DAUBERT, v. MERRELL DOW PHARMACEUTICALS, INC.

509 U.S. 579, 113 S.Ct. 2786) (1992)

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 chemical substances. [FN1] 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.

> FN1. 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.

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. [FN2] 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 structure of the drug and that of other substances known to cause birth defects; and the "reanalysis" of previously ****2792** published epidemiological (human statistical) studies.

> FN2. For example, Shanna Helen Swan, who received a master's degree in biostatistics 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 113-114, 131-132. Stuart A. Newman, who received his bachelor's degree in chemistry from Columbia University and his master's and doctorate in chemistry from the University of Chicago, 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. 84-2013-G(I) (SD Cal.).

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).

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, 113 S.Ct. 320, 121 L.Ed.2d 240 (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, 108 S.Ct. 71, 98 L.Ed.2d 35 (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 attack of late, the rule continues to be followed by a ****2793** majority of courts, including the Ninth Circuit. [FN3]

> FN3. 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).

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.*

[1] The merits of the *Frye* test have been much debated, and scholarship on its proper scope and application is legion. [FN4] 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. [FN5] We agree.

> FN4. 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 Committee on the Rules of Evidence, and

Suggestions for Selective Revision of the Rules, 60 Geo.Wash.L.Rev. 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).

FN5. Like the question of *Frye'* s merit, the dispute over its survival has divided courts and commentators. Compare, *e.g., United States v. Williams,* 583 F.2d 1194 (CA2 1978) (*Frye* is superseded by the Rules of Evidence), cert. denied, 439 U.S. 1117, 99 S.Ct. 1025, 59 L.Ed.2d 77 (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, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992), 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[03], 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, at 28-29 (citing authorities).

[2][3] We interpret the legislatively enacted Federal Rules of Evidence as we would any statute. *Beech Aircraft Corp. v. Rainey,* 488 U.S. 153, 163, 109 S.Ct. 439, 446, 102 L.Ed.2d 445 (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, ****2794** by these rules, or by other rules 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,* 469 U.S. 45, 105 S.Ct. 465, 83 L.Ed.2d 450 (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, 105 S.Ct., at 467, 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, 105 S.Ct., at 469.

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, 105 S.Ct., at 468-469. In *Bourjaily v. United States,* 483 U.S. 171, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987), on the other hand, the Court was unable to find a particular common-law doctrine in the Rules, and so held it superseded.

[4] 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, 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, 109 S.Ct., at 450 (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. [FN6]

> FN6. 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, 58 S.Ct. 817, 82 L.Ed. 1188 (1938).

B

[5][6] That the *Frye* test was displaced by the Rules of Evidence does not mean, ****2795** however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence. [FN7] 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.

> FN7. THE CHIEF JUSTICE "do[es] not doubt that Rule 702 confides to the judge some gatekeeping responsibility," *post,* at 2800, 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.

[7][8][9][10][11][12][13] 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." [FN8] 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 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. [FN9]

> FN8. 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.

> FN9. 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, 28 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*.

[14][15][16] 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, non-helpful." 3 Weinstein & Berger ¶ 702[02], p. 702-18. See also *United States v. Downing,* 753 F.2d 1224, 1242 (CA3 1985) ("An additional consideration ****2796** under Rule 702--and another aspect of relevancy--is whether expert testimony proffered in the 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.

[17][18] 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.

[19][20][21][22][23] Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), [FN10] 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. [FN11] This entails a preliminary assessment of whether the reasoning or methodology ***593** 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.

FN10. 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,* 483 U.S. 171, 175-176, 107 S.Ct. 2775, 2778-2779, 97 L.Ed.2d 144 (1987).

FN11. 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 of Evidence 201.

[24] 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)

****2797** ("[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. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability") (emphasis deleted).

[25][26][27] 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.

[28] 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, 99 S.Ct. 1025, 59 L.Ed.2d 77 (1979).

[29][30] Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although 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 ¶ 702[03], 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.

[31][32][33] The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. [FN12] Its overarching subject is the scientific validity ***595** 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.

> FN12. 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 ¶ 702[03], pp. 702-41 to 702-42 (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.

[34] 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****2798** 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 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

[35] 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. ***596** 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, 107 S.Ct. 2704, 2714, 97 L.Ed.2d 37 (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, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.,* 874 F.2d 307 (CA5 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, 110 S.Ct. 1511, 108 L.Ed.2d 646 (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.

[36] 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 ****2799** insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes. [FN13]

> FN13. 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).

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, ***598** 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.

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 2796.

"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 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 703 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 ****2800** 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 2794-95. 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" "connotes more than subjective belief or unsupported speculation." *Ante,* at 2794-95. From this it concludes that "scientific knowledge" must be "derived by the scientific method." *Ante,* at 2795. Proposed testimony, we are told, must be supported by "appropriate validation." *Ante,* at 2795. Indeed, in footnote 9, the Court decides that "[i]n a case involving scientific evidence, *evidentiary* ***600*** *reliability* will be based upon *scientific validity.*" *Ante,* at 2795, n. 9 (emphasis inoriginal).

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 2796. 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 2796. 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 2796-97.

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.

Supreme Court of the United States
KUMHO TIRE COMPANY, LTD., v.
CARMICHAEL
526 U.S. 137, 119 S.Ct. 1167) (1999).

Justice BREYER delivered the opinion of the Court.

In ***Daubert*** *v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), this Court focused upon the admissibility of scientific expert testimony. It pointed out that such testimony is admissible only if it is both relevant and reliable. And it held that the Federal Rules of Evidence "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." *Id.,* at 597, 113 S.Ct. 2786. The Court also discussed certain more specific factors, such as testing, peer review, error rates, and "acceptability" in the relevant scientific community, some or all of which might prove helpful in determining the reliability of a particular scientific "theory or technique." *Id.,* at 593-594, 113 S.Ct. 2786.

This case requires us to decide how ***Daubert*** applies to the testimony of engineers and other experts who are not scientists. We conclude that ***Daubert's*** general holding--setting forth the trial judge's general "gatekeeping" obligation--applies not only to testimony based on "scientific" knowledge, but also to testimony based on "technical" and "other specialized" knowledge. See Fed. Rule Evid. 702. We also conclude that a trial court *may* consider one or more of the more specific factors that ***Daubert*** mentioned when doing so will help determine that testimony's reliability. But, as the Court stated in ***Daubert,*** the test of reliability is "flexible," and ***Daubert's*** list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination. See *General Electric Co. v. Joiner,* 522 U.S. 136, 143, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (courts of appeals are to apply "abuse of discretion" standard when reviewing district court's reliability determination). Applying these standards, we determine that the District Court's decision in this case--not to admit certain expert testimony--was within its discretion and therefore lawful.
I
On July 6, 1993, the right rear tire of a minivan driven by Patrick Carmichael blew out. In the accident that followed, one of the passengers died, and others were severely injured. In October 1993, the Carmichaels brought this diversity suit against the tire's maker and its distributor, whom we refer to collectively as **Kumho** Tire, claiming that the tire was defective. The plaintiffs rested their case in significant part upon deposition testimony provided by an expert in tire failure analysis, Dennis Carlson, Jr., who intended to testify in support of their conclusion.

Carlson's depositions relied upon certain features of tire technology that are not in dispute. A steel-belted radial tire like the Carmichaels' is made up of a "carcass" containing many layers of flexible cords, called "plies," along which (between the cords and the outer tread) are laid steel strips called "belts." Steel wire loops, called "beads," hold the cords together at the plies' bottom edges. An outer layer, called the "tread," encases the carcass, and the entire tire is bound together in rubber, through the application of heat and various chemicals. See generally, *e.g.,* J. Dixon, Tires, Suspension and Handling 68-72 (2d ed.1996). The bead of the tire sits upon a "bead seat," which is part of the wheel assembly. That assembly contains a "rim flange," which extends over the bead and rests against the side of the tire. See M. Mavrigian, Performance Wheels & Tires 81, 83 (1998) (illustrations).

TABULAR OR GRAPHIC MATERIAL SET AT THIS POINT IS NOT DISPLAYABLE

****1172** Carlson's testimony also accepted certain background facts about the tire in question. He assumed that before the blowout the tire had traveled far. (The tire was made in 1988 and had been installed some time before the Carmichaels bought the used minivan in March 1993; the Carmichaels had driven the van approximately 7,000 additional miles in the two months they had owned it.) Carlson noted that the tire's tread depth, which was 11/32 of an inch when new, App. 242, had been worn down to depths that ranged from 3/32 of an inch along some parts of the tire, to nothing at all along others. *Id.,* at 287. He conceded that the tire tread had at least two punctures which had been inadequately repaired. *Id.,* at 258-261, 322.

Despite the tire's age and history, Carlson concluded that a defect in its manufacture or design caused the blowout. He rested this conclusion in part upon three premises which, for present purposes, we must assume are not in dispute: First, a tire's carcass should stay bound to the inner side of the tread for a significant period of time after its tread depth has worn away. *Id.,* at

208-209. Second, the tread of the tire at issue had separated from its inner steel-belted carcass prior to the accident. *Id.,* at 336. Third, this "separation" caused the blowout. *Ibid.*

Carlson's conclusion that a defect caused the separation, however, rested upon certain other propositions, several of which the defendants strongly dispute. First, Carlson said that if a separation is *not* caused by a certain kind of tire misuse called "overdeflection" (which consists of underinflating the tire or causing it to carry too much weight, thereby generating heat that can undo the chemical tread/carcass bond), then, ordinarily, its cause is a tire defect. *Id.,* at 193-195, 277-278. Second, he said that if a tire has been subject to sufficient overdeflection to cause a separation, it should reveal certain physical symptoms. These symptoms include (a) tread wear on the tire's shoulder that is greater than the tread wear along the tire's center, *id.,* at 211; (b) signs of a "bead groove," where the beads have been pushed too hard against the bead seat on the inside of the tire's rim, *id.,* at 196- 197; (c) sidewalls of the tire with physical signs of deterioration, such as discoloration, *id.,* at 212; and/or (d) marks on the tire's rim flange, *id.,* at 219-220. Third, Carlson said that where he does not find *at least two* of the four physical signs just mentioned (and presumably where there is no reason to suspect a less common cause of separation), he concludes that a manufacturing or design defect caused the separation. *Id.,* at 223-224.

Carlson added that he had inspected the tire in question. He conceded that the tire to a limited degree showed greater wear on ****1173** the shoulder than in the center, some signs of "bead groove," some discoloration, a few marks on the rim flange, and inadequately filled puncture holes (which can also cause heat that might lead to separation). *Id.,* at 256-257, 258- ***145** 261, 277, 303-304, 308. But, in each instance, he testified that the symptoms were not significant, and he explained why he believed that they did not reveal overdeflection. For example, the extra shoulder wear, he said, appeared primarily on one shoulder, whereas an overdeflected tire would reveal equally abnormal wear on both shoulders. *Id.,* at 277. Carlson concluded that the tire did not bear at least two of the four overdeflection symptoms, nor was there any less obvious cause of separation; and since neither overdeflection nor the punctures caused the blowout, a defect must have done so.

Kumho **Tire** moved the District Court to exclude Carlson's testimony on the ground that his methodology failed Rule 702's reliability requirement. The court agreed with Kumho **that** it should act as a *Daubert*-**type** reliability "gatekeeper," even though one might consider Carlson's testimony as "technical," rather than "scientific." See *Carmichael v. Samyang Tires, Inc.,* 923 F.Supp. 1514, 1521-1522 (S.D.Ala.1996). The court then examined Carlson's methodology in light of the reliability-related factors that *Daubert* **mentioned**, such as a theory's testability, whether it "has been a subject of peer review or publication," the "known or potential rate of error," and the "degree of acceptance ... within the relevant scientific community." 923 F.Supp., at 1520 (citing *Daubert,* **509** U.S., at 589-595, 113 S.Ct. 2786). The District Court found that all those factors argued against the reliability of Carlson's methods, and it granted the motion to exclude the testimony (as well as the defendants' accompanying motion for summary judgment).

The plaintiffs, arguing that the court's application of the *Daubert* **factors** was too "inflexible," asked for reconsideration. And the court granted that motion. *Carmichael v. Samyang Tires, Inc.,* Civ. Action No. 93-0860-CB-S (S.D.Ala., June 5, 1996), App. to Pet. for Cert. 1c. After reconsidering the matter, the court agreed with the plaintiffs that *Daubert* **should** be applied flexibly, that its four factors were simply illustrative, and that other factors could argue in favor of admissibility. It conceded that there may be widespread acceptance of a "visual-inspection method" for some relevant purposes. But the court found insufficient indications of the reliability of

> "the component of Carlson's tire failure analysis which most concerned the Court, namely, the methodology employed by the expert in analyzing the data obtained in the visual inspection, and the scientific basis, if any, for such an analysis." *Id.,* at 6c.

It consequently affirmed its earlier order declaring Carlson's testimony inadmissible and granting the defendants' motion for summary judgment.

The Eleventh Circuit reversed. See *Carmichael v. Samyang Tire, Inc.,* 131 F.3d 1433 (1997). It "review[ed] ... *de novo* " the "district court's legal decision to apply *Daubert.*" *Id.,* at 1435. It noted that "the Supreme Court in *Daubert* **explicitly** limited its holding to cover only the 'scientific context,' " adding that "a *Daubert* **analysis**" applies only where an expert relies "on the application of scientific principles," rather than "on skill- or experience-based observation." *Id.,* at 1435-1436. It concluded that Carlson's testimony, which it viewed as relying on experience, "falls outside the scope of *Daubert,*" **that** "the district court erred as a matter of law by applying *Daubert* **in** this case," and that the case must be remanded for further (non-*Daubert*-

type) consideration under Rule 702. 131 F.3d, at 1436.

Kumho **Tire** petitioned for certiorari, asking us to determine whether a trial court "may" consider *Daubert's* **specific** "factors" when determining the "admissibility of an engineering expert's testimony." Pet. for Cert. i. We granted certiorari in light of uncertainty among the lower courts about whether, or how, *Daubert* **applies** to expert testimony that might be characterized as based not upon "scientific" knowledge, but rather upon "technical" or "other specialized" ***147** knowledge. Fed. Rule Evid. 702; compare, *e.g., Watkins v. Telsmith, Inc.,* 121 F.3d 984, 990-991 (C.A.5 1997), with, *e.g., Compton v. Subaru of America, Inc.,* 82 F.3d ****1174** 1513, 1518-1519 (C.A.10), cert. denied, 519 U.S. 1042, 117 S.Ct. 611, 136 L.Ed.2d 536 (1996).

II

A

[1] In *Daubert,* **this** Court held that Federal Rule of Evidence 702 imposes a special obligation upon a trial judge to "ensure that any and all scientific testimony ... is not only relevant, but reliable." 509 U.S., at 589, 113 S.Ct. 2786. The initial question before us is whether this basic gatekeeping obligation applies only to "scientific" testimony or to all expert testimony. We, like the parties, believe that it applies to all expert testimony. See Brief for Petitioners 19; Brief for Respondents 17.

For one thing, Rule 702 itself says:

> "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."

This language makes no relevant distinction between "scientific" knowledge and "technical" or "other specialized" knowledge. It makes clear that any such knowledge might become the subject of expert testimony. In *Daubert,* **the** Court specified that it is the Rule's word "knowledge," not the words (like "scientific") that modify that word, that "establishes a standard of evidentiary reliability." 509 U.S., at 589-590, 113 S.Ct. 2786. Hence, as a matter of language, the Rule applies its reliability standard to all "scientific," "technical," or "other specialized" matters within its scope. We concede that the Court in *Daubert* **referred** only to "scientific" knowledge. But as the Court there said, it referred to "scientific" ***148** testimony "because that [wa]s the nature of the expertise" at issue. *Id.,* at 590, n. 8, 113 S.Ct. 2786.

Neither is the evidentiary rationale that underlay the Court's basic *Daubert* "**gatekeeping**" determination limited to "scientific" knowledge. *Daubert* **pointed** out that Federal Rules 702 and 703 grant expert witnesses testimonial latitude unavailable to other witnesses on the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." *Id.,* at 592, 113 S.Ct. 2786 (pointing out that experts may testify to opinions, including those that are not based on firsthand knowledge or observation). The Rules grant that latitude to all experts, not just to "scientific" ones.

Finally, it would prove difficult, if not impossible, for judges to administer evidentiary rules under which a gatekeeping obligation depended upon a distinction between "scientific" knowledge and "technical" or "other specialized" knowledge. There is no clear line that divides the one from the others. Disciplines such as engineering rest upon scientific knowledge. Pure scientific theory itself may depend for its development upon observation and properly engineered machinery. And conceptual efforts to distinguish the two are unlikely to produce clear legal lines capable of application in particular cases. Cf. Brief for National Academy of Engineering as *Amicus Curiae* 9 (scientist seeks to understand nature while the engineer seeks nature's modification); Brief for Rubber Manufacturers Association as *Amicus Curiae* 14- 16 (engineering, as an " 'applied science,' " relies on "scientific reasoning and methodology"); Brief for John Allen et al. as *Amici Curiae* 6 (engineering relies upon "scientific knowledge and methods").

Neither is there a convincing need to make such distinctions. Experts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called "general truths derived from ... specialized experience." Hand, Historical and Practical Considerations Regarding Expert Testimony, ***149** 15 Harv. L.Rev. 40, 54 (1901). And whether the specific expert testimony focuses upon specialized observations, the specialized translation of those observations into theory, a specialized theory itself, or the application of such a theory in a particular case, the expert's testimony often will rest "upon an experience confessedly foreign in kind to [the jury's] own." *Ibid.* The trial judge's effort to assure that the specialized testimony is reliable and relevant can help the jury evaluate ****1175** that foreign experience, whether the testimony reflects scientific, technical, or other specialized knowledge.

We conclude that *Daubert*'**s** general principles apply to the expert matters described in Rule 702. The Rule, in respect to all such matters, "establishes a standard of

evidentiary reliability." 509 U.S., at 590, 113 S.Ct. 2786. It "requires a valid ... connection to the pertinent inquiry as a precondition to admissibility." *Id.,* at 592, 113 S.Ct. 2786. And where such testimony's factual basis, data, principles, methods, or their application are called sufficiently into question, see Part III, *infra,* the trial judge must determine whether the testimony has "a reliable basis in the knowledge and experience of [the relevant] discipline." 509 U.S., at 592, 113 S.Ct. 2786.

B

Petitioners ask more specifically whether a trial judge determining the "admissibility of an engineering expert's testimony" *may* consider several more specific factors that *Daubert* **said** might "bear on" a judge's gatekeeping determination. Brief for Petitioners i. These factors include:

--Whether a "theory or technique ... can be (and has been) tested";

--Whether it "has been subjected to peer review and publication";

--Whether, in respect to a particular technique, there is a high "known or potential rate of error" and whether there are "standards controlling the technique's operation"; and

--Whether the theory or technique enjoys " 'general acceptance' " within a " 'relevant scientific community.' " 509 U.S., at 592-594, 113 S.Ct. 2786.

Emphasizing the word "may" in the question, we answer that question yes.

[2] Engineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases. See, *e.g.,* Brief for Stephen N. Bobo et al. as *Amici Curiae* 23 (stressing the scientific bases of engineering disciplines). In other cases, the relevant reliability concerns may focus upon personal knowledge or experience. As the Solicitor General points out, there are many different kinds of experts, and many different kinds of expertise. See Brief for United States as *Amicus Curiae* 18-19, and n. 5 (citing cases involving experts in drug terms, handwriting analysis, criminal *modus operandi,* land valuation, agricultural practices, railroad procedures, attorney's fee valuation, and others). Our emphasis on the word "may" thus reflects *Daubert's* **description** of the Rule 702 inquiry as "a flexible one." 509 U.S., at 594, 113 S.Ct. 2786. *Daubert* **makes** clear that the factors it mentions do *not* constitute a "definitive checklist or test." *Id.,* at 593, 113 S.Ct. 2786. And *Daubert* **adds** that the gatekeeping inquiry must be " 'tied to the facts' " of a particular "case." *Id.,* at 591, 113 S.Ct. 2786 (quoting *United States v. Downing,* 753 F.2d 1224, 1242 (C.A.3 1985)). We agree with the Solicitor General that "[t]he factors identified in *Daubert* **may** or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Brief for United States as *Amicus Curiae* 19. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert,* **nor** can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.

Daubert **itself** is not to the contrary. It made clear that its list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged. It might not be surprising in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist. Nor, on the other hand, does the presence of *Daubert's* **general** acceptance factor help show that an expert's testimony is reliable where the discipline itself lacks reliability, as, for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy.

****1176** At the same time, and contrary to the Court of Appeals' view, some of *Daubert's* **questions** can help to evaluate the reliability even of experience-based testimony. In certain cases, it will be appropriate for the trial judge to ask, for example, how often an engineering expert's experience-based methodology has produced erroneous results, or whether such a method is generally accepted in the relevant engineering community. Likewise, it will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.

We must therefore disagree with the Eleventh Circuit's holding that a trial judge may ask questions of the sort *Daubert* **mentioned** only where an expert "relies on the application of scientific principles," but not where an expert relies "on skill- or experience-based observation." 131 F.3d, at 1435. We do not believe that Rule 702 creates a schematism that segregates expertise by type while mapping certain kinds of questions to certain kinds of experts. Life and the legal cases that it generates are too complex to warrant so definitive a match.

[3][4] To say this is not to deny the importance of *Daubert's* **gatekeeping** requirement. The objective of

that requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. Nor do we deny that, as stated in *Daubert,* **the** particular questions that it mentioned will often be appropriate for use in determining the reliability of challenged expert testimony. Rather, we conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. That is to say, a trial court should consider the specific factors identified in *Daubert* **where** they are reasonable measures of the reliability of expert testimony.

[5][6] The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable. Our opinion in *Joiner* makes clear that a court of appeals is to apply an abuse-of-discretion standard when it "review[s] a trial court's decision to admit or exclude expert testimony." 522 U.S., at 138-139, 118 S.Ct. 512. That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion. Otherwise, the trial judge would lack the discretionary authority needed both to avoid unnecessary "reliability" proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises. Indeed, the Rules seek to avoid "unjustifiable expense and delay" as part of their search for "truth" and the "jus[t] determin[ation]" of proceedings. Fed. Rule Evid. 102. Thus, whether *Daubert's* **specific** factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine. See *Joiner, supra,* at 143, 118 S.Ct. 512. And the Eleventh Circuit erred insofar as it held to the contrary.

III

[7] We further explain the way in which a trial judge "may" consider *Daubert's* **factors** by applying these considerations to the case at hand, a matter that has been briefed exhaustively by the parties and their 19 *amici.* The District Court did not doubt Carlson's qualifications, which included a masters degree in mechanical engineering, 10 years' work at Michelin America, Inc., and testimony as a tire failure consultant in other tort cases. Rather, it excluded the testimony because, despite those qualifications, it initially ****1177** doubted, and then found unreliable, "the methodology employed by the expert in analyzing the data obtained in the visual inspection, and the scientific basis, if any, for such an analysis." Civ. Action No. 93-0860-CB-S (S.D.Ala., June 5, 1996), App. to Pet. for Cert. 6c. After examining the transcript in "some detail," 923 F.Supp., at 1518-1519, n. 4, and after considering respondents' defense of Carlson's methodology, the District Court determined that Carlson's testimony was not reliable. It fell outside the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is "shaky." *Daubert,* **509** U.S., at 596, 113 S.Ct. 2786. In our view, the doubts that triggered the District Court's initial inquiry here were reasonable, as was the court's ultimate conclusion.

For one thing, and contrary to respondents' suggestion, the specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection to determine whether overdeflection had caused the tire's tread to separate from its steel-belted carcass. Rather, it was the reasonableness of using such an approach, along with Carlson's particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.* That matter concerned the likelihood that a defect in the tire at issue caused its tread to separate from its carcass. The tire in question, the expert conceded, had traveled far enough so that some of the tread had been worn bald; it should have been taken out of service; it had been repaired (inadequately) for punctures; and it bore some of the very marks that the expert said indicated, not a defect, but abuse through overdeflection. See *supra,* at 1172; App. 293-294. The relevant issue was whether the expert could reliably determine the cause of *this* tire's separation.

Nor was the basis for Carlson's conclusion simply the general theory that, in the absence of evidence of abuse, a defect will normally have caused a tire's separation. Rather, the expert employed a more specific theory to establish the existence (or absence) of such abuse. Carlson testified precisely that in the absence of *at least two* of four signs of abuse (proportionately greater tread wear on the shoulder; signs of grooves caused by the beads; discolored sidewalls; marks on the rim flange), he concludes that a defect caused the separation. And his analysis depended upon acceptance of a further implicit proposition, namely, that his visual and tactile inspection could determine that the tire before him had

not been abused despite some evidence of the presence of the very signs for which he looked (and two punctures).

For another thing, the transcripts of Carlson's depositions support both the trial court's initial uncertainty and its final conclusion. Those transcripts cast considerable doubt upon the reliability of both the explicit theory (about the need for two signs of abuse) and the implicit proposition (about the significance of visual inspection in this case). Among other things, the expert could not say whether the tire had traveled ***155** more than 10, or 20, or 30, or 40, or 50 thousand miles, adding that 6,000 miles was "about how far" he could "say with any certainty." *Id.,* at 265. The court could reasonably have wondered about the reliability of a method of visual and tactile inspection sufficiently precise to ascertain with some certainty the abuse-related significance of minute shoulder/center relative tread wear differences, but insufficiently precise to tell "with any certainty" from the tread wear whether a tire had traveled less than 10,000 or more than 50,000 miles. And these concerns might have been augmented by Carlson's repeated reliance on the "subjective[ness]" of his mode of analysis in response to questions seeking specific information regarding how he could differentiate between a tire that actually had been overdeflected and a tire that merely looked as though it had been. *Id.,* at 222, 224-225, 285-286. They would have been further augmented by the fact that Carlson said he had inspected the tire itself for the first time the morning of his first deposition, and then only for a few hours. (His initial conclusions were based on photographs.) *Id.,* at 180.

****1178** Moreover, prior to his first deposition, Carlson had issued a signed report in which he concluded that the tire had "not been ... overloaded or underinflated," not because of the absence of "two of four" signs of abuse, but simply because "the rim flange impressions ... were normal." *Id.,* at 335-336. That report also said that the "tread depth remaining was 3/32 inch," *id.,* at 336, though the opposing expert's (apparently undisputed) measurements indicate that the tread depth taken at various positions around the tire actually ranged from .5/32 of an inch to 4/32 of an inch, with the tire apparently showing greater wear along *both* shoulders than along the center, *id.,* at 432-433.

Further, in respect to one sign of abuse, bead grooving, the expert seemed to deny the sufficiency of his own simple visual-inspection methodology. He testified that most tires have some bead groove pattern, that where there is reason to suspect an abnormal bead groove he would ideally "look at a lot of [similar] tires" to know the grooving's significance, and that he had not looked at many tires similar to the one at issue. *Id.,* at 212-213, 214, 217.

Finally, the court, after looking for a defense of Carlson's methodology as applied in these circumstances, found no convincing defense. Rather, it found (1) that "none" of the *Daubert* **factors**, including that of "general acceptance" in the relevant expert community, indicated that Carlson's testimony was reliable, 923 F.Supp., at 1521; (2) that its own analysis "revealed no countervailing factors operating in favor of admissibility which could outweigh those identified in *Daubert,*" **App**. to Pet. for Cert. 4c; and (3) that the "parties identified no such factors in their briefs," *ibid.* For these three reasons *taken together,* it concluded that Carlson's testimony was unreliable.

Respondents now argue to us, as they did to the District Court, that a method of tire failure analysis that employs a visual/tactile inspection is a reliable method, and they point both to its use by other experts and to Carlson's long experience working for Michelin as sufficient indication that that is so. But no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience. Nor does anyone deny that, as a general matter, tire abuse may often be identified by qualified experts through visual or tactile inspection of the tire. See Affidavit of H.R. Baumgardner 1-2, cited in Brief for National Academy of Forensic Engineers as *Amicus Curiae* 16 (Tire engineers rely on visual examination and process of elimination to analyze experimental test tires). As we said before, *supra,* at 1977, the question before the trial court was specific, not general. The trial court had to decide whether this particular expert had sufficient specialized knowledge to assist the jurors "in deciding the particular issues in the case." 4 J. McLaughlin, Weinstein's Federal Evidence ¶ 702.05[1], p. 702-33 (2d ed.1998); see also Advisory Committee's Note on Proposed Fed. Rule Evid. 702, Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and Evidence: Request for Comment 126 (1998) (stressing that district courts must "scrutinize" whether the "principles and methods" employed by an expert "have been properly applied to the facts of the case").

The particular issue in this case concerned the use of Carlson's two-factor test and his related use of visual/tactile inspection to draw conclusions on the basis of what seemed small observational differences. We have found no indication in the record that other experts in the industry use Carlson's two-factor test or that tire

experts such as Carlson normally make the very fine distinctions about, say, the symmetry of comparatively greater shoulder tread wear that were necessary, on Carlson's own theory, to support his conclusions. Nor, despite the prevalence of tire testing, does anyone refer to any articles or papers that validate Carlson's approach. Cf. Bobo, Tire Flaws and Separations, in Mechanics of Pneumatic Tires 636-637 (S. Clark ed.1981); C. Schnuth, R. Fuller, G. Follen, G. Gold, & J. Smith, Compression Grooving and Rim Flange Abrasion as Indicators of Over-Deflected Operating Conditions in Tires, presented to Rubber Division of the American Chemical Society, Oct. 21-24, 1997; J. Walter & R. Kiminecz, Bead ****1179** Contact Pressure Measurements at the Tire-Rim Interface, presented to the Society of Automotive Engineers, Inc., Feb. 24-28, 1975. Indeed, no one has argued that Carlson himself, were he still working for Michelin, would have concluded in a report to his employer that a similar tire was similarly defective on grounds identical to those upon which he rested his conclusion here. Of course, Carlson himself claimed that his method was accurate, but, as we pointed out in *Joiner,* "nothing in either *Daubert* **or** the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S., at 146, 118 S.Ct. 512.

Respondents additionally argue that the District Court too rigidly applied *Daubert's* **criteria**. They read its opinion to hold that a failure to satisfy any one of those criteria automatically renders expert testimony inadmissible. The District Court's initial opinion might have been vulnerable to a form of this argument. There, the court, after rejecting respondents' claim that Carlson's testimony was "exempted from *Daubert*-**style** scrutiny" because it was "technical analysis" rather than "scientific evidence," simply added that "none of the four admissibility criteria outlined by the *Daubert* **court** are satisfied." 923 F.Supp., at 1521. Subsequently, however, the court granted respondents' motion for reconsideration. It then explicitly recognized that the relevant reliability inquiry "should be 'flexible,' " that its " 'overarching subject [should be] ... validity' and reliability," and that "*Daubert* **was** intended neither to be exhaustive nor to apply in every case." App. to Pet. for Cert. 4c (quoting *Daubert,* **509** U.S., at 594-595, 113 S.Ct. 2786). And the court ultimately based its decision upon Carlson's failure to satisfy either *Daubert's* **factors** *or any other* set of reasonable reliability criteria. In light of the record as developed by the parties, that conclusion was within the District Court's lawful discretion.

In sum, Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case. The District Court did not abuse its discretionary authority in this case. Hence, the judgment of the Court of Appeals is

Reversed.

Justice SCALIA, with whom Justice O'CONNOR and Justice THOMAS join, concurring.

I join the opinion of the Court, which makes clear that the discretion it endorses--trial-court discretion in choosing the manner of testing expert reliability--is not discretion to abandon the gatekeeping function. I think it worth adding that it is not discretion to perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky. Though, as the Court makes clear today, the *Daubert* **factors** are not holy writ, in a particular case the failure to apply one or another of them may be unreasonable, and hence an abuse of discretion.

Justice STEVENS, concurring in part and dissenting in part.

The only question that we granted certiorari to decide is whether a trial judge "[m]ay ... consider the four factors set out by this Court in *Daubert* ***v.*** *Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), in a Rule 702 analysis of admissibility of an engineering expert's testimony." Pet. for Cert. i. That question is fully and correctly answered in Parts I and II of the Court's opinion, which I join.

Part III answers the quite different question whether the trial judge abused his discretion when he excluded the testimony of Dennis Carlson. Because a proper answer to that question requires a study of the record that can be performed more efficiently by the Court of Appeals than by the nine Members of this Court, I would remand the case to the Eleventh Circuit to perform that task. There are, of course, exceptions to most rules, but I firmly believe that it is neither fair to litigants nor good practice for this Court to reach out to decide questions not raised by the certiorari petition. See *General Electric Co. v. Joiner,* 522 U.S. 136, 150-151, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) ****1180** (STEVENS, J., concurring in part and dissenting in part).

Accordingly, while I do not feel qualified to disagree with the well-reasoned factual analysis in Part III of the Court's opinion, I do not join that Part, and I respectfully

dissent from the Court's disposition of the case.

Berry v.CSX TRANSPORTATION, INC., 709 So.2d 552 (Fla. 1st DCA 1998)

VAN **NORTWICK**, Judge.

In these consolidated appeals, James Chrisco and Carol **Berry,** as personal representatives of the Estate of Roy Lee **Berry,** Jr., deceased, appeal from a final judgment and a partial final summary judgment, [FN1] respectively, which were entered after the trial court excluded the testimony of appellants' expert witnesses. In their actions brought pursuant to the Federal Employers' Liability Act, 45 U.S.C. § 51, *et seq.* (FELA), appellants allege that appellee, CSX Transportation, Inc., exposed **Berry** and Chrisco, railroad employees of CSX, to excessive levels of organic solvents causing them to suffer from toxic encephalopathy. [FN2] In both cases, asserting that the expert opinions were not generally accepted in the scientific community and relying upon ***Frye*** *v. United States,* 293 F. 1013 (D.C.Cir.1923), and its Florida progeny, CSX objected to the proposed expert testimony that long-term exposure to excessive levels of organic solvents can and did cause appellants' toxic encephalopathy. The record reflects that appellants' proposed expert testimony was grounded upon numerous peer-reviewed and published epidemiological studies demonstrating an association between exposure to organic solvents and toxic encephalopathy. [FN3] The trial court nevertheless found that the proposed expert opinions were not based on a "scientific principle or discovery" that has been sufficiently established to have gained general acceptance in the particular field to which it belongs. Accordingly, by separate orders, the trial court disqualified all of the appellants' experts.

> FN1. There remains pending below a suit on behalf of Roy Lee **Berry,** Jr., for injuries due to alleged exposure to excessive levels of asbestos.
>
> FN2. Toxic encephalopathy occurs when there has been an alteration to the brain and central nervous system function due to exposure to various toxins. *See generally* Neil L. Rosenberg, M.D., *Occupational and Environmental Neurology,* 116-17 (1995)(herein *Occupational and Environmental Neurology*). As explained in William N. Rom, M.D. (ed.) *Environmental and Occupational Medicine* at 849 (1992):
>
> The nonspecific effects of long-term exposure to solvents range from a general negative affective state to a subtle reduction in functional reserve capacity to perform well when fatigued or in a distracting environment, to mild slowing of psycho-motor performance, to memory disturbance, and finally to severe intellectual deficits. The most severe condition, which has been called psycho-organic syndrome, presenile dementia, and severe chronic toxic encephalopathy, is also the most controversial. Although the existence of chronic solvent encephalopathy has been questioned, experts now generally agree that it occurs but not on its prevalence.
>
> (Footnotes deleted).
>
> FN3. Some, but by no means all, of the studies relied upon by appellants' experts are set forth in "Appendix A."

This is the first time a Florida appellate court has been asked to decide the issue of what evidence must be ***Frye*** tested in the context of toxic tort litigation. We commend the trial court for its thorough and exhaustive review of the proposed expert testimony. We believe, however, that the trial court went beyond addressing the threshold question of admissibility of expert testimony under ***Frye,*** which was the issue before it, and in effect engaged in an analysis of the weight to be assigned to the expert testimony or the sufficiency of the evidence. As a result, even though appellants adequately demonstrated the reliability of their experts' proposed testimony, the trial court erroneously ruled that testimony inadmissible. Thus, we reverse the final judgment and partial final judgment ***555** and remand these actions for proceedings consistent with this opinion.

Procedural Background

Roy Lee **Berry,** Jr., deceased, worked as an electrician for CSX for over 20 years. James Chrisco worked as a machinist for CSX for over 10 years. Their suits

alleged exposure to unreasonably hazardous levels of organic solvents in their workplace at CSX. The four organic solvents at issue in this case are trichloroethane (TCA), trichloroethylene (TCE), perchloroethylene (PCE), and mineral spirits. The trial court conducted a lengthy evidentiary hearing in **Berry's** suit in connection with CSX's motion to disqualify the opinion testimony of **Berry's** treating physician, Michael Kelly, M.D. In support of Dr. Kelly's proposed testimony, **Berry** proffered the supporting testimony of several other expert witnesses. CSX also filed a similar motion in the Chrisco suit. Although the trial court entered separate orders disqualifying the expert testimony in each case, the court considered essentially the same evidence in both cases. Thus, for purposes of this appeal, the evidence and cases will be considered together.

*The **Frye** Reliability Standard*

The issue of the admissibility of expert testimony is governed by the Florida Evidence Code, section 90.702, Florida Statutes (1995). That section provides:

> Testimony by experts.--If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial.

Like its federal counterpart, Federal Rule of Evidence 702, section 90.702 is "silent as to any requirement that there be general acceptance of a newly developed scientific technique or principle in the particular field in which it belongs." *Hawthorne v. State,* 470 So.2d 770, 783 (Fla. 1st DCA 1985)(Ervin, J., concurring and dissenting). This "general acceptance" test applied to scientific evidence had been espoused decades earlier in the case of ***Frye** v. United States,* 293 F. 1013 (D.C.Cir.1923). The ***Frye*** court succinctly stated the test as follows:

> 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.

Id. at 1014.

After the adoption of the Florida Evidence Code, of which section 90.702 is part, disagreement arose among the district courts of appeal as to whether (i) the relevancy test under section 90.702 combined with the so-called balancing test of section 90.403 or (ii) the ***Frye*** test was to be applied to determine the admissibility of novel scientific evidence. *See Hawthorne,* 470 So.2d at 783-787 (Ervin, J., concurring and dissenting; *see also* Ehrhardt, *Florida Evidence,* § 702.3 at 526 & 528 n. 18 (1997)). This debate ended when the Florida Supreme Court decided *Stokes v. State,* 548 So.2d 188 (Fla.1989).

In *Stokes,* the Florida Supreme Court held that posthypnotic testimony may not be admitted unless it meets the ***Frye*** test. *Stokes,* 548 So.2d at 194- 95. "This test requires that the scientific principles undergirding this evidence be found by the trial court to be generally accepted by the relevant members of its particular field." *Hadden v. State,* 690 So.2d 573, 576 (Fla.1997). In reaching its conclusion in *Stokes,* the Court explained its rationale for continuing the application of the ***Frye*** test:

> The underlying theory for this rule [***Frye***] is that 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 ***556** the procedure must be considered less reliable for courtroom use.

Stokes, 548 So.2d at 193-94.

Later, in *Hadden,* the court further amplified the reasons supporting its allegiance to the ***Frye*** reliability test:

> [W]e firmly hold to the principle that it is the function of the court to not permit cases to be resolved on the basis of evidence for which a predicate of reliability has not been established. Reliability is fundamental to issues involved in the admissibility of evidence. It is this fundamental concept which similarly forms the rules dealing with the admissibility of hearsay evidence.... Novel scientific evidence must also be shown to be reliable on some basis other than simply that it is the opinion of the witness who seeks to offer the opinion.

Hadden, 690 So.2d at 578.

At the same time, a similar debate was ongoing in the federal courts concerning whether ***Frye*** or Federal Rule of Evidence 702 should govern the admissibility of scientific evidence. The United States Supreme Court answered this question in ***Daubert** v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). In what has become known as the "scientific validity" test, the ***Daubert*** court set forth four non-exclusive factors that courts should consider in

determining the admissibility of such evidence: "(1) testability (or falsifiability), (2) error rate, (3) peer review and publication and (4) general acceptance." David L. Faigman, David H. Kaye, Michael J. Saks & Joseph Sanders, *Modern Scientific Evidence: The Law and Science of Expert Testimony* § 1-3.3 (1997)(herein *Modern Scientific Evidence*). [FN4]

> FN4. In their recent treatise, Professors Faigman, Kaye, Saks and Sanders have explained the differences between ***Frye*** and ***Daubert*** thusly:
>
> In fact, if ***Daubert*** is a significant break from the past, the departure lies in the changed focus of the admissibility determination. ***Frye*** asks judges to decide the admissibility of scientific expert testimony by deferring to the opinions of scientists in the "pertinent field." Thus, under ***Frye,*** judges need not have any facility with scientific methods to make the admissibility decision. They must merely have some basis for knowing what scientists believe. Under ***Daubert,*** the trial court itself is initially responsible for determining the admissibility of scientific expert testimony by determining that the science supporting that opinion is valid.
>
> *Modern Scientific Evidence* at § 1-3.0. These authors have further characterized ***Frye*** as "easy to apply and requir[ing] little scientific sophistication on the part of judges." *Id.* at § 1-2.3. "Whereas ***Frye*** require[s] judges to survey the pertinent field to assess the validity of the proffered scientific evidence, ***Daubert*** calls upon judges to assess the merit of the scientific research supporting an expert's opinion." *Id.* at Preface p. viii.

As might be expected, the Florida Supreme Court was faced with the decision whether to continue following ***Frye*** or to adopt ***Daubert.*** In *Flanagan v. State,* 625 So.2d 827 (Fla.1993), the court noted the United States Supreme Court's decision in ***Daubert,*** but "reaffirmed the applicability of ***Frye.***" Ehrhardt, *Florida Evidence* § 702.4 (1997 Edition).

Flanagan was followed by the court's decision in *Ramirez v. State,* 651 So.2d 1164 (Fla.1995), wherein the court emphasized that

> the burden is on the proponent of the evidence to prove the general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts of the case at hand ... The general acceptance under the ***Frye*** test must be established by a preponderance of the evidence.

Id. at 1168. In *Ramirez,* the court delineated a four-step process for applying ***Frye*** in passing on the admissibility of expert opinion testimony concerning a new or novel scientific principle:

> First, the trial judge must determine whether such expert testimony will assist the jury in understanding the evidence or in determining a fact in issue.... Second, the trial judge must decide whether the expert's testimony is based on a scientific principle or discovery that is "sufficiently established to have gained general acceptance in the particular field in which it belongs." ***Frye*** *v. United States,* 293 F. 1013, 1014 (D.C.Cir.1923) ... The third step in the process is for the trial judge to ***557** determine whether a particular witness is qualified as an expert to present opinion testimony on the subject in issue.... Fourth, the judge may then allow the expert to render an opinion on the subject of his or her expertise, and it is then up to the jury to determine the credibility of the expert's opinion, which it may either accept or reject....

Ramirez, 651 So.2d at 1167.

[1][2] Finally, we note that the appropriate standard for our review of a ***Frye*** issue is *de novo. Brim v. State,* 695 So.2d 268, 275 (Fla.1997); *Hadden,* 690 So.2d at 579. [FN5] Thus, we review the trial court's ruling on the admissibility of expert opinion testimony, which is purportedly based on an underlying novel scientific principle or technique, as a matter of law, rather than under an abuse of discretion standard. *Id.; see also Vargas v. State,* 640 So.2d 1139, 1144 (Fla. 1st DCA 1994), *quashed on other grounds,* 667 So.2d 175 (Fla.1995). Our *de novo* review of the ***Frye*** issue in these cases includes an examination of three methods of proof: (1) expert testimony, (2) scientific and legal writings, and (3) judicial opinions. *Flanagan v. State,* 586 So.2d 1085, 1112 (Fla. 1st DCA 1991)(Ervin, J., concurring and dissenting).

> FN5. Recently in *General Elec. Co. v. Joiner,* 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997), the United States Supreme Court has held that an abuse of discretion standard of review applies to the review of a trial court's determination of admissibility under ***Daubert.***

Scientific Background

The evidence and testimony in these cases span several fields, most notably epidemiology and toxicology. As recognized by the trial court, the epidemiological research upon which the numerous experts relied related to studies of subjects ranging from "Danish painters to Venezuelan gluemakers and from Silicon Valley

chipmakers to Michigan autoworkers." Because of the highly technical nature of this epidemiological evidence, to facilitate understanding of these cases and the arguments of the parties, it is necessary for us to provide a brief, but by no means exhaustive, discussion of certain scientific terms and concepts employed by the parties.

"Epidemiology" is a branch of science and medicine which uses studies to "observe the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations." *DeLuca v. Merrell Dow Pharm., Inc.,* 911 F.2d 941, 945 (3d Cir.1990), *quoting* Bert Black & David E. Lilienfeld, *Epidemiological Proof in Toxic Tort Litig.,* 52 Fordham L.Rev. 732, 755 (1984). Epidemiology focuses on the question of general causation, that is, whether a substance is *capable of causing* a particular disease, rather than specific causation, that is, whether the substance did cause the disease in a specific individual. Federal Judicial Center, *Reference Manual on Scientific Evidence,* 126 (1994)(herein the *Reference Manual*).

To establish that a given substance was a necessary causal link to the development of an individual's disease, in theory a scientist might obtain reliable information by engaging in experimental studies with human beings. For example, to determine whether exposure to a certain level of a suspected toxin is associated with a particular disease, the scientist might compare two randomly selected groups of people. One of the groups would be exposed to certain doses of the toxin over a prescribed length of time and the other group would not. For obvious ethical reasons, however, experimental studies with human beings are proscribed where the subject chemical agent is known or thought to be toxic. *See Ethyl Corp. v. United States Envtl. Protection Agency,* 541 F.2d 1, 26 (D.C.Cir.), *cert. denied,* 426 U.S. 941, 96 S.Ct. 2663, 49 L.Ed.2d 394 (1976); *Reference Manual* at 129.

Because of these ethical proscriptions, rather than experimental methods, epidemiologists use observational methods to study persons exposed to a suspected toxic substance to determine whether an association exists between exposure to the chemical and the development of a disease. These epidemiological studies use "statistical methods to detect abnormally high incidences of disease in a study population and to associate these incidences with unusual exposures to suspect environmental factors." (emphasis supplied). *In re "Agent Orange" Prod. Liab. Litig.,* 611 F.Supp. 1223, 1231 (E.D.N.Y.1985) ***558** *quoting* Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact,* 7 Harv. Envtl. L.Rev. 429, 431 (1983); *In re Swine Flu Immunization Prods. Liab. Litig.,* 508 F.Supp. 897, 907 (D.Colo.1981), *aff'd sub nom., Lima v. U.S.,* 708 F.2d 502, 507 (10th Cir.1983)("Where ... the exact organic cause of a disease cannot be scientifically isolated, epidemiologic data becomes highly persuasive.").

Through epidemiological studies, scientists can assess the existence (and strength) or absence of an *association* between an agent and the disease. But "[a]ssociation is not *causation*." *Reference Manual* at 126. Association is a term used to describe the relationship between exposure to a chemical agent and disease that occurs more frequently together than one would expect by chance. *Id.* at n. 7. Establishing an association does not necessarily mean that there is a causal effect between the exposure and the disease. *Id.* Causation, by comparison, constitutes an association between two events in which one event is a necessary link in a chain of events that results in the effect. *Id.* Nevertheless, while "[e]pidemiological methods cannot prove causation ...," epidemiological studies can provide a basis on which an epidemiologist can infer and opine that a certain agent causes a disease. *Id.*

In the event an epidemiological study finds an association between exposure to a substance and a disease, scientists can analyze the study to consider whether the reported association reflects a cause-and-effect relationship or, alternatively, is a spurious finding. *Id.* at 157. "Researchers first look for alternative explanations for the association, such as bias or confounding factors...." *Id.* The primary types of biases are selection bias and information bias. "Selection bias occurs when the exposed group is selected in a way that makes it more or less susceptible to disease for reasons independent of exposure." Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substance Litigation: The Legacy of Agent Orange and Bendectin Litigation,* 86 Nw. U.L.Rev. 643, 649 (1992). Similarly, information bias exists where the participants incorrectly give information about either exposure or health effects. This may exist where an interviewer whose "awareness of the identity of cases and controls ... may influence the structure of the questions and the interviewer's manner, which in turn may influence the response." David E. Lilienfeld & Paul D. Stolley, *Foundations of Epidemiology* 237 (1994).

Although epidemiologists cannot totally control such variables as the genetic background or lifestyle choices of their human subjects or the amount and duration of their exposure to the studied substance, *Reference Manual* at 129, the researchers have systematic methods

for assessing the characteristics of the people in the study and their risk of disease to rule out known sources of bias and errors. *Id.* at 127. For example, to eliminate information bias, whenever possible an interviewer should conduct "blind" interviews without prior knowledge of the cases and controls. *Foundations of Epidemiology* at 237.

Further, even when a statistical association exists and no bias is present, the association may be the result of some other confounding factor, or a so-called "confounder." A confounding factor may be itself a risk factor for the disease or associated with the exposure of interest. *Reference Manual* at 158. As an example, assume a study finds that individuals with grey hair have a higher rate of death than those with another hair color. Instead of hair color impacting on death, however, the test results might be explained by the confounding factor of advanced age. Thus, when a researcher finds an association between an agent and disease, he or she must determine whether the association is causal or the result of confounding. *Id.*

After the researcher has analyzed the epidemiological study for alternative explanations for an association, researchers then consider generally accepted guidelines for determining whether the association between exposure to a substance and a disease is causal. *See Smith v. Ortho Pharm. Corp.,* 770 F.Supp. 1561, 1575-76 (N.D.Ga.1991). Although the guidelines are composed of various ***559** criteria, [FN6] in the instant cases the factors of strength of association, consistency with other research, and biological plausibility are raised in the arguments of the appellee.

> FN6. One generally accepted set of standards for evaluating epidemiological studies is known as the Koch Postulates. Those standards are composed of the following seven factors:
> 1. strength of association;
> 2. temporal relationship;
> 3. consistency of the association in other research;
> 4. biological plausibility;
> 5. consideration of alternative explanations;
> 6. specificity of the association; and
> 7. dose-response relationship.
> Federal Judicial Center, *Reference Manual on Scientific Evidence* 161 (1994)(herein the *Reference Manual); see also* Bert Black & David E. Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation,* 52 Fordham L.Rev. 732, at 762-63 (1984).

Strength of Association. Epidemiologists commonly use "relative risk" to measure the strength of the association between exposure and disease. *Reference Manual* at 126. Relative risk is the ratio of the risk of disease among the group exposed to the chemical agent compared to the risk of disease among the unexposed group. *Id.* at 176. For example, a relative risk of 2.0 indicates that the risk of developing a disease in the exposed group is two times higher than the risk of developing that disease in the unexposed group. A relative risk of 1.0 indicates no association. The higher the relative risk, the stronger or more powerful is the association between exposure to the substance and development of the disease. [FN7]

> FN7. The "relative risk" concept is sometimes referred to as the "odds ratio" depending upon the type of study involved. However, for ease of reference, we will refer to relative risk only. *Reference Manual* at 149.

Scientists use the concept of a "confidence interval" as the means by which an epidemiologist can express confidence in a specific finding of relevant risk. For instance, if relative risk in a study is found to be 2.0, the epidemiologist can estimate the range of numeric values above and below 2.0 in which the relationship of a study sample would be likely to fall if the same study were repeated numerous times. *Id.* at 173. "The width of the confidence interval provides an indication of the precision of the point estimate or relative risk found in the study ..." *Id.* In this appeal, *citing* Black & Lilienfeld, *supra,* 52 Fordham L.Rev. at 757, the railroad urges that the confidence interval should be expressed with estimated 95% accuracy, that is, as a range in which relative risk will predictably fall 95 times out of 100 replications of the study.

Consistency with Other Research. The validity of scientific conclusions is often based upon the replication of research findings, and consistency in these findings is an important factor in making a judgment about causation. *See Kehm v. Proctor & Gamble Co.,* 580 F.Supp. 890, 901 (N.D.Iowa 1982), *aff'd,* 724 F.2d 613 (8th Cir.1983)(noting the persuasive power of multiple independent studies, each of which reached the same finding of an association between the toxic shock syndrome and tampon use); *Cadarian v. Merrell Dow Pharm., Inc.,* 745 F.Supp. 409, 412 (E.D.Mich.1989)(holding a single Bendectin study insufficient to support an expert's opinion, because "the study's authors themselves concluded that the results could not be interpreted without independent confirmatory evidence").

Biological Plausibility. Biological plausibility involves the application of the "existing knowledge about human biology and disease pathology to provide a judgment about the plausibility that an agent caused a disease." *Reference Manual* at 172. Thus, for example, a conclusion that high cholesterol is a cause of coronary heart disease is biologically plausible because cholesterol is found in atherosclerotic plaques. *Id.* at 163.

Briefly, we turn to another scientific discipline, toxicology. Toxicology is defined as "the study of the adverse effects of chemical agents on biological systems." *Id.* at 185. One of the central tenets of toxicology is that "the dose makes the poison" implying that all chemical agents are harmful--it is only a question of dose. *Id.* Thus, even water if consumed in large enough quantities can be toxic. *Id.* A toxicologist attempts to determine at what doses foreign agents produce their effects, and animal studies are used by toxicologists to predict toxic responses in humans. ***560** *Id.* In toxicology, a dose-response relationship is a relationship in which a change in amount, intensity, or duration of exposure is associated with a change--either an increase or decrease--in risk of disease. *Id.* at 173.

The Scientific Evidence Below

The appellants proffered the testimony or affidavits of expert witnesses Dr. W. Lynn Augenstein, Dr. Richard L. Lipsey, Dr. Edward L. Baker, Jr., Dr. Douglas H. Linz, and Dr. Michael Kelly in the **Berry** case.

Dr. Augenstein. Dr. W. Lynn Augenstein, a medical doctor with a board certification in medical toxicology who teaches at the University of Florida Health Science Center, reviewed approximately 150 journal articles, textbooks, and notes of international conferences. He opined that, of the epidemiological studies which had been performed, the studies correlating long-term exposure to organic solvents and toxic encephalopathy outweigh the negative studies by eight or nine to one. He acknowledged that there were negative studies, but he opined that these studies dealt with short term or low level exposures.

Regarding toxic encephalopathy, he explained that it is usually divided into three categories: minimum, moderate and severe. In the lowest category of toxic encephalopathy, a patient suffers from tiredness, mood problems, irritability, sleep disturbances, possibly some poor memory function, depression, headaches and dizziness. A patient suffering moderate toxic encephalopathy shows more specific neurologic signs that would be detectable on neuropsychological testing: memory problems; slower reaction times; and problems with spacial orientation. The patient has more persistent mood and behavioral problems. In the severe category, there is significant global brain dysfunction. The individual is almost in a vegetative state where he cannot function, has very poor memory, and there are significant findings on x-ray tests showing brain atrophy. Dr. Augenstein opined that it is not necessary for a worker to become unconscious in order to suffer toxic encephalopathy.

He further explained that the dose-response relationship, which is a cornerstone of toxicology, is very difficult to assess in an epidemiological study because epidemiological studies are performed on a retrospective basis.

Dr. Lipsey. Richard Lipsey, Ph.D., who stated his profession as a pesticide environmental toxicologist, concurred that in his review of the literature, there was a general consensus in the scientific community that long-term exposure to excessive levels of organic solvents can and does cause toxic encephalopathy.

Dr. Baker. Edward L. Baker, Jr., M.D., is board-certified in occupational medicine and internal medicine. In addition to his doctor of medicine degree, he has two masters degrees from Harvard University, a Master of Public Health with emphasis on epidemiology and a Master of Science with emphasis on epidemiology and occupational health. He has practiced medicine in the Occupational/Environmental Health Clinic at Emory University; has been employed as a professor at Harvard, where he directed research into the health effects of organic solvents; has served as Deputy Director of the National Institute for Occupational Safety and Health, the federal agency responsible for research in occupational health; and, at the time of the evidentiary hearing, was the Director of the Public Health Practice Program Office at the federal government's Center for Disease Control and Prevention.

Dr. Baker has authored chapters for at least four medical textbooks which address the subject at issue; he has published 98 journal articles of which approximately 20 are directly related to the subject at issue; and he has served on the editorial boards, as peer reviewer for submitted articles, of several journals and publications, including the American Journal of Industrial Medicine. He was the only United States scientist to participate in an international conference of scientists, convened in Copenhagen in 1985 by the World Health Organization to reach a consensus on the chronic effects of organic solvents on the central nervous system. The report

generated from the Copenhagen conference concludes that "epidemiological and experimental data indicate that long-term occupational ***561** exposure to organic solvents may cause adverse effects in the central and peripheral nervous systems." Dr. Baker participated in a second international conference which produced the same consensus opinion. As a result of a conference held in 1990, it was agreed that "chronic toxic encephalopathy does occur in workers with excessive exposure to solvents."

Significantly, as can be seen from his credentials, Dr. Baker began studying the effects of solvents well before this litigation arose and arrived at his conclusions independent of his involvement in this lawsuit. [FN8] As a result of his very considerable study on the subject, he has concluded that long-term excessive exposure to organic solvents can cause toxic encephalopathy.

> FN8. As stated by the court in ***Daubert*** *v. Merrell Dow Pharm., Inc.,* 43 F.3d 1311, 1317 (9th Cir.1995):
> One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.... [I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.
> That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science.

Specifically, he opined that if an individual is exposed more than ten years to a concentration that is sufficient to cause acute symptomology (intoxication, light-headedness, dizziness, inebriation) on a regular basis, that person is at risk for developing toxic encephalopathy. He said it was a general consensus in the scientific community that there is a risk of toxic encephalopathy in people excessively exposed to solvents. The only real debate at present, according to Dr. Baker, was over the safe levels of exposure and the degree of reversibility of the damage. He disagreed with appellee's experts that, for there to be a causal relationship, a patient must have been rendered unconscious by the exposure.

Dr. Baker testified that the Occupational Safety and Health Administration (OSHA) has published recommended maximum safe exposure levels for the various solvents at issue in this case. OSHA has arrived at a number 350 parts per million as an eight-hour time-waited exposure for the workplace for TCA that is deemed to be a safe level. Nonetheless, as Dr. Baker recognized, this level does not take into consideration solvent exposure through the skin. He opined that solvents penetrate the skin and can get into the body through percutaneous exposure as well as through inhalation exposure. Thus, even a workplace allegedly below the safe level of 350 parts per million might nonetheless subject a worker to excessive exposure.

Although he was uncertain of the exact biological "mechanism" by which these solvents cause damage, Dr. Baker offered a biologically plausible explanation. He explained that solvents typically accumulate in fat-rich tissues and that the adipose tissues of the brain are tissues that have a high fat content. He postulated that since many organic solvents are highly lipid soluble, they can accumulate in the brain or in the adipose tissue.

Dr. Linz. Douglas H. Linz, M.D., who is board-certified in internal medicine and occupational medicine, submitted an affidavit. His speciality included diagnosing and treating injuries and conditions caused by acute and chronic overexposure to chemicals and solvents. Initially, Dr. Linz had been asked by CSX to examine several of the railroad's employees who, like appellants, worked in the diesel shop. He opined that the employees had suffered neurological and neuropsychological conditions caused by their recurrent exposures to solvents while working for the railroad and that there was a medically significant pattern among the examined diesel shop employees of the railroad who were suffering from solvent-induced brain injury. The employees had described heavy exposures: large amounts of solvents were used at full strength; the solvent was sprayed under pressure which atomized it; respirators were not worn; and employees washed their hands and clothes in solvent. They had the following complaints: headaches; dizziness; nausea; feelings of drunkenness ***562** and/or confusion; and acute mucosal complaints. He opined that it was well recognized that repeated exposures such as the kind noted above over a period of years can result in neurological and neuropsychological conditions including organic brain damage.

Dr. Linz came to the conclusion that the diesel employees had suffered solvent induced brain damage only after interviewing the patients and discussing with

them their general health, their medical histories, and their occupational histories; reviewing the manufacturer safety data sheets on the solvents which were provided to him by the railroad (which included the solvents that are at issue in this case); reviewing the medical records of the employees; performing physical examinations on the men; reviewing diagnostic studies such as neuropsychological evaluations and balance testing performed on the men; reviewing the scientific literature which has been published with regard to solvents; and after eliminating other causes to a reasonable degree of medical certainty. He opined that the overwhelming epidemiological evidence confirms the relationship between long-term exposure to solvents and brain damage.

Dr. Kelly. Michael Kelly, M.D., is board-certified in internal medicine and occupational medicine. Currently he is the Medical Director of Occupational Health Services and Chief of Medicine at St. Lawrence Hospital in Lansing, Michigan. He has extensive experience in diagnosing and treating solvent-exposed workers from all over the country, including approximately 200 railroad workers. He opined that it was a general consensus in the medical and scientific community that long-term exposure to organic solvents can cause toxic encephalopathy.

In arriving at his conclusion that Mr. **Berry** suffered from solvent-induced toxic encephalopathy, Dr. Kelly employed a differential diagnosis [FN9] procedure which he opined was the standard methodology utilized in the field of occupational health. He took a history from both Mr. **Berry** and his wife concerning his current medical problems. After reviewing Mr. **Berry's** work history and symptoms, Dr. Kelly opined that **Berry** had been exposed to very high levels of organic solvents in excess of OSHA standards, which excessive exposure had been confirmed by other railroad employees. Dr. Kelly also conducted a thorough physical examination. He caused various laboratory tests to be performed on **Berry,** and obtained an MRI and an EEG of **Berry.** He referred **Berry** to a neuropsychiatrist for evaluation, which revealed that **Berry** had severe cognitive defects. A psychiatrist to which **Berry** was also referred reported back that **Berry's** cognitive defects were more likely consistent with toxic encephalopathy than with mere depression. Dr. Kelly had a SPECT scan of **Berry** performed, and the physician who performed the scan reported that it showed that **Berry** suffered diminished activity and function in several areas of the brain, consistent with neurotoxic insults. Dr. Kelly asked **Berry** questions about cigarettes, alcohol and other possible confounders.

> FN9. "Differential diagnosis" is a term used "to describe a process whereby medical doctors experienced in diagnostic techniques provide testimony countering other possible causes ... of the injuries at issue." *Hines v. Consolidated Rail Corp.,* 926 F.2d 262, 270 n. 6 (3d Cir.1991).

Regarding his occupational history, Mr. **Berry** told Dr. Kelly that he used materials out of a 55 gallon drum hooked up to house air, as he called it, to spray off the locomotives. He worked in the pit area under the locomotive. He would dip his hands in the material, and wash his clothes with it. He described being wet with the solvent material. He developed headaches, and was tired and lethargic. He had to take naps when he came home from work. Dr. Kelly opined that these symptoms indicated **Berry** had been exposed to "pretty high exposure levels occurring over a fairly long period of time." **Berry** could not remember names, could not remember directions, and could not remember his assignment at work. He was frequently angry, irritable, and was having some sleep disturbances. His gait was abnormal. When he walked, his feet were wide apart indicating a balance disturbance. Regarding **Berry's** cognitive difficulties, Dr. Kelly concluded that **Berry's** ability to interpret visual spacial configurations was at best low average, whereas one would expect an ***563** electrician to be able to visualize diagrams and remember them.

Regarding a biologically plausible explanation for the toxic encephalopathy, Dr. Kelly concurred with Dr. Baker that solvents have the ability to dissolve fatty materials. He felt that this characteristic allowed them to damage the body. He added that the fact these solvents are chlorinated probably adds to their toxicity, because the chlorine atom is more difficult for the body to metabolize and prolongs the exposure. He said there was no support for the notion that it is necessary to have an acute exposure causing unconsciousness before a person can suffer toxic encephalopathy.

CSX presented the expert testimony of Dr. Raymond Harbison and Dr. Robert James.

Dr. Harbison. Raymond Harbison, Ph.D., a toxicologist on the faculty of the University of Florida, opined that there was no biologically plausible explanation for a solvent exposure to cause toxic encephalopathy. As an example, he said that TCA is rapidly eliminated from the body and does not damage

the nervous system because it cannot be converted to a chemical that interacts with the nervous system to cause damage. His testimony regarding TCE and PCE was similar. According to him, nothing in the molecular structure of the chlorinated hydrocarbon is able to produce any pathology in the nervous system. Contrary to plaintiffs' experts, he opined that TCA cannot "bioaccumulate in the brain." He maintained that it was generally accepted among toxicologists that TCA is not able to cause toxic encephalopathy unless there has been a dose sufficient to impair respiration resulting in lowering of the oxygen level in the body or unconsciousness. However, he admitted no study supports his contention that unconsciousness was required.

He was generally of the opinion that the literature contained insufficient evidence of a real causal connection between long-term exposure to organic solvents and toxic encephalopathy because real exposures could not be determined without making accurate air quality measurements, and because only precisely controlled double blind studies could be expected to establish causation. According to him, one should not use patient history to make the diagnosis but should use analytical data and be able to conduct measurements of the actual exposure received. Contrary to Dr. Kelly, he opined that a patient's symptoms could not be used to measure exposure. Instead, to make the diagnosis of toxic encephalopathy one would have to evaluate such factors as the level of chemicals in the workplace, the available ventilation, the temperature, and the air exchange rates in the work area.

Dr. Harbison opined that, before the toxicological scientific community would acknowledge the validity of an epidemiological study relating exposure to disease, there would have to be a known verified exposure, valid testing that is objective, and this testing methodology must have been subjected to a double blind evaluation where neither the investigator nor the individual who was being evaluated knew what the exposure was or what the potential outcome should be.

Dr. James. Robert James, Ph.D., also a toxicologist on the faculty at the University of Florida, presented an analysis of the studies demonstrating an association between exposure to organic solvents and toxic encephalopathy. Dr. James opined that most of the studies were negative and that of the ones which were positive, when flawed methodology was considered as well as other factors, only a few studies could be considered truly positive. Based upon his reanalysis, he said the studies did not demonstrate that long-term exposure to excessive amounts of organic solvents can cause toxic encephalopathy or that this hypothesis was generally accepted by the scientific community at this time. He advocated his reanalysis of the studies as more credible because it eliminated from the classification of positive studies those studies which failed to provide clear and convincing evidence of strong associations and big differences. The studies he eliminated he characterized as false positive studies which had not controlled for confounders. He conceded that he and Dr. Baker had obviously interpreted the literature differently.

***564** While it was his opinion that epidemiology and toxicology use essentially the same type of analysis, nonetheless, Dr. James testified that toxicologists use a more rigorous standard to evaluate the data before determining whether or not a substance causes a particular disease in any population. He rejected studies that do not show a strong dose-response relationship, commenting that if the response does not change as a result of the dose or there is not a dose-response curve, the chemical agent is not the cause of the disease.

To the extent other scientific evidence is deemed relevant, it is discussed in other parts of this opinion.

Trial Court's Order

In the proceedings below, CSX challenged the admissibility of the appellants' expert testimony, contending that the plaintiffs' theory of general causation was based on "junk science" which did not meet the ***Frye/****Ramirez* test of reliability and that Dr. Kelly's specific causation testimony was not credible. The trial court found that the central issue in these cases was the general acceptance of the scientific principles underlying the testimony of appellants' expert witnesses. The appellants argued that ***Frye*** does not require that the experts' opinions themselves must be generally accepted; but, rather, that only the scientific techniques or methodology upon which the expert relies must be generally accepted in the scientific community. The trial court rejected this argument, ruling that ***Frye*** not only applies to scientific methodology, but that the scientific conclusion of the expert witness itself must be generally accepted in the scientific community to which it pertains.

The trial court concluded that there remains a substantial disagreement within the scientific community as to whether or not organic solvents can cause brain damage. In reaching this conclusion, the court recited the findings of numerous of the epidemiological studies upon which the appellants relied. In these studies, the

researchers found an association between exposure and injury, but used the seemingly equivocal term of "association" rather than causation. Moreover, these studies admitted the controversial nature of this subject, and several called for further investigation. The trial court was plainly troubled by the "qualifying phrases and disclaimers" used in the articles. This lead the trial court

> to the conclusion that there remains a substantial disagreement within the scientific community as to whether or not organic solvents, particularly the ones at issue in the instant case, can cause brain damage, particularly chronic toxic encephalopathy, of the nature allegedly experienced by the plaintiff[s] in [these] case[s]. Said another way, the Court concludes that it is *not* generally accepted that exposure to organic solvents causes the condition of which the plaintiff[s] complain.

Arguments of the Parties

[3] Appellants argue that the effect of the trial court's admissibility ruling was to decide the causation issue itself--that is, whether exposure to the four solvents causes toxic encephalopathy--which is a jury issue. They contend that the trial court erred as a matter of law in concluding that it was the experts' ultimate opinions, rather than the underlying methodology from which they derived their opinions, that had to be ***Frye*** tested. *See, e.g., Ferebee v. Chevron Chem. Co.,* 736 F.2d 1529, 1535 (D.C.Cir.), *cert. denied,* 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984); *accord Osburn v. Anchor Lab., Inc.,* 825 F.2d 908, 915-16 (5th Cir.1987), *cert. denied,* 485 U.S. 1009, 108 S.Ct. 1476, 99 L.Ed.2d 705 (1988); and *Cella v. United States,* 998 F.2d 418, 425 (7th Cir.1993). Appellants argue that the "principle or discovery" language in ***Frye*** upon which the trial court seized to arrive at its conclusion that an expert's opinion must be generally accepted in the medical community was merely language used by the ***Frye*** court to label the novel "systolic blood pressure deception test" at issue in that case. They submit that an expert opinion derived from the generally accepted methodology of the science of epidemiology--where numerous published, peer-reviewed epidemiological studies and medical textbooks provide support for the opinion-- is reliable, and therefore admissible.

***565** Regarding the trial court's exclusion of Dr. Kelly's specific opinion on causation, appellants argue that Dr. Kelly followed a "differential diagnosis" methodology which is the standard methodology utilized in the field of occupational health. *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d 717, 758 (3d Cir.1994), *cert. denied sub nom., General Elec. Co. v. Ingram,* 513 U.S. 1190, 115 S.Ct. 1253, 131 L.Ed.2d 134 (1995); *Hines v. Consolidated Rail Corp.,* 926 F.2d 262, 274 (3d Cir.1991). Further, although the trial court was troubled by the fact that Dr. Kelly had merely estimated the levels of exposure to the organic solvents, appellants argue that this was necessary as the railroad had not monitored the work rooms, and therefore verifiable knowledge of the levels of solvents does not exist. Thus, Dr. Kelly could only rely upon an informed estimate derived from the statements of **Berry** and the other people who worked in the shops everyday to arrive at a diagnosis. If this estimate is erroneous, submit the appellants, CSX will have the opportunity to dispute the claimed levels of exposure at trial.

CSX argues that the causal proposition--that long term exposure to TCA, TCE, PCE and mineral spirits at workplace level sufficient to produce transient irritation, dizziness or disorientation, but not hypoxia or anoxia, [FN10] can cause irreversible central nervous system damage--must pass the ***Frye*** test. Appellee contends that upon a *de novo* review of this issue, this court will be compelled to conclude that this causal proposition does not pass the ***Frye*** test. CSX directs our attention to several publications which show some epidemiologic disagreement about causality between long-term exposure to organic solvents and toxic encephalopathy. Further, CSX criticizes the studies upon which appellants' experts rely, contending these studies did not sufficiently take into account the presence of confounders or information bias, or involved exposure to much more damaging chemicals than those at issue in the instant cases. Finally, CSX argues that these studies are deficient because they fail to offer a biologically plausible explanation for the stated effects and do not adequately address the dose response relationship.

> FN10. Hypoxia is a "[d]ecrease below normal levels of oxygen in inspired gases, arterial blood, or tissue, short of anoxia;" anoxia is an "[a]bsence or almost complete absence of oxygen." *Stedman's Medical Dictionary,* at 90 and 756 (25th ed.1989).

CSX suggests that for an epidemiological study to show a statistically significant association between a certain risk factor and disease in the exposed group such that causation may be inferred by the scientists, there must be a relative risk greater than 2.0 within a 95% confidence interval greater than 1.0, and that the calculations must adequately guard against selection and information biases and other confounders. After reviewing the studies, CSX argues there are only three positive studies, or at most five positive studies, and of those, four were subject to obvious selection and information bias.

The appellants reply that the microscopic level of critical analysis to which the railroad has resorted belongs only to the experts. They suggest that neither the trial court nor this court can assume the role of an amateur scientist, examine the materials upon which the expert scientists rely, draw its own scientific conclusion as to whether the material support the opinions of the plaintiffs' experts or not and then declare one set of opinions the victor by excluding the other set of opinions from evidence. *See Joiner v. General Elec. Co.,* 78 F.3d 524, 530-33 (11th Cir.1996), *rev'd on other grounds,* 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997); *In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d 1124, 1137 (2d Cir.1995).

***Frye** Analysis*

[4] At the outset of our ***Frye*** analysis, we must resolve the issue over what must be ***Frye*** tested in this case--the opinion testimony of the witnesses or the underlying scientific principle or methodology utilized by the experts in arriving at their opinions. ***Frye*** expressly addressed whether it is the expert opinion or the underlying principle and methodology from which the opinion is deduced which must be generally accepted in the scientific community. The ***Frye*** court explained: "the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular ***566** field in which it belongs." ***Frye,*** 293 F. at 1014.

Further, the federal cases following ***Frye*** have applied the ***Frye*** test to the underlying scientific principle or methodology on which the opinion is based. *See, e.g., Cella v. United States,* 998 F.2d 418, 425 (7th Cir.1993)("the ***Frye*** standard requires that the methodology and reasoning used by an expert in reaching a conclusion be generally accepted within the relative scientific community"); *Christophersen v. Allied-Signal Corp.,* 939 F.2d 1106, 1111 (5th Cir.1991)(in applying ***Frye*** test ask whether the expert, in reaching his conclusion, used a well founded methodology or mode of reasoning), *cert. denied,* 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992); *Peteet v. Dow Chem. Co.,* 868 F.2d 1428, 1433 (5th Cir.1989)(as long as expert's methodology is well-founded, the nature of his conclusion is generally irrelevant, even if it is controversial or unique), *cert. denied sub nom., Dow Chem. Co. v. Greenhill,* 493 U.S. 935, 110 S.Ct. 328, 107 L.Ed.2d 318 (1989); *Osburn v. Anchor Lab., Inc.,* 825 F.2d 908, 915 (5th Cir.1987)("an expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative in support of a jury finding"), *cert. denied,* 485 U.S. 1009, 108 S.Ct. 1476, 99 L.Ed.2d 705 (1988); *Ferebee v. Chevron Chem. Co.,* 736 F.2d 1529, 1535-36 (D.C.Cir.) (rejecting defendant's argument that expert opinion testimony must be generally accepted in the scientific community before it can be introduced as evidence), *cert. denied,* 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984).

The Florida Supreme Court has, until recently, consistently described the ***Frye*** test as a standard which "requires a determination, by the judge, that the *basic underlying principles* of scientific evidence have been sufficiently tested and accepted by the relevant scientific community." *Brim,* 695 So.2d at 272 (emphasis added). In *Hadden,* however, the court stated that it would "not permit factual issues to be resolved on the basis of *opinions* which have yet to achieve general acceptance in the relevant scientific community." *Hadden,* 690 So.2d at 578 (emphasis added). Specifically, the court held in *Hadden* that "a psychologist's opinion that a child exhibits symptoms consistent with ... 'child sexual abuse accommodation syndrome' ... has not been proven by a preponderance of scientific evidence to be generally accepted by a majority of experts in psychology" and that such opinion could not be used in a prosecution for child abuse where a proper objection is raised to its introduction. *Id.* at 575. The court distinguished such testimony from pure opinion testimony (testimony which is personally developed through clinical experience) on the grounds that profile and syndrome evidence rely on conclusions based upon studies and tests. "Consequently, the expert's opinion was based upon diagnostic standards which must pass the ***Frye*** test." *Id.* at 581.

However, we decline to interpret this language in *Hadden* as meaning that in all cases expert opinion testimony, not otherwise developed through clinical experience, must be ***Frye*** tested. Instead, we believe that this language in *Hadden* must be confined to the facts in that case and the psychological syndrome testimony which was being proposed. It is clear that the syndrome testimony in *Hadden* was not based upon scientifically accepted methodology. As Judge Ervin opined in his dissenting opinion in *Hadden v. State,* 670 So.2d 77, 89 (Fla. 1st DCA 1996)(en banc), approved by the supreme court, the diagnosis of sexual abuse through a syndrome analysis is not a generally accepted method of diagnosing sexual abuse nor is there a consensus among experts that it is useful as substantive evidence of guilt. *Id.* at 579.

In *Hadden,* the expert's opinion testimony was inextricably intertwined with an unacceptable diagnostic

methodology. This circumstance is factually and legally distinguishable from the proposed expert opinion causation testimony in the instant toxic tort case. The proposed expert opinions here are based upon peer reviewed published epidemiological studies undertaken independently of the instant action and clearly recognized in the case law as important sources of evidence of toxic causation. As the Third Circuit observed in *DeLuca,* 911 F.2d at 954:

> ***567** The reliability of expert testimony founded on reasoning from epidemiological data is generally a fit subject for judicial notice; epidemiology is a well-established branch of science and medicine, and epidemiological evidence has been accepted in numerous cases.

Commentators have further explained:

> Epidemiological studies have been well received by courts trying mass tort suits. Well conducted studies are universally admitted. The widespread acceptance of epidemiology is based in large part on the belief that the general techniques are valid.

Modern Scientific Evidence at § 28-1.1; *see also* Green, 86 Nw. U.L.Rev. at 659, 663-64 (1992).

Thus, we hold that, under ***Frye*** and its Florida progeny, when the expert's opinion is well-founded and based upon generally accepted scientific principles and methodology, it is not necessary that the expert's opinion be generally accepted as well. We find persuasive the rationale of the court in *Christophersen:*

> [I]n *Osburn* [*Osburn v. Anchor Lab., Inc.,* 825 F.2d 908 (5th Cir.1987)] the plaintiff's and the defendant's experts relied on essentially the same diagnostic methodologies but drew opposite conclusions from the available information. We did not attempt to determine which expert's conclusion was more in line with the consensus in the scientific community. Instead we stated, "a jury must be allowed to make credibility determinations and weigh conflicting evidence in order to decide the likely truth of a matter not itself initially resolvable by common knowledge or lay reasoning." *Id.* at 916. "An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative in support of a jury finding." *Osburn,* 825 F.2d at 915.

939 F.2d at 1111 (emphasis added).

Our conclusion is supported by the opinion of the Florida Supreme Court in *Brim.* There, the court recognized that ***Frye*** allows opposite opinion testimony from experts relying upon the same generally accepted scientific principles and methodologies. In *Brim,* the court was faced with a ***Frye*** challenge to DNA test results. The *Brim* court held that, for DNA test results to be admissible, both the first step of the testing process (which relies upon principles of molecular biology and chemistry) and the second step (which involves a calculation of population frequency statistics) must satisfy ***Frye.*** *Brim,* 695 So.2d at 269. With regard to the second step, the court found that *multiple* statistical calculations might simultaneously satisfy ***Frye.*** [FN11] *Id.* at 272. "It is clear that scientific unanimity is not a precondition to a finding of general acceptance in the scientific community." *Id.* The court explained that although two conflicting scientific principles cannot simultaneously satisfy ***Frye,*** it would allow multiple reasonable statistical calculations when based upon generally accepted principles of population, genetics and statistics. *Id.*

> FN11. While the court had already ruled in *Ramirez,* 651 So.2d at 1168, that general acceptance under ***Frye*** must be established by a preponderance of the evidence, in *Brim* the court added to the analysis by defining "general acceptance" as meaning acceptance by a clear majority of the members of the relevant scientific community, with consideration by the trial court of both the quality and quantity of those opinions. *Brim,* 695 So.2d at 272.

For all these reasons, we must respectfully disagree with the trial court's conclusion that it was the appellants' expert opinion testimony that was required to be ***Frye*** tested in these cases.

[5] Turning to the trial court's further reasoning for denying admissibility--that the underlying epidemiological studies were equivocal as to causation--we find that the trial court ultimately misunderstood the nature of epidemiological studies and was unnecessarily concerned that the studies did not prove causation. As discussed above, epidemiological studies are designed to assess the existence and strength or absence of an association between an agent and a disease. *Supra,* page 557. As Dr. Baker explained in his testimony, epidemiological studies do not fix the cause--they merely demonstrate the probabilities of cause. *See also* Green, 86 Nw. U.L.Rev. at 647 ("At best, epidemiology assesses the likelihood ***568** that the agent caused a specific individual disease."). From epidemiological studies demonstrating an association, an epidemiologist may or may not infer that a causal relationship exists. However, the epidemiological studies themselves are not designed to demonstrate whether a particular agent *did* cause the disease, and the trial court erred in concluding that the studies were unreliable because they failed to

establish causal relationship. [FN12]

> FN12. Further, the fact that a epidemiological study calls for further research does not indicate uncertainty on the part of the researchers. As explained below by expert witness David Hartman, Ph.D., who submitted an affidavit in the Chrisco case:
>
> Any research design assessing clinical data in the real world will always be considered incomplete by critical reviewers. By its very nature, the medical researcher cannot control all possible factors in the human population under study. Therefore, one must distinguish between a truly erroneous study, and the study which is simply an expression of a particular population ... [and] is correctly constructed and analyzed....
>
> Almost all genres of research articles in the medical and behavioral sciences conclude their discussion with qualifying statements such as "there is still much to be learned." This is not, as might be assumed, an expression of ignorance, but rather an expression that all scientific fields are open-ended and can progress from their present state....
>
> Medical and behavioral statistics is a methodology that seeks to measure degrees of probability, not causality. Uncertainty is never completely abolished in any form of behavioral or medical science statistical manipulation. Therefore, conclusions must be defined in terms of "suggestions" or "associations" rather than causes. This is not due to some inaccuracy or vagueness of the technique or conclusion, but rather is intrinsic to the properties of statistics.
>
> Mr. Hartman's opinion is consistent with other authorities on the subject. *See, e.g., Reference Manual* at 157 ("Most researchers are conservative when it comes to assessing causal relationships, often calling for stronger evidence and more research before a conclusion of causation is drawn.").

Nonetheless, CSX argues that the epidemiological studies upon which appellants' experts rely are infirm because they contain methodological flaws. It is the railroad's position that even if the experts' opinions themselves do not have to be ***Frye*** tested, here the underlying methodology upon which the opinions rely, the epidemiological studies, fail the ***Frye*** test.

[6][7] Before turning to a discussion of the critical analysis employed by CSX, we must emphasize at this juncture that the issue in ***Frye*** and in the instant cases involves the *admissibility* of expert testimony, not the *sufficiency* of that testimony. An inquiry regarding the "sufficiency" of the evidence concerns whether the party has produced sufficient evidence to convince a reasonable juror that the opinion of the party's expert is correct. *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d at 744. "Admissibility," in contrast, "entails a *threshold* inquiry over whether a certain piece of evidence ought to be admitted at trial." *In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d at 1132 (emphasis in original).

[8] At this admissibility stage of the proceedings, under ***Frye*** the court is asked to decide whether the basis of the evidence upon which plaintiffs' experts rely has a sufficient indicia of reliability. "Reliability is fundamental to issues involved in the admission of evidence." *Hadden,* 690 So.2d at 578. We agree with the appellants that under ***Frye*** they have demonstrated the reliability of the scientific evidence upon which their experts rely. While, as Dr. Baker acknowledged in his proffered testimony, there continues to be scientific debate about the safe levels of exposure with respect to certain toxins and the degree of reversibility of the effect of exposure to the toxins, we find the epidemiological science and methodology underlying his testimony to be established, reliable, and well-founded.

[9] CSX asserts that, in deciding the question of admissibility here, as a part of our *de novo* review we must engage in a highly detailed level of critical analysis of each epidemiological study. While an analysis of each study for relative risk, confidence interval, biases, confounders, criteria of causality and other numerous factors may be appropriate in considering the sufficiency of the evidence, that is not appropriate or necessary under the circumstances here or at this stage of the litigation. Further, such a detailed analysis would require this court not ***569** only to have an appreciation for the methodological errors and inadequacies in the studies, an ability to assess the validity of a reanalysis of those studies, and an understanding of the biological underpinnings associated with the disease in question, but also to possess a firm grounding in the concepts of relative risk, statistical significance and confidence intervals, and their relationship to the preponderance of the evidence standard. Green, 86 Nw. U.L.Rev. at 681. While certainly courts must become educated on these subjects when necessary to adjudicate issues regarding the sufficiency of the evidence in the toxic torts arena, the record in these cases is lacking the necessary evidence upon which to make these judgments at this stage of the proceeding. *See, e.g., DeLuca,* 911 F.2d at 955 (declining to rule as a matter of law that any expert

opinion rooted in a statistical analysis where the results of the underlying studies are not significant at a .05 level would not be allowed where the record contained virtually no relevant help from the parties or from qualified experts); *In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d at 1134 (an argument that an epidemiological study must show a relative risk greater than 2.0 is a sufficiency argument not an admissibility argument). [FN13]

> FN13. Though there are certainly a number of cases that suggest a relative risk greater than 2.0 can permit an inference that an individual's disease was more likely than not caused by exposure to the toxic agent, there are also cases which have recognized that a plaintiff may satisfy his or her burden of production even if a relative risk less than 2.0 emerges from the epidemiological evidence. *Reference Manual* at 170. *See, e.g., Grassis v. Johns-Manville Corp.,* 248 N.J.Super. 446, 591 A.2d 671, 675 (App.Div.1991):
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> The physician or other qualified expert may view the epidemiological studies and factor out other known risk factors such as family history, diet, alcohol consumption, smoking ... or other factors which might enhance the remaining risks, even though the risk in the study fell short of the 2.0 correlation.

[10] Our conclusion is strongly influenced by the fact that the epidemiological studies here were conducted independently of this litigation and were peer-reviewed and accepted by journals that are widely acknowledged in the scientific and medical communities. *See generally Modern Scientific Evidence* at § 1-3.3.3 (noting the importance of peer review and publication in highly regarded journals for the purpose of establishing scientific validity under ***Daubert***). Although there is a debate as to whether publication in peer-reviewed journals or other professional literature is necessary to give a study an indicia of reliability, when there exists a mature epidemiological record with numerous peer-reviewed, published studies supporting the expert's analysis, an aura of reliability and validity is accorded those studies. *See* Green, 86 Nw. U.L.Rev. at 694; *Richardson v. Richardson--Merrell, Inc.,* 649 F.Supp. 799, 802-03 (D.D.C.1986), *aff'd,* 857 F.2d 823 (D.C.Cir.1988), *cert. denied,* 493 U.S. 882, 110 S.Ct. 218, 107 L.Ed.2d 171 (1989). While the existence of numerous peer-reviewed, published, epidemiological studies does not guarantee that the studies are without flaws, such publication here alleviates the necessity of thorough judicial scrutiny of each study at the admissibility stage "to sort out the disputes over methodologic errors in studies." Green, 86 Nw. U.L.Rev. at 694. [FN14] At least ***570** until a more refined screening mechanism can be devised, we are satisfied that under ***Frye*** peer review and publication lends sufficient reliability and validity to these studies to allow an expert's testimony based upon these studies to be admissible. [FN15]

> FN14. In an action against CSX factually similar to the instant cases, the Tennessee Supreme Court recently upheld the admission into evidence of expert testimony based upon epidemiological studies showing an association between exposure to certain organic solvents and toxic encephalopathy. *McDaniel v. CSX Transp., Inc.,* 955 S.W.2d 257 (Tenn.1997). We believe that the *McDaniel* court correctly explained the role of the trial court in cases such as this:
>
> Although the trial court must analyze the science and not merely the qualifications, demeanor or conclusions of experts, the court need not weigh or choose between two legitimate but conflicting scientific views. The court instead must assure itself that the opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation. The trial court should keep in mind that the preliminary question ... is one of admissibility of the evidence. Once the evidence is admitted, it will thereafter be tested with the crucible of vigorous cross-examination and countervailing proof. After that occurs, a defendant may, of course, challenge the sufficiency of the evidence by moving for a directed verdict at the appropriate times. Yet it is important to emphasize that the weight to be given to stated scientific theories, and the resolution of legitimate but competing scientific views, are matters appropriately entrusted to the trier of fact.
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> *Id.* at 265 (citations omitted).

> FN15. A review of case law in the toxic torts area demonstrates that the intensity of the "admissibility" inquiry evolved as a result of Agent Orange and bendictin cases. *See* Green, 86 Nw. U.L.Rev. 643. But unlike the present situation, the initial published studies involving both of those allegedly toxic agents were *negative* and the plaintiffs were trying to introduce expert testimony contrary to the published epidemiological studies.

In our ruling here we are not advocating the abdication of the judicial "gate-keeping" role, contemplated by ***Frye,*** to the editors of scientific and medical journals. In part, our ruling is a recognition that at this stage of these proceedings a sufficient record is not in place which would allow judicial scrutiny of these studies, spanning several scientific and medical disciplines, to determine the existence and seriousness of any methodological errors. While the experts in these cases testified at length, they testified only in a very general way about the qualities of the studies upon which they relied. Although the studies themselves are in the record, there is insufficient expert testimony on the quality of those studies to guide the court in making any legal conclusion about the probity of the studies. Researchers have methods for assessing the characteristics of persons included in the study and the risk of disease which can be used to rule out known sources of biases and error. On the basis of this record, this court cannot say that the researchers involved in these studies failed to employ such methods.

In addition, any such errors in these studies would principally affect the weight to be accorded the opinions based thereon. Our focus at this stage, however, is a more narrow one--whether to exclude expert testimony based on mere speculation or unreliable science. *Joiner v. General Elec. Co.,* 78 F.3d at 532. [FN16]

> FN16. Though certain of the federal decisions cited or discussed in this section of the opinion employ a ***Daubert*** analysis, rather than a ***Frye*** analysis, these opinions are nonetheless focusing on the reliability of the expert's methodology. Florida's ***Frye*** test is ultimately concerned with the reliability of the scientific principles or methodology upon which the expert bases his opinion. *See generally,* C. Ehrhardt, *Florida Evidence* §§ 702.3, 702.4 (1997). It is yet a matter of debate whether the ***Daubert*** test, in requiring that the reasoning or methodology underlying the testimony be scientifically valid, will be more liberal and allow more expert testimony than the ***Frye*** requirement that there be general acceptance of the underlying methodology. *Modern Scientific Evidence* at § 1-3.3.4. But we are satisfied that for the purposes of the analysis here, under the ***Frye*** test of general acceptance, that peer-reviewed epidemiological studies conducted independently of the instant litigation are the scientifically accepted means of analyzing human response to exposures to certain substances.

Finally, we decline to adopt the railroad's suggestion that we reject "statistically insignificant" studies. The use of "statistical significance" to reject an epidemiological study has been roundly criticized by the experts in the field. *See, e.g.,* Green, 86 Nw. U.L.Rev. at 681-93. Professor Green, for example, concludes that rejecting studies that are not statistically significant would be cursory and foolish. We find his explanation instructive:

> The *Brock* [*Brock v. Merrell Dow Pharm., Inc.,* 874 F.2d 307 (5th Cir.1989), *cert. denied,* 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed.2d 646 (1990)] decision, in ascribing wondrous powers to the concept of statistical significance, contributes to doubts that these matters are ones that reasonably can be mastered by generalist judges. Statistical significance addresses only random error due to the sampling inherent in any epidemiologic study. It cannot and does not speak to systematic error, which requires an informed review of the methodology employed in conducting the study. Moreover, statistical significance is merely an instrument for assisting in evaluating a study, not a truth serum that can be simplistically prescribed.
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> *Id.* at 681-82.

In sum, for the above reasons we decline to accept the railroad's invitation to examine these studies in detail ourselves and conclude without the basis of record evidence that they are deficient for the variety of reasons advanced by the railroad. CSX's claims of ***571** bias, lack of biological plausibility, and alleged other defects in these studies go to the weight, rather than the admissibility, of the studies. *See Ellis v. International Playtex, Inc.,* 745 F.2d 292, 303 (4th Cir.1984). If there are weaknesses or technical deficiencies in the published epidemiological studies supporting the plaintiffs' experts' opinions as the railroad claims, those perceived deficiencies are appropriate matters upon which to examine and cross examine the experts at trial and, then, for consideration by the fact finder. *In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d at 1132. In the instant cases, however, the claimed deficiencies are not a valid reason for excluding the experts' opinions.

[11] As argued by the appellants, the trial in the instant cases will be primarily a so-called "battle of the experts." The fact that the experts have all derived their opinions from the same generally-accepted methodology, the epidemiological studies contained in the record, but simply disagree upon how to interpret the scientifically (and legally) reliable data, is not a valid reason for excluding the plaintiffs' experts' opinions altogether. As

the court said in *In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d at 1135:

> For the district court to seize on the putative flaws of studies favorable to plaintiff, and then to privilege certain studies favorable to the defendant, was impermissibly to place a thumb on defendant's side of the scale and to encroach on the jury's prerogative to weigh the relative merits and credibilities of competing studies ... Thus, to the extent that none of the studies is flawless or dispositive, their relative merits seems to us to be a classic question for the jury. Trial courts should not arrogate the jury's role in "evaluating the evidence and the credibility of expert witnesses" by "simply cho[o]s[ing] sides in [the] battle of the experts." *Christophersen v. Allied-Signal Corp.,* 902 F.2d 362, 366 (5th Cir.1990).

[12] Finally, we must respectfully disagree with the trial court's rejection of Dr. Kelly's testimony on specific causation. Dr. Kelly employed the differential diagnosis method which is scientifically acceptable. *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d at 758; *Hines v. Consolidated Rail Corp.,* 926 F.2d at 274. Using this differential diagnosis, Dr. Kelly attempted to eliminate the other possible causes of **Berry's** symptoms. Unlike the situation in *In re "Agent Orange" Prod. Liab. Litig.,* 611 F.Supp. 1223, and other cases, Dr. Kelly had physical contact with **Berry** and personally examined him as well as supervised his treatment by other professionals. Dr. Kelly's opinion was not only based upon **Berry's** statements of his symptoms, but was based upon **Berry's** personal history, medical records, physical examinations and medical tests. In short, Dr. Kelly's opinion was based upon sufficient epidemiological data, facts and personal observation, and was therefore reliable.

REVERSED and REMANDED for further proceedings consistent with this opinion.

JOANOS and PADOVANO, JJ., concur.

APPENDIX A

Edward L. Baker, M.D., et al., *Neurobehavioral Effects of Solvents in Construction Painters,* 30 J. Occup. Med. 116 (1988)

Barbara Bazylewicz-Walczak, et al., *The Psychological Effects of Chronic Exposure to White Spirit in Rubber Industry Workers,* 3 Polish J. Occup. Med. 117 (1990)

Stig-Arne Elofsson, Ph.D., et al., *Exposure to Organic Solvents,* 6 Scand. J. Work Envtl. Health 239 (1980)

Evelin Escalona, M.D., et al., *Neurobehavioral Evaluation of Venezuelan Workers Exposed to Organic Solvent Mixtures,* 27 Am. J. Indus. Med. 15 (1995)

Anne T. Fidler, et al., *Neurobehavioral Effects of Occupational Exposure to Organic Solvents Among Construction Painters,* 44 Brit. J. Indus. Med. 292 (1987)

Helena Hanninen, et al., *Exposure to Organic Solvents and Neuropsychological Dysfunction: A Study on Monozygotic Twins,* 48 Brit. J. Indus. Med. 18 (1991)

Lisa A. Morrow, Ph.D., et al., *Alterations in Cognitive and Psychological Functioning* ****572*** *After Organic Solvent Exposure,* 32 J. Occup. Med. 444 (1990)

Lisa A. Morrow, Ph.D., et al., *A Distinct Pattern of Personality Disturbance Following Exposure to Mixtures of Organic Solvents,* 31 J. Occup. Med. 743 (1989)

Andreas Seeber, *Neurobehavioral Toxicity of Long-Term Exposure to Tetrachloroethylene,* 2 Neurotoxicology and Teratology 579 (1989)

A. Spurgeon, Ph.D., et al., *Neurobehavioral Effects of Long-Term Occupational Exposure to Organic Solvents: Two Comparable Studies,* 22 Am. J. Indus. Med. 325 (1992)

Kurt Rasmussen, M.D., et al., *Solvent-Induced Chronic Toxic Encephalopathy,* 23 Am. J. Indus. Med. 779 (1993)

R v. Dallagher

[2003] 1 Cr. App. R. 12)
Court of Appeal (UK)

July 25. Kennedy LJ handed down the following judgment in the Court:

1 On December 15, 1998 in the Crown Court at Leeds this appellant was convicted of murder and sentenced to life imprisonment. He appeals against conviction pursuant to leave which we granted at an early stage of the proceedings before us.

Facts.

2 During the early hours of May 7, 1996 Dorothy Wood was in bed at home at 32 Whitby Avenue, Huddersfield. She was 94 years of age, arthritic and totally deaf. It seems clear on the evidence, and has not been disputed in this appeal, that she was murdered by an intruder who, by means of a jemmy or screwdriver, forced open a small transom window above her bed and scrambled through it. He then suffocated his victim with her pillow. It was the case for the prosecution that the

appellant was the intruder.

3 Examination of the scene revealed ear prints on the glass of the window immediately below the transom window which was forced. The windows had been cleaned three or four weeks earlier. Those prints were examined by two experts who compared them with control prints provided by the appellant and others. The first expert was Mr Van Der Lugt, a Dutch police officer who had specialised in ear print comparison for over a decade. The second expert was Professor Vanezis, Regius Professor of Forensic Medicine and Science in the University of Glasgow. Both of those experts were satisfied that the ear prints found at the scene matched the control prints provided by the appellant, who lived not far away, and who had committed a number of dwelling house burglaries, frequently effecting entry by means of a transom window. In August 1996 he was sentenced to imprisonment for burglary, and shared a cell with X, an informant. According to X the appellant then revealed information about the killing, and in particular about the use of the pillow, which information was not in the public domain. It was therefore the case for the prosecution that the ear print identification was supported by the appellant's *modus operandi* and by what he revealed to X.

4 When interviewed about the killing on August 20, 1996 the appellant denied any involvement, and said that he had been with his girl friend Deborah Booth when the offence was committed, but that because she was asleep and on medication she would not be able to support his account.

At Trial.

5 At trial Mr David Hatton QC, leading counsel for the appellant, did not seek to exclude the evidence of the prosecution experts, but he did submit, unsuccessfully, that the evidence of other burglaries should not be admitted. The experts were cross examined, not on the basis that they had erred in making their comparisons, but on the basis that such comparisons are necessarily imprecise, and cannot point with any certainty to an individual who has provided a control print as being the person responsible for a print found at the scene of a crime. No expert evidence was called on behalf of the appellant who gave evidence ***198** in support of his alibi. The summing up was full and accurate, and the jury received appropriate directions as to the limited use which they could make of evidence that the appellant had committed other offences.

Later Developments.

6 Subsequently it emerged more clearly, if not for the first time, that some forensic scientists have misgivings about the extent to which ear print evidence alone can in the present state of knowledge safely be used to identify a suspect, and reports were obtained from Professor Moenssens in the United States, and Dr Champod of the Forensic Science Service in Solihull. Shortly before the appeal was due to be heard Professor Moenssens became unwell, and a report was then obtained from Professor Van Koppen in the Netherlands.

Grounds of Appeal.

7 Equipped with that additional information Mr Clegg QC and Mr Sturman QC for the appellant, neither of whom appeared at the trial, invited us to admit the report of Professor Moenssens and to receive the oral evidence of Dr Champod and Professor Van Koppen (which evidence was made available to us by video link) and, with the benefit of that evidence, counsel invited us to conclude that the conviction should be regarded as unsafe because it can now be seen that the appellant did not have a fair trial. Although various grounds of appeal are deployed in the amended Grounds of Appeal, and we were asked to permit an amendment to add a further ground, there were in the end only four grounds of appeal argued before us, namely --

(1) The jury should never have heard the expert evidence on which the Crown relied because in law it is inadmissible. If at trial defence counsel had had available the expert evidence on which the appellant now relies then, Mr Clegg submits, counsel would have been in a position to obtain from the trial judge, in the absence of the jury, a favourable ruling as to admissibility.

(2) Even if the ruling had not been favourable the availability of the evidence would have enabled defence counsel to cross examine more effectively, and to substantiate by calling expert evidence the points put in cross examination to the experts called on behalf of the Crown.

(3) In the absence of expert evidence for the defence the experts on whom the Crown relied were able to present their evidence in a way which was too favourable to the prosecution case, sometimes known as ' the prosecutor's fallacy'.

(4) In any event the judge was wrong to rule as he did in relation to the admissibility of evidence of previous burglaries.

8 In order to deal with the first three grounds of appeal it is necessary to look more closely at the expert evidence -- at the evidence given at trial and ***199** accurately summarised in the summing up, and at the fresh evidence from the experts on whom the appellant

now relies, to which evidence the Crown responded with further evidence from Mr Van Der Lugt and Professor Vanezis. We then have to consider what was done by the appellant's lawyers prior to trial to equip themselves with the sort of evidence on which the appellant now relies before we can conclude whether to receive the fresh evidence pursuant to s. 23 of the Criminal Appeal Act 1968. We can then go on to consider the first three Grounds of Appeal. The fourth Ground of Appeal is not entirely free standing, but it can conveniently be dealt with last.

Expert evidence at Trial.

9 As the judge pointed out to the jury, the expertise of ear print comparison "is in its relative infancy" and not many people have become involved with it. Mr Van Der Lugt's conclusion was that "he was sure that these ear prints were made by this defendant". Professor Vanezis considered that conclusion to be "highly likely". So the judge directed the jury as follows --

"If you are sure that Mr Van Der Lugt's evidence is correct and you accept it then you would be entitled to convict on his evidence alone. Professor Vanezis gave strong evidence, but was not as positive as Mr Van Der Lugt, it is for you to evaluate his evidence. If you rejected Mr Van Der Lugt's evidence but accepted Professor Vanezis' evidence then it is for you to decide whether on the basis of that evidence alone you could be sure that these were this defendant's ear prints. ... I direct you that if you reject Mr Van Der Lugt's evidence and you reject all the other supporting evidence you should not convict this defendant on Professor Vanezis's evidence alone."

The judge reminded the jury that although Mr Van Der Lugt had 27 years service as a police officer in Holland, and lectured at the Dutch Police College, he had no formal qualifications. He had simply become interested in ear print identification and read what was available on that topic. He had built up a portfolio of about 600 photographs and 300 ear prints and from his experience and what he had read he was satisfied that no two ear prints are alike in every particular. Professor Vanezis said the same in relation to ears, but questioned the value of measurements in relation to ear prints, because the ear is made up of relatively soft tissue which will distort and which may be presented at different angles to the hard surface on which the print is made. "Both experts agreed that it would be very useful if further research was done to see whether it were possible for prints from two separate ears to be produced showing apparent similarities ... both experts accept that that might well be a real possibility". For present purposes it is unnecessary to rehearse Mr Van Der Lugt's evidence as to the structure of the ear, but he made the point that it is rare for a print to be left by all of the raised parts of the ear, and he said that generally speaking he would look for five or six points when making a comparison, but he emphasised that what mattered was the totality of the evidence which he reviewed by use of overlays, choosing ***200** those from the available control prints which appeared to be set at an appropriate angle. Having carried out that exercise in relation to the four overlapping prints left at the scene of the crime in this case by a left ear he was "absolutely convinced that the prints of the defendant's left ear were identical with the prints of the left ear on the window." He then saw the original windowpane and found a right ear print, which he compared with the controlled prints of the appellant's right ear. He found seven points of similarity and two differences, for which he was able to account, so that "strengthened his initial conclusion that it was this defendant who had placed his ears against the window."

10 Professor Vanezis carried out similar comparisons using overlays, as illustrated on a video film which the jury saw and which we have seen, and the judge summarised his conclusion thus --

"Bearing in mind that we have here a print on the window of a right and left ear to compare against the known prints of the right and left ear of this defendant, there is a remote possibility that the impressions on the window may have been left there by somebody other than the defendant, but his firm opinion was that it was very likely that it was this defendant who made those prints, although he cannot be one hundred percent certain."

He accepted the desirability of a larger database and of more research to establish standards for comparison, but, as Mr Clegg emphasised to us, despite careful cross-examination neither expert on whom the Crown relied qualified his conclusion in any way.

Fresh Evidence

11 The evidence on which Mr Clegg based most reliance before us was that of Dr Champod who, with two others, after the trial in this case, wrote an article which was published in the Journal of Forensic Sciences. Before joining the Forensic Science Service he was an assistant professor at the University of Lausanne. He accepts that all ears are different, and, as we understand his evidence, that differences between ears can be discerned, but, as he put it in his report, "a high variability between ears does not imply necessarily that a high variability is expressed in marks left by different persons" and the evidence as to that is limited. Secondly the protocol used by Mr Van Der Lugt and Professor

Vanezis, although not unscientific, depends heavily at every stage on subjective comparisons and tolerances (e.g. how much to allow for pressure and distortion). With only a relatively narrow data base to work from the question is raised as to the value to be attributed to a match, and Dr Champod expressed serious reservations as to the way in which Mr Van Der Lugt and Professor Vanezis expressed their conclusions. In his view --

"(1) Because of the paucity of relevant research and because of court decisions in the Netherlands and United States the process of establishing the source of an unknown ear print based on a comparative ***201** examination with ear prints from known donors cannot be regarded as 'generally accepted in the scientific community.'

(2) There is no empirical research, and no peer review to support the conclusion that robust decisions can be founded on comparisons which in turn are critically dependant on the examiner's judgment in circumstances where there are no criteria for testing that judgment.

(3) In the present case the expert expressions of opinion could be viewed as manifestations of the prosecutor's fallacy. They should have said no more than that what they found supported to an appropriate degree the conclusion that the marks on the window were made by the defendant's ear."

12 In Switzerland ear prints left at the scenes of burglaries have been compared with controlled prints to assist in the early stages of investigation. They can be used to eliminate, but on occasions those believed to have left ear prints have been found to have genuine alibis. In summary Dr Champod's conclusion seems to be that at the present time ear print comparison can help to narrow the field, and may eliminate, but cannot alone be regarded as a safe basis on which to identify a particular individual as being the person who left one or more prints at the scene of a crime. He points out that neither the Forensic Science Service in the United Kingdom nor the Federal Bureau of Investigation in the United States carries out ear print comparisons.

13 Professor Van Koppen has five standards which he says can be used to test identification evidence, and he is critical of the identification evidence given at trial because in his opinion it did not meet those standards. It did not, for example, explain how different parts of the ear differed as between individuals. He was critical in his report of the assumption that nature does not repeat itself (an assumption which caused Dr Champod no discernible difficulty) and noted the small size of the database available for comparison. His report concludes thus --

"The validity of ear identification is unknown. The research that is necessary to say anything on the validity of ear identification has not been conducted. On top of that the method used by Van Der Lugt and Vanezis is subjective to an extent that they are unable to explain how they came to their judgment that there is a match between the ear mark found at the crime scene and the ear print from the suspect."

He pointed out that two convictions based on ear identification evidence, one in Holland and one in the United States, had been overturned on appeal.

14 We were not impressed by Professor Van Koppen's assertion that Mr Van Der Lugt and Professor Vanezis were unable to explain how they came to their judgment, and in cross examination Professor Van Koppen accepted that many if not all of the other criticisms he made were put to and accepted by Mr Van Der Lugt and Professor Vanezis at the trial. They accepted that there were very few people working in the field, and that the comparison work was in its infancy. They further accepted that the assumption that no ears are the same and ear prints ***202** are equally distinguishable, so that it is possible to avoid ascribing an ear print to more than one ear, is only an assumption based on a limited experience. They also accepted that because a print is two dimensional it does not reflect a three dimensional pliable ear in a way which is consistent and measurable so, perhaps as a consequence, there are no standard criteria to be applied, as there are with fingerprints.

15 The report of Professor Moenssens we consider to add nothing of any value, and we noted that although at an early stage we agreed to admit it pursuant to s. 30 of the Criminal Justice Act 1988 it was barely mentioned by counsel thereafter. Professor Moenssens is laudatory of Dr Champod, of whose work he was the peer reviewer, and he draws attention to the lack of formal academic qualifications of Mr Van Der Lugt and Mr Iannarelli (who was a pioneer in the field) in a patronising way which reflects little credit on the writer of the report.

16 For the respondent Mr Robert Smith QC re-called before us Mr Van Der Lugt and Professor Vanezis. Mr Van Der Lugt explained his comparison technique, including the use of unattributed control prints and overlays, and made the point that there is usually, as in this case, a difference between prints made by the right and left ears of any given individual. It is therefore significant that he was able to match both ears. By reference to the photographs and illustrations which were before the jury he identified the parts of the ears which he said had left a mark on the glass at the scene, and pointed out that he had been comparing ear prints since

1987. He has testified world-wide, and has published a book, copies of which we have. He accepted many of the points made by Mr Hatton (and now by Dr Champod and Professor Van Koppen), as to the limitations of ear comparison evidence at the present time, and would like to see more research work undertaken, but he does not consider that those points undermine his conclusion, which he only reached some time after he was first consulted and after additional information had been supplied.

17 Professor Vanezis pointed out that the methodology used by Mr Van Der Lugt, whom he regards as *the* expert, is grounded in established procedure. Modern technology enables the observer very slowly to wipe off a superimposed image, as can be seen on the video film to which we have already referred, thus enabling an observer to pinpoint similarities and differences. Measurements are of limited value. In the end what matters is the shape and the contour as observed by an experienced observer. Like Mr Van Der Lugt, Professor Vanezis agreed that more research is required, but he saw no reason to qualify the conclusion which he had expressed at the trial.

Reception of fresh evidence

18 Section 23 of the Criminal Appeal Act 1968, so far as material, provides that --

"(1) For the purposes of this Part of this Act the Court of Appeal may, if they think it necessary or expedient in the interests of justice --

(c) Receive any evidence which was not adduced in the proceedings from which the appeal lies.

***203** (2) The Court of Appeal shall, in considering whether to receive any evidence, have regard in particular to --

(a) Whether the evidence appears to the Court to be capable of belief;

(b) Whether it appears to the Court that the evidence may afford any ground for allowing the appeal;

(c) Whether the evidence would have been admissible in the proceedings from which the appeal lies on an issue which is the subject of the appeal; and

(d) Whether there is a reasonable explanation for the failure to adduce the evidence in those proceedings." Clearly the evidence of Dr Champod and Professor Van Koppen satisfies the requirements of s.23(2)(a) and (c), and s.23(2)(b) raises issues to which we turn when we consider the individual grounds of appeal, so we concentrate for the moment on s.23(2)(d). It is clear from the affidavits of counsel who appeared for the appellant at his trial that considerable efforts were made to assemble expert evidence for the defence. Junior counsel contacted Professor Moenssens and others, and concluded that there was at that time no independent expert evidence available to assist the defence. That conclusion was conveyed to leading counsel. In the United States and in Holland ear print comparison evidence given by Mr Van Der Lugt had been received and acted upon, and, having carefully considered the state of English law as to admissibility, Mr Hatton concluded that any attempt to exclude the evidence of Mr Van Der Lugt and Professor Vanezis would fail. He therefore made no such attempt, and, without any expert evidence to assist him, sought by means of cross-examination to expose the limitations of the comparison evidence on which the Crown relied. It was only after the appellant had been convicted that Dr Champod published his article, and that a report was obtained with some difficulty from Professor Moenssens by fresh solicitors acting for the appellant. The report drew attention to the article. It was also after the applicant had been convicted that the first instance decisions in the United States and Holland were reversed on appeal. In those circumstances Mr Clegg submits that there is demonstrated in this case a reasonable explanation for the failure to adduce the evidence of Professor Moenssens, Dr Champod and Professor Van Koppen in the proceedings from which the appeal lies.

19 Mr Smith submits that Mr Hatton was right to conclude as he did in relation to admissibility, and that even if he was wrong the reality is that the evidence now relied upon, or some expert evidence making similar points, could have been obtained by the defence prior to trial. He points out that there was contact with Professor Moenssens, who knew of others who shared his views, and that it is not necessary for an expert to have made ear comparisons himself or herself before the expert can make the sort of criticisms made in cross examination at trial and developed in the fresh evidence. No one suggests that it was for tactical reasons that expert evidence was not adduced by the defence at trial, but Mr Smith submits that this Court should be slow to receive fresh evidence when ***204** in reality all that is demonstrated is that the defence could have been conducted differently.

20 We were reminded that in R. v Ullah [2000] 1 Cr App R 351 Rose LJ said at 357 that the ultimate issue for the Court of Appeal is whether the conviction is safe, but he went on to say that ineptitude "is a necessary prerequisite to any challenge to the safety of a conviction based on counsel's conduct. Put another way, wanting safety in a conviction cannot be based on a decision by counsel merely because other counsel might not have made that decision." That was cited with approval by

Lord Woolf CJ in R. v Martin [2002] 1 Cr App R 323 at 335.

21 In our judgment the evidence laid before us as to the steps taken by defence counsel to prepare for trial, coupled with the developments which have taken place in relation to ear comparison evidence since conviction, constitute a reasonable explanation for the failure to adduce at the trial the expert evidence on which Mr Clegg now wishes to rely. If, in our judgment, that evidence may afford any ground for allowing the appeal then, as it seems to us, it must be necessary or expedient in the interests of justice to receive it. We therefore turn to consider the grounds of appeal in the light of the fresh evidence, bearing in mind the submission made by Mr Smith that the fresh evidence adds nothing because it merely re-iterates points effectively made by Mr Hatton in cross-examination.

Admissibility of Crown's expert evidence

22 As we have indicated, Mr Clegg's first ground of appeal is that in English law the evidence of Mr Van Der Lugt and Professor Vanezis is and should be held to have been inadmissible. He submits that if Mr Hatton had been equipped with the fresh evidence now relied upon he could and would have made that submission to the trial judge, and that his submission should have been accepted.

23 Before we go any further it is worth considering precisely what evidence it is contended should be excluded. It is accepted that there is no basis for excluding evidence of what was found at the scene, including the evidence of the ear prints on the glass. When the appellant was arrested he provided ear prints which, having been anonymised, were put with other prints and compared with the prints found at the scene. It is difficult to see on what basis it would be possible to exclude the evidence of those steps having been taken as part of the investigatory process, or the evidence of the conclusion reached by the examiner. What matters, as it seems to us, is the value of the conclusion. In R. v Robb (1991) 93 Cr App R 161 a phonetician had identified the appellant's voice using an auditory technique which was regarded by orthodox professional opinion as unreliable unless supplemented and verified by acoustic analysis, but this Court refused to hold that the expert evidence was inadmissible. Having referred to R. v Silverlock [1894] 2 QB 766 Bingham LJ said at 165 that the two essential questions are whether study and experience will give a witness's opinion an authority which the opinion of one not so qualified will lack, and (if so) whether the witness in question is skilled and has adequate knowledge. He continued -- ***205**

"If these conditions are met the evidence of the witness is in law admissible, although the weight to be attached to his opinion must of course be assessed by the tribunal of fact."

24 The principled approach to admissibility set out in Robb is not in any way affected by the fact that, as indicated in the recent Northern Ireland case of R. v O'Doherty [2003] 1 Cr App R 77 (reference NICB 3173), technology has moved on, so that at least in Northern Ireland the expert's technique relied upon in Robb would no longer be regarded as adequate.

25 In R. v Stockwell (1993) 97 Cr App R 260 a facial mapping expert was called to assist the jury as to whether the defendant's face appeared on video films taken during two separate incidents, a robbery and an attempted robbery. Lord Taylor CJ referred to what had been said about expert evidence in R. v Turner (1975) 60 Cr App R 80, and continued that where there may have been a disguise a comparison of photograph and defendant may not be straightforward. The same could be said of a comparison of ear prints. Lord Taylor said at 97 Cr App R 260, 264 --

"In such circumstances we can see no reason why expert evidence, if it can provide the jury with information and assistance they would otherwise lack, should not be given. In each case it must be for the judge to decide whether the issue is one on which the jury could be assisted by expert evidence, and whether the expert tendered has the expertise to provide such evidence."

Facial mapping was a relatively new technique, and this Court agreed with the trial judge that "one should not set one's face against fresh developments, provided that they have a proper foundation."

26 In R. v Strudwick and Merry (1994) 99 Cr App R 326 a mother and her co-habitee were convicted of manslaughter and cruelty, the victim being a young child. The trial judge had excluded psychological evidence which counsel for the female defendant wanted to adduce, and this Court held that he was right to do so because the evidence was not likely to afford to the jury the kind of help without which they would be unable to do justice in her case.

27 R. v Clarke [1995] 2 Cr App R 425 was another case concerned with facial mapping. By means of video superimposition a bank photograph of the defendant was compared with photographs taken at the scene of a robbery. This Court upheld the decision of the trial judge that the evidence was admissible. At 429 Steyn LJ said --

"It is essential that our criminal justice system should take into account modern methods of crime detection. It is no surprise, therefore, that tape recordings, photographs and films are regularly placed before juries. Sometimes that is done without expert evidence, but, of course, if that real evidence is not sufficiently intelligible to the jury without expert evidence, it has always been accepted that it is possible to place before the jury the opinion of an expert in order to assist them in their interpretation of the ***206** real evidence. The leading case on that point is Turner (1974) 60 Cr App R 80, [1975] Q B 834. We would add this. There are no closed categories where such evidence may be placed before a jury. It would be entirely wrong to deny to the law of evidence the advantages to be gained from new techniques and new advances in science."

Reference was then made to Stockwell and Steyn LJ went on to say --

"We are far from saying that such evidence may not be flawed. It is, of course, essential that expert evidence, going to issues of identity, should be carefully scrutinised. Such evidence could be flawed. It could be flawed just as much as the evidence of a fingerprint expert could be flawed. But it does not seem to us that there is any objection in principle."

Counsel for the appellant had contended that expert evidence was not necessary and ought not to have been admitted because the jurors could see for themselves the photographs as partly enhanced on the video. The Court rejected that submission, saying at 431 --

"This is clearly a case like Stockwell where the comparison was not an entirely straight forward one."

It added --

"The probative value of such evidence depends on the reliability of the scientific technique (and that is a matter of fact), and it is one fit for debate and for exploration in evidence."

The Court then turned to the second ground of appeal which asserted that the evidence should have been excluded because the technique was "too dangerous". That had been explored at a *voire dire* during which the trial judge heard expert evidence and concluded that the evidence did have probative value.

28 That brings us to R. v Gilfoyle (No 2) [2001] 2 Cr App R 57 on which Mr Clegg places some reliance. The appellant in that case was convicted of the murder of his pregnant wife, and on a reference by the Criminal Cases Review Commission this Court agreed with the trial judge's decision not to admit evidence from a psychologist as to the deceased's state of mind. Six reasons were given for that conclusion, the fifth of which was that there is English, Canadian and United States authority which points against the admission of such evidence. Having referred to some authorities in all three jurisdictions Rose LJ said at para 25, p.68:

"The guiding principle in the United States appears to be (as stated in **Frye** v United States 293 F.1013 (1923)) that evidence based on a developing new brand of science or medicine is not admissible until accepted by the ***207** scientific community as being able to provide accurate and reliable opinion. This accords with the English approach as reflected in Strudwick and Merry (1993) 99 Cr App R 326."

29 It is clear from **Daubert** v Merrell Dow Pharmaceuticals Inc (1993) 509 US 579, to which it seems that this Court in Gilfoyle was only indirectly referred, that **Frye** does not represent the guiding principle in the United States. It was superseded by the adoption of the Federal Rules of Evidence which do not require that a scientific technique be regarded as inadmissible unless the technique is generally accepted as reliable in the relevant scientific community. Rule 702 provides --

"If scientific, technical or other specialised 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."

As to the English approach we have found it necessary to refer not only to Strudwick and Merry but also to a number of other decisions, especially Clarke, from which, as it seems to us, the analogy with rule 702 is clear. As is said in the current ninth edition of *Cross and Tapper on Evidence*at 523 after a reference to **Frye** --

"The better, and now more widely accepted, view is that so long as the field is sufficiently well-established to pass the ordinary tests of relevance and reliability, then no enhanced test of admissibility should be applied, but the weight of the evidence should be established by the same adversarial forensic techniques applicable elsewhere."

We are satisfied that if a submission had been made to the trial judge that the expert evidence upon which the Crown proposed to rely was inadmissible, and if that evidence had been deployed on a *voire dire*, whether with or without expert evidence called on behalf of the defence, the trial judge could not possibly have concluded that the Crown's expert evidence was irrelevant, or so unreliable that it should be excluded. Accordingly in our judgment the first ground of appeal fails.

Grounds 2 and 3

30 We come now to what we regard as the more

difficult question of whether the jury was properly equipped to assess the weight to be attached to the findings of Mr Van Der Lugt and Professor Vanezis, and in that context it is convenient to look first at the criticism of the way in which they expressed their conclusions.

31 In R. v Doheny and Adams [1997] 1 Cr App R 369 this court set out procedures which should be adopted when DNA evidence is involved, and at 373 C Phillips LJ said that -- ***208**

"The prosecutor's fallacy can be simply demonstrated. If one person in a million has a DNA profile which matches that obtained from the crime stain, then the suspect will be one of perhaps 26 men in the United kingdom who share that characteristic. If no fact is known about the defendant, other than that he was in the United Kingdom at the time of the crime, the DNA evidence tells us no more than that there is a statistical probability that he was the criminal of one in 26."

At 373 F Phillips LJ continued --

"The reality is that, provided that there is no reason to doubt either the matching data or the statistical conclusion based upon it, the random occurrence ratio deduced from the DNA evidence, when combined with sufficient additional evidence to give it significance, is highly probative. As the art of analysis progresses, it is likely to become more so, and the stage may be reached when the match will be so comprehensive that it will be possible to construct a DNA profile that is unique and which proves the guilt of the defendant without any other evidence. So far as we are aware that stage has not yet been reached."

At 374 D Phillips LJ said --

"When the scientist gives evidence it is important that he should not over step the line which separates his province from that of the jury.

He will properly explain to the jury the nature of the match ('the matching DNA characteristics') between the DNA in the crime stain and the DNA in the blood sample taken from the defendant. He will properly, on the basis of empirical statistical data, give the jury the random occurrence ratio -- the frequency with which the matching DNA characteristics are likely to be found in the population at large. Provided that he has the necessary data, and the statistical expertise, it may be appropriate for him then to say how many people with the matching characteristics are likely to be found in the United Kingdom -- or perhaps in a more limited relevant sub-group, such as, for instance, the caucasian sexually active males in the Manchester area.

This will often be the limit of the evidence which he can properly and usefully give. It will then be for the jury to decide, having regard to all the relevant evidence, whether they are sure that it was the defendant who left the crime stain, or whether it is possible that it was left by some one else with the same matching DNA characteristics.

The scientist should not be asked his opinion on the likelihood that it was the defendant who left the crime stain, nor when giving evidence should he use terminology which may lead the jury to believe that he is expressing such an opinion."

32 ***209** Mr Clegg submits that in the present case Mr Van Der Lugt and Professor Vanezis did over step the line, when giving the evidence to which we have already referred. Mr Van Der Lugt said that when comparing control print 1061 with the print left at the scene he found them to be the same except for differences that he could account for, then the judge asked --

"Q. Then was the unknown print and the known print made by the same ear or different ears, so that I am absolutely clear?

A. They were made by the same ear.

Q. And how convinced are you of that?

A. I am absolutely convinced that they are from the same donor."

Later the witness said --

"In my opinion the unknown prints found at Miss Wood's home are from donor 1061 which is the defendant in this case. So he produced those left and right ear prints on the window."

33 Professor Vanezis was a little less emphatic. He said --

"My conclusion was that it was the closest match for the overall fit of the prints. That is both left and right. That is 1061."

In cross-examination he said --

"All I can say is that bearing in mind that we have left and right ear prints and with the paucity of knowledge etc, I am prepared to go so far as to say that there is a remote possibility ... that they may have been left by some one else, but it is remote. .... I am of the firm opinion that it is very likely to be the same person, but I cannot be 100% positive."

34 As Mr Smith points out, the firm views expressed by the witnesses have to be read in context. Both experts accepted that they were working on the assumption that any questioned ear print of adequate quality can only be ascribed to one ear and that each ear and each ear print is discernibly different, an assumption supported by relatively limited information. Also, as any juror can appreciate, comparisons such as were made in this case cannot be expressed in terms of statistical probability. On the basis that his assumptions are correct the expert

has made his comparison and has been unable to find any difference between the control print and the questioned prints other than differences for which he can account. His conclusion is obvious, and so as to eliminate any possibility of error it seems better for it to be expressed. So, in our judgment, there is no reason in this case to be critical of the way in which the evidence of the experts was adduced, and there is no substance in ground 3, but the very strength of the Crown's expert evidence is what causes us concern. In R. v Pendleton [2002] 1 Cr App R 441, [2002] 1 WLR 72 the House of Lords considered the test to be ***210** applied by this court when fresh evidence is heard, and at para 19 Lord Bingham said --

"It will usually be wise for the Court of Appeal, in a case of any difficulty, to test their own provisional view by asking whether the evidence, if given at the trial, might reasonably have affected the decision of the trial jury to convict. If it might, the conviction must be thought to be unsafe."

In order to apply that test we are prepared to assume that the evidence of other burglaries was rightly admitted, thus enabling the prosecution to point to the unlikelihood of an erroneous "blind" identification by Mr Van Der Lugt and Professor Vanezis having selected a man who --

(1) lived not far from the scene of the crime

(2) habitually used the means of entry used by the criminal -- listening at the door or window and then forcing open a small and sometimes relatively inaccessible transom window with a chisel or screwdriver so as to enable him with a degree of athleticism to wriggle through

(3) When in custody, if X is to be believed, accepted that he had something to do with the relevant crime, and referred to features (such as the use of a pillow, and the presence of a white fence) which were not widely known.

Even so it seems to us that the fresh evidence, if given at the trial, might reasonably have affected the approach of the trial jury to the crucial identification evidence of the experts and thus have affected the decision of the jury to convict. Mr Smith said at one point that all that was missing was the potential impact on the jury of hearing the defence experts live. That is right, but the omission was significant. As we have observed, the jury was directed that they could convict on the evidence of Mr Van Der Lugt alone. It follows that the fresh evidence does afford a ground for allowing the appeal, it is necessary and expedient in the interests of justice that we receive that evidence, and having received it we must find the conviction to be unsafe.

Ground 4 and conclusion

35 In the light of our conclusion in relation to ground 2 it is unnecessary and undesirable for us to express any reasoned conclusions in relation to ground 4. Suffice to say that we were not persuaded that the trial judge erred, but the issue of the admissibility of evidence of other burglaries will have to be re-assessed in the context of the retrial that we propose to order.

36 We therefore quash the conviction. We are satisfied that the interests of justice require that there be a retrial, indeed Mr Clegg does not argue otherwise, so we order that there be a retrial at Leeds or such other venue as a Presiding Judge of the North Eastern Circuit may direct on an indictment to be preferred within two months of todays date. Meanwhile the appellant, or the defendant as he now is, ***211** will remain in custody. If, as we expect, the appellant wishes to have legal representation for the purposes of the retrial, and is in no position to pay for it, we would grant legal aid for a solicitor and for one leading and one junior counsel.

Appeal allowed. Conviction quashed. Retrial ordered.

R. v. Blanchard

Newfoundland Supreme Court [Appeal Division]

Judgment: December 4, 1996
456 A.P.R. 316, 146 Nfld. & P.E.I.R. 316
Proceedings: Affirming (1994), 118 Nfld. & P.E.I.R. 254, 369 A.P.R. 254 (Nfld. T.D.)

The judgment of the court was delivered by *Cameron J.A.*:

1Both appellants were convicted of the same offence: possession of big game or parts thereof taken contrary to s. 38 (1) of the *Wild Life Regulations, 1984*, an offence under the *Wild Life Act*. Both convictions were appealed to the Summary Conviction Appeal Court where the appeals were denied by Mr. Justice Roberts. There was only one issue before Roberts J., as is the case before this Court: did the trial judge err in admitting the evidence of Dr. Norman Fish as an expert in the field of animal identification and in determining the time of kill through analysis of specimens? The issues in the two cases being identical, before this Court the two cases were heard at the same time and this decision is applicable to both.

2Counsel for the appellants argues that the evidence of Dr. Fish, as it relates to the time of the kill, was in a

novel field of expertise and prior to its admission certain criteria should have been met but were not. In essence, Counsel for the appellants seeks to have applied the test enunciated in ***Frye*** *v. United States*, 293 F. 1013 (U.S. 1923). He cites as additional authority, *R. v. Phillion* (1977), 33 C.C.C. (2d) 535 (S.C.C.) and *R. v. Medvedew* (1978), 43 C.C.C. (2d) 434 (Man. C.A.). The respondent argues that the cases before this Court do not involve novel scientific evidence and, alternatively, even if they do, the standards required by Canadian law have been met.

3With respect, **Frye** does not represent the law in Canada. Indeed, it seems that it no longer reflects the law of the United States (***Daubert*** *v. Merrell Dow Pharmaceuticals Inc.*, 118 S.Ct. 2786 (U.S. 1993)). In *The Law of Evidence in Canada* by Sopinka, Lederman & Bryant (Toronto: Butterworths, 1992) the authors state at p. 569:

4To date, Canadian courts have not attempted to formulate a single rule for the admissibility of new scientific evidence. Rather, the courts first apply the traditional exclusionary rules, the expert evidence rule and then invoke policy reasons specific to the particular proffered evidence to determine admissibility. This appears to be the preferable route and it accords with the present trend in the American federal courts.

5It is not surprising that the view expressed in the text is consistent with that subsequently expressed by Sopinka J., *R. v. Mohan* (1994), 89 C.C.C. (3d) 402 (S.C.C.). In Canada, expert evidence will be received if it is relevant to a fact in issue, the expert is properly qualified, the expert evidence is necessary, in the sense that it provides information which is likely to be outside the experience and knowledge of a judge or jury, and there are no exclusionary rules in operation. On p. 415 of *Mohan*, Sopinka J. said:

6In summary, therefore, it appears from the foregoing that expert evidence which advances a novel scientific theory or technique is subjected to special scrutiny to determine whether it meets a basic threshold of reliability and whether it is essential in the sense that the trier of fact will be unable to come to a satisfactory conclusion without the assistance of the expert. The closer the evidence approaches an opinion on an ultimate issue, the stricter the application of this principle.

7It is clear that unlike the test enunciated in ***Frye***, in Canada, general acceptance in the scientific community need not be established as a prerequisite to admission of evidence based on a novel scientific theory, though this may be a factor in assessing reliability as would validity of the reasoning and methodology underlying the evidence. So then, the failure to establish general acceptance is not fatal in these cases, if indeed we are dealing with a novel theory.

8Counsel for the appellants opposed the qualification of Dr. Fish as an expert witness in both cases. However, in light of Dr. Fish's education, experience, research and extensive history in analysis of animals, which includes 160 appearances before courts in Ontario, the Maritimes and Newfoundland, it is difficult to see how the trial judge could do otherwise than admit the evidence, in the absence of testimony on a voir dire supporting the contention of the defence that no such field of expertise exists. What evidence there was to contradict the evidence of Dr. Fish came in the case for the defence and would have been weighed by the trial judge in deciding whether or not to accept the evidence of Dr. Fish in the cases. The trial judge obviously chose to accept Dr. Fish's evidence. Even if I would have done otherwise, there is no basis to interfere with that decision.

9I see no error in the decisions of the trial judge or the Summary Appeal Court judge that the evidence of Dr. Fish was admissible. Leave to appeal is granted. The appeals are dismissed.

Appeals dismissed.