IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	§ § § §	MDL Docket No. 3:11-MD-2244-K
This Order Relates To:	§	
Lay v. DePuy Orthopaedics, Inc., et al. No. 3:11-cv-03590-K	§ §	
Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al. No 3:12-cv-04975-K	§ § §	

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT DEPUY ORTHOPAEDICS, INC.'S MOTION TO EXCLUDE EXPERT TESTIMONY OF W. GREGORY SAWYER, PH.D.

Before the Court is the motion of Defendant DePuy Orthopaedic, Inc. ("DePuy") to exclude expert testimony of W. Gregory Sawyer, Ph.D. in *Lay v. DePuy Orthopaedics, Inc., et al.*; No. 3:11-cv-03590-K ("Lay") [Dkt. No. 93.] and *Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al.*; No. 3:12-cv-04975-K ("Paoli") [Dkt. No. 86]. Because the Court finds that Dr. Sawyer is qualified as an expert on wear simulation for artificial joints and that his opinions on the inaccuracy of DePuy's testing and marketing messages relating to reduced wear due to lubrication in the Pinnacle Device are reliable and relevant, the Court is of the opinion that the motion should be denied.

Factual and Procedural Background

These cases are part of a Multidistrict Litigation ordered pursuant to 28 U.S.C.§1407 of all actions involving the Pinnacle Acetabular Cup System hip implants ("Pinnacle Device") manufactured by DePuy. The DePuy multidistrict litigation ("MDL") involves DePuy's design, development, manufacture, and distribution of the Pinnacle Device. The Pinnacle Device is used to replace diseased hip joints and was intended to remedy conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture and to provide patients with pain-free natural motion over a longer period of time than other hip replacement devices.

There are over six thousand cases in this MDL involving Pinnacle Devices made with sockets lined with metal, ceramic, or polyethylene. The Plaintiffs act through the Plaintiffs' Steering Committee ("PSC") that is headed by the Plaintiffs' Executive Counsel ("PEC"), a small group of lawyers from the PSC appointed by this Court to conduct discovery and other pretrial proceedings and identify common issues in the MDL. The PEC and DePuy have identified eight bellwether cases, and the Court has chosen *Lay* and *Paoli* to be the first two of the bellwether cases to be called for trial in September 2014. The PEC's basic theory of liability focuses on the differences between the body's reaction to the different wear debris generated by different types of hip implants. In the *Lay* and *Paoli* cases, the PEC alleges that in the metal-on-metal design of the Pinnacle Device, wear of the articulating surfaces can produce metallic ion debris (cobalt and chromium) within the periprosthetic space and that the body can have a

significant inflammatory response to metal debris that can lead to periprosthetic bone and/or tissue necrosis, resulting in the need for revision surgery.

The Plaintiffs' Executive Committee ("PEC") has identified W. Gregory Sawyer, Ph.D., an expert in tribology, the study of friction and wear, to offer the following opinions in the *Lay* and *Paoli* cases:

1. Hydrodynamic lubrication is not active in the Pinnacle Device.

2. DePuy's laboratory testing of the Pinnacle Device was unrealistically gentle.

3. DePuy ignored the problems and warning signs of its own testing of the Pinnacle Device.

4. DePuy failed to make its testing sufficiently precise, and as a result, DePuy's design and testing failed to predict the actual *in vivo* performance experienced by total hip replacement patients.

5. DePuy did not sufficiently replicate real world conditions in its testing.

6. An examination of Ms. Lay and Ms. Paoli's hip explants showed edge wear, failure of fluid film lubrication, scratches and wear in the articulating zone, and corrosion and taper fretting, confirming opinion nos. 1-5 above.

DePuy moves to exclude opinion no. 1, relating to lubrication, contending that Dr. Sawyer's opinion is unreliable and unhelpful. DePuy moves to exclude opinion nos. 2-5, relating to hip simulator testing, contending that Dr. Sawyer is not qualified and his opinions are unreliable. Finally, DePuy moves to exclude opinion no. 6 on the basis that Dr. Sawyer is unqualified to opine on the clinical cause of the failure of the Pinnacle Devices implanted in Ms. Lay and Ms. Paoli. Dr. Sawyer also opines with

respect to the materials science and metal toxicity of the Pinnacle Device; however, Plaintiffs agreed not to offer these opinions so the Court need not address DePuy's objection.

Burden of Proof for Exclusion of Expert Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides that: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact 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." Fed. R. Evid. 702. The Supreme Court affirmed that rule 702 is the standard for admission of expert testimony and stated that the dual standards of "relevance" and "reliability" would determine the admissibility of expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 589 (1993). Rule 702 was amended in 2000 and now provides more guidance, instructing that the Court should assist the trier of fact by admitting expert evidence "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.

Opinions on Lack of Hydrodynamic Lubrication

Reliability of Dr. Sawyer's Opinions

DePuy moves to exclude Dr. Sawyer's opinion that "the Pinnacle Device is prone to wear because it does not achieve hydrodynamic lubrication" as unreliable for the sole reason that it is contrary to all of the opinions of leading orthopedic tribologists as published in peer-reviewed literature made in the late 1990's and early 2000's when the Pinnacle Device was being developed and tested. A difference of opinion regarding the interpretation of literature is not grounds for a *Daubert* challenge but goes to the weight to be given the opinions by the trier of fact. *See Pipitone v. Biomatrix,* 288 F.3d 239, 249 (5th Cir. 2002).

Even if a difference of opinion would support an unreliability argument, DePuy has failed to show that Dr. Sawyer's opinion is in contravention of all peer-reviewed literature. In support of its argument, DePuy cites to Dr. Sawyer's deposition testimony where he states that he cannot identify a single study prior to 2001 that concludes that "fluid film" lubrication does not occur in the Pinnacle Device. Dr. Sawyer explains that there are three types of lubrication that exist between sliding surfaces: (1) hydrodynamic or "full fluid film" lubrication (load bearing surfaces are fully separated and the load is supported by lubricating fluid); (2) boundary lubrication (lubricating fluid is too thin and surfaces rub against one another); and (3) Mixed or "fluid film" lubrication (surfaces not fully separated by lubrication but there are pockets of pressurized fluid supporting

some of the load). Dr. Sawyer's opinion involves hydrodynamic or "full fluid film" lubrication. Dr. Sawyer's deposition testimony responded to questions regarding mixed or "fluid film" lubrication and is not supportive of DePuy's argument. DePuy also argues that Dr. Sawyer's opinion is in direct conflict with a study conducted in 1999 by his colleague, Dr. Tichy, who Dr. Sawyer engaged to help him in forming his opinions in the *Lay* and *Paoli* cases. The evidence shows that Dr. Sawyer did not even know of the existence of Dr. Tichy's report at the time Dr. Sawyer wrote his report; but once he learned of Dr. Tichy's study, he testified at length in his deposition as to the reasons why such study did not contradict his opinions.

The Court finds that Dr. Sawyer's opinions on lubrication are reliable because they are grounded in methodology and are well supported by simulator studies, including data from DePuy's own simulator studies, standard methodologies for determining which lubrication exists, and peer-reviewed literature. Dr. Sawyer calculated the amount of friction and wear that occurs in the Pinnacle Device, and using this friction coefficient, determined what type of lubrication was active *i.e.*, there was no hydrodynamic lubrication because the friction coefficient was too high, indicating the two load bearing surfaces were rubbing against each other and that there could not be full separation between them. DePuy has not questioned this methodology.

Relevance of Dr. Sawyer's Opinions

Because of Dr. Sawyer's findings that hydrodynamic lubrication was not active because the friction coefficient was too high to support total separation between load bearing surfaces in the Pinnacle Device, he disagrees with DePuy's marketing materials wherein DePuy claims that in the Pinnacle Device, "[b]earing surfaces are fully separated and the load fully supported by the lubricating fluid." Dr. Sawyer opines that DePuy's marketing materials erroneously claim hydrodynamic lubrication, not mixed lubrication where the surfaces are not fully separated by lubrication but there are pockets of pressurized fluid supporting some of the load. DePuy argues that since Ms. Lay and Ms. Paoli's surgeon, Dr. Allmacher, testified that he did not rely on DePuy marketing materials in choosing the Pinnacle Device for his patients, Dr. Sawyer's opinions regarding lubrication are not relevant.

DePuy previously made this same argument regarding relevancy with respect to the expert testimony of Dr. Abramson. This Court found then that there was evidence that DePuy conveyed marketing messages to doctors in many ways, not just through advertising, and that Dr. Allmacher did have regular discussions with his DePuy representative, listened to key opinion leaders, attended surgeon dinners and continuing medical education seminars, and read presentations and studies in medical journals regarding the Pinnacle Device. In fact, DePuy's representative was in the operating room with Dr. Allmacher for every surgery for ten years. There is sufficient evidence that

DePuy's marketing messages were conveyed to Dr. Allmacher through Dr. Allmacher's interaction with his DePuy representative and attendance at other DePuy sponsored events. Dr. Sawyer's opinion about the inaccuracy of DePuy's marketing message that the bearing surfaces of the Pinnacle Device are fully separated by lubricating fluid is, therefore, relevant.

Opinions on Hip Simulator Testing

Dr. Sawyer's Qualifications

DePuy argues that Dr. Sawyer is not qualified to express opinion nos. 2-5, opinions critical of DePuy's hip simulator testing, because he lacks experience specific to hip simulators. Dr. Sawyer is an expert in tribology, the study of the science and technology behind friction and wear. He earned bachelor of science and master of science degrees and a Ph.D. in mechanical engineering from Rensselaer Polytechnic Institute. Dr. Sawyer serves as a Distinguished Teaching Scholar and the N.C. Ebaugh Professor in the Department of Mechanical and Aerospace Engineering at the University of Florida. He also teaches in the Department of Materials Science and Engineering and directs the University of Florida' s Tribology Laboratory, which he built.

As Dr. Sawyer explains, tribology involves the types of materials in contact and the contact geometry, the operating conditions of the materials (gross motion, loads, stresses, duration), and the environment and surface conditions (surface chemistry and topography as well as ambient temperature). According to Dr. Sawyer, materials

tribology is an area of research that aims to control friction and wear through appropriate selection of known or newly-developed surface materials and treatments. Dr. Sawyer's area of specialization within tribology is materials tribology. Dr. Sawyer states that the purpose of simulator testing is to approximate the actual forces that the object being tested will undergo once it is put to use. Dr. Sawyer has experience in designing appropriate simulations to test for wear and is more than qualified to testify about the considerations that go into modeling real world friction and wear and how to best test the forces that will be experienced in the real world. He has specific experience in studying metal-on-metal contacts and in using simulators to test for wear. Some of Dr. Sawyer's experience with simulators involves wear on orthopedic implants–in particular, knee replacement implants. Dr. Sawyer has testified that the loads and speeds experienced by a knee joint are similar to that of a hip joint and that the same mechanisms of wear can occur in both joints.

DePuy's argument that Dr. Sawyer's lack of experience with hip replacement simulators makes him unqualified is without merit. While an expert need not have experience in the specific specialty at issue as long as he has sufficient expertise that his opinion is reliable and relevant, *see Huss v. Gayden,* 571 F.3d 442, 452-56 (5th Cir. 2009); *see also United States v. Liu,* 716 F.3d 159, 168 (5th Cir. 2013), *cert. denied,* 134 S. Ct. 1011 (2014); *Dixon v. International Harvester Co.,* 754 F.2d 573, 580 (5th Cir. 1985); *Suzlon Wind Energy Corp. v. Shippers Stevedoring Co.,* 662 F. Supp. 2d 623, 665 (S.D. Tex.

2009), Dr. Sawyer does have experience in the specialty area in this case–experience in simulation of wear on artificial joints. He has studied wear on artificial knees which he testified is similar to artificial hips.

Accordingly, this Court finds that Dr. Sawyer's education and experience in tribology, including his experience in using simulators to test and predict wear in different types of devices such as artificial knees, qualifies him to assess the results of simulators used by DePuy to test artificial hips and to opine about the need for more realistic motion profiles to obtain accurate simulations of friction and wear. Dr. Sawyer's opinions about DePuy's hip simulator testing are well within his area of expertise–testing, simulation, and analysis of friction and wear. DePuy's argument that he does not have any specific experience with hip simulation testing is an attack on the weight of his testimony rather than his qualifications.

Reliability of Dr. Sawyer's Opinions on Hip Simulator Testing

Dr. Sawyer is an expert in wear simulations. DePuy's attack on the reliability of Dr. Sawyer's opinions on hip simulator testing are, therefore, more appropriately an attack on the weight of the testimony rather than its reliability. Dr. Sawyer reviewed the data generated by DePuy's hip simulators as well as DePuy's reports and discussions of this data and interpreted this data based on his experience with motion simulators and his expertise in the field of tribology. Dr. Sawyer learned from this data that DePuy first used on its simulators a "physiological" profile developed from a human's actual

gait, but this profile resulted in so much wear that DePuy changed to a "simplified" profile. Dr. Sawyer opined based on his experience and expertise that the physiological profile rather than the simplified profile was more predictive of the actual wear that the Pinnacle Device would be subjected to in humans and that DePuy ignored warning signs of wear and tear on the Pinnacle Device.

DePuy attacks the reliability of Dr. Sawyer's opinion contending that Dr. Sawyer conceded that at the time of DePuy's testing, the simplified profile was generally accepted in the orthopedic implant industry for use in hip implant simulators and that no other more realistic profile existed for testing wear on a hip implant. DePuy further criticizes Dr. Sawyer for failing to do any scientific work on the accuracy of the simplified profile used in DePuy's hip testing simulator. Dr. Sawyer's opinion is that the physiological profile first used by DePuy was a much more accurate test for real world friction and wear on the Pinnacle Device than the simplified profile actually used by DePuy. DePuy debates the accuracy of Dr. Sawyer's opinion, not the reliability, which is more appropriately an attack made on the weight of the testimony at trial rather than its admissibility. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 595 (1993) (district court's focus must be on the principles and methodology not the conclusions they generate).

Testing Inclination and Angle Opinion.

DePuy's argument attacking Dr. Sawyer's opinions relating to testing for different inclination angles also goes to the weight rather than the admissibility of the opinion. Dr. Sawyer opines that virtually all testing prior to 2011 was based on a 45 degree placement angle, and that testing only one angle is insufficiently representative of real world conditions. DePuy does not directly criticize this opinion but instead criticizes Dr. Sawyer's deposition testimony where he stated that testing should have been made on a series of angles and gave an example of eight different angles. DePuy argues that Dr. Sawyer's opinion is unreliable because he never explained why DePuy should have run tests using the eight different angles and why his preferred method of testing was more accurate than industry standards. DePuy mis-characterizes Dr. Sawyer's opinion. Dr. Sawyer never opined that DePuy should have tested eight inclination angles but merely stated that testing multiple angles would be more accurate than testing just one angle and gave examples of other angles to test. DePuy disputes the accuracy of Dr. Sawyer's opinion, not the reliability, which is more appropriately an attack made on the weight of the testimony at trial rather than its admissibility. *See Daubert,* 509 U.S. at 595.

Case-Specific Opinions on the Cause of Ms. Lay and Ms. Paoli's Hip Implant Failures

DePuy complains that Dr. Sawyer should be precluded as unqualified from offering any opinions on the clinical causes of Ms. Lay and Ms. Paoli's hip failures. Dr. Sawyer supplemented his report after visually inspecting Ms. Lay and Ms. Paoli's hip explants opining that the explants failed for the reasons set forth in his initial report–friction on the devices. Dr. Sawyer observed scratches and wear indicating the devices had been subject to friction as described in his initial report. As DePuy points out, Dr. Sawyer testified that his definition of failure is from an engineering perspective and not a clinical perspective and that he is not qualified to offer a clinical opinion. A reading of Dr. Sawyer's report indicates that he does not purport to offer a clinical or medical opinion with respect to Ms. Lay or Ms. Paoli. His engineering opinion about the amount and effect of wear on Plaintiffs' Pinnacle Devices is the type of opinion that Dr. Sawyer is qualified to give and which DePuy does not challenge.

Conclusion

In its motion to exclude expert testimony of Dr. Sawyer, DePuy has attacked and pointed out numerous weaknesses in the PEC's proffered expert testimony. This does not, however, make the expert testimony inadmissible under rule 702 of the Federal Rules of Evidence or invoke this Court's gate-keeping authority under *Daubert*. DePuy has made no credible argument that Dr. Sawyer is not qualified to make the opinions

in his report or that any such opinions are unreliable or irrelevant. DePuy's arguments against admissibility are more appropriately raised at trial through vigorous cross examination of Dr. Sawyer, presentation of contrary evidence, and this Court's instruction on the burden of proof. For the reasons stated herein, DePuy's motion to exclude the expert testimony of W. Gregory Sawyer, Ph.D. is DENIED.

SO ORDERED.

Signed September 16th, 2014

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE