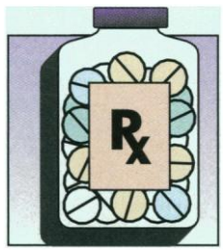
BOOK REVIEWS

Legacies of the Bendectin Case

Judging Science. Scientific Knowledge and the Federal Courts. KENNETH R. FOSTER and PETER W. HUBER. MIT Press, Cambridge, MA, 1997. xii, 322 pp., illus. $40. ISBN 0-262-0692-9.

Bendectin, a three-component drug used to treat nausea during pregnancy, produced one of the significant mass tort cases of the 20th century. Merrell, the manufacturer, introduced the drug in 1957. In the mid-1970s, Betty Mekdeci, a mother who bore a child with severe birth defects, became determined to find the explanation for her son's birth defects. Her quest led her to the Bendectin she had taken and to Melvin Belli (the self-proclaimed "King of Torts"). Thus began a series of lawsuits that included some 2000 claimants over two decades.

In many toxic substances cases, assessment of the causal connection between exposure to the agent and disease depends heavily on evidence developed by the scientific community. That evidence is presented by expert witnesses, who play a critical role in these cases. In the largest of the Bendectin trials, a jury was asked to determine only whether Bendectin was capable of causing a variety of birth defects in the offspring of women who took the drug. The evidence consisted solely of testimony from 19 expert witnesses, from such fields as epidemiology, toxicology, embryology, and pharmacology. *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, another Bendectin case, provided the occasion for the U.S. Supreme Court to set guidelines on the admissibility of scientific expert testimony.



Daubert required trial judges to screen scientific testimony. A judge must determine that a testifying expert's methodology and reasoning are scientifically valid. The Supreme Court identified a nonexclusive list of factors that might assist a judge in evaluating validity: testing for falsification, peer review and publication, error rates, and general acceptance in the relevant scientific community. *Daubert* has wrought a sea change in expert witness practice, with many judges now aggressively examining proposed expert testimony, presenting quite a contrast with judges who proclaimed the case a "battle of [contending] experts," threw up their hands, and left the jury to resolve the conflicting testimony.

Peter Huber, a co-author of *Judging Science*, has been an outspoken and prominent critic of the tort system, especially its performance in the arenas of science and new technology. He is widely credited with popularizing the phrase "junk science," although his work has been dismissed by many academics. The present book lacks the tendentious rhetoric that characterized his earlier work and, perhaps as a result of the collaboration of his former critic Kenneth Foster, is far more balanced, careful, and nuanced.

Judging Science develops three themes. It employs the *Daubert* framework as a taking-off point for explaining science, presumably for judges, lawyers, and students who confront science in legal proceedings. By illustrating most chapters with a vignette from a Bendectin case, the authors also offer judgments on the expert witnesses in that litigation. Finally, by way of a thumbnail sketch of the Bendectin litigation and the science that existed regarding the drug's teratogenicity, they offer their judgment of the litigation.

Each chapter covers one of the factors or issues identified in *Daubert* for assessing the admissibility of an expert's testimony. The central theme of this book is an explanation of science, scientific methods, and error. The authors roam over a broad range of topics, including Karl Popper's philosophy of science, the Popperian critics, trans-science (questions that look like scientific ones but that cannot be answered by existing scientific methods), the pervasiveness of bias and error in contemporary scientific work, the work of Kahneman, Tversky, and Slovic that explains faulty reasoning methods, the "science wars" between the cultural relativists and the objectivists, and Bayes's theorem. Those familiar with those topics will not find much new, although the explanation provides a useful primer for the uninitiated. Some of the matters taken up are far removed from the kinds of scientific disputes that courts confront. Grand theories that explain natural phenomena (the big bang theory of the creation of the universe, prions as infectious agents, quantum mechanics) are most unlikely to be implicated in a lawsuit. Most science that finds its way into the courts is much more prosaic. "Discovering the essence of science," as Judge Richard Posner put it, is not the mandate of *Daubert*. Similarly, although there is much strife in the academy over the relativists' assault on the objectivity of science, the courts have been spared the burden of judging that debate.

At the same time the book's coverage of some critical issues is meager. One particularly salient yet complicated issue in toxic substances cases is the relationship between the level adopted by scientists for significance testing (often 0.05) and the law's 50+ percent burden of proof. The explanation given by the authors, while accurate, is far too cursory to be appreciated by any other than those familiar with statistical techniques.

The authors' judgment of plaintiffs' expert witnesses in Bendectin, consistent with Huber's prior work, is quite critical. Some of the criticism leveled against the experts is quite sound. Alan Done, who frequently testified on behalf of plaintiffs that Bendectin caused their birth defects, continued with his "mosaic" theory (one must look at all forms of evidence, including chemical structure and in vivo and in vitro toxicology studies) long after a salient body of epidemiological evidence developed that tended to exonerate Bendectin as a teratogen. Done's reanalyses of negative epidemiological studies were driven by partisan bias, extraordinary sloppiness, or both.

Some of the authors' criticism is less fair. In any toxic case, epidemiological and toxicological evidence will bear on whether the agent in question is capable of causing the disease at issue. A plaintiff must also establish that the agent caused that particular plaintiff's disease. The authors criticize Shanna Swan, another plaintiff's expert, for her testimony that the epidemiological evidence relied on by Merrell did not rule out Bendectin's teratogenicity and her assessment that it likely is a teratogen. The testimony, the authors tell us, is both nonscientific (because not falsifiable) and inadequate because it fails to address the matter of individual causation. The latter was not at issue in Swan's testimony, however. Because the litigation began while Merrell was still marketing Bendectin, Merrell felt obliged to defend the drug on the broader grounds that it did not cause birth defects. Thus the thrust of Merrell's defense was that in the absence of statistically significant causal associations Bendectin was safe. For strategic reasons, Merrell never attempted to defend itself before a jury by asserting that, regardless of

Bendectin's teratogenicity, there was inadequate proof that it caused a particular plaintiff's birth defect. That would have been, for reasons the authors explain, a much stronger position, given the scientific record. Swan's testimony was a rebuttal to Merrell's strategic defense.

In judging experts, the authors aim their critical artillery at plaintiffs' experts. Had they widened their field of vision, they might have fired at some of Merrell's experts as well. One researcher, hired by Merrell to study Bendectin, wrote to Merrell that he hoped that Merrell would provide a more generous contribution to his university if the results of his work were to "save the company large sums of money in California courts."

Sprinkled throughout the book and elaborated on in an appendix is the authors' critical assessment of the entire Bendectin litigation. The epidemiology exonerating Bendectin as a teratogen is quite strong, and the plaintiffs' experts were guilty of many sins. Why was Merrell subjected to this litigation? Even though it has prevailed in all but two cases (both currently on appeal), Merrell spent an estimated $100 million to defend itself.

The answer begins with the lack of scientific evidence at the time the litigation began. The authors advert to it but leave too much unsaid to permit a fair assessment of the Bendectin litigation. When the drug was first marketed in 1957, exclusively for pregnant women, no reproductive toxicity testing had been performed for any of its three ingredients. The only epidemiological study focusing on Bendectin's teratogenicity until the mid-1970s was performed by Merrell employees and was of such poor quality that Merrell ceased relying on it in litigation. Even in 1980, when the Food and Drug Administration held an Advisory Committee meeting on the matter, the evidence on Bendectin was inadequate to rule out a doubling of specific birth defects. Despite that, Bendectin's labeling contained no mention of the possibility of birth defects until 1981, after the drug had been routinely prescribed to millions of pregnant women. Combine that uncertainty with several disreputable episodes in Merrell's past (including criminal convictions in connection with its MER/29 drug), and one begins to understand why plaintiffs and their lawyers targeted Bendectin. Though uncertainty and culpability are not proof of causation, it seems implausible that the litigation ever would have begun if the drug had been adequately tested by Merrell. A lesson that emerges from Bendectin litigation is the significance of adequate safety research.

The authors find another lesson. They emphatically endorse the "gatekeeping" role for judges established by *Daubert*. Central to this argument is the authors' abiding conviction that judges are better able to determine valid science than juries. "Laypeople have trouble understanding statistical arguments," the authors observe. True indeed, but do judges understand them better? The evidence is sparse, but an experimental study by Gary Wells reveals judges having similar difficulties in processing and reasoning about statistical evidence.

Judges in court may have certain advantages over jurors—they are permitted to educate themselves by reference to earlier cases in a way jurors may not. Another promising way to enable judges to do a better job of judging science is to provide them with expert assistance. Two federal judges recently have employed neutral court-appointed experts to assist them in the silicone-gel breast implant litigation. The Federal Judicial Center has been active in studying this promising mechanism. To be sure, we could provide juries the same assistance, but procedurally it is easier and preferable to have these experts assist judges before trial. Though far from a panacea and fraught with difficulties in implementation, at least in large stakes, mass torts such as Bendectin and breast implants, the use of court-appointed experts may be the best route to providing better science in the courtroom.

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Vignette: Press Relations

"This is John Lear, science editor of the *Saturday Review of Literature*, calling from New York." Heavy emphasis on "calling from New York," then a long pause waiting for me to recover from the thrill of hearing from such an important person, in New York, no less. Actually I did know who he was and had often characterized him as the anti-science editor of the *Saturday Review*. He continued: "I read of your recent report of the discovery of radiation belts of the Earth and thought that I would do a piece on this subject. What I found remarkable was that such important work had been done at a midwestern state university." Well, I don't think that I responded with any profanity but I did manage to convey a suggestion as to what he could do with his piece and hung up. The next day, the president of my university, Virgil M. Hancher, called me to report that Mr. Lear had called him to complain about my discourtesy. I then gave a brief explanation of my reaction, at the end of which Hancher replied "I promised Lear that I would call you and you may now consider that I have done so. And, by the way, Van, my congratulations!" I never heard from the matter again. It's great to have a boss like that.

—*James A. Van Allen*, in *Discovery of the Magnetosphere* (C. Stewart Gillmor and John R. Spreiter, Eds.; American Geophysical Union)

Books Received

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