IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

IN RE DEPUY LITIGATION	Case No. 10-L-10506
CAROL STRUM Plaintiff, vs. DEPUY ORTHOPAEDICS, INC, a Foreign Corporation; DEPUY INTERNATIONAL, LIMITED, a Foreign Corporation; and PREMIER ORTHOPAEDIC SALES, INC, an Illinois Corporation Defendants.	Case No. 11-L-009352

ORDER

This matter coming to be heard pursuant to Carol Strum's ("Plaintiff") Post-Trial Motion and Request For a New Trial pursuant to Section 2-1202 of the Code of Civil Procedure, 735 ILCS 6/2-1202, due notice having been given, the motion having been fully briefed and the Court being duly advised in the premises, IT IS HEREBY ORDERED THAT said Request For a New Trial is GRANTED, as more fully set forth below.

BACKGROUND

On January 29, 2008, Plaintiff was implanted with the DePuy Articular Surface Replacement ("ASR") XL hip replacement device. The device was recalled worldwide by DePuy Orthopaedics, Inc. ("DePuy") on April 24, 2010. Plaintiff alleged DePuy Orthopaedics Inc., and Premier Orthopaedic Sales, Inc. ("Defendants") were negligent in designing an ASR cup that was prone to premature failure and caused excessive wear of the hip replacement. Plaintiff claimed DePuy failed to adequately warn of the dangers associated with the device, to timely recall the ASR, and to monitor the performance of the ASR. A jury trial began on March 7, 2013, and after three weeks of testimony and deliberations the jury returned a verdict in favor of Defendants. Plaintiff now complains of certain pre-trial and trial errors.

First, Plaintiff claims the Court erred when it ruled pursuant to *Fyre v. United States*, 293 F. 1013 (D.C. Cir. 1923), that Dr. David J. Langton's ("Dr. Langton") testimony about volumetric wear analysis would not be heard by the jury. Plaintiff next asserts certain evidentiary

errors at trial entitled her to a new trial. Lastly, Plaintiff contends the Court erred in modifying Illinois Pattern Instruction 31.21 to limit the instruction to negligence claims and to exclude claims for strict liability.

LAW

In Illinois, the admission of expert testimony is governed by the standard first expressed in *Fyre v. United States. Donaldson v. Central Illinois Public Service Co.*, 199 Ill. 2d 63, 76-77 (2002); *In re Commitment of Simons*, 213 Ill. 2d 523, 529 (2004). The *Frye* test, commonly called the "general acceptance" test, dictates that scientific evidence is admissible at trial only if the methodology or scientific principle upon which the opinion is based is "sufficiently established to have gained general acceptance in the particular field in which it belongs." *Frye*, 293 F. at 1014. General acceptance does not mean universal acceptance, and it does not require that the methodology in question be accepted by unanimity, consensus, or even a majority of experts. *People v. Vercolio*, 363 Ill. App. 3d 232, 236 (3d Dist. 2006). Instead, it is sufficient that the underlying method used to generate an expert's opinion is reasonably relied upon by experts in the relevant field. *Donaldson*, 199 Ill. 2d at 77. The proponent of the evidence has the burden of demonstrating to the court that the elicited opinion should be admitted into evidence. *Baley v. Fed Signal Corp*, 2012 IL App (1st) 093312 ¶75 (2012). There are several ways a proponent of evidence subject to *Frye* can prove the "general acceptance" of the proffered evidence. *Mitchell v. Palos Community Hosp.*, 317 Ill. App. 3d 754, 762 (1st Dist. 2000). The proponent may use scientific publications, prior judicial decisions, practical applications, as well as the testimony of scientists as to the attitudes of their fellow scientists. *Id.*; *see also People v. Kirk*, 289 Ill. App. 3d. 326, 332 (1997).

ANALYSIS

Plaintiff claims that Dr. Langton's methodology for calculating volumetric wear was generally accepted in the scientific community and should have been presented to the jury. Defendants assert that the Court correctly applied the governing *Frye* standard because Plaintiff failed to show that Dr. Langton's methodology is generally accepted in the relevant scientific field.

Prior to trial, Defendants filed a motion in *limine* requesting the Court to bar Dr. Langton's volumetric wear testimony under *Frye*. At the *Frye* hearing, Defendants presented expert testimony from Dr. Dana Medlin, a metallurgic engineer, Dr. Av Eddin, a mechanical and biomedical engineer with an orthopedic specialty, and Dr. Paul Bills, a metrologist and senior research fellow at the EPSRC Center for Advanced Metrology at the University of Huddersfield. Plaintiff relied on the testimony of Dr. Langton, a medical doctor and a research fellow at Newcastle University. Dr. Langton had been involved in the practice of hip orthopedic surgery for over thirteen years. He participated in additional specialized training in South Africa and New Zealand particularly in orthopedic trauma. He has since focused his research career on metal-on-metal implants and explants, having analyzed over 1,100 explanted metal-on-metal hips. Plaintiff also introduced affidavits from orthopedic surgeons who relied on Dr. Langton's volumetric wear analysis, and numerous peer-reviewed articles co-authored by Dr. Langton describing volumetric wear testing of explanted hip components. In addition to Dr. Langton's articles, Plaintiff submitted other peer-reviewed articles from various other scientists pertaining to volumetric testing conducted on hip implants. Moreover, Plaintiff submitted depositions of Dr.

Langton, DePuy employees, and DePuy's corporate internal communications, about work done on volumetric wear testing.

At the *Frye* hearing, Dr. Langton's testified to his procedure in its simplest terms. Dr. Langton took Plaintiff's explanted cup and put it into the co-ordinate measuring machine ("CMM") and scanned the dimensions. Dr. Langton then compared the current dimensions of Plaintiff's cup to what he believed was the original cup's dimensions. Dr. Langton determined the original cup's dimensions in three different ways. The first method was to scan an area of the cup that had no wear by using CMM. The second method was to obtain batch sizes as defined in the DePuy manufacturing regulations, for original dimensions of cups and heads. For the purposes of his calculations, Dr. Langton assumed the largest possible cup in the batch number. The third method was to use the upper and lower sizes of the cup, as reported by DePuy, to measure what area was in the cup before implantation. In this way, the worn and unworn areas of the cup could be tested by using simple mathematical principles to come up the amount of volumetric loss of Plaintiff's implant.

Following the *Frye* hearing, the Court found Dr. Langton testimony did not meet the standard established in *Frye*. After a re-examination of all the briefs, transcripts and other submissions, it is clear the Court erred in precluding Dr. Langton's testimony.

A. The Relevant Scientific Community

The first step in applying the *Frye* standard is identifying the relevant fields in which the methodology belongs. *People v. Mckown*, 236 Ill. 2d 278 (2010). Defendants assert that "Dr. Langton's methodology belongs in the fields of biomedical engineering, measurement (metrology) and lubrication/wear (tribology)." Plaintiff contends the relevant scientific community must include all scientists associated with the implant industry, including the manufactures who design and make the implants, and the doctors who implant the devices.

The Court in its pretrial ruling defined the relevant scientific community as the metrology and tribology scientists; however, that ruling was incorrect because that community designation was too restrictive. Here, the relevant scientific community includes all the scientists, experts, practitioners, and surgeons in both the scientific and medical field associated with the implant industry. Further, the relevant scientific community includes the scientists who regulate the safety of implant devices employed at the Federal Drug Administration ("FDA"). The aforementioned scientists and medical professionals rely upon volumetric wear analysis to make their decisions about the safety of device design and patient care. The Court finds a broader designation of the relevant scientific community of scientists, medical professionals, and regulatory specialists more accurate.

B. Generally Acceptance In The Scientific Community.

As previously stated, there are at least four ways a proponent may prove general acceptance in the scientific community. These four ways are: 1.) Scientific publications; 2.) Prior judicial decisions; 3.) Practical applications; and 4.) The testimony of scientists as to the attitudes of their fellow scientists. Evidence at the *Frye* hearing was submitted for three of the four methods. However, it is not surprising that no evidence of prior judicial decisions was presented,

because Mrs. Strum's lawsuit was designated a bellwether case in this mass tort litigation. Plaintiff's lawsuit was one of the first cases in the nation of the DePuy Hip Litigation to go to a jury trial.

i. The Use of Scientific Publications

Turning first to an examination of peer-reviewed scientific publications pertaining to the measurement of wear on explanted hip components in 2013, Plaintiff presented the scientific literature co-authored by Dr. Langton that was published in peer-reviewed journals. His publications include: David J. Langton et al., *Reducing Metal Ion Release Following Hip Resurfacing Arthroplasty*, 42 Orthopedic Clinics of North America 169 (2011); J.K Lord, D.J. Langton, A.V.F. Nargol & T.J. Joyce, *Volumetric Wear Assessment Of Failed Metal On-Metal Hip Resurfacing Prostheses*, 272 Wear 79 (2011); and D.J. Langton et al., *Taper Junction Failure in Large-Diameter Metal-on-Metal Bearings*, 1 Bone & Joint Research 56 (2012). All articles were peer-reviewed before they were published and subjected to rigorous examinations by experts in the area of volumetric wear component testing.

In addition to Dr. Langton's own peer-reviewed literature, Plaintiff submitted numerous peer-reviewed articles by other leading scientists in the volumetric testing field. At least one article, *Estimation of Wear in Total Hip Replacement Using a Ten Station Hip Simulator*, 210 Proceedings of the Institution of Mechanical Engineers, Part H 187 (1996), co-authored by a DePuy employee, C.S. Hardaker, discussed how she performed wear testing on component hips by using CMM measurements and computer software. In other articles submitted by Plaintiff, the authors—all scientists in the relevant scientific community—described the testing they do on implanted and explanted components. All the articles included reference to the use of CMM measurements, mathematical calculations and computer programs to calculate wear on hip components. The articles published in these peer-reviewed journals described testing methodologies strikingly similar to Dr. Langton's method of volumetric testing on explanted hip components.

In ruling on the *Frye* hearing, the Court placed much weight on the absence of peer-reviewed articles that indicated that another expert had used Dr. Langton's method and found it to be generally accepted. Upon review it is clear that the lack of such an article is not evidence that Dr. Langton's method is not generally accepted in the relevant scientific community. The literature submitted by Plaintiff was from Dr. Langton and other experts who published their own work on volumetric wear testing. The purpose of peer-review literature is to operate as quality control in the relevant scientific community. Defendants did not submit any peer-reviewed literature in support of their claim that Dr. Langton's method of testing was not generally accepted, or any peer-review literature criticizing his method of calculating volumetric wear. Here, the peer-reviewed literature submitted supports Plaintiff's claim that Dr. Langton's method of measuring wear for an explanted hip component is generally accepted in the relevant scientific community.

ii. The Testimony of Scientists As To The Attitudes of Their Fellow Scientists.

Turning next to the testimony of scientists as to the attitudes of their fellow scientists, Plaintiff submitted the affidavits of three orthopedic surgeons, Dr. Benjamin Bolland, Dr. Jeremy Latham, and Dr. James P. Holland, from the United Kingdom. All three doctors were intimately familiar with Dr. Langton's volumetric wear testing of explanted hip components. The doctors are extensively published in the area of hip revisions and attest not only to the general acceptance of Dr. Langton's methods in the scientific community but also the invaluable assistance Dr. Langton's work affords them on making clinical decisions on the performance of hip devices that aid them in the treatment of their patients.

The Defendants' consultants who testified at the *Frye* hearing acknowledged Dr. Langton was an expert in the field of volumetric wear testing but further opined his methodology was not generally recognized in the relevant scientific community. The consultants claimed Dr. Langton's test was not recognized because there could be no valid volumetric testing on an explant device. They admitted volumetric testing could be performed but only on hip component devices that have never been implanted in a patient. Defendants' consultants did admit, on cross-examination, that at least six to twelve scientists were not only performing volumetric testing on explants but also using their findings to advise device manufacturers including Defendants. Moreover, Plaintiff provided the Court with internal DePuy correspondence and deposition transcripts of Defendants' employees that revealed Defendants were conducting tests with CMM measurements and computer programs similar to Dr. Langton's method to analyze and calculate wear on explanted ASR components.

iii. Practical Application

In support of her general acceptance claim, Plaintiff also requests the Court to consider the wide spread use of Dr. Langton's method of calculating volumetric wear of explant hip components by orthopedic surgeons, university hospitals and by the FDA. The Court has considered the submissions proffered and agrees it indicates some practical application of Dr. Langton's methodology which was used to calculate and analyze volumetric wear and therefore, favors general acceptance of Dr. Langton's method.

The most compelling evidence of the practical application of volumetric wear analysis was the testimony of Dr. Edidin. Dr. Edidin, a DePuy consultant, admitted that the FDA had directed Defendants pursuant to the regulation 522 of the Federal Food, Drug and Cosmetic Act to perform volumetric wear testing on ASR explants and report back the findings. Surely the FDA, the agency responsible for ensuring safety for patients who have medical devices implanted, would not request a device manufacturer to perform testing that was not generally accepted in the scientific community.

A re-examination of the transcripts of the testimony of Defendants' consultant experts at the *Frye* hearing make clear Plaintiff is correct when she asserts that Defendants' attack on Dr. Langton's volumetric wear calculations does not show his method is not generally accepted but only that the Defendants' consultants disagreed with the way Dr. Langton applied mathematics and computer programs to calculate volumetric wear on explant components. Indeed, Defendants do point to potential flaws in Dr. Langton's analysis; however, those criticisms go to the weight of the evidence and not to the admissibility. Defendants' disputes are not with Dr. Langton's

methodology, but are with his underlying conclusions and thus, Defendants' attacks are best left for cross examination at trial.

CONCLUSION

As a result of the Court precluding Dr. Langton from testifying at trial, the question becomes was the Plaintiff denied a fair trial. In resolving the question, the Court must look at the entire trial and the answer is yes. Plaintiff was precluded from giving the jury evidence of the amount of wear on the explanted ASR that was vital to her case. Therefore, the Court finds the exclusion of Dr. Langton's testimony did cause prejudice significant enough to deny Plaintiff a fair trial. Plaintiff's request for a new trial is granted.

All counsel to appear on September, 21, 2017, at 9:30 a.m. for a trial setting.

ENTERED:

Deborah Mary Dooling
Circuit Court Judge
Law Division

ENTERED
JUDGE DEBORAH MARY DOOLING - 1591
SEP 19 2017
DOROTHY BROWN
CLERK OF THE CIRCUIT COURT
OF COOK COUNTY, IL
DEPUTY CLERK