

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

JOHN RILEY and LISA RILEY,)	
Plaintiffs,)	Civil Action No. 2:10-01071
)	Judge Nora Barry Fischer
vs.)	
)	
MEDTRONIC, INC.,)	
Defendant.)	
)	
)	

MEMORANDUM OPINION

I. INTRODUCTION

Pending before the Court is the Defendant's Motion to Dismiss. (Docket No. 29). Defendant contends that the Second Amended Complaint should be dismissed as Plaintiffs' claims are barred by the applicable two year statute of limitations, 42 Pa.C.S. § 5524(2). In addition, Defendant contends that Plaintiffs' claim for strict liability should be dismissed as it fails to state a claim under Pennsylvania law.

For the reasons outlined in the following Memorandum Opinion, Defendant's Motion to Dismiss is DENIED, without prejudice.

II. FACTUAL BACKGROUND¹

Plaintiffs John Riley and Lisa Riley (husband and wife), are adult individuals, currently residing in Westmoreland County, Pennsylvania. Defendant Medtronic, Inc., is a Minnesota corporation trading and doing business in Minneapolis, Minnesota. Plaintiffs are suing Defendant under Strict Liability and Negligent Manufacture and/or Design and are seeking damages, including loss of consortium, arising from the care and treatment of Plaintiff, Mr. Riley, which involved a guide wire and pacer box, manufactured by Defendant. This case is related to two civil actions now pending at docket numbers GD10-003566 and GD-10-010520 in the Court of Common Pleas of Allegheny County, Pennsylvania. (Docket No. 28 ¶ 1-3). It is important to note that Plaintiffs have indicated that they will be discontinuing all claims against Defendant regarding the guide wire, as during the deposition of treating physician, Dr. Kleist, he admitted that the guide wire malfunctioned due to his operator error. (Docket 39 pg. 3). As a result, this Opinion only addresses the pacer box or machine manufactured by Defendant.

On February 22, 2008, Mr. Riley, experienced a heart attack at his home and was admitted to Forbes Regional Hospital in Monroeville, Pennsylvania. (Docket No. 28 ¶ 5). Three days later, Mr. Riley was transferred to UPMC Shadyside for the purposes of a heart catheterization and angioplasty. (Docket No. 28 ¶ 6). At the time of his admission, his neurological assessment was within normal limits. (Docket No. 28 ¶ 7). On that same date, Mr. Riley underwent a percutaneous coronary angioplasty of the right coronary artery performed by Paul Kleist, M.D.. (Docket No. 28 ¶ 8). During the course of the performance of the

¹ In evaluating a Motion to Dismiss, this Court must accept the allegations as true and construe them in favor of the Plaintiffs. *Phillips v. County of Allegheny*, 515 F.3d 224 (3d. Cir. 2008).

angioplasty, Dr. Kleist utilized a Medtronic Zinger Light Guide Wire manufactured by Medtronic. (Docket No. 28 ¶ 9). The guide catheter became dislodged, resulting in a recoil of the wire in question. *Id.* During the course of the procedure, Mr. Riley experienced a dissection of the right coronary artery after balloon inflation. (Docket No. 28 ¶ 10). He then underwent emergency coronary artery bypass surgery on February 25, 2008. (Docket No. 28 ¶ 11).

On February 26, 2008, Mr. Riley, was extubated. (Docket No. 28 ¶ 12). Forty-five (45) minutes after the extubation, Mr. Riley experienced ventricular fibrillation and two pacer spikes from a certain pacing machine manufactured by Defendant. (Docket No. 28 ¶ 13). The pacer spike was triggered by one or more of three (3) causes which are currently under investigation:

- a. A malfunction of the pacer machine manufactured by Defendant and utilized in the care of Mr. Riley;
- b. A malfunction of a certain pacer wire utilized in the care and treatment of Mr. Riley; and/or
- c. The misuse of said machinery and/or negligence of agents, representatives and/or employees of UPMC Presbyterian-Shadyside. *Id.*

Mr. Riley was reintubated and subsequently developed renal failure, a hypoxic insult, blindness, and other complications. (Docket No. 28 ¶ 14). Subsequent thereto, he also suffered pulmonary failure. (Docket No. 28 ¶ 15). He remained in UPMC Presbyterian Shadyside until March 18, 2008. (Docket No. 28 ¶ 16). His daily functioning and ability to comprehend the facts and circumstances regarding his treatment were significantly impaired for nearly one year. (Docket No. 28 ¶ 19). Mr. Riley continues to suffer significant injuries as a result of the pacer spike in question. (Docket No. 28 ¶ 17).

Plaintiffs, themselves, requested copies of Mr. Riley's medical records from UPMC. (Docket No. 28 ¶ 20). UPMC provided the electronic medical records, but not the actual

handwritten records. *Id.* None of the records referenced or identified the pacer spike in question. *Id.* Mr. Riley and individuals on his behalf, continued to investigate his claim. (Docket No. 28 ¶ 21). Ultimately, Mr. Riley retained counsel on the eve of the expiration of the statute of limitations and litigation was then initiated against the medical providers in the Court of Common Pleas of Allegheny County at GD-10-010410, captioned John Riley and Lisa Riley, his wife v. Medtronics, Inc., on February 24, 2010. (Docket No. 28 ¶ 22). Plaintiffs, through counsel, continued to request the full medical records to determine the cause of his injury. (Docket No. 28 ¶ 23). Said records were finally produced by UPMC on April 1, 2010 and contained a handwritten reference to the pacer spike. (Docket No. 28 ¶ 24). However, the actual cardiac strip showing the pacer spike was not produced. (Docket No. 28 ¶ 25). In addition, the medical records did not identify the manufacturers of the pacer wires or the pacer box. *Id.* The determination of the cause of the pacer spike could not occur until after receipt of the cardiac strip. *Id.*

Mr. Riley, through his counsel, continued to request this information from UPMC counsel, John Heisey. (Docket No. 28 ¶ 26). Plaintiffs next issued a Notice of Deposition directed to UPMC to obtain this information. (Docket No. 28 ¶ 27). UPMC refused to produce a representative. (Docket No. 28 ¶ 28). Accordingly, Plaintiffs threatened to file a Motion to Compel, but the parties agreed that a certain affidavit would be produced instead; and the Affidavit of Katie Kephart was issued. (Docket No. 28 ¶ 29). Said Affidavit identified the manufacturer of the pacer box as the Defendant. This was the first time that Plaintiffs discovered the manufacturer of the pacer box. (Docket No. 28 ¶ 30). Plaintiffs still could not identify the cause of the pacer spike and requested the opportunity to review the original medical records, by

and through counsel. (Docket No. 28 ¶ 31). The original medical records were thus reviewed, but the actual pacer cardiac strips were not obtained until July 1, 2010. (Docket No. 28 ¶ 32).

As of the date of the filing of the Second Amended Complaint (February 15, 2011), Mr. Riley had not determined the cause of the pacer spike and indicated that said cause would not be known until after the depositions of UPMC personnel. (Docket No. 28 ¶ 33). Plaintiffs, therefore, continued their efforts to obtain information concerning the cause of the pacer spike. (Docket No. 28 ¶ 34). As such, Plaintiffs obtained a Court Order compelling UPMC to produce the pertinent information to complete their investigation of their claim. (Docket No. 28 ¶ 35). In addition, Plaintiffs obtained a Court Order compelling the deposition of Katie Kephart. Kephart's deposition was taken on February 14, 2011. (Docket No. 28 ¶ 36). According to the Second Amended Complaint, UPMC remains in violation of Court Orders in the underlying State Court action. (Docket No. 28 ¶ 37). Plaintiffs assert that they have been diligent in their attempts to obtain the information concerning the pacer box. (Docket No. 28 ¶ 38). Plaintiffs further assert that despite their best efforts and due diligence, Plaintiffs did not discover the identity of the manufacturer of the pacer box until May 27, 2010 and still have yet to conclusively determine the cause of the pacer spike. (Docket No. 28 ¶ 40).

III. PROCEDURAL HISTORY

Plaintiffs filed suit against the medical providers on February 24, 2010, in the Allegheny County Court of Common Pleas, at Docket Number GD-10-010410. (Docket No. 28 ¶ 22). Plaintiffs filed a Praecipe for Writ of Summons in the Allegheny County Court of Common

Pleas on May 25, 2010. (Docket No. 1 ¶ 1 and Docket No. 1, Exhibit A). Defendant ruled Plaintiffs to file a complaint, but Plaintiffs failed to do so. Instead, Plaintiffs filed a Motion, on July 29, 2010, seeking to consolidate their action against Defendant with two other pending state court actions against UPMC and Alto, respectively (which were consolidated into a single action, on August 17, 2010 at Docket No. GD-10-003566), asserting that all of the claims concerned the same “incident and injury.” Prior to a decision on Plaintiffs’ Motion to Consolidate, Defendant properly removed the case to this Court in mid-August 2010. (Docket No.1).

A month later, in response to Defendant’s Motion to Dismiss for failure to file a Complaint (Docket No. 5), Plaintiffs filed a Complaint (Docket No. 8) and a Motion to Stay (Docket No. 9). This Court denied Plaintiffs’ Motion to Stay on September 28, 2010 (Docket No. 11), and, on October 4, 2010, Defendant filed a Motion to Dismiss Plaintiffs’ Complaint. (Docket No. 12). On October 25, 2010, Plaintiffs filed a Motion for Extension of Time to File Response/Reply as to Defendant’s Motion to Dismiss (Docket No. 15), which this Court granted the next day. (Docket No. 17). Then, on November 2, 2010, Plaintiffs filed an opposition to Defendant’s Motion to Dismiss and alternatively requested leave to file an Amended Complaint. (Docket No. 19). This Court granted Plaintiffs’ Alternative Motion to Amend and ordered Plaintiffs to file an Amended Complaint. (Docket No. 20). On November 24, 2010, Plaintiffs filed an Amended Complaint (Docket No. 21), and, on December 15, 2010, Defendant filed a Motion to Dismiss Plaintiffs’ Amended Complaint. (Docket No. 22). On January 5, 2011, Plaintiffs filed their Opposition to Defendant’s Motion to Dismiss and alternatively requested leave to file a Second Amended Complaint. (Docket No. 25).

This Court granted Plaintiffs leave to file a Second Amended Complaint on January 25, 2011, warning “that no further amendments will be permitted for Plaintiffs to set forth their

causes of action.” (Docket No. 27). Plaintiffs were directed “to plead additional facts, if any, that would be helpful to a factual determination of when the statute of limitations began and whether Plaintiffs exercised reasonable diligence.” *Id.* Plaintiffs filed their Second Amended Complaint on February 15, 2011 (Docket No. 28), and Defendant filed a Motion to Dismiss the Second Amended Complaint on March 8, 2011. (Docket No. 29). Oral argument was held on April 7, 2011, at which time this Court instructed the parties to file supplemental Briefs, which Defendant did on May 31, 2011 (Docket No. 36), and Plaintiffs followed on June 14, 2011. (Docket No. 38). The Motion is now ripe for disposition.

IV. STANDARD OF REVIEW

On January 25, 2011, this Court entered an Order, which granted leave for Plaintiffs to file a Second Amended Complaint. (Docket No. 27). Said Order required Plaintiffs to more specifically plead facts that would be helpful to a factual determination of when the statute of limitations began and whether Plaintiffs exercised reasonable diligence. *Id.* Plaintiffs then filed their Second Amended Complaint and Defendant challenged with a Motion to Dismiss.

A motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) challenges the legal sufficiency of the complaint filed by a 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, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)). 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, 173 L.Ed.2d 868 (2009).

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. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d. Cir.2008). 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. 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). This Court’s January 25, 2011 Order required Plaintiffs to more specifically plead facts that would be helpful to a factual determination of when the statute of limitations began and whether Plaintiffs exercised reasonable diligence. (Docket No. 27). The Court believes that Plaintiffs have complied not only with this Court’s January 25, 2011 Order, but also with this standard.

V. ANALYSIS

As a preliminary matter, the Court notes that jurisdiction in this case rests on the diversity of the parties pursuant to 28 U.S.C. § 1332. Venue is proper pursuant to 28 U.S.C. § 118 (c) and 1441(a). 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, 58 S.Ct. 817, 82 L.Ed. 1188 (1938), including its choice of law rules, *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). All parties agree that Pennsylvania law applies to this case.

Defendant contends that the Second Amended Complaint should be dismissed as Plaintiffs' claims are barred by the applicable two year statute of limitations, 42 Pa.C.S. § 5524(2). In addition, Defendant contends that Plaintiffs' claim based on strict liability should be dismissed as it fails to state a claim under Pennsylvania law. The Court will address each contention, in turn.

A. Discovery Rule

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.” *Kester v. Zimmer Holdings*, 2010 WL 2696467, *15 (W.D.Pa. 2010) (quoting *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1385, n. 1 (3d. Cir.1994)). However, “where a Complaint is untimely on its face, [...], the plaintiff must include tolling allegations in order to survive a statute of limitations challenge.” *Akrie v. City of Pittsburgh*, 2009 WL 1765846, *4 (W.D.Pa. 2009). Plaintiffs' tolling allegation states that “despite best efforts and due diligence by the Plaintiffs, the Plaintiffs did not discover the identity of the manufacturer of the pacer box until May 27, 2010”, after the statute of limitations period had run. (Docket No. 28 ¶ 47). They base this statement on a series of factual averments concerning their efforts. (Docket No. 28).

As referenced above, Plaintiffs allege that their due diligence included the following. Plaintiffs, themselves, requested copies of Mr. Riley's medical records from UPMC. (Docket

No. 28 ¶ 20). UPMC provided the electronic medical records, but not the actual handwritten records. *Id.* None of the records referenced or identified the pacer spike in question. *Id.* Subsequently, Plaintiffs, through counsel, continued to request the full medical records to determine the cause of his injury. (Docket No. 28 ¶ 23). On April 1, 2010, the medical records were produced, but did not identify the manufacturer of the pacer box. (Docket No. 28 ¶ 24-25). Plaintiffs next issued a Notice of Deposition directing UPMC to obtain this information. (Docket No. 28 ¶ 27). UPMC refused to produce a representative. (Docket No. 28 ¶ 28). Accordingly, Plaintiffs threatened to file a Motion to Compel and the Affidavit of Katie Kephart was issued. (Docket No. 28 ¶ 29). Said Affidavit, dated May 26, 2010, identified the manufacturer of the pacer box as the Defendant. This was the first time that Plaintiffs discovered the manufacturer of the pacer box. (Docket No. 28 ¶ 30). Plaintiffs still could not identify the cause of the pacer spike. Hence, they requested the opportunity to review the original medical records. (Docket No. 28 ¶ 31). The original medical records were thus reviewed, but the actual pacer cardiac strips were not obtained until July 1, 2010. (Docket No. 28 ¶ 32). Plaintiffs maintain that they still have yet to conclusively determine the cause of the pacer spike. (Docket No. 28 ¶ 40).

“In a diversity action, the law of the state where the cause of action arose governs the statute of limitations.” *Mest v. Cabot Corp.*, 449 F.3d 502, 510 (3d Cir.2006) (citing *Bohus v. Beloff*, 950 F.2d 919, 924 (3d Cir.1991)). The parties agree that Pennsylvania law controls. Under Pennsylvania law, the tort actions contested by the Defendants have a two-year statute of limitations. 42 Pa. Cons.Stat. § 5524. “Generally, a statute of limitations period begins to run when a cause of action accrues; *i.e.*, when an injury is inflicted and the corresponding right to institute a suit for damages arises.” *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011)

(citing *Wilson v. El-Daief*, 964 A.2d 354, 361 (Pa. 2009)). “It is the duty of the party asserting a cause of action to use all reasonable diligence to properly inform him-or herself of the facts and circumstances upon which the right of recovery is based and to institute suit within the prescribed period.” *Id.* (citing *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1042 (Pa. 1992)). “Generally, once the prescribed statutory period has expired, the complaining party is barred from bringing suit.” *Id.* (citing *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992)).

“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.’” *Kester v. Zimmer Holdings*, 2010 WL 2696467, *15 (W.D.Pa. 2010) (citing *Mest v. Cabot Corp.*, 449 F.3d 502, 510 (3d. Cir. 2006) (quoting *Pocono Intl' Raceway, Inc. v. Pocono Produce*, 468 A.2d 468, 471(Pa. 1983))). Under the discovery rule, the statutory period “does not begin to run until ‘the 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.* (citing *Mest v. Cabot Corp.*, 449 F.3d 502, 510 (3d. Cir. 2006) (quoting *Debiec v. Cabot Corp.*, 352 F.3d 117, 129 (3d Cir. 2003))). The plaintiff “bears the burden of demonstrating that he exercised reasonable diligence in determining the existence and cause of his injury.” *Mest v. Cabot Corp.*, 449 F.3d 502, 511 (3d. Cir. 2006) (citing *Cochran v. GAF Corp.*, 666 A.2d 245, 249 (Pa. 1995)). This burden “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.*, 542 Pa. 210, 666 A.2d 245, 250 (Pa.1995)).

Reasonable diligence does not refer to what the Plaintiff knew about his injury, but rather, “what might he have known, by the use of the means of information within his reach, with the vigilance the law requires of him?” *Fine v. Checcio*, 870 A.2d 850, 858 (Pa. 2005) (citing *Scranton Gas & Water Co. v. Lackawanna Iron & Coal Co.*, 31 A. 484, 485 (Pa. 1895)).

While reasonable diligence is an objective test, ‘it is sufficiently flexible ... to take into account the difference[s] between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question.’ Under this test, a party’s actions are evaluated to determine whether he exhibited ‘those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interest and the interest of others.’

Id. (quoting *Crouse v. Cyclops Industries*, 745 A.2d 606, 611 (Pa. 2000)).

“[T]he very essence of the discovery rule in Pennsylvania is that it applies only to those situations where the nature of the injury itself is such that no amount of vigilance will enable the plaintiff to detect an injury.” *Wilson v. El-Daief*, 964 A.2d 354, 357 (Pa. 2009) (quoting *Dalrymple v. Brown*, 701 A.2d 164, 170 (Pa. 1997) (citing *Pocono International Raceway, Inc. v. Pocono Produce, Inc.*, 468 A.2d 468, 471 (Pa. 1983))). “Lack of knowledge, mistake or misunderstanding do not toll the running of the statute of limitations, even though a person may not discover his injury until it is too late to take advantage of the appropriate remedy.” *Id.* (quoting *Pocono International Raceway, Inc. v. Pocono Produce, Inc.*, 468 A.2d 468 (Pa. 1983)).

A plaintiff “need not have known the precise medical cause of the injury in order to commence the running of the statute of limitations.” *Bigansky v. Thomas Jefferson University Hospital*, 658 A.2d 423, 430 (Pa.Super.1995). Further, “state and federal courts in Pennsylvania,

applying Pennsylvania law, have expressly rejected application of the discovery rule where a plaintiff merely lacks knowledge as to the defendant's identity.” *Bradley v. Conner*, 2007 WL 4241846, *4 (W.D.Pa. 2007); *See also, Robinson v. Lowe's Home Centers, Inc.*, 2007 WL 2739187, *2 (E.D.Pa. 2007) (“The Pennsylvania Superior court has generally found the discovery rule inapplicable in cases where a plaintiff was aware of an injury and its cause but had not determined the identity of the defendants within the limitations period.”); *Merry v. Westinghouse Elec. Corp.*, 684 F.Supp. 852, 855 (M.D.Pa. 1988) (“Nothing in the discovery rule provides for the tolling of the statute until the responsible party is identified. The burden is on the injured party, once he discovers the cause of his injury, to make that determination within the statutory period. An allegation of mere difficulty in identifying defendants [is] not sufficient to toll the running of the statute of limitations.”). Here, Plaintiffs are pleading that not only were they unaware of Defendant’s identity, but also that, as of the date of the Second Amended Complaint, they still had not determined the cause of the pacemaker spike. (Docket No. 28 ¶ 40). “Time begins to run on the date of the injury unless, because of fraud or concealment by the authority, or in spite of reasonable diligence by the claimant, knowledge of the negligence or its causes cannot be discovered until after the [statute of limitations] period.” *Bayless v. Philadelphia National League Club*, 579 F.2d 37, 40 (3d. Cir. 1978).

Given the circumstances of this lawsuit, an important case to note is *Keating v. Zemel*, 421 A.2d 1181 (Pa.Super.Ct. 1980). *Keating* determined that there should be “a new commencement date for the statute only when the culpability cannot reasonably be discovered within the statutory period following the date of the injuries.” *Id.* at 1184. However, in *Keating*, “the description of the foreign object was to some extent ambiguous in the original hospital

record, information which should have prompted a motion to produce the object for examination instead of relying on the hospital records. Thus, the exercise of reasonable diligence would unquestionably have led to an identification of the source of the tube left in appellant's body.” *Id.*

Here, the question is whether the Plaintiff exercised reasonable diligence in ascertaining the cause of his injuries. Therefore, “the applicable standard is not whether the Plaintiff subjectively knew [of the cause of the injury]. Rather, it is whether [a] diligent investigation would have revealed [it].” *Schach v. Ford Motor Co.*, 210 F.R.D. 522, 527 (M.D.Pa. 2002).

When a court is presented with the assertion of the discovery rule's application, it must address the ability of the damaged party, exercising reasonable diligence, to ascertain that he has been injured and by what cause. Since this question involves a factual determination as to whether a party was able, in the exercise of reasonable diligence, to know of his injury and its cause, ordinarily, a jury is to decide it. Where, however, reasonable minds would not differ in finding that a party knew or should have known on the exercise of reasonable diligence of his injury and its cause, the court determines that the discovery rule does not apply as a matter of law.

Gleason v. Borough of Moosic, 15 A.3d 479, 485 (Pa. 2011) (citing *Fine v. Checcio*, 870 A.2d 850, 858-9 (Pa. 2005)). “Pennsylvania courts have not hesitated, where appropriate, to find as a matter of law that a party has not used reasonable diligence in ascertaining his or her injury and its cause, thus barring the party from asserting his or her claim under the discovery rule.” *Id.* at 485-6 (citing *Cochran v. GAF Corp.*, 666 A.2d 245, 248 (Pa. 1995)). However, this is not one of those instances. Instead, this is a case where, in this Court’s estimation, the facts are such that a jury should determine whether Plaintiffs were sufficiently diligent to determine whether there was or was not injury, due to negligence or strict liability of the medical providers and of the

defendant manufacturer, or whether Mr. Riley's cardiac disease alone caused the sequelae he sustained.

The relevant facts alleged in the Second Amended Complaint, properly viewed in the light most favorable to the Plaintiffs, include the following. Mr. Riley sustained injuries from procedures on February 25, 2008 and February 26, 2008. (Docket No. 28 ¶ 8-15). He remained in the hospital until March 18, 2008. (Docket No. 28 ¶ 16). His daily functioning and ability to comprehend the facts and circumstances regarding his treatment were significantly impaired for nearly one year. (Docket No. 28 ¶ 19). Plaintiffs sought to investigate their claim by requesting copies of Mr. Riley's medical records from UPMC for review. (Docket No. 28 ¶ 20-22).

However, the electronic medical records that UPMC provided did not mention the pacer spike that is in question. (Docket No. 28 ¶ 20). Plaintiffs retained their current attorney on the eve of the statute of limitations. (Docket No. 28 ¶ 22). Upon said retention, the Plaintiffs initiated litigation against UPMC and the doctors involved in the procedures, by filing a Praecipe for Writ of Summons in the Allegheny County Court of Common Pleas, on February 24, 2010. *Id.*

Plaintiffs then continued to request the full medical records from UPMC. (Docket No. 28 ¶ 23). On April 1, 2010, UPMC produced the rest of the medical records, which contained a handwritten reference to the pacer spike, but did not include the actual cardiac strip, documenting the pacer spike. (Docket No. 28 ¶ 24-25). Further, the rest of the medical records that were produced did not identify the manufacturers of the pacer wires or the pacer box. (Docket No. 28 ¶ 25). Plaintiffs continued to request the cardiac strip from UPMC and then issued a Notice of Deposition, directing UPMC to obtain this information, but UPMC refused to produce a representative. ((Docket No. 28 ¶ 26-28). Plaintiffs threatened to file a Motion to

Compel, which led to the production of the Affidavit of Katie Kephart, which identified the manufacturer of the pacer box as Defendant. (Docket No. 28 ¶ 29-30). As a result, Plaintiffs did not discover the identity of the manufacturer of the pacer box until May 27, 2010, after the statute of limitations period had run. (Docket No. 28 ¶ 47). Plaintiffs have yet to conclusively determine the cause of the pacer spike. (Docket No. 28 ¶ 40).

Application of the discovery rule “requires us to consider whether it is undeniably clear that Appellants did not use reasonable diligence in timely ascertaining their injury and its cause, or whether an issue of genuine fact exists regarding [Plaintiff’s] use of reasonable diligence to ascertain [his] injury and its cause.” *Gleason v. Borough of Moosic*, 15 A.3d 479, 486-7 (Pa. 2011). The facts alleged in the Second Amended Complaint, properly viewed in the light most favorable to the Plaintiffs, demonstrate that it is not “undeniably clear” that the Plaintiffs did not use reasonable diligence. Instead, there exists a factual issue, as to whether Plaintiffs should have acted with greater diligence and promptness to investigate the cause of Mr. Riley’s injury by way of securing his medical records and otherwise. “Our jurisprudence has recognized that the point at which the complaining party should be reasonably aware that he or she has suffered an injury and should have identified its cause is ordinarily an issue of fact to be determined by the jury due to the fact intensive nature of the inquiry.” *Id.* at 487. As reasonable minds could differ regarding whether the injury was ascertainable through the exercise of reasonable diligence during the limitations period, this Court has concluded that a jury should determine the point at which Plaintiffs should have reasonably been aware of Mr. Riley’s injury and its cause. Accordingly, the Court believes that dismissal on the basis of the statute of limitations is premature, as the allegations contained in the Second Amended Complaint are sufficient to

permit this case to move beyond the current Motion to Dismiss and into the discovery stage. Upon conclusion of discovery, Defendant can reassert its defense by way of a motion for summary judgment.

B. Strict Liability

Defendant next argues that Plaintiffs' strict liability claim against Defendant should be dismissed for failure to state a claim under Pennsylvania law. Specifically, Defendant contends that the strict liability claim should be dismissed pursuant to comment k of Section 402A of the Restatement (Second) of Torts. Comment k excludes certain products from the definition of "unreasonably dangerous," used in section 402A, on the basis that they are incapable of being made safe for their intended use, but are useful nonetheless. Comment k provides as follows.

k. Unavoidably unsafe products. 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and

marketed, and proper warning is given, where the situation calls for it, is not to be 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 but apparently reasonable risk.

Restatement (Second) of Torts, § 402A cmt. k.

In *Hahn v. Richter*, the Pennsylvania Supreme Court adopted comment k, concluding that strict liability could not be applied to prescription drugs where adequate warnings of the drug's potential risks had been provided. *Hahn v. Richter*, 673 A.2d 888, 890–91 (Pa. 1996). The Pennsylvania Superior Court concluded that comment k applied to medical devices, finding “no reason why the same rationale applicable to prescription drugs may not be applied to medical devices.” *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa.Super. 2006). In addition, several federal district courts have extended comment k to prescription medical devices. The United States District Court for the Eastern District of Pennsylvania noted “that the reasoning behind comment k, and the Pennsylvania Supreme Court's reasoning in *Hahn*, supports [comment k's] application to prescription medical devices.” *Soufflas v. Zimmer*, 474 F.Supp.2d 737, 750 (E.D.Pa. 2007) (citing *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 WL 962062,*7 (E.D.Pa. 1998)). Applying the same reasoning as *Taylor*, several federal courts have determined that prescription medical devices are not covered by Section 402A and have denied plaintiffs' strict liability claims based on prescription medical devices. See *Burton v. Danek Medical, Inc., et al.*, No. 95-5565, 1999 WL 118020 (E.D.Pa. 1999); *Murray v. Synthes*, No. 95-7796, 1999 WL 672937 (E.D.Pa. 1999); *Davenport v. Medtronic, Inc.*, 302 F.Supp.2d 419 (E.D.Pa. 2004); *Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741 (W.D.Pa. 2004); *Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467 (W.D.Pa. 2010).

Because these cases have consistently determined that prescription medical devices are not covered by Section 402A, the Court must determine whether Mr. Riley's pacer box constituted a prescription medical device, where adequate warnings of potential risks were provided. Here, the Defendant is essentially arguing that this Court should infer, from the facts pled by Plaintiffs, that the pacer box is a prescription medical device. However, in their briefs, the parties disagree as to whether the pacer box constitutes a medical device or medical equipment. Neither party provides any basis for this Court to determine whether the aforementioned case law applies to the subject pacer box, as its status as a prescription medical device or medical equipment, has not been established, in the Second Amended Complaint. In evaluating a Motion to Dismiss, this Court must accept the Plaintiffs' allegations as true and construe them in favor of the Plaintiffs. *Phillips v. County of Allegheny*, 515 F.3d 224 (3d. Cir. 2008). Considering the standard of review on a Motion to Dismiss, the Plaintiffs' allegations are therefore sufficient to permit the case to move beyond the current Motion to Dismiss and into the discovery stage, as there exists a question of fact, regarding the nature of the pacer box. Discovery may determine whether the pacer box is indeed a prescription medical device, where adequate warnings of potential risks were provided, or whether it is medical equipment. Hence, the Court denies Defendant's Motion to Dismiss Plaintiffs' claim for strict liability, without prejudice, to it being raised anew, by way of a properly supported Summary Judgment motion.

VI. CONCLUSION

Based on the foregoing, Defendant's Motion to Dismiss is DENIED, without prejudice.

An appropriate Order follows.

s/Nora Barry Fischer
Nora Barry Fischer
United States District Judge

cc/ecf: All counsel of record

Date: August 8, 2011