THE FUTURE OF
LITIGATION
A SUPPLEMENT TO THE AMERICAN LAWYER & CORPORATE COUNSEL FALL 2003

FUTURE | EXPERTS

Inexact Science

How does a federal judge decide what's a valid scientific method and what isn't? Even the experts don't always agree.

THREE WEEKS AFTER GIVING BIRTH, LISA SOLDO, age 28 and previously healthy, suffered a stroke that left her half-paralyzed. Twelve years have passed and still she needs help raising her two children. For a time, her disfigured face and her drooling even made her son afraid to be near her. Soldo blamed the 1991 stroke on a medicine, sold under the brand name Parlodel, that she took right after the birth to block her from producing milk. A single mother, she had wanted to get right back to work. But she would never work again.

In May 1995, Soldo sued the drug's maker, Sandoz Pharmaceuticals Corporation, in federal court in Camden, New Jersey, for selling an unsafe product and failing to warn adequately of a stroke risk. In 1998 the product liability case was transferred to federal district judge Donald Lee in Pittsburgh, closer to where Soldo lived.

Her injury was serious and obvious. But what caused it? Sandoz (by then part of Novartis AG) vigorously disputed Soldo's claims, arguing that there was no evidence that linked Parlodel to strokes. Both sides had highly credentialed experts willing to testify about the arcana of bio-chemistry. But how was Judge Lee to pick between them? He'd been a successful practicing lawyer for 30 years and had served as a well-respected federal judge for nearly a decade. Yet little in his experience could help him with what became his chief task in the Soldo case: deciding whether the testimony of her hired experts was worthy, reliable science.

Lee was hardly the first judge to face the prospect of choosing between dueling scientists. In practice, judges used to leave such choices to juries. This was the standard procedure into the 1990s, as injured people brought suits seeking damages for a host of injuries that they believed were caused by a variety

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BY MATT FLEISCHER-BLACK • PHOTOGRAPHY BY DOUGLAS LEVERE

of drugs or environmental hazards. A backlash developed as both scholars and industry defendants charged that juries, untutored in the methodology of science, were being swayed by experts whose testimony consisted of "junk science." The din grew loud enough that in 1993 the U.S. Supreme Court intervened. In a landmark decision in the case of *Daubert* v. *Merrell Dow Pharmaceuticals*, the Court held that federal judges must measure the "scientific validity" of expert opinions before letting a jury hear them.

But are judges necessarily better equipped to assess scientific opinion than juries? As lay people, they, too, can sometimes have trouble understanding the methods as well as the imperfections of science. Judges also must grapple with the difficulty of translating scientists' reasoning into law: Scientists think in terms of probabilities, while judges must rule about specific circumstances.

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And sometimes, as in Soldo's case, the victims bring scientific mysteries with them. What caused her stroke? Neither clues nor opinions were lacking: Novartis had designated 24 expert witnesses to opine on the cause, while Soldo offered 12 scientists. After 29 expert depositions, Judge Lee took matters into his own hands. He decided he wanted his own scientists to look at the matter. In essence, he decided that he needed experts to advise him on which experts to trust. He appointed three who studied the evidence from both sides and reported their conclusions. The process took two years. Yet even the distinguished scientists that the judge recruited didn't give him a clear-cut answer.

Soldo's lawsuit offers a window into how difficult it is—and will continue to be—to deal with science in the courtroom. The stakes are not diminishing and the technology is only growing more complex. Laden with uncertainty, these matters perhaps don't belong in the courts. But for the moment at least, judges and juries are the national safety net. And absent a fundamental change, judges and juries will be asked to sort out problems on which the experts can't seem to agree.

When Soldo filed her suit in 1995, she was one of dozens of women who had suffered strokes or heart attacks after taking Parlodel. The previous year, the Food and Drug Administration had announced it wanted to end sales of Parlodel to new mothers. The agency had scheduled a hearing to assess whether the medication's risk of strokes to new mothers outweighed its benefit. Faced with that warning and a flood of bad publicity, Sandoz voluntarily stopped selling Parlodel for lactation suppression; the drug remains on the market as a treatment for Parkinson's disease. The FDA cancelled the hearing and barred the drug's future sale to nursing mothers.

The nation's plaintiffs lawyers watched the FDA and Sandoz exchange jabs. Earlier FDA warnings had kicked off mass litigation involving products like silicone breast implants and the antinausea drug Bendectin. Would Parlodel be next? One New York firm, Weitz & Luxenberg, filed suit for 16 victims, including Soldo, in federal court. This was a serious step because the firm could afford a fight—its prominence had grown from taking the lead in New York asbestos litigation. Also, Stephen Orlofsky, the federal judge who initially was assigned Soldo's case, indicated that he would group several cases together, echoing the breast implant litigation that drove defendant companies into bankruptcy in the mid-1990s.

At first, Sandoz moved to settle the Parlodel cases. Then, in 1996, Sandoz merged with Ciba-Geigy AG to form Novartis, and the new company decided to defend itself more aggressively. Novartis turned to lawyers from Washington, D.C.'s Spriggs & Hollingsworth, who convinced Orlofsky that Weitz & Luxenberg's cases had to be separated and sent a cross the country. And then they set out to shoot down each claim, one by one.

Spriggs & Hollingsworth aimed its arrows at the underlying science. In Pennsylvania, Novartis attacked Soldo's key expert witnesses under the Daubert requirement that experts must use reliable methods to come to their conclusions. "*Daubert* is an essential tool for business in today's world, where a single article posing a hypothesis in a medical journal can lead to ruinous litigation," says Novartis counsel Joe Hollingsworth. He primarily targeted two Soldo experts who were pinning the blame on Parlodel: Dr. Denis Petro, a neurologist, and Dr. Kenneth Kulig, a toxicologist.

Their testimony—and that of a dozen other experts in Soldo's case—would delve deep into research about the effects of alkaloid compounds on the brain. In October 1999 Lee, the judge in Soldo's case, told the lawyers on both sides that he had asked Duke University's Private Adjudication Center to find independent scientists who would help evaluate their experts. At the time, the center had a registry of scholars who usually didn't testify in court, but were willing to help judges. By calling on independent experts, Lee thought that he might reach a ruling that would help shape the other Parlodel cases around the country.

Under rule 706 of the federal evidence code, judges have long been able to hire their own experts. But the notion has picked up steam since the Daubert decision. Supreme Court justice Stephen Breyer pushed the idea in a 1995 opinion, citing pledges of aid from scientists. "Given this kind of offer of cooperative effort, from the scientific to the legal community," he wrote, "it seems to me that *Daubert*'s gatekeeping requirement will not prove inordinately difficult to implement."

Following Breyer's suggestion, Lee turned for help from the Duke center. But while he waited, he presided over a long hearing in which the two sides argued over the methodology of

their experts. The hearing ran for seven days, costing plaintiffs $75,000 in expert fees, hotel bills, and other expenses. (Defense counsel declined to reveal their costs.) Lee says that only then, faced with reams of conflicting, highly technical testimony, did he make the final decision to go ahead with retaining his own experts. He wanted an objective opinion on the record, certain that the two sides would appeal his decision. "I expected them to do battle all the way," he says.

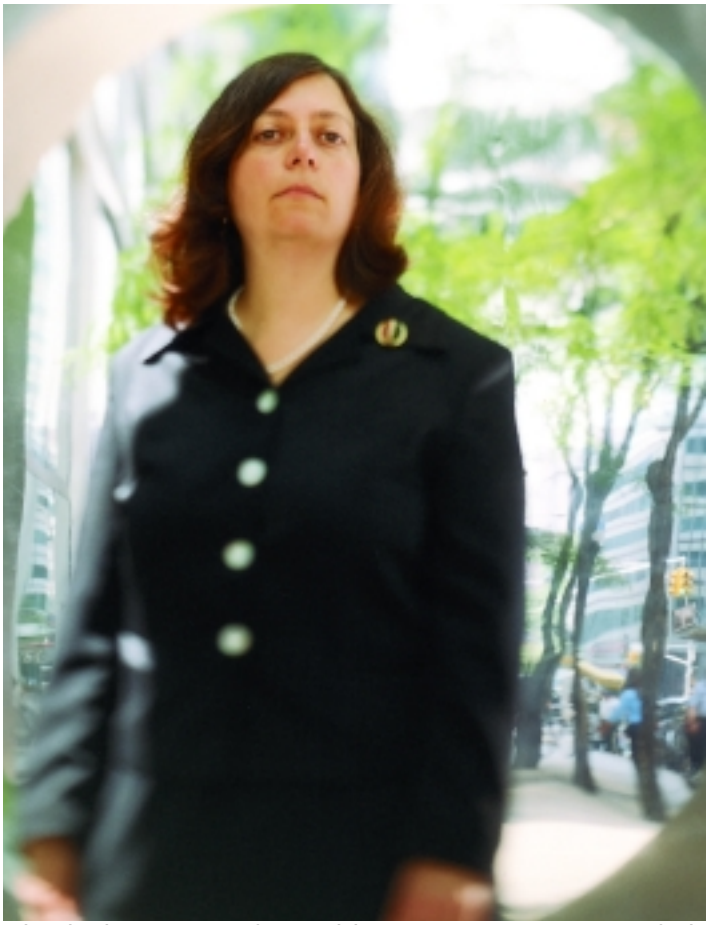
Judge Lee's search for conflict-free experts ultimately took a year, until the end of 2000. He appointed three, each from a different university and each from a field relevant to the testimony of the parties' experts: a clinical pharmacologist, a neurologist, and an epidemiologist. Lee sent his reviewers boxes of transcripts and other evidence from the earlier duel of experts and asked them to decide whether Soldo's experts had used a scientifically reliable method to form their views.

When all the reports came in, Lee's three reviewers were split. Two of them, the neurologist and the epidemiologist, said that the plaintiff's experts had gone too far when they concluded that Parlodel had caused Soldo's stroke. The third, clinical pharmacologist David Flockhart of Indiana University, said that Kulig, the plaintiff's toxicologist, had correctly added up the scientific evidence; Petro, the neurologist, had not. The calendar now said December 2001. After two years of waiting for clarifying advice from his experts, and running up $21,793.75 in expert fees for the parties, the judge had received a muddle.

Lee wasn't flummoxed, however. He went with the majority, concluding that neither of the plaintiffs experts had used scientifically valid methods and thus flunked the Daubert test. Each of the plaintiffs experts had pointed to an aggregate of studies and reports to establish that the drug could cause strokes like Soldo's—a weight-of-the-evidence approach. But Lee thought that this method required too much extrapolation. In a 280-page ruling in January 2003, he excluded the testimony of both Soldo experts, and in the absence of expert testimony for the plaintiff, he granted summary judgment for Novartis.

The Supreme Court has not given judges much instruction on how to resolve conflicting testimony from different sciences. In his ruling, Lee showed a distinct preference for one scientific discipline over the others: epidemiology. Epidemiologists are statisticians who review masses of medical records to see whether someone exposed to a substance, like tobacco, also contracts a disease. Where there's no statistical evidence of causation, wrote Lee, the scientific link of cause to effect must be obvious, "in the same way that a tornado leading to injury is obvious."

"This does not mean that conclusive published epidemiologic studies are required in every case involving cause and effect," the judge allowed. "In this case, however, other types of evidence upon which plaintiff might reasonably rely are equally absent. . . . Plaintiff's experts cannot lump together lots of hollow evidence and reach a reliable conclusion."



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Furthermore, Lee ruled that his own dissenting expert was unreliable. He found that the report by pharmacologist Flockhart was written "in terms of 'possibilities' and speculation," and "suffer[s] from the same methodological flaws as those of plaintiff's experts."

With an air of resignation, Flockhart says that his field couldn't give the judge what he wanted. "He's criticizing me for talking about possibilities and probabilities, which every scientist has to do," says Flockhart. "But I cannot put numbers as well on those possibilities and probabilities." He cautions that judges should be careful about relying on the apparently hard numbers of epidemiology: "The statistical epidemiological data deals with the averages, unfortunately. It is an insensitive tool that cannot pick up and describe things that are very relevant to specific cases," he says.

"*Soldo* reveals what other decisions have obscured," says Joe Cecil, a researcher at the Federal Judicial Center: Some types of scientific experts just don't cut it in federal courtrooms anymore. Flockhart opined that Kulig's methodology met the standards of his field—toxicology is part of pharmacology—yet Lee held that the entire field's methodology failed the Supreme Court's standard for valid science.

Soldo appealed, arguing that the judge's dismissal of Flockhart's opinion was improper. Her team asserted that the

judge committed legal error by disregarding legitimate disagreements between qualified, neutral experts. That was a matter best left to a jury, in their view. Before her appeal was heard, the case settled last June for what sources close to the case say was an amount in the five figures—less than the cost of the Daubert hearing to either party.

Neither side's lawyers thought that Lee's use of outside experts had aided the search for justice. "It was wasteful and costly," says Ellen Relkin, Soldo's lawyer from Weitz & Luxenberg. "It would have been more cost-effective to have these experts review the voluminous submissions before the Daubert hearing." (Rule 706 doesn't establish any funding, so the judge ordered the two sides to split charges.) Even worse, she charges, the legal process itself was perverted.

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"Legal scholars and academicians studying the use of science in the courts will be able to cite this case as an example of Daubert abuse, in that the court would not allow a jury to decide disputed medical issues," says Relkin.

Although the judge's experts turned out to be a gift to the defense, Novartis counsel Hollingsworth didn't like handing legal proceedings over to outsiders, either. He says he would rather have a judge listen to courtroom interrogation to assess whether an expert like Kulig makes the scientific cut. "That's best left to cross-examining at a Daubert hearing," Hollingsworth says.

The judge, now retired, is satisfied with the process. "It helped," he says. "It gave me the creature comfort of [consulting] people who didn't have an axe to grind."

More than 20 percent of federal judges have used outside experts, says Cecil. "That rate won't rise fast," says Pamela Ann Rymer, a judge on the U.S. Court of Appeals for the Ninth Circuit and advisory committee chair for the Court Appointed Scientific Experts project of the American Association for the Advancement of Science. "Most judges have terrific case management pressure. They may be concerned that bringing another entity into the case is more likely to cause a delay." Ironically, although Judge Lee had hoped that his expert-assisted ruling in the Soldo case would influence Parlodel cases pending in other courts, that didn't happen. The Daubert issues in most of those cases were decided while he waited for his experts' reviews.

Plaintiffs complain that judges, post-*Daubert*, are overstepping their traditional authority. They certainly exercise it often now. Michael Green, a Wake Forest University School of Law professor who writes often about scientific evidence, says: "There's a fairly dramatic change in the last 15 years from a very much hands-off, laissez-faire battle of the experts before, to judges' intervening a lot now."

But perhaps judges *should* be intervening more, as science's discussions grow more incomprehensible, and its tools—genetic engineering, nanotechnology—grow more intricate and invisible and difficult to explain to nonscientists on juries. Despite Lee's attack on Flockhart's methods, the scientist would help a judge again, because he prefers to argue to a judge, rather than a jury. "It is much easier to compact complex scientific cases before a single judge who is presented with all the information in a relatively short period of time, than it is with a jury, where all the posturing just expands the amount of time—doubles it, triples it," Flockhart says.

Whether or not judges import their own experts into a case, they are learning to think like scientists in one important respect. "Courts are implicitly adopting the extraordinary caution that science has established in determining what counts as significant findings," says Cecil, who edits the *Reference Manual on Scientific Evidence*, a guide that federal court administrators send to all judges. This caution translates into more decisions to exclude evidence, usually to the detriment of the plaintiff. Thus, "the courts may inadvertently give greater weight to errors favoring defendants' interests rather than errors favoring plaintiffs' interests," Cecil says.

As it happens, Lisa Soldo may not have fared better with a jury of peers. Only two of Weitz & Luxenberg's Parlodel cases have yet made it to a jury. In each, the jury ended up hung, unable to decide.

In the future, plaintiffs like Soldo may find attorneys more reluctant to take their cases, thanks to the expensive battles over science and experts. Defendants file Daubert challenges as a reflex now, says Lee, and not all involve issues as complex as those in the Soldo case. "[Daubert challenges] are definitely on the increase on all kinds of cases," reports the judge, "and on issues—from what I saw—that are no-brainers, and the defendants shouldn't have raised them."

In the end, Novartis dodged a litigation bullet. Parlodel is no longer sold to nursing mothers. And Lisa Soldo, who has since remarried, is no closer to knowing what went wrong after following her doctor's orders one day in 1991.