

NOT FOR PUBLICATION**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ROSALIE MARY DINGLER,

Plaintiff,

v.

AMERICAN MEDICAL SYSTEMS, INC.,
et al.,

Defendants.

Civil Action No. 19-8672 (MAS) (TJB)

MEMORANDUM OPINION**SHIPP, District Judge**

This matter comes before the Court upon Defendants Endo Health Solutions Inc.'s ("Endo Health")¹ Motion to Dismiss (ECF No. 7) and Endo Health and Astora Women's Health LLC's ("Astora")² Motion to Dismiss (ECF No. 10) Plaintiff Rosalie Mary Dingler's ("Plaintiff") Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiff opposed Endo Health and Astora's joint motion (ECF No. 13), and Endo Health and Astora replied (ECF No. 15). The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Endo Health's Motion is denied, and Endo Health and Astora's Motion is granted.

¹ Endo Health was formerly known as Endo Pharmaceuticals Holdings, Inc., a named defendant. (See Endo's Moving Br. 1, ECF No. 8.)

² Astora was formerly known as American Medical Systems, Inc. ("AMS"), a named defendant. (See Endo's Moving Br. 1.)

I. BACKGROUND³

Plaintiff suffered from pelvic organ prolapse and stress urinary incontinence. (Compl. ¶ 14.) On or about July 11, 2012, Plaintiff underwent surgery and received implants of two prescription medical devices, the Elevate Prolapse System and Mini Arc Sling System (“Products”). (*Id.* ¶ 14.) Due to complications associated with the Products—including profound pain, prolapse, chronic urinary tract infection, recurrent or chronic cystitis, incomplete bladder emptying, and weak prolapse muscles—Plaintiff underwent revision surgery on or about June 23, 2015 to remove “all identified mesh elements from her body.” (*Id.* ¶ 15.)

Plaintiff filed suit against Astora, Endo Health, American Medical Systems Holdings, Inc. (“AMS Holdings”), and Endo Pharmaceuticals, Inc. (“Endo Pharmaceuticals”), alleging claims under the New Jersey Product Liability Act (“PLA”), N.J. Stat. Ann. §§ 2A:58C-1, *et seq.*, (Counts One, Two, and Three), as well as common law claims for negligence (Count Four), breach of implied warranty (Count Five), breach of express warranty (Count Six), and fraudulent concealment (Count Seven). Endo Health moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (Endo’s Moving Br., ECF No. 8) Endo Health and Astora moved to dismiss Counts Four, Five, and Seven as barred by the PLA and Counts One, Two, and Six for failure to state a claim. (Defs.’ Moving Br., ECF No. 11.)

II. LEGAL STANDARD

A. **Rule 12(b)(6) Standard**

“Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of

³ In ruling on a motion to dismiss, the Court accepts as true all well-pled factual allegations in the Complaint. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Upon a 12(b)(6) motion, a district court conducts a three-part analysis. See *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). “First, the court must ‘tak[e] note of the elements a plaintiff must plead to state a claim.’” *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must “[review] the complaint to strike conclusory allegations[.]” *Id.* The court must accept as true all of the plaintiff’s well-pleaded factual allegations and “construe the complaint in the light most favorable to the plaintiff[.]” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). In doing so, however, the court is free to ignore legal conclusions or factually unsupported accusations that merely state “the-defendant-unlawfully-harmed-me.” *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether “the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). A facially plausible claim “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678). On a motion to dismiss for failure to state a claim, the “defendant bears the burden of showing that no claim has been presented.” *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005).

III. ENDO HEALTH’S MOTION TO DISMISS⁴

Endo Health contends it is an improper defendant and should be dismissed from the action. Endo Health argues: (1) the Complaint contains conclusory allegations that inaccurately state the relationship between the Defendants; and (2) Plaintiff fails to allege Endo Health engaged in activity related to the Products or that Endo Health assumed AMS’s liabilities as a

⁴ Endo Health avers that, once AMS Holdings and Endo Pharmaceuticals are properly served, they will file similar motions to dismiss. (Endo’s Moving Br. 1 n.2.)

result of its merger with AMS. In its Motion, Endo Health requests the Court to look beyond the pleadings and take judicial notice of certain publicly filed documents “evidencing” Endo Health’s corporate structure. (Endo’s Moving Br. 11 n.7; Request for Judicial Notice, Ex. A, ECF No. 7-2; Endo Pharmaceuticals Holdings’ Aug. 9, 2011 10-Q, Ex. B, ECF No. 7-3; Endo Pharmaceuticals’ and AMS Holdings’ Agreement and Plan of Merger (“Merger Agreement”), Ex. C, ECF Nos. 7-4 to 7-7; Endo Holdings’ April 14, 2011 8-K, Ex. D, ECF No. 7-8.)

“As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). The Third Circuit has held, however, that “a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document.” *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citation omitted).

Mindful that Plaintiff did not respond to Endo Health’s Motion, that discovery may eventually uncover contradictory facts, that the choice-of-law issue has not yet been fully briefed,⁵ and based on the Court’s inherent authority to control matters on its docket, the Court declines to address the full analysis Endo Health proposes.

The Complaint contains the following allegations about the Defendants’ relationships:

- “Endo Health aggregated four operating businesses into one enterprise including AMS and AMS Holdings.” (Compl. ¶ 6.)
- Endo Health, formerly known as Endo Pharmaceuticals Holdings, Inc., is the parent corporation of AMS and AMS Holdings. (*Id.* ¶ 5.)

⁵ Endo Health directs the Court to a choice-of-law provision in the Merger Agreement that requires any dispute arising from the Agreement to be governed by Delaware law. Endo Health, however, also argues in the alternative if New Jersey law was found applicable. Endo Health’s alternative arguments further confirm the inappropriate timing of its request.

- Endo Pharmaceuticals, once a wholly owned subsidiary of Endo Pharmaceuticals Holdings, Inc. (now Endo Health), merged with AMS. (*See id.* ¶ 5.)
- Endo Pharmaceuticals assumed liability relating to claims arising from implantations of defective synthetic pelvic mesh systems, as a result of the merger. (*Id.* ¶ 7.)

Construing the Complaint in the light most favorable to Plaintiff, the Court finds Plaintiff has adequately pleaded Endo Health is a proper defendant. Endo Health’s Motion is, accordingly, denied.

IV. ENDO HEALTH AND ASTORA’S MOTION TO DISMISS

A. Common Law Product Liability Claims—Counts Four, Five, and Seven

Endo Health and Astora argue that Plaintiff’s common law claims for negligence, breach of implied warranty, and fraudulent concealment are subsumed under the PLA. Plaintiff concedes and indicates that she will pursue Counts One, Two, Three, and Six.

The New Jersey “Legislature expressly provided in the PLA that claims for ‘harm caused by a product’ are governed by the PLA ‘irrespective of the theory underlying the claim.’” *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008) (quoting N.J. Stat. Ann. § 2A:58C-1(b)(3)). The Court, accordingly, dismisses Counts Four, Five, and Seven of the Complaint.

B. PLA Claim for Manufacturing Defect—Count One

Endo Health and Astora move to dismiss Plaintiff’s claim for manufacturing defect. A manufacturing defect exists if a product “deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.” N.J. Stat. Ann. § 2A:58C-2(a). Here, Plaintiff alleges that the Products caused adverse reactions and did not perform their intended purposes.

Plaintiff does not allege any standard—be it a design specification, formulae, or performance of the manufacturer, or an identical unit manufactured to the same manufacturing specifications or formulae—from which the Products deviated. Count One is, accordingly, dismissed for failure to state a manufacturing defect claim.

C. PLA Claim for Design Defect—Count Two

Endo Health and Astora argue that Plaintiff fails to state a design defect claim because the Complaint contains no allegations of the Products’ risks outweighing their utility and contains conclusory allegations of feasible and suitable alternatives. “Though there is no per se rule that Plaintiff[] must, under all circumstances, provide a reasonable alternative design, [P]laintiff must plead either that the [Products’] risk [of harm] outweighs [their utility], or that [] alternate design[s] exist[], in order to state a claim for a design defect under the [PLA].” *Mendez v. Shah*, 28 F. Supp. 3d 282, 297–98 (D.N.J. 2014) (citation and internal quotation marks omitted).

Here, Plaintiff alleges that the design of Defendants’ mesh Products are defective because, as the FDA stated, “the benefits of using transvaginal mesh [p]roducts instead of other feasible alternatives did not outweigh the associated risks.” Plaintiff, however, confuses the issue. Plaintiff must allege a risk-utility analysis that assesses the risk and the utility of a product—not one that considers the benefits of one product over another. Plaintiff, consequently, does not plead that the Products’ risk of harm outweigh their utility. Moreover, Plaintiff does not allege any alternative designs.⁶ The Court, accordingly, dismisses Plaintiff’s design defect claim.

⁶ Plaintiff advises the Court that other courts evaluating the risks of similar mesh products have found feasible alternative designs exist. Even if that assertion is true, Plaintiff nonetheless fails to plead alternative designs in her own complaint.


D. Breach of Express Warranty—Count Six

Endo Health and Astora also seek to dismiss Plaintiff's claim for breach of express warranty. "Under New Jersey law, in order to state a claim for breach of express warranty, Plaintiff[] must properly allege: (1) that Defendant[s] made an affirmation, promise[,] or description about the [P]roduct[s]; (2) that this affirmation, promise[,] or description became part of the basis of the bargain for the [P]roduct[s]; and (3) that the [P]roduct[s] ultimately did not conform to the affirmation, promise or description." *Snyder v. Farnam Cos.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (citing N.J. Stat. Ann. § 12A:2-313). "Courts dismiss claims for breach of an express warranty where plaintiffs fail to specify any factual support as to the specific language or source of the alleged warranty." *Schraeder v. Demilec (USA) LLC*, No. 12-6074, 2013 WL 3654093, at *5 (D.N.J. July 12, 2013); *see also Mendez*, 28 F. Supp. 3d at 295–96 (collecting cases dismissing breach of an express warranty claims).

Here, Plaintiff alleges that Defendants made representations as to the Products' safety and efficacy in advertising campaigns, television commercials, print advertisements, billboards, and other commercial media. Plaintiff fails to allege, however, specific statements that Defendants made through those mediums. Because Plaintiff has not alleged any affirmation, promise, or description made by Defendants, Plaintiff's express warranty claim must fail and is, accordingly, dismissed.

V. CONCLUSION

For the reasons set forth above, Endo Health's Motion to Dismiss (ECF No. 7) is denied, and Endo Health and Astora's Motion to Dismiss (ECF No. 10) is granted. An order consistent with this Memorandum Opinion will be entered.



MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE