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CLERK U.S. DISTRICT COURT
SOUTHERN DISTRICT OF IA

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

ROBERT J. KRUEGER and PATRICIA KRUEGER,	)	Civil No. 4-00-cv-10032
Plaintiffs,	)	
vs.	)	
JOHNSON AND JOHNSON PROFESSIONAL, INC., CODMAN & SHURTLEFF, INC., JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., JOHNSON & JOHNSON HOSPITAL SERVICES INC., and JOHNSON & JOHNSON,	)	ORDER
Defendants.	)	

Before the Court are two motions filed by defendants. On April 2, 2001 defendants made motions to exclude the testimony of plaintiff's expert witness, George Otto, and for summary judgment. Plaintiffs filed a resistance on April 27, to which defendants filed a reply on May 23. The matters are fully submitted.

I. BACKGROUND

A. Facts

The following facts are undisputed or viewed in a light most favorable to plaintiffs, Robert Krueger and his wife, Patricia Krueger. Mr. Krueger had anterior cervical diskectomy

and fusion surgery performed by John G. Piper, M.D. at C5-6[1] on March 18, 1997. This surgery failed, as the bone graft at C5-6 did not fuse. After this time, Douglas R. Koontz, M.D., began to treat Krueger. He determined that another surgery was required, and that in it he would attempt to fuse both the C5-6 and C6-7 intervertebral spaces.

Prior to the second surgery, Dr. Koontz and Krueger decided the Codman Anterior Cervical Plate System would be implanted in Krueger. Such a product had not been used in the first surgery. Defendants, hereinafter referenced in this Order as Johnson and Johnson, are the manufactures of the Codman Plate.

A cervical plate is used in patients undergoing this type of surgery if they are at an increased risk of "nonunion" of the vertebrae. Factors which indicate an increased risk of nonunion include the failure of prior surgery, if the patient is a smoker, or if multiple levels of fusion are involved. *See* Appendix Filed in Support of Defendants' Motions at 37 (Koontz Dep.). Krueger fit all three risk categories, and Dr. Koontz decided to implant the Codman Plate to "share the load." *Id.* The plate is designed to bear weight, allowing fusion to occur and the bony structure to heal. After fusion has occurred, the plate is normally extracted from the body.

Krueger underwent his second surgery on October 1, 1997 and the plate was implanted. Dr. Koontz put it in place at the fusion site, C5-7, with six screws. At the first follow-up appointment with Dr. Koontz after this surgery, on November 12, 1997, Dr. Koontz reported that Krueger's x-rays "showed that the bone grafts and the plates are stable, and there is no evidence of abnormal motion." *See* Appendix Filed in Resistance to Defendants' Motions, Exh. A. Dr. Koontz also reported, though, that the fusion sought by the surgery had not yet occurred at that

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[1] This is the abbreviation for the 5th and 6th cervical vertebrae and the intervertebral space which required fusion.

time.

At the next appointment, December 10, 1997, x-rays showed that the fusion was not "solid," but Dr. Koontz did not yet draw a conclusion that the surgery had failed. *Id.* at Exh. 10 and Koontz Affidavit (filed May 7, 2001). At the time, Dr. Koontz did not include in his report anything regarding the Codman Plate or its screws. However, Koontz now states that after reviewing the x-rays taken on that date, "one or both of the screws in the 7th cervical vertebrae were already starting to back out" and that there was "an angulation of one or both of the screws . . . ." *See* Koontz Affidavit.

By February 5, 1998, Dr. Koontz concluded that fusion at the C5-6 level had been successful and the screws in the Codman Plate at this level were holding. However, Dr. Koontz found that the fusion at the C6-7 level had failed, and that the screws at that level on the Codman Plate had both broken. *See* Koontz Affidavit.

Dr. Koontz performed a third surgery on Krueger on April 1, 1998 to remove the Codman Plate and broken screws and re-fuse C6-7.

B. Plaintiff's Expert Witness: George Otto

George Otto graduated from the University of Wisconsin with both bachelor and masters degree in metallurgy, completing the latter in 1947. He also received his license as a professional engineer in 1966. Otto worked for three different companies over a forty-two year career, and spent approximately thirty-six years with The Maytag Company. In his positions, he was responsible for conducting failure analysis on products or pieces of manufacturing equipment that broke or failed. He would also evaluate the designs of the failed parts and make recommendations regarding alternative designs.

Plaintiff retained Otto as an expert witness in this case. Otto has examined the broken screws and the Codman Plate that was extracted from Krueger. Otto performed a chemical analysis and determined the screws and plate were made from the proper titanium alloy. Otto also examined the screws and the plate system under various power levels of microscopes. He opines that the screws broke because of fatigue failure. He asserts that the Codman Plate System is defective because locking cam mechanisms which hold the screws in place acted as a bending force perpendicular to the length of the screw that helped lead to premature breakage of the screws. Otto also believes the screws could have been made stronger with established metallurgy techniques such as cold rolling oversize screws. *See* Appendix Filed in Resistance to Defendants' Motions, "George Otto" (affidavit) and Appendix Filed in Support of Defendant's Motions, 1-32 (Otto's Dep.).

C. Plaintiffs' Claims

Plaintiffs filed their petition in the Iowa District Court for Jasper County on December 29, 1999. Plaintiffs brought claims of negligence (Count I), strict liability (Count II), and breach of warranty (Count III) under Iowa law. Additionally, Patricia Krueger brought a loss of consortium claim. Defendants removed the case to this Court on grounds of diversity of citizenship[2] on January 18, 2000. In their resistance to defendant's motions, plaintiffs have conceded that their breach of warranty claims are not appropriate in light of the facts and circumstances of this case. Thus, only Counts I and II remain.

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[2] Named defendants are either incorporated with their principal places of business in the states of New Jersey or Massachusetts, or they are no longer legal entities.

II. PLAINTIFFS' EXPERT WITNESS

In this case, defendants request the Court rule on the *Daubert* motion to exclude the expert testimony of George Otto without a hearing. *See* Defendants' Reply Brief at 2-3. Defendants argued "[t]he deficiencies in Otto's qualifications and opinions are so great that the Court can rule on [d]efendants' motion to exclude his opinions without a hearing." *Id.* at 2. Plaintiffs request a hearing be held if the Court considers excluding the testimony of George Otto. *See* Plaintiff's Resistance Brief at 12.

The Supreme Court in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) stated:

> The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable.

Courts have interpreted this guidance from the Supreme Court to mean that a district court is not required to hold a hearing to comply with *Daubert*. *See Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 248-49 (6th Cir. 2001) (quoting *Kumho Tire*, 526 U.S. at 152); *Goebel v. Denver and Rio Grande Western R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000) (stating that a *Daubert* hearing is "not specifically mandated"); and *Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3rd Cir. 2000) (finding an in limine hearing was not required to make *a Daubert* determination).[3]

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[3] The Court recognizes *Unites States v. Iron Cloud*, 171 F.3d 587 (8th Cir. 1999) and its holding with regard to *Daubert* motions. The defendant was charged with involuntary manslaughter under federal law as a result of a vehicular accident allegedly caused by the defendant while he was intoxicated. *Id.* at 589. A portable breath test ("PBT") was taken at the scene, and the results were part of the evidence at trial. *Id.* Defendant moved for a *Daubert* hearing regarding the expert testimony which would be presented about the PBT testing to determine whether it was reliable and relevant, but the district court judge refused to allow such a hearing and he summarily found that PBT testing was "'recognized by the scientific community.'" *Id.* at 390 (quoting from the trial transcript). The Eighth Circuit reversed,

This Court finds that the record before it is sufficient to perform its role under *Daubert*, and that a hearing would not be helpful in exercising its duty.[4]

In *Daubert*, the Supreme Court clarified the district court's "gatekeeping" role in evaluating proposed expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (interpreting Federal Rule of Evidence 702). *Daubert* stated that a district court must evaluate whether the proposed testimony is: (1) based on scientific knowledge; and (2) will help the trier of fact understand or determine a fact in issue. *Id.* To help the district courts make the determination of whether the expert's testimony is "reliable" and "relevant," the *Daubert* Court instructed courts to discern the scientific theory or technique which underlies the testimony. A district court is then to evaluate: (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community. *Id.* at 592-95 (stating that "many factors will bear on the inquiry" and that

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finding a *Daubert* hearing should have been held as the PBT is not recognized as reliable other than for purposes of establishing probable cause or as a preliminary screening test. *Id.* at 590-1 (concluding that admitting the PBT test results was not harmless error).

While the panel in *Iron Cloud* determined that the district court in that case should have conducted a hearing, the decision does not dictate that the Eighth Circuit requires a hearing in conjunction with all *Daubert* motions. Rather, *Iron Cloud* appears to stand for the proposition that district courts may not abdicate their gatekeeping functions and need to make a determination of the reliability and relevance of expert testimony. This Court believes it can adequately make such a determination in this case on the record without a hearing, and that it has been given the discretion to decide the manner in which it makes such a decision by the Supreme Court's *Kumho Tire* opinion. *See* 526 U.S. at 152.

[4] *See also* FED.R.EVID. 702, Advisory Committee Notes on 2000 Amendments ("The amendment makes no attempt to set forth procedure requirements for exercising the trial court's gatekeeping function over expert testimony.").

the above listed factors do not constitute "a definitive checklist or test").

Since that time, the Supreme Court decided *Kumho Tire,* 526 U.S. at 137. In this opinion, the Court clarified that the gatekeeping role assigned to district courts in *Daubert* requires judges to not only determine the admissibility of expert testimony of scientists, but also that of all expert witnesses. *Id.* at 147. Following *Kumho Tire*, Federal Rule of Evidence 702 was amended, effective December 1, 2000. It now states:

> 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. It is clear that it is for the Court, and not a jury, to determine whether an expert and the testimony which will be given at trial meet this standard.

In this case, plaintiffs seek to have a metallurgist testify about the cause of the failure of the Codman Plate System as it was implanted in Krueger. The burden is on plaintiffs to show by a preponderance of the evidence the metallurgist, George Otto, is qualified. *Daubert*, 509 U.S. 579. The issue of expert testimony in a case where a medical device used during spinal fusion surgery has caused an injury is not unique. In a Multi District Litigation ("MDL") case that was consolidated for pretrial proceedings there were more than two thousand separate product liability actions filed by more than five thousand plaintiffs in cases where fixation devices used during spinal fusion surgery caused physical injuries. *See In re Orthopedic Bone Screw Products Liability Litigation*, 1998 WL 411380 (E.D.Pa. 1998) (remanding cases following pre-trial proceedings). One specific case involved in this MDL action was *Menges v.*

Depuy Motech, Inc., 61 F. Supp.2d 817 (N.D. Ind. 1999). The plaintiff had spinal fusion surgery, during which an internal fixation instrument was implanted, and following surgery the instrument's screws broke while still implanted in the plaintiff's body. *Id.* at 821. The plaintiff named Dr. Jerry McKenzie as an expert regarding causation for the breakage of the screws. *Id.* at 825. The district court found McKenzie was not qualified because he was not trained in neurology, neurorsurgery, spinal instrumentation or general surgery nor had he researched or published in these areas. *Id.* The district court went on to find that even assuming McKenzie was qualified, his opinion was unrealiable as it lacked specificity and failed to consider other viable causes for the breakage of the screws and the plaintiff's problems. *Id.* The district court granted the defendant's *Daubert* motion regarding McKenzie.[5]

The district court in *Menges* commented on "the MDL Bone screw cases on remand":

> To date, the majority of district courts that have dealt with the MDL Bone Screw cases on remand have found causation lacking . . . . The major difficulty in most of those cases has been the knowledge, skills and training (or lack thereof) of the proffered expert. While courts are not to impose overly rigorous requirements of expertise and must be satisfied with more generalized qualifications, the fact remains that a witness without sufficient knowledge, either through training or experience, may not testify as an expert.

Id. at 824-25 (citations omitted). In at least one recent case where screws broke in an internal fixation device following spinal surgery, the plaintiff has submitted the expert testimony of a metallurgist. *See Muller v. Synthes Corp.*, 2001 WL 521390 (N.D. Ill. May 15, 2001) (not an MDL case). The metallurgist in *Muller* had no training or experience in the design of medical

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[5] The district court in *Menges*, 61 F.Supp. 2d at 826, was going to allow another plaintiff's expert to testify in a limited fashion. Harold Alexander, PhD, was an orthopedic bioengineer who was allowed to testify regarding alleged product defect of the internal fixation instrument, but he was not going to be allowed to discuss medical causation. However, the district court granted the defendant's summary judgment motion as there was not a material issue of fact for trial. *Id.* at 830.

implants or any other medical devices. *Id.* at *2. The district court concluded that the metallurgist came "nowhere near satisfying the standards for expert testimony required under Fed.R.Evid. 702." *Id.* at *8.[6]

In this case, Otto's qualifications and his proposed testimony[7] do not satisfy the Rule 702 standard. First, like the metallurgist in *Muller*, Otto has no experience in the design of medical implants or any other medical devices. Second, under subsection (a) of Rule 702, Otto's opinions are based on insufficient facts. He does not know how much pressure it takes to bend a screw *in vivo*[8] and has never been involved in the testing of a medical device to be used inside the body. And third, under subsections (b) and (c) of Rule 702, Otto bases his opinions on non-applicable principles and methods that are unreliable in this context and he applied them in an unreliable fashion. The Court does not question Otto's understanding of the principles of metallurgy or his ability to apply those principles, but none of his testimony takes any consideration of the fact that this is a medical device which is inserted in a person's body. Any expert testimony in this case must be centrally concerned with the fact that this is not a case where screws merely broke on a device, but the screws broke following the implantation of the device during a spinal surgery inside of a person's body. None of the principles or methods used by Otto adequately reflect even a rudimentary understanding of the context in which this device was implanted and served its purpose of bearing weight, thereby attempting to allow the fusion

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[6] The Court in *Muller* also concluded the plaintiff's other expert, whose specialties were in the areas of ergonomics and biomechanics, did not qualify under *Daubert*.

[7] As it has not held a hearing, the Court bases its assessment of Otto's proposed testimony is on his deposition transcript, which is part of the record before the Court.

[8] *In vivo* is defined as inside the body.

to occur.

In making this ruling, the Court is cognizant of the difficulty which plaintiff faces. Based on the statements of the Court in *Menges*, 61 F.Supp.2d at 824-25, there appear to be only a narrow category of experts who are being found to qualified to testify in cases of this nature across the country. However, it is very clear to this Court that Otto is not qualified to testify in this case – his opinions regarding a medical implant are not reliable, nor is his metallurgical testimony relevant. He has never been involved with the design of medical implant devices such as the Codman Plate System, and does not meet the standard set up by *Daubert*. *See also Glastetter v. Novartis Parmaceuticals Corp.*, __ F.3d ___, 2001 WL 630651 (8th Cir. June 8, 2001) (upholding district court's decision to exclude plaintiff's expert testimony under Federal Rule of Evidence 702 and *Daubert*).

III. REOPENING OF DISCOVERY

Plaintiff's claims of strict liability and negligence based on a theory of design defect are likely precluded without expert testimony to establish causation. *See Dancy v. Hyster Co.*, 127 F.3d 649, 653 (8th Cir. 1997) (finding plaintiff's claims in products liability action could not survive summary judgment following the exclusion of plaintiff's expert). There are several elements that plaintiff must show to establish either a claim of strict liability or negligence under Iowa law, but under both plaintiffs will have to show that the product was unreasonably dangerous and caused Krueger's injuries. It is for these showings that plaintiffs will need expert witness testimony.[9] "In strict liability, the plaintiff must establish the product was in a defective

[9] Plaintiff's other expert witness, Dr. Koontz, will not suffice for this purpose. In his deposition, he stated that he did not intend to offer any opinion at trial regarding whether the

condition and unreasonably dangerous to the consumer." *Lovick v. Wil-Rich*, 588 N.W.2d 688, 698 (Iowa 1999). "In negligence, the plaintiff must show the product was unreasonably dangerous because the manufacturer failed to use reasonable care." *Id.*

However, in light of the apparent difficulty that plaintiffs have had nationwide in finding suitable experts under *Daubert* in cases like this, *see Menges* and *MDL Bone Screw Litigation*, and based on the Court's discretion in handling discovery matters, the Court finds it is warranted to reopen discovery for the limited purpose of allowing plaintiffs to designate a new expert witness. The Court finds this is the most fair manner to handle this case, but cautions the parties to limit all discovery efforts to a new expert which plaintiffs may designate. The re-opening of discovery will obviously delay the trial date of this case, but the Court does not envision a significant delay. The clerk of court will set a new trial date based on the amended scheduling order.

Codman Plate System was defective. *See* Appendix Filed in Support of Defendants' Motions, at 44.

IV. CONCLUSION

Based on the aforementioned reasons, defendants' *Daubert* motion to exclude the expert testimony of George Otto is granted; however, the Court finds discovery should be re-opened for the limited purpose of giving plaintiff a chance to designate a new expert. The trial date in this case, scheduled to begin the three week period starting September 10, 2001, is canceled. Counsel should submit a proposed scheduling order in accord with Local Rule 16.1 by July 23, 2001 to Chief Magistrate Judge Walters. This proposal should detail a new discovery deadline (limited to addressing a new expert witness which plaintiff may designate), dispositive motion deadline, and ready for trial dates.

IT IS SO ORDERED.

Dated this 29th day of June, 2001.

RONALD E. LONGSTAFF, JUDGE
UNITED STATES DISTRICT COURT