

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

MOLLY KESTER,)
Plaintiff,)
) 2:10-cv-00523
vs.)
)
ZIMMER HOLDINGS, INC., I-FLOW)
CORPORATION, HOSPIRA, INC., APP)
PHARMACEUTICALS, LLC, APP)
PHARMACEUTICALS, INC., ABRAXIS)
BIOSCIENCE, LLC AND ABRAXIS)
BIOSCIENCE, INC.,)
Defendants.)

MEMORANDUM OPINION AND ORDER OF COURT

Pending before the court are the MOTION OF APP PHARMACEUTICALS, LLC, APP PHARMACEUTICALS, INC., ABRAXIS BIOSCIENCE, LLC, AND ABRAXIS BIOSCIENCE, INC. TO DISMISS UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) (collectively, “APP” or the “APP Defendants”) (Doc. No. 59) with brief in support (Doc. No. 60), the MOTION OF HOSPIRA INC. TO DISMISS UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) (Doc. No. 62) with brief in support (Doc. No. 63), and the MOTION OF ZIMMER HOLDINGS, INC. TO DISMISS UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) (Doc. No. 72) with brief in support (Doc. No. 73). Plaintiff filed Responses in Opposition to the Motions to Dismiss against Defendants Hospira (Doc. No. 67) and APP (Doc. No. 68). Plaintiff also contests Zimmer’s Motion to Dismiss but filed her Opposition to Zimmer’s Motion to Dismiss (Doc. No. 48) prior to the District Court for the Eastern District of Pennsylvania granting Zimmer’s Motion to Transfer Venue (Doc. No. 55). Only Hospira (Doc. No. 81) and the APP Defendants (Doc. No. 80) filed a Reply in Response to Plaintiff’s Opposition. Accordingly, the motions are now fully briefed and ripe for disposition.

Factual Background

This case arises out of the health conditions allegedly suffered by Plaintiff, which occurred subsequent to her shoulder surgery on November 13, 2007. The Complaint alleges that Plaintiff's orthopedic surgeon implanted a Zimmer¹ ambulatory postoperative "pain pump" into her shoulder that continuously injected "pain relief medication" into her glenohumeral shoulder joint following the procedure. As a result, Plaintiff contends that she was diagnosed with chondrolysis and experienced loss of range of motion and the functional use of her arm, as well as other associated injuries.

According to Plaintiff, glenohumeral chondrolysis is the "progressive destruction of articular cartilage in the glenohumeral joint (the joint that connects the arm to the shoulder) leading to secondary joint space narrowing, which results in constant pain and loss of full use of the shoulder and/or arm." (Compl. at ¶ 25). The condition apparently has no effective treatment and most individuals affected must have shoulder replacement surgery. (Compl. at 34).

The Complaint states that postarthroscopic glenohumeral chondrolysis was first widely identified in 2004 and an epidemiological correlation between the use of pain pumps after arthroscopic shoulder surgery and glenohumeral chondrolysis was established in 2007. (Compl. at ¶¶ 26-27) (internal citations omitted). This correlation allegedly provides support to studies that established Bupivacaine is cytotoxic to chondrocytes in animals and the continuous injection of anesthetic medications into the shoulder causes the destruction of chondrocytes, resulting in the condition known as glenohumeral chondrolysis. (Compl. at ¶¶ 29-30). Plaintiff claims that

¹ The Complaint alleges that the Plaintiff's surgeon implanted a "Zimmer ambulatory 'pain pump,'" yet collectively refers to I-Flow Corp. and Zimmer Holdings, Inc. as "Defendant Pain Pump Manufacturers." (Compl. at ¶¶ 2, 8). However, in Plaintiff's opposition to Zimmer's motion, she asserts that she obtained a positive product identification "showing that the facility where her surgery occurred used a Zimmer pain pump." Pl's Opp. to Def. Zimmer Holdings Inc.'s Mot. to Dismiss at 9. Plaintiff asserts that the Court should deny Zimmer's motion on this basis alone.

the Defendants failed to recognize this correlation despite the wealth of scientific information available.

APP Defendants allegedly “research, develop, manufacture, and market pharmaceutical products, including Sensorcaine (generically, Bupicavaine), which is an anesthetic drug used in the pain pumps manufactured by Defendant Pain Pump Manufactures.” (Compl. at ¶ 14).

Likewise, the Complaint states Hospira, Inc. (“Hospira”) “researches, develops, manufactures, and markets pharmaceutical products, including Marcaine, which is Defendant Hospira Inc.’s “brand name for the generic anesthetic, Bupivacaine, used in pain pumps manufactured by Defendant Pain Pump Manufacturers.” (Compl. at ¶ 11). However, an averment in the Complaint also submits testimony from a witness for Astrazeneca Pharmaceuticals, another manufacturer of Bupivacaine not named in this action, who indicates that he or she has “heard them interchange” Marcaine for Sensorcaine. (Compl. at ¶ 24).

Plaintiff collectively refers to APP and Hospira as “Defendant Anesthetic Manufacturers.” (Compl. at ¶ 15). Additionally, “Pain Pump Manufacturers”² allegedly “designed, manufactured, marketed, and distributed ‘pain pumps’” that deliver a continuous dose of pain relief medication. (Compl. at ¶ 19). The Complaint notes the “pain relief medication” is “generically named Bupivacaine” and “flows directly into the glenohumeral joint. . . . following arthroscopic or open shoulder surgery.” (Compl. at ¶ 20). The Complaint also alleges, “[a]t all relevant times, Defendant Anesthetic Manufacturers designed, manufactured, marketed, and distributed Bupivacaine and Bupivacaine mixed with epinephrine (hereinafter ‘Bupivacaine

² In her response to Hospira’s motion, Plaintiff notes that she and I-Flow were in the process of negotiating its dismissal from this action. Pl.’s Mem. of Law in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at 2, n. 2 (Doc. No. 67). However, the Court notes Plaintiff dismissed I-Flow prior to filing her brief with this Court. *See* Stip. of Dismissal (Doc. No. 40). Thus, it appears Plaintiff filed the same memorandum of law that she previously submitted to the Eastern District Court prior to the order granting Defendant’s motion to transfer venue to the Western District of Pennsylvania. *See generally* Pl.’s Mem of Law. in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss (Doc. No. 28).

products’) under various trade names, for use in orthopedic surgery, specifically arthroscopic surgery.” (Compl. at ¶ 21).

However, Plaintiff also claims that Bupivacaine products are “commonly used in pain pump devices, including the pain pump used following Plaintiff’s shoulder surgery.” (Compl. at ¶ 22). There is not a single averment in the Complaint as to the use of either Marcaine or Sensorcaine in the pain pump inserted into Plaintiff’s shoulder. Rather, the Complaint generically alleges that Plaintiff has “sustained severe and permanent personal injuries” as a result of the “manufacture, marketing, advertising, promotion, distribution, and/or sale of pain pumps containing Bupivacaine and/or Bupivacaine with Epinephrine to the Plaintiff.” (Compl. at ¶ 36).

The Complaint alleges the following causes of action: (1) negligence and negligence per se; (2) strict products liability; (3) breach of express warranty; (4) breach of implied warranty;³ (5) fraudulent misrepresentation; (6) fraudulent concealment; (7) negligent misrepresentation; (8) fraud and deceit; and (9) violation of Pennsylvania Unfair Trade Practices Act and Consumer Protection Law (“UTPCPL”).⁴

Defendants argue that all of these claims should be dismissed for failure to state a claim. In the interest of judicial economy, the Court will not address every defense raised by each individual Defendant. Given the collective averments scattered throughout the Complaint, the parties’ incorporation of various arguments by reference, and the requirement to provide a curative amendment, it would be wasteful and repetitious to address each Defendant seriatim.

Specifically, the Court will only address a defendant’s legal challenge if all co-

³ Plaintiff incorporates by reference the arguments made in her Opp. to Hospira’s Motion to Dismiss and “does not contest or oppose the APP Defendants’ Motion to Dismiss, to the extent it seeks to dismiss Count IX of her complaint.” Pl.’s Mem. of Law in Opp’n to the APP Defs.’ Mot. to Dismiss at nn. 1-2.

⁴ Plaintiff “does not oppose Hospira’s Motion to Dismiss with respect to the implied warranty cause of action.” Pl.’s Mem. of Law in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at n. 2.

defendants raise the defense, if a party individually raises the defense and its application would be dispositive of a collectively asserted claim, or if the Court takes judicial notice in order to promote efficiency and preserve resources if Plaintiff files an amended complaint.

In turn, the Defendants separately or collectively assert variations of the following: (1) that the negligence claim must fail because there is no casual connection between Defendants product and the alleged injury based on Plaintiff's failure to identify the medication or the specific manufacturer or distributor of the medication; (2) that Pennsylvania law bars a strict liability cause of action against a prescription drug manufacturer based on an alleged failure to warn; (3) that the breach of express warranty claim must fail because it is devoid of any factual matter to support or identify the existence of an express warranty; (4) that Pennsylvania law bars a plaintiff from asserting a breach of implied warranty cause of action against a prescription drug manufacturer; (5) that the misrepresentation and fraud-based claims must fail because the allegations are not pled with the requisite particularity; and (6) Plaintiff's UTPCPL claim is barred by the learned intermediary doctrine. Defendants also allege that Plaintiff's product liability and negligence claims, as asserted in Counts I, II, and V-VIII are barred by the applicable statute of limitations.

Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)

Defendants have raised numerous legal challenges to the Complaint. The Court will first address Defendants' contention that the Court should dismiss Plaintiff's Complaint pursuant to Fed. R. Civ. P. 12(b)(6), insofar as such would initially be dispositive of all claims.

Standard of Review

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) challenges the legal sufficiency of the complaint filed by Plaintiff. The United States Supreme Court has held that "[a] plaintiff's

obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)) (alterations in original).

The Court must accept as true all well-pleaded facts and allegations, and must draw all reasonable inferences therefrom in favor of the plaintiff. However, as the Supreme Court made clear in *Twombly*, the “factual allegations must be enough to raise a right to relief above the speculative level.” *Id.* The Supreme Court has subsequently broadened the scope of this requirement, stating that only a complaint that states a *plausible* claim for relief survives a motion to dismiss.” *Ashcroft v. Iqbal*, -- U.S. --, 129 S. Ct. 1937, 1950 (2009) (emphasis added).

Thus, after *Iqbal*, a district court must conduct a two-part analysis when presented with a motion to dismiss for failure to state a claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the Court must separate the factual and legal elements of the claim. *Id.* Although the Court “must accept all of the complaint’s well-pleaded facts as true, [it] may disregard any legal conclusions.” *Id.* at 210-211. Second, the Court “must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” In other words, a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” *Id.* at 211 (citing *Iqbal* 129 S. Ct. at 1949). The determination for “plausibility” will be “‘a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.’” *Id.* at 211 (quoting *Iqbal* 129 S. Ct. at 1950).

As a result, “pleading standards have seemingly shifted from simple notice pleading to a more heightened form of pleading, requiring a plaintiff to plead more than the possibility of

relief to survive a motion to dismiss.” *Id.* at 211. That is, “all civil complaints must now set out ‘sufficient factual matter’ to show that the claim is facially plausible. This then ‘allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *Id.* at 210 (quoting *Iqbal*, 129 S. Ct. at 1948).

However, nothing in *Twombly* or *Iqbal* changed the other pleading standards for a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) and the requirements of Fed. R. Civ. P. 8 must still be met. *See Phillips v. Co. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (internal citations omitted). Fed. R. Civ. P. 8 requires a showing, rather than a blanket assertion, of entitlement to relief, and “contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader’s bare averment that he wants relief and is entitled to it.” *Twombly*, 550 U.S. at 555 n.3 (internal citations and quotations omitted).

Additionally, the Supreme Court did not abolish the Fed. R. Civ. P. 12(b)(6) requirement that “the facts must be taken as true and a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on those merits.”

Phillips, 515 F.3d at 231(citing *Twombly*, 550 U.S. at 553).

Legal Analysis

As a preliminary matter, the Court notes that jurisdiction in this case rests on the diversity of the parties. 28 U.S.C. § 1332(a). Pursuant to 28 U.S.C. § 1332(a), district courts “have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest, and is between . . . citizens of different States.” *Id.* Complete diversity⁵ requires that, in cases with multiple plaintiffs or multiple defendants, no plaintiff be a

⁵ Although jurisdiction is not challenged in this matter, the Court notes that it may “dismiss a suit *sua sponte* for lack of subject matter jurisdiction at any stage in the proceeding.” *Zambelli*, 592 F.3d at 420 (holding that citizenship of an LLC is determined by the citizenship of each of its members); *see* Complaint at ¶ 12. The Court notes that the citizenships of APP Pharmaceuticals, LLC and Abraxis Bioscience, LLC were not identified.

citizen of the same state as any defendant. *See Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 419 (3d Cir. 2010).

Further, a federal court sitting in diversity must apply the substantive law of the state in which it sits, *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), including its choice of law rules, *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). All parties assume that Pennsylvania law applies to this case, as will the Court.

Defendants contend that the Complaint should be dismissed in its entirety. The Court will address each cause of action advocated by Plaintiff seriatim.

I. Negligence and Negligence Per Se

The first count in Plaintiff's Complaint asserts negligence and negligence per se against the Defendants. (Compl. at ¶¶ 37-54). In this particular section, the Court will not collectively refer to the Defendants as one entity, as discussed in more detail below, and will use the Plaintiff's terminology for identification.

Plaintiff collectively avers that "Defendant Pain Pump Manufacturers had a duty to exercise reasonable care in the designing, researching, manufacturing, supplying, promoting, packaging, sale and/or distribution of pain pumps into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects." (Compl. at ¶ 38). Likewise, Plaintiff collectively alleges that "Defendant Anesthetic Manufacturers" had the same duty as to the "Bupivacaine products." (Compl. at ¶ 39). Plaintiff further claims that "Defendant Anesthetic Manufacturers" had "a duty to warn physicians of the dangers of using their Bupivacaine drugs for long periods of time in joint spaces but failed to do so." (Compl. at ¶¶ 46) The last averments that reference either entity states that "Defendant Anesthetic Manufacturers also had a duty to test and investigate the use of their Bupivacaine

and/or Bupivacaine with Epinephrine drugs in arthroscopic surgery, but failed to do so” and “were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Bupivacaine.” (Compl. at ¶¶ 47-48). The remaining averments collectively refer to “Defendants” and collectively assert various acts and omissions, a blanket assertion of proximate cause, the injuries allegedly suffered by Plaintiff, damages, and a demand for judgment. (Compl. at ¶¶ 40-45, 49-54).

In response, “Defendant Anesthetic Manufacturers” argue that Plaintiff has failed to establish a causal link between her injuries and the products that allegedly caused her injury. In particular, “Defendant Anesthetic Manufacturers” assert that the Complaint does not allege which “pain relief medication” or “Bupivacaine product” was injected into Plaintiff’s shoulder and that she does not adequately identify which of the two “Defendant Anesthetic Manufacturers” was the manufacturer or distributor of the medication that was injected and allegedly caused her injuries. In sum, “Defendant Anesthetic Manufacturers” argue that the Complaint fails to specify that any one of the defendants, as opposed to the others, actually caused Plaintiff’s alleged injury.

Under Pennsylvania law, “a cause of action for negligence must fail unless defendant's conduct is shown to have been the . . . cause of plaintiff's injury,” *Long v. Krueger, Inc.*, 686 F. Supp. 514, 517 (E.D. Pa. 1988) (citing *Hamil v. Bashline*, 481 Pa. 256 (Pa. 1978)); see *Skipworth v. Lead Industries Assoc, Inc.*, 690 A.2d 169, 172 (Pa. 1997) (internal citations omitted); *Cuthbert v. Phila.*, 209 A.2d 261, 263-64 (Pa. 1965). Additionally, “[a]bsent such identification, there can be no allegations of duty, breach of duty or legal causation, and hence there can be no liability.” *Cummins v. Firestone Tire & Rubber Co.*, 495 A.2d 963, 967-968 (Pa. Super. Ct. 1985) (internal citations omitted).

The Court finds and rules that the speculative and collective identification of the Defendants fails to adequately identify which Defendant caused Plaintiff's alleged injury and the Complaint, therefore, is insufficient and speculative under *Twombly* and *Iqbal*. Moreover, "Defendant Anesthetic Manufacturers" highlight analogous cases that support this conclusion and which have held that a plaintiff's generic averments and formulaic recitations fail under the federal pleading standard. See *Sherman v. Stryker Corp.*, No SAVC 09-224 JVS (ANx), 2009 U.S. Dist. LEXIS 34105 (C.D. Cal. March 30, 2009); *Dittman v. DJO, LLC*, No. 09-cv-027910WDM-KLM, 2009 U.S. Dist. LEXIS 97106 (D. Colo. Oct. 5, 2009); *Gilmore v. DJO, Inc.*, No. 2:08-cv-1252-HRH, 2009 U.S. Dist. LEXIS 96690 (D. Ariz. Oct. 15, 2009). The Court also takes judicial notice of additional cases that have addressed this very issue and dismissed analogous complaints pursuant to Fed. R. Civ. P. 12(b)(6). See *Combs v. Stryker Corp.*, No. 2:09-cv-02018-JAM-GGH, 2009 WL 4929110 (E.D. Cal. Dec. 14, 2009); *Haskins v. Zimmer Holdings, Inc.*, No. 1:09-CV-236, 2010 WL 342552 (D. Vt. Jan. 29, 2010); *Timmons v. Linvatec Corp.*, CV09-7947 R (SSx), 2010 U.S. Dist. LEXIS 14057 (W.D. Cal. Feb. 9, 2010); *Adams v. I-Flow Corp.*, Case No. CV09-09550 R (SSx), 2010 U.S. Dist. LEXIS 33066 (C.D. Cal. Mar. 30, 2010); *Peterson v. Breg, Inc.*, 2:09-cv-2044 JWS, 2010 U.S. Dist. LEXIS 48985 (D. Ariz. April 28, 2010).

Relying on *Twombly* and *Iqbal*, district courts have dismissed a complaint since it "conspicuously fail[ed] to allege that either defendant manufactured the medication used in the particular pain pump that caused [the] alleged injury." *Sherman*, 2009 U.S. Dist. LEXIS 34105, at *12; see *Dittman*, 2009 U.S. Dist. LEXIS 97106, * 8-9 (noting that plaintiff's failure to sufficiently allege any of the defendants' product was used on plaintiff was a "deficiency fatal to the claim" since plaintiff "had no facts, only speculation, on which to base his claim that

defendants' products caused or contributed to his injury"). In particular, the *Sherman* court held that the plaintiff's claim was "insufficient under *Twombly*" because "[a]t most, the complaint allege[d] that [the manufacturers] could have been one of many different types of brans [sic] of medications that might have been administered" to the plaintiff. *Id.* at *13.

In this case, Plaintiff attempts to differentiate these nearly identical cases and claims that Fed. R. Civ. P. 8(d) permits her to plead in the alternative, as she is unable to identify the exact Bupivacaine manufacturer. Plaintiff further claims that her reliance on alternative pleading is because "Marcaine is often used to refer to Bupivacaine products generally despite it actually being the band [sic] name for Defendant Hospira, Inc.'s Bupivacaine products." Pl.'s Mem. of Law in Opp'n to Def. Hospira Inc.'s Mot. to Dismiss at n. 2. (citing (Compl. at ¶ 23)).

Additionally, Plaintiff's claims collective pleading is appropriate since two named Bupivacaine Defendants "manufactured the relevant anesthetic product, which is commonly used in connection with pain pumps, during the relevant period of time - - [sic] the period during which Plaintiff had her pain pump implanted, and that this anesthetic was at least, in part, the cause of the Plaintiff's injury." Pl.'s Mem. of Law in Opp'n to Def. Hospira Inc.'s Mot. to Dismiss at 7 (citing (Compl. at ¶¶ 11, 12-13, 21, 36)).

However, even if "brand name 'Marcaine' is sometimes used . . . as a generic reference to other drugs in the 'bupivacaine' anesthetic family" and one may not be able to "trust the brand name that is written in the medical records, as it could refer to other similar drugs," courts have held these "[p]laintiffs are merely speculating that Defendants could be liable." *Combs*, 2009 U.S. Dist. LEXIS 115920, *6-7. Additionally, "[t]his mere possibility, *i.e.*, that the medicine used could have been made by these defendants, rather than by any number of other manufacturers of anesthesia drugs is not adequate to state a claim under the prevailing standards

as set forth by *Twombly* and *Iqbal*.” *Dittman*, 2009 U.S. Dist. LEXIS 97106, *9. Thus, Plaintiff’s “allegations do not plead adequate facts for even an inference of Defendants’ liability, and their claims against Defendants cannot stand.” *Combs*, 2009 U.S. Dist. LEXIS 115920, *7-8.

Despite the insufficient pleadings, Plaintiff argues that she should not be foreclosed from undertaking discovery and asserts that her allegations “more than meet the liberal pleading requirements of [Fed. R. Civ. P.] 8(a), especially in light of the limited amount of information available to the Plaintiff.” Pl.’s Mem. in Opp’n to the APP Defs.’ Mot. to Dismiss at 12.

Plaintiff argues that pinpointing “the specific anesthetic manufacturer is impossible at this point of the case [because] *Hospira* is unable to identify whether or not its product is at issue in Plaintiff’s case arguably contravenes the Federal Code of Regulations (the “CFR”). Pl.’s Mem. in Opp’n to the APP Defs.’ Mot. to Dismiss at 12-13, n. 3; Pl.’s Mem. of Law in Opp’n to the Def. Hospira Inc.’s Mot. to Dismiss at 9, n. 5 (emphasis added). Moreover, Plaintiff claims that C.F.R. 211.150 subpart H indicates that “[w]ritten procedures shall be established, and followed, describing the distribution of drug products. They shall include . . . [a] system by which the distribution of each lot of drug products can be readily determined to facilitate its recall if necessary.” *Id.* Plaintiff concludes that if “*Hospira* had done what it was required to do under the law, Kester would have the ability to specifically name the manufacturer of the product.” *Id.*

However, the Court finds Plaintiff’s argument unpersuasive and agrees with “Defendant Anesthetic Manufacturers” that Plaintiff is the only party who has access to the various medical and insurance records that would allow her to properly identify what drug was administered. *See Peterson*, 2010 U.S. Dist. LEXIS 48985, *7-8. To allow Plaintiff to “file first and investigate later,” as Plaintiff attempts to do, “would be contrary to [Fed. R. Civ. P.] 11(b), which mandates an ‘inquiry reasonable under the circumstances’ into the evidentiary support for all factual

contentions prior to filing a pleading.” *Timmons*, 2010 U.S. Dist. LEXIS 14057, *10 (citing Fed. R. Civ. P. 11(b)(3)). Fed. R. Civ. P. 8 “does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions,” *Iqbal*, 129 S. Ct. at 1953, and “a plaintiff who fails to meet the pleading requirements of [Fed. R. Civ. P.] 8 is not entitled to conduct discovery with the hope that it might then permit her to state a claim,” *Timmons*, 2010 U.S. Dist. LEXIS 14057, *10 (citing *Twombly*, 550 U.S. at 570; *Iqbal*, 129 S. Ct. 1937, 1954-55).

Although the same legal analysis discussed above is applicable to “Defendant Pain Pump Manufacturers,” Plaintiff’s Complaint conspicuously alleges that her surgeon implanted a “Zimmer ambulatory ‘pain pump,’” yet she also collectively asserts all claims against “Defendant Pain Pump Manufacturers.” *Infra* note 1 and accompanying text. However, Plaintiff also claims, “**after Kester filed her lawsuit**,” she allegedly obtained a positive product identification “showing that the facility where her surgery occurred used a Zimmer pain pump.” *Infra* note 1 and accompanying text. It is black letter law that when ruling on a motion to dismiss, the Court is required to look only at the Complaint.

Accordingly, the collective averments within the Complaint not only contradict with the statements in Plaintiff’s opposition, but also remain speculative under *Twombly and Iqbal*. In the Complaint, Plaintiff “merely posit[s] that it is possible that one or more of the named defendants manufactured the pain pumps . . . that **caused** [her] injuries. Such speculative pleading is not permissible under the plain text of [Fed. R. Civ. P.] 8.” *Peterson*, 2010 U.S. Dist. LEXIS 48985, *7 (emphasis added). Even though it appears Plaintiff was able to initially name Zimmer as the manufacturer of the pain pump used in her treatment, “the remaining factual bases for their claims are similarly conclusory and vague, and lack the requisite factual information to suggest that plaintiffs’ claims are facially plausible.” *Peterson*, 2010 U.S. Dist. LEXIS 48985, 7-8

(internal citations and quotations omitted). Thus, the Court will dismiss Plaintiff's negligence and negligence per se claims against all of the moving defendants because she fails to allege the factual basis necessary for legal plausibility and the motion to dismiss Count I of the Complaint will be GRANTED.

II. Strict Products Liability

Plaintiff also collectively asserts a strict products liability claim against the Defendants based on a failure-to-warn theory of liability. (Compl. at ¶¶ 55-76). In support, Plaintiff cites to *Bearden v. Wyeth*, 482 F. Supp. 2d 614, 618 n. 5 (E.D. Pa. 2006) and asserts that the district court in that case declined to follow the general rule in Pennsylvania that comment k to Restatement (Second) of Torts § 402A excludes pharmaceutical manufacturers from strict liability.⁶ *See generally* Restatement (Second) of Torts §402, cmt. k (1965). Moreover, Plaintiff claims that Pennsylvania law contrasts with other jurisdictions, which allegedly hold that strict liability claims for failure-to-warn causes of action are not “clearly excluded” in light of the “properly prepared” and “proper warnings” caveats to comment k. Pl.’s Mem. in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at 12 (citing *Bearden*, 482 F. Supp. 2d 614, 618 n. 5) (internal citations omitted)). As a result, Plaintiff contends that it is not clear whether a failure-to-warn cause of action is improper under the above-cited law and avers that this cause of action should be sustained.

However, the Court finds that Plaintiff misconstrues *Bearden* and misinterprets Pennsylvania law. In *Bearden*, the district court conducted a true conflicts analysis and held that Arkansas law applied. *Bearden*, 482 F. Supp. 2d at 622. In its analysis, the *Bearden* court noted

⁶ Plaintiff is correct that Pennsylvania has adopted Restatement (Second) of Torts § 402A as the law of strict products liability. *See Durkot v. Tesco Equip., LLC*, 654 F. Supp. 2d 295 (E.D. Pa. 2009) (discussing the Pennsylvania Supreme Court’s decision not to adopt Restatement (Third) of Torts: Products Liability (1998) as the Court of Appeals for the Third Circuit predicted it would in *Berrier v. Simplicity Manufacturing, Inc.*, 563 F.2d 38 (3d Cir. 2009).

that Pennsylvania’s unique approach in applying comment k for a failure-to-warn claim “unambiguously” denies the application of strict liability against the manufacturers of prescriptions drugs. *Id.* (citing *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 748 (W.D. Pa. 2004) (internal citations omitted)); *see also Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996) (concluding that strict liability could not be applied to prescription drugs). Likewise, the district court in *Parkinson*, noted that the “caveats set forth in comment k are to be evaluated under negligence” and held that the application of strict liability principles to prescription medical devices is precluded under Pennsylvania law. *Parkinson*, 315 F. Supp. 2d at 747; *see also Creazzo v. Medtronic Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2005) (citing *Hahn*, 673 A.2d at 890-91) (extending the rationale of the Pennsylvania Supreme Court in *Hahn* to medical devices).

In summary, the Court finds and rules that Plaintiff has failed to state a cognizable strict products liability claim under Pennsylvania law and Defendants’ motion to dismiss Count II of the Complaint will be GRANTED.

III. Breach of Express Warranty

Plaintiff also asserts a cause of action against the Defendants for their alleged breach of express warranty. (Compl. at ¶¶ 77-89). In Count III of the Complaint, Plaintiff alleges “Defendants Pain Pump Manufacturers expressly warranted that pain pumps were safe and well accepted by users,” and “Defendant Anesthetic Manufacturers expressly warranted that Bupivacaine products were safe and well accepted by users.” (Compl. at ¶¶ 78, 80). Likewise, Plaintiff asserts that the products do not conform to these express representations because they “are not safe and they have numerous serious side effects, many of which were not warned about by Defendants.” (Compl. at ¶¶ 79, 81). Plaintiff contends that she has suffered loss as a “direct and proximate result of the breach of said warranties,” (Compl. at ¶ 81), and claims that she and

members of the medical community have relied on the express warranties (Compl. at ¶¶ 82, 83).

However, Plaintiff only claims “Defendants herein breached the aforesaid express warranties, as their pain pumps were defective.” (Comp. at ¶ 84). Plaintiff further alleges that Defendants expressly warranted their products and “knew or should have known “said representations were false, misleading, and untrue in that the . . . products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.” (Comp. at ¶¶ 85, 86). Plaintiff now seeks damages for her alleged injuries and future medical needs.

Defendants assert that the Plaintiff’s Complaint is facially deficient, does not specify any particular promise that formed the basis of the bargain, and contains only a recitation of the elements for this cause of action. Plaintiff’s reply notes these arguments “could not be further from the truth” and claims she has “pled the requisite elements for stating this cause of action.” Pl.’s Mem. in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at 19. The Court finds Plaintiff’s Complaint insufficient and her arguments unavailing.

In Pennsylvania, an express warranty “arises out of the representations or promises of the seller,” 13 Pa. Cons. Stat. § 2313, and must be “directed at consumers in order to induce purchases of the product,” *Yurcic v. Purdue Pharma, L.P.*, 343 F. Supp. 2d 386, 394-95 (M.D. Pa 2004) (internal citations omitted). Additionally, express warranties are created by a seller, “*inter alia*, through ‘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.’” *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d at 751 (quoting 13 Pa. Cons. Stat. § 2313). A plaintiff meets the basis of the bargain requirement by “proving that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise.” *Id.* (quoting *Cipollone v. Liggett Group, Inc.*,

893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 503 (1992)).

However, under the standard enunciated in *Twombly*, a plaintiff cannot make a conclusory recitation of the elements of a cause of action and assume that it is sufficient to establish the existence of an express warranty. *See Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982, *2 (D. N.J. November 17, 2008). In *Simmons*, the district court dismissed a breach of express warranty claim against a pain pump manufacturer because the plaintiff's complaint was "devoid of any 'factual matter' to support the existence of an express warranty."⁷ *Id.* Specifically, the complaint did not identify the "source whatsoever of any alleged warranty." *Id.* (noting that courts have dismissed breach of warranty actions even where "plaintiffs generally identified "the source of the alleged warranty (*e.g.*, publications, package inserts, advertising)" on the basis that these general identifications were insufficient to survive a motion to dismiss). As a result, the court dismissed the action and held that the plaintiff had "not specified any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with Defendant" and "thus fail[ed] to put the Defendant on notice as to the substance of his claim." *Id.*

As in *Simmons*, Kester's breach of express warranty claim is the precise type of pleading contemplated in *Twombly* and its progeny. That is, the Complaint's formulaic recitation of the elements to this cause of action are devoid of any factual support, and fails to put the Defendants on notice. Additionally, Plaintiff neither specifies any particular promise that formed the basis of her bargain with the Defendants, who are generically and collectively named, nor does she demonstrate any promise was directed at her, as a consumer, to induce her into purchasing the

⁷ It is not material that the district court was applying New Jersey law, as the requirements for the creation of an express warranty under New Jersey law are the same under Pennsylvania law. *See* N.J.S.A. 12A:2-313.

product. Moreover, it appears that Plaintiff cannot identify the source⁸ of the warranty (if one existed) and her cursory legal conclusions will not suffice under the current pleading standard. Thus, Defendants’ motion to dismiss Count III of Plaintiff’s Complaint will be GRANTED.

IV. Breach of Implied Warranty

Plaintiff also asserts a breach of implied warranty claim against the Defendants and alleges that “Defendants . . . impliedly warranted the product to be of merchantable quality and safe and fit for such use. (Compl. at ¶ 93). In response, Hospira noted that an “implied warranty theory is particularly improper in prescription drug cases” since “the very nature of prescription drugs . . . precludes claims for breach of the implied warranty of merchantability.” Mem. of Points and Authorities in Support to Dismiss Filed by Def. Hospira Inc. (quoting *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987)). Subsequently, Plaintiff notes that she does not oppose dismissal of the breach of implied warranty claim as to Hospira. *Infra* note 4 and accompanying text. The Court agrees with Hospira’s analysis, as it also applies to APP and Zimmer.

As with strict products liability claims for failure-to-warn, Pennsylvania courts have held that the nature of prescription drugs *and* prescription medical devices precludes claims for breach of implied warranty. *See Parkinson*, 315 F. Supp. 2d at 752-53 (internal citations omitted). Thus, the Court finds and rules that Plaintiff has failed to state a cognizable claim under Pennsylvania law and Defendants’ motion to dismiss Count III of the Complaint will be GRANTED.

⁸ Plaintiff avers that Defendants, collectively, made the express representations “to Plaintiff, and/or her physicians, healthcare providers and/or the FDA.” (Compl. at ¶ 85). However, Plaintiff’s Complaint is devoid of any factual allegations to support this claim beyond a speculative level.

V.-VIII. Fraud-Based Claims

Plaintiff also asserts the following fraud-based causes of action against the Defendants: (1) fraudulent misrepresentation (Count V); (2) fraudulent concealment (Count VI); negligent misrepresentation⁹ (Count VII); and (3) fraud and deceit (Count VIII). As a procedural matter, the Court notes that Fed. R. Civ. P. 9(b) does not expressly authorize a motion for its enforcement. Motions which allege a lack of particularity can be presented with a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), as it is here, but such motions can also be brought with a motion for a more definite statement, Fed. R. Civ. P. 12(e), or a motion to strike, Fed. R. Civ. P. 12(f). For the reasons included herein, the Court finds that, as pled, Counts V, VI, VII, and VIII do not satisfy Fed. R. Civ. P. 9(b) and dismissal of the claims is warranted.

Generally, fraud consists of any action or conduct that is calculated to deceive, whether by single act or combination or by suppression of the truth, or suggestion of what is false, whether it be by direct falsehood or by innuendo, by speech or silence, word or mouth, or look or gesture. *Tyler v. O'Neill*, 994 F. Supp. 603, 612 (E.D. Pa. 1998) (citing *Michael v. Shiley, Inc.*, 46 F.3d 1316, 133 (3d Cir. 1995); *Sowell v. Butcher & Singer, Inc.*, 926 F.2d 289 (3d Cir. 1991)).

Under Pennsylvania law, in order to prove fraudulent misrepresentation, a plaintiff must prove six elements: (1) a misrepresentation; (2) material to the transaction; (3) made falsely; (4) with the intent of misleading another to rely on it; (5) justifiable reliance resulted; and (6) injury was proximately caused by the reliance. *Santana Products, Inc v Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 136 (3d Cir. 2005) (citing *Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534 (Pa. Super. Ct. 2003)). Additionally, the Superior Court of Pennsylvania has recognized five

⁹ The District Court for the Eastern District of Pennsylvania has noted that the “particularity requirement of Rule 9(b) applies to claims of negligent misrepresentation.” *Hanover Ins. Co., v. Ryan*, 619 F. Supp. 2d 127, 142 (E.D. Pa. 2007).

elements for an action based on common law fraud: (1) a misrepresentation of material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and (5) damages to the party defrauded as a proximate result. *Colaizii v. Beck*, 895 A.2d 36, 39 (Pa. Super. Ct. 2006). Finally, negligent misrepresentation involves only four elements: (1) a duty; (2) failure to conform to the standard required; (3) a causal connection between the conduct and the injury; and (4) actual loss or damage. *Bouriez v. Carnegie Mellon*, 585 F.3d 765, 771 (3d Cir. 2008) (citing *Overall v. Univ. of Pa.*, 412 F.3d 498) (3d. Cir. 2005)).

Additionally, the Federal Rules of Civil Procedure provide that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity,” Fed. R. Civ. P. 9(b), though “malice, intent, knowledge and other conditions of the mind may be averred generally,” *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007); *see also Tredennick v. Bone*, 647 F. Supp. 2d 495, 501 (W.D. Pa. 2007) (noting that “[e]ven where a plaintiff’s allegations of fraud are based on information and belief, supporting facts on which this belief is founded must be set forth in the complaint”). The United States Court of Appeals for the Third Circuit has noted that Fed. R. Civ. P. 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.” *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984).

While “allegations of ‘date, place or time’ fulfill these functions, . . . nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud.” *Id.* In the alternative, a plaintiff may

satisfy the stringent pleading restrictions of Fed. R. Civ. P. 9(b) by pleading with a degree of precision or some measure of substantiation into the fraud allegation. *Frederico*, 507 F.3d at 200. The Court of Appeals for the Third Circuit has further recognized that Fed. R. Civ. P. 9(b) may be relaxed when the relevant ‘factual information is peculiarly within the defendant’s knowledge or control.’ See *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 882 (3d Cir. 2000) (internal citations omitted). In sum, the heightened specificity requirements in Fed. R. Civ. P. 9(b) are intended to “give defendants notice of the claims against them, provide an increased measure of protection for their reputations and reduce[] the number of frivolous suits brought solely to extract settlements.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997).

In this case, Defendants argue that Plaintiff has failed to plead the elements of her fraud-based claims with any particularity.¹⁰ Specifically, Defendants claim that Plaintiff fails to identify a specific person who made any alleged misrepresentations and does not specify the time, place, or form in which the alleged misrepresentations were made.

In response, Plaintiff asserts that her Complaint sufficiently alleges the “who, what, when, where, and how with respect to the fraud-based causes of action.” Pl.’s Mem. of Law in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at 13. Plaintiff avers that her Complaint alleges, “with respect to the who, that a pain pump manufactured by Zimmer Holdings, which contained Bupivacaine manufactured by either the APP Defendants or Hospira, caused the harm. *Id.* (citing Complaint ¶¶ 2-3, 19-24, 36). Additionally, “with respect to the what, where and when,” Plaintiff claims that the Defendant’s fraudulent acts included “both misstatements and omissions, to both the healthcare community, the Plaintiff and the FDA, concerning the risks associated

¹⁰ Defendants also assert that Plaintiff is barred from asserting non-negligence causes of action against prescription drug and device manufacturers. Although this claim is seemingly meritorious based on the foregoing, the Court declines to address the defense at this time.

with the use of shoulder pain pumps when used in connection with Bupivacaine following shoulder surgery.” *Id.* at 14. (internal citations omitted). With respect to “the how,” Plaintiff claims that her Complaint “clearly identifies how the fraudulent acts, misstatements, and omissions occurred,” as the Defendants “knew or should have known, of the risks associated with the use of shoulder pain pumps when used in connection with Bupivacaine following shoulder surgery, and failed to inform the Plaintiff, the healthcare community and Plaintiff’s healthcare providers of these risks.” *Id.*

Plaintiff also argues that her allegations are as specific as possible “when the company and its agents hide critical information.” *Id.* at 15. Moreover, Plaintiff insists that she should be allowed to engage in discovery and she notes that she has “pled with as much specificity as possibility [sic], especially when taking into account that much of the facts constituting the fraud are in the possession of [Defendants], and continue to develop almost weekly.” Pl.’s Mem. of Law in Opp’n to Def. Hospira Inc.’s Mot. to Dismiss at 16. In support, Plaintiff relies on a Wall Street Journal Article and an FDA notice, which allegedly states that “the pump pumps’ [sic] effectiveness at delivering anesthetics is likely causing cartilage damage in people’s shoulder.” *Id.* Again, the Court notes it is black letter law that when ruling on a motion to dismiss, the Court is required to look only at the Complaint.

With these considerations in mind, and considering the facts alleged within the Complaint, the Court finds and rules that Plaintiff’s Complaint offends these principles, as she has not pled the fraud-based causes of action with the requisite level of particularity. Specifically, Plaintiff’s continuous use of collective references to the Defendants is insufficient under Fed. R. Civ. P. 9(b) and the standards enunciated in *Twombly* and *Iqbal*, as discussed above. Plaintiff will not be permitted to engage in discovery at this time and must file an

amended complaint that will suffice under the Federal Rules of Civil Procedure. *See Perry v. Novartis Pharm. Corp.*, 2006 WL 83450, *2 (E.D. Pa. January 12, 2006) (noting that if a plaintiff “really were defrauded, one would expect that [she] would be able to describe when and how, without having to resort to discovery” (citing Fed. R. Civ. P. 11(b)(3))).

Plaintiff attempts to save her fraud-based claims by arguing that she has pled with the requisite particularity and asserts the “who, what, when, where, and how.” However, Plaintiff fails to recognize that “after-the-fact allegations in determining the sufficiency of her complaint under Rule[] 9(b) and [Fed. R. Civ. P.] 12(b)(6)” are not sufficient and will not be considered. *Frederico*, 507 F.3d at 201-202. Plaintiff also conspicuously fails to mention that in every averment in the Complaint that concerns her fraud-based claims, Hospira, Zimmer, APP, and I-Flow are *only* collectively, generically, and wrongfully referred to as one unspecified and misleading entity: “Defendants.” In cases involving multiple defendants, a plaintiff’s complaint “should inform each defendant of the nature of his alleged participation in the fraud” and “[a] complaint that lumps together numerous defendants does not provide sufficient notice of which defendants allegedly made the misrepresentations.” *Silverstein v. Precudani*, 422 F. Supp. 2d 468, 472-473 (M.D. Pa. 2006) (citing *Lum v. Bank of America*, 361 F.3d 217, 224 (3d Cir. 2004) (internal citations omitted)). Thus, Plaintiff not only fails to assert valid allegations that concern the date, place or time of the alleged fraud to fulfill the requirements Fed. R. Civ. P. 9(b), but also lacks any alternative means of injecting precision and some measure of substantiation into her allegations of fraud. In turn, Plaintiff’s request to engage in the discovery process is denied and Defendant’s motion to dismiss counts V-VIII of the Complaint will be GRANTED.

IX. Violation of Pennsylvania's UTPCPL

The final cause of action that Plaintiff asserts against the Defendants is their alleged violation of Pennsylvania's Unfair Trade Practices Act and Consumer Protection Law. *See generally* 73 Pa. Cons. Stats. §§ 201.1-201-9.3. In summary, Plaintiff avers that she was aggrieved by the Defendants' unfair and/or deceptive trade practices. *See* 73 Pa. Cons. Stat. § 201.9.2(a). Moreover, Plaintiff claims that the Defendants "failed to advise [plaintiff] and her healthcare providers of the defects in design and/or manufacture their [sic] respective products." (Compl. at ¶ 179.)

In response, the APP Defendants argue that Plaintiff's UTPCPL claim is barred by the learned intermediary doctrine. *See infra* note 3 and accompanying text. The Court agrees with APP's assertion and finds that Plaintiff has failed to allege a plausible claim for a violation of the UTPCPL.

Under Pennsylvania, a plaintiff does not have a viable UTPCPL cause of action against a manufacturer of prescription drugs. *See Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 384 (D. N.J. 2004) (applying Pennsylvania law as to the UTPCPL). Specifically, a private right of action under the UTPCPL requires proof of justifiable reliance and causation, *Weinberg v. Sun Co.*, 777 A.2d 442, 446 (Pa. 2001), and such requirements cannot be present when the defendant is a pharmaceutical company that did not sell its product directly to the patient, *Heindel*, 381 F. Supp. 2d at 384 (noting the "learned intermediary breaks the chain in terms of reliance, since the patient cannot obtain prescription drugs without the physician no matter what they believe about them.") Thus, even if Kester had pleaded sufficient facts to demonstrate her reliance, "it would ultimately be of no consequence." *Id.*

In summary, the Court finds and rules that Plaintiff has failed to state a cognizable claim

under Pennsylvania law and Defendants' motion to dismiss Count IX of the Complaint will be GRANTED.

Statute of Limitations

Although dismissal of this complaint is pursuant to Fed. R. Civ. P. 12(b)(6)¹¹, the Court will turn now to the allegations concerning the statute of limitations defense raised by Defendants.

In a diversity action, the law of the state where the cause of action arose governs the statute of limitations. See *Mest v. Cabot Corp.*, 449 F.3d 502, 510 (3d Cir. 2006) (citing *Bohus v. Beloff*, 950 F.2d 919, 924 (3d Cir. 1991)). Under Pennsylvania law, the tort actions contested by the Defendants have a two-year statute of limitations. 42 Pa. Cons. Stat. § 5524.

Defendants have asserted that the statute of limitations for the negligence and products liability claims expired no later than November 13, 2009, two years after the alleged exposure, which occurred on November 13, 2007. This lawsuit was filed five days after the expiration of the two-year period on November 18, 2009.

Generally, the statutory period begins to run when a plaintiff has “knowledge that he has an injury caused by another.” *Mest*, 449 F.3d at 511 (quoting *Ackler v. Raymark Indus., Inc.*, 551 A.2d 291, 293 (Pa. Super. Ct. 1988)). However, Pennsylvania recognizes the “discovery rule,” which may toll the statute of limitations if a plaintiff is “unable, despite the exercise of reasonable diligence, to discover the injury or its cause.” *Mest*, 449 F.3d at 510 (quoting *Pocono Intl' Raceway, Inc. v. Pocono Produce*, 468 A.2d 468, 471(Pa. 1983)).

If a court applies the discovery rule, the statutory period “does not begin to run until ‘the

¹¹ The Court of Appeals for the Third Circuit has noted that “[w]hile the language of Fed R. Civ. P. 8(c) indicates that a statute of limitations defense cannot be used in the context of a Rule 12(b)(6) motion to dismiss, an exception is made where the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading.” *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1385, n.1 (3d. Cir. 1994) (internal citations omitted).

plaintiff knows, or reasonably should know, (1) that he has been injured and (2) that his injury has been caused by another party's conduct.” *Id.* (quoting *Debiec v. Cabot Corp.*, 352 F.3d 117, 129 (3d Cir. 2003)). A plaintiff “bears the burden of demonstrating that he exercised reasonable diligence in determining the existence and cause” of an injury, *Mest*, 449 F.3d at 511 (citing *Cochran*, 666 A.2d at 249), which requires a party to “establish[] that he pursued the cause of his injury with those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protections of their own interests and the interests of others,” *id.* (citing *Cochran v. GAF Corp.*, 666 A.2d 245, 250 (Pa. 1995)).

In this case, Plaintiff neither disputes that a two-year statute of limitations applies to her negligence and product liability claims nor that the claims are facially time-barred. Relying heavily on an unpublished opinion of the Court of Appeals for the Third Circuit, Plaintiff argues that the “Defendants have conveniently ignored the fact that the two year statute has a discovery rule” which would toll the limitations period. Pl.’s Mem. of Law in Opp’n to the APP Defs.’ Mot. to Dismiss at 16 (citing *Vitale v. Buckingham Mfg. Co.*, 184 Fed. Appx. 156 (3d Cir. 2006)). Plaintiff only opines that it would be an error to find that her alleged injuries occurred immediately on November 13, 2007 and that it is “simply non-sensical to think” that she would have immediately known what caused her injuries. Pl.’s Mem. of Law in Opp’n to the APP Defs.’ Mot. to Dismiss at 17. Accordingly, Plaintiff asserts that a jury determination is proper to decide when her injury and its cause were discovered or discoverable. *See Fine v. Checcio*, 870 A.2d 850, 859 (Pa. 2005).

Although the Defendants failed to initially address the applicability of the discovery rule, Defendants respond that Plaintiff’s Complaint contains no allegations to support the application of this rule. This assertion, while deficient of any relevant authority in support, is seemingly

meritorious in light of Plaintiff's Complaint. The Court takes judicial notice and agrees that Plaintiff's Complaint is facially time-barred, is certainly insufficient to support the tolling of the statutory period, and fails to meet the requisite burden enunciated by the Court of Appeals for the Third Circuit. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380 (3d Cir. 1994); *Cehula v. Janus Distribs., LLC*, No. 07-113, 2008 U.S. Dist. LEXIS 12011, *17 (W.D. Pa. Feb. 19, 2008) (internal citations omitted). Thus, the Court finds and rules that in addition to or in the alternative to Defendants' other legal challenges, the expiration of the statute of limitations also supports dismissal of Counts I, II, V-VIII of the Complaint.

If Plaintiff files an amended Complaint to clarify this obvious deficiency, it will be important to fully address all relevant aspects discussed above and to avoid the similar use of generic descriptions in describing her alleged injury. In the alternative, if Plaintiff continues to reference the discovery of her injury by way of vague assertions, the viability of Plaintiff's future success on this issue would be questionable. In summary, the Court advises that Plaintiff file a curative amendment to clarify her Complaint or face the likelihood of her time-barred claims being dismissed with prejudice.

Leave to Amend the Complaint

If a complaint is subject to Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile. *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004); *accord Grayson v. Mayview State Hosp.*, 293 F.3d 103 (3d Cir. 2002). A district court must provide the plaintiff with this opportunity even if the plaintiff does not seek leave to amend. *Id.* The district court may dismiss the action if the plaintiff does not file an amended complaint within that time, or if the plaintiff files a notice of her intent to stand on the complaint as filed.

Defendants have raised numerous meritorious legal challenges. If Plaintiff chooses to file an amended complaint, it will be important to address all of these alleged shortcomings to assure that the amended complaint contains sufficient factual allegations to render the claim(s) “plausible” in compliance with the pleading standard set forth and explained in *Twombly*, *Fowler* and *Phillips*. Even if this “plausibility” standard is met, it will be duly important that the Plaintiff address the exceptions that may toll the statute of limitations in order to avoid dismissal with prejudice. Lastly, it would be in the Plaintiff’s interest to provide additional information on diversity pursuant to the jurisdictional issue, as explained in *Zambelli*. *Infra* note 5 and accompanying text.

Conclusion

In summary, Defendants' Motions to Dismiss the Complaint will be GRANTED in all respects. Plaintiff will have the opportunity to file an amended complaint if she so chooses. An appropriate Order follows.

McVerry, J.

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

MOLLY KESTER,)
Plaintiff,)
) 2:10-cv-00523
vs.)
)
ZIMMER HOLDINGS, INC., I-FLOW)
CORPORATION, HOSPIRA, INC., APP)
PHARMACEUTICALS, LLC, APP)
PHARMACEUTICALS, INC., ABRAXIS)
BIOSCIENCE, LLC AND ABRAXIS)
BIOSCIENCE, INC.,)
Defendants.)

ORDER OF THE COURT

AND NOW, this 16th day of June, 2010, for the reasons set forth in the foregoing Memorandum Opinion, it is hereby **ORDERED, ADJUDGED and DECREED** that the MOTIONS TO DISMISS (Document Nos. 59, 62, 72) filed by Defendants are **GRANTED**. Plaintiff may file an amended complaint on or before July 7, 2010, or she may elect to stand on her original complaint as filed.

BY THE COURT:

/s/ Terrence F. McVerry
United States District Court Judge

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