Science in the Courtroom

By ACSH Staff — January 1, 1994

More and more cases which require an understanding of complex scientific issues are being tried in the courts of this nation. Often the scientific questions that come before a court are on the cutting edge of scientific knowledge. In other cases, the tested theories of mainstream science are in conflict with the hypotheses of researchers who perhaps do not follow traditional methods. Juries and even judges may have a hard time distinguishing reliable expert testimony from pseudoscience; and even reliable research on mice or rats, for example, may not be relevant to determining the causes of human disease. The criteria for admitting scientific testimony into the courtroom has a profound effect on the outcome of trials involving some of the most contentious health issues of the day, including electromagnetic fields and multiple chemical sensitivity. Thus, the presentation of scientific evidence has itself become a legal battle ground.

The Supreme Court Takes Up the Question

Scientists, judges and lawyers are grappling over how widely accepted a scientific process or theory must be before it is admissible as evidence in court. Recently, the Supreme Court addressed the controversy in the case of *Daubert v. Merrell Dow Pharmaceuticals Inc*.

In the lower courts, the plaintiffs, the parents of two children born with limb deformities, alleged that Bendectin, a drug marketed by Merrell Dow to control nausea during pregnancy, is a teratogen that caused their children's birth defects. Merrell Dow asserted that in over 30 reliable studies on over 130,000 women, Bendectin was never implicated as a teratogen. They also countered that the plaintiffs' scientific studies used questionable methodology and thus would have erroneously swayed a jury which was unaccustomed to weighing the rigors of scientific testimony and naturally sympathetic to the injured plaintiffs.

The Supreme Court agreed to decide whether the evidence suggesting that Bendectin may cause birth defects was admissible. In a broader sense, the Court would set the criteria that judges should use to decide on whether to admit testimony by expert witnesses.

The Evidence on Trial

For 27 years, from 1956 to 1983, Bendectin was used in 33 million pregnancies. Given the natural background rate of birth defects (three percent of newborns have congenital abnormalities), over one million defects would have occurred among the births of those who took the drug, independent of its use. However, for parents whose children have a defect, it is not hard to lay blame on the use of a drug.

Litigation was the route taken by many of these parents. Even though the drug had been used safely for more than 25 years and had been approved by the Food and Drug Administration, thousands of lawsuits were filed. In 1983, litigation costs became too great and the manufacturer

pulled the drug from the market. Many of the lawsuits were settled out of court, many were dismissed and some continue to languish in the courts more than ten years later. Daubert is one such case.

In their original suit, the Daubert team hoped to counter the weight of the evidence on Bendectin's safety with contrary evidence that the drug was teratogenic. However, there were problems with this evidence. It was based mainly on in vitro studies, animal studies and analyses of the drug's chemical structure. Such evidence may be a useful guide to the effects of a drug if human epidemiologic evidence is not available. But since a vast amount of quality epidemiologic evidence suggested that Bendectin was safe, less definitive studies were judged not to be strong enough to overturn that conclusion. Hense, the judge ruled that such evidence was inadmissible.

The most disputed evidence was a reanalysis of previously published studies that had not shown any significant link between Bendectin and birth defects. The reanalysis, however, reached the opposite conclusion. It was this evidence that was forbidden by the lower courts because it did not meet the "generally accepted" peer-reviewed standard. The Ninth Circuit Court of Los Angeles agreed in appeal that the reanalysis was "not of a type reasonably relied upon by experts in the particular field." Thus, the court was unwilling to allow the presentation of the reanalysis to a jury given the massive weight of the original studies which had been reviewed by the scientific community.

The Second Circuit Court of Appeals in Philadelphia reached an opposite verdict. In that jurisdiction, similar evidence was ruled admissible. This split in circuit court decisions brought the case to the Supreme Court because lower courts had relied on different standards on whether to admit similar evidence. The Ninth Circuit Court relied on the Frye rule, first articulated in *Frye v. United States* in 1923. Under that standard, courts required that the evidence or scientific techniques at issue reach a level of "general acceptance" in the scientific community. The Second Circuit, on the other hand, believed that rule 702 of the 1975 Federal Rules of Evidence superseded the Frye rule and essentially permitted any expert who is qualified in his or her field to present conclusions to a jury if the testimony is relevant to the case even if those conclusions are not accepted by mainstream scientists.

The Supreme Court Rules

The Supreme Court in a seven to two decision rejected the continued use of the Frye rule, which the justices said had been superseded by the Federal Rules of Evidence. But their interpretation of rule 702 sent the message that even without the specific language of Frye, judges must act as the court's gatekeeper.

Rule 702 governing expert testimony states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

The seven justice majority interpreted this rule specifically. According to the opinion: "The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation. . . . In short, the

requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability."

To make sure testimony is reliable, the opinion provides general observations for judges to use when evaluating evidence and stresses that the focus of any evaluation "must be solely on principles and methodology, not on the conclusions that they generate." According to the Court, judges can consider

> *1. whether a theory or technique has been or can be tested by the scientific method;*
> *2. "whether the theory or technique has been subjected to peer review and publication" (however, publication is not required for admissibility);*
> *3. the error rate, in the case of a scientific technique;*
> *4. and finally, judges can still consider general acceptance. The opinion states: "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique that has been able to attract only minimal support within the community may properly be viewed with skepticism.'"*
> *But after suggesting these rules for evaluation, the opinion still emphasized that the inquiry into the reliability of evidence is "a flexible one."*

The decision, however, has left both sides claiming victory. The defendants believe that the Justices' ruling sends a signal to lower courts to weigh carefully the reliability of evidence before it is presented to a jury. On the other hand, with the abandonment of Frye, the plaintiffs believe that the Supreme Court has opened the courts to a more lenient standard. Either way, there will be no hardened rules, and it will be up to judges to consider the evidence presented in their courtrooms.

Guidelines for the Future

One benefit of the Daubert case was that it sparked serious debate among scientists, lawyers and judges about the use of scientific testimony in the legal arena. Out of such debate came a recent article in Science (9/17/93) recommending several ways judges could learn from the recent controversy.

> *1. Judges and lawyers should familiarize themselves with the scientific issues behind the research on which many trials are based. For example, clinical ecologist often appear in personal injury suits diagnosing patients with questionable diseases such as "multiple chemical sensitivity." That diagnosis and medical specialty are rejected by the scientific mainstream.*
> *2. "Courts should examine closely the scope of expertise of expert witnesses. A treating physician, for example, is an appropriate expert to testify about injury or ill health of a patient and his or her treatment. But clinicians are not necessarily*

> *experts on the causes of injury, etiology of disease, or risk assessment."*
> *3. Courts should use independent experts and peer review to evaluate scientific evidence. The Daubert opinion reminds and encourages judges to use their power to hire experts. Also the courts should use the reports of independent scientific consensus groups. Such reports may be more complete, reliable and less biased than testimony prepared specifically for litigation.*

By following these suggestions, judges can better ensure that scientific testimony will lead to truth and justice in their courtrooms.

The Real Tragedy of Bendectin

The real tragedy of Bendectin did not involve birth defects at all; rather the tragedy is that a unique and useful product was unnecessarily removed from the market leaving obstetricians and pregnant women without an FDA approved way to treat a serious condition. That condition, nausea and vomiting during pregnancy, can threaten the health of both mother and fetus.

Another real tragedy occurred at the time of the Bendectin scare originated. The story, which broke in The National Enquirer on October 9, 1979, erroneously implicated Bendectin in causing "several thousand tragically deformed infants in the U.S. alone." The news was soon picked up by more mainstream media. Not surprisingly, pregnant women who were taking the drug panicked. Some even had unnecessary abortions, fearing they would have an abnormal baby.

Lawyers also were attracted by the coverage. Several law firms launched campaigns publicizing Bendectin as a cause of birth defects. At one point, lawsuits against the drug's manufacturer numbered more than 1,800. By 1983, legal costs surpassed income from the product, and the manufacturer took it off the market. Robert L. Brent, M.D., Ph.D., former editor of Teratology, called Bendectin the "most famous tortogen/litogen and the best studied human non-teratogen."

Yes, a non-teratogen. Richard Leavitt, director of science information for the March of Dimes Birth Defects Foundation, told Science magazine (3/16/90) that there is "a general consensus among teratologists that Bendectin was one of the best studied drugs of all time for use in pregnancy, and the great preponderance of evidence generally exonerated it from any harmful effect." Over 30 reliable studies provide evidence that Bendectin was safe. In fact, the CDC's Birth Defects Monitoring Program has provided more evidence that Bendectin did not cause birth defects. At its peak use, 20 to 25 percent of pregnant women in the U.S. used Bendectin, yet the CDC found no change in the incidence of birth defects after the drug was taken off the market. Sadly, according to Steven Lamm, M.D., a consultant in birth-defect epidemiology for the National Center for Health Statistics, since the disappearance of Bendectin, there has been a two-fold increase in hospitalizations fro severe nausea and vomiting among pregnant women.

Today, some obstetricians are reported to recommend bootleg versions of Bendectin or other alternative antinausea drugs for their patients. The FDA has not approved these therapies for use in pregnancy, but unfortunately, pregnant women and their doctors are left with no choice. They are in the same hapless situation when it comes to dealing with other complications of pregnancy

including high blood pressure and preterm labor. There is little information available on the risks during pregnancy associated with the use of many of the drugs commonly prescribed for these conditions.

The unfortunate fate of Bendectin has had another tragic effect. The threat of litigation has chilled the climate for research on women's health problems during pregnancy altogether. The Wall Street Journal (6/22/93) quoted a Merrell Dow representative as saying: "Research and development efforts did shift away from products in the OB-GYN area, and the prospect of litigation was one factor in that." Another cause may have been that in the past the FDA excluded women of childbearing age from participating in early clinical trials. That policy has recently been changed.

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