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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
JULY 15, 2011
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No. 11-10280
Non-Argument Calendar

D.C. Docket No. 7:08-cv-00098-HL

ELIZABETH L. SUMNER,
RAY G. SUMNER,

Plaintiffs - Appellants,

versus

BIOMET, INC.,

Defendant - Appellee.

Appeal from the United States District Court
for the Middle District of Georgia

(July 15, 2011)

Before HULL, PRYOR and FAY, Circuit Judges.

PER CURIAM:

In this products liability case, Plaintiffs Elizabeth and Ray Sumner appeal the district court's exclusion of the testimony of their expert witness, Rex B. McLellan, Ph.D., and its grant of summary judgment to Defendant Biomet, Inc. After review, we affirm.

I. BACKGROUND

A. The Hip Prosthesis

Defendant Biomet, Inc. ("Biomet") manufactures the product involved in this case, the M²a-Magnum™ Press-Fit Acetabular Shell and Modular Head (the "hip prosthesis"). The hip prosthesis is a prescription medical device sold to orthopedic surgeons for surgical use.

The hip prosthesis is a metal-on-metal hip joint. The hip prosthesis includes: (1) one component, the Modular Head, referred to herein as the "ball," and (2) one component, the Acetabular Shell, referred to herein as the "cup."

B. Surgeries

On July 25, 2006, Plaintiff Elizabeth L. Sumner underwent hip replacement surgery. James Scott, M.D., an orthopedic surgeon, performed the surgery and installed the hip prosthesis manufactured by Defendant Biomet.

After being discharged from the hospital, Mrs. Sumner returned for post-operative appointments on August 6, 2006, October 18, 2006, and November 27,

2006. During that time, x-rays taken revealed that the prosthesis was in the proper position, but particulate debris was floating free in the area of the prosthesis.

When Mrs. Sumner returned for an appointment on December 6, 2006, she complained of severe pain. Dr. Scott performed two additional surgeries, eventually removing and replacing the prosthesis on March 20, 2007.

C. The Litigation

On July 22, 2008, Plaintiffs filed this products liability action against Biomet based on diversity jurisdiction. Plaintiffs' Amended Complaint asserts these claims under Georgia law: (1) strict liability for the defective condition of the hip prosthesis and failure to warn (Count I), (2) negligence (Count II), and (3) breach of warranty (Count III). Plaintiffs also brought a count requesting compensatory damages (Count IV) and a final count requesting punitive damages (Count V).

D. Dr. McLellan's 2009 Expert Report

To prove these claims, Plaintiffs retained Dr. McLellan, a metallurgist. Dr. McLellan photographed the hip prosthesis and examined it under a scanning electron microscope ("SEM"). He also used "energy dispersive ex-ray scans" ("EDS") to map out the chemical composition of the surface of the prosthesis.

On February 2, 2009, Dr. McLellan provided an expert report (the "2009 Report") pursuant to Federal Rule of Civil Procedure 26. The 2009 Report noted there were scratches and gouges in the surface of the ball of the hip prosthesis. The 2009 Report opined that these scratches and gouges were caused by metal particles that came from the hip prosthesis itself.

The 2009 Report stated that these metal particles probably "exited," or were "pulled out," from the hip prosthesis due to the uneven, or "[in]homogenous," chemical composition of the metal in the prosthesis. The Report observed that (1) the ball of the prosthesis contained many scratches and gouges and "multiple areas where blocks of metal had exited the surface"; (2) the ball was covered with "finer scratches, some of which clearly emanated from pulled out blocks of metal"; and (3) the undamaged surface of the ball had a chemical composition that was "not homogeneous," meaning that in one part, the surface was high in cobalt and chromium, and in another part, high in tungsten.

As to the surface, the 2009 Report further observed that: (1) one area of gouging on the surface was associated with an area high in tungsten, and (2) another large gouged-out area was also high in tungsten and exhibited the

"denudation"[1] of cobalt and chromium. The Report also noted that the interior of the cup in the hip prosthesis was gouged and scratched, but its chemical composition could not be mapped due to its geometry.

The 2009 Report's conclusions were: (1) the device showed "severe gouging, scratching and particle-dislodgement;" (2) that "[t]he micro-mechanism for these effects is not known but with an overwhelming degree of probability ensues from the chemical inhomogeneities observed on the [] bearing surface"; (3) "[t]he metallic particles generated by abrasion could clearly exit the fluid layer between the head and acetabular cup and enter the patient's body in the vicinity of the device"; and (4) "[t]he device was not suitable for its intended purpose."

E. Dr. McLellan's 2009 Deposition—Cobalt / Chromium

On June 17, 2009, Dr. McLellan was deposed. Dr. McLellan opined that the hip prosthesis failed due to the introduction of particulate debris into the area of the prosthesis which caused the scratches and gouges in its surface. As to the source of those particles, Dr. McLellan identified several areas where he believed metal had been "ejected from the surface" of the prosthesis through some mechanism other than gouging.

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[1] "Denude" means "to strip of all covering or surface layers" or "to lay bare by erosion." Webster's Third New Int'l Dictionary 603 (1993).

Dr. McLellan further stated that the particulate material came from the surface of the prosthesis as a result of the "inhomogeneities in the chemistry of the basic alloy." Dr. McLellan considered these "inhomogeneities" to be the deficiencies in cobalt and chromium in the surface of the prosthesis. While the higher concentration of tungsten was also an inhomogeneity, he "doubt[ed]" tungsten caused the "ejection of large amounts of matter" that he could see in the scans. Dr. McLellan did opine, however, that tungsten carbide particles probably also came out of the surface and caused the smaller gouges.

Importantly, Dr. McLellan had no explanation of how metal could have been ejected from areas of inhomogeneity in the prosthesis. Dr. McLellan testified, "I do not understand the basic micro-mechanism of how material is ejected or ablated as a consequence of that." Dr. McLellan could not speculate as to how these "ejection[s]" happened "without doing experiments or . . . calculations, which would be incredibly difficult to do." He did propose that the pressure applied to the surface of the prosthesis during its articulation may have caused the production of particles due to the varying degrees of strength in the chemical composition on the surface, but cautioned that this theory was only "speculation."

Dr. McLellan admitted he had never heard of the phenomenon he had described occurring in a metal prosthesis. Dr. McLellan had not heard of anyone studying it and concluding that such ejection could or could not occur. Dr. McLellan had never read any literature supporting this theory. Although Dr. McLellan had looked for supporting literature, he had found none in support of it. He was unable to identify any publications, studies, research, or other external source that would support the theory that chemical inhomogeneities in a metal implant could lead to the ejection of particles from the implant. Dr. McLellan even conceded that as far as he knew, no one had ever publicly opined that chemical inhomogeneities in a metal device could lead to the ejection of metal fragments.

Dr. McLellan also has never been consulted on, or testified in, a case involving a metal-on-metal hip prosthesis. Dr. McLellan has never, as a metallurgist, done any independent study or research of metal-on-metal hip prostheses. He has never been involved in a case in which particulate matter came out of a prosthetic implant and caused the deterioration of the surface of the prosthesis. Dr. McLellan has never written about, participated in, or observed the manufacturing of a metal-on-metal product. Other than this case, Dr. McLellan

has never done any research or investigation regarding metal-on-metal medical devices.

F. Defendant's Motion for Summary Judgment

Defendant Biomet filed a motion for summary judgment on all of Plaintiffs' claims, including claims arising from failure to warn. Defendant contended, inter alia, that Dr. McLellan's testimony as to the defects of the hip prosthesis was inadmissible under the standards of Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786 (1993).

Defendant Biomet also argued that summary judgment would be appropriate if Dr. McLellan's testimony is excluded, as it is the only evidence of causation in the record and, to the extent that Plaintiffs' claims were based on an alleged failure to warn, such claims were barred by the "learned intermediary" doctrine.

G. Dr. McLellan's 2010 Affidavit

Plaintiffs filed a response, attaching an affidavit from Dr. McLellan which was notarized on July 6, 2010 (the "2010 Affidavit").[2] The 2010 Affidavit

[2]On July 26, 2010, a second expert report (the "2010 Report") by Dr. McLellan, which is not at issue in this appeal, was filed with the district court. In the 2010 Report, Dr. McLellan examined several Biomet hip prostheses that had been the subject of complaints and had been extracted from patients. The 2010 Report observed that these prostheses "show pronounced scratching and gouging," but they "do not show gross segregation of the constituent alloying elements nor do they exhibit discrete [tungsten]-rich particles associated with surface scratches or gouges." Thus, the 2010 Report concluded that the "causal mechanism" for the scratches in these prostheses was not the same as in the hip prosthesis implanted in Plaintiff Sumner. The

reiterated that the ball of the prosthesis showed scratches and gouging both in photographs and in SEM scans. The 2010 Affidavit stated that Dr. McLellan's EDS scans of the hip prosthesis showed high levels of tungsten segregation on the surface of the ball, which Dr. McLellan now believes produced hard particles of tungsten carbide.[3]

The 2010 Affidavit opined that because tungsten carbide is in the form of hard particles, the tungsten carbide caused the scratching and gouging when it "interacted with the other materials on the surface of the ball thereby scraping against the softer metal of the ball resulting in the scratching and gouging in and on the surface of the ball."

Dr. McLellan's 2010 Affidavit further stated that, in preparing his 2009 Report, he reviewed the report and deposition of Defendant's expert witness, Dr. Thomas Sanders, which included documentation from Biomet of the intended

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2010 Report ultimately concluded that the data from the additional prostheses did not change the findings in Dr. McLellan's 2009 Report.

[3]Tungsten carbide is a compound formed from the elements tungsten and carbon. Tungsten carbide is very hard.

Like Dr. McLellan, Defendant's expert witness Thomas Sanders, Jr., also observed tungsten particles sitting on the surface of the prosthesis. Dr. Sanders testified that tungsten carbide could have been the material causing the scratching and gouging on the surface of the prosthesis. However, Dr. Sanders opined that the tungsten on the surface of the prosthesis did not originate from the metallic alloy in the prosthesis itself. He did not know where the tungsten came from.

chemical composition in the prosthesis. Dr. McLellan agreed with Dr. Sanders' opinion that, pursuant to manufacturing specifications, the high levels of tungsten carbide should not have been present on the surface of the prosthesis.

In his 2010 Affidavit, Dr. McLellan opined that the high levels of tungsten carbide could have only resulted from either (1) the manufacturing process itself or (2) an external source, possibly during Dr. Scott's surgery implanting the prosthesis (as Defendant's experts opined). Dr. McLellan stated that the tungsten carbide must have resulted from Biomet's manufacturing process because (1) there was no evidence or documentation to support the introduction of tungsten during Dr. Scott's surgery, and (2) because the tungsten carbide was "embedded in the surface of the ball."

In his 2010 Affidavit, Dr. McLellan also stated that although he was unable during his first deposition to explain the cause of metal particles coming out of the surface, he had since done additional work. Dr. McLellan continues to believe that the "lack of homogeneity," as evidenced by the level of tungsten carbide particles embedded in and on the surface of the ball, led to the scratching and gouging in the prosthesis. Dr. McLellan opined that, had Biomet manufactured the prosthesis according to specifications, the tungsten carbide would not be present, and the "scraping and gouging" would not have occurred. Because the

tungsten carbide particles are hard, they did not "appropriately mix together" with the other material in the prosthesis.

H. Dr. McLellan's Second Deposition

Defendant then deposed Dr. McLellan a second time. Dr. McLellan testified that the areas of chemical inhomogeneity constituting a defect in the prosthesis were the areas high in tungsten, which then gave rise to the formation of tungsten carbide particles. In contrast to his opinion in his earlier deposition, Dr. McLellan testified that the areas high in cobalt and chromium were probably innocuous and did not constitute a "defect."

Dr. McLellan testified that due to the high levels of tungsten in the prosthesis, the hard particles came from the prosthesis itself: "[D]ue to the forces of articulation acting upon the [tungsten] carbide particles embedded in the surface, some of these became dislodged, loosened and acted as essentially grip particles causing scratches and gouges." Dr. McLellan further testified that "[t]he ejection mechanism comes from the lack of cohesion between the particles interface and the matrix . . . The ejection accrues from the fact that they have a lack of adhesion with the matrix." Later in the deposition, Dr. McLellan stated, "The particle ejection does not result from the chemical inhomogeneity, it results from articulating forces applied to the inhomogenous areas."

Because the specific failure that occurred with the prosthesis was such a "unique occurrence," Dr. McLellan again testified that he was not aware of it happening before, nor had he read about it in the scientific literature. Dr. McLellan stated that "[t]here are no . . . studies" of the ejection of particles from areas of chemical inhomogeneity in a metal product. Dr. McLellan is still not personally aware of any type of medical prosthesis implant that has failed due to the ejection of particles resulting from chemical inhomogeneities created during the manufacturing process.

During the same deposition, Dr. McLellan also stated that he knew of examples of particles ejecting from inhomogenous surfaces in different metallurgical contexts. His examples were "Haynes alloys," which sometimes eject tungsten carbide particles from the matrix, and steel, out of which manganese sulfide particles sometimes fall. Dr. McLellan could provide a list of citations documenting these examples and would provide that list to Defendant. This list of citations was later provided to Defendant. Apparently Plaintiffs filed neither the citations nor the full articles with the district court.[4]

[4]Biomet later attached a list of citations provided by Dr. McLellan to its reply brief in support of summary judgment. Those citations pertained to only two sources, and the sources themselves were apparently never filed with the court.

Defendant moved to exclude the 2010 Affidavit, contending that Dr. McLellan had changed his opinion regarding the alleged nature of the defect since his 2009 Report and 2009 deposition.

I. District Court Order

The district court held a hearing on Defendant's motion to exclude Dr. McLellan's expert opinion and to strike his 2010 Affidavit and motion for summary judgment. In a written order, the district court denied the motion to exclude Dr. McLellan's 2010 testimony and strike his 2010 Affidavit as moot, given that its summary judgment ruling would be the same whether or not the 2010 testimony was considered.[5] In that same order, the district court granted Defendant's summary judgment motion on all claims after concluding that Plaintiffs had failed to prove, by a preponderance of the evidence, that Dr. McLellan used a reliable methodology to reach his opinions and conclusions.[6] The district court determined that Dr. McLellan's theory of defect in the prosthesis

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[5]The district court noted that the apparent change in Dr. McLellan's opinion was that at first he believed chromium and cobalt were the inhomogeneities that caused the failure. However, Dr. McLellan later decided that tungsten and tungsten carbide were to blame. In a footnote, the district court stated, "Counsel 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," and noted that it was not condoning the Plaintiffs' submission of the 2010 affidavit or "'refining'" of Dr. McLellan's opinions.

[6]Dr. McLellan's qualification to testify was not at issue.

was not reliable because it had not been tested, peer reviewed, published, or validated in any way, and because it had been developed expressly for the purposes of the litigation.

Because Dr. McLellan's testimony was the only evidence the product was defective, the district court determined that summary judgment in favor of the Defendant was appropriate as to all claims. Plaintiffs filed a motion to reconsider which the district court denied.

Plaintiffs now appeal the district court's conclusion that Dr. McLellan's testimony was unreliable and its grant of summary judgment on Plaintiffs' strict liability claim based on Defendant's alleged failure to warn.

II. DISCUSSION

Georgia law provides that a manufacturer of a product is strictly liable to a consumer injured by the product where the product "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). Plaintiffs rely solely on Dr. McLellan's expert testimony to prove that the prosthesis was defective and caused Plaintiffs' injuries.

A. Rule 702 and Daubert[7]

The district court denied the admission of Dr. McLellan's testimony based on Federal Rule of Evidence 702, which 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. Rule 702 compels the district court to act as a "gatekeeper" in determining the admissibility of expert scientific evidence. Daubert, 509 U.S. at 589 n.7, 597, 113 S. Ct. at 2795 n.7, 2798-99; United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc).

This Court uses a "rigorous three-part inquiry" in assessing whether to admit expert testimony: (1) the expert must be qualified to testify competently regarding the matters he intends to address, (2) the methodology must be reliable

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[7]"This Court reviews a trial court's decision to exclude an expert's testimony pursuant to Daubert under an abuse of discretion standard." Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1334 (11th Cir. 2010); accord United States v. Frazier, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc). We defer to the district court's ruling unless it is "manifestly erroneous," and a district court has "considerable leeway" in evaluating the reliability of expert testimony, even if such a ruling is outcome determinative. Kilpatrick, 613 F.3d at 1334-35 (quotation marks omitted); Frazier, 387 F.3d at 1258-59. "[W]e must affirm unless we find that the district court has made a clear error of judgment, or has applied the wrong legal standard." Frazier, 387 F.3d at 1259.

under Daubert, and (3) the testimony must assist the trier of fact through the application of scientific, technical, or specialized expertise to understand the evidence or determine a fact in issue. Hendrix ex rel. G.P. v. Evenflo Co., 609 F.3d 1183, 1194 (11th Cir. 2010); accord Frazier, 387 F.3d at 1260. The proponent of the expert testimony bears the burden of proving that the testimony satisfies each prong by a preponderance of the evidence. Hendrix, 609 F.3d at 1194; Frazier, 387 F.3d at 1274.

In Daubert the Supreme Court provided a list of relevant factors to consider in making a determination that an expert's methodology was reliable: (1) whether the theory or technique "can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "in the case of a particular scientific technique, . . . the known or potential rate of error," and (4) whether the theory or technique is generally accepted in the relevant scientific community. Daubert, 509 U.S. at 592-94, 113 S. Ct. at 2796-97; accord Frazier, 387 F.3d at 1262. Even so, this list is non-exhaustive and district courts have "substantial discretion" in determining how to test an expert's reliability. Hendrix, 609 F.3d at 1194 (quotation marks omitted); see id. at 1196.

B. District Court's Exclusion of Dr. McLellan's Testimony

After full and careful review of the record, we cannot say the district court abused its discretion in concluding that Dr. McLellan's methodology was unreliable under Daubert. Plaintiffs have provided no basis for assessing the reliability of Dr. McLellan's opinion. To the contrary, his exact opinion of the defect that caused the prosthesis to fail is itself difficult to ascertain from the record.

In his first deposition, Dr. McLellan testified (1) that he believed chemical inhomogeities in the metal alloy led to the ejection or loosening of particulate matter from the prosthesis, but (2) he did not understand the process by which that would have happened. Dr. McLellan has neither observed such a phenomenon occurring in prior cases, nor has he even ever heard of it occurring.

In the same deposition, Dr. McLellan stated that pressure in the articulation of the prosthesis may have caused the particulate matter to come out of the chemical inhomogeneities in the surface of the prosthesis due to the varying levels of strength in the matrix. But Dr. McLellan himself cautioned this theory was only "speculation."

In his second deposition, Dr. McLellan refined his opinion, this time opining that the pressure from articulation caused embedded tungsten carbide articles to dislodge from the surface of the prosthesis. Yet he continued to testify

that he could not explain the exact mechanism by which metal particles came from the surface of the prosthesis. It is not entirely clear from his testimony whether Dr. McLellan believes the particles were somehow "ejected" from the surface or simply loosened and fell out of the surface. Nor is it clear why he believes the particles became detached. See Frazier, 387 F.3d at 1265 (reliability of expert's opinion is undermined by the fact that his opinion itself is ambiguous).

The first reliability factor under Daubert is whether the theory is capable of being tested. In his first deposition, Dr. McLellan himself testified that he could not state with certainty how particulate matter was dislodged from the surface of the prosthesis "without doing experiments or . . . calculations, which would be incredibly difficult to do." Thus, according to his own testimony, Dr. McLellan's theory is virtually incapable of being tested.[8]

The second factor is whether his theory has been subjected to peer review. Dr. McLellan was unable, both in 2009 and 2010, to identify any publications or scientific studies that supported the theory that chemical inhomogeneities in a

[8]Plaintiffs argue that there is no way to test Dr. McLellan's theory other than to insert a prosthesis with a defective design into a patient, which would be unethical. While we have stated that such an argument "has some merit," we also observed that "in the absence of such studies, the nature of the other evidence . . . becomes that much more important, and the court's consideration of such evidence and the methodologies used must be that much more searching." Kilpatrick, 613 F.3d at 1337 n.9. Here, Dr. McLellan offered no other substantial evidence of the reliability of his opinions.

metal implant can lead to metal particles breaking off or coming out of the implant. Dr. McLellan affirmatively stated in both depositions that there are no prior studies documenting the phenomenon of particle ejection from a metal alloy in the manner he describes. See Frazier, 387 F.3d at 1265 (reliability of expert's opinion undermined where expert could suggest no study supporting his opinion regarding the likelihood of discovering hair evidence after sexual assault). And given that Dr. McLellan identified no studies of particles being ejected from an inhomogeneous metal alloy, there also appears to be no known rate of error in Dr. McLellan's theory, as, according to him, it has yet to be tested or documented.

The fourth factor is whether the theory is generally accepted in the scientific community. In both depositions, Dr. McLellan testified that he has never read of an instance in the scientific literature where particles were "ejected" from a metal prosthesis due to inhomogeneities in the alloy, because such a phenomenon had never been written about or studied.[9] While Dr. McLellan stated that the reason

[9]Plaintiffs contend that they supplied five citations from a professional journal discussing the scientific principles behind Dr. McLellan's opinion in the context of other metal alloys. However, Dr. McLellan never named these sources during his deposition. The citations are also not listed in Plaintiffs' brief on appeal. Although Plaintiffs note that the list of citations they provided Defendant was attached to Defendant's reply brief in support of its motion for summary judgment in the district court, Plaintiffs themselves never filed these citations with the district court, nor did they provide the district court or this Court with copies of the sources. Under these circumstances, the district court was entitled not to consider these sources, and this Court will not consider them either. See Kilpatrick, 613 F.3d at 1341 (a district court's refusal to consider "vague reference" to "unnamed articles" in expert's deposition was not an abuse of discretion).

his theory had not been written about was because it was a "unique" situation, the district court found the fact that Dr. McLellan himself had never published anything or tested his theory was problematic, as it did not allow any peer review of the theory. The district court retained wide latitude to consider this fact in determining the reliability of Dr. McLellan's opinion. See Hendrix, 609 F.3d at 1196 ("We afford the district court substantial discretion to decide how to test the reliability of the general causation evidence presented by [expert witnesses].").

The district court also did not abuse its discretion in considering the fact that Dr. McLellan's theory appears to have been arrived at for the purposes of this litigation, weighing it heavily against the admissibility of Dr. McLellan's opinion. Dr. McLellan has never before been involved a case involving particle ejection from a metal prosthesis. He has never tested or published anything regarding his theory. There is no evidence that Dr. McLellan developed his theory during research conducted independent of this litigation. See Fed. R. Evid. 702, 2000 amend. note ("[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" is relevant to determining the reliability of expert testimony) (internal quotation marks omitted).

We fully recognize that Plaintiffs stress that Dr. McLellan's reasoning was similar to Defendant's expert witness, Dr. Sanders, who opined that tungsten carbide particles likely caused the scratching and gouging in the prosthesis. Thus, Plaintiffs argue this dispute centers on only the differing conclusions of the two experts because the methodology employed by Dr. McLellan was "virtually the same" as that employed by Dr. Sanders. However, Dr. Sanders did not opine that the tungsten carbide particles came from the prosthesis itself. Rather, Dr. Sanders did not know where the tungsten carbide particles came from. Thus, Dr. Sanders' testimony is irrelevant to the reliability of Dr. McLellan's methodology in determining how the metal particles were generated from the prosthesis itself.[10]

For all of these reasons, the district court did not abuse its discretion in excluding Dr. McLellan's expert testimony as unreliable under Daubert and Federal Rule of Evidence 702.

C. Failure to Warn

Because the district court excluded Dr. McLellan's testimony, it properly granted summary judgment to Defendant on all claims, including Plaintiffs' strict

[10]Plaintiffs further argue that the district court mischaracterized Dr. McLellan's testimony when it stated that Dr. McLellan opined that "by some unknown means, particles embedded in the prosthesis ejected from the prosthesis." However, Dr. McLellan clearly testified that tungsten carbide particles "embedded" in the surface of the prosthesis were "ejected" due to the pressure in the prosthesis and the inhomogeneity of the surface, although he did not understand the exact process by which this happened. Thus, the district court did not mischaracterize his testimony.

liability claim (Count I). On appeal, Plaintiffs argue (1) that their strict liability claim for "failure to warn" is separate from their strict liability claim for design defect, and (2) that they are not required, under Georgia law, to prove that a product has a design or manufacturing defect in order to prevail on a failure to warn claim. Instead, they need only prove that the defendant failed to warn of a "non-obvious foreseeable danger from the normal use of its product."

This argument is meritless. Plaintiffs allege only one strict liability claim (Count I) in their Amended Complaint, in which they specifically allege, inter alia, that (1) the hip prosthesis was defective, (2) "Biomet failed to provide proper warnings of the defective condition of the hip prosthesis" (emphasis added), (3) Biomet knew of the defect but failed to correct it or recall the hip prosthesis, and (4) the defective nature of the hip prosthesis was the proximate cause of Plaintiffs' injuries. Plaintiffs do not allege that Defendant is liable for the failure to warn of any danger associated with the prosthesis other than the defect about which Dr. McLellan testified. Without Dr. McLellan's testimony there is no evidence of the prosthesis's alleged defective condition, and the district court did not err in granting summary judgment to Defendant Biomet as to Plaintiffs' failure to warn claim on this basis.

AFFIRMED.