UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
URBANA DIVISION

ARTHUR W. FUESTING,	)	
	)	
Plaintiff,	)	**02-2251**
	)	
v.	)	
	)	
ZIMMER, INC.,	)	
	)	
Defendant.	)	

OPINION

This case is before the court on remand for a new trial. The plaintiff, Arthur W. Fuesting (Fuesting), commenced this action for breach of the implied warranty of merchantability, products liability, and negligence. Fuesting claims that his prosthetic knee joint, manufactured by defendant, Zimmer, Inc. (Zimmer) was defective. He claims that Zimmer's method of sterilization led to severe oxidation and failure of the prosthesis.

After a trial lasting almost five days, a jury returned a verdict in favor of Fuesting, and awarded damages of $650,000. On appeal, the Seventh Circuit reversed and ordered that judgment be entered in favor of Zimmer. Fuesting v. Zimmer, 421 F.3d 528 (7th Cir. 2005) (Fuesting I). The Seventh Circuit later vacated the instruction to enter judgment for Zimmer and ordered a new trial. Fuesting v. Zimmer, 448 F.3d 936 (7th Cir. 2006) (Fuesting II).

Zimmer has now filed a Motion for Summary Judgment. For the following reasons, the motion (#123) is granted.

BACKGROUND

In 1985, after a number of years of decreasing function in his left knee, Fuesting visited Dr. James McKechnie, an orthopedic surgeon. Dr. McKechnie reviewed Fuesting's x-rays and determined that Fuesting was a good candidate for total knee replacement. Dr. McKechnie performed the surgery in 1985, using Zimmer's Insall Burstein Knee System (I/B knee).

In 1990, Fuesting began to complain of increasing pain in his other knee. In February 1992, Dr. McKechnie performed a total knee replacement on Fuesting's right knee, again using an I/B knee. Post-operatively, Fuesting progressed normally and resumed an active lifestyle. Both I/B knees functioned well. Dr. McKechnie did not see Fuesting between 1994 and 2001.

In 2001, Fuesting again began to experience increasing right knee pain. X-rays taken during that visit showed a stable appearance of the prosthesis with no evidence of loosening. But Fuesting continued to have pain and, in November 2001, Dr. McKechnie removed the right I/B knee. During the surgery, Dr. McKechnie noticed fragments of polyethylene in the surgical area.

Fuesting claims that Zimmer's sterilization of the prosthesis by gamma irradiation in air (GIA) rendered the prosthesis defective. Prior to the first trial, Fuesting proffered the testimony of two witnesses in support of his claim: Dr. McKechnie and Dr. James Pugh. Zimmer filed a motion in limine to exclude Dr. Pugh's testimony on causation and damages, which was denied. At trial, Dr. Pugh testified that GIA caused the prosthesis to oxidize and delaminate, resulting in premature failure. He opined that any knee implant manufactured with the same materials and sterilized using GIA would be defective. Dr. McKechnie concurred with Dr. Pugh's opinion.

In Fuesting I, the Seventh Circuit ruled that Dr. Pugh's testimony did not meet the

requirements of Federal Rule of Evidence 702 or the standards set forth in Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Fuesting was unable to show defect or causation because there was "absolutely no other evidence in support of those elements." Fuesting I, 421 F.3d at 537. However, in Fuesting II, the Seventh Circuit noted that "there was other evidence in the record supporting Fuesting's claims even after Dr. Pugh's testimony was excluded." Fuesting II, 448 F.3d at 941.

Zimmer has filed a motion to exclude Fuesting's new expert witness, Dr. Robert M. Rose, as well as the expert testimony of Dr. McKechnie. Arguing that Fuesting's experts do not survive the Daubert analysis, Zimmer has moved for summary judgment, to which Fuesting has responded and Zimmer has replied. At a conference on January 21, 2009, the parties were offered the opportunity to bring their experts to court for additional examination prior to trial. The parties declined to do so and stated that they considered the matter fully and properly briefed.

ANALYSIS

The Seventh Circuit has set out a framework to determine the admissibility of expert testimony – generally, and specific to this case. See Fuesting I, 421 F.3d at 534-37. The admissibility of expert testimony is governed by Rule 702 and Daubert, 509 U.S. 579. The proponent of the proffered testimony bears the burden to show, by a preponderance of the evidence, that the testimony is both relevant and reliable. TRW Title Ins. Co. v. Security Union Title Ins. Co., 890 F. Supp. 756, 758 (N.D. Ill. 1995).

Rule 702 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.

The court is required to make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." Daubert, 509 U.S. at 592-93. Daubert sets forth a list of guideposts to aid in this assessment. Fuesting I, 421 F.3d at 534.

> Daubert factors include:
>
> (1) whether the scientific theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the theory's known or potential rate of error when applied; and (4) whether the technique or theory has been 'generally accepted' in the scientific community.

The 2000 Advisory Committee Notes to Rule 702 set forth additional benchmarks against which to test the expert's reliability:

> (5) whether maintenance standards and controls exist; (6) whether the testimony relates to matters growing naturally and directly out of research they have conducted independent of the litigation, or developed expressly for the purposes of testifying; (7) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (8) whether the expert has adequately accounted for obvious alternative explanations; (9) whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting; and (10) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.

Fuesting I, 421 F.3d at 534-35 (internal citations omitted). The Seventh Circuit rejected Dr. Pugh's testimony on causation because he "did not conduct any scientific tests or experiments to bolster his theory relating polyethylene delamination to gamma irradiation in air, nor did he produce or rely on any studies to verify his conclusions." Fuesting I, 421 F.3d at 536. Moreover, Dr. Pugh "did not bridge the analytical gap between [the] basic principles [which

Zimmer did not dispute] and his complex conclusions." Fuesting I, 421 F.3d at 536. The court had not been presented with evidence that Dr. Pugh's delamination theory had been published or subjected to peer review, or had gained acceptance in the scientific community – specifically, that "his untested and unpublished theory that polyethylene delamination from oxidation triggered by gamma irradiation results in an appearance distinctive from delamination from other causes - leaving a readily identifiable 'signature' or 'hallmark'- has not received any, let alone general, scientific acceptance." Fuesting I, 421 F.3d at 536-37. That Dr. Pugh developed his opinion expressly for this case also supported a finding that "Pugh's testimony on causation stacks up quite poorly against most all indicia of reliability[.]" Fuesting I, 421 F.3d at 537.

The Court of Appeals also rejected Dr. Pugh's testimony on defect because he did not reliably compare sterilization by GIA with the proffered alternatives. Fuesting I, 421 F.3d at 537. The court noted that Dr. Pugh failed to show that better sterilization methods were available in 1991, or that Zimmer should have known of the alternatives at the time. Fuesting I, 421 F.3d at 537. Moreover, Dr. Pugh did not consider other factors that counseled the use of GIA. Fuesting I, 421 F.3d at 537.

I. Zimmer's Motions to Exclude Experts

Dr. Rose states that Fuesting's prosthesis failed *in vivo* because it was sterilized by GIA, which makes the polyethylene components more susceptible to oxidation and deterioration. Fuesting's prosthesis was subjected to three different oxygenated environments in which oxidation might occur. The prosthesis was sterilized in air and stored for seven months until Fuesting's surgery. It remained *in vivo* for approximately nine years before it was explanted. Thereafter, it was sterilized and kept in an air environment for at least six years, until Dr. Rose

performed his testing. The prosthesis could have oxidized in any or all of those environments, though the rate of oxidation in each environment has not been quantified.

Dr. Rose bolsters his opinion with several peer-reviewed articles that he wrote as early as 1979, which describe scientific tests and reported outcomes developed in the course of his academic pursuits. In addition, Dr. Rose cites the studies of others who have done research on the issue of GIA and polyethylene oxidation.[1] Zimmer has cited and adopted some of Dr. Rose's findings in a 1995 internal research report.[2] As noted in Fuesting I, "even Zimmer concedes [that] gamma irradiation of polyethylene can create free radicals that bond with oxygen, thereby decreasing its molecular weight by keeping molecular chains from reforming, increasing its density, and making the polyethylene susceptible to delamination." Fuesting I, 421 F.3d at 536. And Zimmer's internal research publications adopt the conclusion that the oxidation from GIA leaves a tell-tale appearance of a "white band" representing oxidation in polyethylene.[3]

But Dr. Rose has not bridged the analytical gap between accepted principles and his complex conclusions. He has not, and cannot, show that the prosthesis failed because of the

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[1] Dr. Rose concedes that most of the literature he cited in support of his theory was "largely concerned with oxidation which occurred prior to implantation, during storage of the device." Rose Expert Report, at 5. Yet, he contends that Fuesting's implant oxidized mostly *in vivo*. Thus, the literature is of questionable value in supporting this aspect of his conclusion.

[2] See Hawkins, M.E., Ultra-High Molecular Weight Polyethylene (1995) (citing Rose, R., et al., Effect of Radiation Sterilization and Aging on Ultrahigh Molecular Weight Polyethylene, J. Biomed. Mater. Res.; 15:209-250 (1988)). "The effect of oxidation is measurable in the wear performance. In the case of sterilization, oxidation occurs when the polymer is irradiated in the presence of oxygen. . . . The result is a decrease in the wear performance. Rose, et al., demonstrated an increase in wear with increasing radiation dose. The data . . . confirm the findings of the work of Rose." Hawkins, at 3.

[3] See Johnson, T. et al., Nitrogen Packaging and Gamma-Irradiation Sterilization of UHMWPE (1997).

sterilization method used. To bridge the gap, Dr. Rose must show,

> *with respect to Fuesting's implant in particular*, what quantum of each variable is required to set this agreed upon chain reaction in motion. How much radiation does it take to cause oxidation, and to what degree? How much oxidation must occur to render polyethylene more susceptible to delamination? And once polyethylene becomes more susceptible to delamination, how then does oxidation affect delamination? Are all forms of polyethylene, including that used by Zimmer (which the company claims to be oxidation-resistant), susceptible to delamination? What effect, if any, does implantation into the human body have on the rate of oxidation?

Fuesting I, 421 F.3d at 536 (emphasis added).

Dr. Rose does not answer many, if not most, of these questions, and gives some answers generally rather than with respect to Fuesting's implant in particular. Dr. Rose opines that the oxidative degradation of Fuesting's implant largely occurred *in vivo*. Rose Dep. 51. He admitted that oxidation *in vivo* occurs in implants that are sterilized by any method. Rose Dep. 52. He was unaware of any peer-reviewed studies or publications that attempt to compare the rate or severity of oxidation *in vivo* of implants sterilized in an air environment versus other sterilization methods. Rose Dep. 51-52. Nonetheless, he concluded that GIA rendered the prosthesis unsafe and unfit for use. Rose Dep. 53.

Moreover, the explanted prosthesis showed significant oxidation (represented by the white bands) when it was *tested* – more than six years after explantation. Yet, Dr. Rose fails to account for the oxidation that occurred after the explanted prosthesis was steam-autoclaved[4] and stored in an air environment for those six years. This undermines his testimony, especially because he states that the prosthesis showed oxidation levels consistent with those expected after

[4] Dr. McKechnie stated that steam autoclaving requires high heat, making it "likely that any oxidating process would be accelerated during that space of time." He did not quantify the acceleration, however. McKechnie Dep. 66.

five to seven years of shelf aging. Rose Dep. 31. Fuesting's prosthesis had been sterilized with GIA at least sixteen years earlier, and was stored in air for at least six years after explantation and before testing. That *in vivo* oxidation accounts for most of the oxidation in Fuesting's implant is not supported by citation to any reference nor does Dr. Rose explain this conclusion.

In addition, Dr. Rose has not shown that the implant failed *because of* the oxidation. He states that the cratering, pitting and delamination occurred at the level of the white bands (in other words, at the level of significant oxidation). He concluded that "the wear, pitting, cratering and delamination . . . is clearly related to the white layer observed, so it is also clear that the failure of the device was caused by the extensive oxidation which had occurred before explantation." Rose Expert Report, at 5-6. A clear relationship does not equal causation. This analytical gap is most crucial because Dr. Rose fails to account for another possible conclusion. The failure *in vivo* might have been caused by another factor or combination of factors (for example, Fuesting's weight distribution and gait), and, as the prosthesis failed over time, newly damaged areas of polyethylene could have been exposed to an oxygenated environment, resulting in oxidation to the level of the damage. Dr. Rose does not bridge the analytical gap as to causation.

The Court of Appeals also found inadequate Dr. Pugh's testimony on defect because he did not do an adequate comparison of GIA with the proffered alternatives, or show that better methods of sterilization were available in 1991 and that Zimmer should have known of them at that time. Fuesting I, 421 F.3d at 537. Also, Dr. Pugh did not consider factors favoring the use of GIA. Fuesting I, 421 F.3d at 537. As noted above, Dr. Rose opined that oxidation occurs *in vivo* regardless of the sterilization method, and he further stated that radiation sterilization has

the added benefit of molecular cross-linking, which strengthens the polyethylene. Rose Dep. 42-43. Dr. Rose also conceded that in 1991, when Fuesting's I/B knee was manufactured, no orthopedic implant manufacturers in this country sterilized their knee implants with Dr. Rose's preferred method of ethylene oxide sterilization. Rose Dep. 35. Thus, his testimony on defect fares no better than Dr. Pugh's.

In Fuesting II, the court determined that there was other evidence supporting Fuesting's claims after Dr. Pugh's evidence was excluded. Fuesting II, 448 F.3d at 941. Dr. McKechnie provided the other evidence. He is again offered as an expert, but he admits that his opinions about the probable processes that came into play with Fuesting's implant are based on Dr. Rose's interpretation of the test results. McKechnie Dep. 81. Dr. McKechnie's testimony is admissible if limited to the care, treatment, prognosis, and/or conditions present during Fuesting's surgery. His testimony beyond that of a treating physician does not satisfy the Daubert factors, so he is unable to offer an expert opinion as to causation and defect.

Zimmer's Motions to Exclude the Expert Testimony of Dr. Rose and Dr. McKechnie are granted.

II. Motion for Summary Judgment

Zimmer argues that it is entitled to summary judgment on the strict liability and negligence claims. Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The party moving for summary judgment must show the lack of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "[A] complete failure of proof

concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex, 477 U.S. at 323.

To prevail on his strict liability and negligence claims, Fuesting must show the existence of a defective condition in the product when it left the manufacturer's control, and a causal link between the design defect and the injury. Fuesting I, 421 F.3d at 532. Without the testimony of Dr. Rose or the expert testimony of Dr. McKechnie, Fuesting cannot make the requisite showing. Therefore, he cannot prevail on these claims.

Zimmer also moves for summary judgment on Fuesting's claim for breach of the implied warranty of merchantability. Zimmer was granted summary judgment on this claim before the first trial. Fuesting has not attempted to pursue the claim on retrial.

Consequently, the court grants Zimmer's motion for summary judgment in its entirety.

IT IS THEREFORE ORDERED:

(1) Zimmer's Motion to Exclude In Limine the Testimony of Robert Rose (#119) is GRANTED;

(2) Zimmer's Motion to Exclude in Limine the Testimony of Dr. James McKechnie (#121) is GRANTED IN PART and DENIED IN PART; Dr. McKechnie is barred from presenting an expert opinion on causation and damages;

(3) Zimmer's Motion for Summary Judgment (#123) is GRANTED;

(4) All other pending motions (#140, #142, #144) are MOOT;

(5) This case is terminated.

ENTERED this 26th day of January, 2009.

s/Michael P. McCuskey

MICHAEL P. McCUSKEY
CHIEF JUDGE