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Reference Manual on Scientific Evidence

Second Edition

Federal Judicial Center □□□□

Preface

… The *Reference Manual* itself responds to a recommendation of the Federal Courts Study Committee that the Federal Judicial Center prepare a manual to assist judges in managing cases involving complex scientific and technical evidence.2

The first edition of the *Reference Manual* was published in 1994, at a time of heightened need for judicial awareness of scientific methods and reasoning created by the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*3 Daubert assigned the trial judge a "gatekeeping responsibility" to make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."4 The first edition of the Reference Manual has been republished by numerous private publishers and used in a variety of educational programs for federal and state judges, attorneys, and law students. The Center estimates that approximately 100,000 copies have been distributed since its initial publication.

This second edition comes after recent decisions that expand the duties and responsibility of trial courts in cases involving scientific and technical evidence. In *General Electric Co. v. Joiner*,5 the Supreme Court strengthened the role of the trial courts by deciding that abuse of discretion is the correct standard for an appellate court to apply in reviewing a district court's evidentiary ruling. In a concurring opinion, Justice Breyer urged judges to avail themselves of techniques, such as the use of court-appointed experts, that would assist them in making determinations about the admissibility of complex scientific or technical evidence.6 **Last**

year, in *Kumho Tire Co. v. Carmichael*, the Supreme Court determined that the trial judge's gatekeeping obligation under *Daubert* not only applies to scientific evidence but also extends to proffers of "'technical' and 'other specialized' knowledge," the other categories of expertise specified in Federal Rule of Evidence 702.7 Also, **the Supreme Court recently forwarded to Congress proposed amendments to Federal Rules of Evidence 701, 702, and 703 that are intended to codify case law that is based on *Daubert* and its progeny.**

This second edition includes new chapters that respond to issues that have emerged since the initial publication. The Introduction by Justice Breyer reviews the role of scientific evidence in litigation and the challenges that trial courts face in considering such evidence. Supreme Court cases subsequent to *Daubert* are summarized in a chapter by Margaret Berger. The philosophy and practice of science are described in a chapter by David Goodstein. New reference guides on medical testimony and engineering will aid judges with the broader scope of review for cases involving nonscientific expert testimony following *Kumho*. Reference guides from the first edition have been updated with new cases and additional material. The Reference Guide on DNA Evidence has been completely revised to take account of the rapidly evolving science in this area. To make room for the new material, essential information from the chapters on court-appointed experts and special masters was condensed and included in the chapter on management of expert evidence.8
(pp. v-vi)

… I. Introduction

On March 23, 1999, the U.S. Supreme Court decided *Kumho Tire Co. v. Carmichael*,1 the third in a series of cases dealing with the admissibility of expert testimony. **The trilogy began in 1993 with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,2 a toxic tort action, in which the Court promulgated a new test for federal courts to use when ruling on the admissibility of scientific evidence. The second case, *General Electric Co. v. Joiner*,3 decided in 1997, likewise dealt with the admissibility of scientific evidence in the context of a toxic tort suit. In *Kumho*, the Court extended the approach of these prior opinions to nonscientific expert testimony proffered in a product liability action. In doing so, *Kumho* provides new insights into the meaning of *Daubert* and *Joiner*, and offers guidance on how federal trial and appellate courts can appropriately respond when a party seeks to exclude an opponent's expert testimony.** Because of its broad scope, *Kumho* is likely to play a significant role in all future rulings on the admissibility of expert proof.4

The opinions in the trilogy are so interrelated that *Kumho*'s significance and potential impact emerge much more clearly when viewed in conjunction with the Court's analyses in the earlier cases. (p. 10)

… **II. The First Two Cases in the Trilogy: *Daubert* and *Joiner***

A. Daubert v. Merrell Dow Pharmaceuticals, Inc.

In the seminal *Daubert* case, the Court granted certiorari to decide whether the so-called *Frye* (or "general acceptance") test, which was used by some federal circuits in determining the admissibility of scientific evidence, had been superseded by the enactment of the Federal Rules of Evidence. **The Court held unanimously that the *Frye* test had not survived. Six justices joined Justice Blackmun in setting forth a new test for admissibility after concluding that "Rule 702 . . . clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify."5** While the two other members of the Court agreed with this conclusion about the role of Rule 702, they thought that the task of enunciating a new rule for the admissibility of expert proof should be left to another day.6

The majority opinion in *Daubert* continued by setting forth major themes that run throughout the trilogy: The trial court is the "gatekeeper" who must screen proffered expertise, and the objective of the screening is to ensure that what is admitted "is *not only relevant, but reliable."*7 There was nothing particularly novel about a trial judge having the *power* to make an admissibility determination. **Federal Rules of Evidence 104(a) and 702 pointed to such a conclusion, and federal trial judges had excluded expert testimony long before *Daubert*. However, the majority opinion in *Daubert* stated that the trial court has not only the power but the *obligation* to act as "gatekeeper."8**

The Court then went on to consider **the meaning of this two-pronged test of relevancy and reliability in the context of scientific evidence.9** With regard **to *relevancy***, the Court explained that **expert testimony cannot assist the trier in resolving a factual dispute, as required by Rule 702, unless the expert's theory is tied sufficiently to the facts of the case. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to**

admissibility."10 This consideration, the Court remarked, "has been aptly described by Judge Becker as one of 'fit.'"11

To determine whether proffered scientific testimony or evidence satisfies the standard of evidentiary ***reliability***,12 **a judge must ascertain whether it is "ground[ed] in the methods and procedures of science."13 The Court**, emphasizing that "[t]he inquiry envisioned by Rule 702 is . . . a flexible one,"14 then **examined the characteristics of scientific methodology and set out a nonexclusive list of four factors that bear on whether a theory or technique has been derived by the scientific method.15 First and foremost the Court viewed science as an *empirical endeavor: "Whether [a theory or technique] can be (and has been) tested"* is the "'methodology [that] distinguishes science from other fields of human inquiry.'"16 Also mentioned by the Court as *indicators of good science are peer review or publication, and the existence of known or potential error rates and standards controlling the technique's operation*.17** Although general acceptance of the methodology within the scientific community is no longer dispositive, it remains a factor to be considered.18
(pp. 11-13)

… *B. General Electric Co. v. Joiner*

The Supreme Court granted certiorari **in *General Electric Co. v. Joiner*,20 the second case in the trilogy, in order to determine the appropriate standard an appellate court should apply in reviewing a trial court's *Daubert* decision to admit or exclude scientific expert testimony**. In *Joiner*, the 37-year-old plaintiff, a longtime smoker with a family history of lung cancer, claimed that exposure to polychlorinated biphenyls (PCBs) and their derivatives had promoted the development of his small-cell lung cancer. The trial court applied the *Daubert* criteria, excluded the opinions of the plaintiff's experts, and granted the defendants' motion for summary judgment.21 The court of appeals reversed the decision, stating that "[b]ecause the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony."22 **All the justices joined Chief Justice Rehnquist in holding that abuse of discretion is the correct standard for an appellate court to apply in reviewing a district court's evidentiary ruling, regardless of whether the ruling**

allowed or excluded expert testimony.23 The Court unequivocally rejected the suggestion that a more stringent standard is permissible when the ruling, as in *Joiner*, is "outcome determinative."24 In a concurring opinion, Justice Breyer urged judges to avail themselves of techniques, such as the use of court-appointed experts, that would assist them in making determinations about the admissibility of complex scientific or technical evidence.25

With the exception of Justice Stevens, who dissented from this part of the opinion, the justices then did what they had not done in *Daubert*—they examined the record, found that the plaintiff's experts had been properly excluded, and reversed the decision without remanding the case as to this issue.26 The Court concluded that it was within the district court's discretion to find that the statements of the plaintiff's experts with regard to causation were nothing more than speculation. The Court noted that the plaintiff never explained "how and why the experts could have extrapolated their opinions"27 from animal studies far removed from the circumstances of the plaintiff's exposure.28 It also observed that the district court could find that the four epidemiological studies the plaintiff relied on were insufficient as a basis for his experts' opinions.29 Consequently, the court of appeals had erred in reversing the district court's determination that the studies relied on by the plaintiff's experts "were not sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCBs contributed to his cancer."30

The plaintiff in *Joiner* had argued that the epidemiological studies showed a link between PCBs and cancer *if the results of all the studies were pooled*, and that this weight-of-the-evidence methodology was reliable. Therefore, according to the plaintiff, the district court erred when it excluded a conclusion based on a scientifically reliable methodology because it thereby violated the Court's precept in *Daubert* that the "'focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.'"31 The Supreme Court responded to this argument by stating that

> conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But **nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to**

existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.32

Justice Stevens, in his partial dissent, assumed that the plaintiff's expert was entitled to rely on such a methodology, which he noted is often used in risk assessment, and that a district court that admits expert testimony based on a *weight-of-the-evidence* methodology does not abuse its discretion.33 Justice Stevens would have remanded the case for the court below to determine if the trial court had abused its discretion when it excluded the plaintiff's experts.34
(pp. 13-4)

III. *Kumho Tire Co. v. Carmichael*

… *C. The Supreme Court Opinion*

All the justices of **the Supreme Court, in an opinion by Justice Breyer, held that the trial court's gatekeeping obligation extends to all expert testimony46 and unanimously rejected the Eleventh Circuit's dichotomy between the expert who "'relies on the application of scientific principles'" and the expert who relies on "'skill- or experience-based observation.'"47 The Court noted that Federal Rule of Evidence 702 "makes no relevant distinction between 'scientific' knowledge and 'technical' or 'other specialized' knowledge," and "applies its reliability standard to all . . . matters within its scope."48** Furthermore, said the Court, "no clear line" can be drawn between the different kinds of knowledge,49 and "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."50

The Court also unanimously found that the court of appeals had erred when it used a de novo standard, instead of the *Joiner* abuse-of-discretion standard, to determine that *Daubert*'s criteria were not reasonable measures of the reliability of Carlson's testimony.51 As in *Joiner,* and again over the dissent of Justice Stevens,52 the Court then examined the record and concluded that the trial court had not abused its discretion when it excluded Carlson's testimony. Accordingly, it reversed the opinion of the Eleventh Circuit.

The opinion adopts a flexible approach that stresses the importance of identifying "the particular circumstances of the particular case at issue."53 The court must then make sure that the proffered expert will observe the same standard of "intellectual rigor" in testifying as he or she would employ when dealing with similar matters outside the courtroom.54

The crux of the disagreement between the parties was whether extending the trial judge's *Daubert* gatekeeping function to all forms of expert testimony meant that the trial judge would have to apply *Daubert*'s four-factor reliability test in all cases. The defendant had stated at oral argument that the factors discussed in *Daubert* were "always relevant."[55] Justice Breyer's opinion rejects this notion categorically:

> The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.56

The *Daubert* factors "*may*" bear on a judge's gatekeeping determinations, however.57 The four *Daubert* factors "'may or may not be pertinent'"; it will all depend "'on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'"58 Determining which factors are indicative of reliability in a particular case cannot be accomplished solely by categorical a priori characterizations about the particular field in question. The Court explained:

> "Engineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases. . . . In other cases, the relevant reliability concerns may focus upon personal knowledge or experience."59 In all cases, a court must exercise its gatekeeping obligation so that the expert, whether relying on "professional studies or personal experience," will, when testifying, employ "the same level of intellectual rigor" that the expert would use outside the courtroom when working in the relevant discipline.60

How this extremely flexible approach of the Court is to be applied emerges in Part III of the opinion when **the Court engages in a remarkably detailed analysis of the record that illustrates its comment in *Joiner* that an expert must account for "how and why" he or she reached the challenged opinion.61** The Court refused to find that the methodology Carlson was advocating could never be used by an expert testifying about tire failures:

> [C]ontrary to respondents' suggestion, the specific issue before the court was not the reasonableness in general of a tire expert's use of a visual and tactile inspection to determine whether overdeflection had caused the tire's tread to separate from its steel-belted carcass. **Rather, it was the reasonableness of using such an approach, along with Carlson's particular method of analyzing the data thereby obtained, to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant**. That matter concerned the

likelihood that a defect in the tire at issue caused its tread to separate from its carcass.62

(pp. 15, 17-20)

… IV. The Implications of the *Kumho* Opinion

A. A Comparison of Kumho *and* Daubert

1. Differences in emphasis between Daubert *and* Kumho

Nothing the Supreme Court said in *Kumho* is explicitly inconsistent with what it said in *Daubert*. **As Justice Breyer's opinion stated, *Daubert* described "the Rule 702 inquiry as 'a flexible one,'"71 and made "clear that the factors it mentions do not constitute a 'definitive checklist or test.'"72 Nevertheless, *Kumho* may indicate that the Court has somewhat backed away from laying down guidelines for particular categories of expert testimony. Certainly the Court's opinion does not support those who construed *Daubert* as creating a four-factor test for scientific evidence**, or those who thought that the Court might in subsequent cases articulate classification schemes for other fields of expertise.73

The Court seems less absorbed in epistemological issues, in formulating general rules for assessing reliability, or in fleshing out the implications of its having singled out testability as the preeminent factor of concern. It appears less interested in a taxonomy of expertise and more concerned about directing judges to concentrate on "the particular circumstances of the particular case at issue."74 This flexible, nondoctrinaire approach is faithful to the intention of the drafters of the Federal Rules of Evidence, who viewed Article VII as setting forth flexible standards for courts to apply rather than rigid rules. **In *Kumho*, the Court contemplated that there will be witnesses "whose expertise is based purely on experience," and although it suggested that *Daubert*'s questions may be helpful in evaluating experience-based testimony, it did not single out testability as the preeminent factor of concern, as it did in *Daubert*.75**

…**It may also be significant that in *Kumho* the Court was silent about the distinction between admissibility and sufficiency. In the interim between *Daubert* and *Kumho*, disputes involving expert testimony have increasingly been addressed as questions of admissibility**. Because *Daubert* requires judges to screen expert testimony, civil defendants make *Daubert* motions to exclude plaintiff's experts prior to trial instead of waiting to move for judgment as a matter of law if the verdict is unfavorable. **Such an approach furthers both case-processing efficiency and**

economy, as the in limine exclusion of expert proof may eliminate the need for trial by making possible a grant of summary judgment.

In *Daubert,* the Court observed that when expert testimony is admitted, the trial court "remains free to direct a judgment" if it concludes "that the scintilla of evidence presented" is insufficient.77 The Court did not contemplate that a district judge could exclude testimony that meets the "scintilla" standard if the judge concludes that the proponent will not be able to meet its burden of persuasion on the issue to which the testimony relates. Nevertheless, the benefits of economy and efficiency that accrue when expert proof is considered in the context of admissibility determinations may tempt courts to consider sufficiency when ruling on admissibility.78 Moreover, some opinions have held that the "fit" prong of the *Daubert* test and the helpfulness standard of Rule 702 require courts to exclude a plaintiff's expert testimony that does not satisfy the plaintiff's substantive burden of proof on an issue.79 In *Kumho*, the Supreme Court showed no discomfort with this trend toward assessing issues regarding expert proof through admissibility determinations; there is no reminder, as there is in *Daubert*, that if the admissibility test is satisfied, questions of sufficiency remain open for resolution at trial.80
(pp. 21-23)

… *C. Persistent Issues*

The discussion below considers a number of difficult and recurring issues that courts have had to face in ruling on the admissibility of expert testimony. The impact of *Kumho* is considered.

1. Determining if the expert's field or discipline is reliable

As mentioned earlier,110 in *Kumho*, the Supreme Court anticipated that at times proffered expert testimony may have to be excluded because the field to which the expert belongs lacks reliability. However, other than singling out astrology and necromancy as examples of disciplines whose theories would not be admissible, 111 the Court offered no guidance on how a court can properly reach this conclusion.

a. Challenging an expert from a nonorthodox branch of a traditional discipline

One context in which the problem of reliability arises is when practitioners of a traditional discipline, such as medicine, find untenable claims by a nonconformist branch, such as clinical ecology. Thus far, federal courts have sided with the orthodox group and rejected the clinical ecologists' theory that environmental insults may cause people exposed to them to develop a "multiple-chemical sensitivity" that makes them hypersensitive to certain substances.112 Since *Daubert*, decisions excluding the proposed testimony of a clinical ecologist have usually been justified on the ground that the multiple-chemical sensitivity theory has not been validated by testing. Although *Kumho* does not "rule in" testability as a factor to be considered in all cases, neither does it "rule out" testability as a reasonable criterion of reliability in an appropriate

case.113 It is unlikely, therefore, that courts will handle clinical ecologists any differently than before, unless, of course, new research substantiates their theories.

In the future, courts will have to deal with other theories put forth by nonorthodox factions in an established field. For instance, new claims resting on postulates of alternative medicine are sure to arise. It may be in this context— determining the reliability of a novel hypothesis vouched for by a splinter group of self-anointed experts whose views are not acceptable to the traditional majority— that courts will find the full range of *Daubert*'s factors most helpful.

… *2. Challenging an expert's testimony to prove causation*

a. Is evidence used in risk assessment relevant?

Not surprisingly, **each of the cases in the Supreme Court's trilogy involved the proof of causation in either a toxic tort or product liability case. Causation is frequently the crucial issue in these actions, which have aroused considerable controversy because they often entail enormous damage claims and huge transaction costs. Particularly in toxic tort cases, proving causation raises numerous complicated issues because the mechanisms that cause certain diseases and defects are not fully understood**. Consequently, the proof of causation may differ from that offered in the traditional tort case in which the plaintiff details and explains the chain of events that produced the injury in question. **In toxic tort cases in which the causal mechanism is unknown, establishing causation means providing scientific evidence from which an inference of cause and effect may be drawn**. **There are, however, numerous unresolved issues about the relevancy and reliability of the underlying hypotheses that link the evidence to the inference of causation**.

The facts of the *Joiner* case illustrate a number of issues that arise in proving causation in toxic tort cases. **Justice Stevens' separate opinion assumes that evidence that would be considered in connection with risk assessment is relevant in proving causation in a toxic tort action, although the standard of proof might be higher in a court of law.122 Consequently, he would have found no abuse of discretion had the district court admitted expert testimony based on a methodology used in risk**

assessment, such as the *weight-of-evidence methodology* (on which the plaintiff's expert claimed to rely), which pools all available information from many different kinds of studies, taking the quality of the studies into account.123 Combining studies across fields is even more controversial than pooling the results of epidemiological studies in a meta-analysis, *a statistical technique that some find unreliable when used in connection with observational studies*.124 Of course, even if a court has no objection to the particular methodology's relevance in proving causation, it may disagree with how it was applied in the particular case. **As the Supreme Court said in *Joiner*, "nothing . . . requires a district court to admit opinion evidence which is connected to existing data only by *the ipse dixit* of the expert."**125

However, not all would agree with Justice Stevens' assumption that whatever is relied upon in assessing risk is automatically relevant in proving causation in a court of law. Proof of risk and proof of causation entail somewhat different questions because *risk assessment frequently calls for a cost–benefit analysis*. The agency assessing risk may decide to bar a substance or product if the potential benefits are outweighed by the possibility of risks that are largely unquantifiable because of presently unknown contingencies. **Consequently, risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not. *There are therefore those who maintain that high-dose animal studies have no scientific value outside the context of risk assessment.126 These critics claim that although such studies may point to a need for more research or extra caution, they are irrelevant and unreliable in proving causation because of the need to extrapolate from the animal species used in the***

study to humans, and from the high doses used in the study to the plaintiff's much lower exposure.

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122. **General Elec. Co. v. Joiner, 522 U.S. 136, 153–54 (1997) (<u>"It is not intrinsically 'unscientific' for experienced professionals to arrive at a conclusion by weighing all available scientific evidence. . . .After all, as Joiner points out, the Environmental Protection Agency (EPA) uses the same methodology to assess risks, albeit using a somewhat different threshold than that required in a trial."</u>) (footnote omitted) (citing Brief for Respondents at 40–41, General Elec. Co. v. Joiner, 522 U.S. 136 (1997) (No. 96-188) (quoting EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992, 33996 (1986))).**

123. For a discussion of the weight-of-evidence methodology and arguments supporting its use to prove causation in toxic tort cases, see Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science i*n *Toxic Torts after* Daubert v. Merrell Dow Pharmaceuticals, Inc., 16 Va. Envtl. L.J. 1, 67–75 (1996).

124. *See* Michael D. Green et al., Reference Guide on Epidemiology § VI, in this manual.

125. *Joiner*, 522 U.S. at 146. *See supra* text accompanying note 32.

126. *See, e.g.*, Phantom Risk: Scientific Inference and the Law 12 (Kenneth R. Foster et al. eds., 1993).

(pp. 32-33)