

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
VALDOSTA DIVISION**

**ELIZABETH L. SUMNER and
RAY G. SUMNER,**

Plaintiffs,

v.

BIOMET, INC.,

Defendant.

Civil Action No. 7:08-CV-98 (HL)

ORDER

Before the Court is Defendant's Motion for Summary Judgment (Doc. 51) and Motion to Exclude Expert Opinion and Motion to Strike the Affidavit of Rex McLellan (Doc. 111). Plaintiffs have filed a response to both Motions. After hearing oral arguments from the parties, and after reviewing the briefs, affidavits, depositions, and other evidence, Defendant's Motion for Summary Judgment (Doc. 51) is granted and Defendant's Motion to Exclude Expert Opinion and Motion to Strike (Doc. 111) is denied.

I. FACTS

Plaintiff Elizabeth Sumner underwent a right hip replacement on July 25, 2006. The surgery was performed by James Scott, M.D. A metal-on-metal hip joint replacement prosthesis manufactured by Defendant Biomet, Inc. was implanted during Mrs. Sumner's surgery. The prosthesis is a prescription medical device sold to orthopedic surgeons for surgical use.

On August 9, 2006, Mrs. Sumner returned to see Dr. Scott for her first post-operative appointment. An x-ray taken during the appointment showed that the prosthesis was in the proper position, but also revealed particulate debris floating free in the area of the implant.

Mrs. Sumner returned to Dr. Scott's office on October 18, 2006. She indicated that she was pleased with the surgery and was doing well. Mrs. Sumner was ambulating without assistance at that time. An x-ray of the hip showed that the prosthesis was in proper position, but some metal debris was scattered below the acetabulum.¹

After stepping wrong attempting to cross a ditch, Mrs. Sumner went back to see Dr. Scott on November 27, 2006. Dr. Scott noted that he saw some metal debris on the x-ray film. Mrs. Sumner next returned to see Dr. Scott on December 6, 2006. During that visit, she complained of severe pain. Dr. Scott again noted that he observed metallic densities on the x-ray. He recommended arthroscopy, and that was performed on December 7, 2006. Dr. Scott ultimately elected to perform revision surgery, and on March 20, 2007, the prosthesis was removed and replaced.

Plaintiffs subsequently filed this lawsuit against Defendant, asserting claims for strict liability, negligence, and breach of warranty. Plaintiffs' claims are based upon allegations that the prosthesis was defective because of a manufacturing defect. Plaintiffs also contend that Defendant failed to provide adequate warnings

¹The acetabulum is the cup-shaped socket in the hip bone.

of the alleged defect. To prove their case, Plaintiffs rely upon the expert testimony of Rex B. McLellan, Ph.D., a metallurgist.

II. MOTION TO EXCLUDE

Dr. McLellan provided an expert report pursuant to Fed. R. Civ. P. 26 on February 2, 2009 (the “2009 Report”). In the 2009 Report, Dr. McLellan stated that the ball of the prosthesis was severely gouged and scratched, and that there were multiple areas where blocks of metal had exited the surface. He also noted that there were areas of chemical inhomogeneity on the surface of the ball, with one area high in tungsten and another high in cobalt and chromium.

Dr. McLellan was first deposed by Defendant on June 17, 2009 (the “2009 Deposition”). During the 2009 Deposition, Dr. McLellan pointed out an area on the prosthesis which had a high concentration of tungsten. At that time, however, he did not think the tungsten was the problem. Dr. McLellan also stated that while the higher concentration of tungsten was an inhomogeneity, he did not know whether, and rather doubted, that the tungsten had any effect on the ejection of large amounts of matter. Instead, he testified that he believed the inhomogeneities were really deficiencies in cobalt and chromium.

After the initial round of discovery, Defendant filed the pending Motion for Summary Judgment, contending among other things that Dr. McLellan’s testimony did not past muster under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786 (1993). When Plaintiffs filed their response to the Motion, they attached an affidavit from Dr. McLellan, which was

notarized on July 6, 2010 (the “2010 Affidavit”). In the 2010 Affidavit, Dr. McLellan stated that scans of the prosthesis showed high levels of tungsten segregation on the surface of the ball, which he believed produced tungsten carbide.² He opined that the high levels of tungsten should not be present in or on the surface of the ball, and that the tungsten carbide most likely caused the scratching and gouging in and on the surface of the ball. He stated that the high levels of tungsten should not have been present if Defendant manufactured the ball pursuant to the manufacturing specifications. According to Dr. McLellan, there are two possible explanations for the high level of tungsten - either Defendant introduced high levels of tungsten during the manufacturing process, or the tungsten originated from an external source, most likely during the implantation of the prosthesis. However, Dr. McLellan determined there was no evidence to support the latter explanation.

After receiving the 2010 Affidavit, and with permission of the Court, counsel for Defendant deposed Dr. McLellan a second time (the “2010 Deposition”). During the 2010 Deposition, Dr. McLellan testified that the areas high in cobalt and chromium were probably innocuous and did not constitute a defect, but the areas high in tungsten particles constituted a defect.

Defendant believes that between the 2009 Report and Deposition, and the 2010 Affidavit and Deposition, Dr. McLellan changed his opinion regarding the

²Tungsten is a chemical element. When it combines with carbon, it produces a chemical compound called tungsten carbide.

nature of the alleged defect. Defendant has moved to exclude the 2010 Affidavit and Dr. McLellan's most recent opinions regarding the defect.

During oral argument on the Motion to Exclude and Motion for Summary Judgment, counsel for Plaintiffs confirmed that Dr. McLellan's opinion is, and has always been, based on the particle ejection theory. That is, particles came loose from the surface of the ball of the prosthesis because of inhomogeneities in the metal of ball which were introduced during the manufacturing process.³ It appears to the Court that the change in Dr. McLellan's opinion is that at first he believed chromium and cobalt were the inhomogeneities that caused the device to fail, but he now believes tungsten and tungsten carbide were the culprits. Thus regardless of whether the Court allows Dr. McLellan to use his second opinion or limits him to his first opinion, the question becomes whether the particle ejection theory is reliable under Rule 702 and Daubert. Since the ruling on the Motion for Summary Judgment resolves the case, and because the Court's ruling on the Motion for Summary Judgment will not change if the 2009 or 2010 opinions propounded by Dr. McLellan are considered, the Motion to Exclude is denied.⁴

³In addition, during a status conference on March 1, 2010, counsel for Plaintiffs agreed that Dr. McLellan's theory was that "somehow [] particles of metal spontaneously ejected from the ball and [] those particles then got loose in the joint and that caused the degradation of the component and the eventual failure of the device." (Doc. 90, pp. 12-13).

⁴Counsel should be aware that the Motion to Exclude was denied only because the Court determined that the premise upon which Dr. McLellan based his opinion - the particle ejection theory - has not changed throughout this case. In no way is the Court agreeing with or approving of the tactics used by Plaintiffs in delaying the production of Dr. McLellan's affidavit by ten months, or "refining" Dr. McLellan's

III. MOTION FOR SUMMARY JUDGMENT

A. Daubert and Rule 702

District courts are charged with the duty to act as “gatekeepers” to ensure that speculative, unreliable expert testimony does not make its way to the jury. Daubert, 509 U.S. at 597 n. 13. The court must “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” Kuhmo Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152, 119 S.Ct. 1167, 1176 (1999).

Rule 702, which governs the admission of expert testimony in federal court, provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

Under Rule 702, the trial court can admit relevant expert testimony only if it finds that: (1) the expert is qualified to testify about the matters he intends to address; (2) the methodology used by the expert to reach his conclusions is

opinions after the Motion for Summary Judgment was filed and not immediately informing Defendant of the changes to his opinion.

sufficiently reliable; and (3) the expert's testimony will assist the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or determine a fact in issue. McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002) (citing Maiz v. Virani, 253 F.3d 641, 664 (11th Cir. 2001)).

“The burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence.” Id., 298 F.3d at 1256 (quoting Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999)).⁵

Defendant contends that Dr. McLellan's opinions are not reliable. When evaluating the reliability of an expert opinion, the trial court must assess “whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue.” Id. at 1261-1262 (citation omitted). In order to pass muster, the expert testimony must be reliable and must constitute knowledge. Daubert, 509 U.S. at 590.

The Supreme Court has provided four guiding factors that a district court may consider in assessing the reliability of expert testimony: “(1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the

⁵The first test under Rule 702 is whether the witness offering the testimony is qualified to do so. The Eleventh Circuit has noted that “experts may be qualified in various ways. While scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status.” United States v. Frazier, 387 F.3d 1244, 1260-1261 (11th Cir. 2004). Defendant does not argue that Dr. McClellan is unqualified to testify, so this factor is not at issue.

technique has been subjected to peer review and publication; (3) the known and potential error rate of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community.” McDowell v. Brown, 392 F.3d 1283, 1298 (11th Cir. 2004) (citing Daubert, 509 U.S. at 595). These factors do not constitute a strict checklist, but are meant to be helpful to the court. Kuhmo, 526 U.S. at 151. The district court has “substantial discretion in deciding how to test an expert’s reliability.” Rink v. Cheminova, Inc., 400 F.3d 1286, 1292 (11th Cir. 2005) (quotation omitted).

Dr. McLellan contends that the prosthesis failed because of a manufacturing defect. He believes the ejection of material from the articulating surfaces of the prosthesis caused by inhomogeneities in the chemistry of the alloy caused the ultimate failure of the device. Dr. McLellan admits that he does not understand the micro-mechanism of how material was ejected from the surface of the prosthesis as a result of the inhomogeneities. In other words, by some unknown means, particles embedded in the prosthesis ejected from the prosthesis, and that particulate matter began the process of deteriorating the surface of the prosthesis by scratching and gouging the surface, ultimately leading to the failure of the device.

The first factor under Daubert is whether the expert’s methodology has been tested or is capable of being tested. Dr. McLellan did not test the particle ejection theory, and was unable to suggest any ideas as to how the ejection of the metal fragments could have occurred. He stated that he was loathe to speculate as to how the ejection could theoretically have occurred without doing experiments or

calculations, “which would be incredibly difficult to do.” That statement raises the question of whether the theory is even capable of being tested. Not having tested his own theory weighs greatly against the finding of reliability. See McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1251 (11th Cir. 2005) (expert offered no evidence of any testing of his theory); McDowell, 392 F.3d at 1300 (expert had not tested his own theory); Am. Gen. Life & Acc. Ins. Co. v. Ward, 530 F.Supp.2d 1306, 1314 (N.D. Ga. 2008) (expert failed to state whether his observations had been empirically tested); Bowers v. Norfolk S. Corp., 537 F.Supp.2d 1343, 1354 (M.D. Ga. 2007) (at least two experts failed to demonstrate that their causation opinions were testable).

The second Daubert factor is whether the technique has been subjected to peer review and publication. Dr. McLellan testified that he has never previously been involved in a case where a failure mode of this description occurred. He has never consulted on a case where it was believed particulate matter extracted from the implant itself. Dr. McClellan stated that he has never read anything in the scientific literature that supports the notion that the phenomenon can occur, and could not find anything to support the idea, even after specifically looking for literature on the subject. When asked if he could identify any publications, scientific studies, or research that has been conducted or published, or any other external source that supports the idea that chemical inhomogeneities in a metal product could lead to particles ejecting from the product, Dr. McLellan was not able to identify anything. And while Dr. McLellan stated during his second deposition that he would produce a list of articles supporting the particle ejection theory, no such supporting

literature has been submitted to the Court by Plaintiffs. The fact that Dr. McLellan has failed to present any evidence of any peer review of his opinions or theory weighs against a finding of reliability. See McClain, 401 F.3d at 1251 (expert failed to present evidence of any peer review of his opinions); McDowell, 392 F.3d at 1301 (expert's theory had never been published or subjected to peer review); Clarke v. Schofield, 632 F.Supp.2d 1350, 1361 (M.D. Ga. 2009) (expert offered nothing to show that either of his theories have been peer reviewed or published).

The third Daubert factor is the known and potential error rate of the methodology. Here, Dr. McLellan has offered no known or potential error rate for his opinion. This also weighs against a finding of reliability. See United States v. Giambro, 544 F.3d 26, 33 (1st Cir. 2008) (expert failed to provide the known or potential rate of error for his statistical analysis); Polski v. Quigley Corp., 538 F.3d 836, 840 (8th Cir. 2008) (expert's theory had no known or potential rate of error); McClain, 401 F.3d at 1251 (expert failed to offer any testimony about the known or expected rate of error of his theories).

The fourth and final Daubert factor is whether the technique or theory has been generally accepted in the proper scientific community. Dr. McLellan testified that no scientist, metallurgist, physician, or anyone else in the world has ever publicly espoused the opinion that inhomogeneities in the surface of a device can lead to the ejection of metal fragments. Between that and the fact that the theory has never been tested or peer reviewed, it is clear that the particle ejection theory has not been generally accepted in the scientific community. See Am. Honda Corp., Inc.

v. Allen, 600 F.3d 813, 818 (7th Cir. 2010) (Despite the expert's publication of an article regarding his theory, there was no indication that his wobble decay standard had been generally accepted by anyone other than the expert.); Wells v. SmithKline Beecham Corp., 601 F.3d 375, 380 (5th Cir. 2010) (expert's opinion that medication caused problem gambling was not generally accepted); Polski, 538 F.3d at 840 (expert's causation theory was not generally accepted in the scientific community).

Dr. McLellan states in the 2010 Deposition that because the particle ejection theory relates to a unique problem associated with a specific device, it has not been considered before by the scientific community. It necessarily follows, according to Dr. McLellan, that the theory has not been generally accepted in the scientific community. The Court recognizes that publication and peer review, or the lack thereof, are not dispositive in assessing the scientific validity of a particular theory or methodology, but the Court has a problem with the fact that Dr. McLellan never bothered to test the theory or publish anything about the theory. It is quite difficult for other scientists to peer review a theory if the creator of the theory does not attempt to test it or publish anything about it.

Another important consideration in this case is the fact that Dr. McLellan developed the particle ejection theory expressly for the purposes of this case. Whether the expert proposes to testify about matters growing naturally and directly out of research he has conducted independent of the litigation, or whether he has developed the opinion expressly for purposes of testifying, is an additional factor for the Court to weigh. Fed. R. Evid. 702, advisory committee's notes (2000 amends).

The fact that an expert's opinion was obtained for purposes of litigation does not render it unreliable if otherwise supported by "objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1318 (9th Cir. 1995). In this case, unfortunately, there is no objective evidence that Dr. McLellan's opinion is based on scientifically valid principles. Thus, the fact that Dr. McLellan developed this theory for this lawsuit weighs against a finding of reliability.

The sort of novel theory presented by Dr. McLellan in this case is certainly one of the reasons why Daubert and Rule 702 were propounded. What Plaintiffs and Dr. McLellan are basically requesting of the Court is that it assume that a theory that has never been tested, peer reviewed, or validated in any way be accepted as reliable because of Dr. McLellan's experience and qualifications. The Court will not do so. It is not that the Court believes there is no room for new scientific theories - quite the opposite - but there must be some basis for the Court to find that the theory or method is reliable, and there simply is no basis here. This case is similar to Chapman v. Maytag Corp., 297 F.3d 682 (7th Cir. 2002), decided by the Seventh Circuit in 2002. There, the plaintiff's expert presented no proof that his theory was generally accepted in the scientific community. Instead, his theory was novel and was not supported by any article, text, study, scientific literature, or scientific data produced by others in the expert's field. The expert admittedly had not published any writings or studies concerning his theory, and had not tested his theory. The court stated that "[t]he Daubert standard and Rule 702 are designed to ensure that, when

expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work,” and found that the expert’s testimony did not satisfy the required standard of reliability. Id. at 688. Dr. McLellan’s testimony suffers from the same deficiencies as the Chapman expert’s testimony. Applying the Daubert factors, Plaintiffs have not proven by a preponderance of the evidence that Dr. McLellan used a reliable methodology to reach his opinions and conclusions. Accordingly, his opinion testimony will not be considered by the Court.

B. Manufacturing Defect

In this case, Plaintiffs assert a strict products liability claim based on a purported manufacturing defect. To establish a strict liability claim under Georgia law, a plaintiff must prove that “the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.” O.C.G.A. § 51-1-11(b)(1). In other words, to establish a prima facie case and avoid summary judgment in the defendant’s favor, a plaintiff must introduce sufficient evidence to prove that (1) the product was defective; and (2) the defect was the proximate cause of the injury. Id.

A defendant can be held liable for a manufacturing defect only if the plaintiff proves that the product sold was defective. Center Chem. Co. v. Parzini, 234 Ga. 868, 869, 218 S.E.2d 580, 582 (1975). In order to survive summary judgment, Plaintiffs must establish this element of their claim.

In this case, Dr. McLellan is the only witness presented by Plaintiffs who has provided testimony that the prosthesis was defective. However, his testimony has

been excluded, which means Plaintiffs are left with no expert witness to testify regarding the prosthesis' defective nature. Therefore, there is no evidence presented by Plaintiffs establishing that the prosthesis was defective. Federal Rule of Civil Procedure 56 requires entry of summary judgment against a party who fails to make a showing sufficient to establish the existence of every element essential to that party's case on which that party will bear the burden of proof at trial. Celotex, 477 U.S. at 322. With no evidence to establish a defect in the product, Plaintiffs cannot establish an essential element of their claim of strict product liability. Defendant's Motion for Summary Judgment must be granted.

IV. CONCLUSION

For the reasons discussed above, Defendant's Motion for Summary Judgment (Doc. 51) is granted and Defendant's Motion to Exclude Expert Opinion and Motion to Strike (Doc. 111) is denied. The Clerk of Court is directed to close this case.

SO ORDERED, this the 16th day of November, 2010.

s/ Hugh Lawson
HUGH LAWSON, SENIOR JUDGE

mbh