SCIENCE AND THE LAW

Breast-Implant Ruling Sends a Message

When a federal judge in Oregon ruled last month that evidence linking silicone breast implants to autoimmune disorders in about 70 women is too weak to be presented to a jury, he sent a shock through the legal profession. If the ruling holds up, legal experts say it will strike a blow to billions of dollars worth of implant lawsuits nationwide. But the long-term repercussions could be even more important: Some scientists and lawyers believe that the procedure the judge, Robert E. Jones, used to exclude the evidence may provide a model for other high-profile cases where scientific evidence is in dispute.

Jones, faced with the likelihood that the jury would hear a parade of expert witnesses debating esoteric scientific issues, took the unusual step of putting together a panel of experts to sift through the evidence for him before the trial began. As justification, he cited a 1993 Supreme Court decision, known as the *Daubert v. Merrell Dow* case, which called on judges to be "gatekeepers" and screen out testimony that relies on faulty science (*Science*, 2 July 1993, p. 22). The four panelists,* all of whom had no previous connection with the breast-implant issue, included an epidemiologist, a rheumatologist, an immunotoxicologist, and a polymer chemist from institutions in Portland and Seattle. Jones asked the panel to address questions ranging from whether experts' opinions were supported by scientifically reliable data and methods accepted by the scientific community, to whether the data applied to the disease at issue.

"It was quite an education," says panelist Merwyn R. Greenlick, an epidemiologist at Oregon Health Sciences University in Portland. Greenlick says each panelist looked at a range of materials, including testimony in prior cases and relevant studies in their fields. Judge Jones then held a 4-day hearing in August where the scientists heard lawyers and the expert witnesses discuss the evidence. Each panelist then submitted separate reports to the judge, giving the evidence critical but mixed reviews.

In his opinion, released on 17 December, the judge agreed with the companies' request to exclude from the trial "any expert testimony concerning a general causal link between silicone-gel breast implants" and systemic illness. His decision addresses contentions by the plaintiffs' expert witnesses one by one. He noted, for example, that conclusions that were to be presented by Shanna Swan, an epidemiologist who has testified widely in support of implant plaintiffs and consulted for government agencies, hadn't been peer-reviewed. And he called plaintiffs' claims that they suffer from a new disease called "atypical connective tissue disease"—involving headaches, joint pain, and fatigue—"at best an untested hypothesis." (His opinion does not rule out claims for localized complaints such as scar tissue around implants, however.)

Jones was aware that his actions could have broad repercussions, writing: "I am mindful that this opinion goes farther in evaluating and in eliminating plaintiffs' claims than any other opinion in breast-implant litigation pending in this country." Says Margaret Berger of Brooklyn Law School: "It's certainly, I'm sure, going to have some impact on settlement discussions."

The decision is a preliminary one, however. Although Jones said he is "unlikely" to change his mind, he will not make his decision final until another scientific panel,† appointed by Alabama Chief Judge Sam C. Pointer, has sorted through similar evidence in a collection of cases from around the country that have been referred to his court. "They are really just getting started," says Berger, who helped appoint the panel.

If Jones sticks by his original decision, it will likely be appealed. The plaintiffs' attorneys argue that Jones went too far by assessing the experts' conclusions, not just their methodology. "His role is not to judge whether the experts are right," says one of the lawyers, Frederick Ellis of Boston. Law professor Michael Green of the University of Iowa notes that the same appeals court—the 9th circuit—found much of the same evidence admissible in a 1994 case. "But," he says, "there's now a lot of additional science."

Whether or not Jones's ruling holds up, Green says the procedure he used could be a precedent to help judges sort through evidence in other large class-action suits, such as secondhand smoke cases. Adds Paul Carrington, director of the Center for Private Adjudication associated with Duke University: "Whether he [Jones] is right or wrong on the science, I regard it as a positive sign that at least that's one judge who got the message [of the *Daubert* decision] and who is exercising some responsibility."

–Jocelyn Kaiser

* Merwyn R. Greenlick, Oregon Health Sciences University; Robert F. Wilkens, rheumatologist, Seattle practitioner; Mary Stenzel-Poore, immunotoxicologist, Oregon Health Sciences University; Ronald McClard, polymer chemist, Reed College.

† Barbara S. Hulka, University of North Carolina; Betty Diamond, Albert Einstein College of Medicine; Peter Tugell, University of Ottawa; Nancy Kerkvliet, Oregon State University.

JAPANESE BUDGET

Basic Science Spending to Jump in 1997

TOKYO—Basic science is set to receive a big boost in the next Japanese budget, according to a draft budget released late last month by the Ministry of Finance. The increase—a rise of 8% in a category that includes academic and basic researchers at national institutions—is in line with a 5-year plan adopted last summer to raise public spending on science and technology in hopes of securing long-term economic growth. "Given that the budget situation is very tight with the government trying to reconstruct its finances, [science] is getting a lot of support," says Hiroyuki Osawa, a former vice minister of the Science and Technology Agency (STA) and a member of the Council for Science and Technology, an advisory body to the prime minister.

The additional money for science comes at a time when the government's overall budget is growing by only 3%, and many programs are being trimmed. But the focus on science is seen as a remedy for a stalled economy. "In various fields, Japan's [economy] is running into walls," says Masaki Tanaka, director for budget planning at STA. "There is a consensus in the government and the Diet that this kind of investment is needed to break through those walls."

The full extent of that R&D investment won't be known until details of the entire 1997 budget become available. The portion of the finance ministry's draft budget labeled science includes less than a third of Japan's public R&D investment, which this year amounts to about $26 billion. In particular, the science category excludes energy-related research, including Japan's extensive activities involving nuclear power.

For that reason, officials at the research-related ministries, particularly the Ministry of Education, Science, Sports, and Culture and the STA, were reluctant to put final figures on specific programs before a last round of negotiations and final approval by the Cabinet, which were expected as *Science* went to press. But significant increases in support for research in information technologies and neuroscience, as well as the continued growth of programs financing postdoctoral positions, seem assured. The budget covers the 1997 fiscal year, which begins on 1 April.

–Dennis Normile