

# **U.S. Supreme Court**

## DAUBERT v. MERRELL DOW PHARMACEUTICALS, INC., 509 U.S. 579 (1993)

509 U.S. 579

## WILLIAM DAUBERT, ET UX., ETC., ET AL., PETITIONERS v. MERRELL DOW PHARMACEUTICALS, INC. CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT No. 92-102

Argued March 30, 1993 Decided June 28, 1993

Petitioners, two minor children and their parents, alleged in their suit against respondent that the children's serious birth defects had been caused by the mothers' prenatal ingestion of Bendectin, a prescription drug marketed by respondent. The District Court granted respondent summary judgment based on a well-credentialed expert's affidavit concluding, upon reviewing the extensive published scientific literature on the subject, that maternal use of Bendectin has not been shown to be a risk factor for human birth defects. Although petitioners had responded with the testimony of eight other well-credentialed experts, who based their conclusion that Bendectin can cause birth defects on animal studies, chemical structure analyses, and the unpublished "reanalysis" of previously published human statistical studies, the court determined that this evidence did not meet the applicable "general acceptance" standard for the admission of expert testimony. The Court of Appeals agreed and affirmed, citing Frye v. United States, 54 App. D.C. 46, 47, 293 F. 1013, 1014, for the rule that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community.

#### Held:

The Federal Rules of Evidence, not Frye, provide the standard for admitting expert scientific testimony in a federal trial. Pp. 4-17.

- (a) Frye's "general acceptance" test was superseded by the Rules' adoption. The Rules occupy the field, United States v. Abel, 469 U.S. 45, 49, and, although the common law of evidence may serve as an aid to their application, id., at 51-52, respondent's assertion that they somehow assimilated Frye is unconvincing. Nothing in the Rules as a [509 U.S. 579, 2] whole or in the text and drafting history of Rule 702, which specifically governs expert testimony, gives any indication that "general acceptance" is a necessary precondition to the admissibility of scientific evidence. Moreover, such a rigid standard would be at odds with the Rules' liberal thrust and their general approach of relaxing the traditional barriers to "opinion" testimony. Pp. 4-8.
- (b) The Rules especially Rule 702 place appropriate limits on the admissibility of purportedly

scientific evidence by assigning to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. The reliability standard is established by Rule 702's requirement that an expert's testimony pertain to "scientific . . . knowledge," since the adjective "scientific" implies a grounding in science's methods and procedures, while the word "knowledge" connotes a body of known facts or of ideas inferred from such facts or accepted as true on good grounds. The Rule's requirement that the testimony "assist the trier of fact to understand the evidence or to determine a fact in issue" goes primarily to relevance by demanding a valid scientific connection to the pertinent inquiry as a precondition to admissibility. Pp. 9-12.

- (c) 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. Many considerations will bear on the inquiry, including whether the theory or technique in question can be (and has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community. The inquiry is a flexible one, and its focus must be solely on principles and methodology, not on the conclusions that they generate. Throughout, the judge should also be mindful of other applicable Rules. Pp. 12-15.
- (d) Cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, rather than wholesale exclusion under an uncompromising "general acceptance" standard, is the appropriate means by which evidence based on valid principles may be challenged. That even limited screening by the trial judge, on occasion, will prevent the jury from hearing of authentic scientific breakthroughs is simply a consequence of the fact that the Rules are not designed to seek cosmic understanding but, rather, to resolve legal disputes. Pp. 15-17.

951 F.2d 1128 (CA9 1991), vacated and remanded. [509 U.S. 579, 3]

BLACKMUN, J., delivered the opinion for a unanimous Court with respect to Parts I and II-A, and the opinion of the Court with respect to Parts II-B, II-C, III, and IV, in which WHITE, O'CONNOR, SCALIA, KENNEDY, SOUTER, and THOMAS, JJ., joined. REHNQUIST, C.J., filed an opinion concurring in part and dissenting in part, in which STEVENS, J., joined, post, p. \_\_\_\_.

Michael H. Gottesman argued the cause for petitioners. With him on the briefs were Kenneth J. Chesebro, Barry J. Nace, David L. Shapiro, and Mary G. Gillick.

Charles Fried argued the cause for respondent. With him on the brief were Charles R. Nesson, Joel I. Klein, Richard G. Taranto, Hall R. Marston, George E. Berry, Edward H. Stratemeier, and W. Glenn Forrester. \*

[ Footnote \*] Briefs of amici curiae urging reversal were filed for the State of Texas et al. by Dan Morales, Attorney General of Texas, Mark Barnett, Attorney General of South Dakota, Marc Racicot, Attorney General of Montana, Larry EchoHawk, Attorney General of Idaho, and Brian Stuart Koukoutchos; for the American Society of Law, Medicine and Ethics et al. by Joan E. Bertin, Marsha S. Berzon, and Albert H. Meyerhoff; for the Association of Trial Lawyers of America by Jeffrey Robert White and Roxanne Barton Conlin; for Ronald Bayer et al by Brain Stuart Koukoutchos, Priscilla Budeiri, Arthur Bryant, and George W. Conk; and for Daryl E. Chubin et al. by Ron Simon and Nicole Schultheis. Briefs of amici curiae urging affirmance were filed for the United States by Acting Solicitor General Wallace, Assistant Attorney General Gerson, Miguel A. Estrada, Michael Jay Singer, and John P. Schnitker; for the American Insurance

Association by William J. Kilberg, Paul Blankenstein, Bradford R. Clark, and Craig A. Berrington; for the American Medical Association et al. by Carter G.. Phillips, Mark D. Hopson, and Jack R. Bierig; for the American Tort Reform Association by John G. Kester and John W. Vardaman, Jr.; for the Chamber of Commerce of the United States by Timothy B. Dyk, Stephen A. Bokat, and Robin S. Conrad; for the Pharmaceutical Manufacturers Association by Louis R. Cohen and Daniel Marcus; for the Product Liability Advisory Council, Inc., et al. by Victor E. Schwartz, Robert P. Charrow, and Paul F. Rothstein; for the Washington Legal Foundation by Scott G. Campbell, Daniel J. Popeo, and Richard A. Samp; and for Nicolaas Bloembergen et al. by Martin S. Kaufman. Briefs of amici curiae were filed for the American Association for the Advancement of Science et al. by Richard A. Meserve and Bert Black; for the American College of Legal Medicine by Miles J. Zaremski; for the Carnegie Commission on Science,, Technology, and Government by Steven G. Gallagher, Elizabeth H. Esty, and Margaret A. Berger; for the Defense Research Institute, Inc., by Joseph A. Sherman, E. Wayne Taff, and Harvey L. Kaplan; for the New England Journal of Medicine et al. by Michael Malina and Jeffrey I. D. Lewis; for A Group of American Law Professors by Donald N. Bersoff; for Alvan R. Feinstein by Don M. Kennedy, Loretta M. Smith, and Richard A. Oetheimer; and for Kenneth Rothman et al. by Neil B. Cohen. [509 U.S. 579, 1]

OJ JUSTICE BLACKMUN delivered the opinion of the Court.

In this case, we are called upon to determine the standard for admitting expert scientific testimony in a federal trial.

I

Petitioners Jason Daubert and Eric Schuller are minor children born with serious birth defects. They and their parents sued respondent in California state court, alleging that the birth defects had been caused by the mothers' ingestion of Bendectin, a prescription antinausea drug marketed by respondent. Respondent removed the suits to federal court on diversity grounds.

After extensive discovery, respondent moved for summary judgment, contending that Bendectin does not cause birth defects in humans and that petitioners would be unable to come forward with any admissible evidence that it does. In support of its motion, respondent submitted an affidavit of Steven H. Lamm, physician and epidemiologist, who is a well-credentialed expert on the risks from exposure to various [509 U.S. 579, 2] chemical substances. 1 Doctor Lamm stated that he had reviewed all the literature on Bendectin and human birth defects - more than 30 published studies involving over 130,000 patients. No study had found Bendectin to be a human teratogen (i.e., a substance capable of causing malformations in fetuses). On the basis of this review, Doctor Lamm concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.

Petitioners did not (and do not) contest this characterization of the published record regarding Bendectin. Instead, they responded to respondent's motion with the testimony of eight experts of their own, each of whom also possessed impressive credentials. 2 These experts had concluded that Bendectin can cause birth defects. Their conclusions were based upon "in vitro" (test tube) and "in vivo" (live) animal studies that found a link between Bendectin and malformations; pharmacological studies of the chemical structure of Bendectin that purported to show similarities between the [509 U.S. 579, 3] structure of the drug and that of other substance known to cause birth defects; and the "reanalysis" of previously published epidemiological (human statistical) studies.

The District Court granted respondent's motion for summary judgment. The court stated that scientific evidence is admissible only if the principle upon which it is based is "`sufficiently established to have general acceptance in the field to which it belongs.'" 727 F.Supp. 570, 572 (S.D. Cal. 1989), quoting United States v. Kilgus, 571 F.2d 508, 510 (CA9 1978). The court concluded that petitioners' evidence did not meet this standard. Given the vast body of epidemiological data concerning Bendectin, the court held, expert opinion which is not based on epidemiological evidence is not admissible to establish causation. 727 F.Supp., at 575. Thus, the animal cell studies, live animal studies, and chemical structure analyses on which petitioners had relied could not raise, by themselves, a reasonably disputable jury issue regarding causation. Ibid. Petitioners' epidemiological analyses, based as they were on recalculations of data in previously published studies that had found no causal link between the drug and birth defects, were ruled to be inadmissible because they had not been published or subjected to peer review. Ibid.

The United States Court of Appeals for the Ninth Circuit affirmed. 951 F.2d 1128 (1991). Citing Frye v. United States, 54 App. D.C. 46, 47, 293 F. 1013, 1014 (1923), the court stated that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community. 951 F.2d, at 1129-1130. The court declared that expert opinion based on a methodology that diverges "significantly from the procedures accepted by recognized authorities in the field . . . cannot be shown to be `generally accepted as a reliable technique.'" Id., at 1130, quoting United States v. Solomon, 753 F.2d 1522, 1526 (CA9 1985). [509 U.S. 579, 4]

The court emphasized that other Courts of Appeals considering the risks of Bendectin had refused to admit reanalyses of epidemiological studies that had been neither published nor subjected to peer review. 951 F.2d, at 1130-1131. Those courts had found unpublished reanalyses "particularly problematic in light of the massive weight of the original published studies supporting [respondent's] position, all of which had undergone full scrutiny from the scientific community." Id., at 1130. Contending that reanalysis is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field, the Court of Appeals rejected petitioners' reanalyses as "unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." Id., at 1131. The court concluded that petitioners' evidence provided an insufficient foundation to allow admission of expert testimony that Bendectin caused their injuries and, accordingly, that petitioners could not satisfy their burden of proving causation at trial.

We granted certiorari, 506 U.S. 914 (1992), in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony. Compare, e.g., United States v. Shorter, 257 U.S. App. D.C. 358, 363-364, 809 F.2d 54, 59-60 (applying the "general acceptance" standard), cert. denied, 484 U.S. 817 (1987), with DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 955 (CA3 1990) (rejecting the "general acceptance" standard).

II

A

In the 70 years since its formulation in the Frye case, the "general acceptance" test has been the dominant standard for determining the admissibility of novel scientific evidence at trial. See E. Green & C. Nesson, Problems, Cases, and Materials on Evidence 649 (1983). Although under increasing [509 U.S. 579, 5] attack of late, the rule continues to be followed by a majority of courts, including the Ninth Circuit. 3

The Frye test has its origin in a short and citation-free 1923 decision concerning the admissibility of evidence

derived from a systolic blood pressure deception test, a crude precursor to the polygraph machine. In what has become a famous (perhaps infamous) passage, the then Court of Appeals for the District of Columbia described the device and its operation and declared:

"Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone, the evidential force of the principle must be recognized, and while 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." 54 App. D.C., at 47, 293 F., at 1014 (emphasis added).

Because the deception test had "not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made," evidence of its results was ruled inadmissible. Ibid.

The merits of the Frye test have been much debated, and scholarship on its proper scope and application is legion. 4 [509 U.S. 579, 6] Petitioners' primary attack, however, is not on the content, but on the continuing authority, of the rule. They contend that the Frye test was superseded by the adoption of the Federal Rules of Evidence. 5 We agree.

We interpret the legislatively enacted Federal Rules of Evidence as we would any statute. Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 163 (1988). Rule 402 provides the baseline:

"All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules [509 U.S. 579, 7] prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

"Relevant evidence" is defined as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Rule 401. The Rule's basic standard of relevance thus is a liberal one.

Frye, of course, predated the Rules by half a century. In United States v. Abel, <u>469 U.S. 45</u> (1984), we considered the pertinence of background common law in interpreting the Rules of Evidence. We noted that the Rules occupy the field, id., at 49, but, quoting Professor Cleary, the Reporter, explained that the common law nevertheless could serve as an aid to their application:

"In principle, under the Federal Rules, no common law of evidence remains. "All relevant evidence is admissible, except as otherwise provided. . . ." In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers.'" Id., at 51-52.

We found the common law precept at issue in the Abel case entirely consistent with Rule 402's general requirement of admissibility, and considered it unlikely that the drafters had intended to change the rule. Id., at 50-51. In Bourjaily v. United States, 483 U.S. 171 (1987), on the other hand, the Court was unable to find a particular common-law doctrine in the Rules, and so held it superseded.

Here there is a specific Rule that speaks to the contested issue. Rule 702, governing expert testimony, provides:

"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, [509 U.S. 579, 8] or education, may testify thereto in the form of an opinion or otherwise."

Nothing in the text of this Rule establishes "general acceptance" as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the Rules as a whole were intended to incorporate a "general acceptance" standard. The drafting history makes no mention of Frye, and a rigid "general acceptance" requirement would be at odds with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to `opinion' testimony." Beech Aircraft Corp. v. Rainey, 488 U.S., at 169 (citing Rules 701 to 705). See also Weinstein, Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended, 138 F.R.D. 631 (1991) ("The Rules were designed to depend primarily upon lawyer-adversaries and sensible triers of fact to evaluate conflicts"). Given the Rules' permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention "general acceptance," the assertion that the Rules somehow assimilated Frye is unconvincing. Frye made "general acceptance" the exclusive test for admitting expert scientific testimony. That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials. 6

B

That the Frye test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place [509 U.S. 579, 9] no limits on the admissibility of purportedly scientific evidence. 7 Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules, the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.

The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," an expert "may testify thereto." (Emphasis added.) The subject of an expert's testimony must be "scientific . . . knowledge." 8 The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" [connotes more than subjective belief or unsupported speculation.] The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. See, e.g., Brief for Nicolaas Bloembergen 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 et al. as Amici Curiae 7-8 ("Science is not an encyclopedic body of knowledge about [509 U.S. 579, 10] the universe. Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement" (emphasis in original). But, in order to qualify as "scientific knowledge," an inference or assertion must be [derived by the scientific method.] Proposed testimony must be supported by [appropriate validation] - i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability. 9

Rule 702 further requires that the evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This condition goes primarily to relevance. "Expert testimony which does not

relate to any issue in the case is not relevant and, ergo, nonhelpful." 3 Weinstein & Berger 70202., p. 702-18. See also United States v. Downing, 753 F.2d 1224, 1242 (CA3 1985) ("An additional consideration under Rule 702 - and another aspect of relevancy - is whether expert testimony proffered in the [509 U.S. 579, 11] case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute"). The consideration has been aptly described by Judge Becker as one of "fit." Ibid. "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. See Starrs, Frye v. United States Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, 26 Jurimetrics J. 249, 258 (1986). The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night. Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

That these requirements are embodied in Rule 702 is not surprising. Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. See Rules 702 and 703. Presumably, this relaxation of the usual requirement of firsthand knowledge - a rule which represents "a `most pervasive manifestation' of the common law insistence upon `the most reliable sources of information,'" Advisory Committee's Notes on Fed.Rule Evid. 602, 28 U.S.C. App., p. 755 (citation omitted) - is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

 $\mathbf{C}$ 

Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to [509 U.S. 579, 12] Rule 104(a), 10 whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. 11 This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid, and of whether that reasoning or methodology properly can be applied to the facts in issue. We are confident that federal judges possess the capacity to undertake this review. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." Green, 645. See also C. Hempel, Philosophy of Natural Science 49 (1966) ("[T]he statements constituting a scientific explanation must be capable of empirical test"); K. Popper, Conjectures and Refutations: The Growth of Scientific Knowledge 37 (5th ed. [509 U.S. 579, 13] 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability").

Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. Publication (which is but one element of peer review) is not a sine qua non of admissibility; it does not necessarily correlate with reliability, see S. Jasanoff, The Fifth Branch: Science Advisors as Policymakers 61-76 (1990), and, in some instances, well-grounded but innovative theories will not have been published, see Horrobin, The Philosophical Basis of Peer Review and the Suppression of Innovation, 263 JAMA 1438 (1990). Some propositions, moreover, are too particular, too new, or of too limited interest to be

published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. See J. Ziman, Reliable Knowledge: An Exploration of the Grounds for Belief in Science 130-133 (1978); Relman & Angell, How Good Is Peer Review?, 321 New Eng.J.Med. 827 (1989). The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, see, e.g., United States v. Smith, 869 F.2d 348, 353-354 (CA7 1989) (surveying studies of the error rate of spectrographic voice identification technique), and the existence and maintenance of standards controlling the technique's operation, see United States v. Williams, 583 F.2d 1194, 1198 (CA2 1978) (noting professional organization's standard governing spectrographic analysis), cert. denied, 439 U.S. 1117 (1979).

Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although [509 U.S. 579, 14] it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." United States v. Downing, 753 F.2d, at 1238. See also 3 Weinstein Berger 70203., pp. 702-41 to 702-42. Widespread acceptance can be an important factor in ruling particular evidence admissible, and "a known technique which has been able to attract only minimal support within the community," Downing, 753 F.2d, at 1238, may properly be viewed with skepticism.

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. 12 Its overarching subject is the scientific validity - and thus the evidentiary relevance and reliability - of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules. Rule 703 provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 706 allows the court at its discretion to procure the assistance of an expert of its own choosing. Finally, Rule 403 permits the exclusion of relevant evidence "if its probative value is substantially [509 U.S. 579, 15] outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. . . . " Judge Weinstein has explained: "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge, in weighing possible prejudice against probative force under Rule 403 of the present rules, exercises more control over experts than over lay witnesses." Weinstein, 138 F.R.D., at 632.

#### III

We conclude by briefly addressing what appear to be two underlying concerns of the parties and amici in this case. Respondent expresses apprehension that abandonment of "general acceptance" as the exclusive requirement for admission will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. 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. See Rock v. Arkansas, 483 U.S. 44, 61 (1987).

Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, Fed.Rule Civ.Proc. 50(a), and likewise to grant summary judgment, Fed.Rule Civ.Proc. 56. Cf., e.g., Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (CA6) (holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury), cert. denied, 506 U.S. 826 (1992); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (CA5 [509 U.S. 579, 16] 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), modified, 884 F.2d 166 (CA5 1989), cert. denied, 494 U.S. 1046 (1990); Green, 680-681. These conventional devices, 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.

Petitioners and, to a greater extent, their amici exhibit a different concern. They suggest that recognition of a screening role for the judge that allows for the exclusion of "invalid" evidence will sanction a stifling and repressive scientific orthodoxy, and will be inimical to the search for truth. See, e.g., Brief for Ronald Bayer et al. as Amici Curiae. It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment - often of great consequence - about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding, [509 U.S. 579, 17] but for the particularized resolution of legal disputes. 13

#### IV

To summarize: "General acceptance" is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the Rules of Evidence - especially Rule 702 - do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands.

The inquiries of the District Court and the Court of Appeals focused almost exclusively on "general acceptance," as gauged by publication and the decisions of other courts. Accordingly, the judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

#### **Footnotes**

[ Footnote 1 ] Doctor Lamm received his master's and doctor of medicine degrees from the University of Southern California. He has served as a consultant in birth-defect epidemiology for the National Center for Health Statistics, and has published numerous articles on the magnitude of risk from exposure to various

chemical and biological substances. App. 34-44.

[Footnote 2] For example, Shanna Helen Swan, who received a master's degree in biostistics from Columbia University and a doctorate in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects, and has served as a consultant to the World Health Organization, the Food and Drug Administration, and the National Institutes of Health. Id., at degree 113-114, 131-132. Stuart A. Newman, who received his bachelor's in chemistry from Columbia University and his master's and doctorate in chemistry from the University of Chicago, respectively, is a professor at New York Medical College, and has spent over a decade studying the effect of chemicals on limb development. Id., at 54-56. The credentials of the others are similarly impressive. See id., at 61-66, 73-80, 148-153, 187-192, and Attachments 12, 20, 21, 26, 31, and 32 to Petitioners' Opposition to Summary Judgment, in No. 84-20, 3-G(I) (SD Cal.).

[ Footnote 3 ] For a catalog of the many cases on either side of this controversy, see P. Giannelli & E. Imwinkelried, Scientific Evidence 1-5, pp. 10-14 (1986 and Supp. 1991).

[ Footnote 4 ] See, e.g., Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Nw.U.L.Rev. 643 (1992) (hereinafter Green); Becker & Orenstein, The Federal Rules of Evidence After Sixteen Years - the Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory [509 U.S. 579, 6] Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules, 60 Geo. WashLRev. 857, 876-885 (1992); Hanson, James Alphonzo Frye is Sixty-Five Years Old; Should He Retire?, 16 West St.U.L.Rev. 357 (1989); Black, A Unified Theory of Scientific Evidence, 56 Ford.L.Rev. 595 (1988), Imwinkelried, The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony, 67 N.C.L.Rev. 1 (1988); Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J. 235 (1986); Giannelli, The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later, 80 Colum.L.Rev. 1197 (1980); The Supreme Court, 1986 Term, 101 Harv.L.Rev. 7, 119, 125-127 (1987).

Indeed, the debates over Frye are such a well-established part of the academic landscape that a distinct term - "Frye ologist" - has been advanced to describe those who take part. See Behringer, Introduction, Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J., 237, 239 (1986), quoting Lacey, Scientific Evidence, 24 Jurimetrics J. 254, 264 (1984).

[ Footnote 5 ] Like the question of Frye's merit, the dispute over its survival has divided courts and commentators. Compare, e.g., United States v. (Frye is superseded by the Rules of Evidence, Williams, 583 F.2d 1194 (CA2 1978) cert. denied, 439 U.S. 1117 (1979) with Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1111, 1115-1116 (CA5 1991) (en banc) (Frye and the Rules coexist), cert. denied, 503 U.S. 912 (1992), 3 J. Weinstein & M. Berger, Weinstein's Evidence 70203., pp. 702-36 to 702-37 (1988) (hereinafter Weinstein & Berger) (Frye is dead), and M. Graham, Handbook of Federal Evidence 703.2 (3d ed. 1991) (Frye lives). See generally P. Giannelli & E. Imwinkelried, Scientific Evidence 1-5, n. 28-29 (citing authorities).

[ Footnote 6 ] Because we hold that Frye has been superseded and base the discussion that follows on the content of the congressionally enacted Federal Rules of Evidence, we do not address petitioners' argument that application of the Frye rule in this diversity case, as the application of a judge-made rule affecting substantive rights, would violate the doctrine of Erie R. Co. v. Tompkins, 304 U.S. 64 (1938).

[ Footnote 7 ] THE CHIEF JUSTICE "do[es] not doubt that Rule 702 confides to the judge some gatekeeping

responsibility," post, at 4, but would neither say how it does so nor explain what that role entails. We believe the better course is to note the nature and source of the duty.

[ Footnote 8 ] Rule 702 also applies to "technical, or other specialized knowledge." Our discussion is limited to the scientific context because that is the nature of the expertise offered here.

[ Footnote 9 ] We note 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?). See Black, 56 Ford.L.Rev. at, 599. Although "the difference between accuracy, validity, and reliability may be such that each is distinct from the other by no more than a hen's kick," Starrs, Frye v. United States Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, 26 Jurimetrics J. 249, 256 (1986), our reference here is to evidentiary reliability - that is, trustworthiness. Cf., e.g., Advisory Committee's Notes on Fed.Rule Evid. 602, 28 U.S.C. App., p. 755. ("`[T]he rule requiring that a witness who testifies to a fact which can be perceived by the senses must have had an opportunity to observe, and must have actually observed the fact' is a `most pervasive manifestation' of the common law insistence upon `the most reliable sources of information.'" (citation omitted)); Advisory Committee's Notes on Art. VIII of Rules of Evidence, 29 U.S.C. App., p. 770 (hearsay exceptions will be recognized only "under circumstances supposed to furnish guarantees of trustworthiness"). [In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.]

## [ Footnote 10 ] Rule 104(a) provides:

"Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. In making its determination, it is not bound by the rules of evidence except those with respect to privileges." These matters should be established by a preponderance of proof. See Bourjaily v. United States, <u>483 U.S. 171, 175</u>-176 (1987).

[ Footnote 11 ] Although the Frye decision itself focused exclusively on "novel" scientific techniques, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended. Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Federal Rule Evidence 201.

[ Footnote 12 ] A number of authorities have presented variations on the reliability approach, each with its own slightly different set of factors. See, e.g., Downing, 753 F.2d, at 1238-1239 (on which our discussion draws in part); 3 Weinstein & Berger 70203., pp. 7021 to 7022 (on which the Downing court in turn partially relied); McCormick, Scientific Evidence: Defining a New Approach to Admissibility, 67 Iowa L.Rev. 879, 911-912 (1982); and Symposium on Science and the Rules of Evidence, 99 F.R.D. 187, 231 (1983) (statement by Margaret Berger). To the extent that they focus on the reliability of evidence as ensured by the scientific validity of its underlying principles, all these versions may well have merit, although we express no opinion regarding any of their particular details.

[ Footnote 13 ] This is not to say that judicial interpretation, as opposed to adjudicative factfinding, does not share basic characteristics of the scientific endeavor: "The work of a judge is in one sense enduring, and in another, ephemeral. . . . In the endless process of testing and retesting, there is a constant rejection of the dross and a constant retention of whatever is pure and sound and fine." B. Cardozo, The Nature of the

Judicial Process 178-179 (1921).

CHIEF JUSTICE REHNQUIST, with whom JUSTICE STEVENS joins, concurring in part and dissenting in part.

The petition for certiorari in this case presents two questions: first, whether the rule of Frye v. United States, 54 App. D.C. 46, 293 F. 1013 (1923), remains good law after the enactment of the Federal Rules of Evidence; and second, if Frye remains valid, whether it requires expert scientific testimony to have been subjected to a peer review process in order to be admissible. The Court concludes, correctly in my view, that the Frye rule did not survive the enactment of the Federal Rules of Evidence, and I therefore join Parts I and II-A of its opinion. The second question presented in the petition for certiorari necessarily is mooted by this holding, but the Court nonetheless proceeds to construe Rules 702 and 703 very much in the abstract, and then offers some "general observations." Ante, at 12.

"General observations" by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations - they are not applied to deciding whether particular testimony was or was not admissible, and therefore they tend to be not only general, but vague and abstract. This is particularly unfortunate in a case such as this, where [509 U.S. 579, 2] the ultimate legal question depends on an appreciation of one or more bodies of knowledge not judicially noticeable, and subject to different interpretations in the briefs of the parties and their amici. Twenty-two amicus briefs have been filed in the case, and indeed the Court's opinion contains no fewer than 37 citations to amicus briefs and other secondary sources.

The various briefs filed in this case are markedly different from typical briefs, in that large parts of them do not deal with decided cases or statutory language - the sort of material we customarily interpret. Instead, they deal with definitions of scientific knowledge, scientific method, scientific validity, and peer review - in short, matters far afield from the expertise of judges. This is not to say that such materials are not useful or even necessary in deciding how Rule 702 should be applied; but it is to say that the unusual subject matter should cause us to proceed with great caution in deciding more than we have to, because our reach can so easily exceed our grasp.

But even if it were desirable to make "general observations" not necessary to decide the questions presented, I cannot subscribe to some of the observations made by the Court. In Part II-B, the Court concludes that reliability and relevancy are the touchstones of the admissibility of expert testimony. Ante, at 10-11. Federal Rule of Evidence 402 provides, as the Court points out, that "[e]vidence which is not relevant is not admissible." But there is no similar reference in the Rule to "reliability." The Court constructs its argument by parsing the language "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, . . . an expert . . . may testify thereto. . . ." Fed. Rule Evid. 702. It stresses that the subject of the expert's testimony must be "scientific . . . knowledge," and points out that "scientific" "implies a grounding in the methods and procedures of science" and that the word "knowledge" [509 U.S. 579, 3] "connotes more than subjective belief or unsupported speculation." Ante, at 9. From this it concludes that "scientific knowledge" must be "derived by the scientific method." Ante, at 10. Proposed testimony, we are told, must be supported by "appropriate validation." Ante, at 10. Indeed, in footnote 9, the Court decides that "[i]n a case involving scientific evidence, evidentiary reliability will be based upon scientific validity." Ante, at 10, n. 9 (emphasis in original).

Questions arise simply from reading this part of the Court's opinion, and countless more questions will surely arise when hundreds of district judges try to apply its teaching to particular offers of expert testimony. Does

all of this dicta apply to an expert seeking to testify on the basis of "technical or other specialized knowledge" - the other types of expert knowledge to which Rule 702 applies - or are the "general observations" limited only to "scientific knowledge"? What is the difference between scientific knowledge and technical knowledge; does Rule 702 actually contemplate that the phrase "scientific, technical, or other specialized knowledge" be broken down into numerous subspecies of expertise, or did its authors simply pick general descriptive language covering the sort of expert testimony which courts have customarily received? The Court speaks of its confidence that federal judges can make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid, and of whether that reasoning or methodology properly can be applied to the facts in issue." Ante, at 12. The Court then states that a "key question" to be answered in deciding whether something is "scientific knowledge" "will be whether it can be (and has been) tested." Ante, at 12. Following this sentence are three quotations from treatises, which not only speak of empirical testing, but one of which states that the "`criterion of the scientific status of a theory is its falsifiability, or refutability, or testability!" Ante at 12-13. [509 U.S. 579, 4]

I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its "falsifiability," and I suspect some of them will be, too.

I [do not doubt that Rule 702 confides to the judge some gatekeeping responsibility] in deciding questions of the admissibility of proffered expert testimony. But I do not think it imposes on them either the obligation or the authority to become amateur scientists in order to perform that role. I think the Court would be far better advised in this case to decide only the questions presented, and to leave the further development of this important area of the law to future cases. [509 U.S. 579, 1]

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