



January 1994

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Recommended Citation

Harlan Watkins, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: General Acceptance Rejected*, 10 SANTA CLARA HIGH TECH. L.J. 259 (1994).

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DAUBERT v. MERRELL DOW PHARMACEUTICALS, INC.:
“GENERAL ACCEPTANCE” REJECTED
Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786
(1993)

Harlan Watkins†

INTRODUCTION

The “general acceptance” standard of *Frye v. United States*¹ — the dominant standard for determining the admissibility of novel scientific evidence at trial for the last 70 years — has been abandoned by the United States Supreme Court in the case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*² This casenote briefly outlines the facts of *Daubert*, addresses the “general acceptance” standard of *Frye* and its relationship with the Federal Rules of Evidence, and discusses the new standard provided by the United States Supreme Court governing the admissibility of scientific evidence in federal court.

FACTS

The petitioners were two minor children, Jason Daubert and Eric Schuller, and their parents. Both of the children were born with serious birth defects. They sued the respondent, Merrell Dow Pharmaceuticals (Merrell Dow), in California state court, alleging that their birth defects were caused by their mothers’ use of Bendectin during pregnancy.³ Respondent Merrell Dow removed the suits to federal court on diversity grounds.

Before trial, but after extensive discovery, respondent moved for summary judgment on the ground that petitioners were unable to produce any admissible evidence that Bendectin causes birth defects in humans.⁴ The petitioners opposed the respondent’s motion for summary judgment with testimony from eight qualified experts, all of whom possessed impressive credentials. The petitioners’ experts con-

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1. 293 F. 1013 (1923).

2. 113 S. Ct. 2786 (1993).

3. Bendectin is a prescription anti-nausea drug marketed by Merrell Dow. *Id.* at 2791.

4. Merrell Dow submitted an affidavit from a “well-credentialed expert” on the risks of exposure to various chemical substances in support of its motion for summary judgment. The affidavit essentially was a detailed review of all the literature on Bendectin and human birth defects, comprising over 30 published studies that involved over 130,000 patients. *Id.*

cluded that Bendectin does cause birth defects in humans based upon a variety of studies conducted with animals that found a causative link between Bendectin and animal malformations at birth. Additionally, the petitioners' experts reanalyzed previously published epidemiological studies and demonstrated similarities between the chemical structure of Bendectin and other substances that are known to cause birth defects.

Applying the *Frye* "general acceptance" standard, the District Court granted the respondents' motion for summary judgment.⁵ Given the vast body of epidemiological data concerning the effect, or lack thereof, of Bendectin upon humans, the court held that expert opinion not based on epidemiological evidence is not admissible to establish causation. Therefore, the petitioners' studies involving animals and Bendectin were inadmissible. The petitioners' evidence that was based upon epidemiological data — the reanalysis and recalculation of previously published epidemiological studies — was inadmissible because the reanalysis and recalculations were not published and thus not subject to the typically rigorous process of peer review.

On appeal, the United States Court of Appeals for the Ninth Circuit affirmed the trial court's decision, citing the *Frye* "general acceptance" standard.⁶ The court held that the methodology of the petitioners' experts could not be considered "generally accepted" because the practices of those experts diverged significantly from the procedures established by the recognized authorities in the field. The United States Supreme Court granted certiorari in order to determine the proper standard for the admission of expert testimony in federal court.⁷

THE *FRYE* GENERAL ACCEPTANCE TEST

In *Frye*, the defendant, on advice of counsel, took a systolic blood pressure deception test (a precursor to the modern polygraph or "lie detector" test) prior to trial. The defendant's counsel then attempted to offer testimony regarding the results from the scientist who conducted the test. The prosecutor objected, and the trial court sustained the objection. On appeal, the Federal Court of Appeals for the District of Columbia held that "the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts

5. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989).

6. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991).

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

in admitting expert testimony deduced from the discovery, development, and experiments thus far made.”⁸ The court also stated:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.*⁹

This now famous passage was the genesis of the *Frye* “general acceptance” test, which has been the dominant standard for determining the admissibility of novel scientific evidence at trial for the last 70 years.¹⁰

THE *FRYE* TEST AND THE FEDERAL RULES OF EVIDENCE

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹¹ the United States Supreme Court held that the *Frye* “general acceptance” standard was superseded by the adoption of the Federal Rules of Evidence, specifically by Rule 702.¹² The *Daubert* opinion is divided into two separate sections. The first discusses the relationship between the *Frye* standard and the Federal Rules of Evidence. The second section focuses upon the type of inquiry that should be made by the trial judge when determining the admissibility of scientific evidence in general.

8. *Frye v. United States*, 293 F. 1013, 1014 (1923).

9. *Id.* (emphasis added).

10. California courts expressly adopted the *Frye* test in the 1976 case *People v. Kelly*, 549 P.2d 1240 (Cal. 1976). Additionally, several California courts employed the theory of the *Frye* test before *Kelly* expressly adopted it. *See, e.g.*, *Huntington v. Crowley*, 414 P.2d 382, 388 (Cal. 1966); *People v. Jones*, 343 P.2d 577, 588 (Cal. 1959); *People v. Wochnick*, 219 P.2d 70, 72 (Cal. Ct. App. 1950).

The California *Kelly/Frye* test has three distinct prongs all of which must be satisfied: (1) General acceptance in the relevant scientific community; (2) testimony from a properly qualified expert regarding the technique and its application; and (3) proof that the correct generally accepted procedures were applied in the particular case under review. *See People v. Fierro*, 821 P.2d 1302, 1318 (Cal. 1991); *People v. Morris*, 807 P.2d 949, 980-81 (Cal. 1991), *cert. denied*, 112 S. Ct. 421 (1991). The third prong was *Kelly's* addition to the *Frye* test, in large part because of the criticisms leveled at *Frye* for failing to include a “determination of reliability in the particular case before them.” *People v. Axell*, 235 Cal. App. 3d 836, 862 (1991).

11. 113 S. Ct. 2786 (1993).

12. Rule 702 provides: “If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.” FED. R. EVID. 702.

The Court, through Justice Blackmun, first held that the *Frye* test had been superseded by the adoption of the Federal Rules of Evidence.¹³ The Court began its analysis with Federal Rules of Evidence 401 and 402¹⁴ in order to contrast the liberal relevance standard of the Federal Rules with the much more stringent common law "general acceptance" admissibility test of *Frye*.¹⁵ While common law, such as *Frye*, under certain circumstances might serve as an aid to the application of the Rules,¹⁶ in this case the co-existence of Rule 702 and *Frye* is impossible as the two standards are inconsistent with one another.¹⁷ Rule 702 does not establish or require "general acceptance" as an absolute prerequisite to admissibility in either the text of the Rule or in the Rule's legislative history.¹⁸ Furthermore, the stringent *Frye* "general acceptance" standard is directly at odds with the liberal evidentiary policies of the Federal Rules as well as the Rules "'general approach of relaxing the traditional barriers to "opinion" testimony.'"¹⁹ For these reasons, the Court also rejected the argument that either the Federal Rules as a whole, or Rule 702 by itself, impliedly assimilated the *Frye* standard.²⁰

After holding that *Frye* was superseded by the adoption of Federal Rule of Evidence 702, the Court next provided some guidance to federal trial court judges with regard to the proper standard for the admission of any scientific evidence, novel or otherwise. Thus, the post-*Frye*, Rule 702 "reliability" approach envisioned by the majority is as follows:

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

14. Rule 401 provides: "'Relevant evidence' means 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." FED. R. EVID. 401.

Rule 402 provides: "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible." FED. R. EVID. 402.

15. *Frye* is "deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles." *People v. Kelly*, 549 P.2d 1240, 1245 (Cal. 1976). See also *United States v. Downing*, 753 F.2d 1224, 1236 (3d Cir. 1985) (Critics of the *Frye* standard have generally cited two problems associated with it: vagueness and conservatism.).

16. See, e.g., *United States v. Abel*, 469 U.S. 45 (1984) (common law interpretation of admissible evidence to show bias found useful).

17. *Daubert*, 113 S. Ct. at 2794 ("*Frye* made 'general acceptance' the exclusive test for admitting expert scientific testimony. That austere standard, absent from and incompatible with the Federal Rules of Evidence, should not be applied in federal trials.>").

18. *Id.*

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

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

Faced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.²¹

Rule 702's requirement of scientific knowledge thus goes to the reliability of the technique, while the requirement that the evidence assist the trier of fact goes primarily to the relevance of the offered evidence.²²

According to the Court, at least four factors should be weighed while undertaking the two-step Rule 702 "reliability" inquiry. In mentioning these factors, however, the Court stressed that it was not providing a definitive test or list.²³ Rather, the following factors were merely "general observations."²⁴

The first factor involves whether the theory or technique that purports to be scientific knowledge can be tested, i.e., whether the particular theory or technique can be falsified.²⁵ Any information that purports to be a scientific explanation must be capable of being tested. "[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability."²⁶

The second factor concerns whether the theory or technique in question has been subjected to peer review.²⁷ One element of the peer review process that the court acknowledged as particularly important was publication,²⁸ the assumption being that publication increases the likelihood that substantive flaws in the methodology will be detected by others.²⁹ Nevertheless, the Court did emphasize the possibility that certain reliable propositions might be too new, or of too limited interest to be published.³⁰ Thus, "[t]he fact of publication (or lack thereof) in a peer-reviewed journal . . . will be a relevant, though not

21. *Id.* at 2796.

22. *Id.* at 2795.

23. *Id.* at 2796. *See also* United States v. Downing, 753 F.2d 1224, 1238-39 (3d Cir. 1985) (a variation on the reliability approach with a slightly different set of factors).

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

25. *Id.*

26. *Id.* at 2797 [quoting K. POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989)].

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

28. *Id.*

29. *Id.*

30. *Id.*

dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised."³¹

Next, in the case of a particular scientific technique,³² the trial court should consider the known or potential rate of error, and whether sufficient standards exist to control the technique's operation.³³ Obviously, a technique known to have a high rate of error and performed without any regulatory guidelines would be less likely considered valid scientific knowledge and probably would be of little assistance to the jury, implicating concerns of both the reliability and the relevance of the offered evidence.

Finally, the court stated that the *Frye* standard of "general acceptance" might still play a role in the admissibility inquiry. "Widespread acceptance can be an important factor in ruling particular evidence admissible, and a 'known technique that has been able to attract only minimal support within the community' may properly be viewed with skepticism."³⁴

CONCLUSION

The crucial difference then between the *Frye* "general acceptance" test and the Rule 702 "reliability" test is the size of the barrier that each standard imposes upon the admission of scientific evidence, and the nature of the inquiry imposed upon the trial judge. The goal of *Frye* is that the trial judge, as a lay person, should not be required to assess the reliability of a complicated scientific technique, but rather should only conduct an overview of the subject that is sufficient to disclose whether scientists significant in either number or expertise oppose a particular technique as unreliable.³⁵ The aim is not to determine whether there are more supporters than detractors, or whether the judge feels that the supporters are right and the detractors are wrong.³⁶ The point is that if two significant groups, both in number and expertise, cannot agree that a technique is reliable, then that technique is not generally accepted.³⁷ The standard is thus a substantial obstacle to the

31. *Id.*

32. The Court mentions spectrographic voice identification technique as one example. *Daubert*, 113 S. Ct. at 2797. Other forensic techniques such as restriction fragment length polymorphism DNA typing would also presumably qualify.

33. *Id.*

34. *Id.*

35. *People v. Brown*, 709 P.2d 440, 450 (Cal. 1985), *rev'd on other grounds sub nom, California v. Brown*, 479 U.S. 538 (1987).

36. *People v. Wallace*, 14 Cal. App. 4th 651, 660 (1993) (citing *People v. Barney*, 8 Cal. App. 4th 798, 819 (1992)).

37. *Id.*

unrestrained admission of evidence based upon new scientific principles.³⁸

On the other hand, under the Rule 702 “reliability” approach, the trial judge’s task is simply to assess whether the offered expert’s testimony rests upon a reliable foundation and is relevant.³⁹ Theoretically, then, evidence based on a scientific technique that is not generally accepted within the relevant scientific community, may nonetheless be admitted if the trial judge believes that the technique is both relevant and reliable. This result is possible notwithstanding the existence of a controversy in the scientific community with regard to the technique, which of course would prevent the evidence from being admitted under *Frye*.⁴⁰ The liberal standard of Rule 702 is accordingly more consistent with the spirit of the Federal Rules of Evidence.⁴¹

38. See *supra* note 14.

39. The Third Circuit compared the two standards: “The reliability inquiry that we envision is flexible and may turn on a number of considerations, in contrast to the process of scientific ‘nose-counting’ that would appear to be compelled by a careful reading of *Frye*.” *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985).

40. “A ‘reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.’” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2797 (quoting *Downing*, 753 F.2d at 1238).

41. The Court was careful, however, to emphasize that Rule 702 “reliability” assessment does not end the analysis. Other applicable evidentiary rules, such as those regarding unfair prejudice and hearsay play a significant role in evaluating the admissibility of scientific evidence. Once the evidence is admitted, other conventional devices, including cross-examination, contrary expert testimony, and jury instructions, as well as summary judgment, directed verdict and judgment as a matter of law, remain for attorneys and the courts to use against shaky but admissible evidence.

