IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH

ERIC MIKULA, AN INDIVIDUAL; Plaintiff, vs. C.R. BARD, INC., A NEW JERSEY BUSINESS CORPORATION; AND BARD PERIPHERAL VASCULAR, INC., AN ARIZONA BUSINESS CORPORATION; Defendants,	)	2:21-CV-01307-MJH

OPINION

Plaintiff, Eric Mikula, brings the within action against Defendants, C.R. Bard Incorporated and Bard Peripheral Vascular Incorporated (collectively Bard), alleging damages and injuries because of a defective inferior vena cava (IVC) filter. Mr. Mikula's Complaint alleges claims for Negligence (Count I), Negligent Misrepresentation (Count II), Strict Liability under 402A (Count III), Strict Liability under 402B (Count IV), Strict Liability-Failure to Warn (Count V), Breach of Express Warranty (Count VI), Breach of Implied Warranty of Fitness for a Particular Purpose (Count VII), and Violations of the Unfair Trade Practice and Consumer Protection Law (UTPCPL) (Count VIII[1]). (ECF No. 1-2). Bard has filed a Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 10). The matter is now ripe for consideration.

Upon consideration of Mr. Mikula's Complaint (ECF No. 1-2), Bard's Motion to Dismiss (ECF No. 10), the respective briefs (ECF Nos. 13-15), and for the following reasons, Bard's Motion to Dismiss will be granted in part and denied in part.

[1] The Complaint enumerates this Count as XIII, but the Court assumes that this was a scrivener's error. Accordingly, the Court will reference it as Count VIII.

I. Background

Mr. Mikula alleges that, in 2008, he was implanted with a Bard G2 inferior vena cava ("IVC") filter (the "Filter") for pulmonary embolism prophylaxis after being seriously injured in a motor vehicle accident. (ECF No. 1-2 at ¶¶ 9-11). Mr. Mikula further avers that on or about late-July 2020, he "began to experience lower back pain, tiredness in his lower extremities and shortness of breath on exertion." *Id*. at ¶ 12. A CT abdominal scan "showed results of an intact retrievable infrarenal IVC filter . . . with two struts perforating through the wall of the inferior vena cava by up to 5 mm." *Id*. at ¶¶ 33-34. A second CT scan revealed the presence of an IVC filter with a bilateral lower extremity clot burden extending from the IVC filter to the inferior vena cava and bilateral lower extremities." *Id*. at ¶¶ 14-15. Mr. Mikula underwent thrombolysis to remove the clot, had stents placed in his right and left common external iliac veins, and had the filter removed. *Id*. at ¶¶ 16-18. As a result, Mr. Mikula claims damages for "great pain," medical expenses, a loss of earnings, disfiguration, reduced earning capacity, and the inability "to enjoy the ordinary pleasures of life." *Id*. at ¶ 23.

In their Motion to Dismiss, the Bard defendants seek dismissal of the Complaint on the following grounds: 1. Mr. Mikula fails to state a plausible negligence claim (Count I); 2. Pennsylvania law bars Mr. Mikula's strict liability claims (Counts III, IV, and V); 3. Pennsylvania law bars Mr. Mikula's breach of implied warranty for a particular purpose claim (Count VII); 4. Mr. Mikula's breach of express warranty claim fails (Count VI); 5. Mr. Mikula's negligent misrepresentation claim fails (Count II) because a failure to warn claim in the guise of fraud is not recognized, the learned intermediary doctrine negates the reliance element, and it is inadequately pleaded; and 6. the learned intermediary doctrine bars Mr. Mikula's UTPCPL Count (VIII) claim.

II. Standard of Review

When reviewing a motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008)). "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.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (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." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556); *see also Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. "Factual allegations of a complaint must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. A pleading party need not establish the elements of a *prima facie* case at this stage; the party must only "put forth allegations that 'raise a reasonable expectation that discovery will reveal evidence of the necessary element[s].'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir.2009) (quoting *Graff v. Subbiah Cardiology Associates, Ltd.*, 2008 WL 2312671 (W.D. Pa. June 4, 2008)); *see also Connelly v. Lane Const. Corp.*, 809 F.3d 780, 790 (3d Cir.2016) ("Although a reviewing court now affirmatively disregards a pleading's legal conclusions, it must still . . . assume all remaining factual allegations to be true, construe those truths in the light

most favorable to the plaintiff, and then draw all reasonable inferences from them.") (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 154 n. 1 (3d Cir.2014)).

Nonetheless, a court need not credit bald assertions, unwarranted inferences, or legal conclusions cast in the form of factual averments. *Morse v. Lower Merion School District*, 132 F.3d 902, 906, n. 8 (3d Cir.1997). The primary question in deciding a motion to dismiss is not whether the Plaintiff will ultimately prevail, but rather whether he or she is entitled to offer evidence to establish the facts alleged in the complaint. *Maio v. Aetna*, 221 F.3d 472, 482 (3d Cir.2000). The purpose of a motion to dismiss is to "streamline [ ] litigation by dispensing with needless discovery and factfinding." *Neitzke v. Williams*, 490 U.S. 319, 326–327, (1989).

When a court grants a motion to dismiss, the court "must permit a curative amendment unless such an amendment would be inequitable or futile." *Great Western Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 174 (3d Cir. 2010) (internal quotations omitted). Further, amendment is inequitable where there is "undue delay, bad faith, dilatory motive, [or] unfair prejudice." *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002). Amendment is futile "where an amended complaint 'would fail to state a claim upon which relief could be granted.' " *M.U. v. Downingtown High Sch. E.*, 103 F. Supp. 3d 612, 631 (E.D. Pa. 2015) (quoting *Great Western Mining & Mineral Co.*, 615 F.3d at 175).

III. Discussion

A. Negligence-Count I

As noted by Bard and observed by the Court's review of Mr. Mikula's Complaint, Count I appears to aver three separate theories of negligence: negligent design, negligent manufacturing, and negligent failure to warn.

1. Negligent Design

Bard argues that Mr. Mikula's negligent design claim should be dismissed because the Complaint only contains conclusory and broad allegations. Bard contends that Mr. Mikula does not allege any facts regarding Bard's alleged conduct in its design of the Filter. Specifically, Bard maintains that the Complaint does not identify any policies or procedures allegedly in place for the design of the Filter or how said policies or procedures were insufficient or failed to prevent the alleged defect. Further, Bard argues that the Complaint does not describe alternative policies or procedures that Bard should have employed to meet any duty of care.

Mr. Mikula maintains that he has sufficiently alleged a design defect. He contends Bard had a duty to foreseeable users of their product to ensure the device was reasonably safe for its intended use.

In products liability claims sounding in negligence, Pennsylvania courts follow the Restatement (Second) of Torts. *Smith v. Howmedica Osteonics Corp.*, 251 F.Supp.3d 844, 852 (E.D. Pa. 2017). Negligent design claims are governed by § 398. *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434, 445 n. 13 (2014). To plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design. *Smith*, 251 F.Supp.3d at 854. Conclusory allegations that a product was negligently designed are not, on their own, sufficient to plead a viable claim. *Id*. (dismissing negligent design claim where "[t]he only explicit reference to the product's design is the conclusory allegation that [d]efendants were negligent in such design"). District courts in this circuit have consistently dismissed negligent design claims that are insufficiently pled. See, e.g., *Smith*, 251 F. Supp. 3d at 853-54 (dismissing negligent design claim because "it cannot be plausibly inferred" that defendants failed to exercise reasonable care in the adoption of a safe design as required by § 398); *Webb v. Stryker Corp.*, 2017 WL 1406899, at *3 (W.D. Pa. Apr.

20, 2017) (dismissing claim because plaintiff "ha[d] not identified the particular component of the implant system ... that was defectively designed"); *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 754 (W.D. Pa. 2011) (dismissing claim because "baldly stating that there are safer alternatives to [prescription drug], without providing factual support that they exist, is insufficient to survive a 12(b)(6) motion")

Here, Mr. Mikula alleges that the Filter was negligently designed in such a manner that it was unsafe for use as a DVT prophylaxis in trauma patients, otherwise not at risk for clots, such as himself, and in fact caused such patients to experience clotting. Mr. Mikula has further alleged that defendants were negligent by failing to adequately test the Filter for use as a trauma prophylaxis, particularly when it knew or should have known it was being used extensively for this purpose. (ECF No. 1-2 at ¶25(c),(j)). However, these allegations fail to address either the design of Bard's product or the availability of safer, feasible alternatives in any level of meaningful detail. Therefore, Mr. Mikula has not sufficiently pleaded a plausible negligent design claim.

Accordingly, Bard's Motion to Dismiss, as regard Mr. Mikula's Count I negligent design claim, will be granted.

2. Negligent Manufacturing

Bard next contends that Mr. Mikula's Negligent Manufacturing claim should be dismissed because the Complaint is devoid of any facts regarding Bard's manufacturing process. Specifically, Bard argues that a properly pleaded negligent manufacturing claim must aver "what went wrong during the manufacturing process." (ECF No. 13 at p. 6).

Mr. Mikula maintains that he has sufficiently alleged that Bard negligently manufactured the Filter for use as a pulmonary embolism prophylaxis in trauma patients knowing inadequate

testing had been completed for it to be safely used in this manner, knowing the risk of use outweighed the benefit or utility, knowing it contained adequate warnings and/or instructions for use. (ECF No. 1-2 at ¶25(a)- (e)). He further contends that the Complaint alleges that the filter was improperly manufactured and caused him to experience extensive blood clotting, the exact condition it was intended to mitigate, and one that he had no personal or family history of prior to the insertion of this device. *Id*.

Negligent manufacturing claims are governed by Restatement (Second) of Torts § 395. *Lance,* 85 A.3d at 445 n. 13. To plead a viable negligent manufacturing claim, "it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise a reasonable standard of care during the 'manufacturing process.' " *Smith,* 251 F. Supp. 3d at 853. Conclusory allegations that a product was negligently manufactured are not, on their own, sufficient to plead a viable claim. *Id.* (holding that "[w]ithout any factual allegation as to the nature of what went wrong during the manufacturing process, there is no plausible road to recovery for negligent manufacturing).

Here, as accurately argued by Bard, the Complaint does not allege facts concerning Bard's actual manufacturing process. Absent any factual allegation as to the nature of any deficiencies in the manufacturing process, Mr. Mikula cannot state a claim for negligent manufacturing. Therefore, the Complaint has not sufficiently pleaded a plausible negligent manufacturing claim.

Accordingly, Bard's Motion to Dismiss, as regard Mr. Mikula's Count I negligent manufacturing claim, will be granted.

3. Failure to Warn

Bard next argues that Mr. Mikula's failure to warn allegations lack sufficient facts about any warnings on the Filters, its labeling, packaging, or other associated materials. Mr. Mikula contends that his Complaint sufficiently alleges that Bard failed to warn his physicians of all dangers and risks associated with the use of the G2 Filter, and in particular, those risks associated with its use as a pulmonary embolism prophylaxis in trauma patients otherwise not at risk for DVT. (ECF No. 1 at ¶ 25 (f) – (h)).

Negligent failure to warn claims are governed by Restatement (Second) of Torts § 395. *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807, 810 (1984). To assert a viable negligent failure to warn claim, a plaintiff must allege facts sufficient to plausibly show that the defendant "fail[ed] to exercise reasonable care to inform those for whose use the product is supplied of the facts which make it likely to be dangerous." *Id.* Federal courts in Pennsylvania have found such claims viable where plaintiffs' complaints contained factual allegations as to the content of the warnings defendants should have provided. *See, e.g., Terrell v. Davol, Inc.*, 2014 WL 3746532, at *9-10 (E.D. Pa. July 30, 2014) (allowing negligent failure to warn claim where plaintiff alleged what information should have been given to her medical providers, setting forth an extensive list); *Houtz v. Encore Medical Corp.,* 2014 WL 6982767, at *4–5, (M.D. Pa. Dec. 10, 2014) (allowing claim where plaintiff alleged that manufacturer should have warned her/her doctors that a specific component of the device was defective and had a high risk of failure).

Here, Mr. Mikula's Complaint has set forth that Bard did not adequately warn his physician about the dangers and risks associated with the G2 Filter System. More specifically, the Complaint avers that Bard should have provided warnings in the content of its literature to physicians regarding long-term use of the Filter as a prophylaxis for trauma patients who were otherwise not at risk for DVT, the precise injury allegedly suffered by Mr. Mikula. Therefore,

at this stage, the Complaint's factual allegations sufficiently support a negligent failure to warn claim.

Accordingly, Bard's Motion to Dismiss, as regard Mr. Mikula's Count I negligent failure to warn claim, will be denied.

B. Strict Liability Claims-Counts III, IV, and V

Bard argues that Mr. Mikula's strict liability claims against medical device manufacturers are barred under Pennsylvania law. Mr. Mikula argues that the issue, whether strict liability claim can apply to medical device manufacturers, has yet to be addressed by either the Pennsylvania General Assembly or the Pennsylvania Supreme Court. Thus, Mr. Mikula maintains that the Pennsylvania Supreme Court would decline to extend blanket immunity from strict liability to medical device manufacturers.

Pennsylvania law presumes that products can be the subject of strict liability tort actions. *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328, 386 (2014) (citing Restatement (Second) of Torts § 402A cmt. b). In 1996, however, the Pennsylvania Supreme Court adopted comment k of the Restatement (Second) of Torts § 402A to bar strict liability claims against manufacturers of prescription drugs. *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 890 (1996). Comment k exempts "unavoidably unsafe products" that are "quite incapable of being made safe for their intended or ordinary use"—namely prescription drugs—from strict liability claims. Restatement (Second) of Torts § 402A cmt. k. In 2006, the Pennsylvania Superior Court in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006) extended *Hahn*'s holding to bar strict liability claims against prescription medical device manufacturers. In doing so, the *Creazzo* court explained that it could "find no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id*. at 32. However, the Pennsylvania Supreme

Court has not addressed whether to extend comment k to prescription medical devices. Recently, the Third Circuit has certified the following question to the Pennsylvania Supreme Court:

> Under Pennsylvania law, are prescription implantable medical devices categorically subject to strict liability, categorically immune from strict liability, or immune from strict liability on a case-by-case basis? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?

Ebert v. C.R. Bard, Inc., 20-2139, 2021 WL 2656690, at *6 (3d Cir. June 24, 2021), certified question accepted, 260 A.3d 81 (Pa. 2021).

In absence of controlling Third Circuit or Pennsylvania Supreme Court precedent on this issue, the Court is mindful of another Third Circuit principle:

> [a]lthough state intermediate appellate decisions are not automatically controlling where the highest court of the state has not spoken, where, as here, jurisdiction in federal court is based on diversity of citizenship, we must give serious consideration to the decisions of the intermediate appellate courts in ascertaining and applying state law.

Robinson v. Jiffy Executive Limousine Co., 4 F.3d 237, 242 (3d Cir. 1993). The foregoing would strongly favor the application of the Superior Court's holding in *Creazzo.*

Moreover, many federal courts have also predicted that the Pennsylvania Supreme Court would extend comment k to medical devices. *See McGrain v. C.R. Bard, Inc.*, ---F.Supp.3d.---, 2021 WL 3288601, at *5 (E.D. Pa. July 30, 2021) (holding the Pennsylvania Supreme Court would likely apply its reasoning in *Hahn* "to preclude strict liability manufacturing defect claims against medical device manufacturers."); *Lopez v. Ethicon Inc.*, No. 20-CV-2694, 2020 WL 5569770, at *5 (E.D. Pa. Sept. 16, 2020); *Rosenberg v. C. R. Bard, Inc.*, 387 F. Supp. 3d 572, 578 (E.D. Pa. 2019) ("like the Pennsylvania Superior Court and all of the federal district courts to confront this issue, the Court predicts that the Pennsylvania Supreme Court would extend comment k to prescription medical devices"); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804,

833–34 (E.D. Pa. 2016) (citing *Lance*, 85 A.3d at 453); *Runner v. C. R. Bard*, 108 F. Supp. 3d 261, 266 (E.D. Pa. 2015) (dismissing all strict liability claims against Bard in case involving implantable medical device); *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015) (same); *Terrell v. Davol, Inc.*, No. 13-CV-5074, 2014 WL 3746532, at *5 (E.D. Pa. July 30, 2014) (same); *Esposito v. I–Flow Corp.*, No. 10-CV-3883, 2011 WL 5041374, at *4 (E.D. Pa. Oct. 24, 2011); *Geesey v. Stryker Corp.*, No. 09-CV-2988, 2010 WL 3069630, at *3–*4 (E.D. Pa. Aug. 4, 2010); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (agreeing "with the district courts in the Eastern District of Pennsylvania that the same considerations exempting prescription drugs from the ambit of § 402A equally apply to prescription medical devices").

Here, this Court is persuaded that the current state of strict liability law, based upon Pennsylvania Superior Court precedent and decisions by other federal courts in Pennsylvania, compels a prediction that the Pennsylvania Supreme Court would preclude strict liability claims against medical device manufacturers. Therefore, Counts III, IV, and V fail under Pennsylvania law.

Accordingly, Bard's Motion to Dismiss, as regards Counts III, IV, and V, will be granted.

C. Breach of Implied Warranty for a Particular Purpose Claim-Count VI

Bard contends that Mr. Mikula's Breach of Implied Warranty of Fitness for a Particular Purpose claim fails for the same reasons his strict liability claims fail. Mr. Mikula likewise adopts his arguments above and reiterates that neither the Pennsylvania Supreme Court nor the General Assembly have extended Comment k to include prescription medical devices.

Pennsylvania law has recognized an interconnectedness between strict liability and implied warranty claims in the medical device context as well. In *Makripodis ex rel. Makripodis*

v. Merrell-Dow Pharms., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987), the Superior Court held "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes,' as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." *Id*. at 377 (relying on Restatement (Second) of Torts § 402A, comment k). The Superior Court thus affirmed the dismissal of a claim against a pharmacy for breach of the implied warranty of merchantability at the pleading stage. *Id*. Pennsylvania federal courts have applied *Makripodis*'s reasoning in the medical device realm to dismiss implied warranty claims, including fitness for particular purpose, under comment k. *See, e.g., Carson v. Atrium Med. Corp.*, No. 15-CV-830, 2016 WL 3181414, at *4 (W.D. Pa. June 8, 2016) (discussing *Makripodis* and explaining that because medical devices "fall under the umbrella of Comment k, and thus are unavoidably unsafe products, there can be no breach of implied warranty"); *Runner*, 108 F. Supp. 3d at 268 (dismissing implied warranty claim for same reason in case against Bard involving implantable medical device); *Kline v. Zimmer Holdings, Inc.*, No. 13-CV-513, 2013 WL 3279797, at *6–*7 (W.D. Pa. June 27, 2013); *Kester v. Zimmer Holdings*, Inc., No. No. 10-CV-00523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010); *Soufflas*, 474 F. Supp. 2d at 751–52; *Parkinson*, 315 F. Supp. 2d at 752–53. *McGrain* also dismissed an identical claim with regards to the same filter at issue in this case because "there can be no breach of implied warranty with respect to medical devices because they are 'unavoidably unsafe products' under Comment k." *McGrain*, 2021 U.S. Dist. LEXIS 143559 at *15.

Here, similar to the reasoning stated in the strict liability section above and the prevailing case law, an implied warranty claim is not supported in the context of a prescription medical device. Therefore, Plaintiff's implied warranty claim is incompatible with Pennsylvania law.

Accordingly, Bard's Motion to Dismiss, as regards Count VII, will be granted.

D. Express Warranty-Count VI

In his response in opposition to Bard's Motion to Dismiss, Mr. Mikula withdrew his Breach of Express Warranty claim. Accordingly, Bard's Motion to Dismiss, as regard Count VI, will be granted, and Count VI will be dismissed.

E. Negligent Misrepresentation-Count II

Bard contends that Mr. Mikula's negligent misrepresentation fails because the negligent misrepresentation claim is inadequately pleaded under the heightened pleading standards of Fed. R. Civ. P. 9(b) and/or under the general pleading standards of Fed. R. Civ. P. 8; because failure to warn claims in the guise of fraud are not recognized; and because the learned intermediary doctrine negates the reliance element of the negligent misrepresentation claim.

1. Pleading Adequacy

As for the adequacy of the pleading, Mr. Mikula maintains that his Complaint properly pleads a negligent misrepresentation claim because it is not subject the heightened pleading standards under Rule 9(b).

Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999) (citing *Gibbs v. Ernst*, 538 Pa. 193, 647 A.2d 882, 890 (Pa. 1994)).

Additionally, Rule 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other

conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The United States Court of Appeals for the Third Circuit has noted that Rule 9(b) "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges." *Kester v. Zimmer Holdings, Inc.*, Civ. No. 2:10-CV-00523, 2010 WL 2696467, *12 (W.D. Pa. June 16, 2010) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)). Although allegations of time, date or place satisfy the particularity requirements, a plaintiff can also satisfy the pleading requirements by pleading with a "degree of precision or some measure of substantiation into the fraud allegation." *Id*. (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)).

Here, Mr. Mikula has not met the pleading requirements for negligent misrepresentation under Rule 8 or 9. The Complaint alleges broadly that Bard "negligently and carelessly represented to Plaintiff, Plaintiff's physicians, and the general public that the Filter was safe, fit, and effective for use, including for prophylactic use in trauma patients." (ECF No. 1-2 at ¶ 29). Mr. Mikula's allegations omit the content of any representation, who said what to whom, in what medium, when, or where. Likewise, Mr. Mikula's Complaint pleads no more than conclusory facts without the requisite specificity as to purported representations, their falsity, or Mr. Mikula's (or his physician's) alleged reliance. The allegations contained in Count II do not place Bard on notice of the misconduct at issue, and without more precise allegations, Mr. Mikula's Complaint does not support the requisite elements of a negligent misrepresentation claim. Therefore, Count II of Mr. Mikula's Complaint will be dismissed; however, the Court will be granting leave to amend as discussed below.

Because the above disposition will afford leave to amend, the Court will address Bard's other arguments concerning "failure to warn" or "learned intermediary doctrine" in relation to negligent misrepresentation. Mr. Mikula's Brief in Response (ECF No. 14) does not address either of these arguments.

2. Failure to Warn

Bard argues that Mr. Mikula's negligent misrepresentation is a re-stated failure to warn claim in the guise of fraud, which is barred in a medical product case. Bard thus maintains, by extension, that a negligent misrepresentation claim is also barred in a medical product case. Bard bases its contention on the *Hahn* Pennsylvania Supreme Court case, which held that negligence was the sole theory under which a medical product manufacturer could be held liable for a failure to warn of its products' alleged hazards. *Hahn*, 673 A.2d at 891. As such, Bard argues that the negligent misrepresentation claim is barred because it arises under a category of fraud rather than negligence. Bard further asserts that federal courts in Pennsylvania have relied on *Hahn* to dismiss fraud claims against medical device manufacturers where the allegations in those claims overlap with the elements of a negligent failure to warn claim. *See, e.g., Runner*, 108 F. Supp. 3d at 268 (dismissing fraud claim against Bard in action involving implantable medical device); *Kester v. Zimmer Holdings*, Inc., 2010 WL 4103553, at *4 (W.D. Pa. Oct. 18, 2010) (holding that fraud allegations "are rooted in a theory of failure to warn," and therefore barred by *Hahn*, where plaintiff alleged merely that defendant manufacturers breached a duty to disclose their product's defective nature); *Kline v. Pfizer, Inc.*, 2009 WL 32477, at *4–5 (E.D. Pa. Jan. 6, 2009) (relying on *Hahn* to hold the same).

The cases that are relied upon by Bard dismissed fraud claims but not negligent misrepresentation claims. Indeed, *Hahn* itself did not address either negligent misrepresentation

or fraud. Whereas in *Kline*, the court dismissed a fraud count upon reconsideration (see supra), but it permitted a negligence and negligent misrepresentation claim to proceed, holding that a drug manufacturer could be liable for negligent misrepresentation for failing to adequately warn a plaintiff's healthcare providers regarding the dangers of the drug. *Kline v. Pfizer, Inc.*, CIV.A.08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008); *see also Bell v. Boehringer Ingelheim Pharm., Inc.*, 2018 WL 928237, at *4 (W.D. Pa. Feb. 15, 2018); *Leonard v. Taro Pharmaceuticals USA, Inc.*, 2010 WL 4961647, at *5 (W.D. Pa. Dec. 2, 2010). In *Leonard*, the court dismissed the fraud claim because it contained an element of intent that removes it from the realm of negligence, but the court permitted the negligent misrepresentation claim to proceed. Negligent misrepresentation differs from intentional misrepresentation or fraud in that, in a negligent misrepresentation claim, a speaker need not know his or her words are untrue, whereas the speaker in the intentional misrepresentation or fraud context knows that his or her words are untrue. *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (1999).

Here, Mr. Mikula alleges that Bard "negligently provided Plaintiff, Plaintiff's healthcare providers and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning the G2 Filter System; including but not limited to misrepresentations relating to the safety, efficacy, failure rate and approved uses of the G2 Filter System." (ECF No. 1-2 ¶ 27). The Complaint's allegations sound in negligence, but not in fraud. So, while *Hahn* may direct the dismissal of non-negligent claims, such as strict liability or fraud, it does not reach so far as to mandate the dismissal of a negligent misrepresentation claim in the context of a claim against a medical device manufacturer. Accordingly, Mr. Mikula's negligent misrepresentation claim will not be dismissed based upon Bard's arguments that the failure to warn negligent misrepresentation count is a claim for fraud.

3. Learned Intermediary Doctrine

Bard also argues that Mr. Mikula's negligent misrepresentation claim fails under the application of the "learned intermediary doctrine."

"It is well-settled that under Pennsylvania's 'learned intermediary doctrine,' the duty of a drug manufacturer to warn of the possible dangers and side effects of prescription drugs runs to the physician and not to the patient or to the general public." *Kline v. Pfizer, Inc.*, No. 08–3238, 2008 WL 4787577, * 3 (E.D.Pa. Oct.31, 2008) (citations omitted). Indeed, [a] prescription drug manufacturer has "'a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous ...' However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer.'" This is so because the physician acts as a "learned intermediary" between the manufacturer and consumer, and can use the information obtained from the manufacturer, as well as his independent medical knowledge and knowledge of the patient's medical history, in deciding whether or not to prescribe a certain prescription to a certain patient. *Id*. (*quoting Makripodis v. Merrell–Dow Pharm. Co.*, 361 Pa.Super. 589, 523 A.2d 374, 378 (Pa.Super.1987)) (internal citations omitted).

While a defendant may owe no duty to warn a plaintiff or the public, a defendant may still be held liable under a theory of negligent misrepresentation if Plaintiff can prove that Defendants breached their duty to Plaintiff's prescribing physician. *See Kline v. Pfizer, Inc.*, 2008 WL 4787577, at * 3 (finding negligent misrepresentation claim survives motion to dismiss where plaintiff alleges drug manufacturer failed to adequately warn plaintiff's health care providers).

Therefore, the learned intermediary doctrine does not, in and of itself, preclude Mr. Mikula's negligent misrepresentation claim. Instead, Mr. Mikula's negligent misrepresentation

claim, based upon Bard's alleged failure to adequately warn his prescribing physician, may be sufficient if said claim satisfies the pleading requirements for said cause of action. *See Hanover Ins. Co. v. Ryan*, 2007 WL 4456158 at *9 (E.D.Pa. Dec.17, 2007). However, this Court has previously determined that Mr. Mikula's negligent misrepresentation claim has not been adequately pleaded, and those insufficiencies will need to be addressed upon amendment.

Accordingly, Bard's Motion to Dismiss, as regard Count II, will be granted.

F. UTPCPL Claim-Count VIII

In his response in opposition to Bard's Motion to Dismiss, Mr. Mikula withdrew his UTPCPL claim. Accordingly, Bard's Motion to Dismiss, as regard Count VIII, will be granted, and Count VIII will be dismissed.

G. Leave to Amend

In his response, Mr. Mikula requests leave to amend his complaint in the event this Court dismisses his claims. If properly requested, leave to amend "should ... 'be freely given when justice so requires.' " *See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 252 (3d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). The Third Circuit has held that "[d]ismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." *Alston v. Parker*, 363 F.3d 229, 236 (3d Cir. 2004).

Here, for the reasons set forth above, Mr. Mikula's claims for strict liability, and breach of implied warranty of fitness for a particular purpose, Counts III, IV, V, and VII, are precluded as a matter of law. As such, amendment of these claims would be futile, and there will be no leave to amend as to those counts. Mr. Mikula's claims, premised on negligent design, negligent manufacturing, and negligent misrepresentation, Counts I and II, suffer from fundamental

pleading insufficiencies. Therefore, Mr. Mikula will be granted leave to amend these claims, provided Plaintiff can plead facts to support the requisite elements.

IV. Conclusion

After consideration of Mr. Mikula's Complaint (ECF No. 1-2), Bard's Motion to Dismiss (ECF No. 10), the respective briefs (ECF Nos. 13-15), and for the foregoing reasons, Bard's Motion to Dismiss will be granted in part and denied in part. Bard's Motion to Dismiss the negligent design and negligent manufacturing components of Count I will be granted. Bard's Motion to Dismiss the negligent failure to warn component of Count I will be denied. Bard's Motion to Dismiss Counts II, III, IV, V, VI, VII, and VIII will be granted. In accordance with the above, Mr. Mikula will be granted leave to amend his Count I, negligent design and negligent manufacturing claims, and his Count II, negligent misrepresentation claim. A separate order will follow.

DATED this17th day of December, 2021.

BY THE COURT:

MARILYN J. HORAN
United States District Judge