IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SARAH ROSENBERG,	:	CIVIL ACTION
	:	NO. 18-4767
Plaintiff,	:	
	:	
v.	:	
	:	
C.R. BARD, INC.,	:	
	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. June 25, 2019

I. INTRODUCTION

In this products liability case, an individual asserts both negligence and strict liability claims against a prescription medical device manufacturer. In doing so, the Court is presented with an important question of state law that has often been raised but has effectively evaded review by the Pennsylvania Supreme Court: does Pennsylvania law recognize a strict liability claim for a manufacturing defect of a prescription medical device?

The Court predicts that the answer to this question is "no." But given the growing debate among federal district courts regarding this issue, the Court certifies the question to the Third Circuit.

II. BACKGROUND

Plaintiff Sarah Rosenberg suffered from stress urinary incontinence ("SUI") that required surgical intervention. Compl. ¶¶ 1, 7, ECF No. 1. On November 12, 2012, Plaintiff's doctors implanted Defendant C.R. Bard, Inc.'s Align synthetic mesh system in Plaintiff to treat her SUI. Id. ¶ 7. Following this procedure, Plaintiff began experiencing complications such as severe lower quadrant pain, dyspareunia, and mesh erosion. Id. ¶ 8. According to Plaintiff, these complications required further medical care and treatment, including surgical interventions. Id. Plaintiff alleges that she is more likely than not to need to undergo additional procedures related to complications that she attributes to Defendant's pelvic mesh system. See id. ¶ 21.

Plaintiff alleges that she neither knew nor could have reasonably known that her complications were related to design or manufacturing defects of the pelvic mesh system until July 27, 2017. Id. ¶ 9. Further, Plaintiff alleges that, despite safety communications from the FDA in 2011 observing the risks associated with pelvic mesh systems as well as various reports from physicians, patients, and the World Health Organization noting complications from pelvic mesh implantation, Defendant continued to advertise and promote its pelvic mesh system as a

safe and effective treatment for SUI and pelvic organ prolapse. Id. ¶¶ 10-15, 17. According to Plaintiff, Defendant knew that its pelvic mesh system had a defect attributable to erosion, shrinkage, and/or hardening of the mesh material and that there could be life-changing and irreversible complications from pelvic mesh removal. Id. ¶ 16. Plaintiff further alleges that Defendant failed to provide sufficient warnings of the risks of pelvic mesh implantation and concealed the known risks associated with pelvic mesh implantation. Id. ¶¶ 17-22.

Plaintiff filed a complaint against Defendant, originally bringing thirteen causes of action, including strict liability, negligence, and fraud. ECF No. 1. Defendant then filed a motion to dismiss for failure to state a claim. ECF No. 6. In her response in opposition to Defendant's motion to dismiss, Plaintiff abandoned all but three of her original causes of action: (1) strict liability for design and manufacturing defects, (2) strict liability for failure to warn, and (3) negligence. ECF No. 10. Plaintiff's abandoned claims (Counts IV-XIII) will be dismissed with prejudice.

The Court heard argument on Defendant's motion to dismiss, and the motion is now ready for disposition.

III. LEGAL STANDARD

A party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering such a motion, the Court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." DeBenedictis v. Merrill Lynch & Co., 492 F.3d 209, 215 (3d Cir. 2007) (internal quotation marks removed). To withstand a motion to dismiss, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. Although a plaintiff is entitled to all reasonable inferences from the facts alleged, a plaintiff's legal conclusions are not entitled to deference, and the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

The pleadings must contain sufficient factual allegations so as to state a facially plausible claim for relief. See, e.g., Gelman v. State Farm Mut. Auto. Ins. Co., 583 F.3d 187, 190 (3d Cir. 2009). "'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.'" Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In deciding a Rule 12(b)(6) motion, the Court limits its inquiry to the facts alleged in the complaint and its attachments, matters of public record, and undisputedly authentic documents if the plaintiff's claims are based upon these documents. See Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994); Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

Before dismissing a complaint as deficient, the Court should grant leave to amend. See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 252 (3d Cir. 2007). The Third Circuit has previously 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).

IV. DISCUSSION

Defendant moves to dismiss Plaintiff's complaint for two reasons: (1) Pennsylvania law bars all strict liability claims for prescription medical devices, and (2) Plaintiff's negligence

claim is insufficiently pleaded. Each argument is discussed in turn.

A. Pennsylvania Law Bars All Strict Liability Claims for Prescription Products

1. Pennsylvania's Strict Liability Law

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., 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.

2. Comment k Applies to Prescription Drugs and Prescription Medical Devices

But where does comment k apply? To start, comment k explicitly contemplates its application to "many . . . drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Restatement (Second) Torts § 402A cmt. k.

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 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 v. Simplicity Mfg., Inc., 563 F.3d 38, 45-46 (3d Cir. 2009). Therefore, the Court must predict whether the Pennsylvania Supreme Court would expand the scope of comment k to reach prescription medical devices.

To answer this question, the Court first turns to the plain language of comment k. To begin, as previously observed, comment k specifically contemplates its application to prescription products such as "drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Restatement (Second) of Torts § 402A cmt. k. Therefore, comment k's plain language appears to include prescription medical devices because "prescription" medical devices, by definition, are products that require a physician's prescription, just as "prescription" drugs also, by

definition, require a physician's prescription. For the purposes of comment k, no meaningful distinction can be drawn between prescription drugs and prescription medical devices. Indeed, some prescription medical treatments include both a prescription drug delivered by a prescription medical device, e.g., an EpiPen® or an insulin pump.

Second, case law, too, supports this Court's prediction. Although, as noted above, the Pennsylvania Supreme Court has not expressly extended its comment k jurisprudence to prescription medical device manufacturers, the Pennsylvania Superior Court has done so. 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 an implantable neurological electrical stimulation device. Id. at 26, 31. In so holding, the Pennsylvania Superior Court explained that it "[found] no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." Id. at 31. Therefore, the Pennsylvania Superior Court concluded that comment k applied to prescription medical devices and thus strict liability was not a viable basis for liability in that case. Id. To that end, citing both Hahn and Creazzo, the Pennsylvania Suggested Standard Civil Jury Instructions

subcommittee note to § 23.00 regarding the duty to warn in the prescription drug and medical device context expressly states that "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." Pa. Suggested Standard Civil Jury Instructions § 23.00 (May 2015).

Moreover, every federal district court to confront this issue has predicted that the Pennsylvania Supreme Court would extend comment k's application to prescription medical devices.[1] Therefore, 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.

[1] See, e.g., Buck v. Endo Pharm., Inc., Civil Action No. 19-837, 2019 WL 1900475, at *1 (E.D. Pa. Apr. 29, 2019); Horsmon v. Zimmer Holdings, Inc., No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004); Murray v. Synthes (U.S.A.), Inc., No. 95-7796, 1999 WL 672937, at *7-8 (E.D. Pa. Aug. 23, 1999); Burton v. Danek Med., Inc., No. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999); Taylor v. Danek Med., Inc., No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998).

3. Applying the Prescription Drug Jurisprudence to Prescription Medical Devices

Having predicted that the Pennsylvania Supreme Court would apply comment k to prescription medical devices, the Court next turns to the types of strict liability claims that comment k precludes.

To begin, the plain language of comment k precludes strict liability claims for design defects because it specifically carves out "unavoidably unsafe" products from the reach of Section 402A. See Restatement (Second) Torts § 402A cmt. k. Comment k explains that prescription products such as "drugs, vaccines, and the like" are within this category of "unavoidably unsafe" products. Id. To that end, the Pennsylvania Supreme Court has acknowledged the "dangerous propensities" that may accompany prescription drugs and has held that strict liability is unavailable "merely because of [such] dangerous propensities." Incollingo v. Ewing, 282 A.2d 206, 219 (Pa. 1971), abrogated on other grounds by Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980). The Pennsylvania Supreme Court has also explained that strict liability is not available for prescription drugs, which may be "useful and desirable products" that carry a "known but apparently reasonable risk." Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984). In other words,

prescription drugs are by their very nature "unavoidably unsafe products" such that there can be no strict liability for a design defect.[2] See also Smith v. Howmedica Osteonics Corp., 251 F. Supp. 3d 844, 848 (E.D. Pa. 2017) ("Where Comment k applies, its plain language bars strict liability claims that assert a design defect.").

But a design defect is not the only form a strict liability claim may take. In the 1990s, the Pennsylvania Supreme Court addressed whether comment k precluded strict liability claims for a failure to warn. At first blush, it might appear that the plain language of comment k preserves a strict liability claim if the product was not "properly prepared" or "accompanied by proper directions and warning." Restatement (Second) Torts § 402A cmt. k. But the Pennsylvania Supreme Court has said otherwise. See Hahn, 673 A.2d at 890-91. Specifically, the

[2] The Court notes that the Pennsylvania Supreme Court has recognized a strict liability claim for a design defect regarding a surgical tool, known as an endocutter, which is "a linear cutting and stapling instrument, used in place of traditional scalpel-and-suture techniques in various surgical applications." See Beard v. Johnson & Johnson, Inc., 41 A.3d 823, 824-25 (Pa. 2012). But a surgeon's tool appears to be distinguishable from a "prescription" medical device like pelvic mesh or the implantable neurological electrical stimulation device in Creazzo. In fact, this distinction may, at least in part, explain why there is no discussion of comment k in Beard. Therefore, it appears that the mere fact that a device is used in the medical context does not mean that it is a "prescription" medical device for purposes of comment k.

Pennsylvania Supreme Court has interpreted the "proper directions and warning language" to mean that "where the adequacy of warnings associated with prescription drugs is at issue . . . the manufacturer's negligence . . . is the only recognized basis of liability." Id. (emphasis added). Therefore, in Pennsylvania, under comment k, strict liability claims for design defects and failure-to-warn claims lie outside of the reach of Section 402A.

Importantly, however, Pennsylvania case law has not squarely interpreted comment k similarly to foreclose strict liability claims for manufacturing defects. Therein lies the central issue in this case.

4. Strict Liability Claims for Manufacturing Defects regarding Prescription Medical Devices are Prohibited

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. See Hahn, 673 A.2d at 891 (discussing negligence as the only basis for liability where the warnings were inadequate); Incollingo, 282 A.2d at 219 (holding that a drug manufacturer was not strictly liable "merely because of the dangerous propensities of the

product"). But there is no similar Pennsylvania Supreme Court case prohibiting strict liability claims for manufacturing defects in the prescription product context.

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. In several cases, in an effort to determine whether comment k bars strict liability manufacturing defect claims for prescription products, district courts were guided by the decision of the Pennsylvania Superior Court in Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010) [hereinafter Lance I].

In Lance I, following the death of a woman who had taken a prescription diet drug, the woman's estate brought three claims against the drug manufacturer: (1) "Negligence—Unreasonable Marketing of a Dangerous Drug;" (2) "Negligence—Unreasonable Failure to Remove [the drug] from the Market;" and (3) standard negligence. Id. at 162-64. The Superior Court read the "Unreasonable Marketing of a Dangerous Drug" claim as a "design defect claim sounding in products liability" and then explained that, pursuant to comment k, strict liability claims for design defects of prescription drugs were not cognizable. Id. at 164.

Because the Superior Court interpreted the "Unreasonable Marketing of a Dangerous Drug" claim as a strict liability design defect claim rather than as negligence claim, it held that the claim was not cognizable. Id. But in discussing strict liability claims in the prescription drug context, the Superior Court added that "a plaintiff may advance only two possible strict liability claims," one of which is a manufacturing defect claim. Id. at 164-65.

Guided, at least in part, by this discussion in Lance I, which appears to contemplate a strict liability manufacturing defect claim in the prescription drug context, some courts have allowed a strict liability claim for a manufacturing defect of a prescription medical device to proceed. See, e.g., Indeluca v. C.R. Bard, Inc., 17-CV-1355, 2018 WL 807158, at *3 (W.D. Pa. Feb. 9, 2018); Smith v. Howmedica Osteonics Corp., 251 F. Supp. 3d 844, 850 (E.D. Pa. 2017); Wagner v. Kimberly-Clark Corp., 225 F. Supp. 3d 311, 315-19 (E.D. Pa. 2016); Dougherty v. C.R. Bard, Inc., 2012 WL 2940727, at *4-6 (E.D. Pa. July 18, 2012).

The shelf-life of Lance I, however, was short. In Lance II, the Pennsylvania Supreme Court, reversing the Superior Court on other grounds, observed, in a footnote, that "[t]he [Lance I] panel's reasoning in analyzing a negligence claim as one sounding in strict liability [was] neither clear nor apt." Lance

II, 85 A.3d at 440 n.8. Additionally, the Pennsylvania Supreme Court noted that "it seem[ed] that the [Superior Court's Lance I] panel equated the phrase 'products liability' with 'strict liability.'" Id. The Pennsylvania Supreme Court then went on to explain that the Superior Court's analysis of the "Unreasonable Marketing of a Dangerous Drug" claim—"which was expressly stated in negligence—as if it were grounded upon strict liability, [was] deeply flawed." Id. Therefore, this Court concludes that, after Lance II, the Superior Court's observation that a plaintiff may bring a strict liability manufacturing defect claim in the prescription drug context is entitled to no weight.

In Lance II, the Pennsylvania Supreme Court also explained that "for policy reasons [it] ha[d] declined to extend strict liability into the prescription drug arena." Id. at 453. The Pennsylvania Supreme Court, however, added that it "ha[d] not immunized drug companies from other governing aspects of Pennsylvania tort law delineating product-manufacturer duties and liabilities." Id. at 453. In other words, although strict liability claims are not cognizable in the prescription drug context, negligence claims remain cognizable after Lance II.

Therefore, following the Pennsylvania Supreme Court's treatment of the issue in Lance II and given the previous discussion regarding the lack of a meaningful distinction

between the legal treatment of prescription drugs and prescription medical devices, the Court predicts that the Pennsylvania Supreme Court would not recognize a strict liability claim for a manufacturing defect of a prescription medical device.

Finally, both Plaintiff and several district courts have pointed to the Pennsylvania Supreme Court's recent decision in Tincher v. Omega Flex, Inc. as standing for the broad proposition that "[n]o product is expressly exempt" from strict liability. Tincher, 104 A.3d at 382. But the Pennsylvania Supreme Court specifically noted an exception in Tincher to this general proposition, by immediately following this broad statement with a "but see" citation to Hahn. In citing Hahn, the Pennsylvania Supreme Court signaled that at least for a claim regarding the adequacy of a prescription drug's warnings, "strict liability is not recognized as a basis for liability." Id. at 367 n.13, 396. Therefore, nothing in Tincher reopens the door to strict liability claims for prescription drugs or prescription medical devices, a door Hahn had firmly closed.

5. Certification for Interlocutory Appeal

Recognizing that the strict liability claim for a manufacturing defect is open to debate and is a controlling

question of law, the Court certifies this question to the Third Circuit for interlocutory appeal.

Pursuant to 28 U.S.C. § 1292(b), a district court may certify an order, not otherwise appealable, for interlocutory appeal, which the Court of Appeals may hear, in its discretion, even if there are pending claims in the litigation. 28 U.S.C. § 1292(b). Moreover, a district court may certify its orders sua sponte. See United States v. Stanley, 483 U.S. 669, 673 (1987); Gen. Pub. Utils. Corp. v. United States, 745 F.2d 239, 240 (3d Cir. 1984); Amerisourcebergen Drug Corp. v. Meier, No. Civ.A. 03-CV-6769, 2005 WL 2645000, at *3 (E.D. Pa. Oct. 14, 2005).

A district court may certify a question under 28 U.S.C. § 1292(b) if (1) there is a "controlling question of law;" (2) "there is substantial ground for difference of opinion" regarding that question; and (3) "immediate appeal . . . may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). "A controlling question of law must encompass at the very least every order which, if erroneous, would be reversible error on final appeal." Katz v. Carte Blanche Corp., 496 F.2d 747, 755 (3d Cir. 1974).

Here, the Court seeks to certify the following question: does Pennsylvania law recognize a strict liability claim for a manufacturing defect of a prescription medical device?

In this case, the Court predicts that the Pennsylvania Supreme Court would extend comment k's mantle of protection both to prescription drugs and prescription medical devices and that, under this view, comment k precludes strict liability claims based on a manufacturing defect. If, on appeal, however, this prediction is found to be erroneous, then it would compel reversal. Therefore, the question certified to the Third Circuit is a controlling question of law.

Second, there is "substantial ground for difference of opinion" as to whether, notwithstanding the adoption of comment k, there remains a carve-out for strict liability manufacturing defect claims for prescription medical devices. Indeed, there are at least nine district courts within the Third Circuit that have allowed such a strict liability claim to proceed[3] and at

[3] See Wallace v. Boston Sci. Corp., 3:18-CV-01839, 2019 WL 137605, *1 (M.D. Pa. Jan. 8, 2019); Ideluca, 2018 WL 807158, at *3; Smith, 251 F. Supp. 3d at 851; Wagner, 225 F. Supp. 3d at 318–19; Kline v. Zimmer Holdings, Inc., Civil Action No. 13-513, 2013 WL 3279797, at *1 (W.D. Pa. June 27, 2013); Bergstresser v. Bristol-Myers Squibb Co., Civil Action No. 3:12-1464, 2013 WL 1760525, at *6 (M.D. Pa. Apr. 24, 2013); Tatum v. Takeda Pharm. N. Am., Inc., Civil Action No. 12-1114, 2012 WL 5182895, at *5 (E.D. Pa. Oct. 19, 2012); Killen v. Stryker Spine, Civil Action No. 11-1508, 2012 WL 4498865, at *5 (W.D. Pa. Sept. 28, 2012); Doughtery, 2012 WL 2940727, at *6.

least five district courts that have specifically explained that comment k bars all three types of strict liability claims.[4]

Third, this interlocutory appeal would "materially advance the ultimate termination of the litigation," as required by § 1292(b). Determining whether any of Plaintiff's strict liability claims survive will conserve resources and protracted litigation both in this case and in future cases.

Therefore, all three requirements for interlocutory appeal are met, and certification is appropriate.[5]

[4] See Kramme v. Zimmer, Inc., Civil Action No. 3:11-CV-00916, 2015 WL 4509021, at *5 (M.D. Pa. July 24, 2015); Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015); Cogswell v. Wright Med. Tech., Inc., No. 15-295, 2015 WL 4393385, at *7 (W.D. Pa. July 16, 2015); Terrell v. Davol, Inc., Civil Action No. 13-5074, 2014 WL 3746532, at *5 (E.D. Pa. July 30, 2014); Rowland v. Novartis Pharms. Corp., 34 F. Supp. 3d 556, 568-69 (W.D. Pa. 2014).

[5] As an important and controlling question of state law, particularly in light of the closure of the pelvic mesh MDL, the Court is compelled to recognize this question as one best suited for the Pennsylvania Supreme Court. Indeed, the question continues to evade review by the Pennsylvania Supreme Court because cases are frequently brought in or removed to federal court and subsequently settled before even reaching the Third Circuit. Therefore, in this case, the Third Circuit may wish to consider whether it is appropriate to certify the question to the Pennsylvania Supreme Court. See Pa. R. App. P. 3341(a).

B. Plaintiff's Negligence Claim is Not Sufficiently Pleaded

In Count III of her complaint, Plaintiff brings a claim for negligence. A negligence claim requires Plaintiff to allege facts showing that Defendant owed a duty of care and breached that duty, which caused Plaintiff harm and resulted in damages. Although Plaintiff has alleged various facts in the beginning of her complaint, there are only four paragraphs under the Count III heading, one of which merely incorporates by reference the preceding allegations of the complaint and the remainder of which contain largely conclusory statements regarding duty, breach, and causation. Compl. ¶¶ 37-40. But even drawing all inferences from the facts alleged in the light most favorable to Plaintiff, this type of pleading fails to meet the requirements of Federal Rule of Civil Procedure 8(a)(2). Simply put, Plaintiff has failed to plead "a short and plain statement of the claim showing that [she] is entitled to relief." Fed. R. Civ. P. 8(a)(2).

The Third Circuit has criticized such an approach to pleading a complaint, referring to it as "shotgun pleading." Hynson v. City of Chester Legal Dep't, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988). One of the reasons why the Third Circuit has criticized this approach and effectively adopted a policy

against "shotgun pleading" is that it fails "to provide the defendant with sufficient notice of the claims asserted." Id.

In this case, Plaintiff has failed to connect the facts alleged in the beginning of her complaint with the specific negligence claim she asserts. Indeed, the Court (and Defendant) are left to guess not only which facts support Plaintiff's negligence claim but also which aspect of Defendant's conduct Plaintiff asserts was negligent. Therefore, Plaintiff's negligence claim will be dismissed without prejudice with leave to amend.

V. CONCLUSION

For the foregoing reasons, the Court dismisses Plaintiff's strict liability claims with prejudice and dismisses Plaintiff's abandoned claims with prejudice. The negligence claim, however, is dismissed without prejudice with leave to amend. The Court certifies to the Third Circuit the question of whether Pennsylvania recognizes a strict liability claim for a manufacturing defect of a prescription medical device.

An appropriate order follows.