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SOME ANSWERS TO THE *DAUBERT* PUZZLE

RONALD SIMON*

As an author of an amicus brief¹ submitted in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,² I was invited to speak at the August 1993, American Bar Association Convention on the meaning of the up-coming decision. The printer's schedule required that written presentations for the conference be submitted prior to the opinion of the Court being issued. Accordingly, after reviewing the briefs,³ including twenty-two amici briefs that probed deeply

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¹ See Brief of Daryl E. Chubin, Ph.D.; Edward J. Hackett, Ph.D.; David M. Ozonoff, M.D., M.P.H.; Richard W. Clapp, Sc.D., M.P.H., in Support of Petitioner, *Daubert* (No. 92-102).

² 113 S. Ct. 2786 (1993).

³ Fourteen amicus briefs were filed in support of Appellee, Merrell Dow Pharmaceuticals, Inc., see the American Association for the Advancement of Science and the National Academy of Sciences, *Daubert* (No. 92-102); the American Medical Association, American Medical Association-Specialty Society Medical Liability Project *et al.*, *Daubert* (No. 92-102); Nicholas Blombergen, Erminio Costa, Dudley Herschbach, Jerome Karle, Arthur Langer, Wassily Leontief, Richard S. Lindzen, William M. Lipscomb, Donald B. Louria, John B. Little, A. Alan Moghissi, Brooke T. Mossman, Robert Nolan, Arno A. Penzias, Frederick Sietz, A. Frederick Spilhaus, Dimitrios Trichopoulos & Richard Wilson, *Daubert* (No. 92-102); the New England Journal of Medicine, Journal of the American Medical Association, & Annals of Internal Medicine, *Daubert* (No. 92-102); the United States Solicitor General, *Daubert* (No. 92-102); the Washington Legal Foundation, *Daubert* (No. 92-102); the American College of Legal Medicine, *Daubert* (No. 92-102); the Chamber of Commerce of the United States of America, *Daubert* (No. 92-102); the Product Liability Advisory Council, Inc., National Association of Manufacturers, Business Roundtable & Chemical Manufacturers Association, *Daubert* (No. 92-102); the American Tort Reform Association, *Daubert* (No. 92-102); the American Insurance Association, *Daubert* (No. 92-102); the Pharmaceutical Manufacturers Association, *Daubert* (No. 92-102); Professor Alvan R.F. Feinstein, *Daubert* (No. 92-102); the Defense Research Institute, Inc., *Daubert* (No. 92-102).

Seven amicus briefs were filed in support of Petitioners, see Physicians, Scientists & Historians of Science (namely, Ronald Bayer, Stephen J. Gould, Gerald Holton, Peter Infante, Philip Landrigan, Everett Mendelsohn, Robert Morris, Herbert Needleman, Dorothy Nelkin, William Nicholson, Kathleen Joy Property and David Rosner), *Daubert* (No. 92-102); Daryl E. Chubin, Ph.D., Edward J. Hackett, Ph.D., David M. Ozonoff, M.D., M.P.H. & Richard W. Clapp, Sc.D., M.P.H., *Daubert* (No. 92-102); the Association of Trial Lawyers of America, *Daubert* (No. 92-102); the State of Texas, *Daubert* (No. 92-102); the State of Montana, *Daubert* (No. 92-102); the State of Idaho, *Daubert* (No. 92-102); the State of South Dakota, *Daubert* (No. 92-102); Professors Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra & Steven Stellman, *Daubert* (No. 92-102); the American Society of Law, Medicine & Ethics, Devra Lee Davis, Ph.D., *Daubert* (No. 92-102); Marvin S. Legator, M.D., *Daubert* (No. 92-102); Donald R. Mattison, M.D., *Daubert* (No. 92-102); the Natural Resources Defense Council, Program on Gender, Science and Law of Columbia University

into many issues dealing with the overlap of law and science in the area of toxic torts, I predicted that the upcoming decision of the Court would have serious shortcomings because the "wrong" questions had been presented.⁴ Based on my view that *Frye v. United States*⁵ was not good law, and that peer review could not be legitimately used as an outcome-determinative basis for excluding expert testimony,⁶ I conjectured that the focus on these "easy" issues for review would not lead the *Daubert* Court to provide much useful guidance on the issues of "causation" in toxic tort cases.

Thus, in a publication shortly after the decision,⁷ perhaps unconsciously needing to prove that my earlier prognostication had been correct, I pointed out how much the Court did *not* decide. Nonetheless, a few months of further reflection have put the decision in better perspective. Rereading the decision and studying the commentaries already available⁸ have led to the inescapable

School of Public Health, *Daubert* (No. 92-102); Allan Rosenfield, M.D., *Daubert* (No. 92-102); Ellen K. Silbergeld, Ph.D., *Daubert* (No. 92-102).

Two amicus briefs were filed in support of neither party, see Carnegie Commission on Science, Technology & Government, *Daubert* (No. 92-102); and the American Law Professors, *Daubert* (No. 92-102).

⁴ See Ronald Simon, Address at the ABA Program on Scientific Evidence (Aug. 9, 1993).

⁵ 293 F. 1013 (D.C. Cir. 1923) (concerning admissibility of lie detector test results), *overruled by Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993).

⁶ In hindsight, these issues appear to have been easily resolved. However, overruling *Frye* and no longer requiring scientific conclusions to be based in peer-reviewed literature were hardly foregone conclusions. See Brief for the State of Idaho in support of Petitioner, *Daubert* (No. 92-102); Brief for the State of Montana in support of Petitioner, *Daubert* (No. 92-102); Brief for the State of South Dakota in support of Petitioner, *Daubert* (No. 92-102) (noting that number of circuits followed or adopted *Frye* as well as many state courts and including extensive citations to state and federal court decisions that endorsed *Frye*); Brief for the State of Texas in support of Petitioner, *Daubert* (No. 92-102).

For amicus briefs in support of Appellee, see Washington Legal Foundation, *Daubert* (No. 92-102) (arguing that *Frye* was law); the Chamber of Commerce of the United States of America, *Daubert* (No. 92-102) (same); the New England Journal of Medicine, the Journal of the American Medical Association & Annals of Internal Medicine, *Daubert* (No. 92-102) (emphasizing importance of peer review requirement for scientific opinion).

⁷ See Ronald Simon, *High Court Throws Out Rigid Rules Excluding Scientific Evidence, Says Focus Must Be on Methods, Principles*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 11-15 (Summer-Fall 1993).

⁸ Francisco J. Ayala & Bert Black, *Decision Will Lead to Improvement in Courts' Screening of Scientific Evidence*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 28 (Summer-Fall 1993); David E. Bernstein & Peter W. Huber, *"Daubert" Plaintiffs Won Technical Battle but Plainly Lost the War*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 16 (Summer-Fall 1993); Daniel J. Capra, *Decision Unlikely to Have Real Impact on State or Federal Toxic Tort Litigation*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 22 (Summer-Fall 1993); Anne E. Cohen, *Impact of Ruling Will Depend on Weight Courts Give to "Reliability Factors"*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 35 (Summer-Fall 1993); Thomas W. Henderson, *Daubert Unlikely to Change Courts' Treatment of Expert Evidence*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 33 (Summer-Fall 1993); Clifton T. Hutchinson, *"Daubert" Confirms Judge's Gatekeeper Role*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 12 (Summer-Fall 1993); Kenneth J. Rothman, *Supreme Court Ruling Edges Courtroom*

conclusion that the *Daubert* decision represents a major advance in the jurisprudence of law and science.

I. THE COURT REJECTS *FRYE* AND OTHER REDUCTIONIST APPROACHES TO SCIENTIFIC EVIDENCE

The primary thrust of the *Daubert* decision is to reject simplistic, outcome-determinative standards such as "generally accepted" and "peer reviewed," which can be automatically and reflexively applied without examining the entire context and range of facts and theories that pertain to a question. The intellectual strength of the Court's flexible, contextual, and inclusive approach to scientific evidence may be viewed regarding the necessity of statistically significant data. In advancing its position that Bendectin has not been proven to be associated with birth defects, the defendant had argued that the data and studies relied upon by plaintiffs did not reach the level of "statistical significance." The phrase "statistical significance" was used by defendant Merrell Dow and its amici to suggest that studies and data that are not "statistically significant" have no meaning, value, or significance to scientists.

An amicus brief by Dr. Kenneth Rothman et al.,⁹ whom the defendants' counsel at oral argument conceded to be America's pre-

Closer to Science, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 26 (Summer-Fall 1993); Ronald Simon, *High Court Throws Out Rigid Rules Excluding Scientific Evidence, Says Focus Must Be on Methods, Principles*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 5 (Summer-Fall 1993); V. Hale Starr, Ph.D., *Aftermath of "Daubert" Will See Experts Prepared to Explain Testimony More Clearly*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at 38 (Summer-Fall 1993); Gary A. Weinstein, *After "Daubert": Good Lawyering, Expert Preparation, Still the Key*, 21 Prod. Safety & Liab. Rep. (BNA) No. 30, at II-44 (Summer-Fall 1993); see also Jeffrey Mervis, *Supreme Court to Judges: Start Thinking Like Scientists*, SCIENCE, July 2, 1993, at 22; Kenneth R. Foster et al., *Science and the Toxic Tort*, SCIENCE, Sept. 17, 1993, at 1509; Philip H. Abelson et al., *Toxic Terror; Phantom Risks*, SCIENCE, July 23, 1993, at 407; David E. Bernstein & Peter W. Huber, *Defense Perspective*, SHEPARD'S EXPERT & SCI. EVID. Q., July 1993, at 59; Bert Black & John Andrew Singer, *From Frye to Daubert: A New Test for Scientific Evidence*, SHEPARD'S EXPERT & SCI. EVID. Q., July 1993, at 19; George W. Conk, *Commentary: Daubert v. Merrell Dow*, SHEPARD'S EXPERT & SCI. EVID. Q., July 1993, at 55; Michael D. Green, *Relief at the Frying of Frye: Reflections on Daubert v. Merrell Dow Pharmaceutical*, SHEPARD'S EXPERT & SCI. EVID. Q., July 1993, at 43; Barry J. Nace, *Reaction to Daubert*, SHEPARD'S EXPERT & SCI. EVID. Q., July 1993, at 51; David Bernstein, *Hauling Junk Science Out of the Courtroom*, WALL ST. J., July 13, 1993, at A16; Bert Black & John Andrew Singer, *Judicial Control of Scientific Evidence: The Implications of Daubert*, ABA SEC. OF BUS. L. (Aug. 9, 1993); Kathiann M. Kowalski, *Challenging Expert Testimony After Daubert*, ABA SEC. OF NATURAL RESOURCES, ENERGY & ENVTL. L. (Oct. 2, 1993).

⁹ See Brief of Professors Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra & Steven Stellman, in support of Petitioner, at 2 n.2, *Daubert* (No. 92-102).

eminent epidemiologist, explained that "statistical significance" is a term describing one of a variety of tests for a larger concept known as the "stability of numbers." Dr. Rothman stated that no epidemiologist believes that findings that are not statistically significant are without value or should not be considered in making a judgment about whether an association exists. Dr. Rothman also noted that a determination that data is "statistically significant" does not ipso facto lead a scientist to believe that an association exists. Dr. Rothman's views were essentially unchallenged by the defendants and their amici. The strength of the Court's commitment to an open and flexible approach to the admissibility of scientific evidence was underscored by its refusal to even mention the concept of "statistical significance," despite the importance it had played in defendant's arguments. The Court's appreciation of the complexity and uncertainty of scientific information dovetailed with the Court's reiteration that the Federal Rules of Evidence favor admissibility and that new rules to limit admissibility should not be invented by judges.

The second major theme of the *Daubert* decision was the Court's confidence that the American system of trial by jury is adequate to handle complex toxic tort cases. To critics who have sought to castigate the jury system and suggest that citizens-jurors are unable to grasp complex factual and scientific issues, the Court stated:

In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.¹⁰

Having disposed of the approach typified by the easy answers and shallow reasoning of the decision of the United States Court of Appeals for the Ninth Circuit,¹¹ the *Daubert* decision requires courts to undertake a more thorough analysis of underlying evidence and its foundations.¹² The *Daubert* Court offered specific

¹⁰ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993).

¹¹ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991), *vacated*, 113 S. Ct. 2786, 2799 (1993).

¹² *Daubert*, 113 S. Ct. at 2796. The Ninth Circuit's approach was not only superficial but rather cavalier. For example, the citation to the often criticized media celebrity Peter Huber. See Mark M. Hager, *Civil Compensation and its Discontents: A Response to Huber*, 42

language that is the conceptual framework for analyzing the admissibility of expert scientific testimony. The Court repeated that the determination of evidentiary admissibility must be based on an examination of the principles and methods used by an expert in formulating an opinion, and not be focused on the validity of the ultimate opinion itself.¹³

The significance of this distinction between the methods and principles, and the ultimate conclusion can be seen in the Bendectin cases themselves. In reading *Daubert*, there is little question that the principles, methods, and the credentials of plaintiffs' experts were not seriously challenged. None of the techniques relied on by plaintiffs' experts, "in vivo," "in vitro," pharmacological analysis and reanalysis of epidemiological data were said to be novel techniques. Defendant merely quarreled with the conclusions drawn from them. To persuade the courts to throw out plaintiff's Bendectin cases, Merrell Dow will need strategies not pursued in *Daubert*.

II. FUTURE DIRECTIONS FOR DEFENDANTS BASED ON THE COURT'S REQUIREMENT THAT AN OPINION BE BASED ON SCIENTIFIC KNOWLEDGE

A blueprint for defense strategy comes from the Court's statement that the expert opinion must be based on "scientific knowledge."¹⁴ Simply stated, in terms of a Bendectin case, the defendant will argue that there is no scientific evidence that Bendectin causes birth defects. Plaintiffs will rejoin that the question of whether Bendectin causes birth defects is the ultimate conclusion, rather than methods and principles, upon which the Court stated the Court may *not* exclude expert testimony. Furthermore, the plaintiffs will argue that their ultimate opinion on causation is supported by scientific knowledge in the "in vivo," "in vitro," pharmacological and epidemiologic data relied on by plaintiffs' experts.

Defendants will insist in every case that scientific knowledge is required to support each logical step developed by the plaintiff to establish causation. For instance, if epidemiologic studies estab-

STAN. L. REV. 539, 540 (1990); see also Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637, 1638 (1993).

¹³ *Daubert*, 113 S. Ct. at 2797. "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Id.*

¹⁴ *Id.* at 2796.

lish an association between exposure *A* and result *B*, defendant will argue that the requisite scientific knowledge does not exist if any factor in the instant case, such as dose or latency period, varies from what has been demonstrated in scientific studies.

The defendant will frame their attack on plaintiffs' experts in terms of criticism of their overall reasoning. Based on the *Daubert* Court's language that expert testimony must be based on scientific methods and principles, the defendant will argue that the experts' reasoning process are not scientific. The defendant will argue that the plaintiffs' experts' opinion cannot be said to be based on scientific knowledge because the reasoning which ties together the strands of evidence into a conclusion does not have the degree of certainty and support required to justify a scientific conclusion. Plaintiffs will respond that this argument merely raises questions of weight, credibility, and degree of certainty and should not be decided as a question of law. Plaintiffs will also point out that the position of defendants inevitably raises the standard of proof well beyond what is required. The *Daubert* decision provides little support for evidentiary attacks on the experts reasoning as opposed to the underlying foundational basis.

Defense counsel has been encouraged by the *Daubert* Court's citation to *Turpin v. Merrell Dow Pharmaceuticals, Inc.*¹⁵ and *Brock v. Merrell Dow Pharmaceuticals, Inc.*¹⁶ in support of its statement that courts have adequate remedies to dispose of cases that do not have a factual basis, such as through directed verdict, summary judgment, or judgment notwithstanding the verdict.¹⁷ Judge Jack

¹⁵ 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992). The court affirmed the motion for summary judgment. *Id.* at 1360. The evidence, particularly animal studies, was held insufficient to allow a rational jury to find that Bendectin caused minor plaintiff's birth defects. *Id.* at 1350. The district court stated:

Taken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not Bendectin caused the minor plaintiff's injury. Therefore the case should not go to the jury.

Id.

¹⁶ 874 F.2d 307, 315 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) (judgment notwithstanding the verdict). The district court stated: "In light of the evidence presented, we are convinced that the Brocks did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachael Brock's limb reduction defect." *Id.*

¹⁷ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993). The Court stated: "These conventional devices [summary judgment, directed verdicts, etc.], rather than wholesale exclusion under an uncompromising 'general acceptance' test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702." *Id.*; see also FED. R. EVID. 702. Rule 702 provides, in relevant part: "If scientific,

Weinstein of the United States District Court for the Eastern District of New York, has suggested that what he views to be the inadequacies of plaintiffs' evidence on causation in Bendectin cases should not be viewed as a question of evidentiary admissibility, but rather as a question of sufficiency of evidence.¹⁸ Judge Weinstein has argued that the defeat of the plaintiffs' Bendectin claims can be accomplished merely by giving a more lengthy dissertation of the reasons for the Court's holding than was provided in the opinion by the Ninth Circuit.¹⁹ As an example, Judge Weinstein cites the decision of the trial court in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*²⁰ Regardless of whether the point of attack is the alleged lack of "scientific knowledge," criticism of scientific reasoning, or legal sufficiency of evidence, the implicit thrust of defendant's assault on plaintiff's evidence of causation is to raise the standard of proof on elements of plaintiff's case toward scientific certainty and away from the preponderance of the evidence.

technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill experience, training, or education, may testify thereto in the form of an opinion or otherwise." *Id.*

¹⁸ See United States District Court Judge Jack B. Weinstein, Remarks at the ABA Program on Scientific Evidence (Aug. 9, 1993); see also Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181 *passim* (1993). The author contends:

Whether the "tests" are viewed as governed by the admissibility of expert testimony, such as pursuant to Federal Rules of Evidence 702, 703, or 403, or the adequacy or sufficiency of the plaintiff's proofs, the courts are understandably less willing to allow a jury determination of causation in the absence of epidemiological and compelling toxicological proof in mass exposure cases.

Id. The author further states that many commentators and courts erroneously believe that the same standards of proof should be applied to all cases. *Id.* Instead, he postulates that whenever epidemiologic evidence exists, such evidence should be required. *Id.* By contrast, where epidemiologic studies are unavailable, the courts should not demand that such studies be an indispensable element of plaintiff's proof. *Id.*

¹⁹ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1130 (9th Cir. 1991) (holding that plaintiff's reanalysis was neither published, nor subject to peer review and therefore not admissible), *vacated*, 113 S. Ct. 2786, 2799 (1993) (holding that general acceptance not necessary precondition to admissibility of scientific evidence).

²⁰ 791 F. Supp. 1035, 1041 (D. N.J. 1990). The court in a 17 page opinion listed 120 findings of fact, including that approximately 65% of all birth defects are of unknown origin. *Id.* It also listed 41 conclusions of law, including that summary judgment is proper where a party fails to establish the existence of an element essential to his case and where he bears the burden of proof. *Id.* at 1059.

III. PLAINTIFFS' STRATEGY BASED ON THE *DAUBERT* COURT'S RECOGNITION OF SCIENTIFIC UNCERTAINTIES AND JURIES' DETERMINATIONS OF DISPUTED FACTS

Plaintiffs will rely on the Court's repeated statement that the admissibility of plaintiffs' expert opinion can only be attacked by showing that the methods and principles used in formulating that opinion are not scientifically valid, rather than an attack on the ultimate opinion.²¹ Plaintiffs will develop their position during depositions of the defendants' experts in which plaintiffs will seek admissions that defendants' experts have relied on the same kinds of methods, principles, and techniques as the plaintiffs' experts. Plaintiffs will search the defendants' experts' writings to find reliance on similar methods and techniques and will point to government policies and other authorities that rely on similar data, principles, and methods.²²

This strategy will be pursued further by filing motions in limine to challenge the defendants' experts. These motions will point out the similarity of techniques and principles employed by the experts on both sides. The in limine motions will underscore the inherent uncertainties that underlie the scientific questions before the Court. Although science in the abstract is often described as being based on high levels of certainty and empirical verification, day-to-day decisions of scientists and physicians are based on much less definitive data to which their judgment is applied.²³

²¹ See *Daubert*, 113 S. Ct. at 2790. The Court stated:

Faced with a proffer of expert scientific testimony under Rule 702, the trial judge, pursuant to Rule 104(a), must make a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly can be applied to the facts at issue The inquiry is a flexible one, and its focus must be solely on principles and methodology, not on the conclusions that they generate.

Id.

²² The amicus brief of the American Society of Medicine and Ethics et al., demonstrated that federal regulatory agencies as a matter of policy routinely rely on unpublished data. See, e.g., Final Guidelines for Developmental Toxicity Risk Assessment, 56 Fed. Reg. 63,798 (1991); Environmental Protection Agency, Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed. Reg. 24,834 (1988).

²³ See Charles M. Nesson, *Agent Orange Meets the Blue Bus: Fact Finding at the Frontier of Knowledge*, 66 B.U. L. REV. 521 (1988). The author states that there is a difference in the level of certainty between the expert that testifies and the lab scientist. The legal standard requires the expert to express his opinion with assurance. Mere possibility is not enough, nor is complete assurance necessary. Between this range, however, the author states that the lab scientist when given data will delay his judgment on the ultimate question of causation until more testing can be done. In contrast, a doctor or lawyer does not have this privilege and is sometimes required to render his judgment once he obtains a reasonable working conclusion. *Id.*; see also E.K. Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 CTS. HLTH. SCI. & L. 374 (1991).

Being clear, explicit, and unashamed about uncertainties in science will do much to eliminate the kind of inaccurate mischaracterizations which have plagued legal decisions on scientific questions.²⁴ For example, although lawyers and judges have frequently repeated "the evidence proves that Bendectin does not cause birth defects," responsible scientists, including those testifying for defendants in Bendectin cases, acknowledge that this assertion is incorrect. To state that the evidence is not adequate to demonstrate that *A* causes *B* or even that the existing evidence suggests that *A* does not cause *B* is a very far cry from scientific proof that *A* does not cause *B*.

As the courts delve more deeply into the uncertainties that exist in science, more of the knee-jerk responses that are tied to simplistic labels will fall away. A recent example was developed in the Stringfellow acid pits trial.²⁵ A well-known defense expert, Dr. Philip Guzelian, was prepared to testify that there was no harm from toxic exposures because they were below threshold limit values ("TLVs"). This testimony was attacked by plaintiffs on the ground that the TLVs were not based on scientific data. Relying on information from a variety of sources, the plaintiffs demonstrated to the court that these exposure limits, although widely relied on and so often automatically accepted, were not based on scientific knowledge.²⁶

Another strategy to be employed will be the presentation of an epistemologic expert.²⁷ Because the Supreme Court has stated that an evidentiary attack on an expert must be based on methods and principles, the party offering an expert may present a background expert who can testify as to the legitimacy of the primary expert's methods and principles. For example, the Court stated

²⁴ See generally Kenneth J. Rothman, *Supreme Court Ruling Edges Courtroom Closer to Science*, 21 *Prod. Safety & Liab. Rep.* (BNA) No. 30, at II-26 (Summer-Fall 1993). The *Daubert* decision will force courts to look behind labels and understand the underlying uncertainties. *Id.* The author points to the fallacy of a peer review standard by noting that if such articles were the sine qua non of all decisions, the court would simply get the articles and need no experts. *Id.*

²⁵ *Newman v. J.B. Stringfellow*, No. 167122, slip op. (Cal. Super. Ct. Apr. 25, 1991).

²⁶ Barry I. Castleman, Sc.D. & Grace E. Ziem, M.D., Ph.D., *Corporate Influence on Threshold Limit Values*, 13 *AM. J. INDUS. MED.* 531 (1988); Myra Karstadt, *Teratogenesis, Carcinogenesis, and Mutagenesis, Quantitative Risk Assessment: Qualms and Questions*, 8 *AM. J. MED.* 137 (1988); S.A. Roach, Sc.D., Ph.D. & S.M. Rappaport, Ph.D., *But They Are Not Thresholds: A Critical Analysis of the Documentation of Threshold Limit Values*, 17 *AM. J. MED.* 727 (1990).

²⁷ DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 570 (27th ed. 1988). Epistemology is defined as the science of the methods and validity of knowledge.

that scientific evidence must "fit," meaning that the scientific information (the example given was the phases of the moon) must be an appropriate fit to the question it purports to answer (how much moonlight there was on the night in question rather than predictions of strange human behavior).²⁸ The epistemologic expert can provide support for the expert testimony by indicating that the methods and principles are an appropriate fit to answer the question at issue.

In response to the effort of a defendant to repackage arguments formerly made on the basis of evidentiary admissibility and transform them into attacks on evidentiary insufficiency, the plaintiff will have to define more clearly the issues to be addressed and the logical steps needed to reach the ultimate conclusion. In reading the second decision of the district court in *DeLuca*,²⁹ one is struck by an unstructured aggregation of unrelated factual details and arguments that favor one position. Nowhere are the counter-arguments or evidence set out. More significantly, the role that each fact or argument plays in the ultimate puzzle is not set out. A tighter and more logical exposition of the issues (much in the way counsel formulates common issues under Federal Rule of Evidence 23 in a motion for class certification) may prevent courts from justifying a conclusion with a one-sided recitation without revealing the counter arguments or its process of reasoning.

CONCLUSION

The defense counsel's task in litigation is to demonstrate that the plaintiff has failed to meet its burden of proof. For the defendant, the notion of "science" is a useful device because it implies, especially to the scientifically naive, that a very high level of certainty must be achieved for the plaintiff to prevail.

Although defendants have been successful in promoting reductionist notions of science to a few courts looking for easy, once-and-for-all-time escapes from the realities of scientific uncertainty and complexity, the Supreme Court has recognized that it is not for judges to decide factual disputes under the guise of simplistic notions of science or legal conclusions.

Recognizing the ambiguities and uncertainties of science, the

²⁸ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2796 (1993).

²⁹ *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D. N.J. 1992).

Court explained:

. . . arguably, there are no certainties in science. *See, e.g.*, Brief for Nicholas Blombergen *et al.*, as Amici Curiae 9 (“Indeed, Scientists do not assert that they know what is immutably ‘true’—they are committed to searching for new, temporary theories to explain, as best they can, phenomena”); Brief for American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae 7-8 (“Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement”).³⁰

The Supreme Court, in *Daubert*, unequivocally rejected defendant’s strategy of arguing that “plaintiff’s experts opinion must be based on scientific knowledge,” in order to indirectly require the plaintiff to prove elements of its case to a scientific certainty. The Court distinguished between scientific validity and reliability³¹ in recognition that scientists and courts use the same terms in vastly different ways, and in order to avoid possible confusion. The Court took pains to distinguish two key scientific terms and provide its own definition of the pivotal legal term. The Court “note[d] that scientists typically distinguish between ‘validity’ (does the principle support what it purports to show?) and ‘reliability’ (does application of the principle produce consistent results?).”³² The distinction is evidently critical to scientists and, as it turned out, is also essential to the Court’s guidance on Federal Rule of Evidence 702.

Obviously, the determination of whether a specific scientific proposition is to be deemed admissible in a particular case will turn largely on which of these two scientific criteria—fundamental theoretical support for the proposition in question or the ability to obtain consistent results upon application of the proposition—was chosen by a court as the legal threshold. Clearly, the Supreme Court could have decided that both standards were necessary and that neither was sufficient; that is, it could have decided that in order for a particular proposition to be deemed trustworthy and reliable and therefore admissible, the proponent

³⁰ *Daubert*, 113 S. Ct. at 2795.

³¹ *Id.* at 2795 n.9.

³² *Id.*

would have to show that the proposition enjoyed both a sound theoretical basis in the principles of science and a firm factual foundation in consistent experimental results. However, having made the distinction, the Court required only the first, sound theoretical basis. Scientific validity, but not demonstrated empirical results (reliability), is required.

In terms of *Bendectin*, the meaning is clear; the plaintiff need not present scientific experiments that provide scientific proof that *Bendectin* causes birth defects; plaintiffs must only provide scientific opinion based on the methods and techniques generally used that causation is more likely than not.

It is hardly surprising that jurists insist that there must be a very high standard of proof. Nor is it surprising that jurists not trained in science are persuaded to grasp at reductionist formulas to address complex, multilevel uncertainties. But the Supreme Court has unequivocally rejected this approach and left the disputed facts in the hands of the jury.