CAST
COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

ISSUE PAPER

NUMBER 1, JULY 1993 UPDATE, MAY 1997

Admissible Scientific Evidence in Court

F. J. Francis, *Department of Food Science, University of Massachusetts at Amherst;* **Reviewers: Will Carpenter**, *Chesterfield, Missouri;* **Fergus M. Clyesdale**, *Department of Food Science, Chenoweth Laboratory, University of Massachusetts at Amherst;* **Ralph W. Fogleman**, *Upper Black Eddy, Pennsylvania;* **H. H. Van Horn**, *Department of Dairy Science, University of Florida, Gainesville*

The American Association for the Advancement of Science (AAAS) and the National Academy of Sciences (NAS) have filed an *amicus curiae* (friend of the court) brief to the Supreme Court, which is expected to set guidelines for determining what scientific evidence is admissible in a court of law. CAST concurs with the text in the above brief.

The brief states that the ". . . courts should admit scientific evidence only if it conforms to scientific standards and is derived from methods that are generally accepted by the scientific community as valid and reliable. Such a test promotes sound judicial decision-making by providing a workable means of screening and assuring the quality of scientific expert testimony in advance of trial."

History

The court case (*Daubert v. Merrell Dow Pharmaceuticals*), which spurred the Supreme Court to hear the arguments, involved the parents of two children who suffered birth defects allegedly from the mother taking Bendectin to reduce morning nausea. Lawyers for the plaintiff introduced expert testimony from a scientist who had reinterpreted the data of others, in contradiction to 30 published studies that concluded Bendectin did not cause abnormalities. The interpretations of the scientist testifying for the plaintiff were not published and were not even available for peer review. Lower courts had ruled her testimony as inadmissible.

The current criteria for admissibility of evidence originate from a case known as *Frye v. United States* in 1923. The case gave rise to the "Frye rule," which states that expert witnesses should be allowed to give evidence provided that their conclusions derive from a principle that is "sufficiently established to have gained general acceptance in the particular field to which it belongs." This means that a judge, in a pretrial hearing, can determine whether expert witnesses and their testimony meet a reasonable scientific standard. In 1975, Congress enacted a revised set of federal rules of evidence, which were similar to those in the "Frye rule" but omitted any mention about the "general acceptance" of the science being presented. Some courts have followed the "Frye rule" and others have used the revised rule. Consequently, there is a considerable amount of questionable science in the courtroom. The very broad latitude in the procedure of different courts was probably the reason that the Supreme Court decided to hear the criteria for admission of scientific evidence in court.

The Peer-Review System

The general basis of the AAAS/NAS brief for acceptance of the credibility of theories and conclusions is the peer-review system. The peer-review process is accepted by the scientific community. The mechanisms among the sciences may differ because there is no specified format for the conduct of scientific work. In sciences such as agriculture, chemistry, or medicine, experimentation provides the main method of evaluating hypotheses. In other sciences, such as astronomy, observation is relied on to substantiate hypotheses. In yet others such as cosmology, consistency with general theory may be important. In general, across the scientific environment, experimentation is the most common. Although there is no simple format for the conduct of scientific work, science does proceed through a series of steps centered on the generation and testing of hypotheses. Hypotheses that are self-contradictory or inaccurate in predicting outcomes are rejected. Observation, reason, and experimentation constitute the scientific method.

Two major responsibilities assigned to peer reviewers of technical reports are to judge whether the data were collected in an appropriate manner and whether the data support the conclusions. Peer review of individuals is a judgment of professional competence. The system has worked well in the progression of science because it has alerted researchers to methodology and hypotheses that are accepted by their peers. By searching the scientific literature, scientists can develop new experiments that will expand the existing knowledge in their field.

The peer-review system has its critics. For example, some have claimed that it cannot always prevent scientific fraud. But even its most vocal critics do not recommend that the peer-review system be dismantled.

Critics of the peer-review system comment that it stifles innovation. Physicist Juan Miguel Campanario of the University of Alcala in Madrid listed two papers that the journal, *Nature*, had rejected.

1. In 1937, Hans A. Krebs described part of the citric acid cycle. He won a Nobel Prize in 1953 for the research.
2. In 1950, Barbara McClintock described how genes could move around on chromosomes. She won a Nobel Prize in 1983.

> "... COURTS SHOULD ADMIT SCIENTIFIC EVIDENCE ONLY IF IT CONFORMS TO SCIENTIFIC STANDARDS AND IS DERIVED FROM METHODS THAT ARE GENERALLY ACCEPTED BY THE SCIENTIFIC COMMUNITY AS VALID AND RELIABLE."

Scientists as peer reviewers tend to be conservative and to resist dissent and surprises. It is possible that the courts may uncover another unknown who eventually will receive a Nobel Prize, but the odds are very much against it.

Critics of the peer-review system also are concerned about another well accepted statistical concept in science, namely the 95% confidence level. Conclusions are justified when a given observation has 5% or less chance of happening by pure chance. Critics comment that where public health is concerned this level of significance is too stringent since some risks may be missed. Dr. Shana Swan of the California Department of Health Services used the 90% confidence level in the Bendectin case. She commented that because limb deformities are so rare "... even if one were to put all the studies together ... there would still be less than a 50% chance of finding a doubling of limb defects and only a minuscule chance of finding a 50% increase." This approach can be extrapolated even further. For example, if an event occurs in 0.01% of the U.S. population, it still would mean 26,000 events. No feasible statistical procedure to survey the U.S. population would detect this level of occurrence at the 95% level of confidence. There may be events in our society that are very real and very rare and caused by a particular treatment or exposure. It also is possible that they were not caused by the treatment or exposure. This reasoning would seem to strengthen the case for statistical levels of significance.

The possibility of events occurring by pure chance has led to another problem—the "cluster" theory. The existence of apparently larger numbers of events than one would expect has led to a number of frightening media stories, which later were proven to be merely statistical anomalies. There is one notable exception, namely the cluster of seven cases of a very rare vaginal condition in the daughters of women who had taken the hormone diethylstilbestrol (DES). But most cases of "clusters" prove to be statistical anomalies.

The positive aspects of peer review are much more common. Often they involve detection of simple mistakes in methodology unknowingly made by well-meaning researchers. These corrections are usually welcomed by the researcher prior to publication, because such errors could be a source of embarrassment after publication. This position is not always shared by those who operate in the public arena. For example, anecdotal and photographic evidence of malformed infants from Vietnam war veterans fueled public emotion about the problems with Agent Orange. A study involving only 100 cases of malformed infants would never be accepted by peer reviewers. Since the normal occurrence of structural birth defects in still-born and live-born infants is about 2 to 3%, this would mean that 104,000 to 156,000 infants of Vietnam veterans could show birth defects. Properly controlled studies of sufficient size have shown no relationship between exposure to Agent Orange in Vietnam and birth defects. This is an extreme example, but less obvious studies appear consistently.

Photograph courtesy of the Supreme Court of the United States, Franz Jantzen, photographer.

Federal agencies often rely on peer-review processes to allocate federal research dollars. Some federal regulatory agencies often place increasing reliance on the expertise of outside scientists by establishing special advisory committees. In some instances, Congress has mandated the use of peer review for certain agency actions. The system has worked well across a broad spectrum of scientific endeavor.

Expert Witness Industry

The concept of expert witness testimony has spawned a new industry. There are companies whose main activity is to provide safety data, or lack thereof, for the automobile industry. Other consultants provide expert testimony on request. In view of the diversity of opinions, one suspects that the testimony may be adapted to suit the purpose of the person requesting the expert opinion. Numerous books have been written on this subject. The book entitled *Galileo's Revenge: Junk Science in the Courtroom*, by Peter Huber of the Manhattan Institute for Policy Research, created a controversy in 1991. He coined the word "junk science" and used it to describe junk science in a number of well publicized court cases. These included a spermicide causing birth defects; a whooping cough vaccine causing brain damage; a swine flu vaccine causing serum sickness; a luxury car (Audi) accelerating at random; incompetence of obstetricians as a leading cause of cerebral palsy; traces of environmental contaminants causing "chemically induced AIDS"; and the morning-sickness drug, Bendectin, causing birth defects. According to Huber, none of the above are true, but they were supported by expert scientific testimony in the courts. Huber's book provides an important message.

Summary

The AAAS and NAS brief says that ". . . scientific evidence should conform to scientific standards." It does not say how judges should apply this rule, but suggests that claims should be regarded "skeptically" until they have been "subject to some form of peer-review." Publication in a peer-reviewed journal is "the best means of identifying valid research." The AAAS and NAS also suggest that in situations where judges may have trouble determining the validity of scientific research, a scientific review panel be appointed. The AAAS and NAS also advise that when judges are confronted with claims of "revolutionary advances in science," which are difficult to corroborate, the best decision "may be to err on the side of caution and exclude the evidence."

Both the AAAS and NAS urge the court to "uphold the broad authority of trial judges to exclude putatively scientific evidence that does not, according to the standards applied by the scientific community, have the earmarks of scientific reliability."

The Supreme Court decision on this case will have considerable impact on the course of science in the United States, particularly since the United States is gaining the reputation of being a litigious society. The scientific community, not the courts, should decide what constitutes good science.

CAST does not take a position in the Bendectin case. However, CAST does endorse the establishment of guidelines, which will ensure that courts admit only scientific evidence conforming to valid and reliable methods and standards accepted by the scientific community.

Update, May 1997

Shortly after this Issue Paper was published, the Supreme Court in June 1993 issued a verdict on the *Daubert v. Merrell Dow Pharmaceuticals* case. It essentially ruled that judges should exclude testimony based on evidence not generally accepted by the scientific community. The Supreme Court ruling is being taken seriously. In the first year, four cases were dismissed based on the "junk science" concept: (1) dismissal by the Texas Supreme Court of a claim against the Dupont Co. that alleged the fungicide Benlate had damaged a pecan grove, (2) banning by a federal judge of two doctors' testimony claiming that use of a Unisys computer keyboard was linked to carpal tunnel syndrome, (3) dismissal by a federal judge of a case against NEC that cellular phone use caused brain cancer, (4) dismissal by a U.S. District Court of a claim that birth defects were caused by Primatene (for asthma) taken during pregnancy. In 1996, the much publicized claims that electromagnetic fields (EMF) caused cancer were dismissed by the California Supreme Court.

Yet dismissal of these claims does not assure that similar claims in a more litigation-friendly state would not succeed. Two claims may have received the most publicity. The Bendectin case, in which the antinausea drug was claimed to have caused birth defects, was settled by the *Daubert* decision. The second case involved silicone breast implants. Even though several large studies concluded no relationship existed between silicone breast implants and alleged medical problems, implant lawsuits were nicknamed "Litigation Unlimited" because of sheer size—400,000 women and about $4 billion in damages. Scientists at Harvard University concluded in *The New England Journal of Medicine* from a study involving 87,501 women over a period of 14 years that the incidence of women with silicone implants experiencing medical problems was no greater than of women without implants. The American College of Rheumatology issued a rare declaration that there is no evidence that implants caused the diseases claimed by the plaintiffs' lawyers. In spite of this, plaintiffs continue to be awarded damages.

The suggestion that judges act as gatekeepers is making some of them uneasy because they may not have the expertise to judge which testimony is scientifically sound particularly in complex cases, e.g., silicone implants. Consequently, New York federal judges suggested appointing a scientific panel to judge the causality issues. They asked three people—one scientist, one scientist with a law degree, and one lawyer—to "advise trial judges on types of expertise needed to evaluate general causation claims." The panel is empowered "more or less simply to find neutral experts for the court and possibly to oversee their work." These scientific panels could be effective in controlling the "junk science" problem in courtrooms. CAST is one of the ideal scientific bodies to provide advice in panel selection and the CAST membership is an excellent reservoir of scientific talent.

CAST

Council for Agricultural Science and Technology
4420 West Lincoln Way, Ames, Iowa 50014-3447, USA
(515) 292-2125, Fax: (515) 292-4512
Internet: cast@cast-science.org
http://www.netins.net/showcase/cast/
Kayleen A. Niyo, Ph.D., Managing Scientific Editor
Richard E. Stuckey, Ph.D., Executive Vice President

 ISSN 1070-0021