

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

NATHAN GEESEY, :  
Plaintiff, : CIVIL ACTION  
 :  
v. : NO. 09-2988  
 :  
STRYKER CORPORATION, et al., :  
Defendants. :

**OPINION**

Slomsky, J.

August 3, 2010

Before the Court is Defendants Stryker Corporation, Stryker Instruments, and Stryker Sales Corporation's Motion to Dismiss several Counts of Plaintiff's First Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) (Doc. No. 11).<sup>1</sup> On February 15, 2010, Plaintiff filed a Response in Opposition to Defendants' Motion (Doc. No. 17). On February 24, 2010, Defendants filed a Reply in Support of the Motion to Dismiss (Doc. No. 18), and on May 26, 2010, the Court held a hearing on the Motion. On June 7, 2010, Plaintiff filed a Second Amended Complaint (Doc. No. 25).<sup>2</sup> For the following reasons, the Court will grant Defendants' Motion to Dismiss in part and will deny in part.

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<sup>1</sup>Also before this Court are two related cases, Frank Gore v. Stryker Corp., et al., Civil Action No. 09-2987, and Timothy Lehr v. Stryker Corp., et al., Civil Action No. 09-2989, involving similar claims. The parties are represented by the same counsel in all three cases. The Court has contemporaneously issued three separate opinions covering the Motion to Dismiss filed in each case.

In addition, the three cases were part of an attempt to centralize numerous cases under multidistrict litigation rules. On May 5, 2010, the Judicial Panel on Multidistrict Litigation denied a motion to include the three cases before this Court in centralized litigation. (Doc. No. 19.)

<sup>2</sup>As explained in more detail below, several claims in Plaintiff's First Amended Complaint have been either withdrawn or are not subject to this Motion.

## **I. BACKGROUND**

Plaintiff Nathan Geesey is a resident of Lancaster, Pennsylvania. (Compl. ¶ 1.) In his Complaint, Plaintiff alleges that he had shoulder surgery and that after surgery a pain pump manufactured by Defendants was inserted into his shoulder joint. A pain pump is a “medical device designed to deliver continuous doses of pain relief medication directly into the shoulder joint space via catheter.” (Compl. ¶ 11.) Plaintiff maintains that anesthetic medication released by the pain pump caused him to develop in his shoulder arthritis and/or chondrolysis, which is a complete, or nearly complete loss of all cartilage. (Compl. ¶ 12.) Due to the allegedly faulty device, Plaintiff has undergone additional shoulder surgery. To obtain full relief, Plaintiff asserts that he needs a complete shoulder replacement. (Compl. ¶ 14.)

Defendants designed, manufactured, marketed and sold the pain pump inserted into Plaintiff’s shoulder. (Compl. ¶ 5.) Defendants are corporations organized under the laws of Michigan and have principal places of business in Michigan. (Compl. ¶ 4.) This case is brought in federal court under diversity of citizenship jurisdiction pursuant to 28 U.S.C. § 1332.

In the First Amended Complaint (Doc. No. 2), Plaintiff made the following claims: Count I (Fraudulent Concealment); Count II (Strict Liability); Count III (Breach of Implied Warranty of Merchantability); Count IV (Breach of Implied Warranty of Fitness For a Particular Purpose); Count V (Negligent Failure to Warn); Count VI (Negligence); Count VII (Negligent Misrepresentation); Count VIII (Breach of Express Warranty); and Count IX (Fraud).

In the Motion presently before the Court, Defendants move to dismiss Counts I, II, III, IV, VIII, and IX. Defendants do not move to dismiss Plaintiff’s claims rooted in negligence (Counts V, VI, and VII). In Plaintiff’s Response in Opposition to the Motion to Dismiss (Doc. No. 17), Plaintiff

voluntarily withdrew his warranty claims, contained in Counts III, IV, and VIII. (Pl. Resp. 7.)<sup>3</sup> Consequently, the only causes of action covered by the Motion to Dismiss are Plaintiff's fraudulent concealment and fraud claims (Counts I and IX) and the strict liability claim (Count II). For the reasons stated below, the Court will grant Defendants' Motion to Dismiss the strict liability claim and will deny Defendants' Motion to Dismiss the fraud and fraudulent concealment claims.

## **II. STANDARD OF REVIEW**

The Court has jurisdiction over this case pursuant to diversity of citizenship jurisdiction under 28 U.S.C. § 1332. Here, Defendants have moved to dismiss certain counts for failure to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). The Motion to Dismiss standard has undergone recent transformation, culminating with the Supreme Court's Opinion in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009). After Iqbal it is clear that "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice" in defeating a Motion to Dismiss. Id. at 1949; see also Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007).

Applying the principles of Iqbal, the Third Circuit in Fowler v. UPMC Shadyside, 578 F.3d 203 (3d Cir. 2009), articulated a two-part analysis that district courts in this Circuit must conduct in evaluating whether allegations in a complaint survive a Motion to Dismiss. First, the factual and legal elements of a claim should be separated, meaning "a District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." Id. at 210-11. Second, the Court must determine whether the facts alleged in the complaint demonstrate that the

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<sup>3</sup>Additionally, Plaintiff filed a Second Amended Complaint (Doc. No. 25), amending the causes of action as follows: Count I (Fraud/Fraudulent Concealment); Count II (Strict Liability); Count III (Negligent Failure to Warn); Count IV (Negligence); Count V (Negligent Misrepresentation).

plaintiff has a “plausible claim for relief.” Id. at 211. In other words, a complaint must do more than allege a plaintiff’s entitlement to relief, it must “show” such an entitlement with its facts. Id. (citing Phillips v. County of Allegheny, 515 F.3d 224, 234-35 (3d Cir. 2008)). “Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘shown’ – ‘that the pleader is entitled to relief.’” Iqbal, 129 S. Ct. at 1950. This “plausibility” determination under step two of the analysis is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” Id.

### **III. DISCUSSION**

#### **A. Count II: Strict Liability**

The Pennsylvania Supreme Court has adopted § 402A of the Restatement (Second) of Torts as setting forth the law of strict product liability in Pennsylvania. Webb v. Zern, 220 A.2d 853, 854 (1966); Mazur v. Merck & Co., 964 F.2d 1348, 1353 (3d Cir. 1992). Section 402A provides in relevant part:

§402A. Special Liability of Seller of Product for Physical Harm to User or Consumer.

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer. . .is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. . .

Defendants move to dismiss Count II of Plaintiff’s First Amended Complaint on the grounds that strict liability claims involving “unavoidably unsafe products” are barred by comment k to § 402A. Comment k provides in relevant part:

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. . .Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true for many other drugs, vaccines, and the like, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of the physician. . .The seller of such products. . .with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known and apparently reasonable risk.

Restatement (Second) of Torts § 402A comment k.

In Hahn v. Richter, the Pennsylvania Supreme Court recognized that comment k specifically applied to prescription drugs. 543 Pa. 558, 673 (Pa. 1996) (“Comment k. . .denies application of strict liability to products such as prescription drugs, which although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.”).

In this case, Defendants argue that comment k applies equally to cases involving prescription medical devices. Plaintiff, however, contends that the strict liability claim should not be dismissed because the Pennsylvania Supreme Court has not yet extended comment k to cover prescription medical devices. (Pl.’s Brief in Opp’n to Mot. to Dismiss 3.)

In a diversity case, this Court must apply the substantive law of Pennsylvania. Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78-79 (1938); State Auto Prop. & Cas. Ins. Co. v. Pro Design, P.C., 566 F.3d 86, 89 (3d Cir. 2009). Ideally, the Court would simply apply Pennsylvania Supreme Court precedent that is on point. However, the Pennsylvania Supreme Court has not yet determined

whether comment k applies to cases involving medical devices. Consequently, this Court must predict how the Supreme Court would rule on the issue. Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 45-46 (3d Cir. 2009) (“In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state’s substantive law must predict how Pennsylvania’s highest court would decide this case.”). In doing so, this Court “must look to decisions of state intermediate appellate courts, of federal courts interpreting the state’s law, and of other state supreme courts that have addressed the issue,” as well as “dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.” Norfolk Southern Ry. Co. v. Basell USA, Inc., 512 F.3d 86, 92 (3d Cir. 2008) (quoting Koppers Co., Inc. v. Aetna Cas. and Sur. Co., 98 F.3d 1440, 1445 (3d Cir. 1996)); see also Jewelcor, Inc. v. Karfunkel, 517 F.3d 672, 676 (3d Cir. 2008) (“In diversity cases, ‘where the applicable rule of decision is the state law, it is the duty of the federal court to ascertain and apply that law, even though it has not been expounded by the highest court of the state.’”) (internal quotations omitted).

While the Pennsylvania Supreme Court has not yet applied comment k to prescription medical devices, the Pennsylvania Superior Court and numerous district courts applying Pennsylvania law have predicted that the Pennsylvania Supreme Court will extend comment k to medical devices. For example, in Taylor v. Danek Medical, Inc., a district court predicted that the Pennsylvania Supreme Court would, pursuant to its reasoning in Hahn, find that prescription medical devices are excluded from strict liability because they present the same “unique set of risks and benefits” as prescription drugs in that “what may be harmful to one patient may be beneficial to another.” No. 95-7232, 1998 WL 962062, \*7 (E.D. Pa. Dec. 29, 1998) (internal citations omitted).

Similarly, in Murray v. Synthes (U.S.A.) Inc., another district court explained, “The Supreme Court of Pennsylvania recognizes that prescription drugs present a unique set of risks and benefits . . . This Court finds that prescription medical devices presents [sic] the same or very similar risks and benefits.” No. 95-7796, 1999 WL 672937, \*7 (E.D. Pa. Aug. 23, 1999). Likewise, the district court in Davenport v. Meditronic, Inc. found, “Numerous courts in the Eastern District of Pennsylvania have predicted that the Pennsylvania Supreme Court will follow its reasoning in Hahn and hold that prescription medical devices are not covered by Section 402A. . . This Court agrees with the reasoning in these cases.” 302 F.Supp.2d 419, 442 (E.D. Pa. 2004); see also Soufflas v. Zimmer, Inc., 474 F.Supp.2d 737, 750 (E.D. Pa. 2007) (following several district courts in predicting that the Pennsylvania Supreme Court would extend § 402A’s comment k to exclude prescription medical devices from strict liability); Burton v. Danek Medical, Inc., No. 95-5565, 1999 WL 118020, \*7 (E.D. Pa. Mar. 1, 1999) (finding that plaintiffs’ strict liability claims must fail because prescription medical devices are not covered by § 402A).

Furthermore, in Parkinson v. Guidant Corp., a district court found that the direct language of comment k implied application to medical devices, because it lists “other drugs, vaccines, *and the like*, many of which. . . cannot be legally sold except to physicians, or under the prescription of a physician” as unavoidably unsafe products. 315 F.Supp.2d 741, 747 (W.D. Pa. 2004) (emphasis in original). Parkinson also noted the drafters of the Restatement (Third) of Torts combined prescription drugs and prescription medical devices into one section dealing with liability for harm caused by defective products. Restatement (Third) Torts, §6. Although that section has “yet to be adopted by the Pennsylvania Supreme Court, it does bolster the already formidable rationale for treating prescription drugs and prescription devices alike.” Parkinson, 315 F.Supp.2d at 747.

Finally, in Creazzo v. Medtronic, Inc., the Pennsylvania Superior Court affirmed the trial court's holding that plaintiffs' strict liability claim was barred by comment k. In that case, the medical device at issue "was designed to alleviate chronic pain by passing an electrical stimulus through nerve structures in the dorsal aspect of the patient's spinal cord by way of a stimulation lead." In concluding that strict liability could not be the basis for liability in that case, the Superior Court found "no reason why the same rational [sic] applicable to prescription drugs may not be applied to medical devices." 903 A.2d 24, 31 (Pa. Super. Ct. 2006)

In the alternative, Plaintiff argues that even if the Court agrees with Defendants that comment k applies in this case, the Court should withhold dismissal of the strict liability claim until the summary judgment stage of litigation. (Transcript of Hearing, May 27, 2010 ["Tr.,"] at 43:4-12.) In support, Plaintiff submits that nearly every federal court (and the Pennsylvania Superior Court in Creazzo) which found that comment k applies to medical device cases did so on a motion for summary judgment.

The Court is not persuaded by Plaintiff's argument. Recently, two district courts confronted the same argument in a medical device, strict liability case and predicted, as a matter of law, that the Pennsylvania Supreme Court would apply comment k to medical devices and granted motions to dismiss the strict liability claims. See Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 WL 564243, \*6 (D.N.J. Mar. 5, 2009); Kester v. Zimmer Holdings, No. 10-00523, 2010 WL 2696467, \*9 (W.D.Pa. June 16, 2010).

The Court agrees with the above cases that comment k applies to medical devices. Consequently, Plaintiff has failed to state a cognizable strict product liability claim under

Pennsylvania law and Defendants' Motion to Dismiss Count II of the First Amended Complaint will be granted.

**B. Counts I & IX: Fraudulent Concealment & Fraud**

Next, Defendants argue that Plaintiff has failed to plead his claims of fraud and fraudulent concealment with sufficient particularity. Under Fed. R. Civ. P. 9(b), a party must state with particularity the circumstances constituting fraud. A court, therefore, must decide if plaintiff has pled with particularity the "circumstances" of the alleged fraud "in order to place defendants on notice of the precise misconduct with which they are charged, and to safeguard against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984).

In order to satisfy this exacting standard, a plaintiff must "plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage."

Birchall v. Countrywide Home Loans, Inc., 2009 U.S. Dist. LEXIS 106813, \*23 (E.D. Pa. Nov. 16, 2009) (quoting Shapiro v. UJB Fin. Corp., 964 F.2d 272, 284 (3d Cir. 1982)); see also Lum v. Bank of America, 361 F.3d 217, 223-24 (3d Cir. 2004) (requiring some means of precision when pleading fraudulent circumstances, such as date, place, or time of fraud).

As noted above, after the Court held a hearing on this Motion, Plaintiff filed a Second Amended Complaint (Doc. No. 25). In that filing, Plaintiff added facts about the circumstances surrounding his shoulder surgeries at Lancaster General Hospital in Lancaster, PA, such as the dates on which Plaintiff underwent surgery. (Second Amended Complaint, ¶8). Moreover, Plaintiff has

more specifically pled the fraud claims by alleging facts regarding the Food and Drug Administration's warnings between 1998 and 2001 on the use of a pain pump in orthopedic joint surgery. (Id. at ¶¶ 28-31.)

Accordingly, the Court is satisfied that Plaintiff's Second Amended Complaint cures any pleading deficiencies that may have existed in the First Amended Complaint. Consequently, Defendants' Motion to Dismiss Plaintiff's claims of fraudulent concealment and fraud (Counts I and IX) for failure to plead them with particularity will be denied.

#### **IV. CONCLUSION**

For the reasons noted above, the Court predicts that the Pennsylvania Supreme Court will apply comment k of § 402A (excluding manufacturers of unavoidably unsafe products from strict liability) to manufacturers of prescription medical devices. Consequently, the Court finds that strict liability is not a sustainable cause of action in this case and will grant Defendants' Motion to Dismiss Plaintiff's strict liability claim in Count II. Because Plaintiff's strict liability claim fails as a matter of law, an amendment to the complaint would be futile. See Fed. R. Civ. P. 15(a); Murray, 1999 WL 672937, at \*8 (“[F]utility is a ground to refuse an amendment to a complaint.”) (citing Lorenz v. CSX Corp., 1 F.3d 1406, 1413 (3d Cir. 1993)).

As to the fraudulent concealment and fraud claims, alleged in Counts I and IX, Plaintiff's Second Amended Complaint satisfies the pleading requirements under Fed. R. Civ. P. 9(b). Accordingly, the fraud and fraudulent concealment claims will not be dismissed. An appropriate Order follows.

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NATHAN GEESEY, :  
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 : CIVIL ACTION  
 Plaintiff, :  
 :  
 : NO. 09-2988  
 v. :  
 :  
 :  
 STRYKER CORPORATION, et al., :  
 :  
 :  
 Defendants. :

**ORDER**

**AND NOW**, this 3<sup>rd</sup> day of August 2010, upon consideration of Defendants' Motion to Dismiss Plaintiff's First Amended Complaint Pursuant to Federal Rule of Civil Procedure 12(b)(6) (Doc. No. 11), Plaintiff's Response in Opposition to the Motion (Doc. No. 17), Defendants' Reply in Support of the Motion (Doc. No. 18), argument made at the hearing held on May 26, 2010, and after a complete and independent review of Plaintiff's First Amended Complaint (Doc. No. 2) and Second Amended Complaint (Doc. No. 25), and for the reasons set forth in the Court's August 3, 2010 Opinion, it is **ORDERED** that Defendants' Motion to Dismiss (Doc. No. 11) is **GRANTED IN PART** and **DENIED IN PART** as follows:

1. Defendants' Motion to Dismiss Plaintiff's strict liability claim is **GRANTED**.
2. Defendants' Motion to Dismiss Plaintiff's fraud and fraudulent concealment claims is **DENIED**.

3. The Court will schedule a pre-trial conference pursuant to Fed. R. Civ. P. 16 with Plaintiff and Defendants as to the remaining counts.

BY THE COURT:

/s/ Joel H. Slomsky, J.  
JOEL H. SLOMSKY, J.