UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MARILYN ADAMS, Plaintiff, v. ZIMMER US, INC., ZIMMER HOLDINGS, INC., ZIMMER INC., AND ZIMMER SURGICAL, INC. Defendants.	: : : : : : : : :	Civil Action No. 17-621 The Honorable Judge Edward G. Smith

BRIEF IN SUPPORT OF ZIMMER'S MOTION FOR SUMMARY JUDGMENT

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Pursuant to Rule 56 of the Federal Rules of Civil Procedure, the Defendants, Zimmer US, Inc., Zimmer Holdings, Inc., Zimmer, Inc., and Zimmer Surgical, Inc. (collectively, "Zimmer"), move this Court for an order granting summary judgment, in whole or in part, on the claims identified in Plaintiff's Second Amended Complaint ("SAC"). In support, Zimmer states as follows:

INTRODUCTION

This is a product liability action involving a medical hip device manufactured by Zimmer. The Plaintiff filed her original complaint on February 10, 2017, alleging that she was injured as a result of receiving a Zimmer hip device during her total right hip replacement surgery in 2011. [ECF No. 1.] The essence of the Plaintiff's lawsuit is that the Zimmer hip device was defective because it caused her to experience metallosis,[1] an adverse local tissue reaction,[2] and the need for an early revision surgery.

Zimmer successfully moved to dismiss several causes of action in the Plaintiff's original complaint, and the SAC (i.e., the operative complaint) now contains a claim of manufacturing defect based in strict liability, as well as negligence-based claims of failure to warn, design defect, and manufacturing defect. [ECF No. 34.] All of the Plaintiff's remaining claims, however, are time-barred because she filed this action eleven days after the latest possible date that she knew or should have known that her right hip injury was related to the Zimmer hip device. Additionally, the Plaintiff cannot recover on any theory alleging a manufacturing defect because she has no direct or physical evidence that the Zimmer hip device deviated in any way

[1] Metallosis is defined as "metal wear that then causes a reaction to the surrounding tissue" and typically "depends on the patient's own reaction to the presence of metal wear." (Statement of Undisputed Facts ("SUF"), at ¶ 16, filed contemporaneously herewith.)

[2] Adverse local tissue reaction occurs "when a patient has an unusual response around a site that's typically caused by an offending factor. That factor can be metal wear debris causing a proliferation of reactive tissue around that particular joint or local area." (SUF at ¶ 17.)

from Zimmer's intended specifications. Further, none of the Plaintiff's experts have (or could for that matter) opined on that issue, because the Zimmer hip device was never measured after explantation and has since been discarded. In short, this matter presents the precise scenario Rule 56 contemplates: giving the benefit of every doubt to the Plaintiff, no triable issue of material fact remains.

Accordingly, Zimmer is entitled to summary judgment on all of the Plaintiff's claims.

FACTUAL BACKGROUND

The Plaintiff began experiencing right hip pain in 2008. (SUF at ¶ 1.) She went to see Dr. Prodromos Ververeli in 2011 who recommended a total right hip replacement surgery (the "THR"). (SUF at ¶ 2-3.) Dr. Ververeli performed the THR on January 18, 2011, using a Zimmer M/L Taper Kinectiv Stem and Neck (the "Kinectiv") with a Versys Femoral Head (the "Versys Head") (collectively, the Kinectiv and Versys Head are referred to as the "Zimmer Device"). (SUF at ¶¶ 5-6.) The Plaintiff's understanding going into the THR was that she would be receiving a Zimmer prosthetic hip that would completely replace her natural right hip and last approximately fifteen to twenty years. (SUF at ¶ 4.)

The Plaintiff initially did well after the THR, but returned to see Dr. Ververeli in September of 2012 due to recurrent pain in her right hip. (SUF at ¶ 11.) By January 2013, her right hip pain had progressed to the point where it was limiting her "ability to live [her] life." (SUF at ¶ 13.) As a result, she underwent a minimally invasive surgery on January 17, 2013, to determine whether her pain was due to an infection. (SUF at ¶¶ 14, 23.) The Plaintiff's tissue cultures from the surgery were negative for infection, and Dr. Ververeli subsequently diagnosed her with metallosis on February 6, 2013, due to elevated cobalt-chromium ("CoCr") levels in her

blood. (SUF at ¶¶ 14-16, 18-19, 23-26.) At this point, Dr. Ververeli discussed with the Plaintiff that the Zimmer Device was a potential cause of her right hip pain. (SUF at ¶ 27.)

Following months of intermittent swelling without signs of infection, the Plaintiff saw Dr. Ververeli in September of 2014 and was told that further testing would be necessary to check for an adverse local tissue reaction if she experienced an increase in her pain or swelling. (SUF at ¶¶ 28-30.) On November 28, 2014, the Zimmer Device dislocated while she was bending over in the shower. (SUF at ¶¶ 31-32.)

Upon returning from Florida, an x-ray taken on January 7, 2015, showed that the Plaintiff was experiencing an adverse local tissue reaction around the Zimmer Device. (SUF at ¶¶ 33-34.) During that visit, Dr. Ververeli told the Plaintiff that he would likely need to replace the Zimmer Device if further testing confirmed an "adverse local tissue reaction from wear and fretting to the hip junction," i.e., the junction between the Kinectiv Neck and the Versys Head. (SUF at ¶¶ 35-36.) Dr. Ververeli also told her that her adverse local tissue reaction likely caused the Zimmer Device to dislocate the prior month. (SUF at ¶ 34.)

On January 12, 2015, the Plaintiff was told by Dr. Ververeli's office that a CT scan had *confirmed* that she was experiencing an adverse local tissue reaction around the Zimmer Device and that she needed a hip revision. (SUF at ¶¶ 37-40.) On January 21, 2015, Dr. Ververeli explained to the Plaintiff that her adverse local tissue reaction was due to wear and fretting from the Zimmer Device and that a revision surgery was necessary to correct the problem. (SUF at ¶¶ 42-46.)

On January 30, 2015, the Plaintiff saw Dr. Ververeli in preparation for the hip revision surgery already scheduled for February 12, 2015. (SUF at ¶¶ 47-48.) Dr. Ververli re-confirmed the diagnosis of metallosis and extensively discussed the reasons for replacing the Zimmer

Device during that visit. (SUF at ¶¶ at 49-51.) The Plaintiff admitted that by January 30, 2015, she knew the Zimmer Device had to come out because "[i]t was a problem." (SUF at ¶ 52.) She also admitted that she would have objected if Dr. Ververeli had told her during the January 30, 2015, office visit that he was planning on using another Zimmer prosthetic because "if he was taking one out, I didn't want another one put back in." (SUF at ¶ 53.) On February 9, 2015, the Plaintiff signed an informed consent for her revision surgery, which stated "the above treatment/surgery . . . will be done for the care and diagnosis of: *right hip metalosis* (sic)." (SUF a ¶ 54) (emphasis added). Dr. Ververeli testified that the Plaintiff had an adequate understanding of what right hip metallosis meant "as it applie[d] to the local adverse tissue reaction" at the time she signed the informed consent. (SUF at ¶ 55.)

QUESTIONS PRESENTED

1. Whether the Plaintiff's claims are time-barred because she knew or should have known of her injury and its cause, at the latest, on January 30, 2015, but waited to file this action until February 10, 2017, which was eleven days after the statute of limitations period expired?

2. Whether the Plaintiff's strict liability manufacturing defect claim fails because it is not cognizable under Pennsylvania law, or in the alternative, whether the Plaintiff's manufacturing defect claims fail because the Plaintiff has lost the device and has no evidence that the device was defectively manufactured?

LEGAL STANDARD

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "Material" facts are those that could affect the outcome of the suit under the applicable substantive law. *Santini v. Fuentes*, 795 F.3d 410, 416 (3d Cir. 2015) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Disputes of fact are

"genuine" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *In re Asbestos Products Liab. Litig. (No. VI)*, 837 F.3d 231, 235 (3d Cir. 2016) (citing *Anderson*, 477 U.S. at 248)).

The moving party has the initial burden of demonstrating that "there is an absence of evidence that rationally supports the plaintiff's case." *Clark v. Modern Group Ltd.*, 9 F.3d 321, 326 (3d Cir. 1993) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). Once this occurs, the nonmoving party must do more than express doubt as to the truth of the moving party's factual submissions, but instead must point to "concrete evidence from which a reasonable juror could return a verdict in his favor." *Anderson*, 477 U.S. at 256; *see Boyle v. County of Allegheny Pennsylvania*, 139 F.3d 386, 393 (3d Cir. 1998) ("[T]he opposing party must do more than simply show that there is some metaphysical doubt as to material facts."); *Halsey v. Pfeiffer*, 750 F.3d 273, 287 (3d Cir.2014) ("[A]n inference based upon a speculation or conjecture does not create a material factual dispute sufficient to defeat summary judgment.") (citations omitted). "Summary judgment therefore is where the rubber meets the road for a plaintiff, as the evidentiary record at trial, by rule, will typically never surpass that which was compiled during the course of discovery." *Fidler v. Geisinger Med. Ctr*., 2017 WL 4418298, at *7 (M.D. Pa. Oct. 5, 2017) (quotations omitted).

ARGUMENT

I. The Plaintiff's Claims Are Time-Barred Under Pennsylvania Law.

As demonstrated by the plain testimony of the Plaintiff and her treating surgeon, Dr. Ververeli, the Plaintiff knew of her injury and its suspected relationship to the Zimmer Device, at the latest, on January 30, 2015. The Plaintiff, however, did not initiate this lawsuit until February 10, 2017. As a result, the Plaintiff failed to file this action until after Pennsylvania's

two-year statute of limitations had expired, and the Court should award summary judgment to Zimmer.

A. Pennsylvania Law Prescribes a Two-Year Statute of Limitations And Applies A Very Narrow Discovery Rule.

Under Pennsylvania law, "the statute of limitations begins to run as soon as the right to institute and maintain a suit arises," i.e., the date the injury was first inflicted. *Fine v. Checcio*, 870 A.2d 850, 857 (Pa. 2005). Stated differently, the clock starts "from the time when the injury was done even though the damage may not have been known, or may not in fact have occurred, until afterwards." *Danysh v. Eli Lilly and Co.*, 2011 WL 4344601, at *7 (M.D. Pa. July 13, 2011), *report and recommendation adopted*, 2011 WL 4344595 (M.D. Pa. Sept. 15, 2011), *aff'd*, 461 Fed. Appx. 75 (3d Cir. 2012) (unpublished) (quoting *Bernath v. Le Fever*, 189 A.342, 344 (Pa. 1937); *see also Moore v. McComsey*, 459 A.2d 841, 855 (Pa. Super. 1983) ("The general rule is that the statute begins to run from the time the negligent act is done."). Product liability actions grounded in theories of negligence, design defect, and failure to warn are subject to a two-year statute of limitations in Pennsylvania. *Juday v. Merck & Co., Inc.*, 2017 WL 1374527, at *2 (E.D. Pa. Apr. 17, 2017); 42 Pa.C.S. §5524(2). Pennsylvania applies a limited "discovery rule" that "allows a party who has not suffered an immediately ascertainable injury" to toll the commencement of the limitations period where "the injury or its cause was neither known nor *reasonably* knowable" during that time. *Fine*, 870 A.2d at 858 (citing *Lewey v. H.C. Frick Coke Co.*, 31 A. 261 (Pa. 1895) (emphasis added).

The Plaintiff was implanted with the Zimmer Device on January 18, 2011. (SUF at ¶ 5.) Because this lawsuit was not filed until February 10, 2017, the Plaintiff's claims are time-barred unless *she can establish* that the discovery rule applies and tolls the running of the statute of limitations until at least February 10, 2015. *See In re Risperdal Litig.*, 2017 WL 5256400, at *6

(Pa. Super. Nov. 13, 2017) ("[T]he onus of proving the applicability of the discovery rule falls squarely upon the person, or people, asserting its applicability."); *Cochran v. GAF Corp.*, 666 A.2d 245, 249 (Pa. 1995) (emphasizing that the "one claiming the benefit of the [discovery] exception bears the burden of establishing that she falls within it"). As discussed in the next section, given the factual record in this case, the Plaintiff knew of her injuries and the suspected cause well before February 10, 2015, and her claims are therefore time-barred.

B. The Discovery Rule Cannot Save The Plaintiff's Time-Barred Claims.

The testimony of the Plaintiff and Dr. Ververeli establish that the Plaintiff knew, or at least suspected, that the Zimmer Device was the cause of her injury no later than January 30, 2015. Even under the most generous application of the discovery rule, the statute of limitations for the Plaintiff's claims expired on January 30, 2017. Because the Plaintiff waited two years and eleven days to file this lawsuit, all of her claims are time-barred and Zimmer is entitled to judgment as a matter of law.

The discovery rule provides that the limitations period is tolled until "the plaintiff knows or reasonably should know: (1) that he has been injured, and (2) that his injury has been caused by another party's conduct." *Fidler*, 2017 WL 4418298, at *9 (citing *Romah v. Hygenic Sanitation Co.*, 705 A.2d 841, 857 (Pa. Super. Ct. 1997)). Importantly, "Pennsylvania takes a 'narrow approach' to the discovery rule and places a 'greater burden' on plaintiffs than do most other jurisdictions." *Danysh*, 2011 WL 4344601, at *7 (quoting *Gleason v. Borough of Moosic*, 15 A.3d 479, 484–85 (Pa. 2011)) (internal quotations omitted). Pennsylvania's discovery rule is not triggered when the plaintiff learns the full extent of her injury or its precise cause. *Wilson v. El–Daief*, 964 A.2d 354, 363 (Pa. 2009). Rather, the limitations period begins to run "once the plaintiff is on inquiry notice—that is, 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." *Danysh*, 2011 WL 4344601, at *7 (quoting *Gleason*, 15 A.3d at 484–85) (internal quotations omitted).

Further, a plaintiff does not need knowledge that she has a possible cause of action against another, specific medical evidence supporting that cause of action, or a definitive diagnosis to start the commencement of the limitations period in Pennsylvania. *Danysh*, 2011 WL 4344601, at *10; *see also Juday*, 2017 WL 1374527, at *4; *In re Risperdal Litig.*, 2017 WL 5256400, at *5. Instead, "[a]wareness of injury and *suspicion* of its cause are enough to begin the running of the limitations period." *Danysh*, 2011 WL 4344601, at *8 (emphasis added); *see also Debiec v. Cabot Corp.*, 352 F.3d 117, 132 (3d Cir. 2003) ("[S]uspicion that a claimant has a particular disease, which is caused by another, is sufficient to start the clock.") *Mest v. Cabot Corp.*, 449 F.3d 502, 510-511 (3d Cir. 2006) ("[A] plaintiff need not know the exact nature of his injury, as long as it objectively appears that the plaintiff is reasonably charged with the knowledge that he has an injury caused by another."); *Juday*, 2017 WL 1374527, at *7 (finding a reasonable suspicion that the medical product was the source of the plaintiff's symptoms was enough to begin the running of the limitations period). Once a plaintiff knows or suspects, or should know or suspect, that she has suffered an injury, the statute of limitations begins to run and the plaintiff is given "the opportunity to select and consult with a lawyer, conduct the necessary investigation and [timely] commence suit." *Ackler v. Raymark Industries, Inc.*, 551 A.2d 291, 296 (Pa. Super. 1988); *see also Murray v. Hamot Med. Ctr. of City of Erie*, 633 A.2d 196, 201 (Pa. Super. 1993) ("A diligent investigation may require one to seek further medical examinations as well as competent legal representation."); *Bickford v. Joson*, 533 A.2d 1029, 1031 (1987) ("[I]n an era of complex and sophisticated legal rights and the general availability of

legal services, the duty to make legal inquiry within two years of the injury is wholly reasonable."). At the summary judgment stage, the Court is free to fix the commencement date of the limitations period *as a matter of law* where reasonable minds could not differ as to when the plaintiff should have reasonably been aware of her injury and its cause. *Workman v. A.I. DuPont Hosp. for Children of Nemours Found*, 2007 WL 2173395, at *3 (E.D. Pa. July 27, 2007), *aff'd sub nom., Workman v. Nemours Found*., 278 Fed. Appx. 124 (3d Cir. 2008) (unpublished).

1. When the Plaintiff Knew of Her Injury.

The record establishes that the Plaintiff knew of her injury well before January of 2015. Her right hip pain began in 2012, and progressed to the point where it was limiting "her ability to live [her] life" in 2013. (SUF at ¶¶ 11-13, 46, 52.) She admitted that by January of 2015, her right hip pain was "very sharp" and was the kind of pain she had not experienced before, and it had been "going on for years." (SUF at ¶ 46.) She further admitted, "I knew there was a problem with my hip because of the pain, and it was just getting worse all the time[.]" (SUF at ¶ 52.) Thus, it is beyond dispute that the Plaintiff knew that her right hip was injured well before February 10, 2015.

2. When the Plaintiff Knew, or At Least Had a Suspicion, Regarding the Causal Relationship Between the Zimmer Device and Her Injury.

The Plaintiff was repeatedly told that her right hip pain was related to the Zimmer Device outside of the statute of limitations period. Dr. Ververeli first told the Plaintiff in February of 2013 that the Zimmer Device was a potential source of her right hip pain after he diagnosed her with metallosis due to elevated CoCr ion levels in her blood.[3] (SUF at ¶¶ 24-27.) On January 7, 2015, an x-ray showed that she was experiencing an adverse local tissue reaction around the Zimmer Device. (SUF at ¶¶ 33-35.) On that same day, Dr. Ververeli ordered a CT scan and told

[3] Dr. Ververeli also testified that the metallosis could not be coming from anything other than the Zimmer Device because the Versys Head was the only CoCr source in the Plaintiff's body. (SUF at ¶ 50.)

the Plaintiff that the Zimmer Device would need to be replaced if the scan revealed "wear and fretting to the hip junction." (SUF at ¶ 35-36.) Dr. Ververeli also told the Plaintiff that her adverse local tissue reaction likely caused the Zimmer Device to dislocate in November of 2014 while she was in Florida. (SUF at ¶ 34.) On January 12, 2015, the Plaintiff received a call from Dr. Ververeli's office telling her that the CT scan revealed that she was experiencing an adverse local tissue reaction around the Zimmer Device, and that she would therefore need a revision surgery. (SUF at ¶¶ 37-40.) Most tellingly, the Plaintiff conceded that by January 30, 2015, she knew that the Zimmer Device "had to come out" because "[i]t was a problem." (SUF at ¶ 52.) She further admitted:

> Q. But you knew it wasn't going to be a Zimmer device –
> A. Yeah. It was not going to be a Zimmer.
>
> Q, Yeah. Would it have caused you concern if [Dr. Ververeli] said he suggested using another Zimmer device?
> A. Yeah, I would have objected to it because if he was taking one out, I didn't want another one put back in.

(SUF at ¶ 53).

Accordingly, reasonable minds could not differ that by January 30, 2015, the Plaintiff possessed sufficient facts to put her on notice that there was a factual connection between her right hip pain and the Zimmer Device, and there is no question that Plaintiff possessed the requisite "suspicion" to trigger the running of the limitations period. Even though Pennsylvania law does not require a plaintiff to know the medical cause of her injury or receive a definitive diagnosis before triggering the limitations period, Dr. Ververeli told the Plaintiff on several occasions during January of 2015 that the Zimmer Device was the source of her pain and diagnosed her with metallosis and an adverse local tissue reaction, and the Plaintiff even signed an informed consent outside the limitations period that identified her diagnosis as "metalosis

(sic)." (SUF at ¶¶ 34-40, 42-46, 49-55) This is far beyond what is required to trigger the limitations period under Pennsylvania law. *See Danysh*, 2011 WL 4344601, at *10; *Juday*, 2017 WL 1374527, at *4; *Fidler*, 2017 WL 4418298, at *13; *see also Nicolaou v. Martin*, 153 A.3d 383 (Pa. Super. 2016).

The *Nicolau* case is particularly instructive and confirms that summary judgment is appropriate here. In *Nicolaou*, the plaintiff had been treated for lyme disease for several years by the physician defendants without ever having received a definitive diagnosis. *Id.* at 386-387. Years after treatment, a blood test administered by a different physician definitively confirmed that the plaintiff had been suffering from lyme disease. *Id.* The plaintiff initiated her lawsuit within two years of receiving the test results and argued that the discovery rule should toll the limitations period until the date the blood tests confirmed her previously-rendered clinical diagnosis because until that point there was no "basis for a lawsuit." *Id*. at 387, 391. The court rejected this argument, reasoning that once the plaintiff was told that she had "probable" lyme disease, she knew or should have known that her long-standing health problems may have been caused by the physician defendants' failure to diagnose her with the disease. *Id*. at 393, 395. The court reemphasized that Pennsylvania law does not require notice of the full extent of the injury, the precise cause, or even that another was negligent to trigger the limitations period. *Id*. at 395.

The conclusion in *Nicolaou* is consistent with other decisions within the Third Circuit applying Pennsylvania's discovery rule and confirming that mere suspicion that the defendant's conduct or product was the cause of injury suffices to start the running of the limitations period. *See e.g.*, *Fidler*, 2017 WL 4418298, at * 12-13 (limitations period began to run when doctor told plaintiff that he was suffering from infection even though the plaintiff could not establish that defendants were actually negligent until a later date); *In re Risperdal Litig.*, 2017 WL 5256400,

at *5 (rejecting plaintiffs' claim that the statute of limitations should be tolled because they did not have a medical diagnosis at the time and reiterating that Pennsylvania "law does not require a diagnosis before the statute begins to run, only awareness of an injury"); *Danysh*, 2011 WL 4344601, at *10 (plaintiff's suspicion that his injury was possibly caused by pharmaceutical drug was enough to start the limitations period notwithstanding that medical evidence confirming suspicion and extent of injury was not received until a later date); *Juday*, 2017 WL 1374527, at *1 (limitations period triggered when plaintiff's doctor told him that vaccine was a potential cause of symptoms even though diagnosis and extent of injury was not confirmed until later date).[4] In fact, just last year this Court held that an "unrebutted suspicion, that is one not negated by a physician or otherwise, [was] sufficient to start the clock running" even though the plaintiff's doctor never expressed an opinion as to the cause of his injury. *Juday*, 2017 WL 1374527, at *1, 4 (internal quotations omitted).

The record here is even more definitive regarding when the Plaintiff knew of her injury and suspected its causal relationship to the Zimmer Device. For instance, the Plaintiff admitted that she "absolutely" thought it was abnormal when the Zimmer Device dislocated on November 28, 2014, less than four years after it was implanted. (SUF at ¶¶ 31-32.) She also conceded that

[4] The holding in *Nicolaou* is also in accord with other jurisdictions that take a less strict approach to the discovery rule. *See e.g.*, *In re Boston Sci. Corp., Pelvic Repair Sys. Products Liab. Litig.*, 2015 WL 1405498, at *8 (S.D.W. Va. Mar. 26, 2015), *aff'd sub nom.*, *Timothy v. Boston Sci. Corp.*, 665 Fed. Appx. 295 (4th Cir. 2016) (unpublished) (granting summary judgment and finding that statute of limitations for plaintiff's product liability claims began to run on the date her doctor confirmed that she required a second surgery because at that point the plaintiff had inquiry notice of a possible causal relation between the product and her injury); *Gazal v. Boehringer Ingelheim Pharm., Inc.*, 647 F.3d 833, 836 (8th Cir. 2011) (affirming district court's finding that limitations period began to run notwithstanding that injury had not been confirmed by medical diagnosis); *Griffiths-Rast v. Sulzer Spine Tech*, 216 F. App'x 790, 792 (10th Cir. 2007) (unpublished) (granting summary judgment on statute of limitations grounds and finding that limitations period began to run when plaintiff felt there was something wrong with medical implant even though doctor did not confirm suspicion until later date); *Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d 470, 480 (D.N.J. 2002) (limitations period began to run when the plaintiff's doctor told him his injury was possibly related to the product even though definitive diagnosis was not made until later); *Sawtell v. E.I. du Pont de Nemours and Co., Inc.*, 22 F.3d 248, 252 (10th Cir. 1994) (affirming summary judgment because the plaintiff knew or should have known of the connection between her pain and her joint prosthesis before the procedure to remove the joint prosthesis).

she "knew there was a problem with [her] hip because of the pain, and it was just getting worse all the time . . . . And [she] tied in the dislocation so close to the next revision. It just seemed that something was wrong. It had to come out . . . . It was a problem." (SUF at ¶ 52.) Thus, the Plaintiff clearly suspected, or should have suspected, that there was an issue with the Zimmer Device outside the limitations period. This suspicion not only went unrebutted, it was *confirmed* by Dr. Ververeli on multiple office visits during January 2015. (SUF at ¶¶ 34-40, 42-46, 49-55.)

Therefore, even under the most liberal application of Pennyslvania's narrow discovery rule, the limitations period on the Plaintiff's claims expired on January 30, 2017. Because the Plaintiff waited until eleven days after the latest possible date the statute of limitations expired to file her lawsuit, all of her claims are time-barred as a matter of law and should now be dismissed.

II. The Plaintiff Cannot Prove A Manufacturing Defect.

In Count I of the SAC, the Plaintiff asserts that the Zimmer Device deviated in a material way from Zimmer's manufacturing performance standards or from an otherwise identical product. (SAC at ¶ 77.) Her strict liability manufacturing defect claim, however, is not cognizable under Pennsylvania law and cannot stand. Further, her manufacturing defect claim fails as a matter of law, regardless of whether it sounds in negligence[5] or strict liability, because the Zimmer Device was discarded and never made available for inspection by any expert, and the Plaintiff therefore has no direct or physical evidence to prove a manufacturing defect.

[5] It is unclear from the SAC whether the Plaintiff intended to bring a negligent manufacturing defect claim. If she did, she failed to adequately plead such a cause of action. Nowhere in Count II of the SAC does the Plaintiff "identify/explain how the [Zimmer Device] either deviated from [Zimmer]'s intended result/design or how [it] deviated from other seemingly identical product models." *Terrell*, 2014 WL 3746532, at *8 (quoting *Lucas v. City of Visalia*, 726 F.Supp.2d 1149, 1151 (E.D. Cal. 2010). Nevertheless, the difference is immaterial because she lacks the required evidence to sustain either theory of manufacturing defect.

A. The Plaintiff's Strict Liability Manufacturing Defect Claim Fails As A Matter Of Law.

The Pennsylvania Supreme Court has adopted comment k to Section 402A of the Restatement (Second) of Torts ("comment k") as it applies to prescription drugs, and the Superior Court has extended its reasoning to cover medical devices. *Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996); *Lance v. Wyeth*, 15 A.3d 434, 453 (Pa. 2014); *Creazzo v. Medtronic, Inc*., 903 A.2d 24, 31 (Pa. Super. Ct. 2006). A number of federal courts in the Eastern District have predicted that the Pennsylvania Supreme Court would do the same. *See e.g.*, *McLaughlin v. Bayer Corp.*, 172 F.Supp. 3d 804 (E.D. Pa. 2016); *Wilson v. Synthes USA Prods., LLC*, 116 F.Supp.3d 463, 467 (E.D. Pa. 2015); *Runner v. Bard*, 108 F. Supp. 3d 261 (E.D. Pa. 2015); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Esposito v. I–Flow Corp.*, 2011 WL 5041374, at *4 (E.D. Pa. Oct. 24, 2011); *Geesey v. Stryker Corp.*, 2010 WL 3069630, at *3-4 (E.D. Pa. Aug. 4, 2010).[6]

Terrell v. Davol, Inc., 2014 WL 3746532, *5 (E.D. Pa. Jul. 30, 2014), summarizes Pennsylvania's trend towards recognizing comment k as barring *all* strict liability claims (including those based on a manufacturing defect theory) involving medical devices. The *Terrell* Court detailed the split among Pennsylvania courts on this issue, then considered and rejected the plaintiff's argument that that she should be able to proceed based on a strict liability manufacturing defect theory. *Terrell*, 2014 WL 3746532, at *3-5. The court noted that the decisions from courts allowing strict liability manufacturing defect claims to proceed were reached before *Lance v. Wyeth*, in which the Pennsylvania Supreme Court barred all strict liability claims, including manufacturing defect, based on a defective prescription drug. *Id.* at *5

[6] Notably, a number of federal courts in the Western District have also predicted that the Pennsylvania Supreme Court would extent *Hahn* and *Lance* to cover medical devices. *See e.g.*, *Carson v. Atrium Med. Corp*., 191 F.Supp. 3d 473, 476-477 (W.D. Pa. 2016); (dismissing strict liability manufacturing defect claim under *Lance* and *Hahn*); *Cogswell v. Wright Med. Tech*., 2015 WL 4393385, at *3 (W.D. Pa. Jul. 16, 2015) (same).

(citing *Lance v. Wyeth*, 15 A.3d 434, 453 (Pa. 2014)). The *Terrell* court went on to predict that, based on the *Lance* ruling, "the Supreme Court of Pennsylvania would come to the same conclusion with respect to defective medical devices." *Id.* Holding that it was "bound to follow what it predicts Pennsylvania law will be," the *Terrell* court ultimately dismissed all strict liability claims, including manufacturing defect, against the defendant medical device manufacturer. *Id.*; *see also Runner*, 108 F.Supp.3d at 266 (refusing to recognize strict liability manufacturing defect claim against medical device manufacturer under comment k); *Wilson*, 116 F.Supp. 3d at 467 (same).

Zimmer is mindful of the Court's position as to Judge Bettlestone's decision in *Smith v. Howmedica Osteonics Corp*, 2017 WL 1508992 (E.D. Pa. Apr. 27, 2017), as the *Smith* case was discussed at length during the May 31, 2016, hearing on Zimmer's motion to dismiss. However, nothing in the *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328 (Pa. 2014), decision changed the reasoning or approach of the long line of prescription and medical device cases barring strict liability manufacturing defect claims under comment k. *See Lance*, 15 A.3d at 453; *Hahn*, 673 A.2d at 890-91. Indeed, *Tincher* was not a prescription drug or medical device case; rather, it was a garden variety products liability case involving stainless steel tubing used to transmit gas into a home or fireplace.[7] *See Krammes v. Zimmer, Inc.*, 2015 WL 4509021, at *1 (M.D. Pa. July 24, 2015) (dismissing strict liability manufacturing defect claim against medical device manufacturer under comment k and stating that "*Tincher* did not change the existing jurisprudence concerning strict liability with respect to prescription drugs and medical devices"); *McLaughlin*, 172 F.Supp. 3d at 833-34 (rejecting argument that comment k does not encompass strict liability manufacturing defect claims because the Pennsylvania Supreme Court made clear

[7] In fact, the *Tincher* court did not even address comment k except to note that it was recognized under Pennsylvania law.

in *Lance* that comment k's reach was "without qualification") (emphasis in original); *Bell v. Boehringer Ingelheim Pharm., Inc.*, 2018 WL 928237, at *3 (W.D. Pa. Feb. 15, 2018) (rejecting plaintiff's argument that the court should follow *Tincher* instead of *Hahn* and *Lance* and emphasizing that Pennsylvania federal courts are "bound by the law as set forth by the Pennsylvania Supreme Court"). Based on the foregoing, Zimmer respectfully asks the Court to revisit the *Smith* opinion in light of the more complete factual record now before it. In doing so, the Court should reject the Plaintiff's strict liability manufacturing defect claim because it is not cognizable under Pennsylvania law.

B. The Plaintiff's Manufacturing Defect Claims Fail Because She Cannot Prove That The Zimmer Device Deviated From Its Intended Use.

The Plaintiff can offer no evidence of how the Zimmer Device deviated from Zimmer's intended manufacturing performance specifications. Specifically, neither Dr. Ververeli nor any of the Plaintiff's experts rendered an opinion about the Zimmer Device being defectively manufactured because it was discarded after the Plaintiff's revision surgery without ever being inspected or measured. (SUF at ¶¶ 58-59.) As a result, the Plaintiff cannot sustain her burden of proving the existence of a manufacturing defect, and the claim, whether sounding in negligence or strict liability, should be dismissed.

A manufacturing defect occurs when there is "a breakdown in the machine or a component thereof." *Riley v. Warren Mfg., Inc.*, 688 A.2d 221, 224 (Pa. Super. 1997). The Eastern District has explained a manufacturing defect as follows:

> Generally a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line . . . . The manufacturing defect theory posits that a suitable design is in place, but that the manufacturing process has in some way deviated from that design.

Terrell, 2014 WL 3746532, at *7 (quoting *Lucas*, 726 F.Supp.2d at 1154-55) (internal quotations omitted). To prove a negligent manufacture under Pennsylvania law, the Plaintiff must show that Zimmer owed her a duty, the duty was breached, and that such a breach was the proximate cause of her injuries. *Soufflas*, 474 F. Supp. 2d at 753. Failure to establish even one of these elements should result in summary judgment in favor of Zimmer. *See, e.g.*, *Rooney v. City of Philadelphia*, 623 F. Supp.2d 644, 660 (E.D. Pa. 2009). Unlike a design defect theory, "a claim of manufacturing defect is untenable in the absence of the product itself." *Creazzo*, 903 A.2d at 30.

In *Creazzo*, the plaintiffs brought a manufacturing defect claim against a medical device manufacturer even though the device at issue had been explanted and discarded without ever having been inspected. *Creazzo*, 903 A.2d at 26-27. As a result, the only inspection of the device was a "gross pathology examination carried out at the hospital[,]" and neither party was able to submit the device to a retained expert. *Id*. at 27. Nevertheless, the plaintiff submitted an expert report from an engineer that consisted of journal articles and documentation of over 600 other events of failure from essentially the same device. *Id*. The medical device manufacturer moved for and the trial court granted summary judgment based on the plaintiffs' inability to retrieve the product, reasoning that a defense to a "claim of manufacturing defect (not design defect) . . . requires inspection of the individual device." *Id.* at 29. The Superior Court of Pennsylvania affirmed on the basis of spoliation, stating:

> Where, as in this case, the actual device has not been examined even by the plaintiff's own expert, both proof and defense of the claim are severely compromised. Given the paucity of direct evidence that such an absence imposes on the action, per force, we cannot conclude that the trial court erred in dismissing the [plaintiffs'] product defect claim[.]

Id. at 30.

As in *Creazzo*, the Zimmer Device was never measured or inspected after it was explanted from the Plaintiff's hip, and it has since been discarded. (SUF at ¶ 59.) The only person who handled the Zimmer Device is Dr. Ververeli, who inspected it before the THR and did not see any abnormalities. (SUF at ¶ 58.) Dr. Ververeli further noted that he could not point to any specific defect in the Zimmer Device. (SUF at ¶ 57.) Thus, the Plaintiff cannot use Dr. Ververeli's testimony to establish that a manufacturing defect existed in the Zimmer Device or proximately caused her alleged injuries.

Furthermore, the Plaintiff's experts do not provide (and cannot provide) any evidence that Zimmer deviated from the applicable standard of care with respect to the manufacture of the Zimmer Device because they never inspected it. For instance, in *Creazzo*, the plaintiffs tried to circumvent their inability to inspect the device by having their expert tie complaints involving the same device (but from a different product lot) to the specific device at issue. *Creazzo*, 903 A.2d at 30. Because the expert never examined the device at issue, however, the Superior Court found his report invited "rank speculation" about a manufacturing defect because it did not establish that there was a deviation in the design of the specific device implanted into the plaintiff. *Id*.

The same reasoning holds true here, as the expert reports that the Plaintiff submitted are only based on speculation regarding the *design* of all Kinectivs, rather than the specific device (i.e., the Zimmer Device) that was implanted into the Plaintiff. Unlike a claim for design defect, which can be investigated by looking at the entire product line, the Plaintiff's manufacturing defect claim is untenable in the absence of the Zimmer Device itself. Accordingly, the undisputed evidence does not (and cannot) support the Plaintiff's manufacturing defect claim, and it should now be dismissed.

CONCLUSION

For the foregoing reasons, Zimmer requests that the Court grant its motion for summary judgment on all claims and dismiss the Plaintiff's Second Amended Complaint as a matter of law. In the alternative, Zimmer requests that the Court grant as appropriate those portions of its motion for summary judgment for Counts I and II.

Dated: May 29, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

On May 29, 2018, I electronically filed this pleading using the Court's CM/ECF system, which will provide notice of electronic filing to all counsel of record.

/s/Sean J. Powell