



6-1-1994

Nasty Medicine: Daubert v. Merrell Dow Pharmaceuticals, Inc. Applied to a Hypothetical Medical Malpractice Case

Katherine M. Atikian

Follow this and additional works at: <https://digitalcommons.lmu.edu/llr>



Part of the [Law Commons](#)

Recommended Citation

Katherine M. Atikian, *Nasty Medicine: Daubert v. Merrell Dow Pharmaceuticals, Inc. Applied to a Hypothetical Medical Malpractice Case*, 27 Loy. L.A. L. Rev. 1513 (1994).

Available at: <https://digitalcommons.lmu.edu/llr/vol27/iss4/8>

This Notes and Comments is brought to you for free and open access by the Law Reviews at Digital Commons @ Loyola Marymount University and Loyola Law School. It has been accepted for inclusion in Loyola of Los Angeles Law Review by an authorized administrator of Digital Commons@Loyola Marymount University and Loyola Law School. For more information, please contact digitalcommons@lmu.edu.

**NASTY MEDICINE: *DAUBERT V. MERRELL DOW
PHARMACEUTICALS, INC.* APPLIED TO A
HYPOTHETICAL MEDICAL
MALPRACTICE CASE**

I. INTRODUCTION

At the end of its 1992-1993 term, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹ Justice Harry Blackmun's majority opinion discussed at length the considerations that should govern admissibility of scientific expert evidence under the Federal Rules of Evidence.² Rather than adhering to the traditional *Frye v. United States* "general acceptance" test,³ the *Daubert* majority set forth its own "general observations," which, compared to the *Frye* test, it deemed more consistent with the letter and spirit of the Federal Rules of Evidence.⁴ In addition, the majority stressed the role of the trial judge in assessing "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue."⁵ The majority asserted its confidence "that federal judges possess the capacity to undertake this review."⁶

This Note argues that the *Daubert* Court's new standards—if they can be called such—are inadequate as decisional guidelines because they will spawn confusion rather than foster clarity, and that *Daubert* would have been a wiser decision had it embraced the *Frye* test.

1. 113 S. Ct. 2786 (1993).

2. *Id.* at 2796-98.

3. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), *superseded by* FED. R. EVID. 702, *construed in* *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993). *Frye* is discussed in detail *infra* part II.B. In denying admissibility of the results of a primitive lie detector test, the *Frye* court stated that

[j]ust 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.*

Frye, 293 F. at 1014 (emphasis added).

4. *Daubert*, 113 S. Ct. at 2796-98.

5. *Id.* at 2796.

6. *Id.*

The *Daubert* guidelines, as this Note demonstrates, are far too indefinite to be intelligible rules of decision. The Court described "the inquiry . . . [as] a flexible one,"⁷ but almost could have described it as a standardless one. Lawyers undoubtedly will strive to take advantage of the new judicial latitude and ambiguity to gain the sympathy of scientifically ignorant juries through sketchy, pseudoscientific evidence that was previously inadmissible under the *Frye* standard.⁸ The *Daubert* Court's "general observations" are, as Chief Justice Rehnquist stated in his dissent, "not only general, but vague and abstract."⁹ Moreover, the *Daubert* Court did not spell out just how it expected these "observations" to be applied by trial judges: It simply remanded the case for "further proceedings consistent with this opinion."¹⁰ Hence, trial courts are left to their own devices in applying the *Daubert* principles. Thus, this lack of specific standards may inevitably lead to an array of inconsistent results.

Furthermore, the *Daubert* Court's vision that judges will successfully fulfill their "gatekeeping role,"¹¹ effectively excluding unreliable and irrelevant expert testimony, is arguably unrealistic. Judges are not scientists. In many cases it will likely impose immense burdens upon trial judges to expect them to gain an adequate understanding of proffered scientific evidence.¹² Even when judges do possess the skill to

7. *Id.* at 2797.

8. Although both plaintiffs and defendants can attempt to introduce "junk science"—for a definition see *infra* note 283—*Daubert* may prove more of a tactical advantage for plaintiffs' lawyers. This is true particularly in cases like *Daubert*, where natural sympathy for the plaintiff increases the likelihood of a plaintiff's verdict should the plaintiff's case get to the jury. See, e.g., Richard C. Reuben, *Brave New World*, CAL. LAW., Sept. 1993, at 31, 31 (interviewing defense attorney Raoul D. Kennedy, who, when asked about implications of *Daubert* ruling, stated that "plaintiffs got the better of it"). For that reason, the hypothetical presented *infra* part III.A is structured in such a way that the plaintiff is the party offering the questionable evidence. This Author recognizes, however, that defendants may offer junk science as well.

9. *Daubert*, 113 S. Ct. at 2799 (Rehnquist, C.J., dissenting).

10. *Id.*

11. *Id.* at 2798-99.

12. Trial judges are better educated than the average juror, but "[t]rial judges are trained in law and rarely have a technical background." John W. Wesley, Note, *Scientific Evidence and the Question of Judicial Capacity*, 25 WM. & MARY L. REV. 675, 685 (1984) (footnote omitted). Moreover, a judge's use of outside sources for background information will not necessarily guarantee that he or she will adequately grasp the presented scientific evidence. *Id.* at 685-86. Juries also have difficulty in comprehending medical and scientific evidence: "In medical malpractice actions the lay jury simply has no basis in education, training, or experience upon which to arrive at a rational and reasoned verdict." Robert G. Miceli, M.D., *Deprivation of Due Process for Physicians: The "Failure to Diagnose" Cause of Action*, 33 ST. LOUIS U. L.J. 859, 944 (1989). The same problem arguably afflicts judges who lack scientific or technical training in whatever aspect of medicine is at issue. In addition, jurors often regard scientific evidence as more credible than other evidence, regularly overestimating its probative

master the science, time constraints may tempt them to cut corners and make hasty decisions.¹³

Because these matters are difficult to discuss abstractly, and because a *coherent* body of case law will not soon—if ever—develop under *Daubert*,¹⁴ this Note examines the ramifications of *Daubert* in the context of a hypothetical medical malpractice case. Part II reviews the facts of *Daubert*, the traditional *Frye* test for admission of scientific evidence, and the *Daubert* Court's majority and dissenting opinions. Part III analyzes the admissibility of two different hypothetical experts' testimony in a hypothetical medical malpractice case, first under *Daubert*, and then under *Frye*. The problems with admitting each experts' testimony are also discussed. Part IV proposes that *Daubert* be abandoned and that federal courts return to the *Frye* test, utilizing preappointed committees of experts to rule on general acceptance of scientific techniques. These committees will help ensure that only valid, generally accepted scientific evidence is admitted.

II. STATEMENT OF THE CASE AND HISTORICAL BACKGROUND

A. *The Facts of Daubert*

Plaintiffs-petitioners were two children and their parents.¹⁵ They alleged that Bendectin, a drug manufactured by Merrell Dow Pharmaceuticals and ingested by the mothers during pregnancy, caused

value. See Renee A. Forinash, Comment, *Analyzing Scientific Evidence: From Validity to Reliability with a Two-Step Approach*, 24 ST. MARY'S L.J. 223, 243 (1992). Similarly, a judge who lacks the technical training to grasp and evaluate proffered scientific evidence may be tempted to allow such evidence uncritically and let the jury sort it out.

13. Regarding this dilemma, one commentator aptly observed, "The ideal solution would be to have judges who specialize in scientific matters, but I don't see that happening for some time." Natalie Angier, *Court Ruling on Scientific Evidence: A Just Burden*, N.Y. TIMES, June 30, 1993, at A8 (quoting Dr. F. Sherwood Rowland, president of American Association for the Advancement of Science).

14. At best, it will take considerable time for the Court to illustrate the application of its new principles through analyses and rulings upon actual expert testimony dilemmas. The process of fleshing out *Daubert*'s "general observations" cannot happen quickly because courts lack constitutional authority to announce hypothetical results or render advisory opinions. See U.S. CONST. art. III, § 2 (requiring that there be case or controversy before federal courts render decisions); *Princeton Univ. v. Schmid*, 455 U.S. 100, 102 (1982) ("We do not sit to decide hypothetical issues or to give advisory opinions about issues as to which there are not adverse parties before us."); *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975) ("The exercise of judicial power under Art. III of the Constitution depends on the existence of a case or controversy."); *Asbury Hosp. v. Cass County*, 326 U.S. 207, 213-14 (1945) ("This Court is without power to give advisory opinions. It will not decide constitutional issues which are hypothetical, or in advance of the necessity for deciding them . . .").

15. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2791 (1993).

the children's limb-reduction birth defects.¹⁶ The mothers' doctors prescribed Bendectin to treat nausea and vomiting during pregnancy.¹⁷ The district court dismissed the case on summary judgment,¹⁸ reasoning that the plaintiffs did not meet their burden of proof by "com[ing] forward with statistically significant epidemiological evidence"¹⁹ of causation, and that their evidence supported, at best, the contention that "Bendectin could *possibly* have caused plaintiffs' injuries."²⁰ Merrell Dow, for its part, had "introduced evidence that *no* epidemiological study ever performed ha[d] concluded that the use of Bendectin by pregnant women [significantly correlated with the incidence of] birth defects in those women's children."²¹ Furthermore, the plaintiffs relied upon a study that "was apparently never published or subjected to peer review."²² The district court therefore held that there was no competent proof of a causal connection between the use of Bendectin and the birth defects,²³ and accordingly granted summary judgment for the drug manufacturer.²⁴

The Ninth Circuit Court of Appeals affirmed.²⁵ Relying on the *Frye* general acceptance test,²⁶ the district court's decision, and the outcome of Bendectin litigation in three other circuits,²⁷ the Ninth Circuit held that "the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provided insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries."²⁸ The Ninth Circuit further observed that the plaintiffs' reanalyses of epidemiological studies were not "generally accepted by the scientific community" because "they were unpublished, not subjected to the normal peer review process and generated solely for use in litigation."²⁹

16. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570, 571 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991), *vacated and remanded*, 113 S. Ct. 2786 (1993).

17. *Id.*

18. *Id.* at 576.

19. *Id.* at 575.

20. *Id.* at 576.

21. *Id.* at 575 (emphasis added).

22. *Id.*

23. *Id.* at 576.

24. *Id.*

25. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* [*Daubert II*], 951 F.2d 1128 (9th Cir. 1991), *vacated and remanded*, 113 S. Ct. 2786 (1993).

26. *Id.* at 1129.

27. *Id.* at 1130 (citing *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987)).

28. *Id.* at 1131.

29. *Id.*

The United States Supreme Court granted certiorari³⁰ “in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony.”³¹ Agreeing with plaintiffs, the Court concluded that the Federal Rules of Evidence superseded the *Frye* test.³²

B. The *Frye* “General Acceptance” Test

In 1923 the Court of Appeals of the District of Columbia Circuit issued a terse opinion in which it created the *Frye* “general acceptance” test.³³ At issue in that 1923 murder case was the admissibility of a systolic blood pressure deception test,³⁴ “a crude precursor to the polygraph [lie detector] machine.”³⁵ Having undergone this test prior to trial, the defendant offered as an expert witness the scientist who conducted the test to describe its results.³⁶ Both the trial and appellate courts ruled the evidence inadmissible.³⁷ The appellate court held that because it was difficult to define “[j]ust when a scientific principle or discovery crosses the line between the experimental and demonstrable stages,” the proffered scientific testimony “must be sufficiently established to have gained *general acceptance* in the particular field in which it belongs.”³⁸ The *Frye* court concluded that since the systolic blood pressure deception test had not yet gained such general acceptance among scientists, its results were inadmissible.³⁹

Prior to the enactment of the Federal Rules of Evidence, many courts encountering the problem of novel scientific evidence relied upon the *Frye* court’s “general acceptance” standard.⁴⁰ Approval of the *Frye* test, however, was not universal.⁴¹ In the 1960s and 1970s, “the legal profession began to nibble, scratch, pick, and poke at the old [*Frye*] rule,

30. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 320 (1992).

31. *Daubert*, 113 S. Ct. 2786, 2792. Compare *United States v. Shorter*, 809 F.2d 54, 59-60 (D.C. Cir.) (applying general acceptance standard), *cert. denied*, 484 U.S. 817 (1987), with *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990) (rejecting general acceptance standard).

32. *Daubert*, 113 S. Ct. at 2793.

33. See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), *superseded by* FED. R. EVID. 702, *construed in* *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993).

34. *Id.*

35. *Daubert*, 113 S. Ct. at 2793.

36. *Frye*, 293 F. at 1014.

37. *Id.*

38. *Id.* (emphasis added).

39. *Id.*

40. 3 JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN’S EVIDENCE 702-34 to 702-35 (1992).

41. See *infra* notes 47-54 and accompanying text.

until in some circles the tattered remains were swept aside entirely."⁴² Reasons for this challenge may have included the "technologically pessimistic and anti-establishment" mood prevailing in the 1960s and 1970s,⁴³ and the fact that the *Frye* test often prevents the admission of "new, but valid, scientific techniques."⁴⁴ Codification of the Federal Rules of Evidence in 1975⁴⁵ complicated matters. Rule 702, dealing with expert testimony, states that a scientific expert may testify if that testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue" While this rule makes no mention of "general acceptance,"⁴⁶ several circuits—including the Sixth,⁴⁷ Seventh,⁴⁸ and Ninth circuits,⁴⁹ and a district court within the District of Columbia Circuit,⁵⁰ nonetheless continued to follow the traditional *Frye* rule regarding issues of scientific testimony.⁵¹ Other courts, however, including the Second,⁵²

42. Peter W. Huber, *On Law and Sciosophy*, 24 VAL. U. L. REV. 319, 342-43 (1990).

43. *Id.* at 342.

44. Forinash, *supra* note 12, at 228. However, this is not likely to be a concern in medical malpractice cases using the *Frye* standard. See *infra* part IV.

45. Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926 (codified at 28 U.S.C. app. at 733-804 (1988)).

46. See FED. R. EVID. 702.

47. See *United States v. Distler*, 671 F.2d 954, 962 (6th Cir.) (stating that gas chromatograph FID/FRD analysis is generally accepted in field of oil matching), *cert. denied*, 454 U.S. 827 (1981); *United States v. Brown*, 557 F.2d 541, 559 (6th Cir. 1977) (stating that evidence of ion microphobic analysis of human hair should not be admitted because court was not convinced that it had yet reached level of general acceptance in its field).

48. See *United States v. Tranowski*, 659 F.2d 750, 754-57 (7th Cir. 1981) (maintaining that expert astronomer's relying on sun chart to date photograph in question was not generally accepted).

49. See *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978) (stating that Forward Looking Infrared System "is *not* a generally accepted technique among the scientific community for the unique identification of remote objects").

50. See *Robertson v. McCloskey*, 680 F. Supp. 408, 409, 412 (D.D.C. 1988) (holding that psychodynamics of memory and perception was "novel form of scientific evidence" that had not gained general acceptance in its field and was not admissible).

51. One theory that supported the view that the *Frye* test survived the enactment of the Federal Rules of Evidence was that

[b]ecause the Federal Rules were not intended to be a comprehensive codification of the rules of evidence, a number of evidentiary rules are not covered, and many others, though mentioned, are treated only in a general fashion. . . . [B]ecause *Frye* was the established rule and no statement repudiating *Frye* appears in the legislative history, the general acceptance standard remains intact.

Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1229 (1980).

52. See *United States v. Williams*, 583 F.2d 1194, 1200 n.11 (2d Cir. 1978) (using FED. R. EVID. 702 rather than *Frye* general acceptance test), *cert. denied*, 439 U.S. 1117 (1979).

Third,⁵³ and Fourth Circuits,⁵⁴ rejected the *Frye* standard after the enactment of the Federal Rules of Evidence. The *Daubert* decision resolved this dispute among the circuits over viability of the *Frye* test by holding "that the Frye test was superseded by the adoption of the Federal Rules of Evidence."⁵⁵

C. *The Daubert Majority Opinion*

Interpreting the Federal Rules of Evidence "as we would any statute,"⁵⁶ Justice Blackmun's majority opinion noted that the rules, particularly Rule 402,⁵⁷ generally allow the admission of any relevant evidence.⁵⁸ Justice Blackmun further noted that Rule 702, dealing specifically with scientific evidence, mentions neither in its text nor in its

53. See *United States v. Downing*, 753 F.2d 1224, 1237-42 (3d Cir. 1985) (stating that variety of factors, in addition to "a particular degree of acceptance," were important in assessing reliability of scientific evidence (emphasis added)).

54. See *United States v. Baller*, 519 F.2d 463, 466 (4th Cir.) (stating that "[u]nless an exaggerated popular opinion of the accuracy of a particular technique makes its use prejudicial or likely to mislead the jury, it is better to admit relevant scientific evidence in the same manner as other expert testimony"), *cert. denied*, 423 U.S. 1019 (1975).

55. *Daubert*, 113 S. Ct. at 2793.

56. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2793 (1993). Justice Blackmun examined the text of Rules 702, 401, and 402, as well as the legislative history and intent behind the Federal Rules of Evidence. *Id.* at 2793-94.

57. Rule 402 provides that "[a]ll relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible." Rule 401 defines "relevant evidence" as "evidence having 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." See also *New Jersey v. T.L.O.*, 469 U.S. 325, 345 (1985) ("[I]t is universally recognized that evidence, to be relevant to an inquiry, need not conclusively prove the ultimate fact in issue, but only have 'any tendency to make the existence of any fact . . . of consequence . . . more probable or less probable than it would be without the evidence.'" (quoting FED. R. EVID. 401) (emphasis added)).

58. *Daubert*, 113 S. Ct. at 2793-94. Since the adoption of the Federal Rules of Evidence, evidence is found admissible more often than before. See David P. Leonard, *Power and Responsibility in Evidence Law*, 63 S. CAL. L. REV. 937, 956 (1990). One rationale for the modern bias toward admissibility is that "courts and codifiers have come to believe that truth is likely to emerge when more, rather than less, evidence is heard by the trier of fact." *Id.*; see also Victor J. Gold, *Federal Rule of Evidence 403: Observations on the Nature of Unfairly Prejudicial Evidence*, 58 WASH. L. REV. 497, 497 (1983) (arguing that Federal Rules of Evidence expand definition of relevancy); Edward J. Imwinkelried, *The Pretrial Importance and Adaptation of the "Trial" Evidence Rules*, 25 LOY. L.A. L. REV. 965, 970 (noting that Federal Rules of Evidence place pressure on presiding judge "to resolve any doubt in favor of admitting the evidence"); Paul F. Rothstein, *Some Themes in the Proposed Federal Rules of Evidence*, 33 FED. B.J. 21, 21 (1974) (arguing that Federal Rules of Evidence contain bias toward admissibility).

drafting history the *Frye* decision or a "general acceptance" standard.⁵⁹ He reasoned that such a standard "would be at odds with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony.'"⁶⁰

Justice Blackmun next asserted that although the Federal Rules of Evidence supersede the *Frye* test, the Rules still place limits on the admissibility of scientific evidence.⁶¹ Rule 702 in particular "clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify."⁶² The Rule states, "[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, [a qualified expert witness] . . . may testify thereto in the form of an opinion or otherwise." Justice Blackmun reasoned that because Rule 702 requires that the expert's testimony pertain to "scientific knowledge," it "establishes a standard of evidentiary reliability."⁶³ In order to qualify as "scientific," the inference or assertion must be grounded in the procedures and methods of science.⁶⁴ Justice Blackmun further explained that the term "knowledge," as used in Rule 702, implies that the assertion must be more than a "subjective belief or unsupported speculation."⁶⁵ Proposed testimony "must be derived by the scientific method" and must be "based on what is known."⁶⁶ Justice Blackmun observed that Rule 702 addresses the issue of relevance in the requirement that the expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue."⁶⁷ Before the evidence can be admitted, this "helpfulness" standard requires that there be "a valid scientific connection" between the proffered testimony and the issue in question.⁶⁸

According to the *Daubert* majority, trial judges faced with proffered expert testimony must determine whether the litigant is proposing expert evidence that, in accordance with Rule 702, is indeed scientific knowledge that "will assist the trier of fact to understand or determine a fact in issue."⁶⁹ This requires that trial judges make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is

59. *Daubert*, 113 S. Ct. at 2794.

60. *Id.* (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

61. *Id.* at 2794-95.

62. *Id.* at 2795.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.* at 2796.

69. *Id.* at 2795.

scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.”⁷⁰ To assist trial judges in making this determination, Justice Blackmun proposed four “general observations.”⁷¹

First, the verifiability of the theory or technique—“whether it can be (and has been) tested”⁷²—should be considered, because testing a scientific hypothesis helps determine whether it is “falsifiable.”⁷³

Second, courts should consider whether the scientific theory or technique has been published and subjected to peer review.⁷⁴ The majority acknowledged that publication “does not necessarily correlate with reliability” and “is not a *sine qua non* of admissibility”: Occasionally a theory will be well-grounded although it has not been published.⁷⁵ Therefore, publication in a peer-reviewed journal, while not dispositive, should still be considered in determining the scientific validity of a particular technique upon which the expert opinion is based.⁷⁶

Third, courts should consider “the known or potential rate of error” of the given scientific technique.⁷⁷

Finally, even though Justice Blackmun declared that the Federal Rules replaced the *Frye* test, he included “general acceptance” as the fourth factor trial judges should consider in ruling on admissibility.⁷⁸

After setting forth these four factors, Justice Blackmun emphasized that the admissibility inquiry is to remain flexible: It should focus on the relevance and reliability of the scientific principles and methodology of the proposed expert testimony, not on the scientific conclusions themselves.⁷⁹ Justice Blackmun further noted that trial judges should remain

70. *Id.* at 2796.

71. *Id.*

72. *Id.*

73. *Id.* In dissent Chief Justice Rehnquist announced, “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 [the federal district judges] will be, too.” *Id.* at 2800 (Rehnquist, C.J., dissenting).

74. *Id.* at 2797.

75. *Id.*; see, e.g., David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 JAMA 1438, 1440-41 (documenting several cases where innovative scientific hypotheses based on solid scientific evidence were repeatedly rejected for publication by peer-reviewed journals).

76. *Daubert*, 113 S. Ct. at 2797.

77. *Id.*

78. *Id.*

79. *Id.*

“mindful” of applicable rules other than Rule 702—namely, Rules 703, 706, and 403.⁸⁰

Justice Blackmun concluded by addressing two concerns expressed by the parties and amici. First, in addressing defendant-respondent Merrell Dow’s apprehension that abandoning the *Frye* general acceptance test would result in a “free-for-all” where “befuddled juries are confounded by absurd and irrational pseudoscientific assertions,” Justice Blackmun declared that more confidence should be placed in the capabilities of both jurors and the adversary system in general.⁸¹ He maintained that the traditional methods of attacking questionable evidence—namely, cross-examination, showing of contrary evidence, and careful explanation of the burden of proof, as well as the availability of summary judgment—would assure that the foundation of proffered scientific testimony meets the Rule 702 requirements.⁸²

Second, Justice Blackmun addressed the petitioners’ concern that the screening role for trial judges would be “stifling,” “repressive,” and adverse to “the search for truth.”⁸³ Justice Blackmun responded that there are differences between the quest for truth in the courtroom and in the laboratory: Law, he said, must resolve disputes quickly and conclusively.⁸⁴ Although conjectures that are “probably wrong” are useful in

80. *Id.* at 2797-98. Rule 703 states that expert opinions based on hearsay are to be admitted only if the data or facts 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, on its own motion, to appoint and select expert witnesses. Rule 403 permits relevant evidence to be excluded “if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.” Of Rule 403 Justice Blackmun noted that in weighing the possibility of prejudice against probative value, judges exert more dominion over experts than over lay witnesses. *Id.* at 2798.

81. *Id.* Although Justice Blackmun seems to trust lay jurors’ abilities to understand adequately and make decisions based on complex scientific evidence, this ability frequently is questioned, particularly in medical malpractice actions. See, e.g., Elliott M. Abramson, *The Medical Malpractice Imbroglia: A Non-Adversarial Suggestion*, 78 KY. L.J. 293, 295 (1989-1990) (“Juries frequently cannot understand the technical, confusing, and often conflicting testimony of medical experts, or the distinctions between injuries attributable to a physician’s negligence and injuries that fall within normal statistical probabilities of occurrence.” (footnotes omitted)); Kirk B. Johnson et al., *A Fault-Based Administrative Alternative for Resolving Medical Malpractice Claims*, 42 VAND. L. REV. 1365, 1370 (1989) (“[J]uries cannot evaluate independently the expert testimony almost always introduced in malpractice cases.” (footnote omitted)); Miceli, *supra* note 12, at 944-45 (“In medical malpractice actions the lay jury simply has no basis in education, training, or experience upon which to arrive at a rational and reasoned verdict. . . . Lay jurors are no more enlightened as to medical concepts upon which they deliberate than were Socrates’ cave dwellers when deliberating as to the nature of shadows on the wall.”); see also *infra* notes 256-58 and accompanying text.

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

83. *Id.*

84. *Id.*

science, in the law they are of little use in “reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past.”⁸⁵ The majority therefore recognized that in practice, no matter how flexible the trial judge’s gatekeeping role is, occasionally innovative and authentic scientific testimony will be withheld from the jury.⁸⁶ Because the Federal Rules of Evidence were designed for use in legal disputes and not for scientific purposes, however, this was deemed to be the appropriate balance.⁸⁷

Justice Blackmun summarized by reiterating that the Federal Rules of Evidence do not *require* “general acceptance” of proffered scientific testimony, but that under the Rules—particularly Rule 702—trial judges must ensure “that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.”⁸⁸ These requirements will be met if the evidence is “pertinent” and based on “scientifically valid principles.”⁸⁹ Because the district court and court of appeals based their decisions almost completely on “general acceptance” in the form of publication, the Supreme Court vacated the judgment of the court of appeals and remanded the case for further proceedings consistent with its opinion.⁹⁰

D. *The Daubert Concurrence and Dissent*

Chief Justice Rehnquist, joined by Justice Stevens, concurred in part, agreeing that the Federal Rules of Evidence replaced the *Frye* general acceptance test.⁹¹ They dissented in part, however, disapproving of the “general observations” laid out in the majority opinion.⁹² Noting that “[g]eneral observations” by this Court customarily carry great weight with lower federal courts,” the dissenters declared that the offered observations were flawed in that they were “not applied to deciding whether or not particular testimony was or was not admissible,” and were therefore “not only general, but vague and abstract.”⁹³ Furthermore, Chief Justice Rehnquist pointed out that the amicus briefs filed were unusual because they dealt with “definitions of scientific knowledge,

85. *Id.*

86. *Id.* at 2798-99.

87. *Id.* at 2799.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2799-800 (1993) (Rehnquist, C.J., concurring).

92. *Id.* at 2799 (Rehnquist, C.J., dissenting).

93. *Id.* (Rehnquist, C.J., dissenting).

scientific method, scientific validity, and peer review"—matters that the dissenters felt were "far afield from the expertise of judges."⁹⁴ Because scientific evidence constitutes "unusual subject matter," Chief Justice Rehnquist implied that the majority may have "decid[ed] more than [it] ha[d] to" in interpreting the Rules.⁹⁵

The dissenting opinion pointed to many questions that the majority's "general observations" failed to answer.⁹⁶ Do the "general observations," described as "dicta," apply only to scientific testimony or to other types of Rule 702 expert testimony as well?⁹⁷ Should a distinction be drawn between scientific and technical knowledge?⁹⁸ In assessing the scientific status of a theory, will federal judges understand what "falsifiability" of that theory means?⁹⁹ The dissenters closed by acknowledging that Rule 702 does give trial judges "some gatekeeping responsibility" in ruling on the admissibility of proffered expert testimony; they expressed doubt, however, that Rule 702 confers on trial judges the authority or obligation "to become amateur scientists" when making rulings.¹⁰⁰

III. ANALYSIS

In analyzing the potential impact of the *Daubert* decision, this Note proposes a hypothetical medical malpractice case with two variations. Each variation will assume (1) that a physician has negligently failed to diagnose breast cancer, and (2) that the plaintiff is attempting to prove, through the testimony of a purported scientific expert witness, that if the diagnosis had been made earlier, an experimental treatment would have been available, thus affording a chance to cure the breast cancer.¹⁰¹ The

94. *Id.* (Rehnquist, C.J., dissenting).

95. *Id.* (Rehnquist, C.J., dissenting).

96. *Id.* at 2800 (Rehnquist, C.J., dissenting).

97. *Id.* (Rehnquist, C.J., dissenting).

98. *Id.* (Rehnquist, C.J., dissenting).

99. *Id.* (Rehnquist, C.J., dissenting).

100. *Id.* (Rehnquist, C.J., dissenting).

101. The loss of a "substantial possibility of survival" can be actionable. In fact, in some jurisdictions, even a small possibility is enough. See, for example, *Hicks v. United States*, 368 F.2d 626 (4th Cir. 1966), where the lost-chance-to-cure doctrine is stated as follows:

When a defendant's negligent action or inaction has effectively terminated a person's chance of survival, it does not lie in the defendant's mouth to raise conjectures as to the measure of the chances that he has put beyond the possibility of realization. If there was *any* substantial possibility of survival and the defendant has destroyed it, he is answerable.

Id. at 632 (emphasis added); see also *Thomas v. Corso*, 288 A.2d 379, 390-91 (Md. 1972) (affirming jury determination of loss of substantial possibility of survival, since defendant physician's failure to treat decedent increased decedent's risk of death). California courts, however, do "not recognize a cause of action for wrongful death based on medical negligence

two variations will differ, however, as to the scientific basis of the proffered expert opinion. This Note applies the *Daubert* criteria to the scientific evidence proffered in each of the two variations to predict how a court would rule as to its admissibility, and why. This Note then explains the problems of evaluating the discussed testimony under *Daubert*, and explains why the *Frye* test should be retained. This Note discusses the benefits of the *Frye* test, as well as any differences in the outcome of the hypothetical resulting from application of the *Frye* test.

A. *The Hypothetical*

A forty-nine year-old woman (plaintiff's decedent), who has a family history of breast cancer, goes to her family doctor of twenty years, Dr. X, on day one of year one for a physical examination. Dr. X performs a regular physical exam, but fails to examine her breasts—Dr. X only asks her if she has noticed any lumps or discharge. Plaintiff's decedent replies that she has not noticed any discharge, but is unsure about lumps, because she feels that her breast tissue has always felt "irregular" and "lumpy in parts." Based on her statement, Dr. X, who has examined her breasts in previous years, informs her that a problem is unlikely and fails to order a mammogram—a soft-tissue X-ray used to detect breast cancer.

One year later, on day one of year two, an insurance company doctor examines plaintiff's decedent for new insurance coverage. The doctor performs a breast exam, palpates¹⁰² lumps, and tells her to have them followed up.

The same day, plaintiff's decedent returns to Dr. X, who performs a mammogram, a breast biopsy, and biopsies of some regional lymph nodes. Due to her recent onset of severe headaches and impaired vision, Dr. X also orders a Magnetic Resonance Imaging (MRI)¹⁰³ scan of her

where the decedent did not have a greater than 50% chance of survival had the defendant properly diagnosed and treated the condition." *Bromme v. Pavitt*, 5 Cal. App. 4th 1487, 1504-05, 7 Cal. Rptr. 2d 608, 618 (1992); accord *Dumas v. Cooney*, 235 Cal. App. 3d 1593, 1603-11, 1 Cal. Rptr. 2d 584, 589-94 (1991) (declining to establish lenient standard of causation in medical malpractice cases when loss of chance for survival is less-than-likely or mere possibility). Because the details of the loss-of-chance-to-cure theory are beyond the scope of this Note, the hypothetical will assume that the case is otherwise legally viable if the proffered scientific or technical evidence is admitted.

102. "Palpate" means "[t]o examine by touch, esp[ecially] for medical diagnosis." THE DOUBLEDAY DICTIONARY 522 (1975) [hereinafter DOUBLEDAY DICTIONARY].

103. Magnetic Resonance Imaging is a noninvasive radiologic technique. The images produced are based upon the radiofrequency (RF) signal that body tissues' hydrogen nuclei emit in the presence of a strong magnetic field, following exposure to RF pulses. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 867 (Jean D. Wilson et al. eds., 12th ed. 1991). MRI provides excellent resolution of neural structures. THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1323 (Robert Berkow et al. eds., 15th ed. 1987) [hereinafter MERCK MANUAL].

brain. The results of the biopsies show that she has malignant breast cancer, which has spread not only to several axillary¹⁰⁴ lymph nodes, but, as indicated on the MRI, also to an inoperable location in her brain. Plaintiff's decedent is nonresponsive to radiation and chemotherapy. Within one year she dies.

Her estate sues Dr. X for negligence in failing to diagnose her breast cancer on day one of year one. The parties stipulate that this failure to diagnose was negligent.

They also stipulate, however, that given the state of plaintiff's carcinoma as of day one of year two, and the number of locations to which it had spread, it is probable that at the time of Dr. X's admittedly negligent failure to diagnose plaintiff's decedent, tumors were already present, cancerous, and beginning to spread. It is conceded that *traditional* methods of surgery, radiation, and chemotherapy would most likely have yielded a zero percent chance of survival; plaintiff therefore argues that a *nontraditional* treatment would have cured the decedent's cancer. At trial plaintiff's theory is that the failure to diagnose foreclosed any chance of cure.¹⁰⁵ The defense argues that the admittedly negligent diagnosis did not result in a lost chance to cure, and the plaintiff's decedent could not have been treated successfully even if a correct diagnosis had been made on day one of year one.

Assume that the case is in federal court on diversity of citizenship grounds¹⁰⁶ and that the substantive law of California applies.¹⁰⁷ Assume further that the trial judge in this hypothetical adheres to the *Daubert* majority's four "general observations."

1. Hypothetical A: Holistic practitioner

Plaintiff presents as an expert witness a holistic practitioner who does not possess a medical degree. The practitioner testifies that he can prepare a decoction of herbs that will arrest, and often reverse, breast cancer, even after it has begun to spread or metastasize. He states that if the diagnosis of plaintiff's decedent had been correctly made on day one of year one, given the probable stage of the cancer at that point, his treatment could have cured her. This practitioner has independently tested

Although it requires that the patient's head or body be placed in a strong magnetic field, MRI carries no known risk. *Id.*

104. "Axillary" is a term describing the axilla, commonly known as the "armpit" region. See DOUBLEDAY DICTIONARY, *supra* note 102, at 50.

105. For a discussion of loss of chance to cure, see *supra* note 101.

106. 28 U.S.C. § 1332 (1988).

107. In diversity cases the substantive law of the state in which the court sits applies. See *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938).

his preparation on ten patients with breast cancer. Of the ten, seven have shown improvements including shrinkage of palpable tumor mass and loss or reduction of symptoms from the time of treatment to the present—which varies depending on the patient, from one to five years. This “expert” published his results one year ago in a nonpeer-reviewed holistic medical journal. Nine months after publication, a holistic practitioner in another state wrote to this expert, stating that she tried the described treatment on eight of her patients with breast cancer, and that as of the date of the letter, four patients had demonstrated tumor shrinkage and reduction of symptoms. Plaintiff’s expert does not know if any other practitioners have attempted to treat breast cancer with his herbal therapy.

2. Hypothetical B: Ph.D. pharmacologist; experimental drug

In this variation plaintiff presents an expert who is not an M.D., but instead is a Ph.D. pharmacologist employed by a drug company seeking approval of a new experimental drug (Drug *E*). The pharmacologist is the chief investigator for animal studies at the drug company. In the studies performed thus far, breast cancer was induced in rats and monkeys.¹⁰⁸ These animals subsequently were treated with Drug *E*. Different success rates were noted at various stages of breast cancer. At early metastatic stages—plaintiff’s decedent’s condition on day one of year one—the animals showed a ninety percent rate of remission; that is, after cessation of treatment, the cancer did not recur, and ninety percent of the animals appeared symptom-free.¹⁰⁹ To date, adverse side effects and toxicity have been minimal. This pharmacologist and his drug-company colleagues recently published these breakthrough results in the *New England Journal of Medicine*. In addition, the drug company has recently applied to the Food and Drug Administration (FDA) to begin human clinical trials. However, since the FDA has not yet approved the application, human trials have not yet begun.¹¹⁰

108. In testing drugs on animals, typically two or more species are tested, “since a drug may affect one differently from another.” Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 6, 8 (1990) [hereinafter NEW DRUG DEVELOPMENT].

109. “[C]omplete remission or complete response” (CR) refers to a disappearance of any clinical evidence of the cancer. MERCK MANUAL, *supra* note 103, at 1219. A “partial response” (PR) refers to a greater than 50% reduction in size of any tumor masses; although life may be prolonged, tumor regrowth is inevitable. *Id.* “Survival” refers to the time interval between complete remission and death. *Id.*

110. In new drug development, the “FDA first becomes involved when a drug company has completed its testing in animals and is ready to test a drug on humans.” Cohn, *supra* note 108, at 9.

This pharmacologist says that based on his animal studies, Drug *E* would probably be ninety percent effective in bringing plaintiff's decedent into complete remission had she received treatment starting on day one of year one. He does concede, however, that animal studies are not conclusive in determining success with human subjects.

While not officially available for human use in the United States, Drug *E* is currently available in other countries that do not require FDA approval.¹¹¹ Conclusive data as to its efficacy in humans has not yet been obtained. Finally, plaintiff's decedent had the means on day one of year one to go to one of these foreign countries and receive treatment with Drug *E*.

B. Determining the Admissibility of the Hypothetical Evidence Under Daubert and Frye

1. Holistic practitioner

a. Daubert analysis

i. reliability and relevance

Using *Daubert* to determine the admissibility of this testimony, the trial judge first must determine whether the proffered testimony is indeed "(1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue."¹¹² In doing so the trial judge must examine the scientific validity of the underlying reasoning or methodology.¹¹³

The first issue is whether the results of this holistic practitioner's testing of his herbal mixture on ten patients qualify as "scientific knowledge." To be scientific, the *Daubert* Court states that an assertion must be grounded in the procedures and methods of science.¹¹⁴ Here, the assertion is that the mixture is efficacious against early metastatic breast cancer. To a trial judge with no scientific background, this holistic prac-

111. Prior to being FDA approved and available in the United States, new drugs may already be available in foreign countries. See, e.g., K. Wayne Hindmarsh & Donald F. LeGatt, *Mexican Drug Therapy*, 17 *CLINICAL TOXICOLOGY* 85, 85, 93-95 (1980) (discussing non-FDA-approved drug Laetrile as example of drug available in Mexicali, Mexico clinic); Carl G. Kardinal, M.D., *Laetrile in Historical Perspective*, 77 *MO. MED.* 564, 568 (1980) (stating that although Hoxsey medicines for "internal cancer" were not FDA approved and were illegally offered as effective cancer treatment, they were still available in Tijuana). Often, the FDA considers information on drugs used abroad: "[B]efore an investigational drug can be given to the first patient, the sponsor has to provide [the] FDA with . . . information, if there is any, about previous use of the drug in humans . . . abroad." Ken Flieger, *Testing in 'Real People'*, in *NEW DRUG DEVELOPMENT*, *supra* note 108, at 11, 11.

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

113. *Id.*

114. *Id.* at 2795.

titioner's study very well may appear to be scientifically sound. In the *Daubert* opinion, Justice Blackmun states that "the subject of scientific testimony [need not] be 'known' to a certainty; arguably, there are no certainties in science."¹¹⁵ Unfortunately, this reminder may enhance any temptation on the part of the district judge to admit the holistic practitioner's scientifically questionable testimony. The majority's quoting of two amicus briefs may further reassure the trial judge that this nontraditional treatment possibly may qualify as "scientific knowledge."¹¹⁶ Justice Blackmun summarized that the "scientific knowledge" requirement of expert testimony "establishes a standard of evidentiary reliability";¹¹⁷ "evidentiary reliability," he explained in a footnote, "will be based upon scientific validity."¹¹⁸ The trial judge who is ruling on the admissibility of this holistic practitioner's testimony may be easily convinced that because the treatment cured seven patients, the opinion that it is medically efficacious is, therefore, reliable.

The next step in *Daubert's* admissibility analysis requires the judge to inquire whether the testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue."¹¹⁹ This step, according to Justice Blackmun, addresses the issue of relevance.¹²⁰ The holistic practitioner's testimony appears relevant to the issue in this hypothetical case. If the practitioner had treated the plaintiff's decedent with the herbal mixture on day one of year one, she arguably might have experienced tumor shrinkage or reduction of symptoms, as did seven of the ten subjects tested. The connection between the proffered testimony and the issue of causation—that is, lost chance to cure—is clear here. Because the testimony addresses this issue,¹²¹ the trial judge should find that it is relevant and hence that it will "assist the trier of fact to understand the evidence or to determine a fact in issue."¹²²

115. *Id.*

116. *Id.* "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 . . ." *Id.* (quoting Brief for Nicolaas Bloembergen et al. as Amici Curiae in Support of Respondent at 9, *Daubert* (No. 92-102)). "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 . . ." *Id.* (quoting Brief for the American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae in Support of Respondent at 7-8, *Daubert* (No. 92-102)).

117. *Id.*

118. *Id.* at 2795 n.9.

119. *Id.* at 2795 (quoting FED. R. EVID. 702).

120. *Id.*

121. Although the proffered scientific evidence does not address the issue of negligent misdiagnosis, this has already been conceded and is not in question.

122. FED. R. EVID. 702.

ii. general observations

To further ensure that this scientific evidence indeed complies with Rule 702's requirements, the trial judge next must run through the *Daubert* majority's four "general observations."¹²³ First, the trial judge should consider the testability of this holistic practitioner's proposed treatment; the judge should look to whether the proposed theory "can be (and has been) tested."¹²⁴ According to the evidence presented, the expert arguably *has* tested this herbal treatment; his results reveal a success rate of seven out of ten, or seventy percent. In addition, the out-of-state practitioner who wrote to this expert claims to have tested this treatment on eight of her patients, and claims to have observed improvements in four patients after nine months—a fifty percent success rate. Although a twenty percent difference between the success rates of these two independent tests exists, it arguably is due to the small sample size of patients tested.¹²⁵ According to the *Daubert* opinion, "the statements constituting a scientific explanation must be capable of [an] empirical test,"¹²⁶ and "the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability."¹²⁷ Because an out-of-state practitioner reported that the treatment in question caused four of eight of her patients to experience tumor shrinkage and reduction of symptoms, the trial judge easily might conclude that the holistic practitioner's treatment was capable of an empirical test. This treatment was thereby proven to be repeatable, giving it "scientific status."

The second "general observation" that the trial judge must consider is whether the practitioner has published the scientific theory or technique and has subjected it to peer review.¹²⁸ As mentioned, this holistic practitioner has published the results of his study, but the journal in which his study appears is not peer-reviewed. A traditional, peer-reviewed medical journal may not be interested in publishing a holistic

123. *Daubert*, 113 S. Ct. at 2796.

124. *Id.*

125. In planning an experiment such as drug testing, the size of the sample population to be tested must be resolved early on. See Jennie A. Freiman, M.D., et al., *The Importance of Beta, the Type II Error, and Sample Size in the Design and Interpretation of the Randomized Controlled Trial*, in *MEDICAL USES OF STATISTICS* 357, 358 (John C. Bailar III & Frederick Mosteller eds., 2d ed. 1992). Because "very small samples often lead to results that are of no practical use," selecting a sample of appropriate size is critical. WAYNE W. DANIEL, *BIostatistics: A Foundation for Analysis in the Health Sciences* 143 (3d ed. 1983).

126. *Daubert*, 113 S. Ct. at 2797 (quoting C. HEMPEL, *PHILOSOPHY OF NATURAL SCIENCE* 49 (1966)).

127. *Id.* (quoting K. POPPER, *CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE* 37 (5th ed. 1989)).

128. *Id.*

study of this kind. Therefore, courts may have to consider the opinions of other holistic practitioners, without the benefit of traditional publication in a peer-reviewed journal. On peer review the *Daubert* majority states that "it increases the likelihood that substantive flaws in methodology will be detected."¹²⁹ Arguably, the fact that another practitioner tested this treatment could assist in detecting any substantive flaws in methodology. Furthermore, the trial judge could take into account the *Daubert* majority's assertion that "publication (or lack thereof) in a peer-reviewed journal [is] not [a] dispositive consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised."¹³⁰ The trial judge, therefore, may simply conclude that publication in the nonpeer-reviewed holistic medical journal is sufficient to meet this second prong, since an additional holistic practitioner tested the treatment.

The third "general observation" that *Daubert* instructs trial courts to consider is "the known or potential rate of error."¹³¹ The *Daubert* Court neither proposes specific guidelines in this area nor attempts to explain exactly how error-rate analysis would apply to the case before it. The Court does, however, cite *United States v. Smith*¹³² and *United States v. Williams*,¹³³ both of which address the issue of admissibility of spectrographic voice identification evidence in criminal trials.¹³⁴ In *Smith* the court held error rates of 0.31% for false identifications and 0.53% for false eliminations acceptable, while holding error rates of 62.7% and 83.33% unacceptable.¹³⁵ In *Williams* the court deemed a false identification rate of 6.3%—which was reduced to 2.4% after the elimination of doubtful comparisons—tolerable from the standpoint of admissibility of the evidence.¹³⁶

The problem of applying the rate-of-error concept to medical cases, such as this hypothetical, is not at all straightforward. In biomedical research the rate-of-error concept is much more difficult to apply, and numbers are much more difficult to calculate, than in the voiceprint cases cited by the *Daubert* Court. In computer voice analysis, for example, the probability of error should be relatively simple to determine using con-

129. *Id.*

130. *Id.*

131. *Id.*

132. 869 F.2d 348 (7th Cir. 1989).

133. 583 F.2d 1194 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979).

134. *See Smith*, 869 F.2d at 350; *Williams*, 583 F.2d at 1197.

135. *Smith*, 869 F.2d at 354.

136. *Williams*, 583 F.2d at 1198.

trolled blind testing.¹³⁷ Skilled operators could, for example, be confronted with test subjects who are known to the experimenters—but not to the operators—to have either made or not made certain voice exemplars.¹³⁸ The operators then could attempt to match the subjects' voices with the previously made exemplars.¹³⁹ In that way the experimenters could measure directly the rates at which the operators make false and correct identifications because they would know, with certainty, whether the voice identification was correct.¹⁴⁰

In drug clinical trials, however, false-positive findings, or positive responses not attributable to drug therapy, are difficult to identify with certainty; their rates of occurrence are correspondingly difficult to measure.¹⁴¹ In a controlled clinical trial it is not possible to measure accurately exactly how the drug is working in each individual; this is due to differences in test subjects' ages, genders, habits, overall states of health, and genetic backgrounds.¹⁴² In addition, when a patient appears to respond positively to the tested drug, it is impossible to be certain whether the drug, or another factor such as the individual's psychological state, caused the positive effect.¹⁴³ Therefore, in drug efficacy studies it appears almost impossible to calculate with accuracy a true false positive or a true false negative. When drug examiners do attempt to calculate error

137. See, e.g., OSCAR TOSI, VOICE IDENTIFICATION: THEORY AND LEGAL APPLICATIONS 97-106 (1979).

138. See, e.g., *id.*

139. See, e.g., *id.*

140. See, e.g., *id.*

141. See, e.g., James H. Ware et al., *P Values, in MEDICAL USES OF STATISTICS*, *supra* note 125, at 181.

The problem of false-positive findings can be addressed in part by reporting confidence intervals as well as significance levels. The confidence interval identifies the range of values, such as differences in treatment effects, that is compatible with the study results; wide confidence intervals help to identify studies with low reliability. Discussions of power also have a place in reports of study results. For example, the statement that the study had a power of 15 percent to detect a 50 percent reduction in mortality conveys information different from the corresponding confidence interval because it says, "we scarcely had a chance," and it facilitates proper weighing of negative studies.

Id. at 196.

142. See, e.g., Stephen J. Ackerman, *Watching for Problems That Testing May Have Missed*, in *NEW DRUG DEVELOPMENT*, *supra* note 108, at 49, 50.

143. See, e.g., M. ROBIN DIMATTEO & HOWARD S. FRIEDMAN, *SOCIAL PSYCHOLOGY AND MEDICINE* 68-69 (1982).

The psychological state of the individual can either enhance or inhibit the individual's reactions to specific drugs. Human beings are active biological organisms that respond in complex ways to the introduction of foreign agents. Just as the body may be more or less susceptible to various diseases at various times, the body will also react to various therapies and treatments in different ways at different times, depending on the psychological and emotional state of the person.

Id. at 68.

rates in clinical trials, their methods are sometimes questionable.¹⁴⁴ The statistical methods involved are so difficult to comprehend that even “experts” such as drug investigators, study reviewers, and editors of highly respected medical journals may lack a sufficient understanding of statistical techniques to evaluate error rates appropriately.¹⁴⁵

In this hypothetical, according to the studies of plaintiff’s expert, seven of ten patients showed improvement with the herbal treatment, and three did not. There is no evidence, however, about how many of the seven were false positives, nor how many of the three that did not improve were false negatives. Because the holistic practitioner did not measure his results against a control group, this study does not afford any data that would support a comparison of the effects of the treatment at issue with the effects of conventional treatments, nor even with the effects of a placebo. It seems meaningless in this case to speak of an “error rate” when the study was not designed to enable comparison with a control group.¹⁴⁶

If “study” means a testing program carried out in accordance with conventional scientific methods, then it is a misnomer to call this evidence a “study” at all. The study is essentially nothing more than an anecdotal report that patients tried the drug and some of them improved. Absent some comparison with an appropriate control group, the study neither affords a scientific basis to conclude that the drug treatment is what caused the improvement, nor a comparison of its efficacy with conventional treatments.¹⁴⁷

Even if the holistic practitioner’s report were a scientifically designed study with a control group of patients who received either a conventional therapy or a placebo, the error-rate criterion still would be problematical due to the extremely small sample size—ten patients in one study, and eight patients in the other.¹⁴⁸

144. See, e.g., Freiman et al., *supra* note 125, at 357, 358.

145. See, e.g., *id.* at 357-72 (“The almost total lack of discussion of [alpha and beta error rates] in the . . . papers [studied] . . . indicate[s] a need for greater education of investigators, reviewers, and editors . . .”).

146. See, e.g., *id.* at 358 (discussing use of control group in randomized clinical trial).

147. Not including a control group in the investigation of an experimental drug “would defeat the purpose of the clinical trial, making it impossible to learn whether the experimental drug does, in fact, have any more effect than no treatment at all.” Flieger, *supra* note 111, at 12.

148. See DANIEL, *supra* note 125, at 143. One well-known survey of articles published in prestigious medical journals concluded that sample sizes were often too small to support reliable conclusions about drug efficacy. See Freiman et al., *supra* note 125, at 357. Freiman and her coauthors based their conclusions upon two surveys, ten years apart, of papers published in twenty different journals, including *Lancet*, *The New England Journal of Medicine*, and the

Finally, as a fourth factor, trial judges should consider the degree to which the proffered testimony has received "general acceptance" within the "relevant scientific community."¹⁴⁹ Although an herbal treatment for breast cancer may not be "generally accepted" among traditional physicians, it may be considered perfectly acceptable among holistic practitioners. The fact that another practitioner tested this expert's treatment on her own patients tends to show that this treatment either already has gained acceptance or soon will gain general acceptance among the "relevant scientific community" of holistic health professionals. This may be enough to satisfy the trial judge. If not, the *Daubert* opinion will remind the judge that

[n]othing in the text of this Rule [702] establishes "general acceptance" as an absolute prerequisite to admissibility. . . . [Furthermore,] [t]he 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."¹⁵⁰

Moreover, the judge must remember that the *Daubert* opinion emphasized that general acceptance, as well as all other factors of the admissibility inquiry, is to remain a "flexible" criterion.¹⁵¹ Therefore, the hypothetical holistic practitioner's herbal treatment will probably pass the "general acceptance" prong. For example, in *Cantrell v. GAF Corp.*,¹⁵² a case recently decided using *Daubert*, two workers whose jobs involved asbestos exposure, but who also smoked, sued their employer for injuries, including "increased risk of contracting cancer," allegedly resulting from their occupational exposure to asbestos.¹⁵³ Plaintiffs' expert, a physician, had examined a total of 150 workers, including plaintiffs, as a union health screen.¹⁵⁴ He diagnosed three of the 150 as having

Journal of the American Medical Association. Id. at 364. Another commentator summarized the Freiman results as follows: "This means that in 94 percent of the studies there was a greater than 10 percent chance of missing a 25 percent therapeutic improvement, and in 70 percent of the studies there was a similar chance of missing a 50 percent improvement." Ware et al., *supra* note 141, at 195-96 (citing Freiman et al., *supra* note 125, at 367-72). If Freiman and her coauthors are correct, then it appears that even in the world's most prestigious medical journals sample sizes are often inadequate to afford appropriate sensitivity in measuring drug efficacy.

149. *Daubert*, 113 S. Ct. at 2797.

150. *Id.* at 2794 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

151. *Id.* at 2797.

152. 999 F.2d 1007 (6th Cir. 1993).

153. *Id.* at 1010, 1012. Although only two employees sued, an additional employee was diagnosed with cancer as well. *See id.* at 1013.

154. *Id.* at 1012-13.

laryngeal¹⁵⁵ cancer; he testified that in the general population, the incidence of this type of cancer was only four out of 100,000 individuals per year—a significantly lower rate than three out of 150.¹⁵⁶ Defendants objected to the admission of this testimony, “asserting that three cases of laryngeal cancer, all in *smokers* who had been exposed to asbestos, was not probative of the association between asbestos and cancer.”¹⁵⁷ Defendants asserted that the smoker rate was compared erroneously against the general population, which includes smokers, but is not comprised exclusively of smokers.¹⁵⁸ Furthermore, defendants asserted that the prejudicial impact of this evidence outweighed its probative value, so that it should be excluded under Federal Rule of Evidence 403.¹⁵⁹

The appellate court affirmed the lower court’s admission of plaintiffs’ evidence, however, stating that “[n]othing in Rules 702 and 703 or in *Daubert* prohibits an expert witness from testifying to confirmatory data, gained through his own clinical experience”¹⁶⁰ The majority was satisfied with the fact that plaintiffs’ expert was subjected to cross-examination, and that he based his opinion on “recognized sources.”¹⁶¹ The court therefore found “no error in the admission of [this] testimony.”¹⁶² The court seemed to easily admit this evidence of a possible link between asbestos exposure and the three cases of laryngeal cancer, while ignoring the possibility that the cancer very well could have been caused by cigarette use alone.

Having reviewed the *Cantrell* court’s application of the *Daubert* standard, it appears that the hypothetical holistic practitioner’s testimony might be admitted. The hypothetical testimony about an herbal mixture curing cancer seems no less dubious than the *Cantrell* testimony about occupational asbestos exposure, and not cigarette smoking, causing cancer.

Taking all factors into account, it is conceivable that the testimony of the holistic practitioner might be ruled admissible under *Daubert*—despite the small sample size, the lack of any evaluation of the likelihood of false positives and false negatives, the lack of a rigorous comparison

155. The larynx is “the organ responsible for the production of vocal sounds, also serving as an air passage conveying air from the pharynx to the lungs. It is situated in the front of the neck” THE BANTAM MEDICAL DICTIONARY 229 (Bantam Books 1982) (1981).

156. *Cantrell*, 999 F.2d at 1013.

157. *Id.* (emphasis added).

158. *Id.*

159. *See id.*

160. *Id.* at 1014.

161. *Id.*

162. *Id.*

with an appropriate control group, and the failure to rule out the possibility that the cures, or observed improvements, might have been spontaneous and not caused by the herbal therapy.

b. *Frye analysis*

To be admissible under *Frye*, the holistic practitioner's herbal therapy "must be sufficiently established to have gained general acceptance in the particular field in which it belongs."¹⁶³ In order to assess its general acceptance in the relevant scientific community, the trial judge first must identify the "particular field" in which this therapy belongs.¹⁶⁴ How one defines the appropriate field can have a bearing on the admissibility of the proffered evidence.

i. scientific community of medical doctors

Assume the trial judge determines that the plaintiffs must prove that this therapy is generally accepted in the traditional, "orthodox" medical field. Intuitively, one might conclude that a decoction of herbs as a cancer therapy would not be generally accepted among medical doctors. Based upon the *Hoxsey* cases of the 1950s,¹⁶⁵ this speculation is likely to be correct.

Harry M. Hoxsey was not a doctor;¹⁶⁶ yet the pink and black medicines originally developed by his grandfather in 1840,¹⁶⁷ which consisted of mixtures of various barks, blossoms, and other elements, were the main therapy for cancer patients treated at the Hoxsey Cancer Clinics.¹⁶⁸ In 1936 Hoxsey set up his first clinic in Dallas, Texas; his second

163. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), *superseded by* FED. R. EVID. 702, *construed in* *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993).

164. Courts often have difficulty defining the relevant scientific community. See Forinash, *supra* note 12, at 257-58.

165. See, e.g., *United States v. Hoxsey Cancer Clinic*, 198 F.2d 273 (5th Cir. 1952), *cert. denied*, 344 U.S. 928 (1953); *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.D.C. 1957); *United States v. 10 Cartons Labeled in Part "Hoxsey"*, 152 F. Supp. 360 (W.D. Pa. 1957).

166. *Hoxsey*, 198 F.2d at 278.

167. *Id.* It is said that the senior Hoxsey first conceived of this mixture after it allegedly cured his horse's leg cancer. The horse had been grazing in a field containing cascara, bark of prickly ash and buckthorn, red clover blossoms, roots of barberry and burdock, licorice, poke-weed, and alfalfa; these became the ingredients of Hoxsey's "black medicine." Kardinal, *supra* note 111, at 568.

168. Wallace F. Janssen, *Cancer Quackery—The Past in the Present*, 6 SEMINARS IN ONCOLOGY, 526, 528-29 (1979); see *Hoxsey*, 198 F.2d at 277-78.

clinic, in Portage, Pennsylvania, began treating patients in 1955.¹⁶⁹ Due to overwhelming popular demand, Hoxsey established an additional Los Angeles, California clinic in 1957.¹⁷⁰ If a Hoxsey practitioner diagnosed "internal cancer," the practitioner would dispense a prescription for either the pink or the black medicine, depending on the cancer's nature.¹⁷¹ Some 10,000 cancer victims received the Hoxsey treatments.¹⁷² Although the Hoxsey Clinics' staff included some physicians,¹⁷³ the clinic rejected "orthodox" methods of cancer therapy such as surgery and x-ray therapy.¹⁷⁴

The FDA disapproved of the Hoxsey cancer treatments, and issued and displayed a circular in post offices warning the public that these treatments did not cure cancer.¹⁷⁵ Hoxsey's followers led a "crusade of prayer" and initiated a letter campaign to Congress.¹⁷⁶ Nonetheless, in 1952, relying on "the accepted views and findings of science," the Fifth Circuit ruled that the Hoxsey medicines were not effective as cancer cures.¹⁷⁷ The clinics continued to operate, however, and the medications continued to be sold.¹⁷⁸ Finally, in 1960, after ten years of litigation, an injunction stopped the sale of Hoxsey medications in the United States.¹⁷⁹ As of 1980 the Hoxsey cancer medicines were still available in Tijuana, Mexico.¹⁸⁰

169. AMERICAN CANCER SOC'Y, UNPROVEN METHODS OF CANCER MANAGEMENT 108 (1971); see Janssen, *supra* note 168, at 529.

170. See AMERICAN CANCER SOC'Y, *supra* note 169, at 109. Hoxsey opened the Los Angeles clinic after "a large group of southern California citizens" signed a petition requesting that he do so. *Id.*

171. See *10 Cartons*, 152 F. Supp. at 362.

172. Kardinal, *supra* note 111, at 568.

173. See *10 Cartons*, 152 F. Supp. at 362.

174. See *Hoxsey*, 198 F.2d at 274. The clinic criticized these traditional therapies as "ineffective" and "positively harmful." *Id.* However, nonclinic physicians conducted studies showing that the potassium iodide in the black medicine, if taken as recommended, could cause untoward reactions in some people, and could possibly even accelerate the cancer's growth. *Id.* at 278.

175. See *Folsom*, 155 F. Supp. at 377.

176. Kardinal, *supra* note 111, at 568.

177. *Hoxsey*, 198 F.2d at 281. The court relied upon numerous physician-performed studies. *Id.* at 278. Among the determinations made were that the Hoxsey medications were harmful, that the treatment could accelerate cancer growth, and that the therapy had no beneficial effect on cancer-afflicted mice. *Id.*

178. See, e.g., AMERICAN CANCER SOC'Y, *supra* note 169, at 109-10.

179. Janssen, *supra* note 168, at 530; see also AMERICAN CANCER SOC'Y, *supra* note 168, at 109 ("In September 1960, the [FDA] reported that a permanent injunction . . . banned the sale of all Hoxsey medications . . ."). For a detailed discussion of Harry Hoxsey and the events surrounding his controversial cancer treatments, see *id.* at 107-10.

180. Kardinal, *supra* note 111, at 568.

Similar to the medical community's rejection of the Hoxsey cancer medicines of the 1950s, the hypothetical holistic practitioner's herbal mixture probably will be considered contrary to the generally accepted cancer therapy methods, particularly among oncologists.¹⁸¹ If such is the case, this expert's testimony will likely be excluded under *Frye*.

ii. scientific community of holistic practitioners

In contrast to the scientific community of physicians, suppose that the trial judge determines that general acceptance should be proven within the field of holistic medicine. In this case holistic healers such as chiropractors or herbalists would be consulted to determine general acceptance.¹⁸² Because the hypothetical herbal therapy is relatively new and innovative, it is unlikely to have gained general acceptance, even among herbal practitioners.¹⁸³ The simple fact that two known practitioners have used it and believe in its effectiveness probably is not enough to constitute general acceptance.¹⁸⁴

In conclusion, both the medical doctors and the holistic healers are unlikely to determine that the general consensus in each group would be to use plaintiff's expert's relatively new herbal therapy to treat cancer. Therefore, application of the *Frye* test would likely bar the admission of this evidence.

181. Oncologists are physicians specializing in the study of tumors. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1575 (1976). See *infra* part IV.B. (proposing that each district retain panels of scientists representing each scientific discipline, and that questions of general acceptance be submitted to appropriate panel for determination).

182. See *infra* part IV for a suggestion about how courts may assess general acceptance.

183. Use of the *Frye* test often prevents the admission of new or innovative procedures or techniques. See, e.g., Giannelli, *supra* note 51, at 1207 (stating that *Frye* test "eliminates the need for time-consuming hearings on the validity of innovative techniques"); Forinash, *supra* note 12, at 227-28 (stating that *Frye* standard restricts use of new scientific techniques which may be valid); Comment, *The Voiceprint Dilemma: Should Voices Be Seen and Not Heard?*, 35 MD. L. REV. 267, 289 (1975) (noting that use of *Frye* retards "admission of scientific evidence based on new procedures since it may be some time before they 'attain sufficient currency and status to gain the general acceptance of the relevant scientific community'" (quoting *United States v. Addison*, 498 F.2d 741, 743 (D.C. Cir. 1974))).

184. See, e.g., Comment, *supra* note 183, at 289 (stating that in situation where "one half the scientific community testified that a procedure was reliable and one half testified that it was not, the judge . . . could not find that it was generally accepted").

2. Experimental drug

a. Daubert analysis

i. reliability and relevance

The first step under *Daubert* is the reliability issue: Does this testimony qualify as “scientific knowledge”?¹⁸⁵ In deciding this the trial court must determine whether the proffered scientific testimony is grounded in the procedures and methods of science.¹⁸⁶ As discussed below, the animal studies undoubtedly qualify. The ninety percent remission rate further supports this conclusion and favors the study’s validity.¹⁸⁷ Thus, the animal studies appear to pass the test of reliability.

The next step is relevance: Does the proffered testimony “‘assist the trier of fact to understand the evidence or to determine a fact in issue’”?¹⁸⁸ Will these animal studies at all assist in determining the chance to cure issue? Animal studies are likely to be ruled relevant. Before the FDA allows clinical trials in humans, “the agency requires that the drug be administered to and its short-term effects be studied in laboratory animals. The FDA uses data from these studies to decide if the drug is sufficiently safe to be tested in humans.”¹⁸⁹ Furthermore, “animal studies provide information essential to the continued clinical use and, ultimately, the approval of the drug.”¹⁹⁰ Although the results of animal studies do not predict perfectly the drug’s effects in humans,¹⁹¹ “laboratory animals remain the best practical experimental models for

185. *Daubert*, 113 S. Ct. at 2795.

186. *Id.*

187. “In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*.” *Id.* at 2795 n.9.

188. *Id.* at 2795 (emphasis omitted) (quoting FED. R. EVID. 702).

189. PAREXEL INT’L CORP., *NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW* 19 (Mark P. Mathieu & William J. Murphy III eds., 1987).

190. *Id.*

191. Limitations of animal testing include the fact that “[e]xtrapolation of toxicity data from animals to humans is not completely reliable” and the fact that “rare adverse effects are unlikely to be detected.” Bertram G. Katzung, M.D. & Barry Berkowitz, *Basic & Clinical Evaluation of New Drugs*, in *BASIC AND CLINICAL PHARMACOLOGY* 44, 45-47 (Bertram G. Katzung, M.D. ed., 1987); see also COUNCIL FOR INT’L ORGS. OF MEDICAL SCIENCES, *SAFETY REQUIREMENTS FOR THE FIRST USE OF NEW DRUGS AND DIAGNOSTIC AGENTS IN MAN* 16 (1983) (noting that (1) many animal studies involve use of inbred strains with restricted genetic backgrounds, while humans’ genetic backgrounds are more heterogeneous; (2) results obtained are likely to be consistent with test species’ restricted genetic make-up; and (3) interspecies variations in pharmacokinetics, metabolism, or response may depend on functions such as diet, further restricting the reliability of extrapolations between species); Robert E. Scott, Jr., *Junk Science Attempts to Create Medical and Scientific Causation*, 57 DEF. COUNS. J. 462, 469 (1990) (stating that animal studies raise hurdles with regard to causation, including intraspecies variations and unreliability of extrapolation).

identifying and measuring a compound's biological activity and for predicting its clinical effects."¹⁹² Moreover, despite any interspecies differences in metabolism, uptake, and organ distribution, "most toxicologists believe that animal studies do have a role in predicting human toxicity."¹⁹³ On the other hand, many drugs that raise interest in animal and other laboratory tests never get used on humans due to their inefficiency, excessive toxicity, or limited usefulness.¹⁹⁴ One commentator estimated that of every 2000 chemicals studied, only one proves safe and effective enough to be sold for human use.¹⁹⁵ Others pessimistically estimate that only one out of 10,000 ever finds its way to the pharmacy.¹⁹⁶ Therefore, one may think of the relevancy of animal studies to human application as possibly questionable. However, without animal studies, possibly *no* new drugs would ever be discovered to be safe and effective in humans.¹⁹⁷ On balance, findings of efficacy and low toxicity in animals, while far from conclusive as to a drug's suitability for human use, *do tend* to render it "more probable than it would be without the evidence" that the drug *is* safe and effective in humans; therefore, these findings are "relevant" within the definition of Federal Rule of Evidence 401.¹⁹⁸ Accordingly, the evidence is arguably relevant, and the expert's testimony about it will likely be found capable of "assist[ing] the finder of fact to understand the evidence or to determine a fact in issue," thereby satisfying the requirement of Federal Rule of Evidence 702.

192. PAREXEL INT'L CORP., *supra* note 189, at 19.

193. Michael D. 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, 656 (1992) (footnote omitted). Although animals are important in preclinical drug studies, certain limitations must be recognized. Katzung & Berkowitz, *supra* note 191, at 45-47. These include the ethical concerns of using large numbers of animals to obtain adequate data, the unreliability of extrapolating toxicity data from animals to humans, and the unlikelihood of detecting rare adverse effects. *Id.*

194. Flieger, *supra* note 111, at 11.

195. Cohn, *supra* note 108, at 9.

196. *Id.*

197. The first step in developing safety data for new drugs is preclinical animal testing. PAREXEL INT'L CORP., *supra* note 189, at 19. Animal studies provide toxicological and pharmacological information that is necessary if one wishes to obtain FDA authorization to begin clinical trials. *Id.*; see also COUNCIL FOR INT'L ORGS. OF MEDICAL SCIENCES, *supra* note 191, at 35 (noting importance of investigating general pharmacological properties of drugs in animals prior to administration in man).

198. See FED. R. EVID. 401 (" 'Relevant evidence' means evidence having any tendency to make the existence of any fact . . . of consequence . . . more probable or less probable than it would be without the evidence.").

ii. general observations

The next steps of the *Daubert* analysis are the four “general observations.” First is testability: Has the proposed treatment been tested or is it capable of being tested? According to the pharmacologist’s testimony, to date, Drug *E* has been tested formally only in rats and monkeys. It is certainly a testable treatment, since its efficacy already has been tested with a high degree of success in animals. That side effects and toxicity were found to be minimal in these animals supports the proposition that Drug *E* also is testable in humans.¹⁹⁹ Although no tests have yet been performed on human subjects in the United States, nor has any human data been collected here, the fact that Drug *E* is available and used in some foreign countries further strengthens the argument that it is “capable” of being tested²⁰⁰ in humans. Drug *E* therefore should pass the *Daubert* “testability” requirement; it not only “has been” tested on animals, but it also “can be” tested on humans.²⁰¹

This hypothetical unquestionably satisfies the second *Daubert* “general observation” concerning peer review and publication. The *New England Journal of Medicine* is a reputable, mainstream, peer-reviewed medical journal.²⁰² Since the pharmacologist has published a study in that journal, Drug *E* clearly meets this requirement as to the animal tests—despite the fact that there has not been a peer-reviewed or published finding of efficacy in humans.

199. Toxicity is one factor that may prevent a seemingly interesting drug from making the transition from animal studies to human clinical trials. Flieger, *supra* note 111, at 11.

200. “[T]he statements constituting a scientific explanation must be capable of empirical test” *Daubert*, 113 S. Ct. at 2797 (quoting C. HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 49 (1966)) (emphasis added).

201. See *id.* (quoting C. HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 49 (1966)).

202. Physicians consider the *New England Journal of Medicine* one of the most highly regarded medical publications: “The *New England Journal of Medicine* is the premiere, most cited-to journal; it may be the best in the world.” Telephone Interview with John D. Abduhian, M.D., Senior Fellow in Gastroenterology, Department of Medicine, Loma Linda University Medical Center (Jan. 11, 1994). Courts have recognized this journal’s prestige as well. See, e.g., *Bailey v. Lally*, 481 F. Supp. 203, 217 (D. Md. 1979) (describing *New England Journal of Medicine* as “highly regarded” journal); *Grippe v. Momtazee*, 705 S.W.2d 551, 557 (Mo. Ct. App. 1986) (recognizing *New England Journal of Medicine* as “prestigious” journal). Although journals such as the *Journal of the American Medical Association* and the *New England Journal of Medicine* are considered prestigious,

[a]rticles published in periodicals and journals are not vested with the same trustworthiness and reliability as that possessed by standard texts used in the practice and teaching of various professions. . . .

. . . Many of the articles published in such journals are mere expressions of the authors’ opinions on controversial subjects. . . . [Such] articles relate to experimentation and speculation based upon preliminary studies and are intended to invoke comment and criticism.

Id. at 556-57.

The next "general observation" that trial courts are expected to consider under *Daubert* is the error rate, either known or potential. In this hypothetical the rate of remission in animal tests with Drug *E* is ninety percent, with ten percent of the animals tested not responding. Assume that enough testing has been conducted so that known error rates of five percent for false positives and two percent for false negatives have been obtained.²⁰³ The *Daubert* majority opinion is not enlightening as to what the trial judge should do with a known or potential error rate; it only advises that the trial court "should consider" error rates.²⁰⁴ Because the known error rate of two percent for false negatives in this case is within the acceptable range according to *United States v. Williams*,²⁰⁵ cited by the *Daubert* majority,²⁰⁶ it arguably is acceptable—assuming that the results of animal studies are reliable predictors of drug efficacy and safety in humans.²⁰⁷ The five percent rate for false positives falls within the acceptable range in *Williams* before "doubtful comparisons were eliminated."²⁰⁸ Arguably, under *Daubert*, this also would be acceptable—again assuming that animal studies are reliably predictive for humans. Particularly because the admissibility inquiry under *Daubert* is to remain "a flexible one,"²⁰⁹ the fact that these error rates were not obtained in human studies might not bar their admissibility. A court might note, for example, that the tests were performed on monkeys, and that monkeys have been called "a relatively good human predictor."²¹⁰

203. In drug efficacy studies, because of variations in each subject receiving the drug and other factors such as the complexity of the appropriate calculations, true error rates are extremely difficult to ascertain. See *supra* notes 137-48 and accompanying text for a complete discussion of this problem.

204. *Daubert*, 113 S. Ct. at 2797.

205. 583 F.2d 1194 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979). In the *Williams* case, which dealt with spectrographic voice identification in a criminal trial, a false identification rate of 6.3%—which was reduced to 2.4% after eliminating questionable cases—was held to be an acceptable rate of error. *Id.* at 1198. The spectrographic voice analysis evidence was therefore held admissible. *Id.* at 1201.

206. *Daubert*, 113 S. Ct. at 2797 (citing *Williams*, 583 F.2d at 1198).

207. It is not possible to state any generally applicable "error rate" in predicting human safety and efficacy based on animal studies. However, it is well-documented that dramatic differences between drug effects on humans and animals can and do appear. In addition, the fact that a drug is safe and effective in animals is no guarantee that it will be so in humans. See *supra* notes 193, 199 and accompanying text; *infra* notes 210, 218-40 and accompanying text.

208. *Williams*, 583 F.2d at 1198.

209. *Daubert*, 113 S. Ct. at 2797.

210. Green, *supra* note 193, at 655. This is not always the case, however. See, e.g., Andrew G. Hendrickx & Mark A. Cukierski, *Reproductive and Developmental Toxicology in Nonhuman Primates*, in PRECLINICAL SAFETY OF BIOTECHNOLOGY PRODUCTS INTENDED FOR HUMAN USE 73, 79 (Charles E. Graham ed., 1987) (stating that when imported primates are used in drug study, lack of knowledge of animals' medical history could lead to use of animals possessing medical conditions possibly affecting response to drug being studied); David P.

Finally, under *Daubert*, “‘general acceptance’ [within the relevant scientific community] can yet have a bearing on the inquiry.”²¹¹ Although Drug *E*’s apparent success in animal studies was “accepted” in the sense that it was published in the well-respected *New England Journal of Medicine*,²¹² its effectiveness in humans is not yet known, nor is Drug *E* “generally accepted” for use in human patients in the United States. It *is*, however, considered acceptable for human use in some foreign countries.²¹³ Plaintiff’s decedent allegedly had the resources to travel to one of these countries for treatment. Although Drug *E* probably would not pass the “general acceptance” test for human treatment in the United States, it arguably would pass as “generally accepted” in some foreign countries.²¹⁴ Since plaintiff’s decedent would have been able to travel and receive treatment elsewhere had the diagnosis been timely made, Drug *E* could arguably be considered generally accepted under these specific circumstances. Even if the trial judge concluded that Drug *E*’s safety and efficacy are *not* generally accepted, this is only *one* of the factors to consider in the “flexible” inquiry the *Daubert* majority describes.

Although the only promising documented results for Drug *E*’s use in treating breast cancer are from animal studies, in light of the above analysis, this experimental drug would arguably pass as admissible scientific evidence under *Daubert*.

Rall, *Animal Models for Pharmacotherapeutic Studies*, in ANIMAL MODELS FOR BIOMEDICAL RESEARCH III 125, 129 (1970) (noting that in toxicity studies of anticancer drugs, predictability of biological effects from dogs and monkeys to humans failed with respect to renal toxicity—this effect being found in test animals, but not in humans).

211. *Daubert*, 113 S. Ct. at 2797.

212. See *supra* note 202 and accompanying text for a discussion of the *New England Journal of Medicine*.

213. See *supra* note 111 for a discussion of non-FDA-approved drug availability in foreign countries.

214. See *supra* note 111. A counterargument is that “general acceptance” in foreign countries cannot mean *scientific* acceptance, as *Daubert* seems to contemplate, if the laws of the foreign countries in question do not impose stringent FDA-like testing and approval procedures. A rigorous weighing of *Daubert*’s “general observation” about “general acceptance” would therefore arguably require the court to study foreign drug approval laws, and to take evidence as to the strictness and skill with which those laws were enforced, before accepting foreign availability as *any* evidence of a drug’s *scientific* “general acceptance.”

b. Frye analysis

Under *Frye*²¹⁵ first the relevant scientific community must be defined.²¹⁶ In this case because Drug *E* is undergoing the FDA approval process, it is potentially a drug that will be used by physicians; hence, physicians who diagnose and treat cancer should comprise the relevant scientific community. Therefore, the degree of Drug *E*'s general acceptance among oncologists—cancer specialists—should probably be ascertained.²¹⁷

Because animal studies appear successful and the FDA has not yet approved Drug *E* for use in human clinical trials, the expert pharmacologist is suggesting that plaintiff's decedent should have been sent to a foreign country for treatment with Drug *E*. Most oncologists, or physicians in general, would probably not consider this a generally accepted, viable option.

i. reliability of animal testing

Animal studies²¹⁸ of a drug do not always reliably predict the drug's likely effects on humans.²¹⁹ At times a drug may appear extremely toxic in animals, while there are no signs of serious reactions in humans.²²⁰ Conversely, a drug may show no signs of toxicity in animal studies, while

215. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), *superseded by* FED. R. EVID. 702, *construed in* *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993).

216. *Cf. Forinash*, *supra* note 12, at 257-58 (discussing courts' problems in defining scientific community).

217. Patients usually first present themselves to a general practitioner; however, in the case of breast cancer, a gynecologist may be the first to identify a potentially cancerous lump. If the general practitioner or gynecologist suspected cancer, the doctor would then order further testing to obtain a definitive diagnosis. Therefore, Drug *E*'s general acceptance may have to be determined in these fields as well. For the sake of simplicity, however, this Note will analyze general acceptance among oncologists as being representative of all medical disciplines.

218. Preclinical testing (on animals) includes pharmacology and toxicity testing. PAREXEL INT'L CORP., *supra* note 189, at 22-23. Pharmacological studies are aimed at determining dose-response relationships, the drug's duration and mechanism of action, and information about the drug's absorption, distribution, metabolism, and excretion. *Id.* at 23. Toxicity studies identify and measure a drug's long- and short-term toxic effects. *Id.*

219. See *supra* note 191 and accompanying text for a complete discussion of limitations involved in animal testing.

220. See, e.g., Rall, *supra* note 210, at 125 (stating that "penicillin is so toxic in the guinea pig that, had it first been tested in this species, it never would have been developed further"); B.P. Richardson et al., *Bromocriptine*, in *SAFETY TESTING OF NEW DRUGS* 19, 55-56 (D.R. Laurence et al. eds., 1984) (reporting that rabbits receiving pituitary tumor treatment drug bromocriptine reacted with uterine tumors and produced fetuses with cleft palates, while "neither of these effects was relevant for the use of the compound in humans").

humans experience severe adverse reactions.²²¹ For example, animal testing of practolol, a beta-blocker drug used to treat heart conditions, showed no evidence of serious eye problems as a side effect.²²² Later, when humans used this drug, some developed oculomucocutaneous syndrome, a rare but serious eye condition.²²³ Animal testing of practolol was, therefore, one of the "greatest failure[s] of extensive animal testing for prediction of serious side effects"²²⁴

A recent and tragic example of a seemingly safe and promising new drug is filuridine (FIAU), which, despite having passed preclinical tests in animals, caused death in five of fifteen human patients in long-term clinical trials.²²⁵ FIAU, a remarkably promising new drug for the treatment of the often-fatal liver disease hepatitis B,²²⁶ was undergoing its first long-term human clinical trial.²²⁷ The drug appeared effective and safe in animal studies.²²⁸ In March and April 1993, ten patients enrolled in a six-month study of FIAU; five more enrolled in June.²²⁹ By early June "several patients began complaining of nausea, vomiting and lack of appetite."²³⁰ One patient showed elevated liver enzymes, which usually indicates a flare-up of hepatitis. This was puzzling, however, since the hepatitis virus was gone.²³¹ On June 25 one of the study participants developed multiorgan system failure: "His body was overwhelmed with severe lactic acidosis."²³² Later that same day, the patient with the elevated liver enzymes developed lactic acidosis as well.²³³ At that point, all study participants were ordered to stop taking the drug.²³⁴ Within one week seven patients developed serious lactic acidosis; some patients

221. See, e.g., Mary J. Tucker et al., *Tamoxifen*, in SAFETY TESTING OF NEW DRUGS, *supra* note 220, at 125, 157-58 (noting that with tamoxifen, an oral contraceptive used for cancer therapy, most common reasons for withdrawing patient from drug are nausea and vomiting—although neither reaction was observed in studies on dogs, which are normally considered predictive for vomiting in man).

222. See J.M. Cruickshank et al., *Beta-adrenoceptor Blocking Drugs: Pronethalol, Propranolol and Practolol*, in SAFETY TESTING OF NEW DRUGS, *supra* note 220, at 93, 93, 120.

223. See *id.* at 120.

224. *Id.*

225. See Marlene Cimon, *Fifth Patient Dies in Drug Test Gone Awry*, L.A. TIMES, Sept. 1, 1993, at A23.

226. Marlene Cimon, *The Deadly Risks of Research*, L.A. TIMES, Aug. 25, 1993, at A1.

227. *Id.* at A16.

228. *Id.* at A1.

229. *Id.* at A16.

230. *Id.* at A17.

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

Shortly thereafter, a well-controlled clinical trial of Laetrile began.²⁴⁸ Although a lay person may interpret the FDA's authorization of Laetrile clinical trials as lending credibility to the drug's efficacy, in reality the FDA was simply "yielding to public pressure."²⁴⁹

During the Laetrile trial, toxic side effects were discovered including nausea, vomiting, headache, and dizziness.²⁵⁰ In addition, many patients suffered from cyanide poisoning; evidently, the breakdown of Laetrile caused cyanide release.²⁵¹ Cyanide levels in some patients reached levels known to kill animals and possibly humans.²⁵² This study showed that

Laetrile produced no discernible benefit, as measured by decreased tumor size or prolongation of survival More than three-quarters of the patients had died of their disease by the end of the study, and their survival times seemed fully consistent with those of patients receiving no treatment. Moreover, several patients had symptoms suggestive of cyanide toxicity or blood cyanide levels that approached the toxic range (or both). Thus, the study demonstrated that Laetrile could not be considered either safe or effective.²⁵³

Because Laetrile had "been advertised to the public, the state legislatures, and the courts as nontoxic,"²⁵⁴ the authors of the Laetrile study deliberately emphasized the fact that "Laetrile is a toxic drug."²⁵⁵

In light of the well-known problems in animal extrapolation—recently exemplified by the FIAU tragedy—and the history of the Laetrile controversy, most physicians probably would not consider it "generally accepted" that animal-tested, but non-FDA-approved, Drug *E* is safe and effective for use in humans. Therefore, the pharmacologist's expert testimony probably would not be admitted under *Frye*.

248. *Id.*; see Nightingale, *supra* note 243, at 336.

249. Kardinal, *supra* note 111, at 569.

250. Charles G. Moertel, M.D., et al., *A Clinical Trial of Amygdalin (Laetrile) in the Treatment of Human Cancer*, 306 NEW ENG. J. MED. 201, 203 (1982).

251. *Id.* at 203-04.

252. *Id.* at 206.

253. Nightingale, *supra* note 243, at 336-37. Although some patients displayed minimal improvements, these were "within the range that could be anticipated with placebo treatment." Moertel et al., *supra* note 250, at 204-05. Given the great risk of toxicity, the risks of such a treatment appear to be greater than any marginal benefit. See, e.g., *id.* at 204-06.

254. Moertel et al., *supra* note 250, at 206.

255. *Id.*

C. Problems in Admitting Each Hypothetical Expert's Testimony

The *Daubert* decision lowers the barriers to the admissibility of scientific, or so-called scientific, evidence and leaves trial judges with considerable discretion. “[W]ith the right judge—from a plaintiff’s standpoint . . . there is clearly a lower standard of admissibility.”²⁵⁶ Because judges vary in their experience with scientific matters, their knowledge or understanding in deciding what is scientifically valid will also vary, and there will undoubtedly be inconsistencies in what is admitted. Once “scientific” evidence is admitted, it often easily impresses lay jurors and causes them to overestimate its probative value;²⁵⁷ jurors therefore may misinterpret an “erroneous theory” as the prevailing scientific consensus.²⁵⁸ If, in the above hypothetical variations, the proffered expert testimony is indeed admitted, the defendant doctor will be at an unfair disadvantage due to the trier of fact’s tendency to accept scientific testimony as absolute truth—thereby giving it more weight than warranted—and its tendency to sympathize with a plaintiff whose misfortune is unquestionably real, even if causation is in doubt.²⁵⁹

256. Reuben, *supra* note 8, at 31 (quoting attorney Raoul D. Kennedy).

257. *See, e.g.*, *United States v. Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) (claiming that because of its apparent objectivity, scientific testimony will likely carry undue weight with trier of fact); *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974) (asserting that scientific evidence may appear “mystically infallible” in eyes of lay jury); *United States v. Amaral*, 488 F.2d 1148, 1152 (9th Cir. 1973) (stating that “because of its aura of special reliability and trustworthiness,” scientific testimony may cause undue prejudice, or may confuse or mislead jury).

258. Forinash, *supra* note 12, at 243-44.

259. Jurors may improperly consider invalid scientific testimony, because they are impressed by the expert’s credentials or courtroom manner. *See, e.g.*, A. Harold Frost, *Impartial Medical Testimony*, 1960 INS. L.J. 17, 18 (“An ignorant or corrupt doctor may be more impressive on the witness stand than a learned and upright physician.”); Edward J. Imwinkelried, *Judge Versus Jury: Who Should Decide Questions of Preliminary Facts Conditioning the Admissibility of Scientific Evidence?*, 25 WM. & MARY L. REV. 577, 603 (1984) (stating that although jurors may recognize scientific technique as invalid, jurors often nonetheless consider it as evidence because of expert’s impressive credentials); Larry W. Myers, “*The Battle of the Experts*”: *A New Approach to an Old Problem in Medical Testimony*, 44 NEB. L. REV. 539, 556 (1965) (“The testifying doctor who has the greater experience in the courtroom and who is the more eloquent may win the minds of the jurors over the doctor who may give more appropriately qualified but less eloquent testimony on the matter in question.”). Furthermore, many believe that “[p]laintiffs’ attorneys love juries. . . . because juries’ sympathies can be appealed to.” C. Edward Fletcher III, *Learning to Live with the Federal Arbitration Act—Securities Litigation in a Post-McMahon World*, 37 EMORY L.J. 99, 123 (1988).

1. Holistic practitioner: Herbal treatment

One recent case decided under *Daubert, Cantrell v. GAF Corp.*,²⁶⁰ suggests that the hypothetical holistic practitioner's testimony about his self-tested herbal remedy may very well be admitted.²⁶¹ One problem with admitting opinion testimony as to the efficacy of the herbal mixture as scientific evidence is that often such "miracle cures," which will reportedly cure some people with no proven traditional medical explanation, actually are found to be ineffective.²⁶² The explanation for their apparent success is psychosomatic: The mind tells the body to get well, and in some cases, the body heals itself.²⁶³ This occurs not only with holistic medicine, but with faith healing as well.²⁶⁴

As an example, in the 1950s, researchers discovered Krebiozen, a "miracle drug" believed to cure cancer.²⁶⁵ Thousands of cancer patients vigorously attempted to obtain this unusual drug.²⁶⁶ Of those bedridden patients who did take Krebiozen, many were soon out of bed, and in many cases their tumors shrank dramatically.²⁶⁷ However, once research proved that Krebiozen was not an effective cancer cure, patients who were thought to be cured suddenly relapsed and died from their cancer.²⁶⁸ The seemingly positive effects of Krebiozen therefore appear to have been due to psychosomatic factors, rather than an actual pharmacologic mechanism. This situation can be compared to that of the hypothetical herbal mixture allegedly "curing" some patients—that is, any improvement in the patients' condition possibly could have been due to psychosomatic factors, rather than proven pharmacologic action.

260. 999 F.2d 1007 (6th Cir. 1993).

261. See *supra* notes 152-62 and accompanying text for a discussion of *Cantrell v. GAF Corp.*, 999 F.2d 1007 (6th Cir. 1993).

262. Unproven methods of cancer management include everything from overt quackery with intent to defraud to honestly well-intentioned, but unusual, treatments which have no scientific basis. Kardinal, *supra* note 111, at 564. The "confused and terrified cancer patient" who "will search for and cling to anything that gives him hope" is "easy prey" for promoters of such cures. *Id.* Examples of "quack cancer remedies" include Krebiozen and Laetrile; another unproven mixture was Harry Hoxsey's herbal tonic for internal cancer, introduced in the 1950s. *Id.* at 567-68. See *supra* notes 165-80 and accompanying text for a complete discussion of the Hoxsey medicines.

263. DiMATTEO & FRIEDMAN, *supra* note 143, at 61-62.

264. *Id.* at 61-63.

265. *Id.* at 60. Krebiozen "achieved wide acclaim, partly because of the support of Dr. Andrew C. Ivy, who had been a distinguished teacher and investigator." Nightingale, *supra* note 243, at 333. As a cancer remedy, Krebiozen never was approved for use in the United States. See *id.* In 1969 the interstate commerce of Krebiozen was banned permanently. Kardinal, *supra* note 111, at 568.

266. DiMATTEO & FRIEDMAN, *supra* note 143, at 60.

267. *Id.*

268. *Id.*

An additional reason why the holistic practitioner's opinion as to the efficacy of his cancer cure should not be admitted into evidence is the treatment's untested potential for dangerous side effects. Because it has been neither FDA tested nor approved, its potential to cause harmful side effects may not be known; until testing, the proposition that it is safe is speculative. For example, during the clinical trial of Laetrile²⁶⁹ investigators discovered that the drug caused many toxic side effects, including cyanide poisoning.²⁷⁰

Because the pharmacologic effects of the holistic practitioner's cure have not been proven, evidence that it seemingly *did* cure should be excluded. Additionally, due to the lack of formal FDA-approved testing of the mixture, dangerous side effects or harmful byproducts have not been identified; therefore, testimony that plaintiff's decedent should have received this treatment should be prohibited.

2. Ph.D. pharmacologist: Experimental Drug *E*

To a trial judge or a juror, Drug *E* would probably appear to be more scientifically valid than the herbal mixture: After all, the animal studies sound promising, it is already available in some countries, and the drug company has applied to the powerful FDA. Nonetheless, testimony as to Drug *E*'s possibility of curing plaintiff's decedent should not be admitted.

First, a drug's success in animal studies does not always correlate to success in humans. Due to interspecies variation in metabolism and size, as well as other factors, "the causal inference from an animal study to a similar effect in the human population is . . . tenuous."²⁷¹ Furthermore, doses to which animals are exposed are "many multiples or orders of magnitude [greater than] a typical human dose," thus raising questions about the dose-response relationship for animals as compared with humans.²⁷² Because of differences between test animals and humans

269. *Id.* at 64-65. For a further discussion of Laetrile, see *supra* notes 241-55 and accompanying text.

270. Moertel et al., *supra* note 250, at 203-04.

271. Green, *supra* note 193, at 654; see also COUNCIL FOR INT'L ORGS. OF MEDICAL SCIENCES, *supra* note 191, at 12 (stating that in new drug development, "[s]pecies differences in response and the very unsatisfactory nature of many animal models of human disease are important limitations in transferring animal data to man"). For further discussion of problems in extrapolating results of animal studies to man, see *supra* notes 218-40 and accompanying text.

272. Green, *supra* note 193, at 655-56; cf. Bruce N. Ames & Lois Swirsky Gold, *Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis*, 249 SCI. 970, 970 (1990) ("Animal cancer tests are conducted at near toxic doses . . . of the test chemical, for long periods of time . . .").

with respect to effectiveness, toxicity, and other factors, most drugs that appear promising in animal studies are never tested in human clinical trials.²⁷³

Second, the fact that a drug is available and used in a foreign country is not necessarily probative of its safety or efficacy. For example, Laetrile became well-known in the United States in the 1970s.²⁷⁴ However, it was found to be toxic²⁷⁵ and ineffective,²⁷⁶ and was not approved for use in this country.²⁷⁷ Many American cancer patients therefore traveled to Mexico to undergo treatment with this drug.²⁷⁸ Often, patients turn to nonapproved therapies such as Laetrile because of disenchantment or anger with the medical establishment.²⁷⁹ This can prove dangerous and result in enormous costs for patients, their families, and society in general.²⁸⁰

Finally, a drug company's application to the FDA for approval of a specific drug does not mean that the drug will be approved for use in human clinical trials, nor that it will pass the other stages necessary for approval: "[O]f 100 drugs for which investigational new drug applications are submitted to FDA, [only] about 20 of the original 100 will ultimately be approved for marketing."²⁸¹

IV. RECOMMENDATIONS

After *Daubert* the tendency of federal trial judges will probably be to admit scientific evidence that previously was inadmissible, and to instruct jurors as to its weight.²⁸² Lay jurors may not easily recognize when scientific testimony is valid and when it is tenuous or "junk science."²⁸³ As a result, juries may find erroneously in favor of the party

273. Flieger, *supra* note 111, at 11.

274. For a further discussion of Laetrile, see *supra* notes 241-55 and accompanying text.

275. Moertel et al., *supra* note 250, at 206. The toxicity was due to cyanide poisoning. *Id.* at 203-04, 206.

276. *Id.* at 204-05.

277. Nightingale, *supra* note 243, at 337. In fact, the FDA distributed leaflets to consumers, published articles, and disseminated a public warning to educate and warn the public, health professionals, and state legislators about the hazards of Laetrile use. *Id.*

278. DiMATTEO & FRIEDMAN, *supra* note 143, at 65.

279. *Id.*; see also Nightingale, *supra* note 243, at 334 (stating that promise of cure not available from "orthodox" medicine is attractive to cancer patients, and that Laetrile promoters encouraged cancer patients to feel that they were collaborating in effort to "show up" establishment).

280. DiMATTEO & FRIEDMAN, *supra* note 143, at 65.

281. Flieger, *supra* note 111, at 12.

282. Reuben, *supra* note 8, at 31 (comment of attorney David M. Harney).

283. See *supra* notes 257-59 and accompanying text for a discussion of lay jurors' difficulty in adequately comprehending scientific evidence. "Junk science" has been described as "elabo-

offering the questionable scientific testimony, particularly when that party is a plaintiff who has suffered an appalling misfortune and the only real issue is what caused it.²⁸⁴ At best, use of the *Daubert* rather than *Frye* standard will encourage inconsistent, arbitrary admissibility rulings, and hence unpredictable liability exposures and verdict sizes.²⁸⁵ Therefore, *Daubert* should be abandoned.

A. *Frye Plus Some*

To prevent the admission of questionable, unproven hypotheses²⁸⁶ and junk science,²⁸⁷ and to avoid erroneous court decisions based on them, federal courts should return to the *Frye* test. To ensure that a technique, doctrine, or conclusion is indeed "generally accepted" in the relevant scientific community, courts should take advantage of the ability to call their own experts.²⁸⁸ For example, one commentator suggested that

[if] only proponents of a technique appear, the court should *sua sponte* take the responsibility of inquiring not just whether the experts believe the scientific community is generally in agreement, but whether they are in fact aware of any opposing sentiment in the relevant scientific community. The court should then make an effort to ascertain the extent of any opposition so

rate, systematized, jargon-filled, serious-sounding deceptions." PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 2* (1991). It "is a hodgepodge of biased data, spurious inference, and logical legerdemain, patched together by researchers whose enthusiasm for discovery and diagnosis far outstrips their skill. It is a catalog of every conceivable kind of error: data dredging, wishful thinking, truculent dogmatism, and, now and again, outright fraud." *Id.* at 3.

284. See, e.g., Forinash, *supra* note 12, at 223-24 (discussing *Geletucha v. 222 Delaware Corp.*, 182 N.Y.S.2d 893 (N.Y. App. Div. 1959), where New York judge admitted "junk science" that commercial dry cleaning chemical caused decedent's renal failure; despite overwhelming scientific evidence that chemical did not cause renal failure, jury awarded multimillion dollar judgment to decedent's widow).

285. Cf. Giannelli, *supra* note 51, at 1206-07 (stating that proponents of *Frye* test argue, among other things, that *Frye* promotes uniformity in decisions); Miceli, *supra* note 12, at 944 ("The use of the lay jury system in medical malpractice flourishes due to tradition and the doctrine of stare decisis. . . . [T]he current system encourages arbitrary verdicts."); Comment, *supra* note 183, at 290 (noting that use of *Frye* standard results in "greater uniformity in decisions").

286. Unproven hypotheses should not be admitted into evidence. See, e.g., *United States v. Brown*, 557 F.2d 541, 556 (6th Cir. 1977) (noting that "[a] courtroom is not a research laboratory").

287. See *supra* note 283 for a definition of "junk science."

288. FED. R. EVID. 706.

identified, calling its spokes[persons] as court-appointed experts if necessary.²⁸⁹

Similarly, another commentator proposed that trial courts retain a "pool of experts" to consult in questions of general acceptance, or alternatively call experts of their own choosing.²⁹⁰

In sum, courts must find a way to ensure that scientific expert testimony admitted is indeed scientific and possesses a proper foundation. If they do not, it "may tend to confuse or mislead the trier of fact and thus defeat a defendant's right to a fair trial."²⁹¹ Assuring that the subject of scientific testimony is generally accepted is one effective way to achieve this goal.

B. Proposal: Statutory Duty of Courts to Request Rulings on General Acceptance from Preselected Panels of Experts

In order to eliminate the admission of any "manufactured evidence" or nonaccepted scientific techniques, federal courts should be under a statutory duty to request rulings on general acceptance of scientific evidence from preselected panels of experts.²⁹² These groups of experts, the members of which would possess valid licenses in their respective fields and be approved by the National Academy of Sciences²⁹³ or the American Association for the Advancement of Science,²⁹⁴ would include sev-

289. Comment, *supra* note 183, at 293.

290. Mark McCormick, *Scientific Evidence: Defining a New Approach to Admissibility*, 67 IOWA L. REV. 879, 911 (1982).

291. *Brown*, 557 F.2d at 556.

292. Although this approach may appear to be contrary to the adversary system, it will lead to more uniformity in determining "general acceptance" and will avoid problems of comprehension by the trial judge or jury. See, e.g., Wesley, *supra* note 12, at 681-86 (commenting on juries' and trial judges' difficulty in comprehending scientific evidence); Reuben, *supra* note 8, at 32 (quoting attorney Raoul D. Kennedy: *Daubert* will "lead to less consistent results.").

293. The National Academy of Sciences (NAS) is a private scientific organization, membership in which is a "significant honor." Brief for the American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae in Support of Respondent at 2, *Daubert* (No. 92-102). The NAS's "congressional charter, which was signed into law by President Lincoln, provides that the Academy 'shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art . . .'" *Id.* (quoting 36 U.S.C. § 253 (1988)). The NAS works through the National Research Council to examine "scientific and technological questions of national importance, typically referred to it by Congress or the Executive Branch." *Id.* The NAS has a "continuing involvement in the intersection of science and law." *Id.*

294. The American Association for the Advancement of Science (AAAS) "is a non-profit scientific society that, among other objectives, seeks to increase public understanding and appreciation of the importance and promise of science in advancing human progress." *Id.* at 1. Consisting of nearly 300 affiliate organizations and over 134,000 members including scientists, engineers, educators, and policy makers, the AAAS "is now the world's largest general scientific organization." *Id.* at 1-2. Its official journal, *Science*, is "one of the world's most

eral individuals representing each scientific discipline. In order to conserve court time, notice of all scientific evidence questions would be required in advance of trial or any summary judgment motion. The questions would be collected and sent to the appropriate committees of scientific experts. These panels would meet at frequent intervals to determine the "general acceptance" of each issue in question. In a medical malpractice case, for example, the court would refer the particular "general acceptance" question to a panel of professionals having pertinent expertise. An issue of cancer drug efficacy and safety would, for example, be directed to a preappointed group of oncologists and pharmacologists. After the appropriate committee reaches a decision as to the scientific technique's general acceptance, this "ruling" would be sent to the court and accordingly used in determining whether or not to admit the proffered evidence.

Such a system, which would have the effect of screening out expert opinion testimony that has not been shown to rest on scientifically sound principles and methodologies, has several advantages.²⁹⁵ First, it avoids much of the in-court "battle of the experts."²⁹⁶ Because all such opinion testimony previously will have been adjudged to rest on principles and methodologies "generally accepted" in the appropriate field, the problem of judges or juries having to decide between "junk science" and real sci-

frequently cited scientific journals." *Id.* at 2. Like the NAS, the AAAS is involved in the "intersection of science and law" and has an "interest in assuring that the courts avoid reliance on putatively scientific evidence that does not in fact reflect the application of scientific principles." *Id.*

295. At first glance the described system may appear unduly costly. If the system were properly instituted, however, its costs probably would amount to no more than the current trial costs for presenting scientific evidence. Currently, when faced with scientific testimony, the trial judge must rule on its admissibility. This can take considerable time, particularly if the scientific issues are difficult to comprehend. *See supra* notes 12, 257-59 and accompanying text. If the judge errs by admitting evidence that is *not* generally accepted in its field, expenses really start to escalate. Each party must hire expert witnesses to either support or refute the evidence. The cost of keeping the court running each day of trial that the opposing experts "battle it out" should also be considered. Although this cost is not borne entirely by the litigants, it is paid by society: Every day a court is tied up in resolving a scientific evidence admissibility dispute, that court is unavailable for other public business. There are other social costs as well. In particularly long trials, some jurors may not be paid for time away from work; their employers lose their employees' productivity. In addition, doctors have to live with the constant fear of a lawsuit brought on unfounded claims; consequently, they must constantly practice defensive medicine, necessarily fearing that "junk science" could be used against them in a trial. In light of all these factors, the proposed system may actually prove more cost-efficient than the present one. Given the great financial and societal costs paid when "junk science" is admitted under the present system, it is arguable that we cannot afford *not* to institute the proposed system.

296. *See, e.g., Myers, supra* note 259 (discussing battle of experts in medical malpractice cases).

ence is avoided. In addition, if courts adopt this practice, the risk of a possibly "ignorant or corrupt doctor" appearing more impressive to the jury than a "learned and upright physician" is at least reduced.²⁹⁷ Furthermore, because issues of general acceptance will not have to be argued and decided in court, this approach eliminates or reduces the problems of overburdening the courts with scientific issues and loss of judicial time.²⁹⁸ Judges and juries will not have to spend tremendous amounts of time attempting to understand the scientific subject matter of techniques that are not generally accepted.²⁹⁹ Juries will still have to hear scientific evidence, but judges will not have to spend time trying to comprehend an esoteric debate about such things as the statistical significance of the proffered epidemiological evidence.³⁰⁰

Critics of *Frye* cite its restriction on the admission of "new, but valid, scientific techniques."³⁰¹ In issues of drug efficacy and safety, however, this should rarely present a problem. If the expert opinion that the drug is safe and effective rests upon studies of the kind required by the FDA, then the evidence will pass the *Frye* test; it will then be clear that the principles and methodologies underlying the opinion are "generally accepted" within the relevant scientific community. On the other hand, if the opinion rests on anything less than scientifically sound studies, then it is speculative and should be excluded for that reason. In such cases the *Frye* test may be strict, but it is also fair.

Where the issue is negligent treatment, as opposed to negligent failure to diagnose, it should rarely, if ever, be malpractice for a doctor to decline to prescribe an experimental drug whose toxicity has not been

297. Cf. Frost, *supra* note 259, at 18.

298. See, e.g., Wesley, *supra* note 12, at 686 (noting that "[c]ourt dockets are overloaded").

299. See, e.g., *id.* at 681-86; see also *supra* notes 257-59 and accompanying text (discussing juries' difficulty in understanding scientific subject matter).

300. See, e.g., *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570, 575 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991), *vacated and remanded*, 113 S. Ct. 2786 (1993).

301. Forinash, *supra* note 12, at 227-28; see Giannelli, *supra* note 51, at 1223. Coincidentally, the *Daubert* approach also may cause innovative, authentic scientific testimony occasionally to be withheld from the jury, a possibility acknowledged by the *Daubert* court. See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798-99 (1993).

well-tested in humans.³⁰² Indeed, a physician might risk malpractice liability if he or she *does* prescribe the drug in those circumstances.³⁰³

V. CONCLUSION

In the words of Chief Justice Rehnquist,

“General observations” by this Court customarily carry great weight with lower federal courts, but the ones offered [in the *Daubert* majority opinion] suffer from the flaw common to most such observations—they are not applied to deciding whether or not particular testimony was or was not admissible, and therefore they tend to be not only general, but *vague and abstract*.³⁰⁴

By not specifically applying the “general observations” to the *Daubert* case, not concretely explaining how each one *should* be applied, and not defining what each one means, the *Daubert* majority opinion leaves already busy trial judges to figure out for themselves how to interpret and apply this opinion to proffered scientific testimony. Intelligent and proper application of the *Daubert* rule will impose enormous burdens on the time and energies of trial judges.

Daubert appears to leave judges with wide discretion in determining admissibility. Thus, vastly inconsistent outcomes in admissibility rulings will result, depending on each judge’s scientific comprehension and, perhaps, on the judge’s personal inclinations as well. Most judges lack the scientific training necessary to make truly informed decisions in the area of scientific testimony.³⁰⁵ As a result, a great deal of evidence previously inadmissible under *Frye* will be placed before juries. Because most jurors

302. In the United States drugs first are tested on animals and then in humans. Cohn, *supra* note 108, at 6-7. The recent FIAU fiasco illustrates the fact that a drug apparently safe in animals may be fatally toxic in humans. See *supra* notes 225-40 and accompanying text. At least one lawsuit has been filed as a result of this tragedy. See Eva M. Rodriguez, *Drugmaker Defends Fatal Experiment*, LEGAL TIMES, Nov. 29, 1993, at 6, 6.

303. Physicians are increasingly wary of possible malpractice liability. See, e.g., DIMATTEO & FRIEDMAN, *supra* note 143, at 29 (observing recent increase in malpractice insurance rates and fact that “the entire health care system appears to be alarmed at the extensive patient retaliation against physicians”); JAMES ROSENBLUM, MALPRACTICE SOLUTIONS 13 (1993) (stating that “malpractice hangs like a cloud over our health-care system”). As a result, physicians may tend to proceed cautiously when treating their patients, using only treatments proven safe and effective.

304. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2799 (1993) (Rehnquist, C.J., dissenting) (emphasis added).

305. See *supra* note 12 and accompanying text.

lack a solid scientific understanding,³⁰⁶ they are apt to give dubious testimony far more weight than it deserves—particularly when it is offered by a plaintiff whose plight is likely to evoke sympathy and influence a jury to overlook any doubts about causation. The outcome can be quite devastating: Judgments may be entered wrongfully against nonresponsible parties.

The *Daubert* opinion leaves many questions unanswered. Does the opinion apply exclusively to scientific experts, or does it extend to those testifying to “technical” knowledge as well? What if the two “general observations” of low rate of error and testability are satisfied, and the two of general acceptance and peer review are not? What if all factors but general acceptance are met? Or, what if, at first glance, *none* of the factors are *conclusively* met, but the trial judge becomes convinced that by contorting the amorphously defined “general observations,” all four categories will be satisfied? A return to the common-law *Frye* test, along with the use of preapproved scientific committees to determine “general acceptance,” would solve the many problems raised by the United States Supreme Court’s majority opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

*Katherine M. Atikian**

306. See, e.g., Miceli, *supra* note 12, at 944 (“In medical malpractice actions the lay jury simply has no basis in education, training, or experience upon which to arrive at a rational and reasoned verdict.”).

* I would like to thank John D. Abdulian, M.D.; Professor David P. Leonard; H. Reed Metzger, M.D.; John A. Peak, Esq.; Jerrold B. Reilly, Esq.; and Lee E. Vail, Esq.—each of whom patiently read through drafts of this Note and kindly offered insightful comments and suggestions. Thanks are also due to Alison T. Atikian and Raffi G. Najarian, D.D.S., for library assistance. This Note is dedicated to the memory of Deborah L. Haake, Pharm.D., J.D. (Loyola Law School 1988), whose energy and love of science, the law, and life will forever serve as an inspiration.

2