that case, the plaintiffs alleged that "Defendants' manufacturing of the [pelvic mesh products] were [sic] defective due to the use of non-medical grade material and inadequate specifications that were not adhered to in the manufacturing of Plaintiffs' [pelvic mesh products]." 2d Am. Compl. ¶ 128, *Harju*

v. Johnson & Johnson, No. C20-6258BHS-JRC (W.D. Wash. Apr. 15, 2021), Dkt. # 29.[3] The court ruled that the plaintiffs had failed to plead a plausible manufacturing defect claim because they did not allege how the pelvic mesh products that were implanted in them deviated from their intended design. *Harju*, 2021 WL 3929232, at *2. Instead, according to the court, the plaintiffs had alleged that the "products *in general* were defective due to, among others, the use of non-medical grade material." *Id.* (emphasis in original); *see also id.* ("Plaintiffs' allegations do not support an inference that their specific products departed from proper specifications; rather, Plaintiffs allege that every mesh product was defective."). Thus, the court concluded that Plaintiffs' allegations "sound[ed] in a design defect, not in a manufacturing defect" and dismissed the manufacturing defect claim. *Id.*

Here, Ms. Richmond-Prohaska alleges that Ethicon's "manufacturing of Gynemesh was defective due to the use of non-medical grade material and inadequate specifications that were not adhered to in the manufacturing of [Ms. Richmond-Prohaska's] Gynemesh"—an allegation almost identical to the one made by the *Harju* plaintiffs. (2d Am. Compl. ¶ 113.) She also alleges that the "use of non-medical grade polypropylene in [Ethicon's] manufacturing process for Gynemesh resulted in an

[3] Although review of a motion to dismiss is generally limited to the contents of the complaint, courts may "consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). Because the *Harju* second amended complaint is a matter of judicial notice, the court grants Ethicon's unopposed request to consider it in deciding this motion. (*See* Mot. at 5-6; Resp.)

unwanted, elongation, migration and creeping reaction in Plaintiff" and that "[t]he Gynemesh implanted in Plaintiff deviated by its intended designs by utilizing a propylene mesh that degrades, contracts, shrinks, migrates . . . [and] otherwise deforms and disintegrates inside the body." (2d Am. Compl. ¶¶ 114-15.) These allegations, like those of the *Harju* plaintiffs, relate to the properties of Gynecare TVT *in general*, rather than to deviations from Gynecare TVT's design that occurred in the specific units of Gynecare TVT that were implanted in Ms. Richmond-Prohaska. The court concludes that Ms. Richmond-Prohaska's allegations, like those at issue in *Harju*, "sound in a design defect, not in a manufacturing defect," and thus fail to plausibly allege a manufacturing defect claim. *Harju*, 2021 WL 3929232, at *2.

Ms. Richmond-Prohaska protests that, unlike the plaintiffs in *Harju*, she "is alleging that a manufacturing defect exists due to the defective nature of Gynemesh products as a whole." (Resp. at 8.) She asserts that "[n]o manufacturer of such devices should have knowingly designed, manufactured, or sold a product they knew would extrude, elongate, creep, bend, fray or act in any other manner alleged in" her second amended complaint. (*Id.*) The WPLA, however, requires Ms. Richmond-Prohaska to plausibly allege that the product that caused her specific harm deviated in some way from its design specification, its standards, or otherwise identical units of the same product. RCW 7.72.080(2)(a). Ms. Richmond-Prohaska has not done so. (*See generally* 2d Am. Compl.) Accordingly, the court GRANTS Ethicon's motion to dismiss Ms. Richmond-Prohaska's manufacturing defect claim.

3. Leave to Amend

On a Rule 12(b)(6) motion, "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss & Liehe v. N. Cal. Collection Serv.*, 911 F.2d 242, 247 (9th Cir. 1990). Although Ms. Richmond-Prohaska has already amended her complaint twice, the court is not convinced that further amendment would be futile. *See Harju*, 2021 WL 3929232, at *3 (allowing plaintiffs leave to amend their dismissed manufacturing defect claim because it was still possible that they could obtain facts to support such a claim during discovery). Accordingly, the court GRANTS Ms. Richmond-Prohaska leave to file a third amended complaint that addresses the deficiencies identified in this order.

IV. CONCLUSION

For the foregoing reasons, the court GRANTS in part and DENIES in part Ethicon's motion to dismiss (Dkt. # 20). The court GRANTS Ethicon's motion to dismiss Ms. Richmond-Prohaska's manufacturing defect claim and DISMISSES that claim with leave to amend. Ms. Richmond-Prohaska may file a third amended complaint that addresses the deficiencies identified in this order by no later than **September 15,**

//

//

//

//

//

2023. The court DENIES Ethicon's motion to dismiss Ms. Richmond-Prohaska's design defect and failure to warn claims.

Dated this 28th day of August, 2023.

JAMES L. ROBART
United States District Judge