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

| | | |
|---|---|---|
| JOSEPH RUNNER | : | CIVIL ACTION |
| | : | |
| v. | : | |
| | : | |
| C.R. BARD et al. | : | NO. 14-5259 |

MEMORANDUM

Dalzell, J. June 3, 2015

The defendants seek dismissal of Joseph Runner's nine-count lawsuit arising from injuries he allegedly sustained following the implantation during surgery of a Bard Composix L/P Mesh (hereinafter, the "Product" or "mesh product"). For the reasons set forth below, we will grant the defendants' motion in part and deny it in part.

We have jurisdiction to consider the defendants' motion pursuant to 28 U.S.C. § 1332, as the plaintiff is a Pennsylvania resident, defendant C.R. Bard, Inc. ("Bard") is a corporation, with its principal place of business in New Jersey, and defendant Davol, Inc. ("Davol") is a corporation with its principal place of business in Rhode Island. Complaint at ¶¶ 1-3.

## I. Legal Standard

A defendant moving to dismiss under Fed. R. Civ. P. 12(b)(6) bears the burden of proving that a plaintiff has failed to state a claim for relief, see Fed. R. Civ. P. 12(b)(6); see also, e.g., Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). A Rule 12(b)(6) motion tests the sufficiency of the allegations contained in the complaint and "[t]he question, then, is whether the facts alleged in the complaint, even if true, fail to support the claim." Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993) (internal citation and quotation marks omitted). As the Supreme Court held in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556

U.S. 662 (2009), in order to survive a Rule 12(b)(6) motion "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'," Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). A claim is plausible "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.

Our Court of Appeals requires district courts considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6) to engage in a two-part analysis:

> First, the factual and legal elements of a claim should be separated. The district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Second, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'

Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (quoting Iqbal, 556 U.S. at 679).

In deciding a motion to dismiss, all well-pleaded allegations of the complaint must be taken as true and interpreted in the light most favorable to the plaintiff, and all inferences must be drawn in her favor. See McTernan v. City of York, PA, 577 F.3d 521, 526 (3d Cir. 2009) (internal quotation marks omitted). To survive a motion to dismiss, a plaintiff must allege facts that "raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact)." Victaulic Co. v. Tieman, 499 F.3d 227, 234 (3d Cir. 2007) (quoting Twombly, 550 U.S. at 555).

## II. Factual And Procedural Background

We take our recital of the facts from Runner's September 12, 2014 complaint.

Runner alleges that Dr. Luca Giordani implanted the mesh product in him on or about

October 9, 2012 at Aria Health in Philadelphia. Complaint at ¶ 18. The lot number of the mesh product was HUWF0422 and its model number was 0134450. Id. Such products are used in hernia repair surgeries where the mesh product is used to patch or repair weaknesses in a patient's abdominal wall. Id. at ¶ 12. Runner alleges the defendants make mesh products with common features and uses which combine two so-called biomaterials into a single product. Id. at ¶ 13. He also alleges that both defendants have been aware of problems with the mesh products since 2000. Id. at ¶ 14. In December of 2005, the defendants issued a Food and Drug Administration ("FDA") Class I recall for several lots of the mesh product and have since recalled additional lots, products, shapes and sizes. Id. at ¶ 15. As a result, he alleges, the defendants had reason to know their mesh products were not safe and, because of their design and manufacture, could cause physical injury, but they failed to disclose that information. Id. at ¶¶ 16, 17. That failure, the plaintiff contends, prevented him and his medical providers from making informed choices about using the mesh product. Id. at ¶ 17.

Runner states that his injuries from the mesh product implantation include chronic pain and RSD[1] which require ongoing treatment. Id. at ¶ 19.

The defendants filed their motion to dismiss on December 12, 2014. In his response to their motion, the plaintiff stated that this matter should be transferred to Rhode Island and consolidated with the multidistrict litigation pending against the defendants in the United States District Court for the District of Rhode Island, In re Kugel Mesh Hernia Patch Products Liability Litigation, MDL Docket No. 07-1842-ML ("Kugel MDL"). On March 6, 2015, we ordered the

[1] The plaintiff does not spell out this acronym. However, defendants interpret this term to mean reflex sympathetic dystrophy, also known as complex regional pain syndrome, which the National Institute of Health's National Institute of Neurological Disorders and Stroke defines as pain and sensitivity arising from damage to the central nervous system. See http://www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/detail_reflex_sympathetic_dystrophy.htm. Last accessed on May 26, 2015.

parties to show cause why they have not moved for transfer to that Court or to stay the proceeding before us. The defendants responded on March 19, 2015 that Bard had taken no action to transfer this matter to the Kugel MDL because the MDL court has stopped accepting new transfers. Defs. Resp. at 1. That same day the plaintiff, rather than respond to this Court's Order, filed a Notice of Tag Along Action to the United States Judicial Panel on Multidistrict Litigation, requesting the MDL Panel to consider his case part of the Kugel MDL class action pending against the defendants. Not. of Filing at 1. On March 24, 2015, the plaintiff received notice that notification of potential tag along actions had been suspended in the Kugel MDL, which he failed to disclose to us.

The action thus remains before us.

## III. Discussion

### A. Plaintiff's Strict Liability Claims For Design And Manufacturing Defects And Failure To Warn

The defendants argue that plaintiff's two strict liability claims for injuries allegedly caused by a medical device must be dismissed because sellers of prescription medical devices, such as the mesh products at issue here, are not subject to strict liability under Pennsylvania law. MTD at 6. They contend that Pennsylvania adopted Section 402(A)'s comment k in the Restatement (Second) of Torts, which states that prescription products are by definition considered unavoidably unsafe. Id.

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Id. (quoting Restatement (Second) of Torts, § 402(A), comment k) (emphasis in original). This

standard applies equally to prescription medical devices as to prescription drugs the defendants maintain, as a result precluding all strict liability claims against medical device manufacturers. Id. at 7.

Plaintiff responds in opposition that comment k is inapplicable because it specifies that such products must be "accompanied by proper directions and warning[s]," Mem. of Law in Opp. at 4 (quoting comment k), which were absent here. He maintains that he received no "proper warnings" and therefore comment k does not apply. Id. at 5.

In reply, the defendants contend that plaintiff misstates a settled area of Pennsylvania law as the state and federal courts apply it. Reply at 2. They contend that no court has relied on the phrase plaintiff isolates in comment k to deny a motion to dismiss a strict liability claim, rather holding that -- even with such language -- the appropriate liability standard for a medical-device claim is negligence, not strict liability. Id. at 3.

It is settled that Pennsylvania has adopted comment k to exempt prescription drugs from the imposition of strict liability on manufacturers selling products "in a defective condition unreasonably dangerous to the user or consumer." Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 749 (E.D. Pa. 2007) (Robreno, J.) (internal quotation omitted); see also Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996). The Pennsylvania Supreme Court has not ruled whether comment k extends to prescription medical devices. But in Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006), the Pennsylvania Superior Court held that there was "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." And, since Hahn, numerous federal district courts applying Pennsylvania law have predicted that the Pennsylvania Supreme Court will extend comment k to medical devices. See, e.g., Geesey v. Stryker Corp., 2010 WL 3069630 at *4 (E.D. Pa. Aug. 4, 2010) (Slomsky, J.). In

Soufflas, where the plaintiff, with Zimmer devices implanted in each knee, suffered post-surgery complications requiring further surgery, Judge Robreno held that the Pennsylvania Supreme Court would likely extend the reasoning underlying comment k to exclude prescription medical devices from strict liability. 474 F. Supp. 2d at 750.

Plaintiff offers us his views regarding comment k, but nothing more, to counter the settled doctrine among our colleagues that comment k bars the imposition of strict liability against medical device manufacturers. In keeping with the conclusion our colleagues have reached concerning the application of comment k to prescription medical device suits, we will accordingly grant defendants' motion to dismiss as to plaintiff's Counts V (design and manufacturing defect) and VI (failure to warn).

### B. The Claim For Breach Of Express Warranty

The defendants next urge that plaintiff cannot maintain his breach of warranty claim because he fails to allege that they made any "affirmation of fact or promise" relating to the mesh product that "became part of the basis of the bargain." MTD at 8 (citing cases). They contend that in his complaint the plaintiff has done nothing more than make generalized averments without any assertion that plaintiff actually reviewed the defendants' published materials. Id. at 9. "Without such facts," they argue, "there is no basis upon which [p]laintiff can plausibly allege the legal conclusion that '[d]efendants' representations were a material part of the basis of the bargain.' " Id. (quoting complaint at ¶ 32).

The plaintiff responds in opposition that he has properly alleged the defendants "made affirmative statements as to the value and use" of the mesh products through agents and the sales literature "intended for physicians, medical patients, and the general public." Mem. of Law in Opp. at 5 (quoting complaint at ¶ 30). He points, too, to the complaint's subsequent paragraph in

which he alleges that the defendants "expressly warranted" the mesh products were of merchantable quality and not injurious to his health. Id. He contends that this recitation is the language needed in a pleading that would suffice to allow him to survive defendants' motion to dismiss. Id. at 6.

Of course, in a motion to dismiss that "[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. And we accept as true -- as we must -- all factual allegations of the complaint, drawing all inferences in the light most favorable to the plaintiff. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). Nonetheless, Fed. R. Civ. P. 8(a) "contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averments that he wants relief and is entitled to it." Twombly, 550 U.S. at 555 n.3 (quoting 5 Charles Alan Wright and Arthur R. Miller, Federal Practice and Procedure, § 1202 (3d ed. 2015)) (internal quotation marks and alterations omitted).

The plaintiff relies on his recitation of the following allegations:

> 30. Defendants made affirmative statements as to the value and use of [their] [p]roducts and to [their] use through [their] authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public.
> 31. Defendants expressly warranted that the [p]roducts were of merchantable quality, fit and safe and otherwise not injurious to the [p]laintiff's health and well-being.
> 32. The [d]efendants' representations were a material part of the basis of the bargain and [p]laintiff relied upon said representations in deciding to have the [p]roduct implanted.

Complaint at ¶¶ 30-32.

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the

buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. Ann. § 2313(a). In Horsmon v. Zimmer Holdings, Inc., 2011 WL 5509420 (W.D. Pa. Nov. 10, 2011), where Horsmon's allegations parallel those in Runner's complaint, Judge Bissoon concluded that the plaintiff had failed to allege any particular "affirmation of fact or promise," as the statute requires, that would give rise to a reasonable inference that Zimmer had expressly warranted its products were "safe, effective, fit, and proper for the use for which they were intended", 2011 WL 5509420 at *4. Further, the Court held, the allegations could not support any reasonable inference that any affirmation or promise had been "part of the basis of the bargain" between the parties. Id. In short, Judge Bissoon held, by failing to point to specific language on which she relied, for what purpose she relied on that language, or how her reliance touched on her decision to purchase the Zimmer product, the plaintiff had failed to state a plausible claim for breach of express warranty under Pennsylvania law. Id.

We find Judge Bissoon's reasoning persuasive. Runner has failed to identify any affirmative statements by either defendant, or if there were any way in which such statements were a material part of the basis of the bargain, or in fact failed to identify anything he relied on that made him decide on the purchase and use of the mesh product. Plaintiff's complaint makes generalized averments that fail to link the defendants' representations to his acts. We agree with the defendants that plaintiff has failed to state a claim for breach of express warranty under the relevant statute and will grant their motion to dismiss his complaint as to Count II.

### C. The Breach Of Implied Warranty Claim

Defendants urge that we also dismiss plaintiff's breach of implied warranty claim because Pennsylvania law does not recognize such a claim where personal injuries arise from

prescription medical devices. MTD at 9. They maintain that strict liability and breach of implied warranty "are parallel theories of recovery, one in contract and the other in tort." Id. (citing Williams v. West Penn Power Co., 467 A.2d 811 (Pa. 1983)). And they point us to Soufflas and Kester to conclude that comment k precludes claims for breach of the implied warranty of merchantability in the context of prescription drugs and prescription medical devices. Id.

The plaintiff reasserts in opposition his argument that comment k does not apply here because defendants failed to provide sufficient directions and warnings. Mem. of Law in Opp. at 6.

It is well-established under Pennsylvania law that comment k precludes an implied warranty of merchantability in the sale of prescription drugs. Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374, 376 (Pa. Super. Ct. 1987). As the Superior Court explained, "The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used. . . . [T]he 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 376-77. Courts have predicted that the Pennsylvania Supreme Court would extend that holding to embrace medical devices. See Terrell v. Davol, Inc., 2014 WL 3746532 at *6-7 (E.D. Pa. July 30, 2014) (Slomsky, J.); see also Kester v. Zimmer Holdings, Inc., 2010 WL 4103553 at *4 (W.D. Pa. June 16, 2010); see also Soufflas, 474 F. Supp. 2d at 751-52.

The plaintiff offers no case law to counter the settled conclusion that comment k bars his breach of implied warranty claim. Accordingly, we will grant the defendants' motion and

dismiss Count III of the complaint.

### D. Plaintiff's Misrepresentation And Fraudulent Concealment Claims

The defendants argue that plaintiff's misrepresentation and fraudulent concealment claims must fail because these claims are tantamount to failure to warn claims, which courts applying Pennsylvania law have held are noncognizable. MTD at 10. As our colleagues have explained, negligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription drug manufacturer when the claim is essentially that the drug company knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product's safety. Id. (citing Kline v. Pfizer, Inc., 2009 WL 32477 (E.D. Pa. Jan 6, 2009) (Kelly, J.)). The defendants contend that plaintiff's averments are "exactly the type of dressed-up failure to warn claims" that other courts have rejected and his claims should therefore be dismissed. Id. at 11.

The plaintiff responds in opposition that his misrepresentation and fraudulent concealment claims are distinct. Mem. of Law in Opp. at 7. He states his misrepresentation claim also sounds in negligence. Id. He argues that neither prescription drug case on which defendants rely applies to prescription medical devices. Id. (citing James v. Stryker Corp., 2011 WL 292240 (M.D. Pa. Jan. 27, 2011)). He cites James and Bionix Dev. Corp. v. Sklar Corp., 2009 WL 3353154 (E.D. Pa. Oct. 14, 2009) (Joyner, J.), to argue that both negligent and fraudulent misrepresentation claims are cognizable under Pennsylvania law and thus his claims suffice to make out a negligent misrepresentation claim which does not require the heightened Rule 9(b) pleading standard. Id. at 7, 8.

The defendants reply that James does not alter the rule that an intentional misrepresentation claim sounding in failure to warn is not cognizable under Pennsylvania law

because in James the plaintiff could state a fraud claim only "in the limited circumstances [where] a device manufacturer promoted its products for an off-label use specifically rejected by the FDA." Reply at 3. They point out that the plaintiff makes no such claim here. Id. As his misrepresentation and fraudulent concealment claims "fall squarely" within the prohibited failure to warn ambit, they urge that we dismiss both of these claims. Id.

The plaintiff's misrepresentation claims state, inter alia, that defendants

> [M]isrepresented the safety of its [p]roduct and fraudulently, intentionally, recklessly or negligently concealed material adverse information regarding the [product's] safety. . . .
> Made false, misleading, or negligent statements and omissions about the [product's] safety. . . .
> Minimiz[ed] the risks associated with continuing to use these [p]roducts. . . and actively concealed adverse information at a time when [they] knew, or should have known. . . that the [p]roducts had defects, dangers, and characteristics that were other than what was represented to the FDA[.]

Complaint at ¶¶ 43-46.

His fraudulent concealment claim alleges that the defendants

> [F]raudulently concealed and intentionally omitted the following material information:
> a. that the [p]roduct was not safe for use;
> b. that the [defendants] were aware of the dangers associated with the [p]roduct;
> c. that patients implanted with the [p]roduct were susceptible to severe pain, suffering, injury, emotional distress and death; and
> d. that the [p]roduct was manufactured improperly, negligently and defectively.

Id. at ¶ 71. He further alleges that the defendants were under a duty to disclose the product's defective nature and the risks associated with it. Id. at ¶ 72. He alleges that instead, the defendants, who had sole access to the material facts concerning the defective nature of the mesh product, purposefully concealed those facts to mislead the plaintiff and his medical providers.

Id. at ¶¶ 73, 74.

Faced with cognate, if lengthier, allegations in Kline, Judge Kelly concluded that, in spite of the plaintiff's insistence otherwise, the claims asserted imposed liability against the defendant for failure to warn. 2009 WL 32477 at *4. "The very basis of these claims is that Pfizer knew of the dangers associated with Chantix but fraudulently concealed this knowledge and fraudulently misrepresented that the drug was safe by failing to warn of its dangers." Id. The Court concluded that dismissal was proper as the claim was based on failure to warn because "negligence is the sole theory upon which a plaintiff may recover." Id. at 5. See also Kester, 2010 WL 4103553 at *4 (holding that the fraud allegations "are rooted in a theory of failure to warn" because the plaintiff alleged the defendants were under a duty to disclose the product's defective nature).

By contrast, in James, Judge Kane denied a motion to dismiss a fraud claim where the plaintiff alleged the defendants had made "material misrepresentations" concerning the safety of a pain pump despite their knowledge that the FDA had not approved the pain pump for off-label uses, including its insertion into the plaintiff's shoulder. 2011 WL 292240 at *1. Judge Kane concluded that this allegation constituted "a cognizable fraud claim which, as a matter of law, is distinct from a failure to warn claim," which Pennsylvania law bars. Id. at *3.

As the defendants stress, Runner makes no such claim here. Therefore, his reliance on James is unavailing. Likewise, his reliance on Bionix, a patent infringement case, to claim negligent misrepresentation is similarly fruitless, as Pennsylvania law holds that fraudulent misrepresentation claims in medical injury suits are rooted in a failure to warn. We will accordingly grant the defendants' motion as to plaintiff's misrepresentation claims (Count IV) and his fraudulent concealment claim (Count VII).

**E. Plaintiff's Negligence Claim**

Next, the defendants argue that plaintiff failed to plead sufficient allegations to support any of the three theories of negligence he presses -- manufacturing defect, design defect, and failure to warn. MTD at 11, 12. They contend that his negligent manufacturing theory lacks factual support because he would have had to allege that the particular Composite L/P mesh product implanted in him did not meet defendants' specifications or was otherwise impure when compared with the average Composite L/P mesh product. Id. at 12 (citing, inter alia, Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449 (Pa. Super. Ct. 1973)). In the absence of such averments, the defendants maintain, plaintiff's manufacturing defect complaint fails to satisfy the Twombly and Iqbal pleading standard. Id. To maintain a design defect claim, a plaintiff must show the defendants had "actual or constructive knowledge that the [device] [was] too harmful to be used by anyone." Id. (quoting Lance v. Wyeth, 85 A.3d 434, 461 (Pa. 2014)). Defect is simply not pled, the defendants state. Id. Therefore, they urge that we dismiss any negligence claim on this ground. Id. at 13. Finally, as to failure to warn, the defendants contend that the plaintiff has failed to identify any warning that was inadequate or pled any facts that plausibly support causation. Id. They rely on Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971) to argue that the duty to warn is owed only to the physician acting as a "learned intermediary." Id. They contend that cause in fact may only be established by showing that, had the defendants issued him a proper warning, the learned intermediary would have altered his behavior to avoid the alleged injury. Id. They maintain that the complaint lacks any facts to support a conclusion that their warnings were inadequate and caused the plaintiff injury and consequently his complaint must be dismissed.

The plaintiff responds in opposition that the Federal Rules of Civil Procedure require

nothing more than a "short and plain statement of the claim showing that the pleader is entitled to relief." Mem. of Law in Opp. at 8 (quoting Fed. R. Civ. P. 8(a)(2)). He also points to the allegations in his complaint which he contends adequately pleads that the mesh product was defective. Id. at 9, 10.

The plaintiff's negligence claim alleges that:

> 17. As a result of this defective design and manufacture, [d]efendants' [p]roducts can cause serious physical trauma, injury and/or death. Defendants knew or had reason to know of this tendency and the resulting risk of injury, but failed to disclose this information, preventing the [p]laintiff and his health care providers[] from making informed choices about the implantation of the [p]roduct and continued use thereof.
> 23. Defendants failed to exercise reasonable care in designing, testing, manufacturing, marketing, distributing and selling the [p]roducts with defects.
> 24. Defendants had knowledge of said defects yet [d]efendants failed to promptly recall the [p]roducts and alert physicians and users promptly of the substantial problems and issues with the use of the [p]roducts.

Complaint at ¶¶ 17, 23, 24.

Turning first to the plaintiff's negligent manufacturing theory, we find that the cases defendants cite to do not support their contention that Pennsylvania law requires the plaintiff to plead that the particular Composite L/P mesh product implanted in him did not meet defendants' specifications or was otherwise impure when compared with an average Composite L/P mesh product. Rather, in Leibowitz, the Superior Court focused on evidentiary concerns, not pleading standards, holding that "a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover against the seller." 307 A.2d at 458. This decision therefore can lend no support to the defendants in a motion to dismiss. Rather, in the absence of a more stringent requirement, plaintiff satisfies Rule

8 when he pleads the defendants "failed to exercise reasonable care" in manufacturing the mesh product. We will therefore not grant the motion to dismiss this facet of plaintiff's negligence claim.

As to the design defect claim, the Pennsylvania Supreme Court has not addressed the pleading requirements for a prescription medical device. But we find instructive its recent decision in Lance concerning injuries arising from the ingestion of a prescription diet drug. There, the Court considered whether under Pennsylvania law a pharmaceutical company was "immune from the responsibility to respond in damages for a lack of due care resulting in personal injury or death" except resulting from drug impurities or deficient warnings. Lance, 85 A. 3d at 436. The Court did not hold, as defendants contend, that a design defect claim must show the defendants had actual or constructive knowledge that a product was too harmful to be used by anyone. Rather, the majority recognized that pharmaceutical companies could not be insulated from design defect claims: "The public interest requires the holding of companies which make and sell drugs and medicine for use in the human body to a high degree of responsibility under both the criminal and civil law for any failure to exercise vigilance commensurate with the harm which would be likely to result from relaxing it." Id. at 461 (emphasis in original) (internal quotation marks, citation and alteration omitted). Nothing in Pennsylvania law suggests that a plaintiff pressing a negligent design defect claim must allege more than Runner has done here. As the Pennsylvania Supreme Court stated, citing with approval plaintiff's amici briefs,

> [A] manufacturer's negligent conduct can occur at any stage of the marketing process: in the initial design of the drug, in the failure to investigate information about the risks the drug poses, and in its decision to continue to sell the drug despite those unreasonable risks. The defendant's unreasonable behavior at any point in this process should be sufficient to give rise to negligence liability

when that conduct results in injury.

Id. at 458. No greater specificity in pleadings is required. We will accordingly deny defendants' motion to dismiss this aspect of plaintiff's negligence claim.

As to the plaintiff's failure to warn claim, it is well-established that "the manufacturer's duty to warn is directed to physicians," id. at 438 n. 6 (citing Incollingo, 282 A.2d at 220). The Pennsylvania Superior Court recently explained the learned intermediary doctrine:

> Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous. The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.

Gurley v. Janssen Pharm., Inc., -- A.3d --, 2015 WL 1135894 at * 6 (Pa. Super. Ct. 2015) (internal citation omitted). Here, the plaintiff has sufficiently pled that the defendants failed to exercise reasonable care in informing his healthcare providers of any alleged defects thus depriving him of the benefit of his prescribing physician's advice as to those alleged dangers. Whether the defendants exercised reasonable care in informing Runner's doctor, and whether such a warning would have moved his physician to alter the plaintiff's care, are matters of fact that cannot be resolved at this early stage of the litigation. See also Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010) (internal quotations omitted) ("Proximate cause is an essential element in a failure to warn case. . . . Assuming that a plaintiff has established both duty and a failure to warn, a plaintiff must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his

behavior and the injury would have been avoided.").

We will therefore deny defendants' motion to dismiss as to this aspect of Runner's negligence claim as well.

### F. Negligent Infliction Of Emotional Distress

Next, the defendants urge that we dismiss plaintiff's negligent infliction of emotional distress ("NIED") claim because he has failed to plead any facts showing he suffered emotional distress. MTD at 13. Under Pennsylvania law, a NIED claim arises only when (1) the defendant had a contractual or fiduciary duty toward the plaintiff; (2) the plaintiff was subjected to a physical impact; (3) the plaintiff was in a zone of danger and reasonably feared impending physical injury; or (4) the plaintiff observed a tortious injury to a close relative. Id. at 14 (citing Toney v. Chester Cnty. Hosp., 961 A.2d 192, 197-98 (Pa. Super. Ct. 2008)). Under any of these situations a defendant must have unintentionally caused emotional distress to another, an element the defendants argue is absent here.

The plaintiff responds in opposition that the Pennsylvania Supreme Court in Toney v. Chester County Hosp., 36 A.3d 83 (Pa. 2011)[2] recognized a NIED claim "where there exists a special relationship where it is foreseeable that a breach of the relevant duty would result in emotional harm," Mem. of Law in Opp. at 11 (quoting Toney, 36 A.3d at 84). He argues that "to the extent that there has been an emotional impact on [him] from the injuries caused by [d]efendants' conduct, [their] motion should be denied." Id.

The Pennsylvania Supreme Court's decision in Toney, on which the plaintiff relies, offers guidance. In that case, a woman who gave birth to a severely deformed child alleged that

[2] Plaintiffs erroneously cited Toney v. Chester Cnty. Hosp., 961 A.2d 192, 197-98 (Pa. Super. Ct. 2008).

defendants' negligent misrepresentation of the results of a pre-birth ultrasound caused her emotional distress by depriving her of the opportunity to brace herself at the birth of her child or to make appropriate arrangements beforehand. Toney, 36 A.3d at 85. The Pennsylvania Supreme Court expanded NIED claims to encompass "preexisting relationships involving duties that obviously and objectively hold the potential of deep emotional harm in the event of breach." Id. at 95. As that Court further explained, the "special relationship" giving rise to such a potential claim "must encompass an implied duty to care for the plaintiff's emotional wellbeing." Id. Such a relationship exists between a doctor and patient or between a deceased's loved ones and those caring for the corpse. Id. at 92. Here, where Runner filed his putative claim against two corporations, no such special relationship can arise.

It has long been the rule in Pennsylvania that a plaintiff must allege some physical harm. See Love v. Cramer, 606 A.2d 1175, 1179 (Pa. Super. Ct. 1992) ("A review of Pennsylvania case law also makes plain that a plaintiff must allege physical harm to sustain an action for negligent infliction of emotional distress."). A plaintiff must allege some emotional disturbance beyond "transitory, nonrecurring physical phenomena, harmless in themselves" and tantamount to physical harm that "may be classified by the courts as illness, notwithstanding their mental character." Restatement (Second) of Torts, Section 436A, comment c (cited with approval in Crivellaro v. Pennsylvania Power & Light Co., 491 A.2d 207, 210 (Pa. Super. Ct. 1985)). The Toney plaintiff, for example, pled that her emotional shock manifested in "nausea, headaches, insomnia, depression, nightmares, flashbacks, repeated hysterical attacks, stress, and anxiety." Toney, 36 A.3d at 85. Runner has failed to allege any emotional disturbance beyond the bald assertion that he "suffered injuries." Complaint at ¶ 87. He has thus failed to plead an essential element of a NIED claim.

Because Runner has failed to adequately plead the elements of a NIED claim, we will grant defendants' motion as to that claim (Count VIII).

### G. Violation Of The New Jersey Consumer Fraud Act

Finally, the defendants argue that Runner may not assert a claim against them for violating the New Jersey Consumer Fraud Act ("NJCFA") because the law of Pennsylvania governs his claims. MTD at 14. They argue that Pennsylvania law governs for two reasons. First, they assert that, as a federal court sitting in diversity, we must apply the choice of law rules of the forum state, which in Pennsylvania dictate that we must first determine whether any conflict exists between Pennsylvania law and New Jersey law depending upon the relevant statutes and whether the state's policy interests are implicated. Id. at 14, 15. Here, they argue, as only Pennsylvania's interest is implicated because the plaintiff is a Pennsylvania consumer, there is a false conflict with New Jersey law and only Pennsylvania law applies. Id. at 15. Second, even if there were a true conflict with New Jersey law, Pennsylvania has "the most significant relationship with the facts alleged" under the four-factor test established in Knipe v. Smithkline Beecham, 583 F. Supp. 2d 602 (E.D.Pa. 2008) (Buckwalter, J.). MTD at 15.

> In making this determination, this Court must look to an array of factors: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (iv) the place where the relationship, if any, between the parties is centered.

Knipe, 583 F. Supp. 2d at 614 (internal quotation marks and citations omitted). The defendants maintain that these factors argue for application of Pennsylvania law and that New Jersey's sole connection, as Bard's state of incorporation, is insufficient to trump the place the injury occurred in a product liability suit. MTD at 15, 16. Lastly, the defendants contend that even if New

Jersey law were to apply here, it requires a plaintiff in a products liability suit to pursue that claim under the New Jersey Product Liability Act, or PLA, not the NJCFA. Id. at 16 (citing Sinclair v. Merck & Co., Inc., 948 A.2d 587, 589 (N.J. 2008) ("We also hold that the PLA is the sole source of remedy for plaintiffs' defective product claim; therefore, the Consumer Fraud Act [CFA] does not provide an alternative remedy")).

The plaintiff responds in opposition that the unlawful conduct he alleges originated at Bard's principal place of business in New Jersey. Mem. of Law in Opp. at 13. He argues that Pennsylvania courts, applying a "more flexible rule which permits analysis of the policies and interests underlying the particular issue before the court," have often applied the law of the state where the product is manufactured, regardless of the injured party's citizenship or the place of injury. Id. (quoting Griffith v. United Air Lines, Inc., 203 A.2d 796 (Pa. 1964)). He also argues that the significant relationship test requires a qualitative analysis that cannot be undertaken without discovery. Id. And he contends that the PLA specifically excludes from its definition of "harm" the damages he seeks. Id. at 13, 14 (citing Parker Mem. Home, Inc. v. Georgia-Pacific LLC, 945 F. Supp. 2d 543, 552-53 (D.N.J. 2013)). He argues that the defendants' motion should be denied because the PLA defines a product liability action as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory under[lying] the claim, except actions for harm caused by breach of an express warranty," id. at 14 (citing Parker, 945 F. Supp. 2d at 552-53), and his complaint includes a claim for breach of express warranty.

The defendants reply that Runner has failed to show that his claim is cognizable under New Jersey law because he has not refuted their claim that the PLA bars a claim under the NJCFA. Reply at 4. They also argue that plaintiff erred in concluding that his inclusion of a breach of express warranty claim means his claims are not precluded by the PLA because, as

they explain, it is the NJCFA claim itself that the PLA bars. Id. They maintain that, even if New Jersey law did not bar plaintiff's consumer fraud claim, he has failed to show that New Jersey law applies because he states he is a Pennsylvania citizen who had surgery in a Pennsylvania hospital. Id. at 4, 5. "Nothing else in the [c]omplaint -- or the general call for unnecessary jurisdictional discovery -- shifts the focus to New Jersey law," as one defendant is in New Jersey but the other, Davol, is in Rhode Island. Id. at 5.

Although the defendants posit the resolution of this count as a choice of law problem, in point of fact it is not. As the defendants observe, the New Jersey Supreme Court has held that the Consumer Fraud Act "does not provide an alternative remedy" when plaintiffs bring a defect product claim. Sinclair, 948 A.2d at 589. There is no reason, therefore, for us to engage in a cumbersome choice of law analysis because even if we were to find that New Jersey law applies -- and we see no reason to reach that issue -- the law of that state forestalls a claim under the NJCFA.

Accordingly, we will grant defendants' motion as to Count IX (erroneously labelled in the complaint as Count IV).

## IV. Conclusion

For the foregoing reasons, we will largely grant the defendants' motion to dismiss Runner's complaint, with the exception of his negligence claim. An appropriate Order follows.

BY THE COURT:

/s/ Stewart Dalzell, J.
Stewart Dalzell, J.