Prepared by the court

LEE CALDERIO-LEWIS and JOHN LEWIS, Plaintiffs, v. ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, JOHNSON & JOHNSON, AND JOHN DOES 1-20, Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : BERGEN COUNTY DOCKET NO.: BER-L-15109-14 (MCL) MASTER DOCKET NO: BER-L-11575-14 (In Re Pelving Mesh/Gynecare Litigation) Civil Action **ORDER**

FILED
JUN 03 2024
GREGG A. PADOVANO, J.S.C.

THIS MATTER having been brought before the court by way of a motion filed by Riker Danzig LLP and Butler Snow, LLP, counsel for defendants Ethicon, Inc., Ethicon Women's Health and Urology, and Johnson & Johnson (collectively "Defendants"), seeking, in lieu of answer, summary judgment dismissing the claims of Lee Calderio-Lewis and John Lewis (collectively "Plaintiffs"), and opposition having been filed by Seeger Weis LLP, counsel for Plaintiffs, and the court having reviewed each motion and having heard oral argument of all counsel; and for the reasons set forth within the attached rider; and for other good cause shown,

IT IS ON THIS 3rd DAY OF JUNE 2024

ORDERED that Defendants' motion seeking summary judgment to dismiss Plaintiffs' complaint in lieu of answer is **GRANTED**. Plaintiffs' complaint is dismissed in its entirety, with prejudice; and it is further

ORDERED that a copy of this order shall be served upon all counsel of record by eCourts.

GREGG A. PADOVANO, J.S.C.

LEE CALDERIO-LEWIS and JOHN LEWIS,

v.

ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, GYNECARE, JOHNSON & JOHNSON

Docket No.: BER-L-15109-14 - MCL
(Master Docket No.: BER-L-11575-14)

RIDER TO ORDER DATED JUNE 3, 2024[1]

Before the court is a motion filed on behalf of defendants Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare, and Johnson & Johnson (collectively "Defendants") seeking summary judgment and dismissal of the claims of plaintiffs Lee Calderio-Lewis and John Lewis (collectively "Plaintiffs"). This matter involves Plaintiffs' claims of product liability and breach of express warranty claims against Defendants concerning TVT-O bladder sling pelvic mesh product (hereinafter "mesh") manufactured by Defendants. The record reveals that on July 11, 2013, Plaintiffs filed a complaint against Defendants alleging injuries and damages resulting from the May 14, 2004 implantation of the mesh in plaintiff Lee Calderio-Lewis. See Plaintiffs' complaint at ¶¶5, 7. Lee Calderio-Lewis' husband, John Lewis, also filed a loss of consortium claim. Id. at ¶10.

Defendants filed the subject motion seeking summary judgment to dismiss Plaintiffs' complaint as untimely based upon the statute of limitations. Defendants argue that Plaintiffs' claims are time barred as the complaint was filed beyond the applicable two year statute of

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[1] Not for publication without the approval of the committee on opinions (See R. 1:36-1).

limitations. Defendants' Brief at 1. Defendants argue that Plaintiffs' complaint was filed on July 11, 2013 and that the limitations period was commenced no later than over four years earlier on July 6, 2009. Ibid. Defendants argue that plaintiff Lee Calderio-Lewis was implanted with the mesh product on May 14, 2004 by Dr. Sharon Li to treat stress urinary incontinence, a bladder prolapse, and abnormal uterine bleeding. Id. at 3.

Defendants argue that immediately following the 2004 surgery, Lee Calderio-Lewis experienced intense pain, consisting of an "uncomfortable feeling in legs," "exacerbation of sciatica," and incision pain. Id. at 4, citing Certification of Kelly Crawford, Esq., Exhibit. 7, Report of Dr. Ann Marie Mascellino. Defendants assert that plaintiff Lee Caldiero-Lewis certified in her answers to interrogatories that immediately after her 2004 implantation surgery, she went to "all kinds of doctors trying to figure out why [she] was in pain," and that by 2008, Lee Calderio-Lewis discovered there were "a whole lot of women like [her]." Id. at 5, citing Crawford Certification, Exhibit 11. Defendants further assert that during a July 31, 2008 consultation with her physician, Dr. Amir Shariati, ("Dr. Shariati") plaintiff stated that she wanted to discover whether her pain was related to her previous surgeries. Ibid. Defendants assert that Dr. Shariati recorded his impression that he did not advise removal of the mesh, but believed it resulted in significant scarring, and recommended plaintiff undergo pelvic floor physical therapy. Id. at 5-6.

Defendants also argue that on July 6, 2009, Lee Calderio-Lewis' physician, Dr. Jody Blanco, ("Dr. Blanco") administered an obturator nerve block to relieve her groin pain. Id. at 6, citing Crawford Certification, Exhibit 13. Defendants asserts that during Lee Calderio-Lewis' deposition testimony, she testified that Dr. Blanco reported her pain to the U.S. Food and Drug Administration ("FDA") Manufacturer and User Facility Device Experience database ("MAUDE"), and discussed the possibility of removing the mesh. Ibid. Defendants further argue that Plaintiffs' claim is also barred by the statute of limitations because on October 20, 2008, the

FDA issued a Public Health Notification regarding pelvic mesh devices, and Plaintiffs, using reasonable diligence, should have discovered this alert prior to filing her complaint in July 2013. Id. at 7, 14-15.

Defendants assert that since the applicable two year product liability statute of limitations period commences from the date the cause of action accrued, the complaint filed on July 11, 2023 is untimely. Defendants further assert that New Jersey's "discovery rule" does not apply to the facts presented in this matter. Id. at 8. Defendants argue that the discovery rule provides a cause of action will not accrue until the affected party discovers the basis for an actionable claim, or by an exercise of reasonable diligence and intelligence should have discovered the basis for an actionable claim. Id., citing Lopez v. Swyer, 62 N.J. 267, 272 (1973). Defendants argue it is not necessary that a plaintiff have legal or medical certainty in order to trigger the statute of limitations, but only that reasonable medical information connects an injury with fault of another. Id., citing Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 193 (2012); Yarchak v. Trek Bicycle Corp., 208 F. Supp. 2d 470, 487 (D.N.J. 2002). With regard to implanted products, such as the subject mesh here, Defendants argue that the "fault of another" prong is satisfied by linking an injury to the product. Id. at 9, citing Baird v. Am. Med. Optics., 155 N.J. 54, 68-69 (1998).

Defendants argue that this court (in a case similar to the one at bar, also related to pelvic mesh) previously granted a summary judgment motion, holding that the statute of limitations expired despite the plaintiff's argument that her claim did not accrue until her physician told her that her pelvic issues were due to the mesh, but instead, held her claim accrued when, given her circumstances, she reasonably believed her injury was due to the mesh. Id. at 9, citing McFall v. Ethicon, Inc., docket number BER-L-11513-14 (Law Div. Jan. 24, 2019). Defendants also rely upon other the unreported decision in Adams v. Sanofi U.S. Servs. Inc., where the court granted summary judgment after holding that a reasonable person would have been aware of another's

fault despite not consulting with an attorney nor understanding the legal significance of their claim. Id. at 10, citing Adams v. Sanofi U.S. Servs. Inc., docket number MID-L-6088-18, 2023 N.J. Super. Unpub. LEXIS 927 (Law Div. Jun. 8, 2023). Thus, Defendants argue, that July 6, 2009 is the accrual date since the record reveals that this was the date when plaintiff Lee Calderio-Lewis discussed removal of the mesh with Dr. Blanco. Id. at 12. Defendants argue that plaintiff was also advised on this date that Dr. Blanco was going to report plaintiff's issues with the mesh to the FDA's MAUDE database. Ibid. Defendants assert that the record clearly establishes that by July 6, 2009, plaintiff Lee Calderio-Lewis had experienced significant injuries which she related to the mesh product. Ibid. Defendants argue that the record reveals that Dr. Shariati stated the mesh had caused significant scarring, and that plaintiff Lee Calderio-Lewis had seen multiple doctors trying to figure out why she was in pain, and discovered there were other women with similar complaints. Id., citing deposition of plaintiff Lee Calderio-Lewis at 75:16-18, 77:5-6, 115:19-116.5, 142:7-21, 181:8-182:5.

Defendants additionally assert that Plaintiffs' breach of express warranty claim is barred by New Jersey's four year statute of limitations. Id. at 15. In support, Defendants assert that a breach of express warranty accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach, and a breach of warranty occurs when tender of delivery is made, except where a warranty explicitly extends to future performance of the goods. Ibid. Defendants argue that Plaintiffs' express warranty claim accrued on the date of the mesh's implementation, May 14, 2008, which is the date that tender of delivery was made. Id., citing Martinez v. Ethicon, Inc., No. 3:18-cv-17570, 2019 WL 4345867 at *3 (D.N.J. Sept. 12, 2019). Defendants assert that the applicable statute of limitations expired four years after implantation (May 14, 2008) and that as a result Plaintiffs' complaint filed on July 11, 2013 is untimely. Id. Defendants further argue that because Plaintiffs' substantive product liability and breach of express warranty claims are time

barred, plaintiff John Lewis' derivative loss of consortium claim also fails. Id. at 15-16, citing Piemonte v. Viking Range, LLC, No. 2:14-CV-000124 WJM, 2015 WL, 519144 at (3 (D.N.J. Feb. 9, 2015). Defendant additionally asserts that because all of Plaintiffs' substantive claims are time barred, Plaintiffs' punitive damages claims should also be dismissed. Id. at 16.

Plaintiffs argue in opposition that accrual of the statute of limitations is a fact specific analysis, and the record is clear that Lee Calderio-Lewis acted with diligence as she attempted to discover the cause of her pain. Plaintiffs' Brief at 6. Plaintiffs asserts that while Lee Calderio-Lewis did initially begin to experience pain soon after the May 14, 2004 implantation surgery, it was not until much later that she associated that pain specifically with the mesh device, as she testified that none of her physicians ever attributed her pain to the device, and no physician ever recommended that she have the device removed. Ibid. Plaintiffs further assert that while Dr. Blanco did indicate he would report Lee Calderio-Lewis's complaints to MAUDE, she testified that she did not know what "MAUDE" was. Ibid., citing Lee Calderio-Lewis deposition at 116:2-5. Plaintiffs further assert that Defendants have consistently denied that the mesh causes chronic pain and was defectively designed. Id. at 3. Plaintiffs argue that Defendant's argument that the statute of limitations began to accrue no later than 2009 when she spoke with Dr. Blanco is not supported by the record, because Dr. Blanco's chart does not mention the mesh being the cause of her pain. Id. at 11.

Plaintiffs further argue that the cases cited and relied upon by Defendants are inapplicable here, as the facts are distinguishable here. Plaintiffs assert that in Tabor v. Johnson & Johnson, No. A-4703-17T1, 2019 WL 7168666 (App. Div. 2019), cited by Defendants, the plaintiff was found to have reason to know the mesh was a possible cause of the pain because by that time he called Ethicon directly to report the pain he experienced following a hernia mesh procedure, and one of plaintiff's physicians opined his pain was caused by the mesh's implementation. Id. at 7.

Plaintiffs argue that in contrast, here, plaintiff Lee Calderio-Lewis did not make any calls to Defendants, and was never told by any physician that her pain was caused by the mesh. Ibid. Plaintiffs similarly argue that the plaintiff in McFall, supra, called Ethicon's customer support hotline with complaints, and the plaintiff's physician spoke with the medical director of Gynecare Worldwide, a division of Ethicon, and the plaintiff tried to remove the mesh herself, all of which did not occur in the case at bar. Id. at 8-9.

Regarding their breach of express warranty claim, Plaintiffs asserts their claims were timely filed before the applicable four-year statute of limitations expired. Id. at 12. Plaintiffs argues that while a breach of warranty occurs when tender of delivery is made, if a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance, the cause of action accrues when the breach is or should have been discovered. Ibid. Plaintiffs thus assert that because the mesh was intended to be a permanent implant device, its intended use for which it was warranted is extended to the future performance of the device. Ibid. Plaintiffs assert that the accrual date for the breach of express warranty claim would not be on the date tender of delivery is made, but when the breach was or should have been discovered. Id. at 12-13, citing NJSA 12A:2-725(2). Thus, Plaintiffs argue that for its claim for breach of express warranty to be considered untimely, Plaintiffs would have had to have discovered the breach before July 11, 2009 as the complaint was filed on July 11, 2013, and Defendants have not identified anything in the record that would establish Plaintiff had discovered or should have discovered the breach prior to that date. Id. at 13. Plaintiffs further argue that because their product liability and breach of express warranty claims are not time barred, plaintiff John Lewis' associated loss of consortium claim is also not time barred. Ibid.

In reply, Defendants argue Plaintiffs did not provide evidence to reveal that the "discovery rule" sustains their product liability claims. Defendants' Reply at 2 Defendants assert that plaintiff first tied her complaints of pain to the mesh sling in 2009, two years before she consulted with an attorney. Ibid. Defendants argue that while legal knowledge or consultation with an attorney is not required to commence the statute of limitations period, accrual commences when a reasonable person in a plaintiff's circumstances would, or should, have been aware that they were injured through the fault of another. Id. at 6, citing Baird v. American Medical Optics, 155 N.J. 54, 68 (1998); Tabor v. Johnson & Johnson, No. A-4703-17T1, 2019 WL 7168666 at *5 (App. Div. 2019); Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 194 (2012).

Defendants further argue that Plaintiffs wrongly suggest that their denial of liability is relevant to plaintiff's claim being timely filed since the law does not connect an accrual of a statute of limitations to a defendant's admission of liability. Id. at 3, citing Heatherman v. Ethicon, Inc., No. 1:20-CV-01932-RBJ, 2021 WL 21385543 at *4 (D. Colo. Jan 22, 2021). Defendants additionally argue that there is no basis to sustain Plaintiffs' argument that a claim does not accrue until a physician attributes injuries to the subject product or recommends the product be removed. Id. at 4, citing Yarchak v. Trek Bicycle Corp., 208 F. Supp. 2d 470, 487 (D.N.J. 2002). Defendants argue that Plaintiffs do not contest the fact that Lee Calderio-Lewis discussed her concern about the mesh with Dr. Blanco and he told her he would report her concerns about the device to the FDA database. Id. at 7. Defendants argue that whether plaintiff knew the exact nature of the FDA's MAUDE database does not impact the statute of limitations since it is undisputed that she knew Dr. Blanco was reporting her complaints about the mesh. Id. at 9, citing Plaintiff deposition at 116:1-5.

Defendants also further argue that Plaintiffs' breach of warranty claim accrued on the date of the mesh's implementation on May 14, 2004 and that, as a result, the statute of limitations expired four years later on May 14, 2008. Id. at 12. Defendants assert that while Plaintiffs argue the facts presented here are distinguishable from those in Martinez, supra. Defendants assert that implied warranties "cannot extend to future performance because such an extension must be explicit, and an implied warranty cannot explicitly state anything." Id. at 12, citing Martinez, 2019 WL 4345867 at *3. Defendants argue that the Plaintiffs did not offer any evidence of an explicit extension to future performance in the mesh's warranty that would bring their claims under the exception to the four year statute of limitations. Id. at 13.

The court here recognizes that New Jersey's standard for summary judgment, set forth in Brill v. Guardian Life Ins. Co. Am., 142 N.J. 520, 540 (1995), entitles a movant to summary judgment if the adverse party, having all facts and inferences viewed most favorably towards it, has not demonstrated the existence of a dispute whose resolution in its favor will entitle him to judgment. Summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact challenged[.]" R. 4:46-2(c). If the non-moving party "points only to disputed issues of fact that are of an insubstantial nature, the proper disposition is summary judgment." Brill, 142 N.J. at 529. "Bare conclusions in the pleadings, without factual support in tendered affidavits, will not defeat a meritorious application for summary judgment." U.S. Pipe & Foundry Co. v. Amer. Arbitration Association, 67 N.J. Super. 384, 399-400 (App. Div. 1961) (citing Gherardi v. Trenton Board of Education, 53 N.J. Super. 349, 358 (App. Div. 1958)). The Court in Brill encouraged trial courts not to hesitate in granting summary judgment when the appropriate circumstances are presented, such that the "evidence is so one-sided that one party must prevail as a matter of law. Brill, 142 N.J. at 540.

The Brill Court encourages courts to grant summary judgment, stressing the importance of not sending "worthless" cases to a jury. Id. at 541. In deciding whether there is a genuine issue of fact for trial, the motion judge should consider whether the competent evidence submitted on the motion, viewed in the light most favorable to the non-moving party, is sufficient to allow a rational fact-finder to resolve the fact issue in favor of the non-moving party. Brill, 142 N.J. at 540; R. 4:46-2(c). The motion judge should therefore weigh the evidence for its sufficiency, and where the evidence is so one-sided that one party must prevail as a matter of law, the court should not hesitate to grant summary judgment. Id. at 540. Therefore, the opponent of a summary judgment motion must show controverting facts, not merely bare assertions, representations, or allegations in pleadings without affidavit or other evidentiary support to establish the existence of a genuine issue of material fact. The failure to discharge this duty entitles the movant to summary judgment. Judson v. Peoples Bank & Trust Co., 17 N.J. 67, 75 (1954). The court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill, 142 N.J. at 540. "[W]hen the evidence is so one-sided that one party must prevail as a matter of law, the trial court should not hesitate to grant summary judgment." Id. (internal quotation marks and citation omitted).

Personal injury actions, including those based on strict liability, are governed by a two year statute of limitations. Gantes v. Kason Corp., 145 N.J. 478, 485 (1996). The court here recognizes that the applicable New Jersey two-year statute of limitation, under N.J.S.A 2A:14-2(a), provides that

> Except as otherwise provided by law, every action at law for an injury to the person caused by the wrongful act, neglect or default of any person within this State shall be commenced within two years next after the cause of any such action shall have accrued; except that an action by or on behalf of a minor that has accrued for medical malpractice for injuries sustained at birth shall be commenced prior to the minor's 13th birthday.

In product liability actions, such cause of action "generally accrues on the date of injury." Cornett v. Johnson & Johnson, 211 N.J. 362, 377 (2012) (citing Mc Glone v. Corbi, 59 N.J. 86, 94 (1971)). The determination of the accrual of a cause of action is an issue for the court. Baird v. Am. Med. Optics, 155 N.J. 54, 65 (1998), (citing Fernandi v. Strully, 35 N.J. 434, 439 (1961)). The Court in Baird held that in order to

> ameliorate the 'often harsh and unjust results which flow from a rigid and automatic adherence to a strict rule of law', courts have developed the discovery rule. Lopez, supra, 62 N.J. at 273-74, 300 A.2d 563. The discovery rule delays the accrual of a cause of action until 'the injured party discovers, or by an exercise of reasonable diligence should have discovered that he may have a basis for an actionable claim.'
> [Barid, 155 N.J. at 65-66, quoting Lopez, 62 N.J. at 300.]

In evaluating whether the "discovery rule" is applicable, the court must identify and weigh the equitable claims of each party. Szczvelek v. Harborside Healthcare Woods Edge, 182 N.J. 275, 281 (2005). "Among the factors to which courts look in deciding whether a plaintiff is equitably entitled to the benefit of the 'discovery rule' are the nature of the injury and the difficulty inherent in discovering certain types of injuries." Vispisiano v. Ashland Chemical Co., 107 N.J. 416, 428 (1987). Where fault is not "self-evident" at the time of injury, a plaintiff does not need medical certainty but only "have 'reasonable medical information' connecting an injury with fault to be considered to have the requisite knowledge for the claim to accrue." Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 193-94 (2012) (citing Visipiano,107 N.J. 416 at 435.)) An exact medical diagnosis or medical opinion regarding a cause of injury is not needed. Lapka v. Porter Hayden Co., 162 N.J. 545, 555 (2000). Thus, the statute of limitations instead begins to run when the

plaintiff "is aware, or reasonably should be aware, of facts indicating that she has been injured through the fault of another, not when a lawyer advises her that the facts give rise to a legal cause of action." Baird, 155 N.J. 54 at 68. The Court in Baird also held that

> the crucial inquiry is 'whether the facts presented would alert a reasonable person exercising ordinary diligence that he or she was injured due to the fault of another. The standard is basically an objective one—whether plaintiff 'knew or should have known' of sufficient facts to start the statute of limitations running.'
> [Id., quoting Martinez v. Cooper Hosp., 163 N.J. 45, 52 (2000).]

A plaintiff seeking to assert application of the discovery rule has the burden to "show that a reasonable person in her [or his] circumstances would not have been aware, within the prescribed statutory period, that she had been injured by defendant's product." Kendall, 209 N.J. at 198. The Court in Guichardo v. Rubinfeld, 177 N.J. 45, 51 (2003) held

> [t]o start the statute of limitations running in a case involving 'complex medical causation,' in which ' it is not at all self-evident that the cause of the injury was 'the fault of. . . a third party', 'more is required than mere speculation or an uninformed guess 'without some reasonable medical support' that there was a causal connection' between the plaintiff's condition and the third party's conduct. . . Although the discovery rule does not require 'knowledge of a specific basis for legal liability or a provable cause of action,' it does require 'knowledge not only of the injury but also that another is at fault.'
> [citations omitted.]

The court here finds that in order to apply the discovery rule there must be knowledge of an injury, and possession of facts suggesting a third party may be responsible. See Maher v. County of Mercer, 384 N.J. Super. 182, 188 (App. Div. 2006). "The benefit of the discovery rule should be available to [a] plaintiff who remained reasonably 'unaware. . . that the injury was due to the fault or neglect of an identifiable individual or entity." Gallagher v. Burdette-Tomlin Mem. Hosp., 163 N.J. 38, 43-44 (2000) (citing Abboud v. Viscomi, 111 N.J. 56, 62 (1988)).

In order to sustain a claim for breach of express warranty, a plaintiff "must establish 'the failure of the goods to perform as warranted.'" Robey v. SPARC Grp. LLC, 256 N.J. 541, 565 (2024), citing Ford Motor Credit Co. LC v. Mendola, 427 N.J. Super. 226, 242 (App. Div. 2012). The applicable statute of limitations provides, in pertinent part that

> (1) An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued. By the original agreement the parties may reduce the period of limitation to not less than one year but may not extend it.
>
> (2) A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty **explicitly** extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.
>
> [N.J.S.A. 12A:2-725(1)-(2), emphasis added.]

Accordingly, the statute of limitations typically commences upon tender of delivery, even though the buyer does not know the goods are defective, unless there is a beach of an express warranty of future performance where there is a warranty that "explicitly extend to future performance." Docteroff v. Barra Corp. of America, Inc., 282 N.J. Super. 230, 241 (App. Div. 1995) (citing Delgozzo v. Kenny, 266 N.J. Super. 169, 182-83 (App. Div. 1993)). The appellate court in Delgozzo determined that

> [t]he key requirement in finding a warranty of future performance is that it makes specific reference to a future time. Such a warranty: cannot be characterized as a mere representation of the product's condition at the time of delivery rather than its performance at a future time. Additionally, unlike a warranty to repair or replace, such warranty does not assume the product will not perform and will need repair or replacement.
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> [Id. at 241-242, citing Commissioners of Fire District No. 9 v. American LaFrance, 176 N.J. Super. 566, 573 (App. Div. 1980)).

Here, the court first evaluates the evidence presented concerning the alleged July 6, 2009 accrual date which Defendants assert prevented the application of the discovery rule. Therefore, Plaintiffs' product liability claim filed on July 11, 2013 is untimely. A review of plaintiff's medical records here reveals that she began to experience pelvic pain following the mesh's 2004 implantation. See Crawford Certification, Exhibit 7, Dr. Ann Marie Mascellino October 8, 2004 Report; see also Crawford Certification, Exhibit 12, Dr. Shariati Report, July 31, 2008. The court here also recognizes that plaintiff Lee Calderio-Lewis stated in her Plaintiff Fact Sheet that she recognized, in 2008, there were other women who also experienced injuries from the mesh. Plaintiff stated that

> [m]y surgery was in 2004. I went to all kinds of doctors trying to find out why I was in pain, why I can't walk. I felt like no one believed me. I kept telling myself "you have to live with this.". . . It took five years to find someone like me. I thought it was my back causing all these problems. I went back to gynecologists, nerve doctors, a psychiatrist. Finally in 2008 I found there was a whole lot of women like me.
> [Crawford Certification, Exhibit 11, Plaintiff Fact Sheet.]

The court further recognizes that plaintiff admitted during deposition that her physician reported the mesh sling the FDA's MAUDE database in 2009. Plaintiff testified as follows:

> Q. Now, staying just in 2009, do you recall who you were seeing, if anyone, who was a female medicine specialist, so urogynecologist or gynecologist?
>
> A. 2009 I saw two other orthopedics, Dr. Huang and Dr. Girardi. I saw Dr. Blanco.
>
> Q. When did you start seeing Dr. Blanco?
>
> A. Possibly 2008.
>
> Q. And did you have any treatment or undergo any procedures with Dr. Blanco in 2008 or 2009?
>
> A. 2009 I did.

Q. What did you undergo with Dr. Blanco in 2009?

A. I went in and they put some kind of injections internally to help that groin thigh pain.

Q. What, if anything, do you recall him saying about the procedure that he recommended you have?

A. Well, he reported my TVT-O to MAUD, that was the first doctor that actually addressed it.

Q. What do you recall him reporting?

A. **My complaints about this device that was put inside me**. He asked if anybody else reported it. I told him no. Didn't even know what that was. And he reported it.

[Deposition of Lee Calderio-Lewis, 115:6-116:5, emphasis added.]

Further review of the following portion of plaintiff Lee Calderio-Lewis's deposition transcript reveals that reveals that in 2009 she discussed the removal of the mesh with her physician:

Q. Several times today when you were asked about discussions with your health care providers regarding the TVT-O specifically, you were asked whether or not any of the providers recommended that the device be removed. Do you recall that?

A. Yes.

Q. I believe you said no physician has recommended that the d device be removed; is that accurate?

A. Yes

Q. I believe you testified earlier today that there was one physician specifically that you spoke with about the possibility of removal?

A. Yes.

Q. Do you recall which physician that was?

A. Dr. Blanco.

Q. What was that conversation with Dr. Blanco?

A. So I went to him. He as the urogynecologist that I found at Columbia. And I went to him with these complaints that I had. And he did his exam. He asked me if what I had installed had ever been reported to the MAUD database, which I said no, I didn't even know what that was. No other doctor had ever said that to me. That was already five years later.

And so I had been treated by him. He did the injection and it did help but I had to go back to him because that pain was still there again. And I had asked him about removing it, just take it out of me. He was like, it's not something you can just take out. He said it's dangerous and you could be worse from it. . . .

[Id. at 181:5-182:12.]

Based upon the facts and record presented, the court here finds that there is no genuine issue of material fact that a reasonable person in plaintiff Lee Calderio-Lewis position either knew or should have reasonably known of the possibility that Defendants, as the manufacturers of the subject mesh, may have caused or contributed to her injuries. Accordingly, the court here concludes that the discovery rule is not applicable to Plaintiffs' claim. The complaint filed on July 11, 2013 is untimely. The court recognizes that, here, only actual or constructive knowledge of facts that might give rise to a cause of action, not legal or medical certainty, is sufficient for the statute of limitations to begin to accrue. The court finds that there is evidence that Plaintiffs were provided with constructive knowledge of facts that would give rise to a product liability action. The court recognizes that by July 6, 2009, Plaintiffs were aware the fact that Dr. Blanco was reporting plaintiff Lee Calderio-Lewis' issues and complaints with the mesh to the FDA. The court also recognizes that Lee Calderio-Lewis had inquired about removing the mesh by July 6, 2009 as she had been suffering with pelvic pain and associated symptoms immediately since the mesh implantation surgery. While Plaintiffs assert that plaintiff Lee Calderio-Lewis was unaware what the FDA MAUDE database, she does not contest that she was aware that her issues and

symptoms associated with the mesh were being reported to a third-party agency. Considering these occurrences, the court finds that the evidence substantiates that by July 6, 2009, Plaintiffs reasonably should have known that plaintiff Lee Calderio-Lewis' injuries may have been caused through the fault of another. Accordingly, the court here finds that Plaintiffs failed to timely file the subject action within the two year statute of limitations, and therefore, all causes of action, and associated causes of action, identified in the complaint before this court are time barred.

The court further holds, regarding Plaintiffs' alleged breach of warranty claims, that Plaintiff has not presented any evidence that there was an express warranty of future performance concerning the mesh that could potentially lessen the applicable four year statute of limitation period. While the court recognizes there may have been an implied warranty of future performance, as such devices are usually intended to remain within the body for a substantial period, an explicit future warranty of future performance is required to vault the four year statute of limitations pursuant to N.J.S.A. 12A:2-725 (2). Because Plaintiffs have presented no such evidence, the court finds that Plaintiffs' express breach of warranty claim accrued on May 14, 2004, when the device was implanted into plaintiff Lee Calderio-Lewis, and thus such claim must have been filed by July 11, 2013 pursuant to New Jersey's four-year statute of limitation period. The court also finds that the associated loss of consortium claim is also time-barred as there is no viable underlying claim.

For the foregoing reasons, and affording Plaintiffs all reasonable inferences, Defendants' summary judgment motion, dismissing Plaintiffs' complaint in its entirety, is **GRANTED**.