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NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

John Pearson; Stephanie Pearson, Plaintiffs, vs. Wright Medical Technology, Inc., Defendant.	No. CV-09-0485-PHX-FJM **ORDER**

The court has before it defendant's motion for summary judgment and motion to strike the testimony of Lester Hendrickson, Ph.D. (doc. 44), plaintiffs' response (doc. 46), and defendant's reply (doc. 50).

This is a products liability action involving the PROFEMUR® total hip replacement system, a prosthetic hip implant manufactured and sold by defendant Wright Medical Technology, Inc. On April 9, 2007, plaintiff John Pearson underwent left hip replacement surgery, during which the PROFEMUR® prosthetic hip was implanted. The PROFEMUR® implant is comprised of three separate components that are assembled together during surgery: the femoral head, the modular neck, and the femoral stem. The allegedly defective component at issue in this litigation, the modular neck, is manufactured from a titanium alloy and is designed to be inserted directly into the metal femoral stem. On June 26, 2008, the modular neck of plaintiff's PROFEMUR® implant cracked and required replacement.

Plaintiffs filed this action against Wright Medical Technology, alleging that the hip implant was defectively designed and/or manufactured.

A manufacturer is strictly liable for injuries caused by use of any product that was in a "defective condition and unreasonably dangerous." Dart v. Wiebe Mfg., Inc., 147 Ariz. 242, 244, 709 P.2d 876, 878 (1985) (quoting Restatement (Second) of Torts § 402A (1965)). To establish a prima facie case of strict products liability, a plaintiff must show that, when the product left the defendant's control, it was in a defective condition that made it unreasonably dangerous, and that the defect was the proximate cause of the plaintiff's injuries. Jimenez v. Sears, Roebuck & Co., 183 Ariz. 399, 402, 904 P.2d 861, 864 (1995).

Defendant now moves to strike the testimony of plaintiffs' expert witness, metallurgist Lester Hendrickson, Ph.D., contending that his opinions are neither relevant nor reliable. It also seeks summary judgment, arguing that without Dr. Hendrickson's testimony, plaintiffs cannot establish their claim.

The Federal Rules of Evidence allow expert testimony that will assist a trier of fact in understanding the evidence or in determining a fact in issue, so long as "(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 the framework developed in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S. Ct. 2786 (1993), trial courts must serve as gatekeepers to ensure that proffered testimony is both relevant and reliable. Id. at 597, 113 S. Ct. at 2799. The test of reliability is "flexible." Id. at 594, 113 S. Ct. at 2797. We may consider factors such as (a) whether the theory or technique can or has been tested; (b) whether it has been subjected to peer review and publication; (c) the known or potential rate of error; (d) the existence and maintenance of standards controlling the technique's operation; and (d) its general acceptance within the scientific community. Id. at 593-94, 113 S. Ct at 2796-97. The role of the courts in reviewing proposed expert testimony is "to 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." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999). "Our task, then, is to analyze not what the experts say, but what basis they have for saying it." Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Daubert II).

Defendant first argues that Dr. Hendrickson's expert testimony should be excluded as irrelevant and unreliable because it was based on his incorrect assumption that Mr. Pearson received a traditional, non-modular hip implant during his April 9, 2007 surgery, when in fact he had received a modular device, consisting of three separate components. Defendant believes that this distinction is critical because, by assuming that the implant was a single-piece device, Dr. Hendrickson failed to consider the possibility that the implant cracked due to "fretting."

Fretting is a metallurgical phenomenon that occurs at metal-to-metal contact areas placed under load stress and subjected to motion. DSOF ¶ 16. During surgery, the PROFEMUR® neck is inserted into the femoral stem, resulting in a metal-to-metal interface. The surgically implanted device is then repeatedly subjected to force and movement when the patient ambulates. According to defendant, the development and progression of fretting is affected by patient weight and activity level, surgical technique, patient bone structure, and biochemical issues, but is unrelated to the manufacturing process. Motion at 6. Defendant argues that because Dr. Hendrickson believed that Mr. Pearson received a single-piece implant with no metal-to-metal contact, he incorrectly concluded that fretting was not possible. Defendant contends that Dr. Hendrickson's opinion is therefore irrelevant and inadmissible.

Dr. Hendrickson opined that the subject implant failed due to a premature fatigue fracture resulting from a manufacturing defect. He observed through visual inspection and the use of a scanning electron microscope ("SEM") numerous microcracks on the surface of the implant stem. He stated that such surface cracks act as stress concentrations and crack initiation sites, and are known to cause fatigue fractures. He opined that these microcracks "could only be present due to a manufacturing defect," PSOF, ex. 1, ¶ 10, and that "the first

phase of the fracture process is effectively manufactured into the stem." DSOF, ex. G at 5.

Dr. Hendrickson acknowledged that he incorrectly identified the model of the defective prosthetic, but stated that he would have reached the same conclusions even if he had understood that the prosthesis was a modular implant with metal-to-metal contact. He explained that he rejected fretting as the cause of the failed prosthetic because none of the indices of fretting, including linear wear markings, debris, or pitting, was observed during his inspection.

Defendant presents the rebuttal report of expert Brad James, Ph.D., who opined that the subject implant exhibited no evidence of manufacturing defects. His report includes photographs of the surface of the cracked implant neck, purportedly showing debris, pitting and linear wear, thereby establishing that fretting had occurred. This conflicting evidence, however, demonstrates that a genuine issue of material fact remains for trial. It does not establish as a matter of law that plaintiffs' claim is without merit.

Defendant also contends that Dr. Hendrickson's opinions are unreliable because they are not based on any scientifically valid methodology. Defendant argues that Dr. Hendrickson did not review any manufacturing or design history records, or performance specifications, and contends that he knows nothing about the manufacturing process or the condition of the device when it left defendant's control.

Evidence is admissible under Daubert if there is an accepted scientific method for making a reliable measurement, even if the evidentiary significance of the measurement can be disputed. Daubert, 509 U.S. at 595, 113 S. Ct. at 2797 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Although defendant criticizes Dr. Hendrickson's methodology as not demonstrating scientific reliability, both parties' experts employed the same techniques in evaluating the failed implant. Both experts conducted a non-destructive analysis using visual and scanning electron microscope (SEM)-based inspection, and energy dispersive spectroscopy. Dr. James concluded that "[n]o defects were observed on the fracture surface that could have contributed to fatigue crack initiation and growth," and that "[e]xamination of the outside surface of the

neck showed clear evidence of fretting." DSOF, ex. K at 6. Dr. Hendrickson opined, on the other hand, that he observed microcracks near the fracture origin and concluded, based on his educational background and experience of more than thirty-five years analyzing failed consumer products, including artificial hips and prosthetic implants, that these microcracks are evidence of a manufacturing defect. DSOF, ex. G at 5.

We are satisfied that Dr. Hendrickson's opinion, while certainly subject to challenge, is based on valid principles and is sufficiently probative to assist the trier of fact in evaluating the issues presented in this case.

Accordingly, **IT IS ORDERED DENYING** defendant's motion for summary judgment and **DENYING** defendant's motion to strike expert testimony (doc. 44).

DATED this 22nd day of July, 2010.

Frederick J. Martone

Frederick J. Martone
United States District Judge