UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MICHELLE BROWN, Plaintiff,	:	
v.	:	No. 5:21-cv-01552
C.R. BARD, INC., Defendant.	:	

O P I N I O N
Motion to Dismiss, ECF No. 14 – Granted in part, Denied in part

Joseph F. Leeson, Jr. **February 11, 2022**
United States District Judge

I. INTRODUCTION

Plaintiff Michelle Brown brought the above-captioned action for damages resulting from complications she experienced with Defendant C.R. Bard, Inc.'s Ajust pelvic mesh device. Bard has moved to dismiss all counts for failure to state a claim. For the reasons set forth below, the Motion to Dismiss is granted in part and denied in part.

II. BACKGROUND

On October 25, 2010, Brown was implanted with Bard's Ajust pelvic mesh device ("Ajust"). Bard designed, manufactured, marketed, distributed, and sold the Ajust. Brown developed complications arising from the implant of the Ajust, including mesh erosion, tissue erosion, exposed and protruding mesh, pain, bleeding, infection, and dyspareunia, which required a second surgery on December 22, 2016, to remove the Ajust.

Brown initiated this action on April 1, 2021. After Bard filed a motion to dismiss, Brown filed an Amended Complaint alleging twelve counts: (I) negligence, (II) design defect, (III) manufacturing defect, (IV) failure to warn, (V) common law fraud, (VI) breach of express warranty,

(VII) breach of implied warranty, (VIII) constructive fraud, (IX) negligent misrepresentation, (X) negligent infliction of emotional distress ("NIED"), (XI) a violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Act ("UTPCPA"), 73 P.S. §§ 201-1 - 201-9.2, and (XII) unjust enrichment. *See* Am. Compl., ECF No. 12. Bard has moved to dismiss the Amended Complaint in its entirety. *See* Mot., ECF No. 14. The matter is fully briefed. *See* Mem., ECF No. 14-1; Opp., ECF No. 18; Reply, ECF No. 19.

III. STANDARD OF REVIEW

Under Rule 12(b)(6), the court must "accept all factual allegations as true [and] construe the complaint in the light most favorable to the plaintiff." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)) (internal quotation marks omitted). Only if "the '[f]actual allegations . . . raise a right to relief above the speculative level'" has the plaintiff stated a plausible claim. *Id.* at 234 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 540, 555 (2007)). "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* (explaining that determining "whether a complaint states a plausible claim for relief . . . [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense").

Even under the general pleading requirements for states of mind set forth in Rule 9(b) of the Federal Rules of Civil Procedure, "[w]hen pleading knowledge, the complaint must still contain more than a 'conclusory allegation,' and the pleading must meet the 'less rigid — though still operative — strictures of Rule 8.'" *Gotthelf v. Toyota Motor Sales, U.S.A., In.*, 525 F. App'x 94, 103 n.15 (3d Cir. 2013) (quoting *Iqbal*, 556 U.S. at 686-87). When alleging fraud, Federal Rule of

Civil Procedure 9(b), requires the pleadings to go beyond the minimal requirements in Rule 8 and "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy this requirement, a plaintiff "must allege who made a misrepresentation to whom and the general content of the misrepresentation," and also plead either the date, place, or time of the fraud, or "through alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004).

"In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). Additionally, "a document integral to or explicitly relied upon in the complaint may be considered." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotations omitted). The defendant bears the burden of proving that a plaintiff has failed to state a claim upon which relief can be granted. *See Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

IV. ANALYSIS

A. Count I states a negligence claim for design defect and failure to warn.

Bard argues that Brown's negligence claim is overly broad and fails to identify one theory of negligence or any facts to support such a claim. To state a negligence claim, a plaintiff must show: (1) the defendant owed a duty to conform to a certain standard of conduct, (2) the defendant failed to conform to that standard; (3) a causal connection between the conduct and resulting injury; and (4) actual loss or damage occurred as a result. *See Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 61 (3d. Cir. 2009). "There are three types of product defects that are recognized in Pennsylvania: (1)

design defect,[1] (2) manufacturing defect, and (3) a failure to warn."[2] *Terrell v. Davol, Inc.*, No. 13-5074, 2014 U.S. Dist. LEXIS 103695, at *35 n.5 (E.D. Pa. July 30, 2014).

At this stage of the proceedings, Brown has pled sufficient facts to put Bard on notice of her negligence claim. She has also pled sufficient facts to state a claim based on design defect and failure to warn by alleging the specific issues with the design as it relates to material used and placement in the body, *see* Am. Compl. ¶ 42,[3] and the specific warnings that should have been but were not provided, *see id.* ¶ 43.[4] *See Drumheller v. Johnson & Johnson*, No. 20-6535, 2021 U.S. Dist. LEXIS 88941, at *17-18, 24-25 (E.D. Pa. May 10, 2021) (finding that the plaintiff's

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1 "To maintain a design defect claim, a plaintiff must show the defendants had actual or constructive knowledge that the [device] [was] too harmful to be used by anyone." *Runner v. C.R. Bard, Inc.*, 108 F. Supp. 3d 261, 270 (E.D. Pa. 2015) (internal quotations omitted).

2 "Under Pennsylvania law, a medical device manufacturer has a duty to warn implanting physicians about the dangers of a medical device, but has no duty to warn patients directly." *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 831 (E.D. Pa. 2016). This limited duty to warn renders the prescribing physician the "learned intermediary." *See id.* "Under the learned intermediary doctrine, the drug manufacturer owes a duty of disclosure to the prescribing physician, but it is then the duty of the prescribing physician to communicate any risks or other information about the drug to the patient." *Zafarana v. Pfizer Inc.*, 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010) (citing *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31-32 (Pa. Super. Ct. 2006)). "For a warning to be adequate under Pennsylvania law, it must: (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity. To prevail on a failure to warn claim, Plaintiffs must also prove proximate causation by showing that the learned intermediary would have altered his behavior had the defendant issued a proper warning." *Kohn v. Ethicon, Inc.*, No. 19-40004, 2020 U.S. Dist. LEXIS 24996, at *15 (E.D. Pa. Feb. 12, 2020) (internal citations omitted).

3 The Amended Complaint alleges that the Ajust's design defects include, *inter alia*, "the use of polypropylene material . . ., causing adverse reactions and injuries, the placement "into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries," and its propensity "for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time [and] . . . to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury." *See* Am. Compl. ¶ 42.

4 The Amended Complaint alleges that Bard failed to warn, *inter alia*, of "the Ajust's propensities to contract, retract, and/or shrink inside the body, . . . for degradation, fragmentation and/or creep," and the risks of "chronic inflammation, . . .chronic infections, . . . permanent vaginal or pelvic scarring, [and] . . . recurrent, intractable pelvic pain and other pain resulting from the Ajust." *See* Am. Compl. ¶ 43.

allegations that "pelvic mesh products are made of polypropylene, which she alleges to be 'biologically incompatible with human tissue' and to cause 'a severe foreign body reaction and chronic inflammatory response' [that] . . . 'promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment'" were sufficient to state a claim for negligent design); *Terrell*, 2014 U.S. Dist. LEXIS 103695, at *33-34 and n.13 (finding that the plaintiff, who alleged that the defendants failed to warn her medical providers about the mesh's "tendency to shrink or contract inside the body, to fragment and creep from its place of origin, and its inelasticity and erosive quality" and to cause "greater risks . . . of contracting chronic inflammation, chronic infections, permanent scarring and severe pain" stated a claim for a negligent failure to warn). There are also sufficient allegations connecting the same to Brown's injury. *See* Am. Compl. ¶¶ 3-4, 74, 98, 100, 108-110, 239. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *23 (holding that the learned intermediary doctrine does not bar negligent failure-to-warn claims because a plaintiff "can show proximate cause 'by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided'" (quoting *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. 2010))); *Runner v. C.R. Bard, Inc.*, 108 F. Supp. 3d 261, 271-72 (E.D. Pa. 2015) (concluding that whether the defendants' warning would have moved the doctor to alter the plaintiff's care cannot be resolved at the motion to dismiss stage, and that the plaintiff had sufficiently pled[5] that the defendants failed to exercise reasonable care in informing his doctor of any alleged defects so as to state a negligence claim based on failure

[5] The complaint alleged: "As a result of this defective design and manufacture, [d]efendants' [p]roducts can cause serious physical trauma, injury and/or death. Defendants knew or had reason to know of this tendency and the resulting risk of injury, but failed to disclose this information, preventing the [p]laintiff and his health care providers[] from making informed choices about the implantation of the [p]roduct and continued use thereof." *Runner*, 108 F. Supp. 3d at 270 (citing paragraph 17 of the complaint).

to warn). Accordingly, the Motion to Dismiss Count I (negligence) is denied to the extent the claim is based on design defect and failure-to-warn defect.

To the extent Count I is based on a manufacturing defect, however, the Motion to Dismiss is granted. "The manufacturing defect theory posits that a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *Terrell*, 2014 U.S. Dist. LEXIS 103695, at *26 (internal citations omitted). Brown's allegations, in contrast, relate to defective design or are too broad to support her claim. *See id.* (dismissing the manufacturing defect claims for being too vague and unspecific). "Generally, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *20 (internal quotations omitted). Brown's allegations center on Ajust being a design defect. Although she makes conclusory statements of a manufacturing defect, she fails to support her claim. Instead, Brown presents contradictory allegations that "the use of polypropylene material in the Ajust" was a design defect, *see* Am. Compl. ¶¶ 9, 105(a), but then blames the use of the same polypropylene mesh as a manufacturer's defect, *see id.* ¶¶ 115-117. Thus, Brown has failed to state a separate claim for negligence based on a manufacturer defect and this theory of liability in Count I (negligence) is dismissed without prejudice and with leave to amend. If Brown fails to amend, Count I will proceed only on the theories of design defect and failure to warn.

B. Counts II through IV (strict liability) are dismissed.

Bard moves to dismiss all strict liability claims as barred under Pennsylvania law. Bard recognizes that the Pennsylvania Supreme Court has only addressed this issue in the drug context, but argues that the Pennsylvania Superior Court has applied the same reasoning to prescription medical devices. In opposition, Brown asserts that the Pennsylvania Supreme Court would not

categorically preclude such claims, but would instead analyze strict liability claims on a case-by-case basis, which requires a full evidentiary hearing.

1. Strict Liability in Pennsylvania- Review of Applicable Law[6]

As a general matter, Pennsylvania has adopted the strict liability formulation set out in Section 402A of the Restatement (Second) of Torts. *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328, 394-99 (Pa. 2014); *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Pursuant to Section 402A, a plaintiff may recover under a theory of strict liability if his or her injury was caused by a product in "a defective condition unreasonably dangerous to the user or consumer." Restatement (Second) Torts § 402A; *see also Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995). A plaintiff may establish a "defective condition," and thus assert a strict liability claim, by showing that the product suffered from a design defect, failure-to-warn defect, or manufacturing defect. *Id.*

There are, however, situations where strict liability is unavailable as an avenue of relief for plaintiffs alleging harm caused by a product. Specifically, pursuant to comment k of Section 402A, manufacturers of "unavoidably unsafe products" are exempted from strict liability to the extent that the product at issue is "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably dangerous*." *See* Restatement (Second) of Torts § 402A, cmt. k (emphasis in original). In other words, Section 402A defines the general scope of strict liability, and comment k sets the perimeter beyond which Section 402A may not encroach. . . .

In interpreting the scope of comment k, the Pennsylvania Supreme Court has held that comment k applies to prescription drugs. *See Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996) (explaining that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's

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[6] This subsection is taken directly from *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 576-78 (E.D. Pa. 2019).

negligence, is the only recognized basis of liability"). In 2014, the Pennsylvania Supreme Court further explained that it "has declined to extend strict liability into the prescription drug arena." *Lance v. Wyeth*, 85 A.3d 434, 453 (Pa. 2014) [hereinafter *Lance II*].

But the case before the Court today is not one regarding prescription drugs. Rather, the present case involves a prescription medical device, a context in which the Pennsylvania Supreme Court has not addressed comment k's application. "In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide [the] case." *Berrier*, 563 F.3d at 45-46. Therefore, the Court must predict whether the Pennsylvania Supreme Court would expand the scope of comment k to reach prescription medical devices. . . . [If] the Pennsylvania Supreme Court would apply comment k to prescription medical devices, the Court [must then] turn[] to the types of strict liability claims that comment k precludes.

2. Comment k applies to medical devices.

For the following reasons, this Court predicts that the Pennsylvania Supreme Court would extend comment k to medical devices. In reaching this conclusion, this Court looks first at the plain language of comment k. Comment k explains that some products, such as "drugs, vaccines, *and the like*," are unavoidably unsafe and that the seller of such products will "not be held to strict liability for unfortunate consequences attending their use." *See* Restatement (Second) of Torts § 402A cmt. k) (emphasis added). As the language "and the like" indicates, comment k is not limited to prescription drugs. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *29 (reasoning that comment k's language "and the like" extends its scope beyond drugs and vaccines to similar products, such as prescription medical devices). Rather, it applies to medical devices that similarly "cannot legally be sold except to physicians, or under the prescription of a physician." *See* Restatement (Second) of Torts § 402A cmt. k; *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 577 (E.D. Pa. 2019)

(Robreno, J.) ("For the purposes of comment k, no meaningful distinction can be drawn between prescription drugs and prescription medical devices.").

This determination is further supported by Pennsylvania case law. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *29-32 (reasoning that *Creazzo* supports the prediction that the Pennsylvania Supreme Court would extend comment k to prescription medical devices); *Rosenberg*, 387 F. Supp. 3d at 577-78 (explaining that Pennsylvania case law supports the conclusion that comment k applies to prescription medical devices). Although the Pennsylvania Supreme Court has not spoken on this issue, the Pennsylvania Superior Court has spoken. *See Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). In *Creazzo*, the Pennsylvania Superior Court held that the plaintiffs could not pursue a strict liability claim against the manufacturer of a medical device implanted in the body. *See id.* In reaching this holding, the Pennsylvania Superior Court concluded that the plain language of comment k and the Pennsylvania Supreme Court's decision in *Hahn* extended to medical devices. *Id.* at 30-31.[7]

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[7] This Court recognizes some other judges in this district have concluded that *Creazzo* is not persuasive authority that the Pennsylvania Supreme Court would decide comment k covers medical devices. *See, e.g., Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 251 (E.D. Pa. 2020) (Baylson, J.) (allowing the strict liability claims to proceed through discovery). In reaching this conclusion, the *Gross* court reasoned that the parties in *Creazzo* submitted very limited briefing on the issue and, also, that subsequent Pennsylvania Supreme Court decisions cautioned against lightly altering the common law of products liability and discouraged courts from carving out certain categories of products for special treatment within the common law of products liability. *See id* at 251 (citing *Tincher v. Omega Flex*, 104 A.3d 328, 396 (Pa. 2014) ("Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an a priori decision as to which individual products, or categories and types of products, should be exempt."); *Lance v. Wyeth*, 85 A.3d 434, 466 (Pa. 2014) (rejecting that a "blanket application of [comment k] for purposes of strict liability and preclusion of negligence-based liability premises necessarily go hand-in-hand" and finding that *Hahn* "offers a poor foundation for extrapolation" in light of its "rather one-dimensional analysis in its adoption of a blanket approach to comment k")).

This Court finds, however, that given the plain language in comment k and the reasoning of the Pennsylvania courts as to why strict liability is not recognized as a basis of liability in the prescription drug context, the Pennsylvania Supreme Court would extend comment k to prescription medical devices. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *32-36 (explaining the reasons

Pennsylvania's Standard Civil Jury Instructions also support this Court's decision. *See Rosenberg*, 387 F. Supp. 3d at 578 (noting that the subcommittee note to Pennsylvania Suggested Standard Civil Jury Instructions § 23.00 expressly supports the application of comment k to medical devices). The subcommittee note to Instruction 23.00, Duty to Warn, states: "Pennsylvania courts have declined to apply strict liability in cases involving prescription drugs *and medical devices*, in accordance with comment k to the Restatement (Second) of Torts § 402A." *See* Pa. SSJI (Civ) 23.00 (emphasis added) (citing *Hahn*, 673 A.2d at 889-90; *Creazzo*, 903 A.2d 24).

Finally, the prediction that the Pennsylvania Supreme Court would apply comment k to medical devices is consistent with the majority of cases in this district. *See, e.g., Lopez v. Ethicon Inc.*, No. 20-2694, 2020 U.S. Dist. LEXIS 170140, at *10 (E.D. Pa. Sep. 16, 2020) (Quinones, J.); *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 848 (E.D. Pa. 2017) (Beetlestone, J.); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016) (Padova, J.); *Runner*, 108 F. Supp. 3d at 266 (Dalzell, J.); *Keen v. C.R. Bard, Inc.* , 480 F. Supp. 3d 624, 637 (E.D. Pa. 2020) (Pratter, J.); *Kohn v. Ethicon, Inc.* , No. 19-40004, 2020 U.S. Dist. LEXIS 24996, at *7 (E.D. Pa. Feb. 12, 2020) (Tucker, J.); *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 319 (E.D. Pa. 2016) (Stengel, J.); *Wilson v. Synthes USA Prods., LLC* , 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015) (Schmehl, J.); *Terrell*, 2014 U.S. Dist. LEXIS 103695, at *17 (Slomsky, J.); *Shelley v. Ethicon, Inc.*, No. 12-6862, 2013 U.S. Dist. LEXIS 95981, at *7 (E.D. Pa. July 9, 2013) (DuBois, J.); *Murray v. Synthes*, No. 95-7796, 1999 U.S. Dist. LEXIS 13436 (E.D. Pa. Aug. 23, 1999) (Hutton, J.); *Burton v. Danek Medical, Inc., et al.*, No. 95-5565, 1999 U.S. Dist. LEXIS 2619 (E.D. Pa. Mar. 1, 1999)

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for rejecting the decision in *Gross*). This Court agrees with *Rosenberg* that "nothing in *Tincher* reopens the door to strict liability claims for prescription drugs or prescription medical devices, a door *Hahn* had firmly closed." *See Rosenberg*, 387 F. Supp. 3d at 579-81.

(Kelly, J.); *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 U.S. Dist. LEXIS 20265 (E.D. Pa. Dec. 29, 1998) (Broderick, J.).

3. Strict liability claims are precluded for design defects and warning defects, only.

The application of comment k to medical devices does not end the inquiry. This Court further predicts that the Pennsylvania Supreme Court would bar strict liability claims for design defects and failure-to-warn defects, but not for manufacturing defects.

In reaching this conclusion, the Court first considers the plain language of comment k. Comment k states that the "seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability . . . ." *See* Restatement (Second) of Torts § 402A cmt. k. On its face, comment k preserves strict liability claims for manufacturing defects ("properly prepared") and failure-to-warn defects ("proper warning is given"). *See Smith*, 251 F. Supp. 3d at 848 (finding that the conditions in comment k that the product be "properly prepared" and "accompanied by proper directions and warning" seem, on their face, to preserve strict liability claims asserting a manufacturing defect and a failure-to-warn defect). The language of comment k does not provide for strict liability claims based on design defects.

The Pennsylvania Supreme Court, in the area of prescription drugs, has similarly barred strict liability claims based on design defects. *See Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971) (holding that a drug manufacturer may not be held strictly liable "merely because of dangerous propensities of the product"). The Pennsylvania Supreme Court, despite the plain language in comment k, has also barred strict liability claims for warning defects relative to prescription drugs, holding that "negligence is the only recognized basis for recovery." *See Hahn*, 673 A.2d at 848. *See also Smith*, 251 F. Supp. 3d at 848 (concluding that despite the plain language in comment k, "the Pennsylvania Supreme Court [in *Hahn*] has interpreted it to limit recovery for

failure-to-warn in Comment k cases to negligence"). The Pennsylvania Supreme Court has been silent, however, in the area of manufacturing defects, which is why the federal courts have been required to predict how the state's high court would decide. *See Rosenberg*, 387 F. Supp. 3d at 579 ("Although the Pennsylvania Supreme Court has barred strict liability claims for design defects and failure-to-warn claims based on an application of comment k, it has not done so expressly in the context of a manufacturing defect.").

"As a result of the Pennsylvania Supreme Court's silence regarding strict liability for manufacturing defects in the prescription product context, federal district courts, in interpreting Pennsylvania law and predicting how the Pennsylvania Supreme Court would find, have come out differently on this issue." *Rosenberg*, 387 F. Supp. 3d at 581 (finding "substantial ground for difference of opinion"). This Court has reviewed the different possible conclusions.[8] After consideration, this Court predicts that the Pennsylvania Supreme Court would bar strict liability

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[8] *Compare, e.g., Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *29-35 (Kearney, J.) (agreeing with *Gross* that the "properly prepared" language in comment k carves out manufacturing defects from strict liability and that "the Pennsylvania Supreme Court's warning in *Lance* not to expand *Hahn* too quickly suggests the Pennsylvania Supreme Court would not extend *Hahn* to manufacturing defects") *and Smith*, 251 F. Supp. 3d at 848-49 ("Interpreting the 'properly prepared' language to preserve manufacturing defect strict liability claims in Comment k cases would be consistent with the Pennsylvania Supreme Court's recent summary of its strict products liability jurisprudence in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014)"), *with Bernard v. Johnson & Johnson*, No. 19-cv-5184, 2020 U.S. Dist. LEXIS 164299, at *8-9 (E.D. Pa. Sep. 8, 2020) (Younge, J.) (concluding that Pennsylvania law recognizes strict product liability claims against medical device manufacturers and allowing the design defect failure-to-warn defect claims to proceed to trial, but having no need to consider manufacturer defect claims), *with James v. United States*, No. 19-04627, 2020 U.S. Dist. LEXIS 57847, at *8 (E.D. Pa. Apr. 2, 2020) (Pappert, J.) (refusing to apply a blanket rule for all medical devices and recognizing strict liability claims for design, manufacturer, and failure-to-warn defects), *with McGrain v. C.R. Bard, Inc.*, No. 21-1539, 2021 U.S. Dist. LEXIS 143559, at *5-6 (E.D. Pa. July 30, 2021) (Quinones, J.) (concluding that Pennsylvania law precludes strict liability claims against medical device manufacturers for design defects, warning defects, and manufacturing defects) *and Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 637 (E.D. Pa. 2020) (Pratter, J.) (predicting that the Pennsylvania Supreme Court would not "deviate from its otherwise uniform application of comment k in order to permit strict liability claims based on manufacturing defect theory").

claims for design defects and failure-to-warn defects, but not for manufacturing defects. In concluding that a strict liability claim based on manufacturing defects is not barred, this Court relies on the "properly prepared" language in comment k and heeds the statements by the Pennsylvania Supreme Court in *Tincher* cautioning courts against categorical pronouncements and in *Lance* to not expand *Hahn* too quickly. *See also Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *34-35 (finding that comment k's "properly prepared" language, as well as "the Pennsylvania Supreme Court's warning in *Lance* not to expand *Hahn* too quickly suggests the Pennsylvania Supreme Court would not extend Hahn to manufacturing defects").

Consequently, Brown's strict liability claims in Count II (design defect) and Count IV (failure to warn) are dismissed with prejudice. *See McGrain v. C.R. Bard, Inc.*, No. 21-1539, 2021 U.S. Dist. LEXIS 143559, at *33 (E.D. Pa. July 30, 2021) (finding that because the claims for strict liability are barred as a matter of law amendment would be futile). Although a manufacturing defect claim may be based on strict liability, Brown has failed to allege sufficient facts to state such a claim for the reasons set forth in the previous section. Count III (manufacturing defect) is dismissed without prejudice and with leave to amend.

C. Brown's fraud-based claims in Counts V, VIII, IX, and XI are dismissed.

Bard argues that the fraud claims[9] are not recognized because they are simply re-stated failure-to-warn claims, that the learned intermediary doctrine bars all misrepresentation-based claims in medical product liability cases because Brown cannot prove reasonable reliance, and that the claims are inadequately pled. *See* Mot. 14-18.

1. Brown's fraud claims are based on the failure-to-warn.

[9] Brown's four fraud claims are Count V (common law fraud), Count VIII (constructive fraud), Count IX (negligent misrepresentation), and Count XI (a violation of the UTPCPL).

"[N]egligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription drug manufacturer when the claim is essentially that the drug company knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product's safety." *Runner*, 108 F. Supp. 3d at 268. However, "courts have found fraud claims concerning prescription medical devices cognizable if they contain allegations of overt acts, such as affirmative misrepresentations, that go beyond a mere failure to warn." *Cutruzzula v. Bayer Healthcare Pharm., Inc.*, No. 14-1474, 2015 U.S. Dist. LEXIS 166162, at *11-13 (W.D. Pa. Nov. 17, 2015) (internal quotations omitted).

In opposition to the motion to dismiss, Brown contends her fraud-based claims are not merely restated failure-to-warn claims, but allege that Bard actively concealed material facts related to the defective nature of the Ajust and the dangers associated with it, and misled Brown and her doctors to believe the Ajust was safe and effective. *See* Opp. 13-14.

Despite Brown's contention in opposition to the Motion to Dismiss, this Court finds that the crux of her fraud allegations in the Amended Complaint are that Bard had a duty to warn the Ajust had not been adequately tested and found to be safe and effective for the treatment of incontinence, and that the facts allegedly concealed and misrepresented are that the Ajust was dangerous and defective. Brown's allegations are similar to those in *Runner*, which involved products liability claims against Bard for a different mesh product. This Court finds as the *Runner* court did, that the allegations[10] are tantamount to failure-to-warn claims. *See Runner*, 108 F. Supp. 3d at 267-69

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[10] The *Runner* court identified the misrepresentation claims as alleging the defendant:
> [M]isrepresented the safety of its [p]roduct and fraudulently, intentionally, recklessly or negligently concealed material adverse information regarding the [product's] safety. . . .
> Made false, misleading, or negligent statements and omissions about the [product's] safety. . . .
> Minimiz[ed] the risks associated with continuing to use these [p]roducts. . . and actively concealed adverse information at a time when [they] knew, or should have

(concluding that the plaintiff's allegations that the "defendants, who had sole access to the material facts concerning the defective nature of the mesh product, purposefully concealed those facts to mislead the plaintiff and his medical providers" sought to impose liability for failure to warn).

2. The learned intermediary doctrine[11] bars only the UTPCPL claim (Count XI).

Bard asserts that the learned intermediary doctrine bars all misrepresentation-based claims in medical products liability cases because Brown cannot prove reasonable reliance. *See* Mot. 14-15. Brown counters that the learned intermediary doctrine does not bar all her fraud-based claims, but apparently concedes her UTPCPL claim must be dismissed. *See* Opp. 4.

Initially, the Court finds that the learned intermediary doctrine precludes a claim under the UTPCPL.[12] "Under Pennsylvania law, a consumer does not have a cause of action under the UTPCPL against the manufacturer of prescription drugs because prescription drug manufacturers do not have a duty to disclose information directly to consumers." *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012). The same applies to prescription medical devices. Count XI (UTPCPL) is therefore dismissed with prejudice. *See Crockett v. Luitpold Pharm., Inc.*, No. 19-276, 2020 U.S. Dist. LEXIS 13549, at *26 (E.D. Pa. Jan. 28, 2020) (holding that the learned intermediary doctrine precludes a claim under the UTPCPL and dismissing the claim with

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> known. . . that the [p]roducts had defects, dangers, and characteristics that were other than what was represented to the FDA[.]

Runner, 108 F. Supp. at 268-69.

[11] *See* Section A herein

[12] The UTPCPL provides a private cause of action to allow "[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by any person of a method, act or practice declared unlawful by section 3 of this act, [to] bring a private action to recover actual damages or one hundred dollars ($100), whichever is greater." 73 Pa. S.A. § 201-9.2(a). The UTPCPL's causation requirement "demand[s] a showing of justifiable reliance, not simply a causal connection between the misrepresentation and the harm." *Hunt v. United States Tobacco Co.*, 538 F.3d 217, 222 (3d Cir. 2008) (citing *Weinberg v. Sun Co.*, 777 A.2d 442, 446 (Pa. 2001) (explaining that the UTPCPL requires a plaintiff to allege that he purchased the product because he heard and believed the defendant's false advertisement)).

prejudice); *Zafarana v. Pfizer Inc.*, 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010) ("Plaintiffs cannot claim any justifiable reliance, and their UTPCPL claim must fail.").

The learned intermediary doctrine does not, however, bar all fraud-based claims. *See Crockett*, 2020 U.S. Dist. LEXIS 13549, at *25-26 (Beetlestone, J.) (holding that the learned intermediary doctrine, as filtered through Section 310 of the Restatement of Torts, does not demand that the plaintiff's fraud claim be dismissed, but that it does preclude the UTPCPL claim, which is not subject to the Restatement). Unlike the UTPCPL claim, Brown's remaining fraud-based claims are subject to the Restatement of Torts. Section § 310 of the Restatement provides:

> [a]n actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by . . . *a third person* in reliance upon the truth of the representation, if the actor (a) intends his statement to induce or should realize that it is likely to induce action by . . . a third person, which involves an unreasonable risk of harm to the other, and (b) knows (i) that the statement is false, or (ii) that he has not the knowledge which he professes.

Restatement (Second) of Torts § 310 (1965) (emphasis added). Accordingly, Brown may be able to prove justifiable reliance by showing her doctor relied on misrepresentations by Bard, which Bard intended, or knew were likely, to induce the doctor to implant the Adjust and which Bard knew to be false or made without the requisite knowledge.

3. The remaining fraud claims (Counts V, VIII, and IX) are inadequately pled.

For the reasons discussed in subsection 1, Brown's fraud claims are based on the mere failure to warn, for which negligence is the sole theory on which to recover. *See Runner*, 108 F. Supp. 3d at 267-69 (dismissing the plaintiff's misrepresentation and fraudulent concealment claims as barred by Pennsylvania law, which provides that negligence is the sole theory to recover based on the failure to warn). Despite Brown's argument to the contrary, her allegations are insufficient to establish affirmative misrepresentations. *See McGrain*, 2021 U.S. Dist. LEXIS 143559, at *29 (concluding the plaintiff's allegations that the defendants knew their misrepresentations about the

medical device were false and fraudulent regarding the dangers and risks associated with use of product did not take the fraud claims beyond the scope of failure to warn of the alleged risks of the defendants' product); *Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *45-47 (dismissing the fraud claims based on the defendant's concealment of information regarding the dangers of pelvic mesh and misrepresentation about the product's safety because they sounded in failure-to-warn).

Moreover, although § 310 of the Restatement does not bar these counts, the Amended Complaint does not contain sufficient factual allegations as to who, what, when, and where so as to satisfy the heightened pleading requirements in Rule 9. *See Lum*, 361 F.3d at 224-25 (determining that the conclusory allegations, which did "not indicate the date, time, or place of any misrepresentation; nor do they . . . identify particular fraudulent financial transactions . . . [or] which defendant(s) made misrepresentations to which plaintiff(s)," did not satisfy Rule 9). The specific misrepresentations (what) are alleged in paragraphs 183 through 188 of the Amended Complaint.[13] As to who made such representations, Brown alleges they were made by Bard's "retained key opinion leaders, agents, employees, representatives, designees, *or* any other person

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[13] 183. Defendant specifically warranted to Plaintiff and her implanting physician through advertisements and marketing materials that the Ajust was "safe and effective" and "safer and more effective that other alternative procedures and devices" that were on the market on the date the device was implanted in Plaintiff.
184. Defendant prepared and distributed stress urinary incontinence pamphlets that indicated the Ajust device would allow Plaintiff to "[r]egain[] [c]ontrol" and "[r]estor[e] [her] [l]ifestyle."
185. Defendant's pamphlets further warranted that the Ajust provides "extra support of the urethra to prevent accidental leakage."
186. Defendant's pamphlets further warranted that the Ajust works "very well in restoring continence[.]"
187. Defendant's pamphlets further warranted that the Ajust has had an impressive performance record over the years."
188. Defendant's pamphlets further warranted that the Ajust provides "exceptional strength and durability, providing support required for urethral tissues after the procedure."
Am. Compl. ¶¶ 183-188.

acting on behalf of Defendant." *See* Am. Compl. ¶¶ 72-73 (emphasis added). The misrepresentations allegedly appeared in "written and/or oral information," *see id.* ¶ 133, Bard's "Instructions for Use ('IFU') and pamphlets or commercial documents for the Ajust device," *see id.* ¶ 126, "commercial documents, paid-for studies, training and presentation materials," *see id.* ¶¶ 59,[14] 130, and/or "advertisements and marketing materials," *see id.* ¶ 183. Brown alleges such representations were made when "Plaintiff's implanting physician was first trained on the device; when Plaintiff's implanting provider purchased the device for the first time; when Plaintiff's implanting provider purchased the device that was implanted in Plaintiff; immediately before and/or during the consent process/discussion between Plaintiff and her implanting provider; *and/or* at various times after the Ajust was implanted in Plaintiff." *See* Am. Compl. ¶¶ 73, 165 (emphasis added). As to where, the Amended Complaint alleges that Brown's implanting physician received such warnings "at the hospital where he conducted Plaintiff's implant surgery, his office or practice, at any training or educational sessions offered by Defendants, and/or at any professional organization meetings or presentations," *see id.* ¶¶ 72, 165 (emphasis added), and that Brown "likely received one of Defendant's pamphlet(s) from her implanting physician at one of the pre-operative appointment(s) and relied upon the same," *see id.* ¶ 183.

Brown's citation to so many sources, especially when made in the alternative, clearly demonstrate the lack of specificity in the Amended Complaint. Although Bard's alleged misrepresentations might appear to have more specificity when viewed on their own, they too are insufficient to satisfy Rule 9 given the breadth of the allegations as to who made them, when they were made, and how they were communicated. The Amended Complaint quotes Bard's alleged

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[14] The Amended Complaint repeats paragraph numbers 50 through 73, but with different allegations. *See* Am. Compl. pp. 13-23. This citation refers to the second paragraph 59. Throughout this Opinion, unless otherwise noted, any citation to one of these paragraph numbers is to the first time it appears in the Amended Complaint.

statements, but offers no information as to the when, where, or whom for each specific representation. The Amended Complaint also includes mere conclusory allegations that Brown and her implanting doctor relied on Bard's allegedly false misrepresentations. *See, e.g.,* Am. Compl. ¶ 68[15] (alleging that Brown and her implanting physician "justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendant's Ajust pelvic mesh product"). Brown suggests that the particularity requirement should be relaxed because the information was within Bard's "exclusive knowledge and control, the issues are complex, the fraud occurred over an extended period of time and consists of numerous acts, and discovery is not complete," *see id.* ¶ 148, but this would be contrary to Rule 9(b) and Third Circuit law. *See, e.g., Lum*, 361 F.3d at 223-24; *McLaughlin*, 172 F. Supp. 3d 804.[16]

Counts V (common law fraud), Count VIII (constructive fraud), and Count IX (negligent misrepresentation) are dismissed without prejudice and with leave to amend. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *45-47 (dismissing the fraud claims, which rested on a failure-to-warn theory, without prejudice); *McLaughlin*, 172 F. Supp. 3d at 832 (granting the plaintiff leave to amend the fraudulent misrepresentation claim that failed to satisfy the heightened pleading requirements in Rule 9); *Shelley*, 2013 U.S. Dist. LEXIS 95981, at *8 (finding the complaint

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15 This citation is to both paragraph's 68 in the Amended Complaint.

16 In *McLaughlin*, the plaintiff's allegations with respect to the negligent and fraudulent misrepresentation claims respecting an implanted birth control device were virtually identical. *See McLaughlin*, 172 F. Supp. 3d 804. The court found that the complaint failed to include any allegations "as to (1) the date on which each misrepresentation was made, (2) the precise source of certain of the misrepresentations, or (3) the circumstances under which each Plaintiff encountered each misrepresentation prior to having [the birth control device] implanted." *See id.* at 829. Additionally, the fraudulent misrepresentation count "only baldly allege[d] that Plaintiffs 'justifiably relied on the misrepresentations' and 'would have never had [the device] implanted had [they] been aware of the falsity of the representations.'" *See id.* The court concluded that as to the fraudulent misrepresentation claim, the complaint failed to "inject precision and some measure of substantiation into [the] allegations of fraud, and thus fail[ed] to state the circumstances of the alleged fraud with sufficient particularity as required by Rule 9(b)." *Id.* (quoting *Lum*, 361 F.3d at 224 (internal quotations omitted)); Fed. R. Civ. P. 9(b).

averred the defendants made affirmative misrepresentations that, *inter alia*, the Prolene TM soft mesh had "been tested, had a long history of safe use, and were *proven* safe." (citing the complaint at paragraph 59 (emphasis added)).

D. Count VI (breach of express warranty) is dismissed without prejudice.

Bard argues that Brown's breach of express warranty claim should be dismissed for failing to provide even the most basic of information concerning the actual content of the purported warranty, who made any such representation, to whom it was made, when and where it was made, in what format or media it was made, and under what circumstances. *See* Mot. 6-7. Bard asserts that while Brown cites its pamphlets about its products, she failed to even allege she received the same, also that any statement by Bard the mesh was "safe and effective" would have been insufficient to create an express warranty, and that Brown does not sufficiently allege she was induced by any express warranty to use the mesh because it was not sold directly to her. *See id.* 7-9. Brown responds that the Amended Complaint cites several examples of exact language Bard used in its promotional products and that Bard cannot disclaim liability when a purchaser is injured after extending an express warranty to the public that its product is harmless. *See* Opp. 8-9 (citing *Pritchard v. Liggett & Myers Tobacco Co.*, 350 F.2d 479, 484 (3d Cir. 1965) ("If a manufacturer extends to the public an express warranty that his product is harmless and thereafter a purchaser suffers personal injury as a result of its breach, the manufacturer cannot disclaim liability on the ground that there was no reliance on the warranty.")).

Under Pennsylvania law, because an express warranty is "specifically negotiated, . . . the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Goodman v. PPG Indus.*, 849 A.2d 1239, 1243 (Pa. Super. 2004). Express warranties are created in the following ways:

> (1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (3) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

13 Pa. C.S.A. § 2313(a). The seller need not use formal words such as "warrant" or "guarantee," nor need the seller have a specific intention to make a warranty. *See* 13 Pa. C.S.A. § 2313(b). However, "an affirmation merely of the value of the goods or a statement purporting to be merely the opinion of the seller or commendation of the goods does not create a warranty." *See id.*

For the reasons discussed above in section C(3) regarding the overly broad and conclusory allegations, Brown has failed to state a claim for breach of an express warranty. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *44 (concluding that the complaint, which alleged the defendant expressly warrantied that its pelvic mesh "does not contract or shrink" and "will permanently cure or alleviate . . stress urinary incontinence," failed to state a claim for breach of express warranty because it did not allege the specific materials containing these warranties or how the plaintiff became aware of the same); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 501-02 (W.D. Pa. 2012) ("Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently plead."). "To plausibly plead an express warranty claim, some level of meaningful detail is required." *McGrain* , 2021 U.S. Dist. LEXIS 143559, at *25. Although the Amended Complaint cites to several express warranties in Bard's pamphlets, it offers no specific information about such pamphlets. *See McLaughlin*, 172 F. Supp. 3d at 823-24 (dismissing the breach of express warranty claim where the complaint failed to allege the titles of, or any other identifying information for, the defendant's brochures allegedly containing the warranties or to allege any of the circumstances under which the plaintiff read or saw the warranty or how it became a basis of the

plaintiff's bargain with the defendant). Brown's failure to attach the pamphlet in which the alleged warranty was made or to provide more specific information about the same is fatal to this claim. *See McDonnell v. Flowonix Med. Inc.*, No. 21-1404, 2022 U.S. Dist. LEXIS 12916, at *16-17 (E.D. Pa. Jan. 25, 2022) (dismissing the breach of express warranty claim because the plaintiff failed to attach the contract providing the express warranty, without which the defendant was insufficiently informed as to the exact nature of the claim); *Groff v. Pete Kingsley Bldg., Inc.*, 543 A.2d 128, 130-31 (Pa. Super. 1988) (concluding the trial court erred by entering judgment on the pleadings in favor of the plaintiff because the written contract was not attached to any of the pleadings); Pa. R.C.P. No. 1019(i) ("When any claim or defense is based upon a writing, the pleader shall attach a copy of the writing, or the material part thereof, but if the writing or copy is not accessible to the pleader, it is sufficient so to state, together with the reason, and to set forth the substance in writing."). Additionally, Brown alleges only that she "likely" received one of these pamphlets "from her implanting physician at one of the pre-operative appointment(s) and relied[17] upon the same," *see* Am. Compl. ¶ 189, which is insufficient to state a claim. *See Webb v. Volvo Cars of N.A., LLC*, No. 13-2394, 2018 U.S. Dist. LEXIS 49095, at *18-20 (E.D. Pa. Mar. 26, 2018) ("Where an express warranty claim is based on advertisements, a plaintiff must allege that she saw or heard, and also believed, the allegedly false advertisements in order to satisfy her obligation to

[17] Brown's suggestion that a manufacturer's express liability to the public, in itself, is sufficient for a breach of express warranty claim for an injured purchaser is unavailing. Years after *Pritchard*, the Third Circuit Court of Appeals clarified that *Pritchard* stands only for the position that an injured purchaser need not *prove* reliance. *See Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 567-68 (3d Cir. 1990). The injured purchaser must nevertheless establish that "she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise" because only after "the buyer has become aware of the affirmation of fact or promise, [are] the statements . . . presumed to be part of the 'basis of the bargain.'" *See id.*

allege that advertisements formed the basis of the bargain."). Count VI (breach of express warranty) is dismissed without prejudice.[18]

E. Count VII (breach of implied warranty) is dismissed.

Bard asserts that strict liability and implied warranty claims are close cousins, such that Pennsylvania law also forbids implied warranty claims in the medical device context. *See* Mot. 5 (citing *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987) (dismissing the claim for breach of warranty of merchantability for prescription drugs because they are inherently unsafe under comment k)). Brown offers no response.

"The Third Circuit has endorsed the general understanding that the implied warranty of merchantability and the rule of strict products liability in the Restatement (Second) of Torts § 402A are essentially the same." *Smith*, 251 F. Supp. 3d at 854-55 (internal quotations omitted). Thus, for the reasons set forth above in regard to Brown's strict liability claims, the breach of implied warranty claim is dismissed with prejudice to the extent it is based on a design defect and without prejudice to the extent it is based on a manufacturer's defect. *See id.* (dismissing the breach of implied warranty claim based on a design defect with prejudice and based on a manufacturing defect without prejudice). *See also McGrain*, 2021 U.S. Dist. LEXIS 143559, at *16-17 (dismissing with prejudice the plaintiff's breach of implied warranty of merchantability claim for

[18] Although some courts have read *Hahn* broadly to preclude all non-negligence claims including breach of express warranty, *see, e.g. Kline v. Pfizer, Inc.*, No. 08-3238, 2008 U.S. Dist. LEXIS 101655, at *11 (E.D. Pa. Oct. 31, 2008), this Court agrees with those courts that have declined to expand *Hahn* to this extent, *see, e.g. Doughtery v. C.R. Bard*, No. 11-6048, 2012 U.S. Dist. LEXIS 100374, at *33-37 (E.D. Pa. July 18, 2012) (concluding that *Hahn* does not bar claims for breach of express warranty). At issue in *Hahn* were the applicable theories of liability for a manufacturer's failure to provide adequate warnings. *See Hahn*, 673 A.2d 888. In concluding that negligence is the only recognized theory, the *Hahn* court applied tort law. *See id.* at 889-91. The court did not consider a breach of express warranty claim, which is contractual in nature. *See Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *33-37 (concluding that Pennsylvania law does not preclude express-warranty claims against manufacturers of medical devices because such claims sound more in contract than in tort and allowing the plaintiff to amend her complaint).

the same reasons the strict liability claims regarding medical devices were dismissed); *Runner*, 108 F. Supp. 3d at 267-68 (dismissing the breach of implied warranty claim as barred by comment k).

Count VII (breach of implied warranty) is dismissed with prejudice to the extent it is based on a design defect and without prejudice to the extent it is based on a manufacturer's defect.

F. Brown has stated a claim for NIED (Count X).

"Under Pennsylvania law, a NIED claim arises only when (1) the defendant had a contractual or fiduciary duty toward the plaintiff; (2) the plaintiff was subjected to a physical impact; (3) the plaintiff was in a zone of danger and reasonably feared impending physical injury; or (4) the plaintiff observed a tortious injury to a close relative." *Runner*, 108 F. Supp. 3d at 272-73 (citing *Toney v. Chester Cnty. Hosp.*, 961 A.2d 192, 197-98 (Pa. Super. Ct. 2008)). When the plaintiff suffers emotional disturbance without any bodily harm, the plaintiff must allege something beyond "transitory, non-recurring physical phenomena, harmless in themselves." Restatement 2d of Torts, § 436A cmt. c (recognizing that "long continued mental disturbance . . . may be classified by the courts as illness").

Bard argues that the NIED claim is insufficiently pled because Brown fails to allege she suffers from emotional distress. In response, Brown asserts that she has alleged specific injuries caused by the Ajust and cites to the following allegation in the Amended Complaint: "Plaintiff has sustained physical and emotional injuries, including but not limited to pain and suffering, that were caused by psychological trauma (stress, anxiety, sadness, anger, etc.) and vice versa related to the Ajust product that was implanted in her." *See* Am. Compl. ¶ 251.

The Amended Complaint further alleges that Brown's "emotional distress was and is so severe that no reasonable person could have been expected to endure it. Plaintiff's emotional distress is medically diagnosable." *See id.* ¶ 252. Considering this and similar allegations, this Court finds that Brown has stated a claim at this early stage of the proceedings. *See Drumheller*,

2021 U.S. Dist. LEXIS 88941, at *49 (concluding that the plaintiff's allegations that she "suffered severe, medically diagnosable stress and anxiety as a result of her pelvic mesh implantation" was sufficient to state a claim for negligent infliction of emotional distress). *Accord Runner*, 108 F. Supp. 3d at 272-73 (dismissing the NIED claim because the plaintiff "failed to allege any emotional disturbance beyond the bald assertion that he 'suffered injuries'"). The Motion to Dismiss Count X (NIED) is denied.

G. Count XII (unjust enrichment) is dismissed with prejudice.

To state a claim for unjust enrichment "under Pennsylvania law, the plaintiff must demonstrate that [s]he conferred a benefit on the defendant, that the defendant knew of the benefit and accepted or retained it, and that it would be inequitable to allow the defendant to keep the benefit without paying for it." *Zafarana*, 724 F. Supp. 2d at 560 (citing *Mitchell v. Moore*, 729 A.2d 1200, 1203 (Pa. Super. Ct. 1999)). "Courts in this circuit have dismissed unjust enrichment claims in products liability actions where plaintiffs in fact received and used the product they purchased." *See McGrain*, 2021 U.S. Dist. LEXIS 143559, at *31. Such courts reason that where a plaintiff acknowledges that she received and used the defendants' product, the defendant cannot be found to have refused to provide such product. *See id.* at *30-31 (dismissing the unjust enrichment claim where the plaintiff received the product during a medical procedure and kept the product in her body for years). The plaintiff's dissatisfaction with the product received does not state an unjust enrichment claim. *See Drumheller*, 2021 U.S. Dist. LEXIS 88941, at *51. Here, Brown was implanted with the Ajust in October 2010, where it remained for more than six years before being removed in December 2016. She therefore cannot show that Bard refused to provide a service or product and any amendment would be futile. Count XII (unjust enrichment) is dismissed with prejudice. *See McGrain v. C.R. Bard, Inc.*, No. 21-1539, 2021 U.S. Dist. LEXIS 143559, at *31 (E.D. Pa. July 30, 2021) (dismissing the plaintiff's claim for unjust enrichment with prejudice).

V. CONCLUSION

At this stage of the proceedings, Brown has pled sufficient facts to put Bard on notice of her negligence claim and to state a claim based on design defect and on failure to warn. Brown has failed, however, to plead facts beyond a design defect to support a negligence claim based on a manufacturing defect and this theory of liability is dismissed from Count I (negligence) without prejudice. Brown has sufficiently alleged emotional distress to state a claim for NIED (Count X) and the request to dismiss this count is denied.

Because negligence is the only theory of recovery based merely on the failure to warn, the fraud claims in Counts V (common law fraud), Count VIII (constructive fraud), and Count IX (negligent misrepresentation) are dismissed without prejudice. The statutory fraud claim in Count XI, in contrast, is dismissed with prejudice because a consumer does not have a private cause of action under the UTPCPL against the manufacturer.

After consideration of the varying opinions on strict liability claims in products liability cases, this Court predicts that the Pennsylvania Supreme Court would bar strict liability claims based on design defect (Count II) and on failure to warn (Count IV) and dismisses these counts with prejudice. This Court predicts that the Pennsylvania Supreme Court would allow a strict liability claim based on a manufacturing defect, but Brown has failed to allege sufficient facts to state such a claim. Count III (manufacturing defect) is therefore dismissed without prejudice. Because Count VII (breach of implied warranty) is treated the same as the strict liability claims, it is dismissed with prejudice to the extent it is based on a design defect and without prejudice to the extent it is based on a manufacturer's defect.

Count VI (breach of express warranty) is dismissed without prejudice because Brown fails to allege sufficient facts about the pamphlets containing the express warranties on which she relies or to even allege that she read the same.

Finally, Count XII (unjust enrichment) is dismissed with prejudice because Brown cannot state a claim after having received the Ajust.

The Motion to Dismiss is therefore granted in part and denied in part as stated herein. Brown is granted leave to amend all claims dismissed without prejudice.

A separate order follows.

BY THE COURT:

*/s/ Joseph F. Leeson, Jr.*_____
JOSEPH F. LEESON, JR.
United States District Judge