

Inconsistency in Evidentiary Standards for Medical Testimony Disorder in the Courts

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THE SUPREME COURT, BASED ON 3 DECISIONS OVER THE past decade, now requires judges to examine the underlying basis of all testimony to ensure that only expert testimony supported by valid methods of inquiry is introduced as evidence in litigation.¹ Under these standards, expert testimony in the courtroom, including medical testimony, is supposed to meet the same standards of intellectual rigor that professionals use outside the courtroom.² If expert testimony does not meet this standard, the courts are expected to exclude the testimony and may dismiss the case without trial.

Yet this new, closer scrutiny by judges has also yielded inconsistent legal decisions in otherwise similar medical cases that involve injury from putatively toxic substances including drugs (so-called toxic tort cases). In some instances, judges have excluded medical testimony on cause-and-effect relationships unless it is based on published, peer-reviewed, epidemiologically sound studies, even though practitioners rely on other evidence of causality in making clinical decisions when such studies are not available. The courts appear to be asserting standards that they attribute to the medical profession, but that are inconsistent and sometimes more demanding than actual medical practice. As a result, plaintiffs seeking compensation for an illness attributed to a toxic exposure lose the opportunity to present their evidence to a jury. In addition, because courts have disallowed medical experts from providing information consistent with these requirements, some physicians now decline in frustration to participate in legal proceedings. In this article, we review cases that illustrate inconsistencies in the courts' approach to medical expert testimony. We argue that while there may be good reasons to require evidence of a higher quality and quantity than a physician would require in ordinary clinical decision making, as some courts have done, this practice is not faithful to the mandate of the Supreme Court. Courts are misled if they think they are representing medical practice.

THE BACKGROUND

The 3 US Supreme Court decisions (the so-called trilogy) that created the confusion, *Daubert v Merrell Dow Pharmaceuticals Inc.*,³ *General Electric Co v Joiner*,⁴ and *Kumho Tire*

Several recent decisions by the US Supreme Court have strengthened the ability of federal courts to consider medical testimony regarding injuries associated with exposure to toxic substances. Judges are expected to examine the basis of all expert testimony before it is introduced at trial to ensure that it meets the same standards of intellectual rigor that professionals use outside the courtroom. However, courts have been inconsistent in measuring this testimony against the standards of medical practice, especially when courts consider testimony that is not supported by clinical trials or epidemiological studies. A number of courts have required standards for expert testimony that exceed those that physicians use in ordinary clinical decision making. In this article, we illustrate such inconsistencies across federal courts by contrasting different decisions in cases involving similar facts and expert testimony. We argue that there may be good reason to require a standard of admissibility that exceeds the standards of ordinary clinical decision making, but such requirements are not faithful to the mandate of the Supreme Court. Courts with especially demanding standards are misled if they believe that they are fairly representing medical practice. Physicians should respond by correcting courts' misinterpretations of medical practice and assisting in the development of legal standards that encourage thoughtful and informed consideration of medical testimony by judges and juries.

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Co v Carmichael,⁵ were intended to improve the use of science in the courtroom. In the several decades prior to the trilogy, many judges, lawyers, and physicians were dismayed at the way science was treated by the law. Judges often did little to screen evidence submitted to juries, and ju-

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ries in turn sometimes accorded less weight to well-reasoned opinions from acknowledged experts than to the testimony of hired (and well-paid) advocates, some with little scientific credibility. The emergence of high-stakes toxic tort litigation involving widespread exposure to products such as asbestos and the Dalkon Shield focused attention on the courts' use of scientific information to establish a causal relationship between an exposure and an injury. Courts often struggled to adjudicate thousands of claims that involved varying degrees of exposure to a product and diverse claims of injury. Undocumented and unpublished statistical analyses of data were sometimes accepted in evidence. As a result, there was widespread concern that courts often reached irrational and inappropriate verdicts.

In many ways the trilogy of cases has improved the way scientific evidence is handled in the courtroom. Prior to 1993 many courts relied on the 70-year-old Frye Rule, which admitted scientific testimony that had achieved "general acceptance in the relevant scientific community."⁶ In the Daubert case, however, the Supreme Court rejected the deferential standard of the Frye Rule in favor of a more assertive standard that required courts to determine that expert testimony was well grounded in the methods and procedures of science. The Court cautioned, however, that in exercising this authority, federal judges must not intrude on the jury's constitutional role of resolving disputed facts that represent legitimate differences of scientific opinion. Based on these principles, the Court offered guidelines to aid judges in making such assessments. Peer review was one criterion that the Court urged federal judges to look to when assessing the basis of expert testimony. Other criteria included falsifiability, the existence of known or potential error rates, and standards controlling the technique's operation. Although "general acceptance" of methods within the medical community is no longer the exclusive standard, it remains a factor to be considered.

In 2 subsequent decisions, the Supreme Court clarified and supplemented its decision in Daubert. *General Electric Co v Joiner* dealt with the admissibility of scientific evidence of injury caused by exposure to polychlorinated biphenyls.⁴ The trial court had excluded expert testimony, but the US Court of Appeals for the Eleventh Circuit reversed the decision. The Supreme Court then reversed the court of appeals and held that appellate courts should generally defer to determinations of expert evidence by trial court judges. The Court also affirmed the trial court's exclusion of the specific evidence at issue. Chief Justice Rehnquist, writing for the majority, noted that a trial judge need not accept expert testimony "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." (Ipse dixit is an unproved assertion.) Justice Breyer, writing a concurring opinion, urged judges to seek assistance from the scientific community and to use court-appointed experts to strengthen their ability to understand scientific and technical evidence.

In *Kumho Tire Co v Carmichael*, a case involving an allegedly defective automobile tire, the Supreme Court extended the approach of its prior opinions to other kinds of expert testimony, implicitly including medical testimony.⁵ Moreover, the Court indicated that all expert witnesses should use "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." In effect, this decision tethered the standard for admissibility of testimony by physicians to the professional standards of medical practice. The Supreme Court also endorsed a flexible approach to assessing evidence, noting that the trial judge cannot rely on a checklist of factors in assessing admissibility across varying types of evidence. Instead, the judge must consider the particular circumstances of the specific case at issue in determining appropriate standards for admissibility.⁷

ASSESSING EVIDENCE AND CAUSALITY

Several perspectives are useful in trying to appreciate the similarities and differences between the approach of physicians and that of the courts to assessing evidence and causality.

The Epidemiologist's Perspective

Statistical evidence from groups of patients yields correlations between variables that are, in turn, the basis for the epidemiological assessment of causality. Both the US and Canadian task forces on preventive health rate controlled trials, cohort studies, and case-control studies highest in quality and other kinds of data (for example, descriptive studies and case series) lower in quality.^{8,9} Nonetheless, even controlled trials have imperfections and limitations. Studies in humans are likely to be confounded by variables other than the one of interest, and for this reason, every study must be scrutinized not only for such confounders, but for defects in study design, data quality, and the strength of the statistical correlations. Scrutiny of these issues is usually provided by medical journals' peer review process, but just because a study has been published in a prestigious peer-reviewed journal is no assurance that its results or conclusions are correct.¹⁰ Many hoped that critical analysis of the literature and evidence-based medicine would yield unequivocal medical practice guidelines and put an end to squabbling over the interpretation of evidence, but as the ongoing controversy about mammography and prostate-specific antigen measurements illustrate, they have not. With respect to court decisions, it is worth pointing out that evidence-based medicine cannot address many areas in which evidence is more sparse and, for example, dominated principally by a handful of case reports.

Epidemiologists also rely on considerations such as the biological plausibility of the relationship, the temporal proximity between a putative insult and an effect, the intensity of the insult, and the response to removal (and rechallenge) of the putative agent.¹¹⁻¹⁵ In the final analysis, assess-

ment of evidence and causal inferences depend on accumulating *all* potentially relevant evidence and making a subjective judgment about the strength of the evidence.

The Clinician's Perspective

The clinician's task is to determine the cause of a single patient's complaints and findings and to select the optimal therapy. The diagnostic process is more akin to detective work than statistical analysis of hard data.¹⁶ Clinicians collect information on patients' symptoms and signs, generate diagnostic hypotheses, and on the basis of these hypotheses, gather additional clinical data and perform diagnostic tests that help generate a consistent working diagnosis that focuses their therapeutic efforts. They use data derived from epidemiological studies to make diagnostic and therapeutic decisions, but because they must make decisions even in the absence of statistical data, they are accustomed to using *any* reliable data to assess causality, no matter what their source.¹⁵⁻¹⁹ In clinical medicine, a biologically plausible relationship, physiological studies of a drug, animal studies, or even a handful of case reports can be useful in individual cases in helping a practitioner make judgments about cause and effect relationships. Temporal proximity can also be a potent factor in causal decision making, especially if an event follows regularly in time after an exposure.¹⁹

Practitioners vary in the standard of evidence they require in making decisions about the use of a drug when small numbers of cases suggest that the drug might be toxic. Even after a few case reports linking a drug to an adverse event, some physicians will stop prescribing the drug.²⁰ Yet when the incidence of the adverse effect in patients who have taken the drug has often not been compared with those who have not, other practitioners may assume that the adverse effect is unrelated to the drug and they may continue to prescribe it. It often takes years to reach consensus on these issues.

The Regulator's Perspective

Decisions by the Food and Drug Administration (FDA) about the possible toxicity of drugs resemble more closely those of individual physicians. In many instances, the FDA issues warnings and even orders drugs withdrawn from the market based only on reports of a handful of deaths or serious adverse drug complications. On the spectrum of evidence strength, the FDA's threshold for attributing a complication to a drug is far lower than the preponderance of evidence standard required by the courts. In fact, in some litigation, the courts have explicitly stated that an FDA warning is not sufficient evidence to establish causality.²¹

The Court's Perspective

Judges' responsibilities are to assign blame and liability for monetary damages in individual cases, and their decisions can have far-reaching implications.^{22,23} In contrast to the day-to-day decisions that physicians make based on causal in-

ferences, the courts must exert a higher standard: the court must assess whether there is sufficient admissible evidence to enable a reasonable jury to conclude that a "preponderance of evidence" establishes that an injury was caused by an alleged exposure. A judgment by the court about causation cannot be merely "possible" because such a lower standard of evidence could lead to frivolous lawsuits, needless expense, elimination of useful products, and inappropriate damage awards.^{22,23}

Unfortunately, issues that emerge as the subject of litigation rarely have been evaluated by a rigorous statistical study.²⁴ Plaintiffs typically do not have the resources and access to product information necessary to undertake such studies and often must piece together a claim based on existing research and case reports. By contrast, defendants in toxic tort suits often do have the resources and access to data necessary for research and may be able to design studies that can clarify the effects of their products or even benefit their cause.^{25,26}

CONFUSION IN THE COURTS

The trilogy decisions and conforming amendments to the Federal Rules of Evidence mean that federal judges must make their own assessments of the medical evidence in determining whether to allow a jury to hear such evidence. In applying the new requirements, many courts have tried to reduce them to simple all-or-nothing rules, such as accepting a doubling of the background rate of disease as proof of causality. This approach was urged by the United States Court of Appeals for the Ninth Circuit when it reconsidered the *Daubert* case.²⁷ In some instances, courts have required peer-reviewed studies²⁸ and statistical data²⁹ as a condition of permitting the testimony and thus allowing a jury to weigh the evidence. When such evidence is unavailable, the courts struggle to find standards to review medical decisions and often provide inconsistent legal judgments.

Decisions Involving Causal Attribution

The litigation regarding Parlodel (bromocriptine) is a case in point. Parlodel, an ergot derivative, was prescribed for women to stop postpartum lactation until the FDA rescinded approval for this use in 1995. During the time the drug was on the market, many young women who took the drug developed a variety of vascular complications including acute myocardial infarction, cerebral infarction, hemorrhagic stroke, and "cerebral angiopathy," as well as headaches and seizures. Some of these women sued Sandoz, the manufacturer, claiming that the drug caused their vascular disorder. Yet, such vascular complications can rarely occur *de novo*. Convincing epidemiological data were not available to support or refute the inference that the drug and these vascular complications were causally linked. In several cases, Sandoz contended that, absent such data, the opinions of the plaintiffs' experts were nothing more than unscientific speculation.

Granted, these cases do not appear to form a consistent disease group or clinical syndrome, and we take no position on whether the drug caused the complications. Nonetheless, the issue is whether or not the opinion of expert clinicians, based on the judgments they make daily, should go unheard by a jury. The courts have been inconsistent: some judges have admitted expert testimony in these cases and others have excluded the same experts from offering similar testimony. For example, in the case of *Siharath v Sandoz Pharmaceuticals Corp*, involving a woman who experienced seizures and a subarachnoid hemorrhage 5 days after she began taking Parlodel, a federal district court in Georgia excluded expert testimony and granted summary judgment for the company; this decision was recently upheld on appeal.³⁰ The plaintiff alleged that the drug, as an ergot alkaloid, causes vasoconstriction and hypertension, and by implication, Ms Siharath's hemorrhagic stroke. In support of this contention, the plaintiff introduced evidence of several case reports linking Parlodel to vasoconstriction and acute myocardial infarction, the FDA's removal of Parlodel after "reports of serious and life-threatening experiences . . .," animal studies demonstrating Parlodel's vasoconstrictive effects, statements in medical treatises, and the Material Safety Data Sheet that warned of seizures and strokes. The court discounted toxicological animal studies and a number of similar case reports as having too little probative value to support the inference of causation. The court then dismissed the FDA statement and the medical treatises as based on case reports and "therefore provide no more support than the case reports." The court noted the absence of "at least some support for the causal hypothesis" relating Parlodel to vascular complications "in the peer-reviewed epidemiologic literature" and observed that the "reliance on learned treatises is insufficient to make up for the lack of reliable epidemiologic studies." (Two other federal district courts also did not admit such expert testimony in Parlodel cases involving intracerebral hemorrhage and were upheld on appeal.^{31,32})

A different court came to the opposite decision in the case of Mrs Brasher, a woman who developed a cerebral infarction approximately 7 days after starting Parlodel.³³ On the basis of the same evidence and testimony by 2 of the same experts as in Ms Siharath's case, a magistrate judge in Alabama determined that such testimony did meet an appropriate standard of reliability and that a jury should resolve a dispute over such evidence. This same magistrate judge also admitted such "clinical" testimony in cases involving 2 other women who suffered acute myocardial infarction soon after starting Parlodel.³⁴ These rulings are being appealed.

Decisions Involving Differential Diagnosis

Two cases that preceded *Kumho*, the last case of the trilogy, illustrate the difficulties with medical testimony that the trilogy decisions have not resolved. In *Moore v Ashland Chemical Company*,³⁵ Mr Moore developed a respiratory disorder shortly after he cleaned up solvent containing toluene that had leaked from drums in the back of his truck. Moore sued

on the grounds that Ashland was negligent in insisting that he expose himself to the chemical vapors. Although he was a smoker and had a history of asthma, 2 pulmonologists testified that Mr Moore had developed reactive airways disease from the solvent exposure. The pulmonologists relied on the patient's medical history, his physical examination, and a large battery of diagnostic tests that evaluate lung function. In concluding that the disease was caused by solvent exposure, they relied on warnings in the Material Data Safety Sheet that indicated that the solvent may be irritating to lungs, and on the short time between exposure to the chemicals and the onset of Mr Moore's breathing disorder. The district court refused to admit the testimony of a pulmonologist, asserting that his opinion was not based on an objectively validated method. Based on the evidence that remained, the jury decided that it could not be demonstrated by a preponderance of evidence that the chemical exposure caused or aggravated Mr Moore's illness.

Moore appealed this decision to the US Court of Appeals for the Fifth Circuit, and a 3-judge panel reversed the decision of the district court, holding that because clinical medicine is distinct from scientific research, the Daubert standards were not applicable (an interpretation later rejected by the Supreme Court in the *Kumho* case). The defendant sought review by all the judges in the Fifth Circuit Court of Appeals. Relying on a restrictive interpretation of the role of differential diagnosis, a majority of the entire appellate court reinstated the district court's verdict.

In contrast to the Fifth Circuit decision in *Moore*, the US Court of Appeals for the Fourth Circuit applied a more lenient standard for admitting clinical medical testimony in *Westberry v Gislaved Gummi AB*.³⁶ Mr Westberry was not advised to wear protective gear, even though his task of cutting talc-coated gaskets released an enormous amount of talc into the air. Mr Westberry soon experienced sinus problems severe enough to require antibiotics and several surgical procedures. Once when he stayed out of work, his sinus condition improved, but then exacerbated when he returned. Westberry sued the company for failing to protect him from the harmful effects of talc. The jury decided in favor of Mr Westberry, but the company appealed, arguing that the expert's testimony was not based on reliable scientific methods because it lacked citation to epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data. The appeals court affirmed the district court's decision to admit the medical testimony. Even though reliable statistical data were not available, the court permitted the physician to testify that exposure to talc caused the illness based on the warnings in the Material Safety Data Sheet, close proximity between exposure and onset of illness, and a differential diagnosis that ruled out many (but not all) alternative causes of the illness.

The *Moore* and *Westberry* cases reveal a differing degree of trust in clinical judgments regarding the weight accorded to measurement of exposure, temporal proximity be-

tween exposure and onset of disease, and the absence of peer-reviewed literature. Courts often require plaintiffs, as a preliminary matter, to demonstrate that the challenged substance is capable of causing such an injury; thus, experts must “rule in” the suspected cause before “ruling out” other possible causes through differential diagnosis.³⁷ As part of “ruling in” the suspected cause, courts may insist on evidence that the exposure exceeded a dosage level that might cause harm. In *Moore*, the appellate court rejected the expert testimony, in part, because the expert had no information on the level of solvent exposure that might cause such an injury.³⁵ Little weight was given to a warning in the Material Safety Data Sheet that prolonged exposure may lead to respiratory disorders. This court found the pulmonologist’s reliance on this Material Safety Data Sheet unwarranted since he was unaware of the tests that had been done to generate its information. In *Westberry*, by contrast, the appellate court placed more reliance on physician’s inferences based on the warning of the Material Safety Data Sheet that talc can irritate mucous membranes and on the weight of the circumstantial evidence in the workplace suggesting a harmful level of exposure.³⁶

Decisions Involving Temporal and Other Relationships

Temporal proximity between exposure and injury is another factor that divides the courts.^{38,39} The *Moore* court placed little weight on the short time period between exposure to solvent and the respiratory illness.³⁵ Other courts have also found temporal proximity insufficient to support an expert’s opinion that exposure caused an injury.^{37,40} Yet other courts, as in *Westberry* (and 3 dissenting judges in *Moore*), gave more weight to this factor, and in *Westberry*, the court permitted an expert to offer testimony when the major evidence was the temporal order between exposure and illness. In fact, in *Westberry*, the court noted that “depending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease or worsening of symptoms can provide compelling evidence of causation.”³⁶ The evidence of causation in *Westberry* was undoubtedly strengthened by the extent of exposure and the observation that the plaintiff’s condition improved when he was away from the workplace. The 2 courts also differed on the extent to which testifying physicians must support their opinions with peer-reviewed published research studies.

Data from peer-reviewed publications and temporal proximity are only 2 of many factors that physicians consider in making causal inferences and in developing a differential diagnosis. Case reports, toxicological data from animal studies, and expert assertions of causality in textbooks are among the factors that physicians also consider.^{2(pp468-478)} Here, too, courts have difficulty knowing what weight to accord each of these factors. For example, some courts dismiss case reports as non-scientific,^{41,42} whereas other courts give considerable weight to them.⁴³⁻⁴⁵ Some courts discount toxicology animal studies as providing an adequate basis for a conclusion regarding cau-

sation of a human condition,^{29,46} while other courts give such studies more weight.^{47,48} Moreover, courts tend to assess separately the reliability of each component rather than assessing the reliability of the “totality of the evidence” including all relevant clinical factors.⁴⁹ In doing so, courts fail to take into account the complex inferential process that lies at the heart of clinical medical reasoning.^{2,17}

IMPROVING THE PROCESS

Tethering expert testimony to standards of professional practice is likely to improve the ability of courts to render decisions that are consistent with current medical knowledge. But courts need assistance in interpreting these standards. Clinical medical testimony in toxic tort litigation presents an especially difficult circumstance. Causation in such cases is rarely clear-cut, and assessments of responsibility often stir deep-seated beliefs regarding the responsibility of individuals and corporations in responding to unfortunate outcomes. Allocation of such responsibility is a matter of legal policy best left to judges and legislators. But when legal policy seeks to incorporate standards of current medical practice, as the Supreme Court has done implicitly in the *Kumho* case, the medical profession has an obligation not only to help clarify these standards, but to object to any standards that misrepresent the practices of the profession.

By criticizing the overly demanding standards that some courts have attributed to medical practice, we are not suggesting that the standards for admissible evidence must be adjusted to those used in the everyday practice of medicine. Unlike the cooperative setting in medicine where all parties are seeking an accurate diagnosis and appropriate treatment, medical testimony in the courtroom exists in an adversarial setting in which each party seeks to present its strongest case. By its very nature, this clash invariably leads to conflicts among experts representing both sides. Perhaps, in this polarized setting, the broader public interest in allocating responsibility in toxic tort cases justifies setting a standard for medical testimony that exceeds standards of evidence used in everyday medical practice. If so, this more demanding standard would have to be articulated by judges and legislators for reasons of legal policies that are independent of contemporary medical practice.

We believe that the medical profession must be encouraged not to remain aloof from litigation over such issues and must monitor the manner in which medical testimony is presented in court. Moreover, the medical profession must participate in strengthening the presentation of medical testimony. Judges and legislators, of course, must set the standards for admitting medical testimony, but physicians can improve the consideration of medical testimony by providing guidance on how to assess causality at the level of certainty required by the law. In return, the legal profession must do more to educate physicians about the different roles of litigation and the constraints under which the courts seek to resolve conflicts.

Typically, physicians participate in court cases as testifying experts, but many other opportunities are also available. Physicians can prepare amicus briefs explaining professional standards and practices in critical cases. They can also participate on panels that assist the courts in evaluating medical testimony. Recently a federal district court considering Parolodel injury claims assembled a panel of 3 experts from different medical disciplines to help the court consider the expert testimony.⁵⁰ Even though panel members offered contrasting recommendations, they provided the courts with a basis for reaching a reasoned and principled decision that is consistent with medical practice. Standing commissions of physicians might also address some confusion in the courts, such as the extent to which the medical literature including textbooks should be regarded as authoritative statements of current knowledge. Other groups might clarify the status of topics of recurring disputes and indicate issues that remain unresolved. Many groups of experts in "evidence-based medicine" already exist. These panels are skilled in the critical analysis of the literature. Asking individuals from such panels to express their individual judgments in probabilistic terms might also help. They might assert that in their opinion, a causal connection has a probability of 0.2, 0.4, or 0.8, and then explain why their view of the likelihood is so low or so high. Comparisons between experts might be somewhat easier using such an approach. Finally, requesting panelist names from an independent, authoritative agency such as the Institute of Medicine would avoid experts who have financial conflicts of interest. Several organizations, such as the National Institutes of Health, the American Association for the Advancement of Science, and the Duke University School of Law's Private Adjudication Center, are already compiling such lists.

The medical and legal professions have a tradition of mutual wariness that has impeded effective cooperation in developing consistent standards for medical testimony. The courts need help from the medical profession to help them strengthen the role of medical testimony in litigation. The medical community should respond by correcting misrepresentations of medical practice and assisting in the development of standards that encourage thoughtful and informed consideration of medical testimony by judges and juries.

Disclaimer: The views herein are those of the authors and do not necessarily represent the view of the Federal Judicial Center.

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