

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

RAMONA KENNEDY and	:	
RODNEY KENNEDY,	:	
Plaintiffs,	:	
	:	
v.	:	No. 5:20-cv-00185
	:	
ETHICON, INC. and JOHNSON &	:	
JOHNSON,	:	
Defendants.	:	

OPINION
Defendants’ Motion for Summary Judgment, ECF No. 71 — GRANTED

Joseph F. Leeson, Jr.
United States District Judge

July 20, 2020

I. INTRODUCTION

This is a product liability action which originated as part of a multidistrict litigation. Ramona Kennedy (“Kennedy”) and her husband Rodney Kennedy (collectively, “Plaintiffs”) sue to recover damages for injuries suffered as a result of alleged defects in a transvaginal pelvic mesh product manufactured and marketed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Defendants”). The pelvic mesh at issue was implanted into Kennedy on September 23, 2009, at the recommendation of her physician to treat a medical condition known as a cystocele.¹

This action was commenced in the multidistrict litigation court on July 2, 2013, and transferred to this Court upon the completion of discovery in January 2020. Defendants now

¹ A cystocele, also known as anterior prolapse, is a condition that occurs in women when the bladder drops from its normal position in the pelvis and pushes on the walls of the vagina.

move for summary judgment as to each of Plaintiffs' eighteen purported claims,² contending that (1) Plaintiffs' claims are barred by Pennsylvania's two-year statute of limitations for personal injury actions; (2) Plaintiffs' claims premised on strict liability fail because Pennsylvania law does not recognize strict liability claims involving prescription medical devices such as Defendants' pelvic mesh; (3) Plaintiffs' design defect claims fail because (i) they are preempted by federal law, (ii) Plaintiffs cannot meet their burden of proof, and (iii) Plaintiffs cannot establish causation; and (4) Kennedy's derivative loss of consortium claim fails in the absence of any underlying claim.

For the reasons set forth below, the Court finds that there can be no genuine factual dispute that Plaintiffs' claims accrued no later than May 4, 2011. They are therefore barred by

² *See generally*, Plaintiffs' Short Form Complaint ("Pls.' Compl.") [ECF No. 1]. The Court characterizes Plaintiffs' claims as "purported" because, as explained more fully below, Defendants contend (and the Court agrees) that several of Plaintiffs' "claims" are not independent causes of action but rather remedies or derivative claims.

As listed in the Short Form Complaint, Plaintiffs' claims are as follows: negligence (Count I); strict liability — manufacturing defect (Count II); strict liability — failure to warn (Count III); strict liability — defective product (Count IV); strict liability — design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV, however this count is unchecked on the form complaint, likely indicating that Plaintiffs are not asserting this claim); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). *See* Pls.' Compl. at 4-5.

However, Plaintiffs state in their memorandum in opposition to Defendants' motion that they are not proceeding at trial on the following claims: strict liability — manufacturing defect (Count II); strict liability — defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV). *See* Plaintiffs' Memorandum in Opposition ("Pls.' Opp'n.") [ECF No. 75] at 23 n.4.

the applicable two-year statute of limitations, and Defendants’ motion for summary judgment is granted.

II. BACKGROUND

A. The undisputed material facts³

As far as the factual record is concerned, Defendants’ motion for summary judgment rests almost exclusively on the issue of when Kennedy became aware, or should have become aware, that her medical conditions were caused by Defendants’ pelvic mesh. Because Kennedy’s deposition testimony is the primary vehicle for the facts each side thinks supports its position with respect to when Kennedy was put on notice, the Court reviews the undisputed “objective” facts regarding her treatment first — such as the dates of procedures and her doctors’ characterizations of her conditions — before addressing the representations made in Kennedy’s deposition testimony.

1. *Ramona Kennedy’s conditions and treatment*

In June 2009, at the age of sixty years old, Ramona Kennedy presented to her OB-GYN, Dr. Dominic Cammarano, who diagnosed her with a third-degree cystocele, a condition in which the bladder drops from its normal position in the pelvis and bulges into the vagina. Plaintiffs’ Response and Statement of Additional Material Facts (“Pls.’ SAMF”) [ECF No. 75-1] ¶ 24.⁴ Dr.

³ The Court draws the following facts from the parties’ factual statements and responses thereto, and generally cites to these statements rather than the underlying record except where a description of or reference to the record is necessary for comprehension. The Court generally does not recite factual assertions that are not undisputed, not material, not supported by proper citations to the record, or that are supported by citations to the record the substance of which does not actually provide support. *See* FED. R. CIV. P. 56(c)(1); Leeson, J., Policies and Procedures §§ II(F)(7)-(8). Where a fact is purportedly disputed but necessary for context or comprehension, the Court may recite the fact and note the purported dispute in a footnote.

⁴ Plaintiffs’ SAMF contains thirty-eight paragraphs, many of which are comprised of multiple sentences and contain multiple asserted “facts.” For example, Plaintiffs’ first paragraph of additional material facts, numbered paragraph 24, is comprised of five long sentences, each

Cammarano recommended implantation of an anterior Prolift medical device, a transvaginal mesh product designed and marketed by Defendants, to treat her condition. *Id.*; Defendants’ Statement of Undisputed Material Facts (“Defs.’ SOMF”) [ECF No. 71-1] ¶ 6. Dr. Cammarano performed the Prolift implantation on September 23, 2009, at which time he also implanted an Advantage Fit TVT device to treat stress urinary incontinence. Pls.’ SAMF ¶ 24; Defs.’ SOMF ¶ 2. Kennedy did not suffer any intra-operative or immediate post-operative complications. *Id.*

In March 2011, Kennedy began experiencing severe abdominal pain, which she initially attributed to pancreatitis. Defs.’ SOMF ¶ 7. After a CT scan revealed the existence of a bladder stone, Kennedy was referred to a urologist, Dr. Constantine Harris. *Id.* ¶ 8. Dr Harris initially evaluated Kennedy on March 31, 2011. *Id.* ¶ 9. After reviewing her past medical history and performing a physical examination, Dr. Harris concluded, as stated in his examination notes, that Kennedy’s “bladder stone [was] most likely the result of mesh erosion.” *Id.* ¶ 10; Pls.’ SAMF ¶ 25. As to his initial examination of Kennedy, Dr. Harris testified at his deposition as follows: “In my experience, patients that – women who have bladder stones, most times it’s attached to something in the bladder. With [Kennedy’s] history of a Prolift and a TVT, that was the most likely explanation for a fairly large stone in the bladder.”⁵ Defs.’ SOMF ¶ 11.

containing multiple factual assertions. The paragraph contains a single citation to the record. This type of organization greatly complicates the ability of Defendants to respond to the individual facts contained within the paragraph — as well as the Court’s ability to weed out non-genuine factual disputes. This manner of organization thereby contravenes the spirit, if not the substance, of Federal Rule of Civil Procedure 56. Moreover, as a general matter, many of the additional facts Plaintiffs claim are “material” simply are not. The Court will not recite or consider facts that are not truly “material” to the legal issues on which Defendants’ motion is based, as well as facts — like many of those contained in Plaintiffs’ SAMF — that the Court cannot easily untangle, cannot connect to a proper citation to the record, or cannot determine, owing to their organization, are truly undisputed.

⁵ Plaintiffs respond to this fact as follows: “Disputed as stated. By way of further response, Dr. Harris’s deposition is a document in writing. Plaintiffs deny any characterization of it.” Pls.’ SAMF ¶ 11. However, the quote as recited above is verbatim from Dr. Harris’

On April 1, 2011, Dr. Harris performed a cystoscopy that revealed a 2-3 cm bladder calculus adherent to Kennedy's bladder wall; pursuant to the operative report, Dr. Harris' impression continued to be that "[t]he stone may be adherent to exposed TVT or Prolift mesh." *Id.* ¶ 12; Pls.' SAMF ¶ 25.

Dr. Harris performed a second cystoscopy on Kennedy on May 4, 2011, during which he removed the bladder stone and observed "[t]he blue fibers and translucent fibers of the mesh were clearly visible." Defs.' SOMF ¶ 17; Pls.' SAMF ¶ 26. Dr. Harris' notes indicate that "[t]he mesh was seen to dive submucosally at the lateral trigone," and "the mesh was also seen to pass submucosally close to the bladder neck on the left lateral wall." Pls.' SAMF ¶ 26. During the May 4, 2011 procedure, Dr. Harris successfully excised the exposed mesh. Defs.' SOMF ¶ 17.

Because her symptoms persisted after the first mesh removal procedure, on June 30, 2011, Kennedy presented to Dr. Harris for a follow-up visit and cystoscopy, at which time Dr. Harris noted two additional bladder stones.⁶ Pls.' SAMF ¶ 27. One bladder stone was visible "just above the left ureteral orifice," and another "on the left lateral wall," which corresponded "to the locations of the ends of the previous cystine mesh." *Id.* Both stones were "adherent to the wall" and, Dr. Harris noted, "likely underlying the mesh." *Id.* Following the cystoscopy, Dr. Harris diagnosed Kennedy with "recurrent calculi with previous mesh erosion," and recommended possible treatment options of (1) an endoscopic excision of the ends of the mesh and stone removal, or (2) an "open" procedure. *Id.* Dr. Harris recommended an endoscopic approach first before attempting an open procedure, and Kennedy agreed. *Id.*

deposition transcript and is not a characterization. *See* Dr. Harris' Deposition Transcript ("Harris Dep."), Defendants' Exhibit D [ECF No. 71-5] at 15:10-15.

⁶ The June 30 procedure was preceded by a postoperative follow-up on May 12, 2011, at which time Dr. Harris checked Kennedy's urine and discussed future treatment plans. *See* Harris Dep. at 24:4-18. No physical examination was performed during this visit. *See id.*

On July 19, 2011, Kennedy underwent a second revision procedure, during which Dr. Harris performed a litholopaxy with cystoscopic removal of foreign body mesh. Pls.’ SAMF ¶ 28. During the procedure, Dr. Harris noted two calculi adherent to the bladder mucosa, one “immediately medial to the left ureteral orifice,” and the other “on the left wall near the bladder neck.” *Id.* Dr. Harris excised “the visible mesh as deeply as possible,” including “down to what appeared to be the outer detrusor layer of the bladder.” *Id.* Visible mesh fibers were trimmed, and, at “the end of the procedure the only visible mesh was deep through the mucosa and detrusor muscle.” *Id.*

On August 25, 2011, Kennedy presented to Dr. Harris for her next cystoscopy.⁷ Pls.’ SAMF ¶ 29. Dr. Harris noted that during this procedure he observed “bullous edema on the left posterior wall [of the bladder] adjacent to the left ureteral orifice.” *Id.* He also noted “a fibrinous material in the center of the area likely leading to the mesh” and “a large area of bullous edema with fibrinous material in the center of the left lateral wall” corresponding to “sites of prior stone removal and excision of mesh.” *Id.* Following the procedure, Dr. Harris recommended an “open” procedure — as opposed to the previous endoscopic procedures — to “excise the involved areas of mesh,” and Kennedy agreed. *Id.*

On September 12, 2011, Kennedy underwent a third mesh removal procedure — the “open” procedure. Pls.’ SAMF ¶ 30. During this procedure, Dr. Harris excised two areas of eroded mesh, one “immediately lateral and cephalad to the left ureteral orifice,” and one on “the left lateral wall above the bladder neck.” *Id.*

⁷ Plaintiffs state that on this date “Mrs. Kennedy presented to Dr. Harris for her next follow-up visit,” however, it appears there was a previous post-operative follow-up visit on July 29, 2011. *See* Harris Dep. at 35:19-25.

In March 2012, Dr. Harris referred Kennedy to OB-GYN Dr. Jaime Long, who diagnosed Kennedy with mesh erosion into the bladder status post resection, recurrent urinary tract infections, urinary incontinence, and a rectocele, for which Dr. Long recommended a surgical repair. Pls.’ SAMF ¶ 31. The surgical repair was performed on April 24, 2012. *Id.* However, prior to that, on April 12, 2012, Dr. Harris performed another cystoscopy on Kennedy to check for recurrent mesh erosion and recurrent bladder calculi, at which time he noted that there was “no evidence of mesh extrusion or erosion” and “no new stones.” Defs.’ SOMF ¶ 18.

On November 27, 2012, Kennedy underwent a fourth mesh removal procedure, this time performed by urologist Dr. Ariana Smith. Pls.’ SAMF ¶¶ 33-34.

2. Kennedy’s deposition testimony

At her deposition, Kennedy testified at length regarding her many medical treatments. Both sides point to testimony of Kennedy which they contend supports their respective positions: in the case of Defendants, that Kennedy was aware that the mesh was the cause of her ongoing medical conditions as early as March 2011; in the case of Plaintiffs, that Kennedy did not have such knowledge — or at least knowledge insufficient to trigger the limitations period — until she saw Dr. Long in 2012.

The Court recites the portions of Kennedy’s testimony cited by Defendants first, followed by the portions cited by Plaintiffs. The Court reproduces the relevant portions of the deposition without characterization.

a. Testimony cited by Defendants

Q: Understood. And when you met with Dr. Harris, he was the next doctor you met with to discuss the issues you were having with incontinence and the urgency and the frequency we have been discussing?

A: Well, really the first time I saw Dr. Harris was when I had found out that I had the bladder stones and then he told me that they were attached to the mesh and had gone through my bladder.

Q: That was Dr. Harris who told you that?

A: That was in March of 2011.

Ramona Kennedy Deposition Transcript (“Kennedy Dep.”) [ECF No. 71-4] at 113:21-24, 114:2-8; *see* Defs.’ SOMF ¶ 13.

Q: Ms. Kennedy, what were the first symptoms that indicated to you that you were having trouble after the implant surgery with Dr. Cammarano?

A: I want to say I had frequency and leakage right after, but the first real symptoms I had were in March of 2011.

* * *

Q: Is that when you began treating with Dr. Harris?

A: That’s when I began with Dr. Harris then.

Q: And you knew in March of 2011 that the injuries that you were experiencing were because of the mesh?

A: Yes.

Kennedy Dep. at 70:18-23, 71:13-19; *see* Defs.’ SOMF ¶ 14.

Q: Understood. Was it at that point when Dr. Harris had done that cystoscopy and said he saw the mesh going through your bladder that you began to attribute that need to reposition yourself or that painful urination you began to connect that back to your surgery in 2009?

A: I kind of – I kind of did but I kind of didn’t. I mean, I really attributed it to the pancreatitis because I thought for sure I was getting that again but then when I found out I had the bladder stones and not pancreatitis and that the mesh had gone through my bladder, then yes, I did attribute that to the surgery.

Q: And that was in March of 2011?

A: Yes.

Kennedy Dep. at 115:17-24, 116:1-7; *see* Defs.' SOMF ¶ 15.

Q: What do you think that Ethicon did wrong?

A: I think their product was faulty.

Q: Has any medical doctor told you that Ethicon's product was faulty?

A: I'm going to say yes because it was evident when it went through my bladder.

* * *

Q: When you tell me you saw mesh coming through your bladder, what do you mean by that?

A: I mean when I had the cystoscopy done, they had a camera above my head and I could see everything that was going on.

Q: What cystoscopy are you referring to?

A: The one Dr. Harris did, the first one.

Kennedy Dep. at 22:10-15, 25:4-11; *see* Defs.' SOMF ¶ 16.⁸

⁸ Although Defendants do not point it out, it seems a key piece of testimony from Kennedy's deposition supporting their position would be the following:

Q: Is it fair to say that early in 2011 you were aware that you were having problems because of the mesh?

A: March, yes. March 2011.

Q: In March 2011, you were aware that the problems you were having were because of the mesh implanted by Dr. Cammarano?

A: Yes.

Kennedy Dep. at 50:18-24, 51:1.

b. Testimony cited by Plaintiffs⁹

Q: When did you first realize that these symptoms that were occurring ever since the surgery were, in fact, related or attributed to actually the pelvic mesh products that were implanted in you in 2009?

A: Okay. I think that was right around the time I talked to Dr. Long, and she did her procedure and I had talked to Dr. Harris and said I want this stuff out. I said because – I said I had gone through enough pain I thought and I don't know, for some reason, I thought if they took it out, I wouldn't have the pain or the infections, and I know it was after talking to her and what she was going to do, and that it could be related to the mesh, she said. She didn't necessarily say it was related but could have been. And after that, then, I just realized that this was nasty stuff.

Q: And when you say “she”, are you referring to Dr. Long?

A: Dr. Long. Jaime Long.

Kennedy Dep. at 177:16-24, 178:1-11; *see* Pls.' SAMF ¶¶ 14-16.¹⁰

Q: The fact sheet indicates on page seven on C, April 12, 2012 is what [sic] the timeframe you recall attributing your injuries to the pelvic mesh products that were implanted in '09?

A: Right, because even though I had three procedures, I really didn't – I really didn't put it that the mesh was faulty. I just thought it went through my bladder which would be a rare occurrence.

Kennedy Dep. at 178:17-24; *see* Pls.' SAMF ¶¶ 14-16.

B. Procedural Background

Plaintiffs filed their initial complaint in this action on July 2, 2013, in the United States District Court for the Southern District of West Virginia, as part of an ongoing pelvic mesh

⁹ It is noteworthy that portions of the deposition cited by Plaintiffs exclusively represent Kennedy's responses to her own attorney's examination questions at the tail end of the deposition. *See* Kennedy Dep. at 173:3-7 (“Okay. Ramona, I have a couple questions for you, and we talked about it off the record for a moment but I know I am seated beside you and it's going to be seem [sic] strange but you will still focus on the camera.”)

¹⁰ Plaintiffs state that “[t]here is no dispute that Mrs. Kennedy did not see Dr. Jaime Long until March of 2012.” *Id.*

multidistrict litigation (“MDL”). *See* ECF No. 1. The case stayed with the MDL court through the close of discovery and dispositive motion briefing, and on December 19, 2019, the MDL court entered an Order remanding the case and numerous other cases to federal district courts of competent jurisdiction around the country. *See* ECF No. 46. Pursuant to that Order, on or about January 2, 2020, the matter was transferred to this Court. *See* ECF Nos. 48-52. Upon transfer, the Undersigned dismissed Defendants’ pending motion for summary judgment without prejudice and re-set dispositive motion and trial deadlines. *See* ECF No. 59. Defendants re-filed their motion for summary judgment on February 14, 2020. *See* ECF No. 71.

III. LEGAL STANDARD

Rule 56(a) of the Federal Rules of Civil Procedure provides that a “court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). The moving party bears the initial burden of establishing that no genuine issue of material fact exists. *Bacon v. Avis Budget Grp., Inc.*, 357 F. Supp. 3d 401, 412-13 (D.N.J. 2018). In determining if the moving party has satisfied this burden, the Court is obliged to construe all facts and factual inferences in the light most favorable to the non-moving party. *See United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 401 (D.N.J. 2019); *Boyle v. Cty. of Allegheny Pa.*, 139 F.3d 386, 393 (3d Cir. 1998). “[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by ‘showing’— that is, pointing out to the district court — that there is an absence of evidence to support the nonmoving party’s case.” *Bacon*, 357 F. Supp. 3d at 413 (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

Where the movant shows a *prima facie* entitlement to summary judgment, the burden shifts to the non-movant to point to record evidence creating a genuine issue of material fact. See FED. R. CIV. P. 56(e); *Davis v. Quaker Valley Sch. Dist.*, No. 13-1329, 2016 WL 912297, at *8 (W.D. Pa. Mar. 10, 2016), *aff'd*, 693 F. App'x 131 (3d Cir. 2017). “[T]he non-moving party may not merely deny the allegations in the moving party’s pleadings; instead he must show where in the record there exists a genuine dispute over a material fact.” *Gibson-Reid v. Lendmark Fin. Servs., LLC*, No. 2:19-CV-02859, 2019 WL 4139034, at *1 (E.D. Pa. Aug. 30, 2019) (quoting *Doe v. Abington Friends Sch.*, 480 F.3d 252, 256 (3d Cir. 2007)); see *Schoch v. First Fid. Bancorp.*, 912 F.2d 654, 657 (3d Cir. 1990) (“[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment.”). Summary judgment is mandated where a non-moving party fails “to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial. . . . [T]here can be ‘no genuine issue of material fact’” where “a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 n.5 (3d Cir. 1992) (quoting *Celotex*, 477 U.S. at 322-23).

IV. DISCUSSION

As noted previously, Defendants move for summary judgment on four distinct grounds. First, Defendants claim Plaintiffs’ claims are barred by Pennsylvania’s two-year statute of limitations applicable to personal injury actions. See Defendants’ Memorandum in Support of their Motion (“Defs.’ Mem.”) [ECF No. 71] at 5. Second, they contend Pennsylvania law does not recognize Plaintiffs’ claims for strict liability in cases involving prescription medical devices like the pelvic mesh made and marketed by Defendants here. See *id.* Third, Defendants claim

that Plaintiffs' claims for design defects fail because they are preempted by federal law, because Plaintiffs cannot meet their burden of proof, and because Plaintiffs cannot establish causation. *See id.* Fourth and finally, Defendants contend that Mr. Kennedy's derivative loss of consortium claim fails as a matter of law without a viable source claim. *See id.*

As explained below, there can be no genuine factual dispute as to when Kennedy gained knowledge of her injuries sufficient to trigger the statute of limitations; in light of the undisputed factual record, her claims are untimely. As a consequence, Defendants' second, third, and fourth arguments are moot. The Court therefore focuses its analysis exclusively on the issue of when Kennedy's claims accrued and the limitations period was triggered.

A. Review of the law: The statute of limitations

Under Pennsylvania law,¹¹ an action "to recover damages for injury to person or property which is founded on negligent, intentional, or otherwise tortious conduct" is subject to a two-year statute of limitations. 42 PA. CONS. STAT. § 5524(7). The two-year limitations period runs "from the time the cause of action accrued." 42 PA. CONS. STAT. § 5502(a). "Generally, 'a cause of action accrues, and thus the applicable limitations period begins to run, when an injury is inflicted.'" *Carlino v. Ethicon, Inc.*, 208 A.3d 92, 103 (Pa. Super. Ct. 2019) (quoting *Wilson v. El-Daief*, 600 Pa. 161, 174 (2009)), *reargument denied* (June 12, 2019); *Dubose v. Quinlan*, 643 Pa. 244, 258 (2017) ("Statutes of limitations begin to run when the cause of action accrues, which is usually the time a plaintiff is injured."). "Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action." *Fine v. Checcio*, 582 Pa. 253, 266 (2005).

¹¹ There does not appear to be any dispute that Pennsylvania law governs Kennedy's personal injury claims in this diversity action. *See, e.g.,* Pls.' Opp'n. at 23 n.5.

There are, however, exceptions to the general rule that bars a plaintiff from bringing suit once the limitations period has run. The “discovery rule” is one such exception. “Under the ‘discovery rule,’ a cause of action does not accrue until the plaintiff discovers, or should have discovered, the injury.” *Dubose*, 643 Pa. at 252 n.4. The discovery rule “is premised on the concept that where the existence of an injury is not apparent or where the existence of an injury cannot be reasonably ascertained, the statute of limitations does not begin to run until such time as the injury's existence is known or discoverable by the exercise of reasonable diligence.” *Ward v. Rice*, 828 A.2d 1118, 1121 (Pa. Super. Ct. 2003), *aff'd sub nom. Fine v. Checcio*, 582 Pa. 253 (2005). The rule is thus intended “to ensure that persons who are reasonably unaware of an injury that is not immediately ascertainable have essentially the same rights as those who suffer an immediately ascertainable injury.” *Nicolaou v. Martin*, 195 A.3d 880, 892 n.13 (Pa. 2018).

“Pennsylvania's formulation of the discovery rule reflects a narrow approach to determining accrual for limitations purposes and places a greater burden upon Pennsylvania plaintiffs vis-à-vis the discovery rule than most other jurisdictions.” *Gleason v. Borough of Moosic*, 609 Pa. 353, 362 (2011). Under the Pennsylvania discovery rule, the commencement of the limitations period is grounded on “inquiry notice,” which is tied to “actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause.” *Wilson* 600 Pa. at 178; *see Gleason*, 609 Pa. at 362. Accordingly, the discovery rule tolls the statute of limitations until — or conversely, the statute of limitations begins to run when — a plaintiff knows, or, “exercising reasonable diligence,” should have known that (1) he or she was injured and (2) that the injury was caused by another. *Adams v.*

Zimmer US, Inc., 943 F.3d 159, 163 (3d Cir. 2019) (citing *Coleman v. Wyeth Pharms.*, 6 A.3d 502, 510-11 (Pa. Super. Ct. 2010)).

“[I]t is well-settled that the reasonable diligence standard is objective, as the question is not what the plaintiff actually knew of the injury or its cause, but what he might have known by exercising the diligence required by law.” *Nicolaou*, 195 A.3d at 893. At the same time, however, the standard is “‘sufficiently flexible’ to ‘take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question.’” *Adams*, 943 F.3d at 163 (quoting *Fine*, 582 Pa. at 267). Under the “reasonable diligence” standard, “a plaintiff’s actions are examined to determine whether the plaintiff demonstrated ‘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.’” *Nicolaou*, 195 A.3d at 893 (quoting *Fine*, 582 Pa. at 267). In the context of product liability cases, a lay plaintiff is generally not expected to possess more knowledge than his or her medical or healthcare provider who provided treatment and diagnosis. *Nicolaou*, 195 A.3d at 893; *Wilson*, 600 Pa. at 180.

“[B]ecause the reasonable diligence determination is fact intensive, the inquiry is ordinarily a question for the jury”; and yet, “courts may resolve the matter at the summary judgment stage where reasonable minds could not differ on the subject.” *Nicolaou*, 195 A.3d at 893-94; *Wilson*, 600 Pa. at 175. The party asserting the discovery rule — that is, the party claiming the rule tolls the statute of limitations — “bears the burden of proving that reasonable diligence was exercised.” *Nicolaou*, 195 A.3d at 893.

B. Review of the law: Application of Pennsylvania’s “discovery rule”

It is worth briefly reviewing several judicial decisions in which courts applying Pennsylvania law have addressed the discovery rule and the issue of actual and constructive notice.

Recently, in *Adams v. Zimmer US, Inc.*, 943 F.3d 159 (3d Cir. 2019), the Third Circuit addressed an appeal from a district court’s grant of summary judgment in favor of defendants in a product liability case over an allegedly defective hip implant. According to the Third Circuit, the appeal required the Court to determine “whether a reasonable juror could credit plaintiff Marilyn Adams’s contention that she reasonably did not know until February 12, 2015 that the hip implant made by defendant Zimmer, Inc., caused her the injuries.” *Id.* at 161. Although “[t]he District Court concluded there can be no dispute that the information available to Adams in her preoperative visits would have put a reasonably diligent person on notice of her injury as a matter of law,” *id.* at 164, the Third Circuit found that the district court improperly “resolved issues of fact regarding the timing of Adams’s discovery that her hip pain was caused not by her poor adjustment to the implant but instead by the implant itself,” *id.* at 161. The Third Circuit concluded that “a jury could reasonably conclude Adams ascribed her pain to her own poor adjustment to the implant; it was only when her doctor discovered new information ‘intraoperatively’ that she would know the implant’s disintegration, rather than her reaction to the implant, was causing her pain. *Id.* at 165. Other considerations leading the Court to this conclusion included that Adams had had a “difficult” diagnostic history which counseled “against quickly charging her with knowledge of an injury.” *Id.* at 167. “She moreover had confronted the possibility of her implant being replaced once before, during her 2012-13 struggle with infection; the implant was ultimately left in place, which could lead a reasonable person in

her position to believe surgery calling for removal did not mean the device itself was causing her harm.” *Id.*

On the same day the Third Circuit issued its decision in *Adams*, the Pennsylvania Supreme Court decided *In re Risperdal Litig.*, 223 A.3d 633 (Pa. 2019). *In re Risperdal* concerned an appeal from the Superior Court’s affirmation of the trial court’s grant of summary judgment against two plaintiffs who alleged that they developed gynecomastia (enlarged breasts in men) as a result of their ingestion of Risperdal, an antipsychotic drug. The Supreme Court concluded that “[t]he certified record here provides no substantial basis for” the finding of the Superior Court — that the two plaintiffs had sufficient constructive knowledge of their injuries in 1998 and 2002, well outside the statute of limitations. *Id.* at 641. In reaching this conclusion, the Court observed the summary judgment motion at issue was filed in an attempt to obtain a “global” accrual date for all Risperdal claims and prior to any case-specific discovery. *Id.* As such, the certified record contained no pictures of the plaintiffs’ alleged malformations, no medical records, and no deposition testimony of the plaintiffs or their doctors. *See id.* In the absence of any evidence, the Supreme Court cautioned against what it saw as the Superior Court’s improper assumption that the two plaintiffs “either knew or should have known that their breast growth was an outward manifestation of an endocrine disorder known as gynecomastia (thus triggering a duty to investigate its underlying cause).” *Id.* at 642. “Importantly,” the Court observed, “the Superior Court fail[ed] to distinguish between knowledge of the *physical condition* of large breasts and the critical knowledge of an *injury*, gynecomastia.” *Id.* (emphasis in original).

Several months before the *In re Risperdal* decision was issued, the Pennsylvania Superior Court decided *Carlino v. Ethicon, Inc.*, 208 A.3d 92 (Pa. Super. Ct. 2019), *reargument denied*

(June 12, 2019). In this case, the Defendants here — Ethicon, Inc. and Johnson and Johnson — appealed from a \$13,500,000.00 jury verdict in the Philadelphia Court of Common Pleas stemming from implantation of a defective TVT device.¹² The Superior Court found that the question of when the plaintiff had notice sufficient to trigger the statute of limitations¹³ was a fact-intensive question that was properly put before the jury, and explained as follows:

Ethicon makes a spirited argument that the statute of limitations bars Ms. Carlino’s action as a matter of law. Specifically, Ethicon asserts that in view of Ms. Carlino’s history of pain in 2007 and 2010, the advice her physicians gave her on both occasions that the TVT was causing her pain due to erosion, her decision to have corrective surgery on both occasions, and the recurrence of her discomfort in March 2011, Ms. Carlino knew or should have known before June 26, 2011 that the TVT caused her injuries. These are indeed strong points, but the other evidence described above supports a different conclusion: she reasonably believed her pain was a risk of surgery. Because there was conflicting evidence on this subject, the trial court properly denied Ethicon’s motion for judgment n.o.v.

Id. at 105.

In *Nicolaou v. Martin*, 195 A.3d 880 (Pa. 2018), in which the plaintiff brought suit for failure to diagnose her Lyme disease, the Pennsylvania Supreme Court addressed an appeal from a grant of summary judgment in favor of defendants on the grounds that the statute of limitations had expired. In finding that the Superior Court — which had affirmed the trial court’s grant of summary judgment — had erred, the Supreme Court noted that “[w]hen viewed in a vacuum,” the facts relied on by the lower courts “may have alerted a reasonable person that she suffered an injury at the hands of medical professionals who failed to diagnose and treat her Lyme disease.

¹² Kennedy also had implanted a TVT device, yet the instant suit is concerned only with the Prolift mesh product.

¹³ Although the plaintiff’s cause of action in *Carlino* accrued in New Jersey, the Superior Court explained that “both jurisdictions [Pennsylvania and New Jersey] employ parallel discovery rules that toll the statute of limitations until the plaintiff knows or reasonably should know that she suffered injury due to the fault of another.” *Id.* at 103. The Court went on to state that “[s]ince both jurisdictions have the same law, we apply the law of the forum state, Pennsylvania.” *Id.*

Indeed, these circumstances may or may not persuade a jury to so conclude.” *Id.* at 894.

“However,” the Court explained, “courts may not view facts in a vacuum when determining whether a plaintiff has exercised the requisite diligence as a matter of law, but must consider what a reasonable person would have known had he or she been confronted with the same circumstances” as the plaintiff. *Id.* The Court concluded as follows:

In summary, we conclude that it is within the province of a jury to determine whether an untrained lay person who had been repeatedly and definitively diagnosed with [multiple sclerosis] by several previous physicians, had four prior negative Lyme disease tests, and lacked health insurance to cover the costs of further diagnostic testing “reasonably should have known” that she suffered from Lyme disease after [a nurse] informed her of a “probable” diagnosis of that disease based on her clinical symptoms, and when some of her symptoms improved after taking antibiotics prescribed for that condition.

Id. at 895.

Moving backwards in time, the Pennsylvania Supreme Court reached a similar conclusion in *Gleason v. Borough of Moosic*, 609 Pa. 353 (2011). *Gleason* concerned liability for so-called “toxic-mold” contamination in the plaintiffs’ basement stemming from construction of a sewer system near plaintiffs’ home. The plaintiffs filed suit in 2001 against their municipality for health-related injuries suffered as a result of contamination stemming from the sewer. The state trial and Superior Courts concluded the plaintiffs should have known about the contamination in 1997 when they attempted to renovate their basement, because the renovation revealed “mold and discoloration” and plaintiffs “began to experience symptoms of illness during and after the aborted basement renovation.” *Id.* at 360. The Supreme Court disagreed, finding the record evidence was not such as to put the issue firmly to rest. The Court observed that even though it was undisputed that the plaintiffs were aware of the mold in their basement, the defendants did

not recite any facts that would tend to show that [plaintiffs] had been informed by any medical personnel or any layperson, for that matter, that their ailments were or even might be mold-related prior to the year 2000. Moreover, [defendants] do not assert how or why [plaintiffs] should have immediately known or even suspected that their ailments were mold-related. There is no indication in the record that the phrase “toxic mold” entered the nation's lexicon prior to the year 2000, and it cannot be seriously argued that the exercise of reasonable diligence would require one to uncover a relatively new environmental hazard prior to the time it becomes recognized and reported in the media.

Id. at 365. The Court concluded that “given the disputed and somewhat complex factual scenario presented . . . a jury should determine the point at which [plaintiffs] should have reasonably been aware of their injury and its cause.” *Id.* at 367.

Two years earlier, the Pennsylvania Supreme Court in *Wilson v. El-Daief*, 600 Pa. 161 (2009) addressed the discovery rule in a medical malpractice context. The trial and Superior Courts had found that the discovery rule was not available to the plaintiff in tolling the statute of limitations for the following reasons:

Plaintiff admits that she began experiencing excruciating pain at the incision point site immediately after the surgery on August 4, 2000, in contrast to the relief she experienced from her symptoms after the May 2000 procedure. Any soreness associated with the May 2000 surgery resolved after the stitches were removed. The pain Plaintiff experienced following the August 2000 procedure increased, despite removal of the stitches. Significantly, Plaintiff believed “something wasn't right,” and that Defendant had not taken proper care of her, no later than September 24, 2001. Accordingly, the record before this court compels a finding that even if the discovery rule applied it would not extend the running of the statute of limitations past September 24, 2003. Thus, Plaintiff[s] suit is time-barred because it was not commenced until October 10, 2003.

Id. 166-67 (quoting *Wilson v Daief*, No. 03-19723, Slip. Op. at 4-5 (Pa. Com. Pl. Mar. 13, 2006)). The Supreme Court disagreed. The Court took special note of the ability of long-lasting post-surgical symptoms to be confused with injuries resulting from tortious conduct, particularly, in the plaintiff's case, “in the asserted unwillingness or inability on the part of [the defendant doctor] to recognize injury or cause, and in the failure of [a second doctor] to offer [the plaintiff] his assessment upon consultation.” *Wilson*, 600 Pa at 180 (citations omitted). While the Court

“reiterate[d] that knowledge of ‘injury’ and ‘cause’ does not require a precise medical diagnosis,” it “decline[d] to hold, as a matter of law, that a lay person must be charged with knowledge greater than that which was communicated to her by multiple medical professionals involved in her treatment and diagnosis.” *Id.*

Wilson — and most of the above-discussed cases — relies heavily on the Pennsylvania Supreme Court’s decision in *Fine v. Checcio*, 582 Pa. 253 (2005). *Fine* was a consolidated case concerning two plaintiffs’ claims of dental malpractice. In disagreeing with the lower courts as to the applicability of the discovery rule to one of the primary plaintiffs’ (Fine’s) claims, the Supreme Court stated as follows:

It is important to keep in mind that in this case, the record revealed that facial numbness was indicative of two distinct phenomena. Facial numbness was either a temporary physical consequence that resulted from the very nature of the procedure that [the defendant dentist] performed on Fine or it was a manifestation of Fine’s injury, a permanent condition that resulted from underlying nerve damage. Until conflicts in the record were resolved, and inferences from relevant facts were drawn, the issue of whether Fine knew, or should have known through the diligence that a reasonable person would have exercised under the circumstances, that the numbness he was experiencing on July 17, 1998, was a manifestation of injury, as, opposed to, or in addition to, the typical condition that dental surgery produces remained disputed. Therefore, to rule against the discovery rule’s application, the Superior Court had to undertake these fact-resolution and inference-drawing functions. In doing so, the court erred. We emphasize that it is not the court’s function upon summary judgment to decide issues of fact, but only to decide whether there is an issue of fact to be tried.

Id. at 272-73 (citations omitted).

While the above decisions are examples of fact-intensive circumstances precluding a judicial determination of the discovery rule issue as a matter of law, the following decisions present circumstances in which no genuine factual dispute existed.

Very recently, application of the discovery rule was addressed in *McLaughlin v. Bayer Essure, Inc.*, No. 14-7316, 2020 WL 1625549 (E.D. Pa. Apr. 2, 2020). This case is a

consolidated action still pending in this Court in which plaintiffs seek compensation for injuries sustained in connection with the purchase of Essure, a birth control device. The April 2, 2020 decision ruled on objections to a Special Master's Report and Recommendation concerning the timeliness of claims of fifty plaintiffs. The Court both rejected the Special Master's recommendation that certain claims were not time-barred under Pennsylvania law, and adopted the Special Master's recommendation that other claims were time-barred. For example, the Court rejected the recommendation that the claims of one plaintiff ("S.G.") were not time-barred because "her doctor never informed her that Essure may have been the cause of her pain, but rather, attributed her pain to other medical issues, and because her doctor never diagnosed her with a migration or other Essure-related problems." *Id.* at *14. As to this plaintiff, the Court held that

[c]ontrary to the Special Master's assertion . . . the undisputed evidence in the summary judgment record is that S.G. learned of an Essure perforation in November of 2011, or, at the latest, in December of 2012. She specifically admits that she learned in December of 2012 that Essure had perforated her pelvis. The Essure implants were removed from her abdomen in a May 2013 surgery. In light of the known Essure perforation, the undisputed evidence demonstrates that S.G. kn[ew] or, with reasonable diligence, should have known that she was injured by Essure as early as November of 2011 and no later than May of 2013. Moreover, S.G. admits that her doctor told her in June of 2013 that she was suffering a non-pregnancy-related Essure injury.

Id. (citations omitted). The Court adopted the Special Master's recommendation that the claims of another plaintiff ("T.M.") were time-barred. The Court stated as follows:

[W]hen T.M. learned that she was pregnant and subsequently learned that one Essure coil was embedded in her uterus and the other had perforated her fallopian tube, she knew that she had been injured by Essure and the statute of limitations began to run. Although her doctor may have been telling her that her pain, fatigue and other symptoms were not caused by Essure, the fact that T.M. had not connected these additional injuries to her migrated coil and the second coil that had perforated her fallopian tube is inconsequential under Pennsylvania law, which states that the statute begins to run when a plaintiff has "actual or constructive knowledge of at least some form of significant harm and of a factual cause linked

to another's conduct, without the necessity of notice of the full extent of the injury." Thus, a reasonable jury could only conclude that the statute of limitations began to run on Plaintiff's tort claims in 2011, when she knew that she had suffered significant injuries (migration and perforation) as a result of Essure.

Id. at *24. As to another plaintiff ("S.J."), the Court found that

[u]nder these circumstances, the undisputed evidence establishes that S.J. had an unrebutted suspicion that she had been injured by Essure and that her doctor performed a hysterectomy in July of 2012 to, among other things, remove the Essure coils and address unusual bleeding that he told her was Essure-related. Thus, a reasonable jury could only conclude that, no later than July of 2012, S.J. was on inquiry notice that she had been injured by Essure.

Id. at *26.

In *Hartey v. Ethicon, Inc.*, No. CIV.A. 04-CV-5111, 2006 WL 724554 (E.D. Pa. Mar. 20, 2006) — a case involving the implantation of Mersilene mesh manufactured by Ethicon, Inc. — a Judge on this Court applying Pennsylvania law granted Ethicon summary judgment on the basis of the plaintiffs' untimely claims. Plaintiffs had filed a medical malpractice suit against the implantation doctor on March 1, 2002, and this product liability action on September 28, 2004.

Id. at *1. The Court in *Hartey* found that allegations in the 2002 malpractice pleadings made clear that plaintiffs were on notice of the complained-of injury well in advance of two years prior to the filing of the product liability action. Specifically, the Court found as follows:

It is undeniable that as of March 1, 2002 [the date of the filing of their malpractice suit], Plaintiff knew that massive scarring was a risk or complication of the use of Mersilene mesh and that [the implantation doctor] had used Mersilene mesh in the 1999 surgery. She knew that she was required to undergo an additional surgical procedure in 2000 because of complications resulting from that surgery. She also knew that she was continuing to have problems which required "continuing medical treatment" and which caused her to "endure excruciating pain." This was sufficient to "awaken inquiry and direct diligence in the channel in which it would be successful," and to thus trigger the start of the limitations period.

Id. at *3 (citations omitted).

C. Application of law to the undisputed material facts of this case

With an understanding of the legal principles set forth above and as applied in the aforementioned decisions, the Court now turns to the undisputed factual record here.

It is undisputed that Kennedy learned she had a bladder stone attached to her pelvic mesh in March 2011 when she first visited Dr. Harris, and that the abdominal pain she began experiencing at that time was likely associated with the bladder stone and its formation rather than a result of pancreatitis. *See* Defs.’ SOMF ¶¶ 7-13; Pls.’ SAMF ¶ 25; Kennedy Dep. at 114:2-8, 115:17-24, 116:1-7. On this point, Kennedy testified that “the first real symptoms [she] had” as a result of problems with the 2009 implant surgery, apart from bladder leakage and frequency, “were in March of 2011.” Kennedy Dep. at 70:18-23. As a result of his initial examination of Kennedy, Dr. Harris noted that “[t]he bladder stone [was] most likely the result of mesh erosion.” Defs.’ SOMF ¶ 10; Pls.’ SAMF ¶ 25. During the April 1, 2011 cystoscopy, Dr. Harris observed that “[t]he stone may be adherent to the exposed TVT or Prolift mesh.” Defs.’ SOMF ¶ 12; Pls.’ SAMF ¶ 25. This was confirmed during the procedure performed on May 4, 2011, during which Dr. Harris also observed that “[t]he blue fibers and translucent fibers of the mesh were clearly visible,” “[t]he mesh was seen to dive submucosally at the lateral trigone,” and “the mesh was also seen to pass submucosally close to the bladder neck on the left lateral wall.” Defs.’ SOMF ¶ 17; Pls.’ SAMF ¶ 26. During this procedure Dr Harris removed the bladder stone and excised portions of visible, exposed mesh. Defs.’ SOMF ¶ 17; Pls.’ SAMF ¶ 26.

At her deposition, Kennedy testified on multiple occasions and in no uncertain terms that she was aware of the relationship between the medical conditions she was experiencing in March, April, and May 2011 and her pelvic mesh. Specifically, (1) when asked whether in

March 2011 she “knew . . . that the injuries [she was] experiencing were because of the mesh?” Kennedy answered “[y]es,” Kennedy Dep. at 71:13-19; (2) when asked whether it was “fair to say that early in 2011 [she was] aware that [she was] having problems because of the mesh?” Kennedy answered “March, yes. March 2011,” *id.* at 50:18-21; (3) when asked again whether “[i]n March 2011, [she was] aware that the problems [she was] having were because of the mesh implanted by Dr. Cammarano?” Kennedy answered “[y]es,” *id.* at 50:22-24, 51:1; and (4) when asked about Dr. Harris’ first cystoscopy, Kennedy stated as follows: “when I found out I had the bladder stones and not pancreatitis and that the mesh had gone through my bladder, then yes, I did attribute that to the surgery,” and that this was in “March 2011,”¹⁴ *id.* at 115:17-24, 116:1-7.

Kennedy moreover testified that early in her treatment with Dr. Harris, (1) she observed first-hand the damage her mesh implant was causing to her bladder — and specifically, she observed the mesh coming through her bladder, (2) as a result of this observation, she attributed her injuries to the pelvic mesh, and (3) more specifically, she attributed her injuries to *a defect*¹⁵ in the mesh. In particular, Kennedy testified that she thought “their [Ethicon’s] product was faulty,” and when asked if any doctor had told her “that Ethicon’s product was faulty,” responded “yes because it was evident when [the mesh] went through my bladder.” Kennedy Dep. at 22:11-15. She then stated that she made this observation during one of Dr. Harris’ cystoscopy, as “they had a camera” above her head and she “could see everything that was going on.”¹⁶ *Id.* at 25:4-11.

¹⁴ The correct date for the procedure Kennedy refers to here would appear to be either April 1 or May 4, 2011. *See* Pls.’ SAMF ¶¶ 25-26.

¹⁵ However, this is not a required element for her cause of action to accrue, as explained more fully below.

¹⁶ Kennedy testified this took place during “[t]he [cystoscopy] Dr. Harris did, the first one.” Kennedy Dep. at 25:10.

Despite such facts indicating Kennedy's awareness of her injuries and the link between her injuries and Defendants' product in the months of March, April, and May 2011, Plaintiffs contend that Kennedy was not on notice that her injuries were "attributable to the tortious conduct of Defendants" "until after her open abdominal procedure with Dr. Harris in September 2011, and likely sometime in early 2012." Pls.' Opp'n. at 32. In support of this contention, Plaintiffs point to two portions Kennedy's deposition testimony: her testimony (1) that it "was right around the time [she] talked to Dr. Long" in 2012 that she realized her injuries were attributable to the pelvic mesh, *id.* (quoting Kennedy Dep. at 177:16-24, 178:1-11); and (2) that she believed the mesh erosions that had occurred in 2011 were "a rare occurrence" and not the result of the mesh being "faulty," Pls.' Opp'n. at 34 (quoting Kennedy Dep. at 178:17-24). In addition to a reference to Dr. Cammarano's having informed Kennedy that bladder injury and mesh erosion were risks of her mesh implantation procedure, these two statements by Kennedy appear to be the only parts of the record Plaintiffs point to in support of their contentions that she was not aware her medical conditions were being caused by the mesh until late 2011 or 2012, or, at a minimum, that a genuine dispute exists as to when this took place. *See* Pls.' Opp'n. at 32-36. For the several reasons explained below, the Court declines to find that Kennedy's two limited, self-serving statements create or support a "genuine" factual dispute as to when she gained sufficient knowledge of her injuries to trigger the statute of limitations.

As Defendants point out, the testimony Plaintiffs cite was elicited by way of questions posed by Kennedy's own counsel at the tail end of her deposition and after going off the record. *See* Kennedy Dep. at 173:3-7. Her responses to her attorney's questions squarely contradict her multiple previous statements as to when she gained knowledge of the relationship between her injuries and the pelvic mesh. In these circumstances, the Court takes guidance from a seemingly

unrelated doctrine: the “sham affidavit” doctrine. The sham affidavit doctrine stands for the proposition that “a party may not create a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict.” *Jiminez v. All American Rathskeller, Inc.*, 503 F.3d 247, 251 (3d Cir. 2007) (quoting *Baer v. Chase*, 392 F.3d 609, 624 (3d Cir. 2004)). As the Third Circuit has explained, “[i]f a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact.” *Jiminez*, 503 F.3d at 252 (alteration in original).

The Court finds significant similarities between (1) self-serving deposition testimony elicited by one’s own counsel which contradicts previous testimony and is relied upon in opposition to a summary judgment motion, and (2) a self-serving affidavit which contradicts previous deposition testimony and is also submitted in opposition to a summary judgment motion. Based on these similarities, the Court finds the logic of the “sham affidavit” doctrine to be readily applicable to the instant circumstances.¹⁷ See *Smith v. Johnson & Johnson*, 593 F.3d 280, 285 n.3 (3d Cir. 2010) (stating that “although the ‘sham affidavit’ doctrine is not applicable here, the principle of that doctrine surely is,” where a plaintiff asked the court to limit the significance of her inculpatory deposition testimony; the Third Circuit explained that it was “unwilling to ignore [plaintiff’s] testimony to hold that there is an issue of material fact merely

¹⁷ Cf. *McLaughlin v. Bayer Essure, Inc.*, No. 14-7316, 2020 WL 1625549, at *6 (E.D. Pa. Apr. 2, 2020) (“Based on these Third Circuit precedents, we cannot conclude that the sham affidavit rule is strictly limited to circumstances in which an affidavit or declaration contradicts prior deposition testimony and never applies to circumstances in which the affidavit or declaration contradicts a prior interrogatory answer.”).

because of [plaintiff's] request that [it] do so");¹⁸ *see also EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 268 (3d Cir. 2010) (holding "that when reviewing a motion for summary judgment, a district court does not abuse its discretion under Rule 30(e) [regarding alterations to deposition testimony] when it refuses to consider proposed substantive changes that materially contradict prior deposition testimony, if the party proffering the changes fails to provide sufficient justification").¹⁹

Under the logic of the sham affidavit doctrine, Plaintiffs must, at a minimum, make some attempt to explain the apparent contradiction in Kennedy's testimony for the Court to consider the latter, contradictory portions of it. However, the most Plaintiffs offer in this vein is an allegation that Defendants have "cherry-pick[ed]" lines from Kennedy's testimony as to her knowledge of her injuries and presented them out of context, Pls.' Opp'n. at 34-35, and a general argument that "[t]o the extent there is contradiction in the evidence regarding timeliness, Pennsylvania law makes clear that this issue should be decided by a jury," *id.* at 23. In the Court's view, these responses are insufficient to explain the contradictions in Kennedy's

¹⁸ The Court went on to state the following: "[W]hen [plaintiff] testified she surely understood the significance of her testimony in the context of this case. In the circumstances before us, we accept [plaintiff's] deposition testimony as an accurate description of her position and thus we will affirm the order granting [defendant] summary judgment." *Id.* at 285.

¹⁹ The Court further explained as follows:

We see no principled reason to distinguish between affidavits and errata sheets in this context, and we conclude that the proper analysis for each is the same. Requiring consideration of contradictory errata in all cases, no less so than contradictory affidavits, would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact. But nothing in the foregoing requires courts to strike contradictory errata if sufficiently persuasive reasons are given, if the proposed amendments truly reflect the deponent's original testimony, or if other circumstances satisfy the court that amendment should be permitted.

Id. at 270 (quotation and citation omitted).

testimony, especially since the “contradictions” appear to stem from a change in the identity of Kennedy’s examiner and style of examination after going off the record. In the absence of a meaningful explanation of her latter, contradictory statements, the Court declines to credit or consider these portions of Kennedy’s deposition testimony. *See Smith*, 593 F.3d at 285; *EBC, Inc.*, 618 F.3d at 268-270.

Without these pieces of testimony, the Court finds that there can be no genuine dispute of material facts as to the application of the discovery rule. As recounted above, the record unambiguously shows that by the time of the May 4, 2011 procedure at the latest, Kennedy was aware that she had suffered injuries and that these injuries shared some causal connection to the pelvic mesh she had implanted in 2009. *See Adams v. Zimmer US, Inc.*, 943 F.3d 159, 163 (3d Cir. 2019); *Coleman v. Wyeth Pharms.*, 6 A.3d 502, 510-11 (Pa. Super. Ct. 2010). Under the discovery rule, May 4, 2011 is the latest date her cause of action accrued. Accordingly, any claims subject to a two-year statute of limitations filed after May 4, 2013 are untimely.

In reaching this conclusion, the Court recognizes that where application of the discovery rule requires a determination as to whether a plaintiff exercised “reasonable diligence” in learning of her injuries, this inquiry is “ordinarily a question for the jury.” *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018). It is important to note, however, that there is no “reasonable diligence” inquiry to perform here: by her own several admissions, Kennedy had *actual* knowledge of her injuries and a causal connection to her pelvic mesh during March, April, and May 2011. *See Kennedy Dep.* at 22:10-15, 25:4-11, 50:18-24, 51:1, 71:13-19, 115:17-24, 116:1-7. Thus the question of whether, “exercising reasonable diligence,” she *should have* known of her injuries and their relationship to the mesh, is inapposite. *Adams v. Zimmer US, Inc.*, 943 F.3d 159, 163 (3d Cir. 2019) (“The statute of limitations accordingly begins to run when the plaintiff

knew *or*, exercising reasonable diligence, should have known (1) he or she was injured and (2) that the injury was caused by another.”) (emphasis added).

A brief examination of Plaintiffs’ several counterarguments further supports the conclusion that there can be no genuine dispute that Kennedy had actual notice of her injuries sufficient to trigger the limitations period by May 4, 2011.

As noted, Plaintiffs contend that Defendants “cherry-pick” portions of Kennedy’s testimony (page 71 of her deposition transcript in particular), such that, without context, they inaccurately show that Kennedy had a concrete understanding of the cause of her medical conditions. *See* Pls.’ Opp’n. at 34-35. Plaintiffs claim that rather than the picture portrayed by Defendants, Kennedy “suspected her symptoms were due to pancreatitis or bladder stones.”²⁰ *Id.* at 35. The Court disagrees; to the contrary, Plaintiffs’ characterization is belied by Kennedy’s plain words here and elsewhere. In particular, Kennedy believed that her injuries — of which the bladder stones were a manifestation — were the result of the mesh, not that the bladder stones (or pancreatitis) were themselves the root causes of her distress. Indeed, she testified as follows as to first seeing Dr. Harris: “when I found out I had the bladder stones and not pancreatitis and that the mesh had gone through my bladder, then yes, I did attribute that to the surgery.” Kennedy Dep. at 116:2-5.

²⁰ At pages 34-35 of their opposition, Plaintiffs state as follows:

First, Defendants cherry-pick three lines from Mrs. Kennedy’s deposition where she was asked if she “knew in March of 2011 that the injuries [she] [was] experiencing were because of the mesh.” *See* Defendants’ Motion at p. 3 (citing Kennedy Dep. at 71:16–19). But this excerpt, in addition to not being legally dispositive, is taken out of context. Mrs. Kennedy testified with respect to her visit with Dr. Harris in March of 2011 that she suspected her symptoms were due to pancreatitis or bladder stones. Although Dr. Harris’s records indicate that the mesh had begun to erode, this does not conclusively demonstrate that Mrs. Kennedy knew her symptoms were caused by the tortious conduct of Defendants.

The argument that Defendants have mischaracterized (or de-contextualized) Kennedy's testimony illuminates a second flaw in Plaintiffs' reasoning. Plaintiffs state that "[a]lthough Dr. Harris's records indicate that the mesh had begun to erode, this does not conclusively demonstrate that Mrs. Kennedy knew her symptoms were caused by the tortious conduct of Defendants." Pls.' Opp'n. at 35. They contend that it "remains undisputed" that "Dr. Harris never informed her that the mesh implanted into her pelvis was defective," *id.* at 33, and claim that the facts known to Kennedy in the spring of 2011 "gave no indication . . . of a defect in the product," *id.* at 34. Each of these statements is premised on an incorrect standard for triggering the limitations period under the discovery rule. "The commencement of the limitations period is grounded on 'inquiry notice' that is tied to 'actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another's conduct, *without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause.*'"

Gleason v. Borough of Moosic, 609 Pa. 353, 362 (2011) (emphasis added) (quoting *Wilson v. El-Daief*, 600 Pa. 161, 178 (2009)); *Burton–Lister v. Siegel, Sivitz and Lebed Assoc.*, 798 A.2d 231, 237 (Pa. Super. Ct. 2002) ([T]he fact that a plaintiff is not aware that the defendant's conduct is wrongful, injurious or legally actionable is irrelevant to the discovery rule analysis.").

Accordingly, Kennedy did not need to know that her injuries were caused by a *defect* in the mesh or by any *tortious* conduct of Defendants for the limitations period to be triggered. Rather, she was only required to have actual or constructive knowledge of her injury — severe abdominal pain, bladder stones, and related medical issues — and a link to a potential cause — erosion of

her pelvic mesh. By her own admissions, Kennedy had actual knowledge of both by May 4, 2011 at the latest.²¹

Plaintiffs' use of an incorrect standard in applying the discovery rule in turn highlights a third defect in their arguments. Relying on *Carlino v. Ethicon, Inc.*, 208 A.3d 92 Pa. Super. Ct. (2019) and *Wilson v. El-Daief*, 600 Pa. 161 (2009), Plaintiffs argue that because “mesh erosions and injury to the bladder were known risks of the [mesh implantation] procedure,” Kennedy would have been unable to tell whether her injuries were the result of a defect in the mesh or rather lingering post-operative symptoms, until she saw Dr. Long in 2012. Pls.' Opp'n. at 36. They contend that where a plaintiff's physical ailments could reasonably be understood as transient effects of a procedure rather than a permanent injury, the question of whether the plaintiff knew or should have known she was injured must be decided by a jury. *Id.* at 28. They similarly argue, in discussing *Wilson*, that “while atypical and lasting post-surgical symptoms may trigger the limitations period, where evidence of potential sources of confusion exist, such as a defendant doctor's inability or refusal to identify the cause of the plaintiff's injuries, summary judgment is inappropriate.” *Id.* at 30.

The problem with these arguments — that (1) because mesh erosion and bladder injuries were potential side effects of the mesh implantation, Kennedy could not have known whether her injuries were lingering post-operative symptoms or something else, and (2) summary judgment is

²¹ It would be curious to require knowledge of *tortious* conduct or a *defective* product before commencing the statute of limitations, the very existence of which conduct or defectiveness necessarily cannot be “known” until adjudication by a court. However, even if the standard required knowledge or suspicion of tortious conduct or a defective product, by her own testimony Kennedy would meet this standard within the relevant time period. She affirmatively testified that she thought “their [Ethicon's] product was faulty,” and that this conclusion was “evident” as a result of her observation of the mesh coming “through” her bladder. Kennedy Dep. at 22:10-15, 25:4-11.

inappropriate “where evidence of potential sources of confusion” as to the source of injuries, such as a doctor’s inability or refusal to diagnose the cause of an injury — is that neither describes the circumstances of this case.

First, the undisputed facts make clear that Kennedy’s injuries were not lingering post-surgical conditions; rather, Kennedy testified that she suffered an immediate and unexpected onset of severe abdominal pain in March 2011 that she had not experienced before. *See* Kennedy Dep. at 70:18-24, 71:1-5 (“Q: Ms. Kennedy, what were the first symptoms that indicated to you that you were having trouble after the implant surgery with Dr. Cammarano? A: I want to say I had frequency and leakage right after, but the first real symptoms I had were in March of 2011. Q: What symptoms do you recall experiencing in March of 2011? A: When we were – went up to our place in the mountains, and I had severe abdominal pain, which I thought was pancreatitis again. So I had my husband bring me back home.”); *see also id.* at 130:15-22 (“Q: And the bladder stones, were you actually experiencing physical symptoms at the time Dr. Harris diagnosed the bladder stone or was it similar to your experience with the kidney stone and the bladder stone where testing revealed it? A: No. I had terrific pain because I thought it was the pancreatitis. Pancreatitis is very painful.”).

Second, Dr. Harris was not unable, nor did he refuse, to diagnose Kennedy’s condition in the spring of 2011. To the contrary, the evidence shows that Dr. Harris directly connected Kennedy’s conditions to the eroding pelvic mesh. During his initial examination, he noted that “[t]he bladder stone [was] most likely the result of mesh erosion.” Defs.’ SOMF ¶ 10; Pls.’ SAMF ¶ 25. During the April 1, 2011 cystoscopy, he further observed that “[t]he stone may be adherent to the exposed TVT or Prolift mesh.” Defs.’ SOMF ¶ 12; Pls.’ SAMF ¶ 25. This was confirmed during the procedure performed on May 4, 2011, during which Dr. Harris also noted

that “[t]he blue fibers and translucent fibers of the mesh were clearly visible,” “[t]he mesh was seen to dive submucosally at the lateral trigone,” and “the mesh was also seen to pass submucosally close to the bladder neck on the left lateral wall.” Defs.’ SOMF ¶ 17; Pls.’ SAMF ¶ 26. Accordingly, there was no “inability or refusal to diagnose the cause” of Kennedy’s injuries, and no “sources of confusion” as to the cause. Pls.’ Opp’n. at 30.

Finally, as set forth below, the Court observes that the conclusion that there is no genuine dispute that Kennedy had knowledge sufficient to trigger the statute of limitations by May 4, 2011 is not inconsistent with the principles underlying the several judicial decisions previously examined.

In *Adams v. Zimmer US, Inc.*, 943 F.3d 159 (3d Cir. 2019), the Third Circuit concluded that it was only when the plaintiff’s doctor discovered new information “intraoperatively” that she would know her hip implant’s disintegration, rather than her reaction to the implant, was causing her pain. *Id.* at 165. For Kennedy, that “intraoperative” moment was likely the April 1, 2011 cystoscopy, and under no circumstances was it later than the May 4, 2011 procedure, at which time which Dr. Harris removed Kennedy’s bladder stone and excised portions of her eroding mesh.

In *In re Risperdal Litig.*, 223 A.3d 633 (Pa. 2019), the Pennsylvania Supreme Court overturned the Superior Court’s affirmation of summary judgment against two plaintiffs where the summary judgment motion was an attempt to obtain a global accrual date of many claims related to Risperdal and preceded any case-specific discovery. *See id.* at 641. As a result, the record on summary judgment contained no pictures of the plaintiffs’ alleged malformations, no medical records, and no deposition testimony of the plaintiffs or their doctors. *See id.* In the absence of any record evidence, the Supreme Court cautioned against what it saw as the Superior

Court's unwarranted assumption that the plaintiffs "either knew or should have known that their breast growth was an outward manifestation of . . . gynecomastia (thus triggering a duty to investigate its underlying cause)," and failure "to distinguish between knowledge of the *physical condition* of large breasts and the critical knowledge of an *injury*, gynecomastia." *Id.* at 642 (emphasis in original). Unlike *In re Risperdal*, the record here is robust, containing both medical records and deposition testimony. From this evidence, there can be no dispute that Kennedy was, by May 4, 2011, aware not only of a physical condition, but of an actual *injury*, as well as a causal link to a third party.

In *Carlino v. Ethicon, Inc.*, 208 A.3d 92 (Pa. Super. Ct. 2019), the Superior Court found that a reasonable jury could have (and did) find that the plaintiff reasonably believed the pain she was experiencing was a routine consequence of the implantation surgery. Importantly, in *Carlino* the plaintiff's condition swung back and forth between improvement and regression over the course of several years, and during this period her doctor advised her that her injuries were consistent with transient side effects of her pelvic mesh procedure. *See id.* at 104-05. The plaintiff's doctor even noted, with respect to pain she was experiencing, that he "did not believe that it [was]" related to the mesh. *Id.* at 104. Here, by contrast, the severe abdominal pain that made Kennedy seek medical attention in March 2011 commenced suddenly and was unique from the symptoms she had been experiencing since the surgery (frequency and leakage). *See Kennedy Dep.* at 70:21-23. Moreover, Dr. Harris did not advise Kennedy that her bladder stone and associated pain were unrelated to her eroding mesh.

The circumstances of the plaintiff in *Nicolaou v. Martin*, 195 A.3d 880 (Pa. 2018) are also dissimilar to Kennedy's circumstances. In *Nicolaou*, the plaintiff "had been repeatedly and definitively diagnosed with [multiple sclerosis] by several previous physicians, had four prior

negative Lyme disease tests, and lacked health insurance to cover the costs of further diagnostic testing.” *Id.* at 895. The court found that under those circumstances, the question of whether the plaintiff “reasonably should have known’ that she suffered from Lyme disease after [a nurse] informed her of a ‘probable’ diagnosis of that disease based on her clinical symptoms, and when some of her symptoms improved after taking antibiotics prescribed for that condition,” was a question for the jury. In Kennedy’s case, there are simply no analogous sources of confusion over the cause of her injuries. Rather, all of the information Kennedy had as of May 4, 2011 pointed to the mesh as the source of her injuries, and her testimony that she believed the mesh was causing her injuries is illustrative of this.

In *Gleason v. Borough of Moosic*, 609 Pa. 353 (2011), the Pennsylvania Supreme Court considered whether the plaintiffs should have known, prior to the year 2000, that the toxic mold in their basement was related to a sewer near their property. Importantly for the Court, the phrase “toxic mold” had not entered the nation’s lexicon prior to the year 2000, and, in the Court’s view, “it cannot be seriously argued that the exercise of reasonable diligence would require one to uncover a relatively new environmental hazard prior to the time it becomes recognized and reported in the media.” *Id.* at 365. Unlike “toxic mold,” there is no argument being made (nor could there be) that the health risks associated with pelvic mesh were unknown at large as of 2011. More importantly, this question — a form of the “reasonable diligence” inquiry — is moot, because Kennedy affirmatively testified on several occasions that *she actually knew* of the cause of her injuries in March, April, and May of 2011.

In *Wilson v. El-Daief*, 600 Pa. 161 (2009), the Pennsylvania Supreme Court found that whether the plaintiff had knowledge of her injuries resulting from alleged medical malpractice was a question of fact for a jury. The Court took special note of the ability of long-lasting post-

surgical symptoms to be confused with injuries resulting from malpractice and of “the asserted unwillingness or inability on the part of [the defendant doctor] to recognize injury or cause, and [] the failure of [a second doctor] to offer [the plaintiff] his assessment upon consultation.” *Id.* at 180. (citations omitted). The Court declined to hold that “a lay person must be charged with knowledge greater than that which was communicated to her by multiple medical professionals involved in her treatment and diagnosis.” *Id.* Here, there was no unwillingness or inability on the part of Dr. Harris to connect Kennedy’s injuries to the pelvic mesh — quite the opposite. Moreover, as explained above, there was no risk of confusing the onset of Kennedy’s severe abdominal pain in March 2011 with lingering post-operative symptoms: her severe abdominal pain was not “lingering” since the implantation surgery, but a sudden and new condition.

In *Fine v. Checcio*, 582 Pa. 253 (2005), the Pennsylvania Supreme Court found that in the context of a wisdom tooth extraction, where “facial numbness was indicative of two distinct phenomena”— either a temporary physical consequence of the procedure or a manifestation of injury — conflicts in the record mandated that the question of actual or constructive notice to trigger the statute of limitations was a fact question for the jury. *Id.* at 272. Here, there is no conflict in the factual record as to whether Kennedy’s abdominal pain in March 2011 was a lingering, post-operative condition: as a sudden and new condition, it could not have been a lingering effect of the implantation surgery.

As explained above, Kennedy’s circumstances are distinct from circumstances underlying decisions finding application of the discovery rule to properly be a fact question. In the Court’s view, her circumstances are more analogous to those of several of the plaintiffs who had sufficient knowledge to trigger the state of limitations in *McLaughlin v. Bayer Essure, Inc.*, No. 14-7316, 2020 WL 1625549 (E.D. Pa. Apr. 2, 2020). As examined previously, these plaintiffs’

claims were found to be time-barred based on their first-hand knowledge of a birth-control device's perforation of and migration through their internal organs. Significantly, the Court found the claims of plaintiff "T.M" time-barred even where her doctor "may have been telling her that her pain, fatigue, and other symptoms were *not* caused by Esure." *Id.* at *24 (emphasis added).

In sum, for the reasons discussed at length herein, the Court finds that there is no genuine dispute of fact that Plaintiffs' causes of action, which arise out of Kennedy's injuries resulting from Defendants' pelvic mesh, accrued no later than May 4, 2011.

Plaintiffs state that of their initial eighteen claims, they are only pursuing the following: negligence (Count I); strict liability — failure to warn (Count III); strict liability — design defect (Count V); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). *See* Pls.' Opp'n. at 23 n.4. "Punitive damages are a remedy incidental to cause of action, not a substantive cause of action in and of themselves." *Hassoun v. Cimmino*, 126 F. Supp. 2d 353, 372 (D.N.J. 2000). Similarly, "discovery rule and tolling" is not an independent cause of action; these doctrines are "appropriately regarded as an application of statutory construction arising out of the interpretation of the concept of the 'accrual' of causes of action." *Wilson*, 600 Pa. 176-77. Plaintiffs are therefore pleading four independent causes of action: negligence, failure to warn, design defect, and loss of consortium.

The statute of limitations applicable to Plaintiffs' claims of negligence, failure to warn, and design defect, is two years. *See* 42 PA. CONS. STAT. § 5524(2); *Flanagan v. Martfive, LLC*, No. 16CV1237, 2017 WL 661607, at *3 (W.D. Pa. Feb. 17, 2017) ("Products liability cases in Pennsylvania are controlled by the personal injury statute of limitations. Thus, the applicable Pennsylvania statute of limitations for a product liability case is two years." (citing *Hahn v.*

Atlantic Richfield Co. (3d Cir. 1980), 625 F.2d 1095, 1104, *cert. den.* 101 S. Ct. 1516 (1981))).

Loss of consortium is a derivative claim under Pennsylvania law, the statute of limitations for which is governed by the statute of limitation of the source claim. *See Patterson v. Am. Bosch Corp.*, 914 F.2d 384, 387 n.4 (3d Cir. 1990). All four of Plaintiffs' claims are therefore subject to the same two-year statute of limitations. Because their claims accrued no later than May 4, 2011 and they initiated their suit on July 2, 2013, Plaintiffs' four claims are untimely.

V. CONCLUSION

For the reasons discussed above, the Court concludes there can be no genuine dispute of material fact that under Pennsylvania's discovery rule, Plaintiffs' claims accrued no later than May 4, 2011. As their claims are subject to a two-year statute of limitations and were filed on July 2, 2013, they are time-barred, and Defendants are entitled to summary judgment on this basis.

A separate Order follows this Opinion.

BY THE COURT:

/s/ Joseph F. Leeson, Jr.

JOSEPH F. LEESON, JR.

United States District Judge