Daubert and the Quest for Value-Free "Scientific Knowledge" in the Courtroom

Alexander Morgan Capron
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"SCIENTIFIC KNOWLEDGE" IN THE COURTROOM*

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In a world that grows more technologically complex every day and in which scientific research continually expands both our understanding of, and our questions about, the operation of the natural and man-made world, it is hardly surprising that science should show up with increasing frequency in our courtrooms. Science itself is sometimes at issue, for example, in proceedings on allegations of scientific misconduct or in disputes over the ownership or patentability of technologies. But more frequently, science enters in aid of resolving a case in which a complex question of causation is at issue. To establish or rebut causation, each side may seek to introduce evidence from expert witnesses.¹ With crowded dockets, the simpler cases are more likely to settle, while more complex ones—especially class actions and mass tort suits—go to trial, which may explain

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¹ Experts typically testify about how something (such as an injury) occurred, but sometimes their causative explanation is forward looking—that is, the expert provides a theory of causation to justify or challenge a decision that rests on a prediction of future outcomes. For example, a factory owner whose operations have been restricted on the grounds that they create an unreasonable risk of environmental damage might seek to demonstrate that the prediction of harm is not scientifically valid; likewise, if a patient challenges a healthcare insurer's refusal to cover a particular medical intervention that it deems to be "experimental," one issue at trial could be whether the intervention has been shown reliably to produce a particular outcome.
why in some jurisdictions, experts take part in upwards of eighty percent of all trials.

Expert testimony raises many issues for the legal system. Most broadly, to some observers science and the law seem to be a bad fit; at least as idealized, their aims and methods are radically different.\(^2\) Science is oriented toward the truth but its claims are presented tentatively and are subject to refutation, with an emphasis on the quality of the data rather than on decision produced by an hierarchical structure. Although science has its share of respected individuals and institutions, the acceptance or rejection of theories and data is supposed to depend on the quality of the evidence and methodology, not solely on a scientist's position in a hierarchy. In contrast, the law is oriented toward the just resolution of cases rather than truth-finding; verdicts must be rendered even when information is incomplete (hence the acknowledged importance of presumptions and burdens of proof), and each dispute rests within a particular hierarchy in which there are established procedures for coming to a single, definitive answer.

As the debate has heated up over science in the courtroom, a great deal of attention has focused on the adequacy of judicial processes to deal with disputes involving large quantities of scientific evidence. Unlike the legislative and executive branches, the judiciary has not had a reliable source of advice on matters of science and technology. This raises many questions. For example, in cases that involve substantial disputes about scientific questions, would it be better to turn to alternative dispute resolution rather than to long trials that tie up the courts and leave the ultimate decision in the hands of lay jurors who lack sufficient knowledge to sort out good scientific claims from bad, and may be misled by irrelevant aspects of an expert's presentation or appearance?\(^3\)

\(^2\) See Margaret G. Farrell, *Coping With Scientific Evidence: The Use of Special Masters*, 43 EMORY L.J. 927 (1994);

Science is essentially descriptive, positive and predictive. The goal is to tell us what is and what will be in the future. Law, on the other hand, is prescriptive and normative. The effort is to tell us what ought to be, to define rules of conduct and responsibility grounded in events of the past.

*Id.* at 942.

\(^3\) After carefully reviewing the transcripts of a number of the 30 Bendectin
I. THE DAUBERT CASE

Beyond questions about the advisability of relying on the judicial process, scientific experts also confront courts with practical problems in deciding about their qualifications to testify, and the relevance of their evidence to the issues in contention. In a landmark 1993 decision, Daubert v. Merrell Dow Pharmaceuticals, Inc., the Supreme Court reexamined the issue of the admissibility of scientific evidence under the Federal Rules of Evidence. The plaintiffs in these cases were two young children, Jason Daubert and Eric Schuller, who with their parents filed suits against the manufacturer of Bendectin, a drug prescribed to treat nausea and vomiting during pregnancy. The boys sought damages for their limb reduction birth defects which they contended were caused by their mothers having taken Bendectin while they were in utero. The district court granted the defendant's motion for summary judgment on the ground that the plaintiffs had failed to sustain their burden of establishing a genuine issue of material fact regarding causation. As summarized by the United States Court of Appeals for the Ninth Circuit, which affirmed the trial court:

Plaintiffs' evidence of causation consisted primarily of expert opinion based on in vitro and in vivo animal tests, chemical structure analyses and the reanalysis of epidemiological studies. Among the contrary evidence proffered by Merrell Dow was the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistical-

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trials to date, and in light of the virtually uniform view of the judges in all the cases that the evidence was insufficient to allow plaintiffs to collect even though 40% of the jury verdicts had been in plaintiffs' favor, Joseph Sanders concluded:

[C]urrent litigation practices inevitably lead to situations in which juries are unable to appropriately weigh the complex scientific evidence presented at trial. As a result, trial verdicts and damages awards bear little relation to the weight of scientific opinion.

5. Id. at 2792.
ly significant association between Bendectin and birth de-
fects. Plaintiffs do not challenge this summary of the pub-
lished work.\(^6\)

In the past fifteen years, thirty Bendectin cases have been
tried, primarily in the federal courts, and several have under-
gone appellate review focusing on the causation evidence that a
plaintiff would need to adduce. At the time of \textit{Daubert}, three of
the four circuit courts had held that plaintiffs could not estab-
lish that Bendectin was responsible for their limb deformities in
the absence of epidemiologic studies that had either "been pub-
lished [or] subjected to the rigors of peer review."\(^7\) The trial
and appellate courts in \textit{Daubert} took the same view and exclud-
ed all four categories of the plaintiff's evidence: first, the so-
called structure-activity studies (that the similarity of chemical
structure between ingredients in Bendectin and known
teratogens constitutes evidence that Bendectin causes birth
defects); second, the \textit{in vitro} or animal cell experiments (that
the ingredients in Bendectin cause minor DNA damage to cells
in culture or inhibit limb bud cell differentiation, for example);
third, the \textit{in vivo} or live animal research (in which pregnant
animals, such as rats, rabbits, and monkeys, are studied and
the defects seen in their fetuses are extrapolated to humans);
and fourth, reanalysis of the epidemiological data (in which
some of the reported instances of injury or noninjury following
use of the drug are reclassified, with the result that the corre-
lation between drug-usage and birth defects becomes statistical-
ly significant).\(^8\)

These rulings on admissibility were based on two lines of
reasoning. First, the district and circuit courts held that absent
scientific understanding of the cause of the birth defects in
question, causation may only be shown through epidemiological
evidence.\(^9\) Second, both courts followed earlier appellate deci-
sions in refusing to allow the recalculated epidemiological data

\(^{6}\) Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128, 1129 (9th Cir.
\(^{7}\) \textit{Id.} at 1130.
\(^{8}\) \textit{Id.} at 1129.
\(^{9}\) See Daubert v. Merrell Dow Pharmaceuticals, Inc., 727 F. Supp. 570, 572, 575
(S.D. Cal. 1989), \textit{aff'd} 951 F.2d 1128 (9th Cir. 1991), \textit{rev'd} 113 S. Ct. 2786 (1993);
\textit{Daubert}, 951 F.2d at 1130.
offered by plaintiffs' experts, particularly Drs. Adrian Gross and Alan K. Done, because (in the words of the District of Columbia Circuit in Richardson v. Richardson-Merrell,6) unlike the studies "rejected by [the plaintiffs' experts, which] had been published in peer-reviewed scientific journals," the plaintiffs' experts had "neither published [their] recalculations nor offered them for review."11

This latter point—that the procedures followed by an expert witness in reaching a conclusion must be those generally accepted as reliable among the scientific community—is usually referred to as "the general acceptance standard" or "the Frye test" because of the 1923 case Frye v. United States,12 in which the District of Columbia Circuit articulated what became the dominant gauge of the admissibility of novel scientific evidence: "[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."13 The Supreme Court granted certiorari in Daubert in order to decide whether this seventy-year-old standard was superseded by the Federal Rules of Evidence. Justice Blackmun, writing for a unanimous Court, rejected the Frye test, not because he found fault in its "general acceptance" rule (though that rule has had many detractors over the years), but because he concluded that Congress, in adopting the Federal Rules of Evidence twenty years ago, chose not to incorporate Frye into the Rules.

The Court might have stopped there and vacated the Ninth Circuit's judgment, which clearly rested on the latter court's conclusion that findings which have not been "subjected to verification and scrutiny by others in the field" do not meet the "general acceptance" requirement of Frye. Instead, Justice

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11. See Daubert, 727 F. Supp. at 573 (quoting Richardson, 857 F.2d at 831); see also Daubert, 951 F.2d at 1131 (also citing Lynch v. Merrell-National Labs., 830 F.2d 1190 (1st Cir. 1987) and Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, modified, 884 F.2d 166 (5th Cir. 1989)).
12. 293 F. 1013 (D.C. Cir. 1923).
13. Id. at 1014.
14. Daubert, 951 F.2d at 1131.
Blackmun construed the relevant Rules on expert evidence and provided some "general observations" on new standards for the admissibility of such evidence, a move that Chief Justice Rehnquist, joined by Justice Stevens, criticized in a partial dissent as an unwarranted expansion of the issue before the Court.\(^1\)

II. WHAT STANDARD OF RELIABILITY DO THE RULES ESTABLISH?

Justice Blackmun began his gloss on the Federal Rules of Evidence by noting the very liberal standard that Rule 402 establishes in favor of admission of "all relevant evidence."\(^{16}\) If this were the only criterion, the points on which an expert would testify would simply have to fit the facts of the case. For example, the claim that Bendectin causes limb deformities in

\(^{15}\) "General observations" by this Court . . . suffer from the flaw common to most such observations—they are not applied to deciding whether or not particular testimony was or was not admissible, and therefore they tend to be not only general, but vague and abstract." Daubert, 113 S. Ct. at 2799 (Rehnquist, C.J., concurring in part and dissenting in part). Although this article explores the problems with Justice Blackmun's "general observations" and with their implications for the trial of cases involving expert testimony, it is not obvious that the problems would have been overcome had the Court waited, as the Chief Justice preferred, for the question to be presented in a subsequent case. It is true that Justice Blackmun relied heavily on the 22 amicus curiae briefs filed in Daubert to explore what the Chief Justice described as "one or more bodies of knowledge not judicially noticeable, and subject to different interpretations in the briefs of the parties and their amici," which largely deal "with definitions of scientific knowledge, scientific method, scientific validity, and peer review—in short, matters far afield from the expertise of judges" rather than with "decided cases or statutory language—the sort of material we customarily interpret." Id. Yet had the interpretation of the Federal Rules been left to a subsequent case, it nevertheless seems likely that such questions as the meaning of "scientific knowledge" would have become part of the case largely through arguments advanced in briefs before trial upon motions to admit or exclude proffered experts and that the same amici as appeared in Daubert would have filed the same briefs once the issue went up on appeal. A different process of inquiry—and perhaps a different result—would be expected only if one thinks that the problems with the standard articulated in Daubert flowed primarily from the absence of cross examination of those who held the position adopted by Justice Blackmun. Since interpretations of the scientific method that differ from the Court's were forcefully advanced in the case by some of the amici, to say nothing of the defendants, it seems doubtful that the difficulty confronting the Court—of grappling with "unusual subject matter" where its "reach can so easily exceed [its] grasp"—would have been avoided had the Court waited for a later case. Id.

\(^{16}\) FED. R. EVID. 402.
children when their mothers take it during the first trimester of pregnancy would be "relevant" and hence admissible once the plaintiff had submitted evidence from which a jury could find that the mother in the case at bar took the drug at that time in her pregnancy.

But, in addition to the relevance requirement of Rule 402, Rule 702 sets forth a further requirement for expert testimony. "If scientific, 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."\textsuperscript{17} Recognizing that expert testimony can be both powerful and misleading, the Court rejected the notion that the rules disable judges from screening "purportedly scientific evidence" and admitting only that which they believe to be trustworthy.\textsuperscript{18} Justice Blackmun found in Rule 702 a "helpfulness" criterion, based on the rule's provision that expert testimony regarding "scientific knowledge" is allowed when it will "assist the trier of fact."\textsuperscript{19} He concluded that the term "scientific knowledge" implies adherence to scientific methodology and support by "appropriate validation."\textsuperscript{20} In footnote nine (which is likely to be the subject of a good deal of commentary in the years to come), Justice Blackmun explained that when scientific evidence is involved, "evidentiary reliability will be based on scientific validity."\textsuperscript{21} In sum, the trial judge must assess "whether the reasoning or methodology underlying the testimony is scientifically valid" as well as being "properly . . . applied to the facts in issue."\textsuperscript{22}

While the majority may have gone well beyond the language of the Federal Rules of Evidence in creating its "scientific validity" criterion, some limitation on expert testimony is both necessary and clearly intended by the Rules. The normative question is thus: what values are implicit in the Court's conclusion that admissible evidence must be scientifically valid? This inquiry

\textsuperscript{17} FED. R. EVID. 702.
\textsuperscript{18} Daubert, 113 S. Ct. at 2795.
\textsuperscript{19} Id. at 2794.
\textsuperscript{20} Id. at 2795.
\textsuperscript{21} Id. at 2795 n.9 (emphasis in original).
\textsuperscript{22} Id. at 2796.
involves two levels of analysis: first, the content of the standard for admissibility; and second, the way it allocates authority in making that judgment.

A. What is “Scientific Knowledge”?

The Court explained that a “key question” in deciding whether testimony qualifies as scientific knowledge is “whether it can be (and has been) tested,” or, in language the Court took from Karl Popper, “its falsifiability, or refutability, or testability.” Among scientists, such notions are commonplace, but they simply shift the inquiry back one step: what methods are acceptable to “prove” or “disprove” a theory, and what evidence counts in reaching a judgment by whom?

Quoting a dictionary, Justice Blackmun stated that knowledge, rather than being mere belief is “known facts” or ideas “accepted as truths on good grounds.” That this sounds suspiciously like Frye’s “generally accepted” test is not surprising, since the commonplace idea is that science is whatever scientists do.

23. Id. at 2797 (quoting KARL POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989)). A difficulty with this use of Popper is that Blackmun seems to be answering a question that Popper explicitly said he was not addressing. The quest under Daubert is for “scientific validity” as a basis for evidentiary reliability, whereas at the beginning of the section that concludes with the “falsifiability” passage Popper states:

The problem which troubled me at the time was neither, “When is a theory true?” nor, “When is a theory acceptable?” My main problem was different. I wished to distinguish between science and pseudo-science, knowing very well that science often errs, and that pseudo-science may happen to stumble on the truth.

KARL POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 33 (1962) (emphasis in original). While courts must search for scientific validity, Popper was not concerned with a theory’s validity: “neither the problem of truth, . . . nor the problem of exactness or measurability.” Id. at 34.

24. Modern theorists argue that falsification is socially constructed. “[W]hether a methodology can falsify the conclusion will be determined by the standards, equipment, measurement, and error rates agreed upon by those within the relevant scientific community.” Margaret G. Farrell, Daubert v. Merrell Dow Pharmaceuticals, Inc.: Epistemology and Legal Process, 15 CARDOZO L. REV. 2183, 2205 (1994).

25. Daubert, 113 S. Ct. at 2795 (quoting WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1252 (1986)).

26. Thus, Daubert’s reliability analysis may just be another way of asking whether the theories and methodologies in question have been reviewed using gener-
Thus, rather than having scuttled Frye, the Daubert Court has simply rejected equating “general acceptance” with peer review and publication.\textsuperscript{27} Even so, whether a theory has been subject to these processes is “pertinent,” it is just no longer “a sine qua non of admissibility.”\textsuperscript{28} In support of this sensible conclusion, the Court notes that on the one hand, publication does not guarantee reliability, and on the other, some well-grounded theories will not have been published.\textsuperscript{29} “Good science” does, however, depend on some form of scrutiny and acceptance by “the scientific community.”\textsuperscript{30}
B. Decision by Judge, Jury, or Scientist?

The apparent simplicity of this conclusion may mask two underlying issues of authority. Attention has mostly been directed toward the first: within the courtroom, who should decide whether the reasoning or methodology underlying expert testimony is scientifically valid and can properly be applied to the facts at issue? In civil cases, this comes down to a power struggle between those (usually potential plaintiffs and their lawyers) who favor leaving the resolution of disputes to juries, and those (usually potential defendants and their lawyers) who want trial judges to have maximum authority to control juries' sympathetic impulse to award damages to injured parties.\(^3\)

To reassure those who feared that the abandonment of *Frye* would lead to a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions,\(^3^2\) the *Daubert* Court looked beyond vigorous cross examination and other devices of the adversary system and made clear that trial judges must act as gatekeepers not only in deciding on the admissibility of evidence, but also by directing verdicts or entering summary judgments when the scintilla of expert evidence presented for a position is not enough to permit "a reasonable juror to conclude that the position more likely than not is true."\(^1\)(1993)\(^2\)(No. 92-102)).

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31. This division emerges in a dialogue about *Daubert* between David M. Harney, a plaintiffs' attorney from Los Angeles, and Raoul D. Kennedy, a defense lawyer from Oakland, in the pages of the California Bar Association's journal shortly after the decision. *Brave New World*, *CALIFORNIA LAWYER*, Sept. 1993 at 31 (Richard C. Reuben ed.). Kennedy insists that "judges still have a gatekeeper function" though the "grounds for admission of evidence are somewhat more flexible" than they had been under *Frye*. *Id.* Harney, on the other hand, sees *Daubert* as a "big change" that is consistent with his own philosophy—"let all the evidence in"—under which it is up to "the jury [to] determine what effect it should be given" since the jury is the judge of the facts and "opinion evidence becomes factual testimony in the sense that the jury can adopt it as a fact. Judges are not juries, and judges should not keep out this evidence." *Id.* at 34.

32. *Daubert*, 113 S. Ct. at 2798.

33. *Id.* Despite these observations about trial judges' roles in evaluating the sufficiency of the evidence, *Daubert* "was primarily about admissibility," as the United States Court of Appeals for the Second Circuit observed in reversing the judgment granted as a matter of law by a district court in favor of the defendant in a suit brought by the widow of a sheet metal worker who died at age 40 of colon cancer where a jury had found that the cancer was caused by his workplace exposure to an
This creates an opposite danger, of course, that a judge’s screening role will promote a “stifling scientific orthodoxy” and will prevent jurors from hearing about genuine insights and valuable new findings. Rather than gainsaying this risk, the Court ascribed it to the very purpose of the Rules of Evidence, which exist “not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.”

This underlines another difference between science and the law: while science is advanced by an open and uninhibited debate about, and testing of, competing hypotheses, “[c]onjectures that are probably wrong are of little use . . . in the project of reaching a quick, final, and binding legal judgment . . . about a particular set of events in the past.”

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asbestos-containing product. In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1131 (2d Cir. 1995). The district court judge in that case had reviewed the plaintiff's evidence in light of five “Sufficiency Criteria” for epidemiological studies drawn from the work of noted epidemiologist A. Bradford Hill. In re Joint E. & S. Dist. Asbestos Litig., Maiorana v. United States Mineral Products Company, 827 F. Supp. 1014, 1037-38 (S.D.N.Y. 1993), rev'd 52 F.3d 1124 (2d Cir. 1995). In so doing, the district court failed to consider the evidence in the light most favorable to the plaintiff and engaged in “independent assessments of the witnesses' conclusions and comparative credibilities,” thereby departing from the well-established rules for judicial rulings on the sufficiency of the evidence. In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d at 1133 (citing Smith v. Lightning Bolt Prods., Inc., 861 F.2d 363, 367 (2d Cir. 1988)). Yet in one of the cases cited by the Daubert Court to illustrate appropriate uses of summary judgment or judgment as a matter of law, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir.), modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990), the Court of Appeals had found the plaintiff's epidemiological evidence was insufficient to support a jury's finding that Bendectin caused birth defects in plaintiff's child because it judged the risk ratios derived from the evidence were too low once adjusted by confidence intervals. Id. at 312. Although the Second Circuit characterized Brock as consistent with the general rule for judging the sufficiency of evidence and concluded that Daubert “did not alter the traditional sufficiency standard,” Judge Cabranes acknowledges:

[S]ufficiency poses unique difficulties for trial courts in toxic or carcinogenic tort cases . . . which hinge on competing interpretations of epidemiological evidence. By its nature, epidemiology is ill-suited to lead a factfinder toward definitive answers, dealing as it does in statistical probabilities and the continual possibility of confounding causal factors.

In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d at 1133.

34. Daubert, 113 S. Ct. at 2798.
35. Id. at 2799.
36. Id. at 2798. The tension between Daubert's endorsement of the scientific method and its rejection of "conjectures," can be seen in one lower court's attempt to place hypotheses in context:

A hypothesis is synonymous with a theory. Consequently, any hypothesis or theory is not a fact until it has been scientifically proven. Anyone who has been trained in the scientific method realizes that a hypothesis is a
Yet the *Daubert* Court's standard for when trial judges may—and should—take cases involving science away from the jury masks a second and less recognized issue of authority. The unresolved value questions embedded in the Court's "scientific validity" standard ought to have become unmistakable once the Court recognized that trial judges would have to decide whether statements would be "accepted as truths on good grounds" by the "relevant scientific community." Particularly in those cases where the battle of experts involves not just differing opinions about the significance of mutually agreed scientific theories but disagreement about methodology and theories themselves, a second question becomes inescapable: how is the threshold of scientific validity to be established? Is it to be established by a process conducted by the normal methods of the scientific community or by a preliminary "trial" in the courtroom? In other words, who is going to judge science, judges or scientists?  

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scientist's educated speculation. . . . It is important to underscore again that a court of law is not a scientific experiment. When a court of law determines responsibility for human suffering and awards damages, it must do so based upon reasonable evidence, not just speculation or hypothesis.


37. *Daubert*, 113 S. Ct. at 2795, 2797. One court has applied this standard in the negative as a ground for exclusion, without specifying whether the judge's determination is to be based on a judicial assessment of the failure of the evidence to meet the relevant standard or a judicial recognition of the assessment of the relevant scientific community:

[We] think the primary limitation on the judge's admissibility determinations is that the judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude evidence if the flaw is large enough that the expert lacks "good grounds" for his or her conclusions.

*In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (2nd Cir. 1993).

38. The fear that the effect of *Daubert* is to place that responsibility squarely upon the shoulders of lay judges has prompted a number of states to retain *Frye*, despite its limitations. "[A] courtroom is not a laboratory, and as such it is not the place to conduct scientific experiments. If the scientific community considers a procedure or process unreliable for its own purposes, then the procedure must be considered less reliable for courtroom use." Flanagan v. State, 625 So. 2d 827 (Fla. 1993). This view is far from unanimous, however; other states have asserted that the admissibility of scientific evidence remains a legal question. "[I]n testing for the admissibility of a particular type of scientific evidence, whatever the scientific 'voting' pattern may be, the courts cannot in any event surrender to scientists the responsibility for determining the reliability of that evidence." Taylor v. State, 889 P.2d 319, 329 (Okla. Crim. App. 1995) (quoting United States v. Williams, 583 F.2d 1194, 1198 (2d Cir. 1978)).
The Court gives no explicit attention to this second "authority" question of judge-versus-scientist because it does not seem to understand how contentious and value-laden its notion of "scientific validity" is, as opposed to how Justice Blackmun would have it: a mere description of some external reality that can be drawn uncontroversially from dictionaries and the writings of philosophers of science. Yet the issues of why and exactly how authority should be allocated between judges and "the scientific community" seem at least as significant as the more familiar authority issue of judge versus jury. Indeed, precisely because it involves a less familiar problem, one that prior cases and commentary have done less to illuminate, it seems a more troubling question. Frye's effective reliance on publication as the measure of peer review and hence of "general acceptance" may have been "uncompromising," but the alternative, many-factored test with which the Supreme Court has replaced it, opens the door to a complex task for which judges have no necessary preparation. 39 This difficulty has not gone unnoticed in subsequent decisions, especially among state courts grappling with the applicability of Daubert to state standards of admissibility. Arizona's high court for example, in refusing to replace a Frye-based standard, commented on the as yet amorphous and

39. In declining to Daubertize its own standard (dubbed Kelly-Frye, after the California case in which it followed Frye, People v. Kelly, 17 Cal.3d 24 (1976)), the California Supreme Court suggested that scientists are the appropriate entities to make decisions concerning reliability. "It may be preferable to let admissibility questions regarding new scientific techniques be settled by those persons most qualified to assess their validity." People v. Leahy, 882 P.2d 321, 330 (Cal. 1994). The Ninth Circuit panel handling the remand of Daubert was openly skeptical about the transition from Frye. The court lamented that "the judge's task under Frye was relatively simple: to determine whether the method employed by the experts is generally accepted in the scientific community," but the judge's responsibility under Daubert is "a far more complex and daunting task," particularly when courts are faced with "matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995). "Mindful of our position in the hierarchy of the federal judiciary," the appellate court continued, "we take a deep breath and proceed with this heady task." Id.; accord Cavallo v. Star Enterprises, 892 F. Supp 756, 761 (1995) ("The second part of the admissibility analysis [the relevance requirement] gives the court a more familiar role to play.").
indeterminant multi-factor analysis: "The nature of [the scientific-validity] requirement is currently unknown, may vary from case to case, and is to be fashioned by trial judges using an analytical framework as yet unspecified." Similarly, a federal district court observed, "[w]hether the Daubert analysis is ultimately viewed as 'wise' law, or whether it promotes 'good' science, must be answered at some time in the future."

III. SCIENTIFIC VALUE JUDGMENTS

Judges' concern that they are ill-equipped for the task assigned them by Daubert cannot be brushed aside, any more than one ought to be unconcerned that both the vagueness and the unfamiliarity of the task will lead to inconsistent outcomes. But the central point is that the Supreme Court gave

40. State v. Bible, 858 P.2d 1152, 1183 (Ariz. 1993). The Second Circuit has set forth a total of eight factors that district courts should analyze when conducting a Daubert inquiry, including several not mentioned by the Supreme Court: (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (2d Cir. 1994). Other courts in other circuits have included similar factors in their Daubert inquiries. See, e.g., Daubert, 43 F.3d 1311. The proliferation of other factors may tend to give judges more discretion and potentially lead to inconsistent outcomes.

41. Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1382 (N.D. Cal. 1995). The responsibilities of district courts under Daubert are indeed heavy ones. The training of a judge is of course in law and not in medicine. . . . A court's analysis of medical causation necessarily forces a court to become as familiar as it can, with little or no scientific training, to understand the medical and scientific concepts. The vocabulary alone is daunting; and the danger of merely grabbing at words, and attaching too much significance to them, is very real. The Daubert analysis also requires courts to focus heavily on what has occurred in the past, rather than what the future of medicine and science might be. And history has frequently taught that the conventional scientific wisdom of one generation is later looked upon as shocking ignorance by future generations.

Id. at 1382-83.

42. The improbability that judges will rule consistently on the validity of scientific theory is amply demonstrated by the number of multi-factor tests that have been recommended by state high courts for carrying out this analysis. See, e.g., State v. Alberico, 861 P.2d 192, 203 (N.M. 1993) (Is the technique based upon well-recognized scientific principle and is it capable of supporting opinions based upon reasonable probability rather than conjecture?); State v. Bullard, 322 S.E.2d 370, 382 (N.C. 1984) (Were visual aids used before the jury so that it was not asked "to sacrifice its independence by accepting [the] scientific hypothesis on faith[?]?"); State v. O'Key, 899
no inkling that it was aware of the epistemological problem at
the heart of its new standard, and of the ramifications of that
problem, especially where the notion of "a relevant scientific
community" is nonsensical.

To make these concerns concrete, suppose that the evidence
originally proffered in Daubert and other Bendectin cases was
presented to a trial judge after the Court's decision. Assume
that the defendant objected to the admissibility of all or part of
this evidence under Daubert, and the court ordered a hearing
in limine to decide whether the evidence should be admitted.
How should the judge decide whether a particular method of
analyzing the results of the epidemiologic studies is "valid," or
just sophisticated nonsense? If the findings in question have
not been formally submitted "to the scrutiny of the scientific
community," should the judge assemble a group of scientists to
review them? If scientists hold differing views about the meth-
ods used, how should a judge go about selecting these review-
ers, and what values should the judge tell them to apply in
making their own assessments of whether the evidence is "good
science"? Or are judges going to proceed on the quaint notion of
"value-free" science? Seen in this light, Justice Blackmun's
recitation of the familiar notion that what counts about science
is its methodology of testing hypotheses, and attempting to
disprove them, seems rather naive. The decision that any par-

P.2d 663 (Or. 1995) (listing at least 18 separate factors trial courts could consider in
exercising their gatekeeping role).

43. Daubert's four factor analysis itself does not provide a definitive means for
drawing the line between valid and invalid science. "Even were we to use Daubert's
reliability/scientific validity analysis, we would still be left with the problem posed by
Frye: precisely when 'in [the] twilight zone the evidential force of the [scientific] prin-
ciple must be recognized." Bible, 858 P.2d at 1183 (Ariz. 1993); see also State v.
Carter, 524 N.W.2d 763, 778 (Neb. 1994). Oregon's Supreme Court also likened this
task to navigating through the Twilight Zone:
"There is a fifth dimension beyond that which is known to man. It is a
dimension as vast as space and timeless as infinity. It is the middle
ground beyond light and shadow, between science and superstition. And
it lies between the pit of man's fears and the summit of his knowledge.
It is an area we call the 'Twilight Zone.'" (citation omitted) In determining
whether scientific evidence is admissible, the trial court is to make sure
that the decision by the trier of fact is based on scientific facts, not sci-
ence fiction.

O'Key, 899 P.2d at 678 n.20.
ticular theory has been defeated or confirmed may well turn on which types of evidence, and what degree of proof, one applies.

Writing for the Ninth Circuit on remand of Daubert, Judge Kozinski repeatedly raises considerations that suggest the difficulties facing the lower courts in applying the Supreme Court's decision. For example, taking note of Justice Blackmun's mention of "whether the known or potential rate of error is acceptable" as one consideration in deciding whether to admit scientific expert testimony, Judge Kozinski observes that the factors recited by the Court "raise many questions, such as how do we determine whether the rate of error is acceptable, and by what standard?" Judge Kozinski goes on to point out that two of the factors mentioned by the Supreme Court "would be difficult or impossible to apply to the expert testimony in this case," since most of it was reanalysis of data rather than the sort of original research contemplated in the Court's description of the scientific process. "As to such derivative analytic work, it makes little sense to ask whether the technique employed 'can be (and has been) tested,' . . . or what its 'known or potential rate of error' might be."

The epistemological problem is further illustrated by Oxendine v. Merrell Dow Pharmaceuticals, Inc., the only verdict for a plaintiff in the Bendectin litigation thus far which has survived appellate review. The Superior Court granted the defendant's motion for judgment n.o.v. because it concluded that the testimony of the plaintiff's sole causation witness, Dr. Alan Done, should not have been admitted. The District of Columbia Court of Appeals held that the trial court had erred because Dr. Done (who was also one of the eight witnesses offered by the plaintiffs in Daubert) had provided a sufficient foundation for his testimony even though he admitted that none of the four categories of scientific evidence was probative about Bendectin's teratogenic effects "when . . . considered separately from the others. The [trial] court focused on this fact and concluded that if each type of data, viewed in isolation, was not

44. Daubert, 43 F.3d at 1316 (citing Daubert, 113 S. Ct. at 2797).
45. Id. at 1316 n.3.
46. Id. at 1317 n.4.
47. Id.
sufficient to prove that Bendectin caused birth defects, then all of them taken together could not prove it either.”49 When the Court of Appeals found this reasoning to be in error, was it applying a legal standard of reasoning or was it finding that Dr. Done had used a method of reasoning that qualifies as “scientific”?50

A further illustration of this problem can be seen in the usually ignored side of the plaintiffs’ proffered evidence in Daubert itself. The Supreme Court focused on the statistical reanalysis of the epidemiological studies, but the plaintiffs were also prepared to introduce three other types of evidence. Was District Judge Gilliam wrong to exclude this evidence because there was so much epidemiological evidence? To support his conclusion, he quoted the D.C. Circuit’s Richardson decision:

These three types of studies—chemical, in vitro, and in vivo—cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.51

Again, should this be taken as a judicial or scientific proposition? If scientific, should it be held to the very standards that the Supreme Court articulated for expert testimony in Daubert? That is, should one take this as a hypothesis—that strong evidence of type A (no observable effect of X on the population) renders useless evidence of other types (X does cause mutations

49. Id. at 1104.
50. See In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1133 (2d Cir. 1995) (stating that sufficiency assessments of causation evidence—in determining whether to enter summary judgment or judgment as a matter of law—entail a review of the sum total of epidemiological studies, while admissibility assessments entail a review of each study (or piece of evidence) in isolation.) The Ninth Circuit in the Daubert remand held that insufficient epidemiological evidence (i.e., evidence that does not show that it is statistically more likely than not that Bendectin causes birth defects) may be aggregated with “other evidence” to make an issue of causation. Daubert, 43 F.3d at 1321. However, the court uses statistical re-analysis as the only example of “other evidence,” and does not mention either animal studies, chemical structure, or clinical evidence as a similar supplement.
in cultured cells and animals)—and how would one test and confirm or refute the hypothesis?\footnote{52}

Of course, the particular holding in Richardson may itself be mooted by the Supreme Court's having opened the door to the recalculated epidemiological evidence, but some variation of this problem will present itself in every case involving scientific disputes: what kind of judgment is involved in deciding that one type of evidence is superior to another?\footnote{53} On remand of Daubert, the Ninth Circuit excluded the testimony of the plaintiff's experts without having to delve into this thorny problem because it concluded that the evidence of plaintiff's witnesses did not meet "the two principal ways the proponent of expert testimony can show that the evidence satisfies the first prong of

\footnote{52. Several recent cases demonstrate the potential contradictory outcomes among courts when judges encounter scientific disagreement about methodologies or theories. Whiting v Boston Edison Co., 891 F. Supp. 12, 23 (D. Mass. 1995), expressly rejected the contention of the plaintiff's expert witness that a "linear exposure" model of exposure (instead of the more traditionally accepted "threshold" model) was applicable to the causal link between nuclear radiation exposure and a form of leukemia. The epidemiological evidence pointed to a possible correlation between radiation exposure and leukemia in small children and older adults, but no correlation in adults in a similar age range as the plaintiff. In contrast, in Benedi v. McNeil—P.P.C., Inc., 66 F.3d 1378, 1384 (4th Cir. 1995), the court cited City of Greenville v. W.R. Grace & Co., 827 F.2d 975 (4th Cir. 1987), for the proposition that expert testimony need not be based upon identical case studies or epidemiological data in order to be admissible. (In City of Greenville, with little epidemiological evidence available, the court allowed the plaintiff's expert to testify to the fact that, because there was a correlation between asbestos-related diseases and exposure to high levels of asbestos, low levels of asbestos exposure may cause serious harm—an apparent endorsement of the linear, non-threshold model of exposure.) Whiting and Benedi thus involve similar situations but opposite results regarding admissibility. Presumably, a model rejected in one instance should not be accepted as "scientifically valid" in another simply because of a lack of data on the relevant subject, especially given the view of many courts—asserted as a matter of certainty—that the lack of epidemiological evidence is fatal to a plaintiff's case. "Regardless of the particular articulation of the teratology community's methodology, positive human epidemiologic studies are always required to reach a conclusion as to whether a specific agent is teratogenic [causes birth defects] in humans." Wade-Greaux v. Whitehall Lab., 874 F. Supp. 1441, 1451 (D. St. Thomas & St. John 1994).

53. For example, competing forms of causation evidence were at issue in Hopkins v. Dow Chemical Corp., 33 F.3d 1116, 1125 (1995) (plaintiff's expert witness allowed to testify about his experience as a toxicologist, his review of medical records and defendant's studies, and his general scientific knowledge of silicone's ability to cause immune disorders as established by animal studies and biophysical data in the absence of a solid body of human epidemiological data to review). See also In re Paoli R.R. Yard Litigation, 85 F.3d 717 (2d Cir. 1993); In re Joint E. & S. Asbestos Litig., 52 F.3d 1124 (2d Cir. 1995).}
Rule 702,” namely, that it grows out of pre-litigation research and that it has been subjected to peer review. Absent such a showing, the experts were required to show some objective source that could verify the validity and reliability of their methodology, which they had failed to do. The court did not mention whether the animal studies or chemical structure studies proffered would have a bearing on the epidemiologists’ conclusions.

In *Wade-Greaux v. Whitehall Laboratories*, the district court attempts to deal with this problem of comparative evidence by falling back on a Frye-like analysis. In *Wade-Greaux*, the plaintiff claimed that the chemicals found in Primatene Mist were teratogens and caused her baby’s birth defects. The district court judge excluded all of the testimony proffered by the plaintiff’s experts on conclusive causation (including all of the testimony of Dr. Alan K. Done, mentioned above) because the experts: (1) had not followed the generally accepted methodology used by the scientific community of teratologists; (2) had not subjected their methodology to peer review or publication; (3) had not developed their testimony independent of the litigation, (4) did not possess the qualifications or stature in the scientific community to proffer an opinion on general or specific causation; and (5) relied too heavily on animal studies and case reports (anecdotal human data), scientific techniques that the court felt frequently lead to erroneous results. Except for the

54. *Daubert*, 43 F.3d at 1318.
55. The court concluded that it was unnecessary to remand to the district court to offer the plaintiffs’ experts an opportunity to explain their methodology because none of them had testified it was more likely than not that the plaintiffs’ injuries were caused by their mothers’ ingesting Bendectin. Hence even if admissible, the evidence scientifically failed the second prong of Rule 702—the requirement of “fit” or relevancy—because under the substantive law of California something (here, ingesting Bendectin) would have at least to double the probability of an event to be presented to the finder of fact as a legal cause of that event. *Id.* at 1321.
58. *Id.* at 1478-82. It is noteworthy how easily courts dismiss case reports. For example:

Such case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes;
third rationale, all of these reasons can be traced back to a “general acceptance” analysis grounded in Frye, with nothing added by Daubert other than uncertainty as to whether the judgment being made is essentially a description of what the judge believes constitutes “good science,” or what the parties have established “the relevant scientific community” holds to be good methodology. 59

The problem with the latter is not only that it is very vague but that it begins what could become an infinite regression: by what methodology does the scientific community establish which methodologies are scientifically sound? Is that methodology established by the courts or by scientists themselves? The existence of this conundrum is central to the problem created by the Court’s approach in Daubert, because the Court there emphasized that the judicial function is limited to deciding whether the methods used to support the proffered evidence is scientifically valid and does not extend to passing on the validity of the conclusions reached by these methods. 60 Yet if the

and do not investigate or explain the mechanism of causation. Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). While not surprising or counter-intuitive, such assertions by judges are nevertheless remarkable. When a scientist proposes to testify about his or her conclusions based upon such reports and a court declines to allow the testimony, is the court describing what it takes to be the attitude of the scientific community toward such reports or is declaring as a matter of law (based upon the court’s own sense of the scientific process or the judicial process?) that such evidence is too unreliable to be considered “scientific knowledge” as the Court has defined that category for purposes of Rule 702?

59. Glaser v. Thompson Medical Co., 32 F.3d 969 (6th Cir. 1994), and In re Joint E. & S. Asbestos Litig., 52 F.3d 1124 (2d Cir. 1995), are examples of cases in which the judges raise questions about the basic scientific methodologies employed by expert witnesses (for example, limited sample size and statistical significance evaluations) which again emphasizes the complex role judges are being asked to play when they have to pass on the methodology employed by scientific witnesses.

60. The problems are, of course, only increased when the validity of scientific conclusions are at issue, as in regulation of environmental risks. Wendy Wagner has recently argued that efforts to incorporate science into toxic risk regulation have been confounded by scientists’ and policymakers’ unwillingness to set out clearly the respective roles of science and policy in the promulgation of regulations, instead masking them as scientific decisions. Wendy E. Wagner, The Science Charade in Toxic Risk Regulation, 95 Colum. L. Rev. 1613 (1995). In particular, the number of untestable assumptions that must be made in attempting to determine a “safe” or “acceptable” level of human exposure argue against simply leaving the question to the “scientific process” to obtain a value-free answer. See id. at 1619. For example, a judgment about how to extrapolate high dose exposures of a potential toxin given to an animal to acceptable levels for human consumption requires a number of decisions
epistemological problem and its normative derivative (by what authority is who deciding what constitutes "scientific knowledge," scientist or judge?) inhere in establishing the methodology by which a methodology can be judged to either be scientifically valid or invalid, then the purported limitation of the subject under review does not remove the difficulty.

Indeed, suppose for a moment that the epidemiological reanalyses did not exist but that the plaintiffs' laboratory experimenters and chemists contended that in their scientific circles evidence of the type they had accumulated was considered superior to epidemiological studies? It is not far fetched that these experts could hold such views for the very reason relied upon by the plaintiffs' epidemiology experts in the Bendectin cases namely that the original studies had sampling errors, clinical evaluation biases, and other problems. For example, in a cohort study, if one counts in the "exposed" group women who took Bendectin at times in their pregnancy when limb formation was not occurring, then the absence of adverse effects in their offspring would not provide any evidence that the drug does not cause limb deformities. Thus, either a statistical reanalysis (which placed these women into the "unexposed" category) or use of chemical or biological studies or models would provide superior evidence; the mere numbers of people included in the Bendectin epidemiological studies should count for nought if the studies employed flawed data. As the computer folks say, garbage in, garbage out.

normally not considered scientific in nature. See id. at 1625-26. One instance of "transcientific" decisionmaking in this example is the proper extrapolatory model to be employed among a number of equally scientifically plausible scenarios. Id. at 1626. Though each model has been arrived at through testing and experimentation, a selection among them must necessarily include factors such as the risk-aversion of the decisionmaker. In fact, the necessity of experimentation to arrive at these models often cloaks, in the final decision, the role of policy judgments in arriving at the risk assessment, a fact not often recognized by lay persons (including judges). Id. at 1627. The suggestion that judges would rely on science to establish the validity—and hence the evidentiary reliability and admissibility—of proffered evidence could thus be seen as another instance of the "science charade" through which value judgments are cloaked as science so that judges, like the high agency officials whose actions Professor Wagner examines, can avoid being held accountable for their decisions.
IV. Conclusion

Perhaps those who have heaped praise on Daubert may prove right, and trial judges, with a little extra work, will gain enough understanding about scientific methodology to make decisions about expert witnesses that seem sensible to most knowledgeable observers most of the time. That would not remove the underlying problems with the method by which the Court assumes scientific validity will be determined, but it could render such problems largely of theoretic concern. To inform them in this process, the courts would be well-advised to think of the peer-oriented processes that stand at the heart of the scientific enterprise as much broader than merely editorial peer review. But implementing Daubert in this fashion would not only amount merely to a modest modification of Frye (whereas the Court seemed to think it was formulating a substantially different rule), but would also do nothing to resolve the problem of discovering what judgments “true peer review” can offer about particular scientific testimony, particularly when the dispute between the parties centers on their reliance on different branches of science and no single relevant scientific community exists with the authority, or perhaps even the ability, to address all the conflicting expert testimony proffered.

Of course, if, as seems likely, the courts read Daubert as encouraging liberal allowance of testimony whenever there is any well credentialed scientist who supports the theory, then time-consuming minitrials will not be necessary, and judges will avoid addressing the deeper questions of the value assumptions in science raised here. Yet if that occurs, many who now are pleased with Daubert will be disappointed to find that Justice Blackmun’s detailed parsing of the meaning of “scientific knowledge” amounted to nothing more than “if a scientist supports it, let it in.”

Finally, if the problems that federal judges—and their colleagues in the states—are already experiencing in applying

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61. See Chan, supra note 30 (contrasting editorial peer review with “true peer review”).
62. The state courts have been far from unanimous in embracing the test articulated in Daubert. A minority of states have accepted Daubert’s holding as well as the application of its four-factor test. State v. Brooks, 643 A.2d 226 (Vt. 1993); State
Daubert continue to vex the application of the requirements of Rule 702, then some more direct way will have to be found to grapple with the unacknowledged problems of meaning, value, and authority that Daubert failed to resolve. Certainly the way chosen by the House of Representatives in the Attorney Accountability Act of 1995 is no solution to the problem. Section 3 of the bill ("Honesty in Evidence") merely enshrines a very conservative reading of the Daubert opinion in the language of Rule 702, but does not address the conceptual or normative problems in determining what is "scientifically valid." The only escape, such as it is, from the problem is frankly to acknowledge the problem, and to use Daubert hearings as forums in which the witnesses address the underlying methodological assumptions upon which their scientific methodology rests, and the judge at least becomes aware of the value assumptions (such as degrees of certainty and measures of proba-

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64. Section 3(2) of H.R. 988 would add the following to the end of Rule 702:

(b) Adequate basis for opinion.—Testimony in the form of an opinion by a witness that is based on scientific knowledge shall be inadmissible in evidence unless the court determines that such opinion—

(1) is scientifically valid and reliable;

(2) has a valid scientific connection to the fact it is offered to prove; and

(3) is sufficiently reliable so that the probative value of such evidence outweighs the dangers specified in Rule 403.

Subsection (c) provides that testimony that would otherwise be admissible should be ruled inadmissible if the witness "is entitled to receive any compensation contingent on the legal disposition of any claim with respect to which the testimony is offered," and subsection (d) makes subsection (b) inapplicable to criminal proceedings.
bility) that are hidden in the arcane language of scientific discourse. In this way, the relative distribution of authority among jury, judge, and scientist can become a matter of iterative examination by the courts, and provide a grounding on which the Court at a later date could confront these issues head on, informed by the thinking of those at the trial and intermediate levels with repeated experience with the issues.