nature medicine
VOLUME 3 • NUMBER 2 • FEBRUARY 1997

Scientific "experts" and the law

Robert E. Jones, a United States federal court judge in the state of Oregon, is little known in the world of biomedical research. But a decision he handed down in December regarding the probative value of scientific evidence in lawsuits against the makers of silicone breast implants should earn him the respect of researchers and physicians worldwide. Thousands of women in the US have sued implant-makers, claiming that silicone gel causes a host of diseases including scleroderma, rheumatoid arthritis, and connective tissue diseases (see Kidder *et al.*, page 235). The trouble is, there are no sound scientific data to support these claims. And that is where Judge Jones comes into the picture.

Jones created a panel of four scientists with expertise in epidemiology, rheumatology, immunotoxicology and polymer chemistry, asked them to review the literature and to participate in a four-day hearing with attorneys and expert witnesses for both sides. In the end, the judge accepted the panelists' view that scientific data fail to support allegations that silicone implants cause systemic disease. With that, Jones then proceeded to exclude from trial any "expert" testimony on the subject. His pretrial decision was a victory for the companies that make implants, but it was also a victory for common sense. It is a sham to expect jurors to distinguish good science from bad during a trial and, all too often, in the face of confusion juries have reached decisions based on emotion and sympathy rather than fact.

It is no secret that science and law don't mix, or that biomedical research and the law make particularly uneasy bedfellows. Scientific studies often result, quite reasonably, in a call for further study. But trials end with a definitive result: someone is judged to be right, someone wrong. Therefore, it frequently happens that when a dispute involving scientific data ends up in court, the jury's decision and scientific evidence are at odds. The jury's disregard of the DNA evidence in the O.J. Simpson trial is a familiar and recent example. Painstaking lessons in the courtroom about the structure of DNA were lost on jurors conditioned to believe that science is too difficult to understand and, indeed, the pedantic way in which data were presented was more than the untrained mind could absorb.

In a series of cases in the 1980s regarding the allegation that the morning-sickness drug Bendectin is a teratogen, juries awarded millions of dollars in damages to families of children born with a range of birth defects despite the absence of any evidence of cause and effect. In the process, the manufacturer took a useful drug off the market, leaving pregnant women with serious morning sickness in the lurch.

The Bendectin story came to an important conclusion in 1993 when the U.S. Supreme Court heard a case known as *Daubert v. Merrell Dow*, (Merrell Dow used to manufacture Bendectin). In a landmark ruling regarding science and the law, the Supreme Court said that, in complex cases involving medicine and science, judges have a duty to independently assess the validity of so-called "expert testimony" before allowing its presentation to unknowing juries. The essence of the Court's decision was that judges should refuse to admit evidence that is not based on sound scientific methodology .

Jones, in the breast implant decision, is one of the first federal judges to implement the Supreme Court's decision in *Daubert*. In fact, Jones took it one step further. Instead of limiting his decision to issues about scientific methodology and peer review, he reached an opinion on the validity of the data, not just the process by which they were obtained. Whether this is taking judicial discretion too far remains to be seen. But soon there will be another similar case for comparison. A judge in the state of Alabama, who is also presiding at trials against breast-implant makers, has set up an expert scientific panel of his own, much like the one created by the Oregon judge. That panel's review of the evidence should be completed within several months.

These are important precedents in US law that may bring a much needed element of reason to trials that are subject to emotion. As attorney Lee Loevinger wrote recently in a book review for *Nature**, in cases "lacking scientific evidence of causation, litigation becomes a lottery." Interestingly, Loevinger also notes that legal practices in other countries (Britain, for example) do not allow conflicting and unconfirmed 'scientific' evidence to go to a jury in the first place.

The ruling by the Oregon judge may have gone too far, but it certainly did so in the right direction. There are any number of cases involving environment and disease in the courts and on the horizon, among them cases alleging that electromagnetic fields cause cancer in children (for which there are no good data) and claims that environmental agents have caused a new disease — Gulf War Syndrome — among soldiers who fought in the Middle East. If Judge Jones' decision to evaluate the credibility of scientific evidence prior to trial is imitated by other courts, he will indeed have done science and medicine a real service.

— **Barbara J. Culliton**

*Science on Trial: The Clash of Medical Science and the Law in the Breast Implant Case, by Marcia Angell. *Nature*, **383**, 784–785 (1996).