UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MARYANN GUISTO and JERRY GUISTO,

Plaintiffs,

– against –

STRYKER CORPORATION, HOWMEDICA OSTEONICS CORPORATION and STRYKER ORTHOPEDIC CORPORATION

Defendants.

MEMORANDUM, ORDER, & JUDGMENT

12-CV-2489

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I. Introduction

Plaintiffs sue the manufacturers of a hip implant for injury resulting from the device's alleged defect. Maryann Guisto, the plaintiff who received the implant, required revision surgery.

Defendants have moved for summary judgment. They assert that the statute of limitations bars each of plaintiffs' causes of action. The defendants' motion is granted. All of plaintiffs' claims are barred by statutes of limitations.

II. Facts and Procedural History

Beginning in July of 2006, plaintiff Maryann Guisto's left hip joint caused her difficulty. Second Amended Compl. ("Sec. Am. Compl.") ¶ 9, Oct. 25, 2012, ECF No. 41. *See* Def. Statement of Undisputed Material Facts ("Def. 56.1 Stmt.") ¶ 1, Mar. 4, 2013, ECF No. 54. She was diagnosed with avascular necrosis and degenerative joint disease. *See* Pl. Stmt. of Undisputed Facts Pursuant to 56.1 ("Pl. 56.1 Stmt.") ¶ 5, Mar. 28, 2013, ECF No. 61 On September 7, 2006, her orthopedic surgeon replaced the hip using a Stryker Trident Acetabular Hip implant ("Trident System") manufactured by the defendants. *See id.* ¶¶ 6-8; Sec. Am. Compl. ¶ 9

Plaintiffs' amended complaint alleges that "immediately following…replacement surgery, the hip prosthesis…failed." Sec. Am. Compl. ¶ 15. "Since [then], the plaintiff has been dogged by persistent pain in her spine, hip and pelvis and an uneven gait." *Id.* ¶ 10. Within three months after the surgery Mrs. Guisto started expressing concerns to her physicians, including the orthopedic surgeon who performed the replacement procedure, about discomfort with her left hip and left leg, an "increased leg length," and an uneven gait. *See* Def. 56.1 Stmt. ¶ 2. Pain and discomfort continued "[i]n the years after the hip implantation." Pl. 56.1 Stmt. ¶ 19.

Between 2006 and 2011, Mrs. Guisto visited a series of diagnosticians. *Id* ¶ 19. She repeatedly reported continuing pain in her left hip and in surrounding parts of the lower left side of her body. *See id.*; Def. 56.1 Stmt. ¶¶ 13. Plaintiffs claim that the pain had continued to increase after surgery. *See e.g.*, Def. 56.1 Stmt. ¶ 4, 7. The physicians performed a battery of tests, including bone scans and x-rays. Pl. 56.1 Stmt. ¶ 19. They confirmed that the problem was in her left hip. *See* Def. 56.1 Stmt. ¶¶ 5, 9, 11, 13. Between December 2008 and February 2009 one doctor she visited expressed concern that the implant's cup could have loosened even if

the bone scans did not show that. *See* Catullo Decl., Ex. C ("Medical Records"), at HAM00008-9, Mar. 4, 2013, ECF No. 51. In September 2008 and again in March 2009, Mrs. Guisto requested hip revision surgery from her doctors. *See* Def. 56.1 Stmt. ¶ 4 ("Essentially what she is asking for is someone to revise her hip…as she feels she is worse now than she was before….") (quoting Catullo Decl., Ex. C, at HAM000029). *See also id.* ¶ 11 ("She is very anxious to undergo revision surgery.") (quoting Catullo Decl., Ex. E ("Medical Records"), at Drucker000013).

On March 4, 2009, the plaintiffs commenced a medical malpractice lawsuit against the orthopedic surgeon who had implanted the Trident System. Def. 56.1 Stmt. ¶ 17 (citing Catullo Decl., Ex. I (complaint in malpractice action). Although plaintiffs filed that action pro se, by September 2011 they were represented by counsel of record from the instant case. Hr'g. Tr., May 17, 2013. Defendants in the present action were not parties to the malpractice case. That litigation is pending in state court. *See* Hr'g. Tr.

According to Mrs. Guisto, "[i]t was not until [February 28,] 2011 that she came to know…her ill-fitting defective artificial hip was the cause of her battle with hip pain and spinal pain over a period of at least four (4) years." Sec. Am. Compl. ¶ 11. She alleges it was on this date that she learned from a doctor that her implant had failed to biologically fixate in her body. *See* Pl. 56.1 ¶ 23; Pl. Mem. of Law in Opp. to Def. Mot for Summ. J. ("Pl. Mem."), at 1, 8, Mar. 28, 2013, ECF No. 63. Prior to this date, the plaintiffs contend, Mrs. Guisto believed that the source of her pain was surgical error. Pl. 56.1 ¶ 22. She asserts that none of the prior doctors were aware of implant failure because it was not revealed through earlier tests. *Id.* ¶¶ 19, 22.

The Trident System was "manufactured to fixate or integrate into the patient without the need for cement or external fixations…." *Id.* It was designed to capitalize on the human body's

natural process of bone growth to stabilize the implant's components. *Id.* ¶¶ 9-10. This process is known as osseointegration. *See* Burden Decl. Ex. N ("Mani Dep."), 53:1-25, Mar. 28, 2013, ECF No. 65. It occurs over time and is complete twelve to eighteen months after the surgery. *See id.* 53:19-25 ("[Osseintegration] occurs over time. Technically, anywhere from one year to 18 months before it is absolutely complete....If you were to take studies, it would take about a year to 18 months."). Ultimately, failure of the implant's biological fixation through ossesointegration can result in loosening of the implant cup and cause pain. *See* Mani Dep 54-55:20; Pl. Mem. at 12.

Mrs. Guisto asserts that her defective prosthesis failed in the process of osseointegration and biological fixation, Pl. 56.1 Stmt. ¶ 9, because the device became adulterated during the manufacturing process. *See* Pl. Mem., at 2-3, 6. It was, she asserts, covered with a residual "that interfered with the bod[y's] ability to biologically fixate or integrate the component implanted in the plaintiff." *Id.* at 6-7. A "residual" is "an organic sterile compound that was left on a component after manufacture and washing." *Id.* at 2. The plaintiffs assert that the device's residual precluded osseointegration, resulting in the implant's failure to biologically fixate within the body. *See* Pl. Mem. at 17, 23.

The defendants had issued a voluntary recall of some of their Trident System devices in 2008 after residual levels on the device exceeded internal specifications. *See* Pl. Mem. at 7; Burden Decl. Exs. D, E, Mar. 28, 2013, ECF No. 62. By then the FDA had issued two warning letters to Stryker in 2007 about defects in some of its devices, including the Trident System. *See generally* Burden Decl. Ex. B, Ex C ("Warning Letters"). The agency warned that it would not grant premarket approval for future such devices if the adulterated ones were not first remedied. *See*

Burden Decl. Ex. C. It is, plaintiffs contend, that Mrs. Guisto's implant suffered from the "adulteration" about which the FDA was concerned.

On March 15, 2011 Mrs. Guisto underwent revision surgery. Pl. 56.1 Stmt. ¶ 21. The reason for the surgery, she contends, was the "failure of the mechanical hip to operate as a hip joint." *Id.* ¶ 22.

Plaintiffs began the instant action on May 17, 2012. They filed an amended complaint on June 12 of 2012.

Defendants filed their motion to dismiss the amended complaint on July 3, 2012. Plaintiffs then sought leave to file a second amended complaint. On October 18, 2012, the court heard argument on defendants' motion to dismiss the pleadings. Their motion was denied. Order, October 19, 2012, ECF No. 37. Directed by the court was limited expedited discovery on the statute of limitations governing each of plaintiffs' claims, followed by defendants' prompt filing of the instant summary judgment motion based on statutory time-bars. *Id.* Plaintiffs were permitted to file a second amended pleading within 10 days of argument. *Id.*

The current amended complaint states four causes of action. *See generally* Sec. Am. Compl, Oct. 25, 2012, ECF No. 41. Alleged are: 1) negligence, in the manufacturing, design, testing, and distribution of the product, resulting from defendants': a) failure to adhere to the federal regulations that govern the manufacturing and quality control of medical devices such as the hip implant; b) deviations from acceptable standards of practice; c) failure to supervise their employees; d) improper marketing of the product; and e) violation of state common law for failing to comply with the requirements of premarket approval for the device; 2) breaches of express and implied warranties for: a) merchantability and b) fitness for a particular purpose; 3) selling of a device unreasonably unfit, unsuitable and unsafe for its intended purpose (strict

liability) as a result of defendants' a) deviations from design standards (design defect); and b) failure to adequately warn; c) violation of state common law for failing to comply with the requirements of premarket approval for the device; and 4) loss of consortium.

On March 4, 2013, defendants moved for summary judgment asserting that plaintiffs' claims have been barred under the relevant statutes of limitations. They had previously argued that federal law preempts all causes of action. *See generally* Def. Mem. of Law in Supp. of Mot. to Dismiss, Jul. 3, 2012, ECF No. 11. But preemption need not be considered since the State statutes of limitations prevent the suit from going forward.

Summary judgment is granted to the defendant.

III. Law

Summary judgment is appropriate if "there is no genuine issue as to any material fact and if the moving party is entitled to judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see, e.g.*, *Mitchell v. Washingtonville Cent. Sch. Dist.*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when, after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact and the movant is entitled to a judgment as a matter of law. Fed.R.Civ.P. 56(a); *see Anderson*, 477 U.S. at 247-50, 255. Evidence offered or pointed to in order to demonstrate a genuine dispute regarding a material fact may not consist of "mere conclusory allegations, speculation or conjecture." *Cifarelli v. Vill. Of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see Del. & Hudson Ry. V. Consol. Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue"). If the non-movant fails "to come forth with evidence sufficient to permit a reasonable juror to return a verdict in his or her

favor on" an essential element of the claim, summary judgment is granted. *Burke v. Jacoby*, 981 F.2d 1372, 1379 (2d Cir. 1992). *See e.g.*, *Anderson*, 477 U.S. at 248-49.

IV. Application of Law to Facts

The claims in this action are barred under their relevant statutes of limitations. No possible further evidence supports any contrary conclusion.

a. Negligence and Strict Liability

Claims for negligence and strict liability are subject to the ordinary statute of limitations for personal injury actions. *See* NY CPLR § 214 (5). For implants the time period is three years from the date of injury resulting from malfunction, not from the date of implantation of the device—unless implantation and malfunction occur at the same time. *See* NY CPLR § 214 (5); *Martin v. Edward Labs., Div. of Am. Hosp. Supply Corp.*, 60 N.Y.2d 417, 422 (N.Y.1983) ("The Statute of Limitations for personal injury caused by the malfunctioning of a prosthetic or contraceptive device implanted or inserted into the human body runs from the date of the injury resulting from the malfunction, not necessarily from the date of implantation or insertion."), *superseded by statute only as to toxic tort claims*, NY CPLR 214(c), *as recognized in Desieno v. Crane Mfg. & Serv. Corp.*, 127 Fed. Appx. 551 (2d. Cir. 2005). If "the onset of the process traceable to the [device], which is claimed to have caused plaintiff's injury, began more than three years before the commencement of the action, the defendant will be entitled to dismissal of the entire complaint on Statute of Limitations grounds." *Fitzpatrick v. A.H. Robins Co., Inc.*, 99 A.D.2d 478, 479 (2d Dept. 1984).

Plaintiffs assert that the implant's malfunction was the failure of osseointegration and biological fixation because of residuals that adulterated the device, and that this failure led to the pain starting immediately after implantation. They began their action in May 2012. For their

claims to be viable under the three-year statute of limitations Mrs. Guisto must have experienced injury caused by the claimed malfunction *no earlier* than May 2009. If they are to avoid the applicable three-year statute, any of the continuous pain Mrs. Guisto felt before this cutoff date could not have been caused by, or traceable to, the failure of osseointegration, that is to say, caused by the alleged adulteration due to a residual on the device—the claimed defect.

According to the plaintiffs, the implant failed "immediately" after the surgery in September 2006. Sec. Am. Compl. ¶ 15. Mrs. Guisto, it is explained by them, was "dogged by persistent pain" and suffered from an "uneven gait" since that time. *See id.* ¶ 10. Within three months of the surgery, she began consulting doctors, including the operating surgeon, about worsening pain in her left leg and hip—the hip that was replaced. *See, e.g.*, Def. 56.1 Stmt. ¶¶ 2-4 (citing medical records). Over the next five years she visited specialists on many occasions about this continuing pain. By December 2008 and through February 2009 one of the doctors she visited expressed repeated concerns that the implant's cup was loosening. *See* Catullo Decl. Ex. C, at HAM00008-9; Pl. Mem. at 12 ("Loosening of the Acetabular Component would be evidence that the process of fixation or ossesointegration had failed…."). And at least as early as September 2008, and then again in March 2009, Mrs. Guisto requested revision surgery for her hip. *Id.* ¶ 4, 11 (citing Catullo Decl. Ex. C, at HAM000029; Ex. E, at Drucker000013). As already noted, she also sued her operating surgeon in March 2009 for malpractice.

In the present action Mrs. Guisto alleges that "her ill-fitting defective artificial hip was the cause of her battle with hip pain and spinal pain over a period of at least four (4) years." Sec. Am. Compl. ¶ 11.

It is plaintiffs' contention that the pain in and around Mrs. Guisto's left hip that she started to experience almost immediately after her surgery and continuous until May 2009—pain which

ultimately lasted for "over a period of a least four (4) years"—was caused by the adulterated device's failure to integrate with her body. That claim is long barred. According to plaintiffs' clear and explicit contentions, the injury resulting from the implant's malfunction began long before the cutoff date for a negligence action to be timely.

Plaintiffs cannot now contend that the hip pain was wholly unrelated to the malfunction at issue in this case. They have failed to claim or demonstrate any injury resulting from any defect other than the excess residuals on the adulterated device. That is the only defect alleged or that can be proven by the plaintiffs. They have provided no claim or evidence of injuries caused by any other malfunction that first occurred on or after May 17, 2009, the cutoff date for the purpose of the statute of limitations.

Nor can the plaintiffs contend that the pain resulting from the device's failure to fixate only began approximately 4.5 years after the surgery; and that all instances of pain experienced by the plaintiff prior to that time were due solely to a "spine condition" or post-operative discomfort. *See* Pl. Letter in Opp. to Mot. to Dismiss, at 4-6, May 30, 2103, ECF No. 73. Plaintiffs' own operating surgeon testified that the process of osseonteigration—if it succeeds—is fully complete between twelve to eighteen months after the surgery. *See* Mani Dep. 53:4-25; Pl. Mem. at 18-19. This failure of biological fixation through ossesointegration can result in the loosening of the implant cup and cause pain. *See* Mani Dep 54-55:20; Pl. Mem. at 12. Between September 2006 and March 2009, Mrs. Guisto visited multiple specialists about worsening pain in and around her left hip; at least one of her doctors expressed repeated concerns about potential loosening of the cup; and she requested revision surgery on more than one occasion. Given these facts no reasonable jury could find that Mrs. Guisto did not experience pain resulting from the alleged malfunction at issue in this case before the cutoff date in May 2009—more than 2.5 years after

the implant surgery. The allegation that plaintiffs only learned of the device's lack of ingrowth and fixation in March 2011 is immaterial; they were aware of the pain that flowed, allegedly, from the defect even if they did not know its source. The causes of action for personal injury are barred under NY CPLR § 214 (5), a three year statute of limitations.

The State's toxic tort statute does not apply. *See* NY CPLR § 214-c. The statute covers exposure to toxic substances from implantation of the substance. Plaintiffs' case is not based on any harmful exposure or on any latent disease from an implant. Their claims concern physical pain and discomfort resulting from a defective or malfunctioning device. They have made no allegations of developing any condition or contracting any disease because of the device. *Cf. Schwartz v. Osteonics Corp.*, No. 98-9354, 1999 WL 425892 (2d Cir. June 10, 1999) (analyzing claims arising from a failed hip replacement under NY CPLR § 214-c where the plaintiff asserted that she developed osteolysis (dissolution or loss of bone) because of the failed hip implant)). Instead they assert that the implant was ill-fitting and caused her immense pain from the time of implantation. That claim does not fall within the ambit of CPLR § 214-c. *See Giordano v. Market America, Inc.*, 15 N.Y.3d 590, 598 (N.Y. 2010) ("The Legislature's concern when it enacted the statute was the problems raised by toxic tort cases in which the latency of a substance's effect could prevent the plaintiff from bringing a timely lawsuit....[T]he whole point of CPLR 214-c was to deal with substance exposure cases. No other kind of case is discussed in the legislative history....").

b. Implied and Express Warranties

Warranties in the product liability context are subject to a four-year limitation from tender of delivery. NY UCC § 2-725(1), (2). If a plaintiff demonstrates that the defendant made an explicit warranty as to the future performance of its device, that could toll the limitations period

for an express warranty cause of action until the "breach is or should have been discovered." NY UCC § 2-725(2). Implied warranties do not get the benefit of this exception for future performance. *Gelber*, 788 F.Supp.2d at 166-67.

Plaintiffs' implied warranty claims expired in 2010—four years from the tender of delivery, or when Mrs. Guisto received the device. The express warranty claims expired then as well. The future performance exception does not apply to them. The record is devoid of any evidence that the defendant made an explicit warranty of future performance that would toll the statutory period.

c. New Defect Claim

If plaintiffs were to now claim a timely break in the device, due to its undue fragility, or other such defect, they could not prove it. Their claims would be dismissed on the ground of lack of merit. Summary judgment for defendants would lie.

V. Conclusion

Defendants' motion for summary judgment is granted. The case is dismissed. No costs or disbursements are awarded.

A motion for leave to amend the complaint would be denied. The case has been fully briefed and argued. No enforceable claim can be appropriately alleged or proven.

SO ORDERED.

Jack B. Weinstein
Senior United States District Judge

Date: June 4, 2013
Brooklyn, New York