In the
United States Court of Appeals
For the Seventh Circuit

No. 04-2158

ARTHUR W. FUESTING,

Plaintiff-Appellee,

v.

ZIMMER, INC.,

Defendant-Appellant.

Appeal from the United States District Court
for the Central District of Illinois.
No. 2:02-CV-02251—**Harold A. Baker**, *Judge.*

ARGUED JANUARY 4, 2005—DECIDED AUGUST 30, 2005

Before FLAUM, *Chief Judge*, and EVANS and WILLIAMS, *Circuit Judges.*

WILLIAMS, *Circuit Judge.* In this strict liability and negligence case, plaintiff Arthur W. Fuesting sued defendant Zimmer, Inc., an orthopaedic implant manufacturer, for damages resulting from the failure of his prosthetic knee. After a jury trial, where Fuesting was awarded $650,000, Zimmer appeals, arguing that the district court erroneously applied Federal Rule of Civil Procedure 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) in admitting unreliable expert testimony. Because we find that the district court did err in admitting unreliable expert testimony, we reverse. We further find that Fuesting cannot prevail on his claims as a mat-

ter of law without this improperly admitted testimony. Finally, we remand the case to the district court with instructions to direct a verdict in defendant's favor.

I. BACKGROUND

Zimmer is a manufacturer of orthopaedic implants and in 1991 manufactured an implant known as the I/B Knee, which was designed to increase the mobility of knee joints and to restrict involuntary knee motion. It is used in a medical procedure called total knee anthroplasty, which is a procedure that involves the replacement of three bone surfaces with artificial components: the lower end of the femur (thigh bone); the top surface of the tibia (shin bone); and the back surface of the patella (knee cap). The I/B Knee has a metal femoral component, a dome-shaped patellar component, and a metal tibial bone plate with an ultra-high molecular weight polyethylene surface molded on top. In 1991, Zimmer sterilized all of its I/B Knee implants through a process known as gamma irradiation in an air environment—a sterilization method almost universally employed by knee prosthesis manufacturers at that time.

Fuesting, who suffers from arthritis in both knees, had his right knee replaced with one of Zimmer's I/B Knee implants on February 5, 1992.[1] The procedure was performed by Fuesting's treating orthopaedic surgeon, Dr. James McKechnie. The tibial component of this particular implant had been manufactured and sterilized seven months before the procedure—a period of "time on the shelf" considered short by industry standards. By May of 2001, Fuesting began experiencing pain and swelling in the right

[1] In 1985, Fuesting had his left knee replaced with one of Zimmer's I/B Knee implants. To date, this implant continues to function well.

knee. Accordingly, on November 14, 2001, Dr. McKechnie replaced the Zimmer knee implant with a Johnson & Johnson model.[2] Due to grinding and crunching in the new model, the knee was replaced yet again on April 23, 2003.

In October 2002, Fuesting brought two claims against Zimmer related to its I/B Knee based on theories of strict liability and negligence related to design defect. The defect in the design of the I/B Knee, according to Fuesting, was the method in which it was sterilized at the time of its manufacture (gamma irradiation in air). In support of his claim, the plaintiff proffered two witnesses: his treating orthopaedic surgeon (Dr. McKechnie) and an expert witness by the name of James Pugh.

Pugh, a litigation consultant, was vital to both Fuesting's theories of liability, opining as to both causation and defect. With respect to causation, Pugh opined that Zimmer's chosen method of sterilization, as well as the implant's time on the shelf, caused the implant's polyethylene to oxidate, and ultimately delaminate and prematurely fail. As to defect (and negligence for that matter), it was Pugh's opinion that alternative sterilization methods (such as ethylene oxide and gamma irradiation in an inert environment) were available to Zimmer in 1991; that these methods were better than gamma irradiation in air; and that Zimmer should have known of them at the time of the I/B Knee's manufacture.

In a pre-trial motion in limine, Zimmer moved to exclude Pugh's opinions on causation and defect as unreliable under Federal Rule of Evidence 702. The district court denied the motion, allowing Pugh to testify at trial. At trial, Pugh—attributing his opinions to "basic polymer science"—testified that the cause of Fuesting's right I/B Knee's

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[2] The orthopaedic community refers to the replacement of a knee implant as a "revision."

premature failure was its sterilization through gamma irradiation in air, and concluded that any knee implant (with a polyethylene tibial component) sterilized in such a manner would be defective. Dr. McKechnie concurred, based solely on his "major in chemistry."

To debunk the plaintiff's theory on causation, Zimmer offered its own expert testimony at trial. Dr. William Maloney—an orthopaedic surgeon and leading researcher in the field of joint replacement and osteolysis—testified that the delamination in Fuesting's implant was likely attributable not to oxidation of its polyethylene component, but rather to physical abrasions and wear and tear of the implant's components due to peculiarities in Fuesting's gait and bone growth. Maloney further testified that the plaintiff's post-implant weight gain—in contravention of his doctor's advice—exacerbated this wear and tear. In addition, Dr. Albert Burstein, the implant co-inventor, testified that the gamma sterilization process probably did not cause oxidation, that wear and tear caused the failure, and that the implant was a tremendous clinical success. Burstein further testified that Pugh's proffered, alternative sterilization process was more dangerous and more likely to cause wear.

In response to Fuesting's theory on design defect, Zimmer sought to introduce evidence on the state of the art of implant sterilization in 1991 through Dr. Albert Burstein. In contrast to Pugh's opinion on defect, Dr. Burstein would testify as the I/B Knee's co-inventor that in 1991 it was virtually universal industry practice to sterilize implants by gamma irradiation in air. Fuesting objected to this testimony, arguing that the data and other information that Burstein considered in forming his opinion on state of the art had not been disclosed to the plaintiff as required of Rule 702 witnesses by Federal Rules of Civil Procedure 26(a)(2)(A) & (B). The district court agreed, and, despite having allowed Fuesting to introduce evidence that Zimmer

and other manufacturers today sterilize implants in inert (as opposed to open air) environments, barred Dr. Burstein's state of the art testimony.

The jury found in favor of Fuesting, awarding him $650,000. On appeal, Zimmer challenges, among other things, the denial of its motion to exclude Pugh's testimony on causation and defect.

II. ANALYSIS

In both strict liability and negligence actions regarding design, Illinois law (under which Fuesting's claims proceed) requires plaintiffs to establish "the existence of a defective condition in the product at the time it left the manufacturer's control," *Carrizales v. Rheem Mfg. Co.*, 589 N.E.2d 569, 580 (Ill. App. Ct. 1991), and "a causal link between the alleged design defect . . . and [the plaintiff's] injury," *Baltus v. Weaver Division of Kidde & Co.*, 557 N.E.2d 580, 586 (Ill. App. Ct. 1990). Toward both these ends, Fuesting proffered the expert testimony of Pugh—the propriety of which rests at the center of this appeal. Before reaching the merits of Zimmer's appeal, however, we must first address its motion to strike a portion of Fuesting's appellate response brief.

A. Zimmer's Motion to Strike Portions of Fuesting's Brief on Appeal Granted

In the first five pages of his Response brief—a portion of his statement of facts entitled "Published Literature"—Fuesting cites several medical journal articles that suggest that implant sterilization by gamma irradiation in air causes ultra high molecular weight polyethylene components to oxidize. He marshals these articles here in an apparent effort to bolster his expert's testimony on causation and defect. Indeed, these works may suggest that

Pugh's challenged conclusions have received some modicum of acceptance from the scientific community. The problem is, these articles cannot be found in the record.

Accordingly, Zimmer argues that this portion of Fuesting's statement of facts must be stricken as violative of Seventh Circuit Rule 28(c). Rule 28(c) requires that an appellate brief's statement of facts "be a fair summary without argument or comment. No fact shall be stated as part of the brief unless it is supported by reference to the page or pages of the record or appendix where that fact appears." The articles cited in the first five pages of Fuesting's Response were neither before the district court during its *Daubert* briefing on the admissibility of Pugh's testimony, nor referenced by Pugh in his expert report, nor authenticated, moved, or admitted into evidence. And while the quotes from these articles can be found on the trial transcript, they appear there only by virtue of Fuesting's counsel having read sentences from each article to Zimmer's expert witness (Dr. Burstein) during cross-examination. What's more, once read to him, the quotes almost invariably met with Dr. Burstein's disapproval. *Cf.* Fed. R. Evid. 803(18) (excepting "statements contained in published treatises, periodicals, or pamphlets on a subject of . . . medicine, or other science" from the rule excluding hearsay provided that such treatises have been "called to the attention of an expert witness upon cross-examination" and "*established as a reliable authority by the testimony or admission of the witness* or by other expert testimony or by judicial notice") (emphasis added).

This is not the first time that the propriety of this portion of Fuesting's brief has been challenged. In a previous motion to strike pursuant to Rule 28(c), which we granted on October 4, 2004, Zimmer noted these very same deficiencies, as well as one more—a failure to provide cites to the record or an appendix where the contested articles could be

found. Fuesting has since revised his brief to include requisite cites to the record, arguing now that such amendments have cured any previously found deficiencies.

But Rule 28(c) requires more of litigants than mere support citations and record references. It also requires that appellate brief fact statements be a *fair* summary of the facts. *See Day v. N. Ind. Pub. Serv. Corp.*, 164 F.3d 382, 384-85 (7th Cir. 1999) (granting motion to strike pursuant to Rule 28(c) where portion of fact statement was argumentative and unsupported by citation). The reasons for requiring a fair summary are patent and aplenty, and chief among them is the efficient administration of the appellate process. *See id.* ("Rule 28(c) is vital to efficient performance of the appellate task."). Citations to the record designed to convince the court of a fact devoid of basis in the record impede that administration. They are in effect designed to mislead the court, and for that reason are, to put it mildly, not fair. Thus, misleading factual assertions and citations violate Rule 28(c) too. *See McDonald v. Village of Winnetka*, 371 F.3d 992, 1009 n.11 (7th Cir. 2004) (noting that misleading cites to the record violate Rule 28(c)). Set forth without context or qualification, Fuesting's quotations from articles neither before the court nor in evidence as "facts" are misleading, and thus violate Rule 28(c). Therefore, Zimmer's renewed motion to strike is granted, and this court will not consider the first five pages of Fuesting's amended response.

B. Inadequate *Daubert* Inquiry

Proceeding to the merits of the appeal, Zimmer challenges the district court's denial of its pre-trial motion to exclude Pugh's expert testimony on causation and defect. The admissibility of scientific expert testimony is governed by Federal Rule of Evidence 702, and in particular *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). "We first undertake a *de novo* review of whether the district court properly followed the framework set forth in *Daubert*." *Bradley v. Brown*, 42 F.3d 434, 436 (7th Cir. 1994). "Provided the district court adhered to *Daubert*'s parameters, we will not disturb the district court's findings unless they are manifestly erroneous." *Id.* at 436-37.

Rule 702 provides:

> 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.

Daubert has construed Rule 702 as requiring the district court to perform a "gate-keeping function" before admitting expert scientific testimony. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993). This function is to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* Before even considering whether the testimony "will assist the trier of fact to understand or determine a fact in issue," a district court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is

scientifically valid." *Id.* at 592-93.

To aid courts in assessing the reliability of scientific expert testimony, the *Daubert* Court set forth the following, non-exhaustive list of "guideposts" for consideration: (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 theory has been "generally accepted" in the scientific community. *Id.* at 593-94; *see also Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002). In addition to these factors, the 2000 Advisory Committee's Notes to Rule 702 suggest other benchmarks for gauging expert reliability, including: (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 purposes of testifying"; (7) "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; (8) "[w]hether the expert has adequately accounted for obvious alternative explanations"; (9) "[w]hether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting"; and (10) "[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give." Fed. R. Evid. 702 advisory committee's note (2000 amends.).

While the particular factors identified in *Daubert* may not always be pertinent in assessing the reliability of expert testimony, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999), they are precisely apt for analysis here, *see Daubert*, *supra* (concerning the admissibility of expert testimony regarding the deleterious medical effects of introducing a foreign substance—the antinausea drug, Bendectin—into the human body). And while we again must emphasize that the *Daubert* inquiry is a flexible one, and that an expert's

testimony need not satisfy each of the above factors to be admissible, it is nonetheless crucial that a *Daubert* analysis of some form in fact be performed. *Chapman*, 297 F.3d at 687.

Although the district court offered a relatively lengthy discussion of Pugh's credentials, the court's *Daubert* factor analysis was not sufficient. As the court noted in assessing whether the expert had the requisite "knowledge, skill, experience, training, or education," Pugh obtained an undergraduate degree from the Massachusetts Institute of Technology (MIT) in Metullurgy and Materials, and a doctorate from MIT in Biomedical Engineering; he has extensive experience in the fields of biomedical engineering, metullurgy, and materials science, including professorships at colleges of engineering and medicine; and he has long studied polyethylene failure (the chemical that allegedly delaminated, causing Fuesting's implant to fail). Accordingly, the court rightly concluded that "Dr. Pugh possesses the requisite knowledge, skill, experience, training, and education pursuant to Fed. R. Evid. 702."

But possessing requisite credentials alone is not enough to render expert testimony admissible. *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999) ("A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are reliable and relevant under the test set forth by the Supreme Court in *Daubert*."). The district court must also, in keeping with its gatekeeper's duty, assess the reliability of the *methodology* the expert has employed in arriving at his opinion. This the district court did not do. Instead, the court made reference to Pugh's deposition, satisfying itself that "his analysis was discussed at length throughout the deposition [where] he articulated a scientific reason for the failure of the polyethylene in Fuesting's knee" without "rely[ing] on generalized analogies or inapplicable scientific principles." But nothing is said as to what exactly that articulated scientific reason

is, or how it measures up to *Daubert*'s indicia of reliability. The court, invoking again Pugh's deposition as well as his expert report, further found that the expert had sufficiently ruled out Fuesting's weight and activity level as potential causes of polyethylene failure in the plaintiff's implant. But the court made no mention of how Pugh ruled those alternative causes out, let alone whether and why it found that method reliable. To satisfy its essential role, the gatekeeper must do more than just make conclusory statements. A more searching *Daubert* analysis is required, and we find the district court's examination of Pugh's testimony inadequate.

Indeed, when subjected to a more thorough *Daubert* analysis, Pugh's testimony proves unreliable, as its juxtaposition against the *Daubert* guideposts plainly reveal. Turning first to his testimony on causation, Pugh opined that Zimmer's chosen method of sterilization (gamma irradiation in air), as well as the implant's time on the shelf (seven months), caused the implant's polyethylene to oxidate, then delaminate, and ultimately fail. "The first and most significant *Daubert* factor is whether the scientific theory has been subjected to the scientific method." *Bradley,* 42 F.3d at 438. Here, it is undisputed that Pugh 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 upon any studies to verify his conclusions. *See Chapman*, 297 F.3d at 688 (finding error in the admission of expert testimony unsupported by scientific tests, experiments, and studies). Such insulation of his theory from the dispassionate crucible deeply, if not fatally, compromises his testimony's reliability.

Another indicator of unreliability is the unjustifiable extrapolation from an accepted premise to an unfounded conclusion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great

an analytical gap between the data and the opinion proffered."); *McMahon v. Bunn-O-Matic Corp.*, 150 F.3d 651, 657-58 (7th Cir. 1998) (holding that a "bare conclusion" offered without explanation or empirical support fails the reliability requirement of Rule 702); Fed. R. Evid. 702 advisory committee's note (2000 amends.) (listing "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion" as a relevant factor in determining reliability of expert testimony). Rather than relying upon tests, experiments or studies, Pugh attributed his opinion to "basic polymer science," which, even Zimmer concedes, reveals that gamma irradiation of polyethylene can create free radicals that bond with oxygen, thereby decreasing its molecular weight by keeping molecular chains from re-forming, increasing its density, and making the polyethylene susceptible to delamination. The problem here is that Pugh did not bridge the analytical gap between these basic principles and his complex conclusions. For example, he did not specify, 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? Basic polymer science alone cannot answer these questions. Some greater methodology is required to bridge the analytical gap between general principles and particular conclusions, and to vest thereby the opinion with requisite reliability.

Furthermore, Pugh's delamination theory has not

been published or otherwise subjected to peer review, and there is no evidence that his theory has gained general acceptance in the scientific community. *See Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996) ("Rule 702 is designed to ensure that, when expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work. This objective can be accomplished in a number of different ways, including through the review of experimental, statistical, or other scientific data generated by others in the field."). In particular, 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. To the contrary, the record suggests that the I/B Knee at issue is one of the most successful knee implants ever studied, has the longest and highest survivorship rate published for any knee prothesis, and has even been called the "gold standard" of its kind.

Finally, while there is some genuine disagreement as to whether Pugh has adequately accounted for alternative causes of the implant's failure, Fuesting does not dispute that Pugh developed his opinion expressly for this litigation. All told, Pugh's testimony on causation stacks up quite poorly against most all indicia of reliability, rendering the district court's decision to admit the opinion error.

Nor does Pugh's testimony on defect pass Rule 702 muster. As to defect, Pugh testified that alternative sterilization methods (such as ethylene oxide and gamma irradiation in an inert environment) were available to Zimmer in 1991; that these methods were better than gamma irradiation in air; and that Zimmer should have known of them at the time of the I/B Knee's manufacture. But here again Pugh failed to perform a reliable comparison

of the chosen sterilization technique with the proffered alternatives. Instead, he relied solely on the fact that the gamma irradiation in air causes more oxidation than other methods, while neglecting to consider other factors that may have counseled the use of that chosen method (such as effectiveness in sterilization, or minimizing implant wear and tear).

Furthermore, Pugh's testimony that Zimmer should have sterilized the subject implant through gamma irradiation in an inert environment is wholly unfounded. The record reveals that, at the time of the subject I/B Knee implant's manufacture (1991), it was virtually universal industry practice to sterilize such implants by gamma irradiation in air. Indeed, no manufacturer at that time employed any of Pugh's proffered methods, and Pugh has cited no contemporary articles counseling the use of such methods. Accordingly, the district court's decision to admit Pugh's opinion on defect was also error.

Without Pugh's testimony, Fuesting cannot establish either defect or negligence, as he proffered absolutely no other evidence in support of those elements. And, save for Dr. McKechnie's sparse testimony on the subject—based merely on his "major in chemistry," presenting another untested extrapolation susceptible to Rule 702 challenge—Fuesting has offered no other evidence as to causation. In the absence of such evidence, Fuesting cannot establish the requisite elements of his claim, and thus cannot prevail on his claims as a matter of law. Therefore, we see no reason to remand for a new trial, nor to reach the other issues raised on this appeal. Instead, we reverse this case and remand the matter to the district court with instructions to direct a verdict in favor of defendant.

III. CONCLUSION

For the reasons stated above, we REVERSE the district

court's decision to admit Pugh's expert testimony on causation and defect, and REMAND this case to the district court with instructions to direct a verdict in defendant's favor.

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Clerk of the United States Court of Appeals for the Seventh Circuit