Virtual Mentor. December 2004, Volume 6, Number 12.
doi: 10.1001/virtualmentor.2004.6.12.hlaw1-0412

Health Law

What Counts as Expert Medical Testimony?

Medical standards of care and legal standards of reliability and relevance sometimes conflict in courtroom settings.

Mollie E. O'Brien

Introduction

In *Daubert v Merrell Dow*, the Supreme Court determined that scientific testimony, including testimony by medical experts, is admissible as long as it is both "relevant" and "reliable" to assist a jury in their fact-finding determination [1]. *Daubert* sets a more permissive standard for the kind of expert testimony that will be considered admissible. On the other hand, *Daubert* vests the judge with more discretion to decide whether the expert provides the court with "good" or "bad" science. Ultimately, physicians and scientists should be aware that judges still require sound science in their courtrooms.

Daubert v Merrell Dow

Jason Daubert and Eric Schuller were both born with severe limb reduction birth defects. Such abnormalities were arguably linked to their mothers' ingestion of Bendectin, an anti-nausea drug given to pregnant women. Shortly after Jason and Eric's births, and after hundreds of law suits alleging that the drug triggered teratogenic effects, Merrell Dow Pharmaceuticals Inc, a unit of Dow Chemical Co, withdrew the drug from the market in 1983 [2].

Jason and Eric also sued Dow. Alleging pharmaceutical products liability, Jason and Eric had to provide pre-trial evidence suggesting that: (1) Dow owed and breached a duty of care to them; and (2) Bendectin actually *caused* their particular birth defects [3]. In order to provide supporting evidence for the latter, Jason and Eric used scientific evidence and medical testimony.

In its own defense, Dow presented a well-credentialed medical expert, a physician and epidemiologist, Dr. Steven H. Lamm. In his affidavit, Lamm stated that no published report confirmed Bendectin caused teratogenic effects in humans [4].

The plaintiffs did not directly refute Lamm's characterization of the published record. In fact, both plaintiffs and defendant acknowledged that all published data gave no indication that Bendectin caused birth defects [5]. Instead, Jason and Eric obtained 8 of their own experts who testified that in their *unpublished* research, they found a pharmacological link between Bendectin and teratogenic malformations through in vitro and in vivo animal studies. Additionally, 2 of the experts testified that if Dr. Lamm's epidemiological evidence were re-analyzed, it could arguably support a finding that Bendectin caused teratogenic effects in humans.

Despite the unquestionable credibility of Jason and Eric's witnesses, the District Court of California found that the testimony based on unpublished scientific results was not legally relevant to establish that Dow's product caused their birth defects. After discovery and prior to any arguments being presented at trial, the court dismissed the case on "summary judgment." A case can be dismissed on summary judgment if one party establishes that the other side has not proved sufficient facts to support their legal claim. The trial judge found that animal, chemical, and in vitro studies were insufficient to establish that Bendectin caused birth defects in humans [5]. Finding Dow's epidemiologic

evaluation more persuasive, the judge concluded that Jason and Eric's scientific evidence was inadmissible because it was not "generally accepted" by epidemiologists, the field of study that could best judge the veracity of such data [5].

On appeal, the Ninth Circuit, the federal court of appeals for California, Washington and Oregon, affirmed the lower court decision. It held that, based on the existing rules of evidence at the time, expert testimony was only admissible if it was "generally accepted by the scientific community" and "subjected to verification and scrutiny by others in the field" [6]. Consequently, the Court rejected the re-analysis data produced by Jason and Eric's experts. The court adopted the reasoning that this data was inadmissible solely because it had not been subjected to the peer review process that is associated with publication of scientific articles.

The Supreme Court agreed to review the Daubert case, stating that there was a general lack of uniformity among the lower federal courts over what to accept as expert testimony [7]. Some courts, like the *Daubert* District Court, used the "general acceptance" test for expert testimony that had been established in the 1923 decision of *Frye v United States* [8]. Other courts rejected "general acceptance" and admitted testimony according to Rule 702 of the Federal Rules of Evidence, as established in 1973.

Writing for the high Court, Justice Blackmun with the support of 7 out of 9 justices held that the Federal Rules of Evidence and not the "general acceptance" test should control the admissibility of expert testimony [9]. The Supreme Court reasoned that the Federal Rules of Evidence were far more liberal than the general acceptance [10] test. In effect, Rule 702 deems all "*relevant* evidence admissible" [11]. So, while *Frye's* general acceptance standard could have been part of the lower court's inquiry, the court should not have ended its investigation there [12]. By its very language, 702 expressly permits any scientific, technical, or other specialized knowledge, assuming such knowledge will assist the Court to understand evidence.

Once testimony is deemed "relevant" to assist the jury, it must also prove "reliable." To this, the Court simply stated that the testimony's "*evidentiary reliability* will be based upon its *scientific validity*" [12]. Although the Court expressly refused to adopt a comprehensive checklist for determining whether expert testimony is in fact reliable, it offered a non-exhaustive list of what lower courts might consider in the future. Some of these considerations include whether:

1. the theories and techniques employed by the scientific expert have been tested;
2. they have been subjected to peer review and publication;
3. the techniques employed by the expert have a known error rate;
4. the theories and techniques are subjected to standards governing their application; and
5. the theories and techniques employed by the expert enjoy widespread acceptance [12].

While the absence of one of these factors is insufficient to exclude expert testimony, the absence of more than 1 may indicate that the testimony lacks scientific validity. The district court had found Daubert's expert testimony insufficient based solely on 1 of the reliability criteria—that the research presented had not been published. So, the Supreme Court ordered the lower court to revisit the evidence, utilizing this new standard of "relevance and reliability" to guide its decision.

How *Daubert* Applies to Physicians

Some commentators have argued that the *Daubert* ruling permitted more "junk science" into the courtroom. Others claim that *Daubert* leaves the burden of identifying and excluding inappropriate testimony to the judge and the court system [13]. That is, if evidence lacks relevance or reliability, vigorous cross-examination, presentation of contrary evidence, and careful instructions to jurors will eliminate this evidence. At the very least, then, these internal checks of judicial "gate keeping" will insure that the expert's testimony is based on science that is methodologically and theoretically sound enough to satisfy the reliability criteria of *Daubert*.

The *Daubert* Rule means that experts must present opinions that are specifically relevant and highly developed in order to withstand the scrutiny of the judge and opposing counsel. The witness will be appropriate if, as a prerequisite, her experience contributes some meaningful explanatory purpose to the party's case.

The AMA's *Code of Medical Ethics* agrees. Opinion 9.07 states, "Medical experts should have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise" [14]. Hence, a physician will both comply with *Daubert* and the ethical standards of the medical profession if her clinical, research, or academic experience helps explain a party's case.

Although the *Daubert* Court did not employ express "standard of care" language, the list of considerations in the Court's opinion—particularly whether the opinion has been peer reviewed and gained widespread professional acceptance—resembles the criteria that the medical profession employs in determining standards of care. Indeed, from an ethical perspective, the degree of one's clinical experience and knowledge necessarily conditions and ultimately limits one's ability to testify in the first place.

While it is true that physicians are obligated to serve as patient advocates, in court they have a greater duty to testify to their truthful, objective beliefs. On the stand, a physician is bound by an obligation "to aid and assist in the administration of justice" rather than to "insure a favorable outcome for the patient" [14]. Providing relevant and reliable testimony under *Daubert* will surely satisfy this ethical duty.

Compliance with the *Daubert* standard insures that physicians acting as expert witnesses provide relevant and reliable testimony to the Court. In order for testimony to prove both relevant and reliable, physician opinions are subject to aggressive scrutiny both by judges and opposing counsel. From an ethical perspective, the *Daubert* requirements complement provisions of the *Code of Medical Ethics*. Complying with these ethical provisions from the beginning, then, may insure that testimony satisfies legal rules of admissibility, relevance, and reliability later.

References

1. *Daubert, et al v Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 113 s/ Ct. 2786 (1993).
2. Annas GJ. Scientific evidence in the courtroom—the death of the Frye rule. *N Engl J Med.* 1994;330:1018-1021.
   View Article PubMed Google Scholar
3. *Daubert*, 583.
4. Annas, 1019.
5. *Daubert v Merrell Dow Pharmaceuticals, Inc.*, *Schuller v Merrell Dow Pharmaceuticals, Inc.*, 727 F Supp 570 (SD Cal.1989).
6. *Daubert v Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991).
7. See *Daubert*, 509 US at 598.
8. The *Frye* Rule asks whether evidence is "generally accepted" among the expert's peers; *Frye v US*, 293 F.1013,1014 (1923). The *Daubert* District court rejected Eric and Jason's witness, holding that an expert must publish his research, subjecting his methodologies to peer review in order to testify before the court. See *Daubert*, 509 US at 593-595.
9. *Daubert*, 509 US at 593-595.
10. Ibid, 586.
11. Ibid, 481.
12. Ibid, 591.
13. Kassirer JP, Cecil JS. Inconsistency in evidentiary standards for medical testimony, disorder in the courts. *JAMA* 2002;288:1382-1387.
    View Article PubMed Google Scholar
14. American Medical Association. Opinion 9.07 Medical testimony. AMA *Code of Medical Ethics Current Opinions with Annotations 2004-2005* ed. Chicago: AMA Press; 2004:272. Available at: http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-9.07.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-8.21.HTM&nxt_pol=policyfiles/HnE/E-9.01.HTM& Accessed November 29, 2004.