

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)	ORDER
PROFESSIONAL, INC.,)	
CODMAN & SHURTLEFF, INC.,)	
JOHNSON & JOHNSON HEALTH)	
CARE SYSTEMS, INC.,)	
JOHNSON & JOHNSON HOSPITAL)	
SERVICES INC., and JOHNSON &)	
JOHNSON,)	
)	
Defendants.)	

On June 29, 2001, this Court found the testimony of plaintiffs' expert, George Otto, inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). At that time, rather than rule on a pending motion for summary judgment, the Court re-opened discovery and gave plaintiffs the opportunity to designate a new expert witness. Now before the Court are defendants' second motions to exclude the testimony of the newly designated expert witness, Edward W. Reese, Ph.D., and for summary judgment. Defendants renewed their motions on April 30, 2002. Plaintiffs filed their resistance on June 4, and defendants filed their reply on June 14. The matters are fully submitted. For the reasons that follow, the Court holds that under *Daubert*, Dr. Reese is not qualified to give expert testimony in this case and grants defendants' motion for summary judgment.

I. BACKGROUND

A. 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 citizenship¹ on January 18, 2000. In their resistance to defendants' first motions for exclusion of an expert witness and for summary judgment, plaintiffs conceded that their breach of warranty claims were not appropriate in light of the facts and circumstances of this case. Thus, only Counts I and II remain.

B. Facts

The underlying facts giving rise to this case were set forth in this Court's ruling in *Krueger v. Johnson & Johnson, Inc.*, 160 F. Supp.2d 1026 (S.D. Iowa 2001), and are incorporated by reference. The facts are undisputed or viewed in a light most favorable to plaintiffs. Additional facts relevant to the present motions will be incorporated in the body of this order.

C. Plaintiffs' Expert Witness: Edward W. Reese, Ph.D.

Dr. Reese is a self-described "regulatory affairs expert, FDA rules and regulations expert." *See* Supplemental Appendix Filed in Support of Defendants' Second Motion to Exclude the Testimony of

¹ 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.

Plaintiffs' Expert and Second Motion for Summary Judgment at 342 (hereinafter "Defendants' Appendix")² (deposition of Dr. Reese at 60). Dr. Reese worked as director of technical services for a company called Medtronic, Inc. from 1971 to 1980. He also worked as the manager of manufacturing operations for a company called Astro-Med, Inc. from 1981 to 1983, and as vice president of operations for another company, Angiomedics, from 1983 to 1986. *See* Defendants' Appendix at 376 (curriculum vitae). These companies were involved in the design and manufacture of medical devices, but none designed or manufactured anterior cervical plate systems. *See* Defendants' Appendix at 339 (deposition of Dr. Reese at 48). Dr. Reese worked in research and development for these companies, supervised an engineering design department, and performed management duties. In 1986 he started his own company, Genesis Medical, Inc. Genesis advertises itself as a company that "determines if a causal relationship exists between a suspect medical device and the manufacturer, distributor, physician and/or hospital." *See* Defendants' Appendix at 406 (print out of the company's web site home page).

Dr. Reese earned his undergraduate degree from Metropolitan State University in St. Paul, Minnesota in 1988 with a major in management. *See* Defendants' Appendix at 332 (deposition of Dr. Reese at 18) and 375 (curriculum vitae). In 1989, he received his masters degree in management from Cardinal Stritch University in Milwaukee, Wisconsin; and in 1993, he received his Ph.D. in Medical Technology Studies from Union Graduate School in Cincinnati, Ohio. *See* Defendants' Appendix at 375 (curriculum vitae). In his deposition, Dr. Reese was asked about his Ph.D. program, which was a self-study program that did not have significant course work:

² The Court will not differentiate between references to the parties' initial appendices or their supplemental appendices as the appendices are consecutively paginated.

Q: Do you know of any other student who has received a degree in medical technology from that school?

A: No. That's quite frankly the uniqueness of the program.

See Defendants' Appendix at 333 (deposition of Dr. Reese at 21). Dr. Reese also stated his academic advisor in the medical technology Ph.D. program had a background in literature, natural history, mythology, religious studies and educational administration. *Id.* at 22-23.

Dr. Reese has submitted an eighteen-page written opinion in this case, relying primarily on documents provided to him from plaintiffs' counsel. *See* Plaintiffs' Supplemental Appendix Filed in Resistance to Defendants' Second Motion to Exclude Expert Testimony and Second Motion for Summary Judgment (hereinafter "Plaintiffs' Appendix") at 452-469. Dr. Reese's conclusions are summarized as follows: (I) a design or manufacturing defect in defendants' device likely caused Krueger's injury;³ (II) defendants' device was mislabeled;⁴ (III) defendants did not adequately test the

³Dr. Reese claimed that:

- defendants recognized that fusion might take six months and that the device needed to last that long, *See* Plaintiffs' Appendix at 456 (¶ 8);
- the screws at the C-7 level fractured "most likely as a result of mechanical stress" and that "it appears highly probable that the failure can be attributed to a defect or anomaly in the design and/or manufacturing process," *id.* at 457 (¶ 9); and
- "[t]he subject implantable orthopedic hardware device failed to respond to its design objective intent in a safe, effective, and reliable manner," and Krueger's injury occurred because the device did not respond to its design objective, *id.* at 458 (¶¶ 12-13).

⁴ Dr. Reese stated that:

- defendants did not "provide appropriate objective data and information in their labeling specific to the issue of life expectancy under specific patient applications and other anatomically related issue[s]," *id.* at 462 (¶ 19);

Codman system;⁵ and (IV) defendants failed to comply with certain FDA regulations.⁶

II. APPLICABLE LAW AND DISCUSSION

Defendants request that the Court rule on the *Daubert* motion to exclude the expert testimony

- the product’s original label indicated the Codman device was intended for short- term use, but after FDA review that instruction was not allowed to be part of the product label, *id.* at 461 (¶ 19); and

- the surgical plate system was a misbranded medical device prohibited by 21 U.S.C. § 331, *id.* at 463 (¶ 20).

⁵ Dr. Reese opined that:

- defendants “should have, but did not, conduct adequate testing and development in order to produce a more effective and reliable device,” *id.* at 455-56 (¶ 8);

- the surgical plate system at issue was not subject to an appropriate clinical review process, *id.* at 460 (¶ 18);

- defendants failed to conduct reliability assurance testing of the plate system at issue, *id.* at 465 (¶ 24), and failed to adequately determine the estimated life expectancy of the plate system, *id.* at 465-66 (¶ 25);

- the plate system at issue was prematurely released into commercial distribution, *id.* at 467 (¶ 32); and

- defendants did not conduct adequate product design testing and validation, *id.* at 466 (¶ 29).

⁶ Dr. Reese claimed that:

- defendants have failed to submit certain “Medical Device Reports” (MDRs) in a case like this one that involved malfunctions and serious injuries as those terms are defined in FDA regulations, *id.* at 459 (¶ 15), although 87 MDRs have been submitted by defendants with respect to the plate system at issue in this case, *id.* (¶ 16); and

- defendants failed to conduct appropriate in-house audits to assure compliance with applicable FDA rules and regulations, *id.* at 466 (¶ 28).

of Dr. Reese without a hearing. See Defendants' Reply Brief at 1. 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 *Hanford Nuclear Reservation Litigation v. Jeanne Jaros*, 292 F.3d 1124, 1138-39 (9th Cir. 2002) (affirming the district court's decision to refuse a *Daubert* hearing where the district court had the experts' reports, deposition testimony, and the experts' affidavits); *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 249 (6th Cir. 2001) ("The district court is not required to hold an actual hearing to comply with *Daubert*."); *Krueger v. Johnson & Johnson*, 160 F. Supp. 2d 1026, 1029 (S.D. Iowa 2001) (holding that a *Daubert* hearing was not required); *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 146, 151-55 (3rd Cir. 2000) (finding an in limine hearing was not required to make a *Daubert* determination).⁷ 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.⁸

⁷ As explained in *Krueger v. Johnson & Johnson*, 160 F. Supp. 2d 1026, 1029 (S.D. Iowa 2001), the Eighth Circuit's decision in *United States v. Iron Cloud*, 171 F.3d 587 (1999), does not require district courts to hold hearings in conjunction with all *Daubert* motions.

⁸ 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.").

In *Daubert*, the Supreme Court clarified the district court's "gatekeeping" role in evaluating proposed expert testimony. *Daubert*, 509 U.S. 579, 588-93 (1993) (interpreting

Federal Rule of Evidence 702). *Daubert* stated that a district court must evaluate whether the proposed testimony: (1) is based on scientific knowledge; and (2) will help the trier of fact understand or determine a fact in issue. *Id.* at 589-591. 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 the above listed factors do not constitute "a definitive checklist or test").

In *Kumho Tire v. Carmichael*, 526 U.S. 137 (1999), the Supreme Court clarified that the gatekeeping role assigned to the district court in *Daubert* requires judges to determine the admissibility of expert testimony not only 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, or 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. Clearly, 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. The burden is on plaintiffs to show by a preponderance of the evidence that Dr. Reese is qualified and that his opinions satisfy this standard. *Estate of Mitchel v. GenCorp., Inc.*, 968 F. Supp. 592, 595 (D.Kan. 1997), *aff'd* 165 F.3d 778 (10th Cir. 1999).

A. Design/Manufacturing Defects

Dr. Reese's opinion that a design or manufacturing defect caused Krueger's injury does not satisfy the Rule 702 standard. Dr. Reese is not a medical doctor or an engineer. He has no metallurgical training, is not formally trained in biomechanical, biomedical, or health care fields, and has not authored any professional publications. (Defendants' Appendix at 339) (deposition of Dr. Reese at 46-47). While Dr. Reese did his best to bolster his experience in medical device design, he conceded that he "did not develop [] product specifications. That certainly was very complex technology well beyond me." (Defendants' Appendix at 335) (deposition of Dr. Reese at 29-30). The Court finds that Dr. Reese's knowledge of, and experience with, anterior cervical plate systems is highly suspect: he has never worked for a company with an anterior cervical plate product; he could not address the risks associated with other cervical plate devices; and he could not even name other anterior cervical plate systems marketed at the same time as the Codman System.

In addition to Dr. Reese's lack of qualifications, the Court is concerned with the methods employed by Dr. Reese in forming his opinions. Dr. Reese did not evaluate the plate system explanted from Mr. Krueger. He did not analyze or test the design of the Codman System, nor did he compare

the design features of the Codman System to other cervical plate systems. While Dr. Reese opined that the screws at the C-7 level fractured “most likely as a result of mechanical stress,” and that “it appears highly probable that the failure can be attributed to a defect or anomaly in the design or manufacturing process,” Plaintiffs’ Appendix at 457 ¶9, he was unable to identify any specific flaw that caused the Codman Plate System to fail. *See* Defendants’ Appendix at 349 (deposition of Dr. Reese at 86-87).

As the Eighth Circuit instructed in *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 988-89 (2001), district courts must “separate[] expert opinion evidence based on ‘good grounds’ from subjective speculation that masquerades as scientific knowledge.” Dr. Reese’s opinions are far from being based on “good grounds.” He has no experience in the design of cervical plate systems, and his opinions are based on insufficient facts. Therefore, this Court holds that Dr. Reese is not qualified under Rule 702 to opine on whether an alleged design or manufacturing defect in the Codman Plate System caused Krueger’s injuries. *See Krueger v. Johnson & Johnson*, 160 F. Supp 2d 1026, 1031 (S.D. Iowa 2001) (holding that a metallurgist was not qualified to testify as an expert in this action as to the cause of broken cervical fusion plate screws implanted in patient, where metallurgist had no experience in design of such implants, was not involved in testing medical devices inside the body, and based his opinions upon non-applicable principles of metallurgy); *Muller v. Synthes Corp.*, 2001 WL 521390 at *8 (N.D. Ill. May 15, 2001) (holding that a metallurgist who had no training or experience in the design of medical implants came “nowhere near satisfying the standards for expert testimony . . .”); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817 (N.D. Ind. 1999) (holding that a physician not trained in neurology, neurosurgery, spinal instrumentation, or general surgery was not qualified to testify as to medical causation in spinal fusion device case).

B. Labeling Defects

The Court must next evaluate Dr. Reese's qualifications to opine on the issue of labeling defects. Dr. Reese claimed that the labeling of defendants' device was ineffective in communicating necessary information to the treating physician. Dr. Reese sought to give similar opinions in *United States v. Gebhardt*, 191 F.R.D. 180 (D. Ariz. 1999), a case involving the implantation of an anti-reflux device in a patient's abdomen. The district court ruled that Dr. Reese was not qualified to give medical opinions about device labeling or warnings. *Id.* at 183. The Ninth Circuit agreed, stating:

Reese did not have a medical degree, medical training, or more specifically, experience as a surgeon. As such, Reese was not in a position to offer an opinion as to how a warning label would have affected a surgeon's decision to use the . . . device [W]e conclude that Reese's work with the FDA was not enough to qualify him to testify on how a medical device's warning label would have affected a surgeon's decision of whether to use the device.

Gebhard v. Mentor Corp., 2001 WL 868453 at *2 (9th Cir. 2001). Dr. Reese's lack of medical qualifications have not changed since *Gebhardt*.

In this case, Dr. Reese conceded that he has never drafted a label for an anterior cervical plate system. (Defendants' Appendix at 349) (deposition of Dr. Reese at 88). Dr. Reese did not design an alternative warning in this case or review the labeling of Codman's competitors. *Id.* at 349 (deposition of Dr. Reese at 86, 88). Moreover, Dr. Reese has not spoken to any treating orthopedic surgeons about the effectiveness of the device labeling. *Id.* at 351 (deposition of Dr. Reese at 94-95). This Court finds that Dr. Reese is not qualified to give expert testimony about the labeling of the Codman System.

C. Inadequate Testing and Non-compliance with FDA regulations

Finally, the Court must evaluate Dr. Reese's ability to testify regarding defendants' testing procedures and their compliance with FDA regulations. Dr. Reese generally alleged that defendants failed to adequately test the Codman device, but he was unable to identify any specific problem or deficiency in the testing.⁹ Dr. Reese also stated that defendants failed to comply with certain FDA regulations. Specifically, Dr. Reese asserted that defendants neglected to conduct in-house audits and to file one Medical Device Report. *See supra* n. 5-6. This Court need not decide whether Dr. Reese is qualified to give these opinions in order to enter its ruling today. Even if believed, this evidence alone is insufficient to establish plaintiffs' prima facie case. Such testimony does not prove that the Codman device implanted in Krueger was defective, or that it was a proximate cause of his injuries. Therefore, even if the Court were to find that Dr. Reese is qualified to give expert testimony on these two issues, its summary judgment ruling would stand.

IV. SUMMARY JUDGMENT

Summary Judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P.

⁹ Q: . . . Are you able to tell us any specific reliability assurance testing that should have been performed on this device?

A: Well, in general terms but not specific terms.

Q: . . . In other words, generally you think that post market release testing should have been done, you don't know if it has been done, but specifically the kind of testing that should have been performed you don't know as you sit here; is that fair?

A: Yes.

(Defendants' Appendix at 352-53) (deposition of Dr. Reese at 100-01). When asked why he couldn't be more specific, Dr. Reese explained, "I don't have that insight with regards to the manufacturers to what their capabilities are or et cetera" *Id.* at 354 (deposition of Dr. Reese at 107-08).

56(c). In considering a summary judgment motion, the court views the evidence in the light most favorable to the non-moving party. *State Farm Mut. Auto. Ins. Co. v. Shahan*, 141 F.3d 819, 821 (8th Cir. 1998).

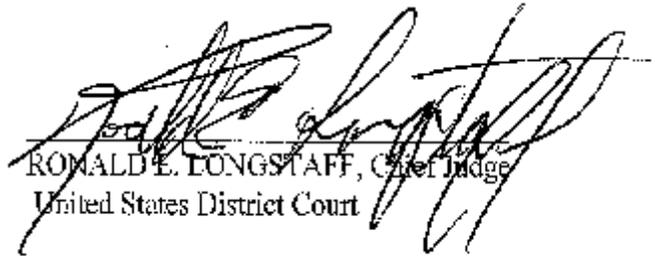
Plaintiffs brought claims of negligence (Count I) and strict liability (Count II) against defendants. There are several elements that plaintiffs establish to succeed on either a claim of strict liability or negligence under Iowa law. Under both theories, plaintiffs must prove that the product was unreasonably dangerous and proximately caused Krueger's injuries. *See Lovick v. Wil-Rich*, 588 N.W.2d 688, 698 (Iowa 1999). Without expert testimony, plaintiffs cannot meet their burden. *See Muller v. Synthes Corp.*, 2002 WL 460827 at *8 (N.D. Ill.) (granting defendants' motion for summary judgment after having ruled that expert's testimony was inadmissible under *Daubert*, because "evidence of cracked [cervical spine locking plates] is not sufficient by itself to raise a question of fact—or to prove—that the [cervical spine locking plates] were defective"); *Cooper v. Smith & Nephew Inc.*, 259 F.3d 194, 203-04 (4th Cir. 2001) (affirming the district court's grant of summary judgment in favor of the defendant in a spinal fusion device case where the testimony of plaintiffs' expert witness was excluded under *Daubert*); and *Jaurequi v. Carter Manu. Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999) (affirming summary judgment for manufacturer in design and warning product liability case after affirming exclusion of expert testimony under *Daubert*). Accordingly, defendants' motion for summary judgment is granted.

V. CONCLUSION

For the reasons outlined above, defendants' motion to exclude expert testimony and for summary judgment, filed originally on October 11, 2001 (clerk's #58), and renewed on April 30, 2002 (clerk's #75), are granted. The Clerk of Court is directed to enter judgment in favor of defendants and against plaintiffs.

IT IS ORDERED.

Dated this 10th day of September, 2002.



RONALD E. LONGSTAFF, Chief Judge
United States District Court