Supreme Court to Weigh Science

It may set standards for who can qualify as an expert witness and what kinds of science can be presented to a jury; scientists and scientific organizations are giving the Court plenty of advice

The difference between "good" and "bad" science may be easier to detect than to define. But the Supreme Court has signaled that it's ready to take a crack at defining high- and low-quality science—or at least to set some new standards for expert scientific testimony in court. And if the Court weighs in on this issue, it may set a landmark that could affect many cases hinging on complex science issues in the future—ranging from DNA fingerprinting to the health effects of exposure to substances such as Agent Orange and asbestos.

The Court signaled its interest when it agreed recently to hear arguments in a case in which parents of two children with birth defects are suing the manufacturer of a drug called Bendectin, claiming that it caused the defects. In lower courts, the attorneys for the children had assembled evidence against the drug from several scientists with credentials in epidemiology and pathology. The manufacturer, Merrell Dow, responded that—regardless of credentials—the science was poor. Judges in the lower courts had agreed with defense lawyers, ruling that the plaintiffs' science didn't deserve to be presented to a jury —indeed, barring it from use. Now the Supreme Court has positioned itself to make landmark law by examining the lower courts' rationale for rejecting "expert" testimony.

JOHN HARDING

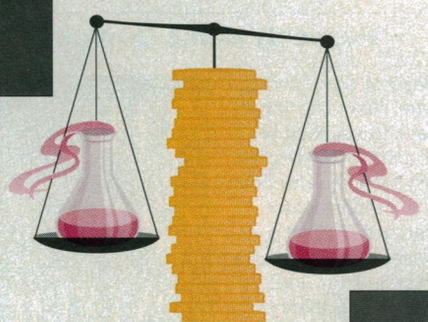
For the scientific community, the stakes —and opportunity—of this case, which has received widespread public attention with a front-page article in *The New York Times*, were immediately obvious. To many scientists and their institutions, the Court was suddenly providing them with a chance to strike out against "junk science." In a flurry of legal briefs, the American Association for the Advancement of Science (AAAS), which publishes *Science*, the National Academy of Sciences (NAS), and the American Medical Association—among many others—have rushed to argue that the judges must exercise the same kind of peer review that scientists do, keeping untested theories out of the courtroom. On the other side, trial lawyers, concerned epidemiologists, and some historians of science—including Stephen Jay Gould—have argued that judges cannot use any simple rule to decide what makes for good science, and that they should let jurors weigh relevant evidence from all qualified experts. These contradictory stances, offered in the form of at least 20 advisory "amicus," or friend-of-the-court, statements, had reached the Court by the final deadline of 19 January (see scorecard).

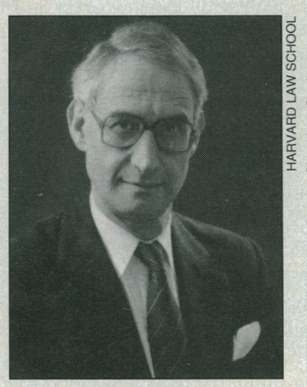
SPECIAL NEWS SECTION

A special News report on breast cancer research begins on page 616. The News section that begins on this page combines News & Comment and Research News.

Standards of credibility

The roots of the events that triggered this flurry of legal paperwork go back to the 1970s, when millions of pregnant women took Bendectin to reduce morning nausea. In 1983, Merrell Dow, faced with a barrage of lawsuits from parents who claimed Bendectin caused their children to be born malformed, took the drug off the market. But one of the cases that prompted this action proved to have a life of its own. In it, attorneys for Jason Daubert and Eric Schuller, two children with birth defects, gathered evidence from test-tube and animal testing of Bendectin that suggested the drug could cause birth defects. And they assembled expert witnesses to testify that epidemiological evidence showed an association between Bendectin use and human birth defects. The most prominent of these experts was Shanna Helen Swan, an epidemiologist trained at the University of California, Berkeley, and now director of a California state health department group that monitors reproductive risk.





HARVARD LAW SCHOOL

Who should judge? Epidemiologist Shanna Helen Swan's *(above)* unpublished data were ruled inadmissible; lawyer Charles Fried *(right)* says only widely accepted science should be allowed.

Merrell Dow's attorneys, however, argued that the evidence wasn't credible because it had not been peer reviewed or published and was contradicted by 30 published epidemiological studies. Judges in two lower courts in California agreed, ruling that the plaintiffs' science was inadmissible. And, so far, it hasn't been presented to a jury, because the case has been dismissed in each courtroom, most recently by the Ninth Circuit Court of Appeals.

But the children's attorneys took the matter all the way to the Supreme Court. Oral arguments are to be made in late March, and the Court is expected to issue a decision by summer.

The Court's interest came as a surprise to the likes of Richard Meserve, a Washington, D.C., attorney at the Covington & Burling law firm who filed the AAAS and the NAS amicus brief. The Court has had many opportunities to review the standards of scientific testimony in the past and has repeatedly avoided doing so. Indeed, the last time the federal courts issued a broad ruling on scientific testimony was in 1923, in a case known as *Frye* v. *United States*. It gave rise to a standard known as the "Frye rule," which states that expert witnesses should be permitted to give evidence only if their conclusions derive from a principle that is "sufficiently established to have gained general acceptance in the particular field in which it belongs." As a practical matter, this means a judge has the power to hold a pretrial hearing to determine whether expert witnesses and their testimony meet a reasonable scientific standard. And in fact, this is what happened in the Daubert *et al.* case.

Both the district court judge and the

Ninth Circuit Court judges used the Frye rule to reject the scientific testimony of the Daubert and Schuller case. The reason: The animal data were not backed up by credible human epidemiological data.

The status of the Frye rule is unclear, however. Some courts have continued using it while others have relied instead on revised federal rules of evidence enacted by Congress in 1975. Like the Frye rule, they ask the judge to use discretion in limiting scientific witnesses to people who are "qualified as an expert by knowledge, skill, experience, training, or education," to give opinions on scientific or technical data. But, unlike Frye, they say nothing about the "general acceptance" of the science being presented.

A broad interpretation of these rules, some lawyers argue, opened the flood gates to questionable science being presented in courtrooms. This development, along with the differing interpretations around the country over which rules of evidence apply, may have been the invitation that brought the Supreme Court to the party. Now the Court seems ready to focus on what credentials expert witnesses should have, and what they should be permitted to say to nonexpert juries.

Publication in a peer-reviewed journal is "the best means" of identifying valid research.

–AAAS/NAS brief

A 70-year opportunity

If the Supreme Court Justices were eager, the scientific community was even more so. Indeed, it is hard to remember any previous occasion when the NAS and the AAAS joined forces to speak out on a public issue. To understand why there's such eagerness, consider the remarks of Richard Wilson, a distinguished Harvard physicist and cosigner of one of the amicus briefs: "It's been 70 years since the courts have really looked at this, and it is probably going to be another 70 before they will look at it again." There's no point in "grumbling like hell all your life" about the way the law will permit un-peer-reviewed testimony Wilson adds, and then ignoring an opportunity to change it. "Scientists should either put up or shut up."

And they have—on both sides of the fence. An impressive group of scientists that includes Stephen Jay Gould and historian of science Gerald Holton of Harvard supported the arguments of Kenneth Chesebro, lead attorney for the Daubert and Schuller families, before the Supreme Court. Pointing out that they have no opinion on the Daubert case itself, they weighed in with an amicus brief stating that the lower court rulings are "premised on a remarkable misunderstanding of the nature of scientific inquiry." The Ninth Circuit's "myopic mode of decision making" dismissed one expert witness's testimony (epidemiologist Swan) out of hand, without checking on the quality of her approach—merely because it had not been published. "It would be a grave mistake to require that all scientific analysis be supported by a consensus and published in a particular form in order to be considered," they conclude.

Others who reached this conclusion for similar reasons include a group of scientists and lawyers led by the American Society of Law, Medicine, and Ethics; a group of epidemiology professors led by Kenneth Rothman, editor of *Epidemiology*; and a group led by Daryl Chubin of the U.S. Office of Technology Assessment, whose brief pours scorn on the peer-review process. Chubin *et al.* state, for example, that: "Although professional basketball referees must go to school to learn what is or is not a foul, peer-review journal referees receive no comparable training"—a remark calculated to infuriate many scientists. But the brief goes on, stating: "Even more amazingly, the peer-review industry is a wholly unregulated collection of completely independent and unsupervised periodicals...."

The epidemiology group also excoriates the Ninth Circuit—for its "blind deference" to publication in peer journals and its "talismanic" worship of the phrase, "statistically significant." There is no short cut, says the Rothman group, for actually thinking carefully about the data, and that is what Rothman urges judges and juries to do in each case: Weigh all the relevant scientific evidence themselves.

In the mainstream

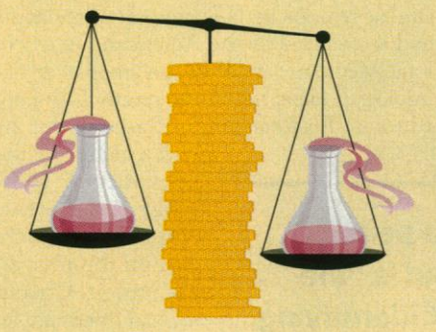
Equally vehement are two rather different groups—those who support Merrell Dow and those who take no position on the Bendectin case itself but support the principle that judges should screen out low-quality science. Harvard University constitutional scholar Charles Fried leads the former. As the company's attorney, he argues that both the congressionally mandated federal rules, and the Frye rule, require that testimony from an expert must rest on "a foundation reflecting the generally accepted standards in that field for validating expert assertions." Science, Fried writes, is a collective enterprise, and its most basic requirement is that a hypothesis be "written up, with supporting reasons, and disseminated to the scientific community for the process of independent scrutiny." He notes that none of the experts cited by the Daubert and Schuller families "has ever set out in writing the data, premises, and methodology" leading to their conclusions. Nor do they have a valid excuse for their failure to publish, Fried claims, for "these are not brand-new discoveries, too fresh to publish ...not narrow claims of little interest." In these circumstances, Fried concludes, the claims must be treated as not based on good science.

HOW THE AMICUS BRIEFS LINE UP

Merrell Dow	Daubert *et al.*
AAAS, NAS	Ronald Bayer, Stephen Jay Gould, Gerald Holton, Peter Infante, Philip Landrigan, Everett Mendelsohn, Robert Morris, Herbert Needleman, Dorothy Nelkin, William Nicholson, Kathleen Joy Propert, and David Rosner
American Medical Association, *et al.*	Daryl E. Chubin, Edward J. Hackett, David Michael Ozonoff, Richard W. Clapp
Nicolaas Bloembergen, Erminio Costa, Dudley Herschbach, Jerome Karle, Arthur Langer, Wassily Leontief, Richard S. Lindzen, William N. Lipscomb, Donald B. Louria, John B. Little, A. Alan Moghissi, Brooke T. Mossman, Robert Nolan, Arno A. Penzias, Frederick Seitz, A. Frederick Spilhaus, Dimitrios Trichopoulos and Richard Wilson	American Trial Lawyers Association
New England Journal of Medicine, Journal of the American Medical Association, Annals of Internal Medicine	Texas, Montana, Idaho, South Dakota
U.S. Solicitor General	Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra, and Steven Stellman
Washington Legal Foundation	American Society of Law, Medicine, and Ethics; Devra Lee Davis; Marvin S. Legator; Donald R. Mattson, Natural Resources Defense Council; Program on Gender, Science, and Law–Columbia University; Allan Rosenfield; Ellen K. Silbergeld
American College of Legal Medicine	
Chamber of Commerce	
Product Liability Council *et al.*	
American Tort Reform Association	
American Insurance Association	
Pharmaceutical Manufacturers Association	
Alvan Feinstein	

At Issue in the Bendectin Case

Bendectin was prescribed as an anti-morning sickness drug in the United States from 1956 until 1983, and during that time, about 17.5 million U.S. women took it. In the 1970s and 1980s, the manufacturer, Merrell Dow Pharmaceuticals Inc., was hit with an "avalanche" of lawsuits alleging that the drug caused birth defects. In 1983, the beleaguered pharmaceutical firm removed its product from the market. And yet Bendectin was judged safe the last time the Food and Drug Administration examined it—in 1980.



It's no surprise, then, that of about 2000 suits filed against the company (the numbers from Merrell Dow's lawyer, Charles Fried) so far only one has resulted in an unfavorable jury verdict, sustained on appeal. Most have been dismissed. The company's attorney boasts that no damages have been paid as yet.

The suits against Bendectin have done poorly because the courts demanded direct evidence that it injured humans. Some laboratory data show that Bendectin affects the development of embryonic cells in vitro, and that, if fed to animals at high concentrations, it can cause birth defects. But no one has published a study demonstrating that humans have been affected, though millions were exposed to it. On the contrary, 30 published studies, including one by the Centers for Disease Control, found no statistically significant association between Bendectin use and birth defects.

One of the chief witnesses for the families suing Merrell Dow in the case before the Supreme Court—Shanna Helen Swan, a California state health worker—argues that the failure to detect Bendectin-induced deformities is merely a sign that epidemiology is a weak tool for spotting rare ailments. She estimates that the drug probably caused limb reduction defects in one in 1000 babies born to mothers using it, while birth defects from all causes occur at a rate of 20 to 30 per 1000. Swan argues that it's easy to lose the drug's effect in the pool of natural ills—unless a researcher takes great care to sift the data.

And that is precisely what Swan attempted to do in her court testimony. She picked apart the best of the 30 studies published earlier, showing how their methods could have obscured the one in 1000 incidence of Bendectin-induced deformities. Then she went back to the raw data and reanalyzed them, establishing a new set of "controls." Rather than use all children with deformities as the control group (on grounds that doing so would include Bendectin effects in the controls and underestimate the effect), she used children with chromosome abnormalities as controls. The result, by her calculation, was a statistically significant association between use of the drug and the risk of having a child with birth defects.

This reanalysis was rejected by the courts as scientifically invalid because Swan never published it, though she presented it orally to the Society for Epidemiological Research in 1984. Swan points out that abstracts of the presentation were screened by a peer-review committee in advance. So why didn't she publish the analysis—or at least write it up? She says a coauthor backed out, and "it got pushed farther and farther down the agenda....I fully intended to write it up, but it didn't happen." The result: Two U.S. courts have rejected her work as not credible, and now the Supreme Court will have its say.

–E.M.

Sherwood Rowland, president of AAAS, isn't stepping into the case to argue on behalf of Bendectin; he points out that his organization, like several others, has come down on the Merrell Dow side out of necessity rather than love. The law stipulates that neutral amicus briefs must be filed by the deadline set for petitioners—2 December of last year in this case. While negotiating the text of their joint statement, AAAS and NAS missed that deadline, Rowland says, and decided to file with the defense on 19 January.

"It would be a grave mistake to require that all scientific analysis be supported by consensus."
–Gould *et al.* brief

So what do the two organizations believe? The AAAS-NAS statement to the court focuses on the importance of using good scientific methods and supports Merrell Dow's view that judges should be asked to "exclude expert testimony that is based upon unreliable or misapplied methodologies." Scientific evidence, say AAAS and NAS, "should conform to scientific standards and should be based on methods that are generally accepted by the scientific community as valid and reliable." The brief doesn't say how judges should apply that rule, but states that claims should be regarded "skeptically" until they have been "subject to some form of peer scrutiny." Publication in a peer-reviewed journal is "the best means" of identifying valid research, the brief says, though it adds that it is just one of many. AAAS and NAS also suggest that judges should appoint expert review panels when they have trouble determining validity of scientific evidence. And they advise that when judges are confronted with claims of "revolutionary advances in science" that are difficult to corroborate, the best decision "may be to err on the side of caution and exclude the evidence."

Middle ground

One of the few briefs that proposes a method for screening scientific testimony was filed by the Carnegie Commission on Science, Technology, and Government. It went to the Court on the early deadline, permitting it to support neither party. The Carnegie position is that the Frye rule is too "simplistic," "vague," and "misleading" to continue in use. Instead, the brief urges the Court to apply a three-step test in which judges ask of a scientific claim: Is it testable? Has it been empirically tested? And has the testing been carried out according to a scientific methodology? A negative answer on any one of these points, Carnegie argues, should disqualify the evidence.

Whether the Court will actually heed any of the advice it's getting remains to be seen. But one message does come across in briefs filed on behalf of the scientific community: Many believe that the 70-year-old Frye rule fails to give adequate advice to the judges on how to think as scientists do when considering technical issues. For this reason, and because of apparent confusion in the lower courts on how to interpret the rules of evidence, it looks as though Frye is due for a rewrite. Some clues to how the Supreme Court intends to set standards for good and bad science may come in March, when the justices question attorneys for both sides.

–Eliot Marshall