Evidentiary Framework

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I. Introduction

The aim of this paper is to provide a framework for judges in considering disputes over the admissibility of various kinds of scientific evidence. The paper is not intended to be a review of the law of evidence; case citations are included for illustrative purposes primarily. The object is not to suggest that evidence is or ought to be admissible or excluded in any particular case. Instead, this paper is designed to assist judges in structuring inquiries necessary for making rulings on objections to expert evidence in pretrial proceedings, in connection with motions for summary judgment, or in connection with judgments as a matter of law at trial where the legal sufficiency of evidence is challenged.

Rules 702–705 of the Federal Rules of Evidence govern testimony by experts selected by the parties. These rules have a number of characteristics:

1. They were drafted as an integrated solution to the subject of expert testimony.
2. They abolished previous common-law constraints on expert testimony, such as the need for hypothetical questions, the bar on ultimate conclusions, and the *Frye* test.[1]
3. They were drafted in such general terms that the appellate courts have had to give content to the broad objectives mandated in the rules.
4. They accord a great deal of discretion to the trial courts to proceed on a case-by-case basis.

These characteristics have an impact when experts seek to testify about complex science and technology issues. The closely intertwined nature of the rules coupled with the lack of detailed content afford judges the possibility of approaching the same problem from different avenues. What one court has viewed as raising a Rule 702 issue is treated as a Rule 703 matter in a neighboring circuit. In addition, the meaning of particular phrases in the rules has been fleshed out by varying formulas in different courts. To complicate matters further, courts

1. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993), the Supreme Court applied to the expert testimony rules the plain-meaning approach it had previously applied to other Federal Rules of Evidence. Consequently other common-law doctrines that are not mentioned in Article VII of the Federal Rules of Evidence may also have been eradicated. For a discussion of other common-law clichés relating to expert testimony that are not referred to in the Federal Rules, see Margaret A. Berger, *United States v. Scop: The Common-Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brook. L. Rev. 559 (1989).

have disagreed on how Rule 403 operates in conjunction with the rules on expert testimony. It is too soon to determine the extent to which these differences will be resolved in the aftermath of the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

Coherence is at first glance difficult to discern when one surveys the case law on expert testimony. The disagreement among circuits, compounded by the great discretion afforded trial judges, results in a seeming lack of uniformity and consistency that surfaces whenever any two opinions on expert testimony are compared. Contributing to the want of cohesion is the fact that evidentiary rules are applied in a variety of procedural contexts, and courts differ as well in their procedural approaches when they implement evidentiary decisions.

If one looks at the body of recent cases dealing with expert testimony in cases with scientific evidence, however, a considerable amount of the variation turns out to be superficial. Although disparities in judicial methodology are common, there is much less divergence in result. While courts have approached the highly complex, intertwined legal and scientific issues presented by many recent cases from different starting points, the ultimate outcome with regard to expert testimony in groups of related cases has been remarkably consistent within the federal system and was so even before the *Daubert* decision.

As the first case in which the Supreme Court analyzed principles and rules of evidence and procedure governing expert testimony grounded in scientific knowledge, *Daubert* will be cited routinely whenever issues of scientific proof, or indeed any type of expert proof, arise. The majority's approach is, however, extremely general and does not address the many concrete interrelated scientific and legal issues that courts regularly must confront when a case revolves around scientific evidence. Furthermore, although the majority acknowledges that other rules bear on the admissibility of expert proof, its detailed analysis is concerned only with Rule 702 of the Federal Rules of Evidence; the appropriate scope of some of the other rules is not completely clear.

Rather than organizing the discussion in this paper about specific evidentiary rules or *Daubert*, therefore, it seems more fruitful to concentrate on specific problems that require a considerable investment of judicial time when experts seek to testify about scientific matters. Looking at how courts address frequently occurring fact patterns may identify the kinds of questions, scientific as well as legal, that must be considered, and evidentiary and procedural solutions, compatible with *Daubert's* objectives, that courts have used effectively. Although *Daubert* is concerned solely with scientific evidence, the scope of Rule 702 is considerably broader. In a number of sections, therefore, particularly in section II, which deals with an expert's qualifications, this paper considers experts who offer opinions on technological issues in addition to experts whose realm of expertise is classified as scientific knowledge.

After a number of background issues are surveyed, the body of this paper addresses four broad categories that seem to capture the central concerns that permeate judicial opinions:

1. Is the expert qualified?
2. Is the expert's opinion supported by scientific reasoning or methodology?
3. Is the expert's opinion based on reliable data?
4. Is the expert's opinion so confusing or prejudicial that it should be excluded pursuant to Rule 403?

The discussion in sections II–V examines particular issues that courts view as within the scope of these four questions and explores how courts analyze these issues from an evidentiary standpoint in the context of typical scientific fact patterns. Complicating the task of sorting out the various analyses is the fact that many opinions consider all four questions with regard to a particular expert. It may well be that failing to meet a combination of these requirements is what results in the exclusion of expert testimony. Consequently, although issues have been separated out for purposes of discussion, the reader should bear in mind that the distinctions made may at times be somewhat artificial and arbitrary. Cross references to further discussions of the same case have been added in the hope of obviating this problem somewhat.

A. Impact of *Daubert*

Before considering these four central problems, however, a few words are appropriate about the significance of *Daubert* in relationship to this organizational scheme and scientific expert proof in general. The first of the questions posed above—whether the expert is qualified—was not dealt with in *Daubert*; at each level of the litigation, the courts assumed that the proffered experts were adequately qualified pursuant to Rule 702. Clearly, however, Rule 702 mandates a qualified expert, and section II indicates that considerable case law exists dealing with a variety of problems in the context of qualifying scientific experts. The last of the categories to be discussed—when exclusion is warranted by Rule 403—also was not addressed by the *Daubert* court beyond an acknowledgment that the rule may operate to exclude expert testimony in some unspecified instances. Section V discusses the different approaches judges have used when relying on Rule 403 to exclude expert testimony. The ways in which the *Daubert* opinion may affect issues treated in sections III and IV, relating to the validity of the scientific methodology and reasoning and the reliability of the data on which the expert relies, are examined in connection with those sections.

The *Daubert* opinion is significant as well in a more general sense. In what is the first Supreme Court case to examine the governing legal principles that bear on expert scientific evidence, the justices made a number of statements that are

broadly applicable to the problems caused by disputed scientific proof. Of central significance is the Court's recognition both of the Federal Rules' "liberal thrust" with regard to the admissibility of expert testimony and the trial judge's "gatekeeping" role vis à vis expert proof on scientific issues.[2] Although stressing that in the usual case the evaluation of expert testimony must be left to the jury, the majority acknowledged the trial judge's responsibility pursuant to Rule 104(a) of the Federal Rules of Evidence to screen scientific evidence in order to keep unreliable evidence out of the courtroom.[3] The Court emphasized that a trial court must determine at the outset "whether the reasoning or methodology underlying the testimony is scientifically valid," and it discussed a number of nondefinitive factors that bear on the inquiry.[4] Rule 702 applies as well to forms of specialized knowledge other than scientific knowledge. Where courts will draw the line between scientific evidence and other types of evidence requiring expert proof is not yet clear.[5]

In *Daubert*, the majority's opinion concentrates primarily on the appropriate meaning of Rule 702, but advises trial judges to be mindful as well of Rules 703, 706, and 403 in handling scientific evidence. The Court also suggests that "conventional devices," like vigorous cross-examination, careful instruction on the burden of proof, grants of summary judgment, and directed verdicts, may be appropriate instead of the "wholesale exclusion" of scientific evidence under Rule 702.[6]

Finally, in a reprise to the "gatekeeping" role of the trial judge at the end of the opinion, the Court reminds the reader that the goals of science and the law differ. While acknowledging some similarities between the scientific and legal endeavors, the opinion recognizes that

2. *Daubert*, 113 S. Ct. at 2794, 2798–99.

3. *Id.* at 2796. Even Chief Justice Rehnquist and Justice Stevens, who dissented in part because they felt that "general observations" were not needed to dispose of the case, agreed that "Rule 702 confides to the judge some gatekeeping responsibility." *Id.* at 2800.

4. *Id.* at 2796–97. *See* discussion *infra* § III.B.

5. *See* Richard D. Friedman, *The Death and Transfiguration of Frye*, 34 Jurimetrics J. 133, 140 (1994) (expressing hope that courts "will recognize that the dangers that led the court to impose such a requirement are very strong only in cases of great technical complexity and that, even in some fields of great difficulty, at least some issues are not readily susceptible to full exploration by the scientific method"). The American College of Trial Lawyers has suggested extending *Daubert's* approach to expert testimony in general. American College of Trial Lawyers, Standards and Procedures for Determining the Admissibility of Expert Evidence After *Daubert,* 157 F.R.D. (forthcoming Dec. 1994). *See, e.g.*, Iacobelli Constr., Inc. v. County of Monroe, 32 F.3d 19 (2d Cir. 1994) (expert testimony in construction contract dispute does "not present the kind of 'junk science' problem that *Daubert* meant to address"); Tamarin v. Adam Caterers, Inc., 13 F.3d 51, 53 (2d Cir. 1993) (*Daubert* does not apply to testimony by accountant concerning the contexts of payroll records because "that case specifically dealt with the admissibility of scientific evidence"; "payroll records are straightforward lists of names and hours worked"); United States v. D'Ambrosio, No. 92-10526, 1993 U.S. App. LEXIS 27088, at *6 (9th Cir. Oct. 14, 1993) (unpublished disposition) (expert testimony on clothing comparison was central factor in court's decision to sustain defendant's bank robbery conviction; court did not address whether there was a scientific basis for clothing comparison). *See also* discussion of social science evidence *infra* § III.C.2.a.2.

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

> there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly . . . . [The consequence is that] a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.[7]

The *Daubert* opinion's emphasis on the jury's role and recognition of the trial judge's responsibility to keep unreliable evidence out of the courtroom are fully consistent with this manual's approach of providing information about the ways in which the courts have dealt with representative and recurring scientific issues in pretrial and trial contexts. The objective is to ensure the fair and efficient resolution of legal controversies.

B. A Note on Relevancy, or "Fit"

Other than in this section, this paper does not treat relevancy issues. Although Rule 402 of the Federal Rules of Evidence provides that "all relevant evidence is admissible" and "[e]vidence which is not relevant is not admissible," courts often analyze relevancy problems with regard to expert proof pursuant to the expert testimony rules in Article VII of the Federal Rules of Evidence. The Supreme Court endorsed this approach in *Daubert* when it located within Rule 702 the obligation of the trial court to determine whether the proffered scientific evidence "properly can be applied to the facts in issue."[8] The Court, adopting terminology used by Judge Becker in *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985), characterized this consideration as one of "fit."[9] The Court placed the requirement of fit within Rule 702 because evidence or testimony that does not relate to any issue in the case cannot satisfy the rule's requirement of "assist[ing] the trier of fact to understand the evidence or to determine a fact in issue."[10]

Problems with fit occur independently of an expert's qualifications or deficiencies in the expert's scientific knowledge. The difficulty is that the proffered expert opinion may relate to facts or data that have not been adequately established in the case.[11] For instance, a plaintiff will not be able to succeed in a toxic

7. *Id.* at 2798–99.

8. *Id.* at 2796.

9. *Id.*

10. Fed. R. Evid. 702. The Court offers the example of the expert whose scientific training about the phases of the moon enables him or her to establish whether it was dark on a particular night. If that is the issue, the expert's testimony fits. Yet evidence that the moon was full on the night in question does not assist the trier on the issue of whether an individual is likely to be irrational when the moon is full. *Daubert*, 113 S. Ct. at 2796.

11. *See, e.g.*, Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1113–14 (5th Cir. 1991) (plaintiff's expert premised his opinion on a twenty-year history of exposure, although the record indicated that Christophersen had worked in defendant's plant for only fourteen years; majority held that Rule 703 would permit re-

tort case unless he or she can prove adequate exposure to a toxic substance that was somehow connected to the defendant. Even if an expert testifies that Substance X can cause the plaintiff's injury, this testimony will not suffice if the plaintiff failed to produce evidence that he or she was exposed to Substance X,[12] or to a specific defendant's Substance X,[13] or at a significant level.[14]

In excluding an expert opinion as not based on the evidence, the court performs the same analysis in a science-rich case as in a routine motor vehicle accident case, although the complex nature of scientific evidence may make it more difficult in the former case to detect that the expert's testimony fails to provide "a valid scientific connection to the pertinent inquiry."[15] In an accident case, a court will exclude an expert's opinion that the defendant's speeding caused the accident when the record contains no evidence about this possibility—neither direct proof that the defendant was speeding, nor evidence, such as skid marks, from which an inference of speeding may be drawn.[16]

Prior to *Daubert*, a number of federal courts had analyzed the "opinion that does not fit the facts" problem pursuant to Rule 703. Because Rule 703 speaks of an expert's opinion being based upon the "facts or data" in the particular case, some courts had concluded that exclusion is warranted pursuant to Rule 703

jection of an opinion "founded on critical facts that are plainly untrustworthy, principally because such an opinion cannot be helpful to the jury"), *cert. denied*, 112 S. Ct. 1280 (1992); Bernhardt v. Richardson-Merrell, Inc., 892 F.2d 440, 445 (5th Cir. 1990) (affirming grant of summary judgment for defendant when discovery established that drug exposure occurred after that point in pregnancy at which a particular birth defect could have occurred; the court refused to allow statements by the plaintiff's expert which "may be generally true" to create a genuine issue of material fact, relying on its "duty to scrutinize the probative value of the evidence"); Novak v. United States, 865 F.2d 718, 723–24 (6th Cir. 1989) (even if epidemiological evidence supported expert's contention of an increased incidence of persons contracting dermatomyositis/polymyositis (DM/PM) within fifteen days of a swine flu vaccination, evidence showed that decedent's symptoms commenced considerably after fifteen days); Peterson v. Sealed Air Corp., No. 86-C3498, 1991 U.S. Dist. LEXIS 5333, at *21–22 (N.D. Ill. Apr. 22, 1991) (even if Cytoxan may cause transitional cell carcinoma, evidence in the case indicated that plaintiff's cancer was basaloid cell type and not transitional); Bailiff v. Manville Forest Prods. Corp., 772 F. Supp. 1578, 1583–84 (S.D. Miss. 1991) (summary judgment for defendants; plaintiff's expert concluded that plaintiff's respiratory problems were caused by exposure to defendants' products after reviewing Material Data Safety Sheets for chemicals manufactured at defendants' plant; court notes no listing in sheets for only Manville product to which plaintiff was allegedly exposed); Mateer v. United States Aluminum, No. 88-2147, 1989 U.S. Dist. LEXIS 6323, at *21–22 (E.D. Pa. June 2, 1989) (summary judgment for defendant; experts' reports claimed that certain contaminants found in plaintiffs' well may be toxic to humans depending on dose and duration of exposure, but failed to state what level of exposure is hazardous to humans; plaintiffs failed to show that their levels of exposure created a risk); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1089–90, 1093 (D. Md. 1986) (plaintiff's expert relied on study to conclude that there is a three- to five-fold increased rate of pelvic inflammatory disease in women wearing IUDs; only one participant in study, who did not develop pelvic disease, was wearing defendant's device; trial court ultimately directed verdict for defendant because of plaintiff's failure to prove causation after three-week trial and a jury that was unable to reach a verdict), *aff'd sub nom.* Wheelahan v. G.D. Searle & Co., 814 F.2d 655 (4th Cir. 1987).

12. The presence of signature diseases, such as mesothelioma, may, however, permit an inference of exposure.

13. *See* Celotex Corp. v. Catrett, 477 U.S. 317 (1986).

14. *See* Mateer v. United States Aluminum, No. 88-2147, 1989 U.S. Dist. LEXIS 6323 (E.D. Pa. June 2, 1989).

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

16. *Cf.* Newman v. Hy-Way Heat Sys., Inc., 789 F.2d 269, 270 (4th Cir. 1986) ("nothing in the Rules appears to have been intended to permit experts to speculate in fashions unsupported by, and in this case indeed in contradiction of, the uncontroverted evidence in the case").

when the expert's testimony is not tied to any facts or data in the case. These cases should now be resolved pursuant to Rule 702. Details about the expert's methodology may be needed to assess fit and at times, the line between lack of fit and a flawed methodology may be somewhat blurry.[17]

In terms of judicial efficiency, a problem in some cases is that the lack of correspondence between the expert's opinion and the facts of the case is not brought to the court's attention until trial. The increased opportunities for expert discovery under the 1993 amendments to the Federal Rules of Civil Procedure may result in objections based on lack of fit being raised prior to trial by a motion in limine or for summary judgment.

C. Related Procedural Issues

The *Daubert* opinion did not address many of the complex issues that will have to be elucidated in order to reconcile the Supreme Court's recognition of the Federal Rules' liberal admissibility policy for expert proof with its endorsement of the trial judge's gatekeeping function. Many of these issues raise procedural concerns that were not dealt with by the Court. In the future, courts will have to examine the interrelationship of discovery rules and *Daubert*, the nature of judicial screening pursuant to Rule 104(a), and the interplay between issues of admissibility and sufficiency when expert testimony is challenged. In addition, issues may arise as to whether the differing natures of criminal and civil litigation warrant procedural distinctions.

1. Discovery issues

Less than six months after the Supreme Court's decision in *Daubert*, amendments to Rule 26(a)(2) and (b)(4) of the Federal Rules of Civil Procedure became effective that require a party, independently of any discovery request, to disclose the identity of all expert witnesses expected to testify at trial; to provide, among other things, the experts' written signed reports stating all opinions to be offered and support for opinions; and to make the expert available for deposition after the report is submitted.[18] In the absence of court order or stipulation, a party must disclose these items at least ninety days before the trial date or the date on which the case is to be ready for trial. Rule 16(a)(1)(E) of the Federal Rules of Criminal Procedure was simultaneously amended to provide that the

17. *See, e.g.*, DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 955 (3d Cir. 1990), *summ. judgment granted on remand*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (in directing remand, appellate court had determined that fit was satisfied so that district court was not required to consider this factor; opinion on remand notes, however, that plaintiff's expert included in his chart studies that dealt with an ingredient that was not found in the two-ingredient formula of Bendectin ingested by Mrs. DeLuca; the inclusion of these data was treated as an aspect of the expert's suspect methodology), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994). *See* further discussion of this case on remand *infra* §§ III.C.2.b, III.C.3.a. *See also* discussion *infra* §§ IV.B.2.c.2, IV.B.2.c.3.

18. As of this writing, a number of districts have opted out of these procedures.

government must disclose at the defendant's request "a written summary of testimony the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case in chief at trial."

Neither rule specifically requires divulgence of the methodological details that according to *Daubert* bear on the admissibility of expert testimony.[19] It remains to be seen whether courts will require summaries and reports to disclose information bearing on *Daubert*'s nondefinitive checklist of factors and on additional factors that should be considered in particular kinds of cases.[20]

The timing of the disclosures, in the absence of order or stipulation, is geared to trial; yet *Daubert* suggests that in civil litigation, issues concerning the admissibility or sufficiency of expert testimony should be raised before trial. How timing requirements should be adjusted relates to other issues posed by judicial screening that *Daubert* does not address.

2. Judicial screening

The *Daubert* opinion states that when expert scientific testimony is proffered, the district court must make a determination about admissibility "at the outset, pursuant to Rule 104(a)."[21] This Rule 104(a) inquiry requires the proponent of the expert to show by a preponderance of the evidence that the expert's opinion is admissible.[22]

Daubert does not, however, discuss the circumstances that will trigger in limine judicial screening pursuant to Rule 104(a), or the nature of an in limine hearing. While courts are unlikely to undertake the inquiry envisioned by *Daubert* whenever scientific evidence is proffered,[23] it is not yet clear when they must do so. The courts will have to determine whether judicial economy and the "liberal thrust" of the rules pertaining to experts justify placing a burden on

19. Fed. R. Crim. P. 16(a)(1)(E) provides that the "summary must describe the witnesses' opinions, the bases and the reasons therefor, and the witnesses' qualifications." Fed. R. Civ. P. 26(a)(2)(B) requires the report to contain

> a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.

See discussion *infra* § III.B.

20. For example, courts might require divulgence of the background statistical information on which the probative value of an expert's opinion often depends. *See* discussion *infra* § III.C.3.c.

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

22. *Id.* at 2796 n.10 (citing Bourjaily v. United States, 483 U.S. 171 (1987)).

23. Indeed, much of the scientific evidence that is proffered in federal court undoubtedly falls into routine categories in which qualified experts disagree about the interpretation of data that were obtained through standard methodologies. A recent survey by the Federal Judicial Center concluded that orthopedists (17.9%) and neurologists (15.6%) are the two most prevalent types of experts testifying in federal civil cases. *See* Molly Treadway Johnson & Joe S. Cecil, Problems of Expert Testimony in Federal Civil Trials (Federal Judicial Center, forthcoming 1995). *Daubert* is unlikely to affect most of these cases.

the opponent of the expert proof to come forward with evidence showing deficiencies in the expert's testimony before the court has any obligation to engage in a Rule 104(a) analysis. If there is a burden, the courts will also have to consider the height of the burden, and the materials on which the opponent may rely in discharging its burden.[24]

Answering these questions will require consideration of the relationship between in limine screening and the discovery process. In light of the new discovery rules, for instance, must the opponent produce its experts' reports and make its experts available for deposition before a court will entertain an in limine motion?[25] May the opponent rely on affidavits either in seeking in limine consideration or on the motion itself, or should courts restrict their review to materials developed during discovery or at an evidentiary hearing? In a number of cases discussed elsewhere in this paper, judges have expressed concern that expert testimony will be excluded without the proponent of the expert testimony being provided an opportunity to develop an adequate record tested in an adversarial context.[26]

3. Admissibility versus sufficiency

In *Daubert*, the majority acknowledges that scientific evidence that is admissible may not always suffice to discharge the plaintiff's burden of proof. The Court observed that even if evidence is ruled admissible, if "the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, Fed. Rule Civ. Proc. 50(a), and likewise to grant summary judgment, Fed. Rule Civ. Proc. 56."[27] Thus, the distinction between admissibility and sufficiency, though perhaps often blurred in

24. *See* Margaret A. Berger, *Procedural Paradigms for Applying the Daubert Test*, 78 Minn. L. Rev. 1345 (1994).

25. *See In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *31 (3d Cir. Aug. 31, 1994) (citations omitted):

> [W]e generally agree . . . that because under *Daubert* a judge at an *in limine* hearing must make findings of fact on the reliability of complicated scientific methodologies and this fact-finding can decide the case, it is important that each side have an opportunity to depose the other side's experts in order to develop strong critiques and defenses of their experts' methodologies. Given the 'liberal thrust' of the federal rules, it is particularly important that the side trying to defend the admissibility of evidence be given an adequate chance to do so.

26. *See, e.g.*, *In re* Paoli R.R. Yard PCB Litig. (Paoli I), 916 F.2d 829, 855 (3d Cir. 1990) ("At least some process should have been devised to afford plaintiffs a surrogate for that trial scenario where the equivalent evidentiary exclusion and adverse judgment might occur."), *cert. denied*, 111 S. Ct. 1584 (1991) (*see* discussion *infra* § III.C.2.b); Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1122 (5th Cir. 1991) (en banc) (Reavley, J., dissenting) (objecting to exclusion of plaintiff's expert testimony where exclusion was based on affidavits of defendant's experts who were never deposed), *cert. denied*, 112 S. Ct. 1280 (1992) (*see* discussion *infra* § IV.B.2.a).

27. 113 S. Ct. at 2798. *See also* Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After Daubert*, 78 Minn. L. Rev. 1387, 1433 (1994) (urging courts to distinguish between decisions based on the inadmissibility of evidence and decisions based on the insufficiency of evidence).

the past by courts when handling issues relating to scientific evidence, is clearly reaffirmed in *Daubert*.[28] Of course, whether a particular issue should be resolved in terms of the admissibility of expert testimony or the insufficiency of the expert proof to discharge the plaintiff's burden will depend on the circumstances of each case. But it is important for courts to have in mind the differences in the applicable standards depending on which procedure is followed.

The standards that apply to resolution of a motion in limine, primarily Rules 702, 703, and 403 of the Federal Rules of Evidence, are governed by the principles discussed in this paper.[29] The standard that applies under Rule 56 (and its functional equivalent, Rule 50) is quite different. As stated in *Celotex Corp. v. Catrett*, the moving party must demonstrate the absence of a triable issue of fact.[30] Expert evidence may be admissible under the rules of evidence but fail to be sufficient to raise a triable issue.[31] Thus, while in passing on admissibility a judge under *Daubert* may have to rule on whether the methodology or reasoning relied on by an expert in arriving at an opinion was scientifically sound, on summary judgment the judge may have to determine whether the opinion expressed raises a genuine issue of material fact that entitles the proponent to trial.[32]

Even though a defendant may in some instances be able to discharge its burden of production on a summary judgment motion by merely "pointing" to deficiencies in the plaintiff's case,[33] a higher burden may be more appropriate when the defendant is attacking the plaintiff's scientific evidence. Evaluating the validity and sufficiency of a scientific expert's methodology and reasoning may require a more complex determination than that required when the judge merely has to ascertain the availability of evidence on an issue. In making a summary judgment ruling that turns on expert scientific evidence, the court may need to be informed about the kinds of factors discussed in *Daubert*. Affidavits may not suffice to apprise the judge adequately. If a defendant must satisfy a higher burden than merely pointing to alleged deficiencies in the plaintiff's scientific proof, the defendant may have more of an incentive to depose the

28. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 884 F.2d 167, 169 (5th Cir. 1989) (Higginbotham, J., dissenting from the majority's refusal to rehear en banc an appeal granting judgment n.o.v. to defendant in a Bendectin case because the panel had shied away from addressing the crucial issue—the admissibility of the evidence in the first place rather than its sufficiency: "Yet, while skepticism permeates its opinion, the panel does not seem to engage the question at this juncture. Rather, the panel chooses to accept the admissibility of the testimony and to quarrel with its effect.").

29. For a discussion of the relative burdens of the parties on a Rule 104(a) in limine motion, see Berger, *supra* note 24.

30. 477 U.S. 317, 322–23 (1986). *See also* Justice Brennan's dissenting opinion elaborating on the procedure for demonstrating the absence of a triable issue. *Id.* at 328–37; William W Schwarzer et al., The Analysis and Decision of Summary Judgment Motions: A Monograph on Rule 56 of the Federal Rules of Civil Procedure 45–47, 53–57 (Federal Judicial Center 1991). For particular reference to the parties' relative burdens, see William W Schwarzer & Alan Hirsch, *Summary Judgment After Eastman Kodak,* 45 Hastings L.J. 1, 4 (1993).

31. *See, e.g.*, Maffei v. Northern Ins. Co., 12 F.3d 892, 897–900 (9th Cir. 1993); Mid-State Fertilizer Co. v. Exchange Nat'l Bank, 877 F.2d 1333, 1339 (7th Cir. 1989).

32. *See, e.g.*, Bulthuis v. Rexall Corp., 789 F.2d 1315 (9th Cir. 1985).

33. *See Celotex Corp.,* 477 U.S. at 323.

plaintiff's experts in order to substantiate its claims about the defects in the plaintiff's expert proof. Consequently, the court will have the benefit of a record developed through the adversarial process in making its Rule 56 determination. It is not yet clear at this time, however, how courts will handle the procedural issues stemming from the *Daubert* case.

4. Special problems in criminal cases

The *Daubert* opinion deals with the admissibility of scientific evidence in a civil case. With a few exceptions, this paper discusses issues that arise in civil litigation.

Judges may want to consider whether special procedures with regard to scientific evidence need to be devised for criminal cases. The accused may be more handicapped in challenging expert scientific proof proffered against him or her than the civil litigant because of less extensive discovery rights and fewer resources. In addition, the prosecution may have considerable control over the expertise if it participated in creating and applying the forensic technique in question. In light of these factors, burdens of production with regard to in limine hearings might be allocated differently in criminal cases than in the civil context discussed above.[34] When novel scientific evidence is offered, courts might consider the desirability of obtaining more information by appointing experts pursuant to Rule 706, or referring the motion to a magistrate judge for fact-finding and recommendation.[35]

D. A Note on Appellate Review

It must also be noted that the different levels of determinations trial judges make with regard to expert testimony—on the expert's qualifications, reasoning, and methodology, and on underlying data and the applicability of Rule 403—perhaps require different standards of review by the appellate courts. The *Daubert* opinion does not address this issue. The Ninth Circuit, in its opinion below, had applied a de novo standard in finding that the plaintiffs' expert opinion did not satisfy the *Frye* test.[36] Although *Daubert* rejects *Frye*, the opinion does not address the issue of the standard of review.

The Ninth Circuit treated determinations about scientific validity as akin to rulings on matters of law, to which de novo standards customarily apply, reason-

34. *Cf*. Ake v. Oklahoma, 470 U.S. 68 (1985) (expert must be provided for indigent defendant in capital case).

35. *See, e.g.*, United States v. Yee, 134 F.R.D. 161 (N.D. Ohio 1991) (adopting a magistrate judge's 120-page report and admitting DNA evidence), *aff'd sub nom*. United States v. Bonds, 12 F.3d 540 (6th Cir. 1993).

36. Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128, 1130 (9th Cir. 1991), *rev'd*, 113 S. Ct. 2786 (1993). *See* David L. Faigman et al., *Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying About the Future of Scientific Evidence*, 15 Cardozo L. Rev. 1799 (1994). Of course, subsequent developments may warrant a changed ruling. The Supreme Court acknowledged that "[s]cientific conclusions are subject to perpetual revision." *Daubert*, 113 S. Ct. at 2798.

ing that the appellate court is in as good a position as the trial court to make this determination.[37] Other circuits have applied an abuse-of-discretion standard when reviewing a trial court's exclusion of an expert's testimony.[38] Some issues that courts address with regard to the admissibility of expert testimony may present more of a mixed question of law and fact.[39] Even issues regarding an expert's qualifications may perhaps be classified as raising mixed questions, since the court is assessing the expert's qualifications in light of a scientific theory that the court considers relevant.[40] The courts have not yet clarified the appellate courts' role vis à vis expert testimony in instances when the court has to deal with mixed issues of fact and law.[41]

Finally, the Supreme Court acknowledges in *Daubert* that Rule 403 may play a role in the exclusion of expert testimony.[42] Decisions under this rule are clearly viewed as committed to the discretion of the trial court and therefore are reviewed under an abuse-of-discretion standard that examines whether the court below took into account the appropriate factors in arriving at its conclusion.

37. *See also In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *69, 71 (3d Cir. Aug. 31, 1994) (emphasis added) (citations omitted):

> [E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses and thus is often not significantly more difficult on a cold record." The court concludes that "when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' (more stringent review) to determine if a district court has abused its discretion in excluding evidence as unreliable.

38. *See, e.g.*, Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1109 (5th Cir. 1991) ("A trial court's ruling regarding admissibility of expert testimony is protected by an ambit of discretion and must be sustained unless manifestly erroneous."), *cert. denied*, 112 S. Ct. 1280 (1992); United States v. Bonds, 12 F.3d 540, 554 (6th Cir. 1993) ("We review the trial court's admission of testimony and other evidence under the abuse of discretion standard"; post-*Daubert* review of admissibility of DNA evidence admitted at trial pursuant to a *Frye* standard). *See also* DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 944 (3d Cir. 1990) ("Our review of a district court's decision to exclude the testimony of an expert is ordinarily limited to ensuring there has been no abuse of discretion, but to the extent the district court's ruling turns on an interpretation of a Federal Rule of Evidence our review is plenary.").

39. *See* discussion of Rule 703 *infra* § IV.

40. *See also infra* § II.

41. *See* Ursula Bentele & Eve Cary, Appellate Advocacy: Principles and Practice 93 (1990):

> Courts have sent decidedly mixed signals about what is the appropriate standard of review for such hybrid questions, with some courts announcing that a de novo standard should apply, others deciding that mixed findings are essentially factual, and therefore entitled to great deference, and several courts swinging back and forth between the two positions.

42. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2798 (1993).

II. When Is a Person Qualified to Testify As an Expert?

The courts generally agree that issues with regard to an expert's qualifications are governed by Rule 702 of the Federal Rules of Evidence. 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.

A. General Approach: A Two-Pronged Test

To ascertain whether a proposed expert is qualified to act as a witness, a court must undertake a two-step inquiry:

1. The court should determine whether the proffered expert has minimal educational or experiential qualifications in a field that is relevant to a subject which will assist the trier of fact.
2. If the expert passes this threshold test, the court should further compare the expert's area of expertise with the particular opinion the expert seeks to offer. The expert should be permitted to testify only if the expert's particular expertise, however acquired, enables the expert to give an opinion that is capable of assisting the trier of fact.[43] The more difficult question—the extent to which a court may have to inquire into the methodological underpinnings of the theory on which the expert is relying in order to determine whether the expert's opinion is admissible—is discussed in section III. It should be noted, however, that the two categories may overlap. In determining whether the expert is relying on a methodologically sound theory pursuant to Rule 702, the court may take

43. See the helpful discussion in Carroll v. Otis Elevator Co., 896 F.2d 210, 214–15 (7th Cir. 1990), as to why a specialist in experimental psychology and visual perception would be able to assist the trier in determining whether children would be likely to push a particular button on an escalator. *See also* Kloepfer v. Honda Motor Co., 898 F.2d 1452, 1458–59 (10th Cir. 1990), which held that the lower court had properly excluded the testimony of a pediatrician who was experienced as a children's accident preventionist. The lawsuit involved the death of a child while a passenger on an all-terrain vehicle manufactured by the defendant. The excluded testimony, however, related to the conduct of the adult driver and had no bearing on the behavior of the child passenger.

into account the degree of specialized knowledge the expert possesses about the particular issues in dispute.[44]

B. Other Considerations Bearing on an Expert's Qualifications

A combination of the factors discussed in section C below may suffice to disqualify an expert even when a particular factor standing alone would not. Even if the court finds the expert qualified to offer some opinions, it may preclude the expert from offering others because of a lack of expertise with regard to certain issues.[45]

Although rarely explicitly discussed, another factor that may affect the court's determination is the degree to which experts are available to all the parties. When the experts in a field are all arrayed on one side of the case—typically the defendant's—a court may have to allow some leeway in the plaintiff's choice of an expert in order to provide the plaintiff with fair access to the courts. This is especially true if virtually all of those with the requisite expertise are persons currently or formerly associated with the defendant.

C. Issues Bearing on an Expert's Minimal Qualifications

1. Education or experience

The Federal Rules of Evidence state that an expert may be qualified by virtue of education or practical experience, or some combination of the attributes stated in Rule 702. An expert should not be excluded from testifying merely because he or she lacks an educational background if the requisite expertise has been acquired through training or experience. For example, in *Circle J. Dairy, Inc. v. A.O. Smith Harvestore Products, Inc., a* witness was found qualified to testify as to cattle's injuries, since he had "significant practical experience with feed-related health problems in dairy cattle" even though he was not a veterinarian and held no advanced degrees.[46] But the court may exclude an expert who does not

44. *See, e.g.*, O'Conner v. Commonwealth Edison Co., 13 F.3d 1090, 1107 & n.19 (7th Cir. 1994) (in affirming district court's exclusion of plaintiff's expert, who claimed that plaintiff's cataracts were radiation-induced, because he lacked a proper methodology (*see infra* § III), the court noted that the expert had treated only five cases of radiation-induced cataracts in twenty years: "We do not believe that this limited exposure . . . qualifies as a basis for a scientifically sound opinion."); Chikovsky v. Ortho Pharmaceutical Corp., 832 F. Supp. 341, 344–46 (S.D. Fla. 1993) (plaintiff alleged that defendant's product, Retin-A, caused birth anomalies; on defendant's motion for summary judgment, the court, citing *Daubert*, found that testimony of plaintiff's sole expert, an obstetrician–gynecologist, would not be admissible; the court noted that the expert had no specialized training in embryology or teratology, did not know if genetic explanations existed for the child's birth defects, and did not know how much Retin-A the mother might have absorbed through topical applications; the court also stressed that expert's theory that topical applications of Retin-A during pregnancy can cause birth defects had not been tested; the court pointed to total lack of data; the court, citing *Daubert,* stated: "This is precisely the kind of evidence that the trial judge must exclude in performing the gatekeeper function.").

45. *See infra* § II.E.

46. 790 F.2d 694, 700 (8th Cir. 1986). *See also* Davis v. United States, 865 F.2d 164, 168 (8th Cir. 1988) (witness with university degree in journalism qualified to testify about likelihood of female to male transmis-

have the appropriate experience, education, or training to offer a helpful opinion with regard to the controverted issue.[47]

2. Expertise in particular field

Courts recognize that experts in a variety of fields may be helpful with regard to a particular issue. For instance, a Ph.D. who is a toxicologist may be as qualified as an M.D. to express an opinion about causation in a toxic tort case.[48] Furthermore, different fields of expertise may be relevant to different aspects of an issue. For instance, in *Williams v. Pro-Tec, Inc.*, a products liability action in which the plaintiff claimed that an eye guard produced by the defendant was unreasonably dangerous, the appellate court agreed that a mechanical engineer was properly qualified.[49] The engineer testified with regard to "the factor by which the eye guard reduced the force that a racquetball exerted upon a simulated eyeball at different speeds." An ophthalmologist would have been able to testify about the force necessary to injure an eye.

Some issues, however, clearly require expertise in a particular field. For example, in *Edmonds v. Illinois Central Gulf Railroad,* the district court committed reversible error in permitting a clinical psychologist to testify that stress worsened the plaintiff's preexisting heart condition, since causation of a heart condition is a medical issue.[50] Similarly, in *Stull v. Fuqua Industries, Inc.*,[51] a mechanical engineer was found not qualified to state that the plaintiff's leg would have broken had the accident occurred in the manner claimed by the plaintiff, since the expert lacked expertise in human anatomy.[52]

sion of gonorrhea; witness had worked for more than eight years as a public health investigator and had received Centers for Disease Control training).

47. *See, e.g.,* Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 800 (4th Cir. 1989) (abuse of discretion for trial court to have allowed testimony about credit discrimination by witness who was not an economist and whose general business education did not indicate "*any* training in the area of anti-trust or credit" and who admitted "that she lacked *any* other experience in such matters.") (emphasis in original), *cert. denied*, 493 U.S. 1073 (1990); Hughes v. Hemingway Transp., Inc., 539 F. Supp. 130, 133 (E.D. Pa. 1982) (exclusion of witness's opinion testimony was proper because deposition revealed that witness could not calculate the coefficient of friction on the roadway at the time of the accident and therefore could not determine whether the driver of a tractor–trailer was using the proper technique for coping with a skid during icy conditions).

48. Genty v. Resolution Trust Corp., 937 F.2d 899, 916–17 (3d Cir. 1991); Peterson v. Sealed Air Corp., Nos. 86-C3498, 88-C9859 consolidated, 1991 U.S. Dist. LEXIS 5333, at *31 (N.D. Ill. Apr. 22, 1991).

49. 908 F.2d 345, 348 (8th Cir. 1990).

50. 910 F.2d 1284, 1287 (5th Cir. 1990).

51. 906 F.2d 1271 (8th Cir. 1990).

52. *Id.* at 1275. *See also* Livshits v. Natural Y Surgical Specialties, Inc., No. 87-C2403, 1991 U.S. Dist. LEXIS 17245, at *23 (S.D.N.Y. 1991) (certified toxicologist with a doctorate in experimental pathology was qualified to testify about possible dangers posed by breast implant, but was not qualified to express a diagnostic opinion as to cause of acceleration of cancer in plaintiff's breast; he admitted that he was not qualified to render diagnoses in humans), *reaff'd*, No. 87-C2403, 1991 U.S. Dist. LEXIS 18445 (S.D.N.Y. Dec. 19, 1991); Owens v. Concrete Pipe & Prods. Co., 125 F.R.D. 113, 115 (E.D. Pa. 1989) (although nonphysicians who are doctors of pharmacology and chemistry are qualified to testify as to risks associated with exposure to certain chemicals, they "may not be qualified to diagnose [plaintiff's] medical condition"). *Cf.* Fox v. Dannenberg, 906 F.2d 1253, 1256–57 (8th Cir. 1990) (two engineers who had more than twenty years of experience in accident reconstruction could offer opinion on who was driving even though one factor entering into their opinion was the pattern of injuries; court concluded that as a consequence of their long practical training, they had undoubtedly acquired some knowledge of the medical aspects of traffic injuries).

3. Meaning of minimal qualifications

The fact that an expert has a particular title or degree is not dispositive in either qualifying or disqualifying the expert. The lack of a title or degree does not require exclusion of the expert; knowledge or skill, however obtained, is what counts.[53] Nor is the expert automatically qualified merely because he or she possesses a particular degree or title. In *Genty v. Resolution Trust Corp.*, for instance, the court held that the district judge had not erred in excluding a proffered witness where nothing appeared in the record to substantiate his credentials other than the bare assertion that he was a scientifically trained toxicologist holding a Ph.D.[54] The appellate court noted the absence of a curriculum vitae and the failure to recite studies conducted or methods used, or to include articles published.[55]

4. Discretion

District courts are accorded considerable deference with regard to their rulings on qualification. Consequently, the same appellate court may affirm a ruling excluding an expert who has received only academic training and lacks practical experience, and a ruling excluding an expert with extensive practical experience who lacks academic training.[56]

D. Issues Bearing on Relationship of Expert's Qualifications to Subject Matter of Proposed Testimony

The expert's credentials or experience, or both, may enable the expert to meet a threshold test. But before the expert is found qualified to offer an opinion about a particular issue, the court must also decide whether the actual qualifications of the expert enable him or her to assist the trier of fact with regard to each controverted issue about which the expert seeks to testify.[57]

1. How much of a specialist must the expert be?

A recurring problem concerns the requisite level of specialization required of the expert. In 1954, Professor Charles McCormick wrote: "While the court may rule that a certain subject of inquiry requires that a member of a given profes-

53. *See supra* § II.C.1.

54. 937 F.2d 899, 917 (3d Cir. 1991).

55. *See* discussion of specialization *infra* § II.D.1.

56. *Compare* Lavespere v. Niagara Mach. & Tool Works, Inc., 910 F.2d 167, 177 (5th Cir. 1990), *cert. denied*, 114 S. Ct. 171 (1993) *with* Sullivan v. Rowan Cos., 952 F.2d 141, 145–46 (5th Cir. 1992). In both cases, the circuit court acknowledged that a contrary decision by the district court would not necessarily have required a reversal.

57. *See, e.g.,* United States v. Roldan-Zapata, 916 F.2d 795, 805 (2d Cir. 1990) ("A witness may be qualified as an expert on certain matters and not others."), *cert. denied*, 111 S. Ct. 1397 (1991). *See also* Livshits v. Natural Y Surgical Specialties, Inc., No. 87-C2403, 1991 U.S. Dist. LEXIS 17245 (S.D.N.Y. 1991), *reaff'd*, No. 87-C2403, 1991 U.S. Dist. LEXIS 18445 (S.D.N.Y. Dec. 19, 1991). See *infra* § II.E for examples of cases in which courts have limited the scope of the expert's testimony.

sion, such as a doctor, an engineer or a chemist, be called, *usually* a specialist in a particular branch within the profession will not be required."[58] Some courts quote the sentence without reflecting on whether the usual nonspecialization rule is applicable given the scientific issue posed in the particular case before the court.[59] The governing principle should be whether the expert can assist the trier of fact. How much of a specialist the proffered witness needs to be will depend on the relationship between the expert's particular expertise and the subject matter of the opinion that is being offered. For example, in *Wilkinson v. Rosenthal & Co.*, a professor of finance who taught a basic course at the Wharton School at the University of Pennsylvania was not sufficiently qualified to testify about what constitutes excessive trading in commodity futures, even though he was permitted to testify about basic principles of commodity investing.[60] From the reported cases, it appears that the issue of specialization arises primarily with regard to physicians and engineers.

a. Physicians

Language in some cases suggests that the holder of an M.D. degree is qualified to render an opinion about anything possibly characterized as a medical question. For example, in *Payton v. Abbott Labs*, the court stated, "The fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it."[61] The facts of such cases do not necessarily support such a broadly stated rule. In *Payton*, for example, the physicians in question testified that the drug diethylstilbestrol (DES) is a teratogen and that the plaintiff's injuries were caused by her mother's ingestion of DES during pregnancy. The experts were board-certified obstetrician–gynecologists who served as clinical instructors at Harvard Medical School. Although they were not research scientists, both had studied the literature on DES and embryology and had treated numerous DES daugh-

58. Charles McCormick, Evidence § 14, at 29 (1954) (emphasis added). This statement also appears in subsequent editions. *See* McCormick on Evidence § 13, at 34 (Edward W. Cleary ed., 3d ed. 1984), quoted in Peteet v. Dow Chemical Co., 868 F.2d 1428, 1432 (5th Cir. 1989), *cert. denied*, 493 U.S. 935 (1989).

59. *See, e.g.,* Mateer v. United States Aluminum, No. 88-2147, 1989 U.S. Dist. LEXIS 6323, at 21 n.7 (E.D. Pa. June 2, 1989) (quoting McCormick in assuming that an osteopath would be qualified to express an opinion as to health effects of exposure to contaminants in well water; dictum).

60. 712 F. Supp. 474, 477–78 (E.D. Pa. 1989). *See also* LeMaire v. United States, 826 F.2d 949, 951–52 (10th Cir. 1987) (in medical malpractice case in which plaintiff claimed that treatment led to fatal episode which may have been stroke, court found no error in permitting opinion testimony on the subject of neurology by the defense witness who "was endorsed at trial, without objection, as an expert on internal medicine and cardiology" because "plaintiff's counsel should have foreseen the general nature of . . . [the expert's] testimony in light of his endorsement . . . and the undisputed relationship between the patient's neurological and cardiovascular condition").

61. 780 F.2d 147, 155 (1st Cir. 1985) (citing Alvarado v. Weinberger, 511 F.2d 1046, 1049 (1st Cir. 1975)). *See also* Quinton v. Farmland Indus., Inc., 928 F.2d 335, 337 (10th Cir. 1991) (in rejecting contention that a doctor of veterinary medicine, as opposed to a toxicologist, is unqualified to proffer opinion regarding toxic effects of substances on dairy cows, the court stated: "This assumption about the insufficiency of general medical study, which reflects the implausible view that such training qualifies a doctor to diagnose and treat a wide range of physical disorders in the real world but not to render expert opinions about particular examples in the courtroom, has been expressly rejected in the case of physicians.").

ters.[62] They had far more specialized knowledge about DES than a physician whose knowledge about DES was acquired for the purpose of becoming an expert witness.[63]

Other opinions focus on the actual expertise of the physician in light of the issue on which expert assistance is sought. For instance, in *Christophersen v. Allied-Signal Corp.*, the court

> caution[ed] . . . that although credentials can be significant, they alone are not necessarily determinative. The questions, for example, do not stop if the expert has an M.D. degree. That alone is not enough to qualify him to give an opinion on every conceivable medical question. This is because the inquiry must be into actual qualification—sufficient to assist the trier of fact. The trial judge here rightly scrutinized Dr. Miller's lack of specialized experience and knowledge.[64]

In a number of cases, courts have excluded the testimony of a physician on the ground that he or she lacked adequate knowledge about the issue before the court. For example, in *Will v. Richardson-Merrell, Inc.*, a Bendectin case, the court refused to admit testimony on causation by a plastic surgeon with "relatively little, if any, scientific knowledge regarding Bendectin, its components, or its effects."[65] Similarly, in *Chikovsky v. Ortho Pharmaceutical Corp.*, a post-*Daubert* case, the court found that the testimony of the plaintiff's sole expert that the defendant's product caused birth defects would not be admissible, noting that the expert, an obstetrician–gynecologist, had no specialized training in embryology or teratology, did not know if genetic explanations existed for the child's birth defects, and did not know how much Retin-A the mother might have absorbed through topical applications, and that the theory that topical applications of Retin-A during pregnancy can cause birth defects had not been tested.[66]

62. *Payton*, 780 F.2d at 155–56.

63. *See* discussion of the professional witness or the physician whose expertise is derived solely from the work of other experts *infra* § II.D.3. *See also* discussion of the secondhand expert *infra* § II.D.2.

64. 939 F.2d 1106, 1112–13 (5th Cir. 1991) (en banc) (citation omitted), *cert. denied*, 112 S. Ct. 1280 (1992).

65. 647 F. Supp. 544, 548–49 (S.D. Ga. 1986). *See also* Maddy v. Vulcan Materials Co., 737 F. Supp. 1528, 1533 (D. Kan. 1990) (osteopath specializing in pulmonary medicine had "no special skill or expertise in determining the health effects of toxic chemical exposure"; court granted summary judgment because of plaintiff's inability to establish causation); Carroll v. Litton Sys., Inc., No. B-C-88-253, 1990 U.S. Dist. LEXIS 16833, at *31–38 (W.D.N.C. Oct. 29, 1990) (doctor not permitted to opine about length and degree of plaintiff's exposure to substance; doctor lacked training and knowledge about substance and was not familiar with relevant scientific literature).

66. 832 F. Supp. 341, 344–46 (S.D. Fla. 1993). *See also* O'Conner v. Commonwealth Edison Co., 13 F.3d 1090, 1107 & n.19 (7th Cir. 1994), and discussion *supra* note 44. *But see* Rubinstein v. Marsh, No. CV-80-0177, 1987 WL 30608, at *6–7 (E.D.N.Y. Dec. 10, 1987) (in action claiming that infants' birth defects were caused by the defendant's product, court found that plaintiffs' experts "were qualified by virtue of the fact that each was a doctor"; court ultimately granted judgment for defendants in this bench-tried case on the ground that plaintiffs had completely failed to prove causation; the court stated that one of plaintiffs' experts was a pediatrician who had never diagnosed a drug-related birth defect in his own practice, had no experience in obstetrics or gynecology, did not know when hands and fingers differentiate in embryo (one infant had suffered a severe hand malformation), and did not know the properties of defendant's drug; the second expert's testimony was characterized as even less compelling). *Cf.* Payton v. Abbott Labs, 780 F.2d 147, 157 (1st Cir. 1985) (*see*

It is the actual knowledge of the physician and how it relates to the controverted issue that must be examined, rather than credentials bearing on specialization. For instance, a physician in general practice who is not a board-certified psychiatrist may express an opinion about the mental condition of a patient for whom the physician is prescribing medication to counter depression.[67] A treating physician may express an opinion about whether his or her patient's exposure to benzene resulted in leukemia if the physician is acquainted with the body of epidemiological literature relating benzene exposure to leukemia.[68] In *In re Joint Eastern & Southern District Asbestos Litigation*, the Second Circuit found that the district judge had been "overly harsh" in rejecting as an expert a specialist in internal medicine who had been retained to testify that the plaintiff's colon cancer was caused by asbestos exposure.[69]

b. Engineers

The opinions indicate that in some cases a court will find that the proffered expert's knowledge of general engineering principles does not entitle the expert to render a particular opinion about a specialized topic. For example, in *Perkins v. Volkswagen of America, Inc.*, a specialist in mechanical engineering with no experience in designing entire automobiles was properly permitted to express opinions on general mechanical engineering principles, but prohibited from testifying as an expert in automotive design.[70] In other cases, courts have found an engineer's knowledge adequate in light of the subject matter of the testimony and the engineer's education and training. For example, in *Martin v. Fleissner GmbH*, experts who had no direct experience with the particular crimper machine involved were permitted to testify because they were specialists in machine design and were familiar with the general principles of the machine's rollers as a result of experience with similar machines.[71]

discussion within this section); in *Payton*, court denied defendants' motion for a directed verdict, noting that the uncontradicted testimony provided by plaintiff's experts, that the DES-affected organs developed between the sixth and twenty-second weeks of pregnancy, and that mother of plaintiff took DES commencing in the fifteenth week, was sufficient evidence to allow the jury to have found causation.

67. Sprague v. Bowen, 812 F.2d 1226, 1231–32 (9th Cir. 1987) (patient was seeking disability payments).

68. Mason v. Texaco, Inc., 741 F. Supp. 1472, 1496–97 (D. Kan. 1990), *aff'd in part and modified in part,* 948 F.2d 1546 (10th Cir. 1991), *cert. denied*, 112 S. Ct. 1941 (1992).

69. 964 F.2d 92, 97 (2d Cir. 1992).

70. 596 F.2d 681, 682 (5th Cir. 1979). *See also* Hoban v. Grumman Corp., 717 F. Supp. 1129, 1133–34 (E.D. Va. 1989) (licensed professional engineer was not permitted to testify as an expert regarding aircraft engines or fuel systems where his only formal education in aerodynamics was as an undergraduate and he had never worked in the field), *aff'd without op.*, 907 F.2d 1138 (4th Cir. 1990); Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co., 762 F. Supp. 1016, 1017–18 (D.P.R. 1991) (proposed witness's work as civil engineer in construction field did not qualify him as an expert concerning the design and manufacture of cranes), *aff'd,* 958 F.2d 1169, 1173–75 (1st Cir. 1992) (court agreed that trial judge's refusal to permit someone of expert's background to offer opinion as to "defect" in crane was not clear error; court stated that it was a closer question whether the expert, who had investigated the cause of crane accidents, should have been permitted to render opinion about how accident occurred; but court affirmed, noting that the expert had never inspected crane or spoken to operator, and that he had a "hired gun" background). *See* further discussion *infra* § II.D.3.

71. 741 F.2d 61, 63–64 (4th Cir. 1984). *See also* Coleman v. Parkline Corp., 844 F.2d 863, 865–66 (D.C. Cir. 1988) (although expert had no practical experience with loading domes for elevator cab interiors, he was

2. The "secondhand" expert

May an expert testify when his or her expertise is based solely on work done by others so that the expert is summarizing other people's work? In an extreme case, the court may conclude that the testimony amounts to nothing more than "a conduit for hearsay testimony."[72] At other times, it may be much more difficult to determine the extent to which the proffered witness is adding something of his or her own to information derived from others. For example, in *Loudermill v. Dow Chemical Co.*, the plaintiff claimed that the decedent's cirrhosis of the liver was a direct result of the decedent's exposure to a halogenated hydrocarbon while working at the defendant's plant.[73] The plaintiff's expert on causation had extensive academic and practical knowledge in the field of toxicology, but admitted on voir dire that he was not specifically familiar with the relationship between halogenated hydrocarbons and liver toxicity. The appellate court stated that "Dr. Lowry's credentials are not unassailable in the specific area of the relationship between halogenated hydrocarbons and liver injury," but found no abuse in discretion in permitting opinion on causation based on examination of microscopic specimen slides, pathology and autopsy reports, government records, and publications concerning liver injuries caused by halogenated hydrocarbons.[74]

3. The "professional" witness

Closely related to secondhand witnesses are the "professional" witnesses who spend the bulk of their time testifying in court rather than working in their alleged field of expertise, particularly those who have testified as an expert "in an extraordinary array of dissimilar fields."[75] The fact that proffered experts spend substantially all of their time in connection with litigation is not in itself a disqualification.[76] The time spent in court does not, however, add to the witness's qualifications.[77]

experienced in the investigation of accidents involving the loading of industrial materials and knowledgeable about OSHA regulations and the safety literature on loading); Exum v. General Elec. Co., 819 F.2d 1158, 1163–64 (D.C. Cir. 1987) (professional engineer with special expertise in the area of safe industrial design was qualified to testify on feasible and economical alternatives to french fryer although he had no experience with kitchen equipment; he had worked at OSHA and Institute of Safety Analysis); Knight v. Otis Elevator Co., 596 F.2d 84, 87–88 (3d Cir. 1979) (engineer specializing in materials engineering and safety could testify even thought he was not a specialist in elevators).

72. Hutchinson v. Groskin, 927 F.2d 722, 725 (2d Cir. 1991) (defendant's medical expert testified that he had reviewed three letters from eminent oncologists that had been sent to defense counsel).

73. 863 F.2d 566, 568–570 (8th Cir. 1988).

74. *Id.*

75. *See* Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co., 958 F.2d 1169, 1174–75 (1st Cir. 1992) (expert had testified on behalf of insurance companies in eighteen dissimilar fields).

76. *See In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *84 (3d Cir. Aug. 31, 1994) ("The fact that most of [the expert's] work since 1976 has been for plaintiffs in litigation may undermine her credibility but does not eradicate her expertise. For litigants to have access to experts, it may be necessary for some experts to concentrate on litigation.").

77. *See* Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 800 (4th Cir. 1989) ("Although it would be incorrect to conclude that Gordon's occupation as a professional expert alone requires exclusion of her testi-

Some courts have viewed an expert's career as a professional witness as a reason for scrutinizing the expert's opinion carefully to see whether it should be excluded on grounds discussed above. In *Tokio Marine & Fire Insurance Co. v. Grove Manufacturing Co.*,[78] the court stated, "In a field like accident reconstruction that is more art than science, the trial judge has particular liberty to eschew 'professional witnesses.'" The court agreed with the district judge below that the expert's "'hired gun' background as an instant expert in an astonishing number of other areas suggested he 'would not possess the professional safeguards ensuring objectivity.'"[79]

E. Limiting Expert's Testimony

Although the expert may be qualified, the court may impose restrictions on the opinions that the expert will be allowed to express. When the proffered witness's expertise with regard to the relevant issues is of a generalized nature, the court may decide that the expert is incapable of assisting the trier with regard to the ultimate issues in a case. Instead, the court may, for instance, limit the scope of the testimony to foundational or background matters.[80]

Courts may also restrict an expert's testimony to the field in which he or she has specialized knowledge, and refuse to allow the expert to testify to related matters in a field in which the expert has no special expertise. This issue arises with regard to probabilistic evidence that may require a statistical analysis in addition to testimony about the principles of some other scientific field. For the results of DNA testing to be admitted, for instance, testimony might be required from a population geneticist or statistician in addition to testimony from someone knowledgeable about DNA testing techniques.[81]

mony, it would be absurd to conclude that one can become an expert simply by accumulating experience in testifying."), *cert. denied*, 493 U.S. 1073 (1990).

78. 958 F.2d 1169 (1st Cir. 1992).

79. *Id.* at 1174–75. Courts have hinted that they might reject an opinion if the expert reached his conclusion before having acquired the expertise needed to form the opinion. *See* Viterbo v. Dow Chem. Co., 826 F.2d 420, 423 n.2 (5th Cir. 1987) ("We agree that an expert who forms an opinion before he begins his research is biased and lacking in objectivity. *See* Perry v. United States, 755 F.2d 888 (11th Cir. 1985). Because we reject Dr. Johnson's opinion on other grounds, it is not necessary to resolve this question. We would note, however, that this could be an additional ground indicating lack of reliability of his opinion."). *Cf. In re* Air Crash Disaster at New Orleans, 795 F.2d 1230, 1234 (5th Cir. 1986) ("[E]xperts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an 'expert.'"). The expert's professional witness status, when combined with other problems, may contribute to a decision to exclude expert testimony.

80. *See, e.g.,* Perkins v. Volkswagen of Am., Inc., 596 F.2d 681, 682 (5th Cir. 1979) (mechanical engineer with no experience in designing automobiles permitted to testify about general mechanical engineering principles but not as an expert in automotive design); *In re* Related Asbestos Cases, 543 F. Supp. 1142, 1149–50 (N.D. Cal. 1982) (environmental consultant could testify as a foundational witness and identify articles that he located written on asbestos hazards but could not qualify the articles as evidence or render an opinion about controverted issues); Wilkinson v. Rosenthal & Co., 712 F. Supp. 474, 478 (E.D. Pa. 1989) (expert permitted to testify about basic principles of commodity investing but not about what constitutes excessive trading).

81. *See* Judith A. McKenna et al., Reference Guide on Forensic DNA Evidence § III.C, in this manual.

It should also be noted that the judge's determination that an expert is qualified does not require the judge to make a finding in open court in the hearing of the jury. Some judges believe that such a finding by the court might unduly influence the jury "and the better procedure is to avoid an acknowledgment of the witnesses' expertise by the Court."[82]

F. Lay Opinion Testimony on Scientific Issues

Rule 701 of the Federal Rules of Evidence may permit lay witnesses to express opinions relating to scientific issues that could also be the subject of expert proof. It provides:

> If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.[83]

The distinctions that once existed between lay and expert testimony have been blurred by the liberalization of Rule 701.

> No longer is lay opinion testimony limited to areas within the common knowledge of ordinary persons. Rather, the individual experience and knowledge of a lay witness may establish his or her competence, without qualification as an expert, to express an opinion on a particular subject outside the realm of common knowledge.[84]

Consequently, as many of the opinions discussed below acknowledge, the witness in question could have been qualified pursuant to either Rule 701 or Rule 702.[85] At times, however, a proffered lay witness will not have the experience and knowledge required to render the desired opinion. For example, in *Willard v. Bic Corp.*, the court, in granting summary judgment to the defendant in a product liability action, stated that a water patrolman who was present at the accident scene and who conceded that he was not an expert in the reconstruction of boat fires would not be permitted to testify that he had concluded that plaintiff's lighter was the origin of the fire.[86]

82. United States v. Bartley, 855 F.2d 547, 552 (8th Cir. 1988). *See also* Charles R. Richey, Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules of Evidence in Civil and Criminal Jury Trials, 154 F.R.D. 537 (1994).

83. Fed. R. Evid. 701.

84. United States v. Paiva, 892 F.2d 148, 157 (1st Cir. 1989).

85. *See, e.g.*, Eckert v. Aliquippa & Southern R.R. Co., 828 F.2d 183, 185 n.5 (3d Cir. 1987); Ernst v. Ace Motor Sales, Inc., 550 F. Supp. 1220, 1224 (E.D. Pa. 1982), *aff'd without op.*, 720 F.2d 661 (3d Cir. 1983). *See also* Farner v. Paccar, Inc., 562 F.2d 518, 529 (8th Cir. 1977) (court emphasized that it was unnecessary to decide whether witness could be qualified as an expert, but hinted that he could have testified pursuant to Rule 702).

86. 788 F. Supp. 1059, 1066–67 (W.D. Mo. 1991).

1. Distinctions between Rule 701 and Rule 702

The choice of the rule pursuant to which the witness testifies may make a difference in some instances. A lay witness's opinion must be rationally based on the witness's personal perception; consequently, the nonexpert may not express an opinion until adequate personal knowledge is demonstrated.[87] Because the opinion must be based on facts or data personally perceived, the lay witness cannot be asked hypothetical questions.[88]

At times, a witness may be precluded from testifying as an expert because the party calling the witness failed to list him or her as required in a pretrial order. If the court did not also require listing the names of lay witnesses, the witness may be able to testify pursuant to Rule 701.[89]

2. Situations in which Rule 701 witnesses testify

Testimony by lay witnesses concerning scientific and technical issues falls into two general categories:

1. when the witness's personal knowledge is used to authenticate or identify something that would otherwise be established by expert proof; and
2. when the witness's experience, combined with personal knowledge of facts being litigated, amounts to sufficient expertise to support an opinion that could also be provided by a Rule 702 witness.

a. The identifying witness

Lay witnesses routinely testify as to whether a handwriting sample[90] or voice sample[91] is that of a particular person. The Federal Rules of Evidence expressly contemplate authenticating testimony of this type as an alternative to expert testimony.[92]

87. *See* United States v. Rea, 958 F.2d 1206, 1216–18 (2d Cir. 1992) (it was error, though harmless, for trial court to admit co-worker's opinion that defendant must have known that he was participating in a tax evasion scheme; judge did not permit inquiry into the basis for the opinion, so that there was no way to know if the opinion was based on the perception of the witness); United States v. Paiva, 892 F.2d 148, 157 (1st Cir. 1989) ("the individual experience and knowledge of a lay witness may establish his or her competence, without qualification as an expert, to express an opinion on a particular subject outside the realm of common knowledge"; district court did not abuse its discretion in admitting lay witness's opinion that substance she found was cocaine because her opinion was "rationally based on her own perceptions").

88. Teen-Ed, Inc. v. Kimball Int'l, Inc., 620 F.2d 399, 403–04 (3d Cir. 1980).

89. *Id*. at 404. *See also* MCI Telecommunications Corp. v. Wanzer, 897 F.2d 703, 706 (4th Cir. 1990).

90. Experts frequently testify to the same issue, although the proficiency of handwriting experts has been questioned. *See* D. Michael Risinger et al., *Exorcism of Ignorance as a Proxy for Rational Knowledge: The Lessons of Handwriting Identification "Expertise,"* 137 U. Pa. L. Rev. 731 (1989). *But see* Moshe Kam et al., *Proficiency of Professional Document Examiners in Writer Identification*, 39 J. Forensic Sci. 5 (1994).

91. For a discussion of issues that arise with regard to voiceprint evidence, see *infra* § III.C.1.a.2.

92. *See* Rule 901(b)(2) (nonexpert opinion on handwriting) and Rule 901(b)(5) (voice identification). *See, e.g.,* United States v. Tipton, 964 F.2d 650, 655 (7th Cir. 1992) (co-worker identified defendant's handwriting); United States v. Barker, 735 F.2d 1280, 1283 (11th Cir.) (two co-workers testified that defendant's handwriting matched that on checks), *cert. denied,* 469 U.S. 933 (1984); United States v. Vega, 860 F.2d 779, 789–90 (7th Cir. 1988) (police officer permitted to identify speaker on a recorded telephone conversation conducted primarily in Spanish on the basis of a two-hour conversation with defendant in English two years previously).

Courts also allow a nonexpert to state an opinion as to whether the person depicted in a surveillance photograph is a particular person.[93] Courts have also permitted drug users associated with the defendant to identify a substance as a particular illegal drug.[94]

b. Lay witnesses with special expertise

1. *Causation.* Provided the witness has sufficient experience, courts have allowed a lay witness to express an opinion about the cause of the accident or damage which is the subject of the suit. For example, in *Hurst v. United States,* a pilot who flew over the scene of a river flooding was permitted to testify that flooding had not been caused by jetties built by one of the defendants.[95] In affirming the jury verdict for that defendant, the appellate court stressed the witness's unique background in having had thirty-nine years of experience in flying over that particular river to monitor ice jams and floods.

2. *Economic issues.* Although experts frequently furnish valuations which may require complex calculations, courts also allow lay valuation testimony. In *MCI Telecommunications Corp. v. Wanzer,* the court ordered a new trial on damages because the trial court excluded the testimony of a bookkeeper as to the profits made by a company with whom the defendant negotiated in breach of his fidu-

93. *See* United States v. Wright, 904 F.2d 403, 404–05 (8th Cir. 1990); United States v. Langford, 802 F.2d 1176, 1179 (9th Cir. 1986) ("such testimony is particularly valuable where . . . lay witnesses are able to make the challenged identifications based on their familiarity with characteristics of the defendant not immediately observable by the jury at trial"), *cert. denied*, 483 U.S. 1008 (1987). *Cf.* United States v. Stanley, 896 F.2d 450, 451–52 (10th Cir. 1990) (in trial for receiving child pornography, court allowed testimony of postal inspector that photographs in seized magazines were of children under eighteen years of age). Expert proof comparing the defendant with the person depicted in the photograph has also been allowed. *See, e.g.*, United States v. Alexander, 816 F.2d 164, 166–69 (5th Cir. 1987) (trial court erred in excluding proffered testimony by an orthodontist specializing in cephalometry, the scientific measurement of the dimensions of the head, and by an FBI agent with expertise in photographic comparisons), *cert. denied*, 493 U.S. 1069 (1990).

94. *See, e.g.*, United States v. Paiva, 892 F.2d 148, 156–57 (1st Cir. 1989) (defendant's stepdaughter, a cocaine user, was permitted to testify that a few years previously she had discovered a bag of a white powder in his shoes, that the substance looked and tasted like cocaine, and that in her opinion it was cocaine; court admitted the testimony under Rule 701). *See also* United States v. Zielie, 734 F.2d 1447, 1456 (11th Cir. 1984) (chemical analysis not essential to conviction; two experienced marijuana dealers permitted to testify that the substance given to the defendant was marijuana), *cert. denied,* 469 U.S. 1189 (1985); United States v. Sweeney, 688 F.2d 1131, 1145 (7th Cir. 1982) (prior use, knowledge, and sampling of drug identified sufficient to qualify witness to testify as to identity of a drug under Rule 701).

95. 882 F.2d 306, 311–12 (8th Cir. 1989). *See also* Soden v. Freightliner Corp., 714 F.2d 498, 510–12 (5th Cir. 1983) (a lay witness was permitted to testify to dangerousness of truck design; witness had eighteen years of experience working on large trucks and worked as a service manager in charge of repairs and preventive maintenance on a fleet of 500 trucks, mainly defendant's); Eckert v. Aliquippa & Southern R.R. Co., 828 F.2d 183, 185 n.5 (3d Cir. 1987) (witness who was "employed by the railroad for thirty years and fully familiar with railroad procedures" was permitted to state whether proper coupling of railway car would have prevented injuries); Ernst v. Ace Motor Sales, Inc., 550 F. Supp. 1220, 1222–24 (E.D. Pa. 1982) (police officer who arrived on scene five to ten minutes after accident permitted to opine on cross-examination as to point of impact; court noted that testimony would have been admissible under either Rule 701 or 702), *aff'd without op.*, 720 F.2d 661 (3d Cir. 1983); Gravely v. Providence Partnership, 549 F.2d 958, 961 (4th Cir. 1977) (witness with twenty-six years of experience in stairway construction allowed to express an opinion regarding safety of conventional and spiral staircase construction); Farner v. Paccar, Inc., 562 F.2d 518, 528–29 (8th Cir. 1977) (witness with thirty years' experience in trucking industry could testify as to the proper design of a truck suspension system).

ciary duty to his employer.[96] The bookkeeper's testimony would have been based on records she kept, and her projection of profits would have been predicated on her personal knowledge and perception. If the jury credited her testimony, the amount of damages awarded might have been lower.[97]

96. 897 F.2d 703, 706 (4th Cir. 1990).

97. *See also* Joy Mfg. Co. v. Sola Basic Indus., 697 F.2d 104, 111–12 (3d Cir. 1982) (court reversed and ordered new trial when trial judge excluded plaintiff's supervisor of production control from testifying as to the percentage of increased cost and downtime the company incurred that was attributable to the failure of the defendant's furnaces; no statistical expert was required).

III. Is the Expert's Opinion Supported by Scientific Reasoning or Methodology?

Probably the thorniest problems surrounding expert proof center on a court's scrutiny of an expert opinion to determine if the expert's reasoning and methodology are scientifically valid. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court recognized the importance of this question; it termed the "scientific validity . . . of the principles that underlie a proposed submission" as the "overarching subject" of the inquiry the trial judge must undertake.[98] It confirmed the trial judge's responsibility to make a preliminary assessment pursuant to Rule 104(a) "of whether the reasoning or methodology underlying the testimony is scientifically valid" and recognized that "[m]any factors will bear on the inquiry."[99]

Disputes as to whether evidence is based on "scientifically valid princi ples"[100] arise primarily with regard to novel scientific evidence: Scientific principles gradually gain recognition until they are viewed as incontestable and become the subject of judicial notice.[101] When, however, experts seek to substantiate their conclusions by reference to as yet disputed scientific theories, a number of pervasive and related questions have to be considered by the court:

1. Under what circumstances can judges with limited scientific expertise exclude an expert's opinion because of flaws in the scientific reasoning or methodology on which it rests? The expert, after all, is an expert precisely because he or she has specialized knowledge that a nonexpert in the relevant field lacks.
2. When is scientific validity a question of law for the court rather than a question of fact to be resolved by the trier of fact?
3. When will a lack of scientific validity result in the inadmissibility of expert testimony, and when will it lead to a finding of insufficiency?

98. 113 S. Ct. at 2797.
99. *Id.* at 2796.
100. *Id.* at 2799.
101. *Id.* at 2796 n.11.

A. The *Frye* Test

Before the enactment of the Federal Rules of Evidence, federal courts typically approached questions relating to the validity of an expert's theory by applying the "general acceptance," or *Frye,* test.[102] In 1993, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[103] the Supreme Court unanimously concluded that the *Frye* test did not survive the enactment of the Federal Rules of Evidence.[104] The Court's determination wrote *finis* to an enormous judicial and scholarly output devoted to discussing the applicability of *Frye*, the meaning of *Frye*, and alternatives to *Frye*. When one looks at the actual results in comparable cases, however, it is considerably less clear how much it mattered whether a circuit purported to employ *Frye* or some other test.[105] What was significant and continues to be significant under *Daubert* is the extent to which a court is willing to look at the methodological underpinnings of the scientific principles being espoused and the circumstances in which courts find that a flaw in scientific reasoning leads to exclusion of the expert's opinion, or takes an issue from the jury as a matter of law. As will be seen in the discussion below, pre-*Daubert* courts scrutinized and screened scientific testimony in a variety of situations regardless of whether they subscribed to *Frye* or to other tests.

As *Daubert* acknowledges and the cases decided before *Daubert* illustrate, the scientific issues and the differing procedural postures in which these issues arise are too complex to be amenable to resolution by precise verbal formulas. Furthermore, judicial attitudes toward issues of scientific validity may change over time. In toxic tort litigation, this evolution appears attributable to two simultaneously occurring phenomena:

1. Courts become more conversant in general with the parameters of scientific and probabilistic reasoning as they are exposed to complex statis-

102. The "general acceptance" test had its genesis in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). In that case, in the course of discussing whether polygraph evidence should be admitted, the court made the following statement: "[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained *general acceptance* in the particular field in which it belongs." *Id.* at 1014 (emphasis added).

103. 113 S. Ct. 2786 (1993).

104. The Court employed the plain-meaning approach it had previously used when interpreting the Federal Rules of Evidence in construing Rule 702, which does not mention "general acceptance." *Id.* at 2793–94. *See, e.g.,* Bourjaily v. United States, 483 U.S. 171 (1987). Consequently, *Frye*, upon which the Ninth Circuit, as well as other circuits, had relied, is dead as the talisman for determining when scientific evidence is admissible, although general acceptance remains a factor that may be considered in assessing the validity of reasoning and methodology. *Daubert*, 113 S. Ct. at 2797. *See* discussion *infra* § III.C.1.

105. *See, e.g.*, United States v. Smith, 869 F.2d 348, 351–54 (7th Cir. 1989), in which the court relied on *Frye* to admit voiceprint evidence (despite a National Research Council study showing an absence of scientific consensus) by using factors previously used in United States v. Williams, 583 F.2d 1194 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979), the Second Circuit's leading case on abandoning the *Frye* methodology.

tical issues and problems of causation in cases rife with scientific uncertainty.[106]

2. Courts become more knowledgeable about particular factual issues through the gradual accumulation of evidence as categories of related cases work their way through the litigation process and mature.[107]

Consequently, the judicial desire for efficiency must be balanced against the need to allow scientific issues an opportunity to develop.

B. The *Daubert* Test

The opinion for the majority commenced its discussion of the trial judge's obligation to screen "purportedly scientific evidence" by construing the words "scientific" and "knowledge," which appear in Rule 702.[108] It explained that "'scientific' implies a grounding in the methods and procedures of science," while "the word 'knowledge' connotes more than subjective belief or unsupported speculation."[109] When the Court put these two words, "scientific" and "knowledge," together, it concluded that Rule 702 limits expert testimony on scientific issues to opinions that are the product of a scientific thinking process. The Court wrote:

> [I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.*, "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.[110]

The Court went on to explain that in order to determine whether the expert's proffered testimony pertains to "scientific knowledge," the trial judge must assess "whether the reasoning or methodology underlying the testimony is scientifically valid."[111] The Court stressed that "[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."[112] It also provided a list of illustrative factors that bear on the trial judge's inquiry. This inventory, which the Court cautioned should not be considered definitive, corroborated the Court's conception of science as an empirical endeavor in which testing plays a crucial role. Mentioned by the Court were

106. For a comprehensive discussion of why legal and scientific approaches to the issue of causation may differ, see Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 Cornell L. Rev. 469 (1988).

107. *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992).

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

109. *Id.* When an expert seeks to testify about scientific knowledge pursuant to Fed. R. Evid. 702, the inferences or assertions that the expert is making "must be derived by the scientific method." *Id.*

110. 113 S. Ct. at 2795.

111. *Id.* at 2796.

112. *Id.* at 2797.

1. "falsifiability" (whether the theory or technique can be, and has been, tested);
2. peer review and publication (submission to peer review is not dispositive, but is viewed as a component of good science);
3. the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and
4. general acceptance of the methodology in the scientific community (still a factor to be considered but not dispositive).[113]

The trial court must also decide whether the expert's testimony fits the facts of the case. This condition, as the Court recognized, is essentially one of relevance.[114] The "helpfulness" standard incorporated in Rule 702 means that the expert's opinion must relate to an issue that is actually in dispute and must provide a valid scientific connection to the pertinent inquiry.[115]

C. Contexts in Which Questions Relating to Scientific Validity Arise

The discussion which follows is broken down into three broad areas which encompass the situations in which courts have confronted the issue of scientific validity:

1. issues with regard to a particular discipline;
2. issues with regard to the methodology and reasoning of a particular scientific theory; and
3. issues with regard to statistical estimates.

Although pre-*Daubert* cases did not necessarily frame the evidentiary issues in these terms, the cases are useful in illustrating the kinds of fact patterns that arise.

These questions differ from the qualification problems discussed in section II, which focus on whether the expert knows enough about the particular theory he or she is seeking to espouse; the emphasis here is on whether the alleged science has something to offer the judicial system. The line between qualification questions and validity questions is at times blurred, as the discussion of treating physicians and the *Christophersen* case indicates,[116] and may be even more indistinct after *Daubert*.[117] The boundary between discipline and theory, drawn

113. *Id.* at 2796–97. *See* Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 Tex. L. Rev. 715, 782–86 (1994) (other factors a court might consider).

114. *Daubert*, 113 S. Ct. at 2795–96.

115. *Id.* The Court offered an example of the expert whose scientific training about the phases of the moon enables the expert to establish whether it was dark on a particular night. If that is the issue, the expert's testimony fits. But evidence that the moon was full on the night in question does not assist the trier on the issue of whether an individual is likely to be irrational when the moon is full. *Id.* at 2796. *See* discussion of this aspect of *Daubert supra* § I.B.

116. *See* discussion of Christophersen v. Allied-Signal Corp., 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1280 (1992) *supra* § II.D.1.a.

117. *See supra* § II.A.

in Questions 1 and 2 below, was generally ignored by the courts before *Daubert.* An attempt is made to separate the two types of questions, however, for reasons which are discussed below. The discussion proceeds as to each category by considering the different ways in which courts have analyzed the relevant issues and the consequences of their approach.

1. Issues with regard to a particular discipline

A basic question that courts may have to resolve is whether the expert's discipline or field can make any contribution to the resolution of the controverted issue to which the expert proof is directed. Prior to *Daubert*, the *Frye* test, with its "general acceptance" formulation, was not well suited to resolving this issue. Even though experts may have been relying on generally accepted theories in their field, as required by *Frye*, the field was perhaps not capable of providing assistance with regard to the controverted issue before the trier of fact. After considering some of the contexts in which these problems arose, the following discussion considers a post-*Daubert* approach.

a. Challenging a group of experts' methodology as lacking the characteristics of science

Judges would undoubtedly exclude certain evidence—such as predictions based on astrology—as incapable of proving a fact in issue. But on what basis does a court reach this conclusion? The expert who acknowledges reliance on a theory that has not been validated by methods accepted by his or her acknowledged peers is discussed in the next subsection. But suppose the proffered expert belongs to an organized discipline that holds regular meetings and publishes journals to put forth its theories. The proposed expert is clearly qualified in terms of the tenets of this group. Under these circumstances, what evidentiary test must the expert's testimony satisfy? Relatively few cases to date have confronted this issue directly.

1. *Clinical ecology: Is a field scientific if its theories are not testable?* Clinical ecologists claim that various kinds of environmental insults may depress a person's immune system so that the exposed person develops a "multiple chemical sensitivity," that is, becomes hypersensitive to other chemicals and naturally occurring substances. According to this theory, not all persons will necessarily develop the same symptoms as a consequence of this hypersensitivity; each person exposed may present a distinctive profile. Clinical ecologists have not been recognized by traditional professional organizations within the medical community,[118] al-

118. *See* discussion in Sheila Jasanoff, *Science on the Witness Stand*, 6 Issues in Sci. & Tech. 80, 86 (1989) (identifying criticisms of the theory and methods of clinical ecology by the American Academy of Allergy and Immunology and the California Medical Association).

though other authorities are somewhat more open about their contributions,[119] and recent studies may provide some support for some of their claims.[120] The leading professional societies in the fields of allergy and immunology have rejected clinical ecology "as an unproven methodology lacking any scientific basis in either fact or theory," but "numerous other professional organizations and societies . . . have not discredited completely the potential usefulness of clinical ecology."[121] According to the reported cases, federal courts have rejected the opinions of clinical ecologists, although clinical ecologists have fared better in some state courts.

In *Sterling v. Velsicol Chemical Corp.*, a class action in which the plaintiffs claimed that hazardous chemicals from the defendant's landfill had contaminated the water supply, damages had been awarded to the plaintiffs for alleged impairment to their immune systems and to one plaintiff for additional learning disorders resulting from immune system impairment.[122] On appeal, the defendant argued that the district court had improperly admitted the testimony of clinical ecologists supporting these claims "because the principles upon which the experts based their conclusions were not in conformity to a generally accepted explanatory theory."[123]

The appellate court agreed with the defendant and reversed the entire award of damages related to immune system impairment. The court stated the following test for confirming the existence of a "generally accepted explanatory theory":

> In order to prevent deception or mistake and to allow the possibility of effective response, there must be a demonstrable, objective procedure for reaching the opinion and qualified persons who can either duplicate the result or criticize the means by which it was reached, drawing their own conclusions from the underlying facts.[124]

In applying this test, the court pointed to the lack of replication ("plaintiffs' experts neither performed nor could identify any studies of the effects of carbon tetrachloride or chloroform on the immune system"[125]) and the lack of standard, objective procedures ("plaintiffs' experts neither personally examined or interviewed plaintiffs, nor performed the requisite medical tests"[126]).

The court's language in *Sterling* is consistent with the Supreme Court's reference to testability in *Daubert*. "General acceptance," which the Supreme Court listed as a relevant factor, also played a role in *Sterling,* as the court buttressed its

119. *See* discussion in Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. Pitt. L. Rev. 1, 59–62 (1989).

120. *See* Jon R. Luoma, *New Effect of Pollutants: Hormone Mayhem*, N.Y. Times, Mar. 24, 1992, at C1.

121. Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1208 (6th Cir. 1988).

122. *Id.* at 1188.

123. *Id.* at 1208.

124. *Id.*

125. *Id.* at 1208–09.

126. *Id.* at 1209.

conclusion by stating that plaintiffs' experts lacked "a widely accepted medical basis for reaching" their conclusions.[127] Although the court's discussion of methodology and general acceptance seems couched in terms of the admissibility of the expert testimony, the court does not ultimately state that the testimony should not have been admitted, only that it was "insufficient to sustain plaintiffs' burden of proof."[128]

A theory whose central feature is that persons react differently to various substances because of their individual peculiarities is of course difficult to test. Whether the courts in the post-*Daubert* era will treat inability-to-test cases differently from failure-to-test cases and whether they will rule on admissibility or sufficiency grounds remains to be seen.

2. *Forensic techniques: How much inquiry into testing is required?* Over the years a number of forensic techniques that initially found their way into the courtroom have subsequently fallen into disfavor.[129] The original judicial approval of these techniques was perhaps facilitated by the *Frye* test. Because *Frye* emphasized "general acceptance" in a particular field, a well-organized group of expert witnesses in some instances became "the field." "General acceptance" by these experts then verified the reliability of the evidence. For instance, voiceprint evidence was introduced into the courts through the efforts of a small number of experts who were former employees of Bell Labs and the Michigan state police even though their conclusions had never been proven by empirical evidence.[130] Voiceprint evidence gradually faded from the courtroom after a blue-ribbon Committee on Evaluation of Sound Spectrograms, appointed by the National Academy of Sciences, concluded that the scientific results reported to date did not provide quantitative information about improvements in accuracy of voice identifications associated with the use of voice spectrograms.[131] The "paraffin test" is another example of a technique that passed *Frye* and is now discredited.[132] Handwriting analysis is currently the subject of debate.[133]

Whether the *Daubert* case, with its emphasis on testing, will cause courts to be more cautious before admitting evidence produced by a new forensic tech-

127. *Id*.

128. *Id.*

129. *See, e.g.*, Michael J. Saks, *Implications of the Daubert Test for Forensic Identification Science*, 1 Shepard's Expert & Sci. Evidence Q. 427 (1994); Randolph N. Jonakait, *Forensic Science: The Need for Regulation*, 4 Harv. J.L. & Tech. 109 (1991).

130. Andre A. Moenssens, *Admissibility of Scientific Evidence—An Alternative to the Frye Rule*, 25 Wm. & Mary L. Rev. 545, 556–57 (1984).

131. Committee on Evaluation of Sound Spectrograms, National Research Council, On the Theory and Practice of Voice Identification 10 (1979) (technique "lacks a solid theoretical basis of answers to scientific questions concerning the foundations of voice identification. This disparity between practice and theory appears to be recognized by practitioners and scientists involved in the field of voice identification.").

132. Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 Colum. L. Rev. 1197, 1224–25 (1980).

133. *See* the argument in Risinger et al., *supra* note 90. *But see* Kam et al., *supra* note 90, at 7, 13 (conceding "a lamentable lack of empirical evidence" but finding that FBI document examiners performed significantly better than college-educated nonexperts).

nique remains to be seen.[134] Certainly, however, *Daubert* requires the proponent to bear the burden of demonstrating the technique's capacity to produce a reliable result. Recent experience with DNA evidence indicates that prosecutors may have overstated their claims in the early cases,[135] and that the defense may lack the training and resources to make the inquiries that *Daubert* requires. It takes time, money, and effort to understand a new technique sufficiently to ask the right questions about how it has been tested and how it works.[136]

Commentators on forensic evidence have noted that many courts are reluctant to provide expert assistance to indigent defendants.[137] A failure to do so may be especially problematic when the prosecution is relying on a novel forensic technique that must pass the *Daubert* test. When the defense is unable to put forward an expert, questions about the methodological validity of the new technique may not be adequately explored.[138] Whether or not funds are made available to the defense to hire experts, the court might want to seek assistance for itself. It could either direct a magistrate judge to conduct an appropriate inquiry[139] or appoint a methodological expert or experts pursuant to Rule 706 of the Federal Rules of Evidence to assist the court in understanding the issues that are likely to arise.

134. Randolph N. Jonakait, *Real Science and Forensic Science*, 1 Shepard's Exp. & Sci. Evidence Q. 435 (1994) (if *Daubert* is taken seriously, a "dramatic change" will occur with regard to scientific evidence in criminal cases). *Cf.* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 77 Judicature 77, 81 (1993) (pointing out that "[w]hether or not a theory or technique has been adequately tested is as much a social as a scientific question," and that a particular community of experts is unlikely to question testing if an issue is not contentious within a given community). This criticism suggests the possibility of having a court employ a methodological expert outside the particular community in question.

135. *Compare* Andrews v. State, 533 So. 2d 841, 843 (Fla. Dist. Ct. App. 1988) (first case in which DNA evidence was admitted to prove guilt in a criminal trial; prosecution expert testified that the probability that the DNA in question came from someone else was 1:839,914,540), *aff'd*, 533 So. 2d 851 (Fla. Dist. Ct. App. 1988) *with* United States v. Yee, 134 F.R.D. 161, 164 (N.D. Ohio 1991) (FBI first stated the likelihood of a match at 1:270,000 and then recalculated the odds at 1:35,000), *aff'd sub nom.* United States v. Bonds, 12 F.3d 540, 552 (6th Cir. 1993) (on appeal, defense argued that under the ceiling principle advocated by the report of the National Research Committee of the National Academy of Sciences (issued after trial), probability of defendant's DNA being found in the relevant population was 1 in 17; government rejoined that even under the ceiling principle, the odds would be 1 in 6,200).

136. *See, e.g.*, Peter J. Neufeld & Neville Colman, *When Science Takes the Witness Stand*, Sci. Am., May 1990, at 46, 53.

137. See Paul C. Giannelli, "Junk Science": The Criminal Cases, 84 J. Crim. L. & Criminology 105, 122–23 (1993) (concludes that "[w]ithout an effective right to defense experts, the accused often lacks the resources to combat junk science"; provides numerous examples).

138. For instance, the defense offered no expert in the first DNA case, Andrews v. State, 533 So. 2d 841 (Fla. Dist. Ct. App. 1988), *aff'd*, 533 So. 2d 851 (Fla. Dist. Ct. App. 1988), which is discussed *supra* note 135.

139. In United States v. Yee, the magistrate judge conducted a six-week *Frye* hearing to determine the admissibility of DNA evidence; at the hearing, the government called six expert witnesses, the defendants called five expert witnesses, and the court called its own witnesses. The magistrate judge issued a 120-page report and recommendation, which was adopted by the district court. 129 F.R.D. 629 (N.D. Ohio 1990), *adopted*, 134 F.R.D. 161 (N.D. Ohio 1991), *aff'd sub nom.* United States v. Bonds, 12 F.3d 540 (6th Cir. 1993).

b. Challenging a methodology as lacking probative value

The Court did not discuss in *Daubert* an issue that may prove critical in the post-*Daubert* era—may a court exclude an opinion that is the product of a standard, reliable methodology on the ground that the opinion is not sufficiently probative with regard to the issue for which it is being offered? The problem is not—as in the previous section—whether the expert's conclusions were adequately tested in accordance with the types of factors discussed in *Daubert*. In the cases now being discussed, the expert has reached a conclusion that was empirically verified according to the expert's discipline. That conclusion is offered to prove a consequential, material issue in controversy. The opponent claims, however, that the expert's opinion does not adequately tend to establish the controverted issue and should therefore be excluded pursuant to an evidentiary rule[140] or on sufficiency grounds.

The controversy centers on the Supreme Court's statement in *Daubert* that "[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."[141] Some commentators interpret this comment to mean that an opinion must be admitted once an expert demonstrates reliance on a standard scientific methodology; otherwise, the court would be second-guessing the expert's conclusion contrary to *Daubert*.[142] According to this approach, if the expert uses a standard methodology, the court may not exclude the opinion as not adequately probative of an issue in controversy.

Others, however, view the Supreme Court's remark as directed to an entirely different concern—as not permitting a court to choose between competing conclusions when both are based on a reliable methodology and the probative value of the conclusion in question is established.[143] But reliability alone does not make evidence probative. In the arena of nonexpert proof, for instance, courts often reject evidence not because it is untrustworthy but because no valid evidential hypothesis connects the evidence to the proposition for which it is offered.[144] Similarly, "a scientist may reach the wrong conclusion because the prediction being tested is not really a logical consequence of the hypothesis or

140. Objections might be phrased in terms of Fed. R. Evid. 401 (the opinion is not relevant), Rule 702 (it does not assist the trier), Rule 703 (experts would not reasonably rely on such an opinion), or Rule 403 (the probative value of the opinion is substantially outweighed by "the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . .").

141. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2797 (1993).

142. *See* Kenneth J. Chesebro, *Taking Daubert's "Focus" Seriously: The Methodology/Conclusion Distinction*, 15 Cardozo L. Rev. 1745 (1994); Anthony Z. Roisman, *Conflict Resolution in the Courts: The Role of Science*, 15 Cardozo L. Rev. 1943 (1994).

143. If, for instance, two physicians reach differing prognoses with regard to the permanency of a plaintiff's injuries after using standard tests and employing standard medical practices, both opinions will be sufficiently reliable to gain admission. According to *Daubert*'s analysis, a court may not decide that it prefers one of the physician's conclusions—the issue must be left to the jury.

144. Impeccably reliable evidence that a defendant in an accident case was speeding before the accident at a point twenty miles from where the accident occurred may still be rejected to prove that the defendant was driving too quickly when the accident occurred.

because of erroneous assumptions in an experiment's design."[145] Experts, however, are permitted to testify about scientific matters because of their specialized scientific knowledge. Does this mean that the court must defer to the expert's assessment about what the opinion proves without scrutinizing the expert's assumptions? Should the expert's conclusion about what the evidence proves in the world of science be dispositive in determining what the evidence proves in a court of law? These are questions the courts will have to decide after *Daubert*.

1. *Extrapolation problems; animal studies.*[146] To what extent may a court reject an expert's opinion on the ground that it rests on unfounded extrapolation? The question arises with some frequency in toxic tort litigation, when plaintiffs seek to prove that exposure to a defendant's product caused the nonsignature disease or birth defect that is the subject of the suit. In support, the plaintiff offers studies that show a correlation between the product and the disease in a number of animal species. For the results of these studies to be probative, at least two assumptions must be made: (1) that if a substance is toxic in these species of animals it must also be toxic in humans; and (2) that one can extrapolate from the higher and more intense dosage level used in the study to the lower level to which the plaintiff was actually exposed. Although scientists are willing to make these assumptions, and animal studies are routinely used in risk assessment,[147] a number of courts have rejected this evidence to prove causation on the ground that the underlying premises cannot be confirmed. These courts view the discrepancy between humans and animals not as a weight-of-the-evidence question for the jury, but as a matter of law requiring judicial resolution.

The contours of the courts' conclusions are still somewhat vague. For although a number of recent federal court opinions deal with animals studies, many in the context of Bendectin litigation, a number of issues have not been clearly or uniformly resolved. For instance, under what circumstances, if any, is such testimony inadmissible, and when is it insufficient? Should this problem be handled pursuant to Rule 702 or 703, or the relevancy rules? To what extent does it matter that in all of these cases contrary epidemiological evidence was available? In the Bendectin litigation, for example, the defendants introduced two types of evidence pointing to no effect in humans: epidemiological studies

145. Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 Tex. L. Rev. 715, 773 (1994). The authors use the term "implicit error" for this problem, which they illustrate with the example of a scientist testing whether a parasite causes a particular disease in humans by injecting the parasite into an animal species that is immune to the disease in question. The problem is with the assumption "that animal models, particularly mammals, are generally appropriate for testing harmful effects on humans." *Id.* at 774.

146. For a more detailed discussion of animal studies in the context of toxicological proof, see Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology § III, in this manual. Extrapolation issues also arise in other contexts. For instance, it has been pointed out that the epidemiological data on asbestos have been derived almost entirely from studies of workers. In estimating risk to the general population, one must extrapolate from effects at the high exposures seen in the workplace to the much lower doses typically seen in the ambient environment. Devra Lee Davis et al., *Assessing the Power and Quality of Epidemiologic Studies of Asbestos-Exposed Populations*, 1 Toxicol. & Indus. Health 93, 94 (1985).

147. Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology § I.E, in this manual.

showing no statistically significant increased risk of birth defects in children born to mothers who had taken Bendectin during pregnancy, and secular trend studies showing no decrease in birth defects after Bendectin was taken off the market. Is it significant that the expert in some of these cases acknowledged the limits of animal study methodology, or may a court take judicial notice of these limitations? Will studies showing toxicity in animals by themselves discharge a plaintiff's burden of proof sufficiently to make out a question for the jury?[148]

In *Brock v. Merrell Dow Pharmaceuticals, Inc.*,[149] a Bendectin case, the court discussed the methodological flaws in animal studies in general[150] and the Bendectin studies in particular, pointing out the various extrapolations that have to be made. The court's discussion is in the context of granting judgment n.o.v. to the defendant; the court found the plaintiff's evidence insufficient and did not consider whether it was admissible.[151]

The Sixth Circuit in *Turpin v. Merrell Dow Pharmaceuticals, Inc.* rested its affirmance of summary judgment for the defendant in large measure on the insufficiency of the particular animal studies relating to Bendectin.[152] The opinion suggests that the court does not view animal studies as inherently incapable of proving causation because of the extrapolation problems discussed above. It left open the possibility that "there may be other animal experiments which . . . because of the extreme toxicity of the substance tested, would permit a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans."[153] Rather than relying on methodological flaws, the court seems to be evaluating the probative value of the evidence.[154] The court also emphasized, however, that with one exception,[155] all of the experts claimed only that the animal studies showed that Bendectin could possibly cause birth

148. *Cf*. discussion of Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), *infra* § III.C.1.b.2.

149. 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990).

150. The court began its discussion with a case in which it had rejected animal study results used in risk analysis and commented that the "circuit has previously realized the very limited usefulness of animal studies when confronted with questions of toxicity." 874 F.2d at 313.

151. *Id.* at 315. On petition for rehearing en banc, Judge Higginbotham concurred in the dissent from the refusal to rehear the case en banc. 884 F.2d 167, 168–69 (5th Cir. 1989). Judge Higginbotham dissented on the ground that the panel had shied away from addressing the crucial issue—the admissibility of the evidence in the first place rather than its sufficiency after it is admitted. *Id. Cf. In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1267, 1273–83 (E.D.N.Y. 1985) (granting summary judgment to defendants; plaintiff's expert's "resort to inappropriate studies of animals . . . cannot redeem his unfounded opinion. The conclusions set forth in the Carnow affidavit would be excluded at trial under Rule 703 of the Federal Rules of Evidence."), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988). *See also* Villari v. Terminix Int'l, Inc., 692 F. Supp. 568, 571 n.1 (E.D. Pa. 1988) (defendants made in limine motion to exclude animal studies and testimony of experts based on studies of the carcinogenicity of pesticide; court found evidence admissible; court noted that it was not deciding sufficiency issue and that if defendants could show at trial that "an overriding segment of the scientific community repudiates the value of the studies, it would be appropriate to seek their exclusion at that time").

152. 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992).

153. *Id.* at 1359.

154. *See* discussion *supra* § III.C.1.b.

155. The court's rejection of the expert testimony of the medical doctor who testified that Bendectin did cause the defects in issue is discussed *infra* note 170.

defects; they did not assert that Bendectin had more probably than not caused birth defects.[156]

The admissibility of animal studies was considered at length in an extensive post-*Daubert* opinion by Judge Becker for the Third Circuit in *In re Paoli Railroad Yard PCB Litigation* (Paoli II).[157] The court reviewed the cases decided prior to *Daubert* and concluded that the case law "is mixed."[158] It decided that the trial court had abused its discretion in excluding the particular animal studies at issue. The court distinguished other cases in which studies had been found inadmissible

> because most involved the exclusion of animal studies in the face of *extensive* epidemiological data that failed to support causation, because none involved studies on animals particularly similar to humans in the way they react to the chemical in question, and because none involved studies the federal government had relied on as a basis for concluding the chemical was a probable health hazard.[159]

2. *The need for probabilistic evidence: clinical medicine*. The testimony of a physician that he or she is convinced to a reasonable degree of medical certainty that a plaintiff's problem was caused by a physician's negligence is frequently encountered in medical malpractice cases. Testimony that the plaintiff's problem was caused by the defendant's product is more problematic. Except in the case of signature diseases and certain known carcinogens and teratogens, some would maintain that a clinician's opinion alone is inadequate to link a particular birth injury or cancer diagnosis with exposure to a product in the absence of probabilistic evidence.[160] Cancers and most birth defects differ from diseases for which it can be demonstrated that exposure to a particular bacterium or virus obtained from one person will result in the development of the same disease in

156. *Turpin*, 959 F.2d at 1359–60. *See also* Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988) (plaintiff's expert himself acknowledged that "'animal data alone would not be a sufficient bases [sic] for you to give an opinion with reasonable medical certainty that Bendectin causes birth defects in humans'"), *cert. denied*, 493 U.S. 882 (1989).

157. 1994 U.S. App. LEXIS 23722 (3d Cir. Aug. 31, 1994). The Third Circuit had previously, prior to the *Daubert* opinion, reversed a grant of summary judgment for the defendant. *In re* Paoli R.R. Yard PCB Litig. (Paoli I), 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 499 U.S. 961 (1991). On remand, after five days of in limine hearings, the district court granted summary judgment again. 811 F. Supp. 1071 (E.D. Pa. 1992).

158. Paoli II, 1994 U.S. App. LEXIS at *173.

159. *Id*. at *175 (emphasis added). In applying the *Daubert* factors, the court noted that the studies themselves are testable, follow a generally accepted methodology, were published in peer-reviewed journals, and were used for purposes outside the litigation. *Id.* at *178. "Finally," wrote the court, "although their 'fit' to proof of causation in humans is in dispute, all experts acknowledge they are of some use—at least in eliminating those chemicals not likely to cause disease in humans." *Id*. The court also found that the district court had abused its discretion in concluding that the studies could be excluded pursuant to Rule 403. *Id.* at *178–79. *See* discussion *infra* § V.

160. See Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous Substance Litigation*, 73 Cornell L. Rev. 469 (1988), for a discussion of the need for probabilistic evidence to prove causation. *See also infra* § III.C.3.b, which considers the effect of a treating physician's testimony that specific facts about the injured party rule out causes for the disease other than the defendant's product and therefore affect the relative risk that would otherwise apply.

another person.[161] Because no validated theory as yet furnishes an adequate explanation about cancer formation or most birth defects, a claim by a physician that a particular product caused a plaintiff's injury based on the observation that the plaintiff developed a disease after exposure may amount to nothing more than a description of two events, exposure and disease, that are sequentially, but not causally, connected.[162]

Of course, the physician may have training in toxicology or epidemiology or possess specialized information about a particular controverted issue before the court.[163] Unlike the qualification issue discussed in section II, however, the question considered here is not whether the particular physician has enough specialized knowledge, but whether testimony by a physician relying on the methodology of clinical medicine will suffice to establish causation. *Ferebee v. Chevron Chemical Co.*, a case in which the manufacturer of paraquat, a herbicide, was sued for causing the decedent's death from pulmonary fibrosis, is often cited as holding that causation can be established by the testimony of treating physicians.[164] The *Ferebee* court stated:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That Ferebee's case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.[165]

In a subsequent Bendectin case, *Richardson v. Richardson-Merrell, Inc.*,[166] the District of Columbia Circuit explained its *Ferebee* opinion as follows:

161. *See* discussion of Koch's postulates in Linda A. Bailey et al., Reference Guide on Epidemiology § IV.B, in this manual.

162. *See, e.g.*, Porter v. Whitehall Lab., Inc., 9 F.3d 607, 611–16 (7th Cir. 1993) (court affirmed trial judge, who found that experts' conclusions were based on temporal relationship unsupported by studies or scientific methodology; appellate court found that trial court had anticipated *Daubert* in its analysis). *See also In re* Joint E. & S. Dist. Asbestos Litig. (Maiorana), 827 F. Supp. 1014, 1048–50 (S.D.N.Y. 1993) (finding that treating physician's differential diagnosis did not suffice to prove that plaintiff's colon cancer was caused by asbestos exposure in the absence of epidemiological proof).

163. *See* discussion *supra* §§ II.C–D.

164. 736 F.2d 1529, 1535–36 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

165. *Id.* at 1535–36.

166. 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).

> *Ferebee* stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and "*stand[s] at the frontier of current medical and epidemiological inquiry.*" If experts are willing to testify to causation in such situations and their methodology is sound, the jury's verdict should not be disturbed.[167]

Distinctions can be drawn between *Ferebee* and *Richardson.* Paraquat was known to be a toxic chemical; the particular injury to the lungs after chronic exposure[168] was biologically plausible;[169] and the physicians in question were experts on lung disease who relied on their examination of the patient as well on studies of the particular substance.

Recent cases suggest that courts may be unwilling to allow nonsignature cancer and birth injury claims to reach the jury solely on the basis of causation testimony by a clinical physician even in a case of first impression regarding the substance in question.[170]

2. Issues with regard to the methodology and reasoning of a particular scientific theory

Unlike the previous section, which concentrates on various issues that arise with the methodology of an entire discipline, this section examines expert testimony offered by a witness in an established field. The discussion focuses on a number of contexts in which courts have been confronted with challenges to a variety of theories on the ground that the expert's reasoning does not comport with the scientific method.

a. When does the expert's reasoning satisfy the *Daubert* test?

The *Daubert* opinion views science as an empirical enterprise and emphasizes the need for validation through testing. Does this mean that once an issue is labeled as "scientific," the parties must rely solely on theories that have been sub-

167. *Id.* at 832 (emphasis in original) (quoting *Ferebee*, 736 F.2d at 1534).

168. *See In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1262 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

169. *See* Linda A. Bailey et al., Reference Guide on Epidemiology § IV.B.4, and Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology § III.E, in this manual. *See also* Cella v. United States, 998 F.2d 418, 421 (7th Cir. 1993) (plaintiff's expert offered plausible explanation, discussed in medical literature, for why stress might cause disease from which plaintiff suffered).

170. *See* Porter v. Whitehall Lab., Inc., 9 F.3d 607, 614–15 (7th Cir. 1993) (granting summary judgment post-*Daubert*); Chikovsky v. Ortho Pharmaceutical Corp., 832 F. Supp. 341, 345–46 (S.D. Fla. 1993) (same). Pre-*Daubert* cases: Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1360 (6th Cir.) (in Bendectin case, court found affidavit by physician claiming that Bendectin caused plaintiff's birth defects insufficient to meet plaintiff's burden of proof on summary judgment motion: "Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences."), *cert. denied*, 113 S. Ct. 84 (1992); *See also* Felgenhauer v. Texaco, Inc., No. 85-3671, 1987 U.S. Dist. LEXIS 11258, at *4–9 (E.D. Pa. Nov. 30, 1987) (not officially reported) (plaintiff claimed that liver damage was caused by exposure to aromatic hydrocarbons in paints and solvents at his place of employment; court granted summary judgment after plaintiffs submitted affidavit of their expert physician (board certified in internal medicine) claiming a causal connection, although he had conceded in correspondence that he was not aware of any case reports or studies establishing such a connection). *See also* discussion of theories of cancer causation *supra* § III.C.1.b.2.

jected to an empirical investigation? Or does Rule 702 still allow experts to rely on other types of "specialized knowledge" that do not satisfy the *Daubert* test for "scientific knowledge?"

1. *Theories as to the cause of plaintiff's cancer*. After *Daubert*, may a plaintiff establish causation in the absence of studies implicating a product as having a connection with the plaintiff's disease? The Thalidomide experience suggests that in some situations anecdotal observations will provide sufficient validation even in the absence of a formal study. But in the absence of a well-documented, strong association between a product and a disease, how does a party satisfy Rule 702's requirement of "a valid scientific connection to the pertinent inquiry as a precondition to admissibility?"[171]

For instance, in *Christophersen v. Allied-Signal Corp.*,[172] the majority held that the district court had not erred in excluding expert testimony that the decedent's death from a rare form of colon cancer was due to exposure to nickel and cadmium fumes at his place of work. The plaintiffs' expert conceded that he had never seen epidemiological, animal, or in vitro studies demonstrating a causal association between exposure to nickel or cadmium, or both, and colon cancer. Instead, he argued that nickel and cadmium had been implicated in small-cell carcinoma of the lungs, that the cells in the decedent's colon cancer were likewise small, and that one could conclude that small-cell carcinoma throughout the body had a similar pathogenesis.[173] The majority, invoking *Frye*, found that the witness had not "used a well-founded methodology or mode of reasoning."[174] It termed the expert's conclusion "a scientific hunch, which as far as the record shows, no one else shares."[175] The majority stressed that it was basing its conclusion on the lack of support in the scientific community for the expert's methodology and not on an evaluation of the correctness of the methodology.[176]

After *Daubert*, the admissibility of scientific evidence does not depend on the "general acceptance" of the expert's theory, although "general acceptance" is still a factor to be considered.[177] In the future, courts will have to determine whether reasoning by analogy, which the expert in *Christophersen* was attempting to do, might in some instances be scientifically sound.[178] *Daubert* suggests, however, that an expert who has not investigated the proposed analogy to the ex-

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

172. 939 F.2d 1106 (5th Cir. 1991) (en banc), *cert. denied,* 112 S. Ct. 1280 (1992).

173. *Id.* at 1115–16.

174. *Id.* at 1111.

175. *Id.* at 1115.

176. *Id.* at 1116.

177. *Cf.* O'Connor v. Commonwealth Edison Co., 13 F.3d 1090, 1106 (7th Cir. 1994) (court found inadmissible expert's testimony that plaintiff's cataracts were radiation-induced; authorities on whom expert purported to rely agree that diagnosis cannot be made on observation alone and expert failed to use proper methodology for diagnosis).

178. *See* Edward J. Imwinkelried, *The Admissibility of Expert Testimony in Christophersen v. Allied-Signal Corp.: The Neglected Issue of the Validity of Nonscientific Reasoning by Scientific Witnesses*, 70 Denv. U. L. Rev. 473 (1993).

tent feasible is offering a hunch rather than an explanatory theory, and should not be permitted to offer an opinion.[179] A complicating problem in *Christophersen* was the weakness of the plaintiff's evidence on exposure, which came from a fellow worker's affidavit that provided no information about the composition of the fumes to which Christophersen was exposed or the physical facilities of the plant.[180]

2. *Social science evidence*. A fundamental question that the courts will have to address after *Daubert* is whether the Supreme Court's opinion applies to the social sciences or is limited to the physical and "hard" sciences. Are experts in such fields as psychology,[181] economics,[182] sociology, and political science testifying about "scientific knowledge" so that the *Daubert* standard of admissibility applies? If *Daubert* applies, how does a court determine whether an expert opinion grounded in the social sciences rests on a valid methodology? Although there has been a marked increase in proffers of social science evidence, especially psychological evidence, the federal courts rarely explored these issues in much depth prior to *Daubert*, in part because cases involving rape and child abuse in which syndrome evidence is prevalent were not usually brought in federal courts.[183]

179. *See, e.g.,* Chikovsky v. Ortho Pharmaceutical Corp., 832 F. Supp. 341, 346 (S.D. Fla. 1993) (plaintiff claimed that defendant's product, Retin-A, which pregnant mother had used topically, had caused child's birth defects; Retin-A is a Vitamin A derivative, and there are no data linking Retin-A to birth defects; plaintiff's expert, an obstetrician–gynecologist with no specialized training in embryology or teratology (*see supra* § II.D.1.a), testified that high doses of other Vitamin A derivatives have been implicated in birth defects; however, he did not know how much Vitamin A could have been absorbed through the skin, and "most significant" according to the trial court which excluded his testimony as not meeting *Daubert*, he had performed no comparisons between the dose of Vitamin A in the studies showing fetal harm and that found in Retin-A).

180. *Cf.* Peteet v. Dow Chem. Co., 868 F.2d 1428 (5th Cir.), *cert. denied*, 493 U.S. 935 (1989), in which plaintiffs claimed that decedent's death, probably of Hodgkin's disease, was due to exposure to defendant's herbicide. The plaintiffs' expert, a certified toxicologist, testified that numerous studies linked the herbicide and cancer. The opinion does not discuss to what extent, if any, these studies found a link to Hodgkin's disease. The expert relied on a "one-hit" theory of cancer that "suggests that one molecule of carcinogen, in the right place and at the right time, can cause cancer." *Id.* at 1433. The court quoted from an earlier case in which it had stated that "[w]hat is necessary is that the expert arrived at his causation opinion by relying upon *methods* that other experts in his field would reasonably rely upon in forming their own, possibly different opinions, about what caused the patient's disease." *Id.* at 1433 (quoting Osburn v. Anchor Lab., Inc., 825 F.2d 908, 915 (5th Cir. 1987)). Testimony had established that the decedent had worked on a weed control project and that the herbicide had frequently gotten on the workers' clothing and skin. *Id.* at 1430.

181. United States v. Amador-Galvan, 9 F.3d 1414, 1418 (9th Cir. 1993) (*Daubert* governs expert testimony about unreliability of eyewitness evidence).

182. *See, e.g.*, Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co., 998 F.2d 1224, 1241 (3d Cir.) (court cited *Daubert* with regard to economists' testimony), *cert. denied*, 114 S. Ct. 554 (1993). *See also* Joy v. Bell Helicopter Textron, Inc., 999 F.2d 549, 569 (D.C. Cir. 1993); Scales v. George Washington Univ., No. 89-0796, 1993 U.S. Dist. LEXIS 10692, at *25 (D.D.C. July 27, 1993).

183. Prior to the middle 1970s, courts almost never applied *Frye* to the social sciences. *See* David McCord, *Syndromes, Profiles and Other Mental Exotica: A New Approach to the Admissibility of Nontraditional Psychological Evidence in Criminal Cases*, 66 Or. L. Rev. 19, 77 (1987). Thereafter, some courts began extending *Frye* to social science evidence. *See, e.g.*, United States v. Shorter, 809 F.2d 54, 59–61 (D.C. Cir.) (psychological testimony), *cert. denied,* 484 U.S. 817 (1987); United States v. Carmel, 801 F.2d 997, 998–99 (7th Cir. 1986); Spencer v. General Elec. Co., 688 F. Supp. 1072, 1076 (E.D. Va. 1988); Barrel of Fun, Inc. v. State Farm Fire & Casualty Co., 739 F.2d 1028, 1031–32 (5th Cir. 1984) (psychological stress evaluation). Finally, some courts did not use *Frye* as a test for "hard" or "soft" scientific evidence. The Third Circuit's approach, rejecting *Frye* and focusing on reliability and fit, upon which the Supreme Court relied in part in

Are there reasons why the "hard" and "soft" sciences should perhaps be handled differently? Two schools of thought about this issue can conveniently be compared by looking at the views of Professors David McCord[184] and David L. Faigman.[185] Even though McCord and Faigman wrote before *Daubert* and were primarily concerned with psychological syndrome evidence, their differing attitudes shed light on some underlying factors and assumptions. The crux of their disagreement centers on when evidence should be kept from a jury. McCord is much more willing to take the risk, which he thinks is low, that jurors will be swayed by worthless social science evidence if there is a chance that the evidence might be helpful. Faigman puts much greater stock in shielding against juror misuse of invalid evidence.[186]

According to McCord, the fundamental difference between hard and soft scientific evidence (at least of a psychological nature) makes a stringent test wholly inappropriate for the latter type of evidence. The justification for a stricter admissibility test—keeping from the jury evidence which "juries are not in a position to fairly and intelligently weigh" and which "appears to be unassailably 'scientific'"—does not apply to psychological evidence.[187]

> The essence of such "soft" psychological evidence is not locked up in some mysterious nonhuman device or process, and the expert on the stand can be grilled regarding the foibles of psychological research. Further, and perhaps more important, most jurors do not conceive of psychological research as very, if at all, "scientific." It is not likely to elicit unquestioning juror acceptance. In short, the jury most likely has the ability to fairly and intelligently weigh the strengths and weaknesses of psychological evidence without being overwhelmed or overawed by it.[188]

The Supreme Court's opinion in *Barefoot v. Estelle*[189] might be read as consistent with McCord's position. In *Barefoot*, a death row inmate argued that the government should not have been permitted to call an expert psychiatrist at the guilt phase of his trial in order to predict the defendant's future dangerousness. The defendant claimed that psychiatrists are not capable of predicting future behavior, especially without interviewing the person.[190] The Court rejected this view, stating that if it is constitutionally permissible to base a death sentence

Daubert (113 S. Ct. at 2797 n.12), was developed in United States v. Downing, 753 F.2d 1224 (3d Cir. 1985), a case dealing with the admissibility of a psychologist's testimony about eyewitness testimony.

184. McCord, *supra* note 183.

185. David L. Faigman, *To Have and Have Not: Assessing the Value of Social Science to the Law as Science and Policy*, 38 Emory L.J. 1005 (1989). *See also* American College of Trial Lawyers, *supra* note 5.

186. To perhaps a lesser extent, the same two camps exist with "hard" scientific evidence as well. As is discussed elsewhere, judges obviously differ in how willing they are to exclude evidence from a jury's consideration. One of the clearest reflections of this difference is the extent to which courts scrutinize the validity of the social science research underlying an expert's opinion.

187. McCord, *supra* note 183, at 85.

188. *Id.* at 85–86 (footnotes omitted).

189. 463 U.S. 880 (1983).

190. *Id.* at 896. An amicus brief filed by the American Psychiatric Association quoted by the dissent had concluded that "*two out of three* predictions of long-term future violence made by psychiatrists are wrong." *Id.* at 920 (citing Brief for American Psychiatric Association as Amicus Curiae at 9, 13).

on the likelihood of future behavior, then an expert may give an opinion on that behavior.[191] The dissent agreed that future behavior is a permissible consideration, but objected strenuously to the expert testimony's lack of reliability.[192]

McCord concedes that "[e]ven with respect to 'soft' psychological evidence, some inquiry into reliability is still appropriate since the jury may well not be in the best position to completely understand the probative value of the evidence."[193] He suggests, however, that flexible, less stringent standards of reliability are appropriate, and that no one factor should be dispositive. "Even somewhat unreliable evidence may be admitted in certain circumstances, particularly where it is offered on a nondispositive issue in the case or offered by the defendant."[194] Ultimately, McCord endorses a four-factor balancing test that focuses on necessity, reliability, understandability, and importance.[195]

A very different view is expressed by Faigman. He endorses a test that sounds remarkably like the Supreme Court's language in *Daubert*. According to him, social science evidence should not be presented to jurors unless it rests on a scientific theory that has been empirically tested: "[f]alsifiability or testability represents the line of demarcation between science and pseudo-science, and the strength of particular scientific statements depends on the extent to which they have been tested appropriately."[196] He would insist on threshold screening by the judge of the methodology on which the social science evidence rests.[197] To Faigman, tying threshold admissibility determinations to "scientific" validity is as essential for "soft" evidence as it is for "hard" evidence. A restrictive test prevents scientific statements by the experts that "reflect personal values rather than scientific observation" and guards against "experts . . . [who] nullify legal rules themselves, by confusing jurors, or . . . call upon the jury to nullify a legal rule on the basis of policy considerations that the rule does not reflect."[198] Prior to

191. *Id.* at 896–97.

192. *Id.* at 938 (Blackmun, J., dissenting). *See* Giannelli, *supra* note 137, at 113–17 (discussion of *Barefoot* to illustrate "junk science" in criminal cases).

193. McCord, *supra* note 183, at 86.

194. *Id.* at 88.

195. *Id.* at 94.

196. Faigman, *supra* note 185, at 1015. For a discussion of the empirical approach in the social sciences and references to more detailed discussions, see John Monahan & Laurens Walker, Social Science In Law: Cases and Materials 33–82 (2d ed. 1990). In a series of articles, Professors Walker and Monahan have also proposed an alternative concept for providing jurors with information stemming from social science research that treats such research more like legal precedents than factual findings. *See* John Monahan & Laurens Walker, *Empirical Questions Without Empirical Answers*, 1991 Wis. L. Rev. 569; Laurens Walker & John Monahan, *Social Facts: Scientific Methodology as Legal Precedent*, 76 Cal. L. Rev. 877 (1988); Laurens Walker & John Monahan, *Social Frameworks: A New Use of Social Science in Law*, 73 Va. L. Rev. 559 (1987); John Monahan & Laurens Walker, *Social Authority: Obtaining, Evaluating and Establishing Social Science in Law*, 134 U. Pa. L. Rev. 477 (1986).

197. Faigman, *supra* note 185, at 1090.

198. *Id.* at 1084, 1088.

Daubert, some courts reached the result Faigman advocates by relying on Rule 403 rather than Rule 702.[199]

Faigman would require courts to look for the hallmarks of scientific methodology before he would allow any expert to render an opinion based on the social sciences. He would require of the proffered expert "a cogent explanation of the methods and analyses that produced the scientific opinion."[200] Expert testimony about the accuracy of eyewitness identifications meets a minimum threshold standard because it is based on a research design and statistical studies.[201]

3. *Psychological syndrome evidence*. The difference between the two approaches is apparent if one considers how courts have treated the admissibility of psychological syndrome, or profile, evidence. Expert testimony, usually by a psychologist, has been proffered in the federal courts concerning rape trauma syndrome (RTS).[202] Testimony about RTS or post-traumatic stress disorder (PTSD) is most often offered in a rape prosecution to counter the defendant's consent defense or to explain the victim's behavior. The absence of RTS has also been offered by the defense to show that the complainant was not raped, and the presence of RTS has been proffered in civil cases on a number of theories. The courts are divided on the admissibility of RTS expert testimony; some exclude all RTS evidence,[203] whereas others admit RTS evidence, although they differ on how the expert testimony may be used.[204]

A "*Daubert*" approach to social science evidence that insists on empirical validation might exclude expert testimony that the existence of certain symptoms proves that the alleged victim has been raped, but might admit testimony offered

199. *See infra* § V.

200. Faigman, *supra* note 185, at 1081.

201. *Id.* at 1089. Faigman concedes that some validity problems will remain for the jury because most eyewitness identification studies involve college students and are conducted under contrived circumstances. These are issues that he thinks jurors can comprehend and that can be explored adequately on cross-examination of the expert. *Id.*

202. *See, e.g.*, Spencer v. General Elec. Co., 688 F. Supp. 1072, 1075–77 (E.D. Va. 1988) (court held that such evidence is not a scientifically reliable means of proving that a rape occurred and therefore does not satisfy *Frye* test; court noted that expert's methodology "bore little, if any, resemblance to traditional scientific or medical methodologies" and that probative value of such evidence is outweighed by its unfair prejudicial effect, citing Rule 403). *See also* United States v. Arcoren, 929 F.2d 1235, 1238–42 (8th Cir. 1991) (court upheld admission of evidence of battered woman syndrome to explain why witness recanted her testimony), *cert. denied*, 112 S. Ct. 312 (1991); United States v. Azure, 801 F.2d 336, 339–41 (8th Cir. 1986) (allowing expert testimony concerning post-traumatic stress reactions to child abuse but not permitting expert to give opinion as to truth of victim's story).

203. *See, e.g.*, People v. Bledsoe, 681 P.2d 291, 300–01 (Cal. 1984) (error, although not prejudicial, to admit testimony of rape counselor as expert testimony that victim was suffering from RTS; rape counselors neither question the credibility of their clients nor probe inconsistencies, and therefore use of these opinions as expert testimony is problematic; scientific literature does not purport to claim that RTS is a scientifically reliable means of proving that a rape occurred); State v. Black, 745 P.2d 12, 15–19 (Wash. 1987); Commonwealth v. Gallagher, 547 A.2d 355, 358–59 (Pa. 1988).

204. *See infra* notes 205–07. For a recent survey that considers the entire body of psychological research on rape, see Patricia A. Frazier & Eugene Borgida, *Rape Trauma Syndrome: A Review of Case Law and Psychological Research*, 16 Law & Hum. Behav. 293 (1992). Faigman has faulted much of the research in this area. *See* David L. Faigman, Note, *The Battered Woman Syndrome and Self-Defense: A Legal and Empirical Dissent*, 72 Va. L. Rev. 619 (1986).

to rebut the defendant's defense that the complainant's behavior was inconsistent with the claim of rape.[205] A less rigid but still "scientific" view would permit experts who have interviewed or treated the victim to testify about the typical behavior of rape victims, and allow experts to state that the victim's behavior is consistent with that of rape victims.[206] Cross-examination of the experts could develop the limits of present scientific knowledge. Courts least inclined to take a rigid scientific approach to social science evidence, who believe that jurors are capable of evaluating soft evidence for what it is worth without being unduly swayed by the expert, allow RTS evidence as part of the prosecution's case in chief on the issue of whether a rape occurred in cases in which the defendant is claiming consent.[207]

b. Rejecting expert testimony because of skewed methodology

Courts may also be confronted with experts who purport to rely on a standard methodology. In the instant case, however, the opponent claims that this methodology is somehow skewed—nonconventional assumptions or irregular techniques were used, or errors have been found. Is this a Rule 702 problem under *Daubert*, a Rule 703 problem, a Rule 403 problem, or a problem of weight for the jury?

205. *See* discussion in *Spencer,* 688 F. Supp. at 1076–77 ("[T]he relevant issue is not whether rape victims may display certain symptoms, but 'whether the presence of various symptoms, denominated together as "rape trauma syndrome" [or PTSD], is a scientifically reliable method admissible in evidence and probative of the issue of whether an alleged victim was raped.'" (quoting State v. Black, 745 P.2d 12, 17 (Wash. 1987)); court excluded PTSD testimony by an expert to prove rape in tort case because expert's methodology "bore little, if any, resemblance to traditional scientific or medical methodologies"; but court allowed testimony to establish damages). *See also* People v. Taylor, 552 N.E.2d 131, 138 (N.Y. 1990) (allowing testimony concerning rape victim's lack of emotion after attack because RTS evidence is "relevant to dispel misconceptions that jurors might possess regarding the ordinary responses of rape victims in the first hours after their attack," but excluding RTS evidence to prove that rape occurred in a companion case; court stressed that "evidence of rape trauma syndrome is inadmissible when it inescapably bears solely on proving that a rape occurred"). When the evidence is being permitted to counter the defendant's defense, to prevent jurors from drawing the prohibited assumption—that the expert has concluded that the victim was raped and that the expert has a basis for this opinion—it has been suggested that the testimony about the rape victim's behavior be given by an expert who has not examined the victim. Deborah A. Dwyer, Note, *Expert Testimony on Rape Trauma Syndrome: An Argument for Limited Admissibility*, 63 Wash. L. Rev. 1063, 1084 (1988).

206. People v. Fasey, 829 P.2d 1314, 1315–17 (Colo. 1992) (expert in state's case in chief first described the symptoms of PTSD and stated that a sexual assault could be a traumatic experience that would cause the symptoms; he then described the symptoms exhibited by the victim and concluded that the victim did suffer from PTSD; he did not state that the syndrome was necessarily caused by a sexual assault; court found no error).

207. *See, e.g.*, State v. Allewalt, 517 A.2d 741, 748 (Md. 1986) (defendant claimed consent in rape prosecution; psychiatrist permitted to state that victim's PTSD was caused by rape:

> He [the expert] did not purport to have invented a scientific test for determining consent to sexual intercourse had months earlier. He did claim that he could use his special knowledge and the interviewing techniques of his profession to diagnose whether Mrs. Lemon, at the time of his examination of her, suffered from a medically recognized anxiety disorder. He did not claim that psychiatry could demonstrate conclusively that the cause of the PTSD was rape. He did claim the special knowledge and experience to be able to identify the cause of the PTSD by utilizing the history furnished by the patient . . . .).

The Third Circuit has dealt with this question in a number of contexts that illustrate the issues that may arise. Recently, in *In re Paoli Railroad Yard PCB Litigation* (*Paoli II*), the court considered at length to what extent plaintiffs' experts, specialists in internal medicine, had to employ the technique of differential diagnosis in order for the court to find that their opinions were based on a reliable methodology that satisfied the standards of *Daubert.*[208] The court

> agree[d] with the defendants that performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable.[209]

But the court also

> agree[d] with the plaintiffs that a doctor does not always have to employ all of these techniques in order for the doctor's differential diagnosis to be reliable. . . . [S]ometimes differential diagnosis can be reliable with less than full information, and to the extent that the district court concluded otherwise, we hold that it abused its discretion.[210]

The court then concluded that the district court could not exclude the opinions of the plaintiffs' physicians unless

> (1) [they] engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes *and* the doctor offered no good explanation as to why his or her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and [the plaintiff's physician] offered no reasonable explanation as to why he or she still believed that the defendants' actions were a substantial factor in bringing about that illness.[211]

In a previous review of the same case, *In re Paoli Railroad Yard PCB Litigation (Paoli I),* the court discussed the admissibility of an expert's opinion based on a meta-analysis.[212] Meta-analysis is a statistical method for combining the

208. 1994 U.S. App. LEXIS 23722, at *87–140 (3d Cir. Aug. 31, 1994).

209. *Id.* at *100–01 (footnote omitted).

210. *Id.* at *102–03 (footnote omitted). The court gives as an example a patient who comes to a physician with a medical record "demonstrating illness A known to be strongly associated with chemical X and evidence of exposure to that chemical." Even if the patient has been exposed to other chemicals that sometimes, though less frequently, cause the same illness, "[w]ith a basic understanding of probabilities, a physician might very well be able to reliably conclude that a person exposed to chemical X was more likely than not to have contracted illness A as a result of that exposure than as a result of any other cause." *Id.* at *104 n.30.

211. *Id.* at *104–05 (emphasis in original). The court concluded that a court could exclude a physician's conclusions that were based solely on the "plaintiff's self-report of illness in preparation for litigation." *Id.* at *111. One reliable source for the opinion, such as a physical examination or medical records, will ordinarily suffice. *Id.* The court ultimately found that the testimony of one of the plaintiff's physician experts was properly excluded and that the testimony of the other physician should have been admitted to a limited extent.

212. 916 F.2d 829, 856–59 (3d Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991). Because the defendants were challenging the meta-analysis technique itself, the court invoked the standard it had announced in United States v. Downing, 753 F.2d 1224 (3d Cir. 1985), for analyzing expert testimony based on novel scientific techniques. *Paoli I,* 916 F.2d at 856. The majority opinion in *Daubert* acknowledged that its discussion of the reliability of scientific evidence was "draw[n] in part" from the Third Circuit's opinion in *Downing,* 753 F.2d at 1238–39. *See* Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2791 n.12 (1993). Judge Becker was the author of both *Downing* and *In re Paoli*. The admissibility of meta-analysis was not addressed in *In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722 (3d Cir. Aug. 31, 1994).

results from separate published studies on a common scientific issue to see if all available data looked at collectively produce a result different from that obtained when small studies are looked at individually. Combining studies that measure different parameters may be controversial, although such a technique is often used by scientists.[213] Indeed, in *In re Paoli (Paoli I),* the court noted that defendants' own experts did not question the reliability of all meta-analyses; they merely questioned the way in which plaintiffs' experts had applied meta-analysis in the instant case.[214] The court suggested, however, that a district court could exclude a particular meta-analysis pursuant to Rule 702 if it was "sufficiently unreliable."[215] The court declined "to define the exact level at which a district court can exclude a technique as sufficiently unreliable. Reliability indicia vary so much from case to case that any attempt to define such a level would most likely be pointless."[216]

A Bendectin case in the Third Circuit, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.,* illustrates a situation in which the district court concluded after an in limine evidentiary hearing that the expert's methodology was so unreliable as to warrant exclusion.[217] The district court relied primarily on Rule 702, but also concluded that the testimony was excludable pursuant to Rule 703.[218] The district court, while recognizing that the defendant was attacking the plaintiff's expert's "methodology and not the underlying data he relied upon in making his calculations," stated that "[t]his is where Rules 702 and 703 intersect" and acknowledged that the expert had "used data upon which no epidemiologist would rely."[219]

In *DeLuca*, the plaintiff's principal expert acknowledged that published studies showed no statistically significant association between Bendectin and limb reduction defect, but claimed that his reanalysis of the studies established such

213. *See generally* Frederic Marc Wolf, Meta-Analysis: Quantitative Methods for Research Synthesis (1986) (basic text on meta-analysis); Larry V. Hedges & Ingram Olkin, Statistical Methods for Meta-Analysis (1985) (discussion of strengths and weaknesses of statistical procedures); Handbook of Research Synthesis (Harris Cooper & Larry V. Hedges eds., 1994) (strengths and weaknesses of various approaches to meta-analysis); Thomas R. Einarson et al., *A Method for Meta-Analysis of Epidemiological Studies,* 22 Drug Intelligence & Clin. Pharmacy 813 (1988) (meta-analysis of Bendectin studies); Michael O. Finkelstein & Bruce Levin, Statistics for Lawyers 254–55 (1990).

214. Paoli I, 916 F.2d at 857.

215. *Id.* at 858. "A reliable methodology . . . [that is] so altered as to skew the methodology itself" is properly subject to a Rule 702-based exclusion. *Id.*

216. *Id.* The court remanded for a fuller record and specific findings on reliability issues.

217. 911 F.2d 941, 944 (3d Cir. 1990) (reversing and remanding grant of summary judgment), *on remand*, 791 F. Supp. 1042 (D.N.J. 1992) (granting summary judgment), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994).

218. 791 F. Supp. at 1058–59.

219. *Id.* at 1048 n.10, 1059. The district court quoted the court of appeals: "'If a study's method of data collection is faulty, it may be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject.'" *Id.* at 1059 (quoting *DeLuca*, 911 F.2d at 955 n.14). The district court also noted that the Third Circuit in *Paoli* made reference to its decision in *DeLuca*: "' *DeLuca* announces an important rule by making clear that when it is a scientist's methodology that is being attacked, in contrast to the data relied on, the court must analyze the reliability of that methodology under *Downing* (and Rule 702).'" *Id.* at 1047–48 n.10 (quoting *In re* Paoli R.R. Yard PCB Litig. (Paoli I), 916 F.2d 829, 856 (3d Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991)).

an association. At the in limine hearing, however, none of the epidemiologists testifying was able to replicate the expert's numbers, and his methodology was termed a "mystery."[220]

In a case such as *DeLuca*, the data collection problems that are discussed in section IV corroborate the weakness of the expert's methodology; separating the methodology and data issues is somewhat artificial, since both relate to the reliability of the expert's opinion. Whether courts will continue to make this distinction after *Daubert* is not clear;[221] the Supreme Court mentioned Rule 703 as a rule to consider but did not discuss its scope. Nevertheless, some of the problems with the expert's testimony in *DeLuca* are considered in section IV because, when screening expert testimony, many courts have considered the data on which the expert's opinion is based independently of methodological concerns.

The nondefinitive checklist the majority offers in *Daubert* of factors bearing on scientific validity all point to the flawed methodology of the expert's testimony in *DeLuca*. A more difficult case arises when no obvious errors emerge but the parties disagree about the research design of particular epidemiological studies. What must the judge do if one side argues, for instance, that the control group was improperly constituted, or that the classification scheme for identifying exposed individuals was faulty, or that confounding factors were not taken into account?[222] No epidemiological study can be perfect; will less blatant flaws

220. 791 F. Supp. at 1047. In addition to transposing numbers on his charts, relying on data that authors had corrected, and including anecdotal data which he conceded could not be used to show causation, the plaintiff's expert apparently calculated results for studies that did not specify odds ratios or relative risk and that did not contain data from which such calculations could easily be made. With respect to another study, he specified a relative risk far in excess of the confidence intervals specified in the study, although a relative risk must fall between these limits. For yet another study, he recalculated the odds, although he claimed to use the authors' calculations when possible. The expert also failed to consider the strength of the various studies in conjunction with their results, and he ignored two recent studies, one quite large, that found no causal relationship between Bendectin and birth defects. Although he testified that he included data from all studies he knew of, he did not include any data from post-1986 studies. Articles on two of these studies had been published in a peer-reviewed scientific journal. In addition, the court noted that he had failed to identify any literature or other expert who endorsed his technique. *Id.* at 1047–57.

221. In *In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *52–53 (3d Cir. Aug. 31, 1994), the court stated:

> we no longer think that the distinction between a methodology and its application is viable. To begin with, it is extremely elusive to attempt to ascertain which of an expert's steps constitute parts of a "basic" methodology and which constitute changes from that methodology. If a laboratory consistently fails to use certain quality controls so that its results are rendered unreliable, attempting to ascertain whether the lack of quality controls constitutes a failure of methodology or a failure of application of methodology may be an exercise in metaphysics. Moreover, any misapplication of a methodology that is significant enough to render it unreliable is likely to also be significant enough to skew the methodology.

222. See Linda A. Bailey et al., Reference Guide on Epidemiology § II, in this manual, for a discussion of factors to be considered in evaluating an epidemiology research design.

than those in *DeLuca* warrant exclusion of an expert's opinion?[223] Few cases have, as yet, considered methodological challenges.[224]

3. Issues with regard to statistical estimates

The *Daubert* opinion does not discuss the statistical issues that frequently emerge in connection with scientific evidence.[225] The parties may, for instance, agree that an appropriate way to prove the controverted issue—does Substance A cause Disease B—is through an epidemiological study. They may even concur in finding no problems with the methodological design of the study.[226] But they may disagree strongly about the statistical significance of the study and the consequences with regard to admissibility or sufficiency. Or they may differ on what, if anything, the jury must be told about background statistical information. Finally, issues arise about the extent to which results of particular studies should be discounted by error rates. Each of these issues is discussed below.

223. *See In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722 (3d Cir. Aug. 31, 1994). The majority concluded that

> [t]he evidentiary requirement of reliability is lower than the merits standard of correctness. . . . A judge frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate. He or she will often still believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct and may certainly still believe that a jury attempting to reach an accurate result should consider the evidence. *Id.* at *49–50.

In concurring, Judge Roth specifically declined to join this portion of the opinion, stating: "I do not believe that it is 'helpful' for the jury to receive information which the trial judge concludes is not accurate. In my opinion, the 'gatekeeper' function of the trial judge established by the Supreme Court in *Daubert* would not be fulfilled by permitting inaccurate information to go to the jury even though the trial judge may have determined that the methodology used to produce such results is reliable." *Id.* at *245.

224. *See* discussion in Renaud v. Martin Marietta Corp., 749 F. Supp. 1545, 1553 (D. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992) (court appointed a geological expert to advise court as to whether it was methodologically proper to extrapolate all conclusions about exposure from a single water sample; court took into account expert's report and granted summary judgment). *See also* the various opinions rendered by the district court after remand in *In re* Paoli R.R. Yard PCB Litig., 790 F. Supp. 94 (E.D. Pa. 1992), *aff'd without op.*, 980 F.2d 724 (3d Cir. 1992), *on remand*, 1992 U.S. Dist. LEXIS 16287, 18427, 18428, 18429, 18430, 18431, 18432, 18433, 18434, 18435, 18436, 18437 (E.D. Pa. Oct. 21, 1992); 811 F. Supp. 1071 (E.D. Pa. 1992), *aff'd in part, rev'd in part, In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722 (3d Cir. Aug. 31, 1994) (most recently the court of appeals affirmed exclusion of much of proffered expert testimony; it reversed with regard to some of the excluded evidence on exposure and harmful effects of PCBs so that the summary judgments entered by the district court on the thirty-eight plaintiffs' personal injury claims were reversed with regard to two of the plaintiffs).

225. Indeed, the parties at times seem unaware that statistical issues exist and that the expert who has specialized knowledge about the underlying physics, chemistry, or biology may lack adequate statistical training to explain the probabilities associated with his or her conclusion. *See, e.g.,* United States v. Stifel, 433 F.2d 431, 435–41 (6th Cir. 1970) (participants seemingly failed to appreciate that neutron-activation-analysis testimony that tape samples came from same batch was misleading in the absence of testimony about the frequency with which such matches could be expected), *cert. denied*, 401 U.S. 994 (1971), *conviction vacated*, 594 F. Supp. 1525, 1537 (N.D. Ohio 1984) (conviction vacated primarily because of *Brady* violation, but evidentiary hearing also demonstrated that sample tape from bomb packing did not differ from other samples of tape from different batches).

226. See Linda A. Bailey et al., Reference Guide on Epidemiology § II, in this manual, for a discussion of methodological questions.

a. Statistical significance: An issue for scientists or for the court?

A threshold issue with regard to expert proof based on many different kinds of studies is whether courts ought to use the level of statistical significance that is conventionally used in the particular discipline to which the expert belongs and, if so, for what purpose. Although this problem has received some judicial attention, it has not been conclusively resolved. The problem has been discussed primarily in the context of epidemiological studies to prove causation in toxic tort cases.[227] Scientists customarily employ a 5% significance level in testing a hypothesis. In the context of an epidemiological study that reports a particular relative risk, this means that there is at most one chance in twenty of seeing such a big relative risk if the true relative risk is 1.0.[228]

A not-proven verdict in court, however, has very different consequences than a not-proven verdict in the context of scientific research.[229] A failure to satisfy the 5% significance level means only that more research is in order—it is not a statement of an established "truth."[230] Virtually no mechanisms exist for deferring judicial decisions until more proof is available or for correcting decisions erroneously made. The plaintiff or the defendant generally wins or loses at the moment the case is ripe for decision. The plaintiff, who has the burden of persuasion, bears the risk, and the loss, if the case is not proven.

Some commentators have suggested that the use of "confidence intervals" provides more meaningful information than statistical significance because a range of possible values is presented that is consistent with the observed data.[231] The use of confidence intervals does not eliminate the need to designate the

227. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 312 (5th Cir. 1989) (in granting judgment n.o.v., court referred to plaintiff's failure to provide a study with statistical significance that concludes that Bendectin is a human teratogen), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 948–49 (3d Cir. 1990) (discusses issues arising from use of statistical significance concepts).

228. However, the significance level cannot be interpreted as the probability that the true relative risk differs from 1.0. *See* David H. Kaye & David A. Freedman, Reference Guide on Statistics §§ IV.B.1–2, in this manual. Social scientists as well adopt the .05 level of statistical significance. *See* discussion *infra* § III.C.2.a.2. *See also* Segar v. Smith, 738 F.2d 1249, 1282–83 (D.C. Cir. 1984) (Title VII action), *cert. denied*, 471 U.S. 1115 (1985).

229. The Supreme Court explicitly recognized this difference between science and the law in Daubert v. Merrell Dow Pharmaceuticals, Inc.: "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly." 113 S. Ct. 2786, 2798 (1993).

230. *Id. Cf.* Chemical Carcinogens, 50 Fed. Reg. 10371, 10377 (Office of Science & Technology Policy 1985) (final document) ("A high-quality negative epidemiological study, while useful, cannot prove the absence of an association between chemical exposure and human cancer."). *See also* Brief Amicus Curiae of Professor Kenneth Rothman et al. in Support of Petitioners, Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) (No. 92-102), *reprinted in* 1 Shepard's Expert & Sci. Evidence Q. 75, 80 (1993) ("The result of using significance testing as a criterion for decision making is that the focus is changed from the information presented by the observations themselves to conjecture about the role chance *could* have played in bringing about those observations.") (emphasis in original).

231. *See* discussion in David H. Kaye & David A. Freedman, Reference Guide on Statistics § IV.A.3, and Linda A. Bailey et al., Reference Guide on Epidemiology § III.C.1, in this manual.

confidence levels.[232] A court would still ultimately have to decide at what level it finds the evidence sufficiently probative.

In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, the Third Circuit summed up its extensive discussion of statistical significance by observing that "[t]he root issue . . . is what risk of what type of error the judicial system is willing to tolerate."[233] The court did not reach a conclusion because it found the record inadequate to resolve the issue. It expressed the hope that on remand, legal scholars and epidemiologists would assist the court with this problem, perhaps through amicus briefs.[234] On remand, as discussed in section III.C.2.b, the court excluded the plaintiffs' expert's reanalysis on the ground of unacceptable methodology and unreliability as well as on Rule 403 grounds. It never considered the level of statistical significance a study would have to satisfy in order to be admissible.[235]

Courts may consider that although the plaintiff ordinarily bears the burden of producing evidence, the plaintiff, particularly an individual plaintiff, often has no control over the amount of data that are available and no means of compelling anyone, including the defendant, to undertake additional research. Even if the evidence is admissible, however, whether it is sufficient is a separate issue. How these issues should be resolved may also rest more on substantive policy concerns than on the law of evidence.[236]

232. Brief Amicus Curiae of Professor Alvan R. Feinstein in Support of Respondent, Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) (No. 92-102), *reprinted in* 1 Shepard's Expert & Sci. Evidence Q. 91, 104 (1993):

> The use of confidence intervals, however, does not in any way eliminate the necessity for numerical standards. The most common and widely accepted standard is the use of a 95% confidence interval, which is precisely analogous to a p value of .05, which denotes 'statistical significance.' The critical issue is what level of α is to be acceptable . . . . The choice of α must be made whether statistical significance or confidence intervals are used.

233. 911 F.2d 941, 955 (3d Cir. 1990). Many opinions, even those that are sophisticated about statistical concepts, fail to consider this basic issue. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 312 (5th Cir.) (makes statements about significance of confidence intervals without specifying the significance level used in constructing the confidence interval), *modified per curiam*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990).

234. *DeLuca*, 911 F.2d at 956 & n.17.

235. DeLuca v. Merrell Dow Pharmaceuticals, Inc., 791 F. Supp. 1042 (D.N.J. 1992) (granting summary judgment on remand), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994). The court did state in its findings of fact that "[i]n the analysis of Bendectin limb defect studies, the choice of a confidence interval of 90% or 95% does not change the result if that confidence interval contains the number 1.0." *Id.* at 1052. It is not clear whether this finding means that relative risk was calculated at a 90% confidence level in addition to a 95% level. The Third Circuit did not suggest that changing to a 90% level would resolve the issue of what type of error to tolerate.

236. For a discussion arguing that substantive state law issues must accordingly be taken into account, see Michael H. Gottesman, *Should Federal Evidence Rules Trump State Tort Policy? The Federalism Values Daubert Ignored*, 15 Cardozo L. Rev. 1837 (1994). *See also In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *72–77 (3d Cir. Aug. 31, 1994) (holding Pennsylvania's requirement that experts testify that defendant's actions caused plaintiff's illness with a reasonable degree of medical certainty constitutes part of the plaintiff's burden of proof and, as a substantive rule, is not in conflict with the Federal Rules of Evidence and governs in a diversity action in federal court).

b. Correlation of statistical results with the burden of proof

A perplexing problem for the courts has been the interrelationship between an opinion couched in probabilistic terms and the applicable burden of proof. If, for instance, an expert testifies that epidemiological studies show that exposure to a defendant's product results in an increased risk of a particular form of cancer, how much of an increase in risk has to be demonstrated for plaintiffs to satisfy their burden of proof?[237] Epidemiological studies typically assign a relative risk ratio to a cohort study, or an odds ratio to a case-control study.[238] How much higher than 1.0 (which is the equivalent of no difference between the exposed and unexposed groups) must the relative risk or odds ratio be for the plaintiff to make out a prima facie case based on epidemiological proof?

As an abstract statistical proposition, a ratio under 2.0 does not comport with a preponderance-of-the-evidence standard. This conclusion was the basis for the district court's grant of summary judgment in *In re Joint Eastern & Southern District Asbestos Litigation*,[239] on the ground that plaintiff could not establish that her husband's colon cancer was caused by exposure to asbestos:

> Only when the risk level exceeds 2.0 can it be said that the one risk factor is more likely to cause the disease than any other factor affecting the unexposed cohort.
>
> As an example, if it is the case that in a random sample of 5000 people 100 are likely to contract colon cancer, and in a random sample of 5000 people who have been exposed to asbestos 150 are likely to develop the disease, then asbestos exposure would have a relative risk of 1.5 for this disease. However, only one third of the afflicted people in the exposed cohort could be said to have contracted colon cancer as a result of their exposure, because on average 100 would have developed it anyway. Epidemiology alone would offer no way to identify which 50 victims were attributable to asbestos. In the absence of any other evidence, the strongest conclusion which could be drawn would be that for each of the 150 afflicted individuals there was a one in three chance that the disease was caused by asbestos. As this probability is less than fifty percent, none of the victims could satisfy the legal standard of showing that it was more probable than not that the cancer was due to asbestos exposure.[240]

On reargument, the district court explained further that the plaintiff could not avoid summary judgment by adducing epidemiological studies indicating that some groups exposed to asbestos possess relative risks greater than 2.0.[241]

237. *See* Linda A. Bailey et al., Reference Guide on Epidemiology § V, in this manual.

238. *See id*. § III.A.

239. 758 F. Supp. 199 (S.D.N.Y. 1991), *rev'd*, 964 F.2d 92 (2d Cir. 1992).

240. *Id.* at 202–03 (footnote omitted). *See also In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 785 (E.D.N.Y. 1984) *aff'd on other grounds*, 818 F.2d 145 (2d Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988):

> A court . . . must observe the tort law requirement that a plaintiff establish a probability of more than fifty percent that the defendant's action injured him. This means that at least a two-fold increase in incidence of the disease attributable to Agent Orange exposure is required to permit recovery if epidemiological studies alone are relied upon.

241. *In re* Joint E. & S. Dist. Asbestos Litig., 774 F. Supp. 113, 114–15 (S.D.N.Y. 1991) (court denied motion for reargument).

The plaintiff also had to introduce evidence that her husband shared the heavy exposure that had been experienced by those in the exposed cohorts who had a relative risk over 2.0.[242]

The Second Circuit reversed, without, however, reaching the issues discussed above. The court found that the "plaintiff did not need to provide epidemiological evidence of a certain magnitude in order to defeat a summary judgment motion because she did not rely on epidemiological studies alone."[243] Plaintiff's experts had relied on the decedent's medical records and personal history as well as on epidemiological studies. On the basis of these, they had opined that other causes for the colon cancer, such as a diet high in fats, could be ruled out.[244]

In an individual case, it is unlikely that a plaintiff would ever rely solely on epidemiological studies. A failure by experts to consider medical records and personal history could lead a court to conclude that the expert was failing to consider evidence on which experts customarily rely and that the proffered opinion failed to satisfy Rule 703.[245]

At this time it appears that courts are reluctant to conclude that an epidemiological study will not be an adequate basis for an expert's conclusion about causation solely because there has been less than a twofold increase in risk, provided some positive correlation between exposure and disease is demonstrated.[246] This

242. *Id.* at 115 & n.3. The court denied motion for rehearing of grant of summary judgment. *In re* Joint E. & S. Dist. Asbestos Litig., 774 F. Supp. 116 (S.D.N.Y. 1991).

243. 964 F.2d at 97. The court quoted with approval from a New Jersey case, Grassis v. Johns-Manville Corp., 591 A.2d 671, 675 (N.J. Super. Ct. App. Div. 1991). *Id.* In *Grassis*, the court found that plaintiff's expert should not have been precluded from testifying even though she confirmed that most authoritative epidemiological studies linking asbestos and colon cancer were below the 2.0 level. The court explained:

> [A] particular study might show a high correlation between asbestos and colon cancer, but it also might show a high correlation between the consumption of excessive alcohol and colon cancer. If there were also a very high correlation between those working with asbestos and the high consumption of alcohol, one could not tell whether the alcohol or asbestos or both actually were causative factors of the colon cancer, or even whether the presence of both were needed in order to be a producing factor of the disease. Each study must be analyzed to determine whether the asbestos factor was really isolated. Where, however, study after study has shown some positive correlation, although not to the factor of 2.0, it might be said that asbestos is at least a producing factor in some colon cancers, even if the precise biological process has not yet been defined.
>
> . . . The physician or other such qualified expert may view the epidemiological studies and factor out other known risk factors such as family history, diet, alcohol consumption, smoking (surprisingly, generally recognized as not being a risk in colon cancer, according to the testimony in this case), or other factors which might enhance the remaining recognized risks, even though the risk in the study fell short of the 2.0 correlation.

591 A.2d at 675.

244. 964 F.2d at 96. After trial, resulting in a verdict for plaintiff of over $4.5 million, the trial judge granted judgment n.o.v. on the ground that epidemiological studies failed to demonstrate a sufficiently strong and consistent association between asbestos exposure and colon cancer. *In re* Joint E. & S. Dist. Asbestos Litig., 827 F. Supp. 1014, 1037–43 (S.D.N.Y. 1993).

245. *See* discussion *infra* § IV.B.2.c.1.

246. In Landrigan v. Celotex Corp., 605 A.2d 1079 (N.J. 1992), the court reversed a directed verdict for defendant granted on the ground that epidemiological studies showed a relative risk smaller than 2.0. The court instructed the trial court to proceed as follows:

> Without limiting the trial court on remand, its assessment of Dr. Sokolowski's testimony should include an evaluation of the validity both of the studies on which he relied and of

issue is independent of problems with the study's underlying methodology or statistical significance.

c. Confusing the probability of a sample identification with a probability of guilt

The so-called "prosecutor's fallacy" occurs when a prosecutor presents statistical evidence to suggest that the evidence indicates the likelihood of the defendant's guilt rather than the odds of the evidence having been found in a randomly selected sample.[247] The danger that jurors will erroneously confuse the probability of a match with the probability of guilt exists whenever a test can reliably match two samples and the resulting match is being used to identify the defendant.

In *United States v. Massey,* for instance, an expert witness testified that three out of five hairs found on a ski mask worn by a bank robber matched one or more out of nine mutually dissimilar hairs taken from the defendant's scalp.[248] He further testified that in his work on more than 2,000 cases, there had only been a couple of occasions on which he had seen hair from two individuals that he couldn't distinguish. He also made reference to a Canadian study which concluded that for a hair that "matched in the manner which I have set forth, there's a chance of one in 4,500 these hairs could have come from another individual."[249] While the appellate court found this evidence somewhat confusing, it found reversible error because of comments the prosecutor made in closing argument which suggested that the hair evidence made the defendant's guilt 99.44% certain.[250]

> his assumption that the decedent's asbestos exposure was like that of the members of the study populations. The court should also verify Dr. Sokolowski's assumption concerning the absence of other risk factors. Finally, the court should ascertain if the relevant scientific community accepts the process by which Dr. Sokolowski reasoned to the conclusion that the decedent's asbestos exposure had caused his cancer. Thus, to determine the admissibility of the witness's opinion, the court, without substituting its judgment for that of the expert, should examine each step in Dr. Sokolowski's reasoning.

Id. at 1088.

247. *See, e.g.*, William C. Thompson & Edward L. Schumann, *Interpretation of Statistical Evidence in Criminal Trials: The Prosecutor's Fallacy and the Defense Attorney's Fallacy*, 11 Law & Hum. Behav. 167, 181–82 (1987); Jonathan J. Koehler, *Error and Exaggeration in the Presentation of DNA Evidence at Trial,* 34 Jurimetrics J. 21 (1993) (discussing instances of "prosecutor's fallacy" in the presentation of DNA evidence); *see also* David H. Kaye & David A. Freedman, Reference Guide on Statistics § IV.B.2, in this manual.

248. 594 F.2d 676, 678–79 (8th Cir. 1979). *See also* United States v. Chischilly, 30 F.3d 1144, 1156 (9th Cir. 1994) (assessing the potential for prejudice arising from the possibility that the jury will accept the estimate of a coincidental match of a DNA profile "as a statement of source probability (i.e., the likelihood that the defendant is the source of the evidentiary sample)" rather than as an estimate of the rareness of the DNA profile).

249. *Massey,* 594 F.2d at 679. The appellate court found the expert's testimony confusing and the foundation for the witness's reference to the Canadian study insufficient because the witness "testified that he did not know the nature and extent of the studies conducted from which the statistics were gathered." *Id.* at 680.

250. *Id.* at 680. The prosecutor said:

> Now in order to convict the defendant, you must find him guilty beyond a reasonable doubt.
>
> . . . A handful [let's say that's] 3 to 5 out of 2,000. That's better than 99.44 percent; it's better than Ivory Soap, if you remember the commercial. It's very convincing.

Although trial judges can obviously prevent such a blatant misuse of statistical evidence, difficult problems remain. Should a court permit evidence of matching samples when no background rate is offered of the probability of a match or when there are disputes about the appropriate background rate?[251] The issue can arise with many varieties of trace evidence, such as fibers, soil, and tool marks.

A match without more undoubtedly satisfies the relevancy test set forth in Rule 401 of altering the probabilities, but when no background rate is offered, may the jury erroneously give the evidence far more weight than it actually has?[252] If, for instance, the samples that match are tape to which defendant had access at his place of work and tape used in manufacturing a bomb sent through the mails from an unknown location, the probative value of the evidence is virtually nonexistent if thousands of identical rolls of tape were distributed throughout the world.[253] *Daubert* contains a reminder of the trial judge's power to exclude pursuant to Rule 403 and quotes Judge Weinstein: "'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'"[254]

d. Reducing odds because of sampling uncertainties; DNA

One of the central issues in the debate about the admissibility of DNA evidence concerns the probability estimate that an expert may properly make when testing reveals a match.[255] Population geneticists have identified a number of problems

> Now hair samples are not like fingerprints. It is not positive identification. There is a theoretical possibility (and it actually happened in the case of this examiner in 3 to 5 times out of say, 2,000) where the hairs of two different heads can look the same when you examine the whole range of their characteristics.
>
> However, it is infinitesimally rare, and when we talk about the range of proof which we can use in deciding questions for us, these kinds of percentages are higher than the percentage we use in any other area I can think of in terms of making a decision.
>
> I submit to you that if hair samples are found a known and an unknown and they are microscopically identical, that it is at the very least proof beyond a reasonable doubt that the unknown hair comes from the same head as the known hair.

Id. at 680.

251. Disputes about background rates are considered *infra* § III.C.3.d.

252. *See, e.g.,* United States v. Bynum, 3 F.3d 769, 773 (4th Cir. 1993) (prosecution sought to link coconspirators by showing through gas chromatography that cocaine seized at different locations had identical composition; no evidence appears to have been offered about the extent to which batches of cocaine differ from each other), *cert. denied*, 114 S. Ct. 1105 (1994).

253. *See* United States v. Stifel, 433 F.2d 431, 435 (6th Cir. 1970) (expert testified that fragments of tape on bomb packing matched samples of tape taken from defendant's place of work and were "'of the same manufacture'" and from "'the same batch'"), *cert. denied*, 401 U.S. 994 (1971), *conviction vacated*, 594 F. Supp. 1525 (N.D. Ohio 1984) (conviction vacated primarily because of *Brady* violations, but evidentiary hearing also demonstrated that sample from bomb packing did not differ from other samples of tape that came from different batches).

254. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2798 (1993) (quoting Jack B. Weinstein, Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)).

255. *See* Judith A. McKenna et al., Reference Guide on Forensic DNA Evidence § VII, in this manual.

that may cause serious underestimation of the probability of a coincidental match. Currently, there is considerable debate as to the frequency with which gene components known as alleles are found in particular populations. Furthermore, not enough may be known about whether specific alleles are independently inherited so as to warrant use of the product rule to multiply the frequency with which each allele is found.

Because of these as yet unresolved questions, the National Research Council (NRC) recommended using a "ceiling principle" in applying the multiplication rule for estimating the frequency of a particular DNA profile until more research is done.[256] This principle seeks to ensure that the assigned probability will always be greater than or equal to the true probability of a match despite our present lack of knowledge.[257]

The heated debate among population geneticists exemplifies the difficult issues that a court may face when an expert seeks to testify in probabilistic terms. How should a court deal with the proffered opinion if there is disagreement in the relevant scientific communities about the precise statistical conclusions that may validly be drawn, although a general consensus exists that the evidence on which the opinion is based does substantially alter probabilities with regard to an issue in controversy?

One approach, taken by the Second Circuit, is to treat this issue as one of weight. In *United States v. Jakobetz*, defense experts had challenged the statistical interpretation offered by the FBI on the ground that insufficient information was available about population substructures, making it "inappropriate to use one data base for all Caucasians and to use the product rule to calculate an allele pattern's frequency."[258] The Second Circuit found that the FBI's conclusion that the probability of a coincidental match was "one chance in 300 million" had properly been admitted.[259] Furthermore, the court disclaimed the need to conduct extensive hearings and findings thereafter:

> [I]n future cases with a similar evidentiary issue, a court could properly take judicial notice of the general acceptability of the general theory and the use of these specific techniques. . . . Beyond such judicial notice, the threshold for admissibility should require only a preliminary showing of reliability of the particular data to be offered, *i.e.*, some indication of how the laboratory work was done and what analysis and assumptions underlie the probability calculations. The probability data may well vary among different segments of the population. Affidavits should normally suffice to provide a sufficient basis for admissibility. DNA profiling evidence should be excluded only when the government cannot show this threshold level of reliability in its data. The district court should focus on whether [an] accepted protocol was adequately followed

256. Committee on DNA Technology in Forensic Science, National Research Council, DNA Technology in Forensic Science 13–14, 82–85 (1992) [hereinafter NRC Report]. *See also* Judith A. McKenna et al., Reference Guide on Forensic DNA Evidence § VII.B.2, in this manual.

257. *Id*.

258. 955 F.2d 786, 799 (2d Cir.), *cert. denied*, 113 S. Ct. 104 (1992).

259. *Id.* at 789, 799.

> in a specific case, but the court, in exercising its discretion, should be mindful that this issue should go more to the weight than to the admissibility of the evidence. Rarely should such a factual determination be excluded from jury consideration. With adequate cautionary instructions from the trial judge, vigorous cross-examination of the government's experts, and challenging testimony from defense experts, the jury should be allowed to make its own factual determination as to whether the evidence is reliable.[260]

Rather than admitting the expert's probability assessment or excluding the DNA evidence, a court could take the intermediate position of requiring a modification of the probability estimate. The NRC Report recommended that experts couch their opinions as follows in the interval before additional research furnishes needed information:

> 1) If no match is found with any sample in a total databank of N persons (as will usually be the case), that should be stated, thus indicating the rarity of a random match. 2) In applying the multiplication rule, the 95% upper confidence limit of the frequency of each allele should be calculated for separate U.S. "racial" groups and the highest of these values or 10% (whichever is the larger) should be used. Data on at least three major "races" (*e.g.*, Caucasians, blacks, Hispanics, Asians, and Native Americans) should be analyzed.[261]

Although no federal court has followed the specific recommendation of the NRC Report, recently the U.S. Court of Appeals for the Ninth Circuit upheld the admission of probability estimates of a coincidental matching DNA profile that included conservative adjustments similar to those recommended by the NRC.[262]

Other possible solutions are discussed in the NRC Report.[263] Experts could also be instructed to state a range of probabilities that take into account a variety of hypotheses, to use verbal formulations instead of numbers,[264] or to use more than the usual four probes in order to decrease the probability of a coincidental profile match.

260. *Id.* at 799–800. *See also* United States v. Bonds, 12 F.3d 540 (6th Cir. 1993) (agreeing that substructure argument goes to weight; post- *Daubert*).

261. NRC Report, *supra* note 256, at 95. This approach is being questioned and being praised. *Compare* B. Devlin et al., *Comments on the Statistical Aspects of the NRC's Report on DNA Typing*, 39 J. Forensic Sci. 28, 34 (1994) ("no scientific motivation for the NRC panel's ceiling principle") *with* Richard Lempert, *DNA, Science and the Law: Two Cheers for the Ceiling Principle*, 34 Jurimetrics J. 41 (1993). *See also* David H. Kaye, *The Forensic Debut of the National Research Council's DNA Report: Population Structure, Ceiling Frequencies and the Need for Numbers,* 34 Jurimetrics J. 369 (1994) (reviewing judicial opinions that discuss the "ceiling principle" technique). The NRC has impaneled another committee to consider criticism of the recommendations of the report. Rorie Sherman, *New Scrutiny for DNA Testing,* Nat'l L.J., Oct. 18, 1993, at 3.

262. United States v. Chischilly, 30 F.3d 1144, 1158 (9th Cir. 1994) (probability estimation employed conservative statistical estimates even though "not calculated pursuant to the NRC Report's controversial recommendation to adopt the ceiling principle").

263. NRC Report, *supra* note 256, at 84–85.

264. *See, e.g.*, various suggestions for explaining significance of human leukocyte antigen (HLA) paternity testing in 1 Paul C. Giannelli & Edward J. Imwinkelried, Scientific Evidence § 17-9(A), at 578 (2d ed. 1993) (ABA and AMA approved guidelines provide for six steps, ranging from "no significance" to "paternity practically proven").

The court's decision on how to permit the probability estimate to be stated may in part turn on the quantum of other evidence in the case. In *United States v. Jakobetz*, for example, the victim positively identified the defendant, and the prosecution introduced an enormous amount of conventional circumstantial evidence linking the defendant to the kidnapping and rape with which he was charged.[265] It seems highly unlikely that a conviction obtained without the use of DNA evidence would have been overturned on insufficiency grounds. Consequently, an underestimation of the true probability would, at most, amount to harmless error. This conclusion suggests, however, that courts should perhaps hesitate in according judicial notice to the probabilistic underpinnings of a particular theory until a sufficient period has elapsed for the statistical assumptions to be thrashed out by the scientific community. Frequently, probability issues with regard to a particular form of evidence arise only in the context of forensic application; even though the underlying scientific theory is well grounded, as is the case with the theory of DNA typing, time is needed to consider the probabilistic implications.

e. Incorporating proficiency test performance results; DNA

An additional contributor to uncertainty is that some risk of error with regard to test results stems from laboratory practices, such as improper handling of samples, and mistakes in interpreting and reporting results.[266]

The *Daubert* Court mentioned "the known or potential rate of error" and "the existence and maintenance of standards controlling the technique's operation" as methodological factors a court "should consider."[267] It cited two voiceprint evidence cases in which the courts found the evidence admissible.[268] Whether this means that once evidence passes a certain threshold with regard to error, the issue is solely one of weight to be considered by the trier of fact is not yet clear. In *United States v. Bonds*, the court reviewing the admissibility of DNA evidence after *Daubert* termed "troubling" deficiencies in calculating the rate of error and the failure to conduct external proficiency testing, or to specify the rate of error.[269] The court found, however, that when the district judge below affirmed the magistrate judge's finding under the then applicable *Frye* test that

265. 955 F.2d 786 (2d Cir.), *cert. denied*, 113 S. Ct. 104 (1992).

266. Whether errors of this type might cause a court to reject evidence as unreliable is discussed *infra* § IV.B.2.c.

267. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2797 (1993).

268. United States v. Smith, 869 F.2d 348, 353–54 (7th Cir. 1989); United States v. Williams, 583 F.2d 1194, 1198 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979). *Cf.* John I. Thornton, *Courts of Law v. Courts of Science: A Forensic Scientist's Reaction to Daubert*, 1 Shepard's Expert & Sci. Evidence Q. 475, 481 (1994) (expressing dismay at court's reference to *Smith* because error rates testified to ranged from zero to 88.3%; author argues that "the types of examinations that are often conducted in crime laboratories do not lend themselves to analysis by conventional statistics").

269. 12 F.3d 540, 560 (6th Cir. 1993).

the FBI's procedures are generally accepted, this finding implicitly decided "that the rate of error is acceptable to the scientific community as well." [270]

The American Society of Crime Laboratory Directors (ASCLD) and the American Society of Crime Laboratory Directors—Laboratory Accreditation Board (ASCLD-LAB) have both recommended mandatory proficiency testing at regular intervals as a requirement for accreditation of forensic-science laboratories engaged in DNA typing.[271] If proficiency testing comes to pass, it will be possible to assign an error rate to each laboratory. Should the proficiency test performance rate then be somehow integrated with the estimation of the probability of a match?[272] Of course, the same issue may arise in connection with tests and studies relating to matters other than DNA. It may be that the discussion of proficiency testing with regard to DNA will have a spillover effect.[273]

270. *Id.*

271. *See* NRC Report, *supra* note 256, at 102–06, for information about these entities and their recommendations for laboratory accreditation.

272. *See* Michael J. Saks & Jonathan J. Koehler, *What DNA "Fingerprinting" Can Teach the Law About the Rest of Forensic Science*, 13 Cardozo L. Rev. 361, 368–69 (1991) (discusses a number of different models for how this could be done). *But see* Devlin et al., *supra* note 261, at 38 ("[A]n a priori estimate of a handling error is not sufficient to evaluate the probability of a handling error in any particular case.").

273. Saks & Koehler, *supra* note 272. *See also* discussion of errors in data leading to exclusion pursuant to Rule 703 *infra* § IV.B.2.c.

IV. Is the Expert's Opinion Supported by Reliable Data?

A. Rule 703

The objection that a witness is basing his or her opinion on evidence not "reasonably relied upon" is frequently encountered in judicial opinions treating a challenge to expert testimony. The phrase is derived from Federal Rule of Evidence 703, which provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The meaning of Rule 703 has always been the subject of controversy.[274] Although the Supreme Court's opinion in *Daubert* clarified the meaning of Rule 703 in some respects because Rule 703 no longer applies to issues the Court allocates to Rule 702, other issues remain about the two rules' interface that require resolution in the wake of *Daubert*. The *Daubert* opinion also contains a brief comment about Rule 703 itself, which while clearly dictum—the rule played no role in the majority's analysis—may nevertheless shed some light on Rule 703 issues. Furthermore, the Court's recognition that Rule 403 plays a role in the exclusion of expert testimony means that courts must also consider the boundary between Rule 703 and Rule 403.[275]

The discussion first examines how the Court's discussion of Rule 702 impacts on Rule 703 and then considers the Court's observation about Rule 703. It turns next to a variety of theoretical issues about the application of Rule 703 that the Court's opinion does not address. It concludes with a survey of contexts in which courts have relied on Rule 703 to exclude evidence.

274. *See* 3 Jack B. Weinstein & Margaret A. Berger, Weinstein's Evidence: Commentary on Rules of Evidence for the United States Courts and State Courts ¶ 703[03] (1993).

275. *See infra* § V.

B. Rule 703; Scope of Rule

1. The impact of Daubert

a. Reclassifying issues under Rule 702 that some courts had classified under Rule 703

1. *Fit.* In *Daubert*, the Court defined the scope of Rule 702 to encompass issues that some courts previously handled pursuant to Rule 703. Rule 702, rather than Rule 703, is now the proper vehicle for excluding expert opinions that do not "fit." By this term, the Court means that the court must make a preliminary assessment "of whether the reasoning or methodology underlying the testimony . . . can be applied to the facts in issue."[276]

2. *Methodology.* *Daubert* states that Rule 702 governs determinations about the experts' use of scientific reasoning in arriving at their conclusions. In making a preliminary inquiry into the admissibility of an opinion, the court is directed to examine its methodological underpinnings and not to rely solely on *Frye's* "general acceptance" approach. Consequently, issues concerning the reliability of a theory or discipline should be handled pursuant to Rule 702.[277] As the discussion in section III.C.2.b *supra* indicates, however, questions about data an expert used in applying a particular methodology may at times raise issues that straddle Rules 702 and 703.[278]

b. Rule 703 reference

1. *Standard of proof.* In *Daubert*, the Court stated:

> Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules. Rule 703 provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject."[279]

Does the mention of Rule 703 in connection with preliminary determinations pursuant to Rule 702 mean that inquiries under Rule 703, like those under Rule 702, are subject to a Rule 104(a) preponderance-of-the-evidence standard? Courts have rarely explicitly considered this issue. Furthermore, in a number of cases in which courts used a Rule 104(a) standard when excluding evidence pursuant to Rule 703, they were excluding scientific evidence on methodologi-

276. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2796 (1993). *See* discussion *supra* § I.B.

277. *See* discussion *supra* § III.

278. *See, e.g.*, DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 955 n.14 (3d Cir. 1990) ("In this respect, Rules 702 and 703 intersect. If a study's method of data collection is faulty, it may well be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject."). *See also* discussion of *In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722 (3d Cir. Aug. 31, 1994), *supra* note 221.

279. *Daubert*, 113 S. Ct. at 2797–98. The majority opinion also cites Rule 703 as well as Rule 702 after stating that "an expert is permitted wide latitude to offer opinions, including those that are not based on first-hand knowledge or observation." *Id.* at 2796.

cal grounds that according to *Daubert* raise Rule 702 issues.[280] This issue will be revisited in section IV.B.2 in the discussion of the various issues that courts have resolved pursuant to Rule 703.

2. *Function of Rule 703 as a rule of admissibility.* One function of Rule 703, which no one disputes, was to expand the common-law bases for an expert's opinion by authorizing experts to base their opinions on reliable inadmissible data. Some controversy exists over whether Rule 703 authorizes experts to testify on direct to the hearsay basis for their conclusions or whether the basis of an expert's opinion may only be brought out on the cross-examiner's option pursuant to Rule 705.[281] The Court's comment in *Daubert*—that expert opinions are to be admitted only if the test in Rule 703's second sentence is satisfied—seems to also acknowledge Rule 703's role as an independent source for excluding expert testimony. This approach is consistent with prior practice in the federal courts which construed Rule 703 as imposing conditions on admissibility, rather than as limited to expanding the bases of expert testimony and possibly the scope of expert testimony on direct.

2. Other theoretical issues about the function of Rule 703

a. Does the second sentence of Rule 703 apply only when an expert relies on inadmissible evidence?

According to one view, the plain meaning of Rule 703 is that the "reasonably relied upon" language in the second sentence is a ground for exclusion only when an expert's opinion is based on otherwise inadmissible evidence. If the expert's opinion is based upon admissible evidence, Rule 703 does not apply. Consequently, a court must first determine whether the facts and data underlying the opinion could have been admitted into evidence.

280. *See, e.g.*, Renaud v. Martin Marietta Corp., 972 F.2d 304, 308 (10th Cir. 1992) (excluding study based on only one sample of water pursuant to Rules 703 and 104(a)); Head v. Lithonia Corp., 881 F.2d 941, 944 (10th Cir. 1989) (court rejected evidence based on topographical brain mapping pursuant to *Frye* test; despite liberality of Rule 703, court must not abdicate its responsibility to assure minimum standards for admissibility as required by Rule 104(a)) (citing *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1245 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988)).

281. *See* Ronald L. Carlson, *Collision Course in Expert Testimony: Limitations on Affirmative Introduction of Underlying Data*, 36 U. Fla. L. Rev. 234, 238, 251 (1984) (discusses objective of Federal Rules to sweep away cases in which, for instance, a physician was not permitted to base his or her opinion on nonrecord laboratory reports; objects to allowing examiner on direct to get inadmissible hearsay before the jury, particularly in criminal cases); James W. McElhaney, *Trial Notebook: Fixing the Expert Mess*, 20 Litigation 53, 56 (1993) (unfairness of allowing expert to get inadmissible hearsay before jury by mentioning basis of opinion on direct). *See also* University of R.I. v. A.W. Chesterton Co., 2 F.3d 1200, 1219 (1st Cir. 1993) ("we are given some pause by the district court's blanket statement that it 'always requires' the proponent to disclose on direct examination the factual basis for an expert opinion"; the court cites as a comparison example Lis v. Robert Packer Hosp., 579 F.2d 819, 822, 822–23 (3d Cir.) (expressed disapproval of such an invariable practice), *cert. denied*, 439 U.S. 955 (1978)). *Cf.* Datskow v. Teledyne Continental Motors Aircraft Prods., 826 F. Supp. 677, 684 (W.D.N.Y. 1993) (converts Rule 703 into hearsay exception by allowing letters to be admitted into evidence because they were the basis of expert's opinion).

Chief Judge Clark of the Fifth Circuit forcefully expressed this view in his concurring opinion in *Christophersen v. Allied-Signal Corp.*:[282]

> If the facts or data are admissible, Rule 703 does not authorize exclusion of the expert opinion. If they are admissible, the inquiry ends, and nothing in Rule 703 authorizes exclusion of the expert's testimony. If they are not admissible, the district court must determine whether the reliability inquiry is satisfied. If it is satisfied, Rule 703 does not authorize exclusion. If it is not, the district court should exclude the testimony. No other reading is consistent with the plain language, history, and purpose of Rule 703.[283]

As the *Christophersen* en banc opinion itself demonstrates, however, a narrow view about the permissible ambit of Rule 703 does not mean that a court has no power to screen expert testimony. Despite his restrictive view of the scope of Rule 703, Chief Judge Clark concurred in upholding a grant of summary judgment for the defendant because he found the opinion of the plaintiff's expert excludable under Rule 403:

> [I]f an opinion is fundamentally unsupported, then it offers no expert assistance to the jury; and that lack of reliable support can render an opinion substantially more prejudicial than probative, making it inadmissible under Rule 403.[284]

How courts apply Rule 403 to expert testimony is further discussed in section V.

The majority opinion in *Christophersen* takes a broader view that suggests that Rule 703 plays a role in screening expert testimony regardless of the evidentiary posture of the data on which the expert relies:

> Although this rule is primarily directed toward permitting an expert to base his opinion on hearsay or otherwise inadmissible sources, the inquiry into the "types" of "facts and data" underlying an expert's testimony is not limited to the admissibility of that data. District judges may reject opinions founded on critical facts that are plainly untrustworthy, principally because such an opinion cannot be helpful to the jury.[285]

b. Determining what is "reasonably relied upon"

In situations in which courts agree that Rule 703 applies, appellate courts do not speak in unison about the trial court's role in determining whether an expert

282. 939 F.2d 1106, 1118 (5th Cir. 1991) (en banc), *cert. denied*, 112 S. Ct. 1280 (1992).

283. *Id.* at 1118. The judge suggested that facts and data might often be admissible pursuant to Rule 803(6) as records of regularly conducted activities, or Rule 803(18) under the learned treatises exception to the hearsay rule. *Id.* at 1119.

284. *Id.* at 1120.

285. *Id.* at 1114 (citation and footnote omitted). *See also* Soden v. Freightliner Corp., 714 F.2d 498, 505 (5th Cir. 1983) ("Though courts have afforded experts a wide latitude in picking and choosing the sources on which to base opinions, Rule 703 nevertheless requires courts to examine the reliability of those sources.") ; Head v. Lithonia Corp., 881 F.2d 941, 943 (10th Cir. 1989) (Rule 703 "provides a mechanism by which the court can evaluate the trustworthiness of the underlying data on which the expert relies."); Shatkin v. McDonnell Douglas Corp., 727 F.2d 202, 208 (2d Cir. 1984) (district judge had "the discretionary right under Fed. R. Evid. 703 to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony").

"reasonably relied." They disagree about the extent to which a court may peer beneath experts' averments that their testimony is based on data upon which experts in their field rely.

Before *Daubert,* courts espousing a "liberal" approach stressed that the Federal Rules of Evidence sought to expand the admissibility of expert testimony. Consequently, "Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue."[286] Courts advocating a more "restrictive" approach treated the reliability of expert testimony as a preliminary question of admissibility no different than other issues appropriate for determination under Rule 104(a). After *Daubert,* this distinction may no longer be tenable.[287] In any event, the disagreement between the two camps is one of emphasis that is perhaps reflected more in procedural distinctions than in evidentiary ones. Courts subscribing to the liberal view seemed more inclined to treat the proffered expert testimony as presumptively reliable unless and until the opponent made an adequate showing, and then to insist on a fully developed record before a judge will exclude the testimony.[288] Other courts have been willing to grant summary judgment without requiring motions in limine first.[289]

Because theoretical distinctions may fail to accord with what courts actually do, the discussion below concentrates on fact patterns of expert testimony that some courts have found problematic owing to the data on which the expert relied. The material is organized in terms of the most common categories that courts use when they screen testimony under Rule 703. The commentary also indicates other approaches that some courts use to deal with the problems that some of their judicial colleagues classify as falling within the ambit of Rule 703.

c. Circumstances in which courts use a "reasonably rely" test to exclude

1. *Expert's failure to consider data that must be taken into account.* Courts have at times relied on Rule 703 in excluding an opinion where the specific facts and data on

286. DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 953 (3d Cir. 1990), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994).

287. *See In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *62–63 (3d Cir. Aug. 31, 1994).

> Court stated that its former view is no longer tenable in light of *Daubert*. . . . By requiring the judge to look to the views of other experts rather than allowing the judge to exercise independent judgment, current Third Circuit case law eviscerates the judge's gatekeeping role with respect to an expert's data and instead gives that role to other experts. The gatekeeping role is reduced even further by our *DeLuca* holding that the opinion of one expert that a type of data is reliable will generally be enough to render that data reliable.

288. *See, e.g.*, *DeLuca*, 911 F.2d at 953 (remanding for record-supported factual findings); *In re* Paoli R.R. Yard PCB Litig. (Paoli I), 916 F.2d 829, 855 (3d Cir. 1990) (summary judgment would have had to be set aside solely on ground that plaintiffs were afforded insufficient process at the evidentiary stage), *cert. denied*, 499 U.S. 961 (1991).

289. *See* Christophersen v. Allied-Signal Corp., 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1280 (1992).

which the expert relies "are critically inaccurate or incomplete, as determined by what other experts would or would not be willing to base opinions upon."[290] The gist of this objection is that the expert has failed to consider data that must be taken into account in reaching the opinion that the expert is rendering.

An oft-cited case in the Fifth Circuit, *Viterbo v. Dow Chemical Co.*, is illustrative.[291] The plaintiff claimed that exposure to the defendant's pesticide had caused his nervousness, depression, renal failure, and hypertension. The district judge granted summary judgment on the ground that the testimony of the plaintiff's expert was excludable pursuant to Rule 703. The expert had reached his conclusion without considering the plaintiff's family history, even though a number of the plaintiff's relatives had been hospitalized for depression and hypertension. He failed to explain why the plaintiff had no reaction when he was exposed to the defendant's product in the expert's office. Furthermore, although a blood test of the plaintiff revealed a high level of another chemical that can cause depression, the expert ignored this result on the ground that the plaintiff had denied having had contact with that chemical, even though he failed to explain why the substance was found in the plaintiff's bloodstream. The appellate court affirmed, stating that the expert's "opinion simply lacks the foundation and reliability necessary to support expert testimony."[292]

2. *Expert's reliance on data that should not be taken into account.* Courts have also cited Rule 703 when faulting an expert for reaching a conclusion on the basis of facts or data that ought not to be taken into account.[293] A detailed illustration of problems considered pursuant to Rule 703 can be found in *DeLuca v. Merrell*

290. *Id.* at 1115.

291. 826 F.2d 420, 423 (5th Cir. 1987).

292. *Id.* at 424. *Cf.* Cella v. United States, 998 F.2d 418, 420–22 (7th Cir. 1993) (Jones Act action; plaintiff claimed that his disease, polymyositis, could have been caused by trauma on a ship; defendant attacked damage award to plaintiff as an example of "junk science" entering the courtroom, but court affirmed in an extensive opinion that explained the basis for plaintiff's conclusion about a possible link between plaintiff's disorder and stress; expert had conducted extensive neurological testing of plaintiff and had excluded all other possible factors, such as genetic defects, viral infections, vaccinations, and certain tropical diseases; although he conceded that the etiology was unknown in many cases, he pointed to references in the medical literature that discussed the possibility of stress as a precipitating cause, and a study that showed a link in some instances, and he articulated a plausible hypothesis for why stress would play a role in the etiology of the disease). *See also In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1250–51 (E.D.N.Y. 1985) (court granted summary judgment for defendant; court found that testimony of experts was "insufficiently grounded in any reliable evidence"; for instance, one expert who concluded that plaintiffs' difficulties were caused by exposure to Agent Orange had failed to consider individual plaintiffs' past medical histories or their families' histories, smoking or drinking habits, or exposure to other substances and drugs), *aff'd*, 818 F.2d 187 (2d Cir. 1987). *See also* discussion of differential diagnosis in Paoli II, *supra* § III.C.2.b.

293. *See, e.g.*, United States v. Tran Trong Cuong, 18 F.3d 1132, 1143–44 (4th Cir. 1994) (although experts may consider hearsay, including reports of other experts, in reaching their opinions, the reports must qualify as data "of a type reasonably relied upon by experts in the particular field"; a physician in the field of family medicine would not usually rely upon forensic medical opinions "specifically prepared for purposes of litigation"; error in a criminal case for an expert testifying for the government to state that a prominent physician who had been a former president of the medical society agreed with him merely to convince the jury of the accuracy and reliability of the expert's opinions; this is unfair, as it denies the defendant his right to cross-examination "and is an improper use of expert testimony."). *See also* Marsee v. United States Tobacco Co., 866 F.2d 319, 323 (10th Cir. 1989) (excluding expert's testimony regarding conversations with other physicians about cases that supported his opinion).

Dow Pharmaceuticals, Inc.[294] In *DeLuca*, the trial judge found that Rule 703 requires the exclusion of the testimony of the plaintiff's expert because he "specifically relied upon several types of data experts in the field would not use in forming their opinions."[295] The court concluded that epidemiologists would not rely on their own unpublished reanalyses of adverse drug reaction reports (ADRs) and drug experience reports (DERs),[296] would not rely on preliminary drafts of studies that were later replaced by finalized published studies,[297] and would not rely on another expert's unpublished reanalysis of data.[298] The plaintiffs' expert conceded that the reporting of DERs is incomplete and may contain information from lawsuits and news accounts.[299]

Courts may be more hesitant to exclude testimony where experts make no such concessions. In *Mendes-Silva v. United States*, the court reversed a grant of summary judgment in an action under the Federal Torts Claim Act brought by a plaintiff who claimed that her encephalomyelitis was caused by having received yellow fever and smallpox vaccines on the same day.[300] The district court had rejected testimony relating to studies counseling against simultaneous administration of vaccines, on which the plaintiff's experts relied, because they did not involve adults and because they did not involve the same two vaccines. The court of appeals found that the district court's conclusion that such evidence is not of a type reasonably relied upon by experts in the field was "unsupported by the evidence available at the summary judgment stage of the proceedings below."[301] The court of appeals specifically noted that the experts did not concede that studies were not of a type reasonably relied upon.[302]

294. 791 F. Supp. 1042 (D.N.J. 1992), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994). The trial court also relied on Rule 702 in excluding plaintiffs' expert's testimony. 791 F. Supp. at 1055. In concluding that the expert had used data on which experts in the field would not rely, the district court commented: "This is where Rules 702 and 703 intersect." *Id.* at 1059. *See also* discussion *supra* § III.C.2.b.

295. 791 F. Supp. at 1059.

296. Plaintiffs conceded that the expert's reanalyses of the FDA's ADR and DER data could be disregarded. 791 F. Supp. at 1059 n.20. In addition, the court noted in its "Factual Findings" that a review of DER data "cannot be used by itself to prove causation, but rather is merely a stimulus for further study." *Id.* at 1050.

297. One draft on which the expert relied had been labeled a preliminary draft by the author, who submitted an affidavit explaining that his subsequent draft corrected errors. The expert admitted the unreliability of the preliminary draft. 791 F. Supp. at 1050.

298. 791 F. Supp. at 1059.

299. *Id.* Furthermore, the expert admitted that he could not verify his DER data because he did not have a list of the DERs he had consulted. *Id.* at 1051. "ADRs have inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions." *Id.* at 1050. *See also In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *86–87, *149 (court affirmed district court's holding that one expert could not rely on immunological test results from a chemical injury kit because results were not the type of data reasonably relied upon by experts in the field under Rule 703, and that another expert could not rely on recalculations that were "too rough to be considered reliable at all").

300. 980 F.2d 1482, 1486–87 (D.C. Cir. 1993).

301. *Id.* at 1486.

302. *Id. Cf.* Cantrell v. GAF Corp., 999 F.2d 1007, 1014 (6th Cir. 1993) (neither Rule 702 nor Rule 703 bars a physician from testifying "to confirmatory data, gained through his own clinical experience"; in action claiming personal injuries from asbestos exposure in the workplace, court found no error in allowing expert who testified about medical sources attesting to a link between asbestos and cancer to also state that 3 out of 150 employees had laryngeal cancer; court noted that expert was subject to cross-examination and conceded

3. *Expert's reliance on data that are erroneous.* The *DeLuca* case also illustrates an expert's reliance on data that are wrong.[303] In *DeLuca*, the plaintiff's expert could not account for some of the relative risk numbers he had entered on his charts. He seems to have transposed numbers, made arithmetical mistakes, changed numbers from an earlier draft chart without giving much of an explanation, and included the numbers from one study twice.[304] The court observed as part of its Rule 703 analysis that the "new data" that he used could not "in many instances be replicated by other experts in the field or even be explained."[305]

Exclusion on the ground that an error in data exists does not fit easily into the plain meaning of Rule 703, which speaks of the "type" of data.[306] Some commentators would argue that neither does Rule 702 apply, as Rule 702's concern is with the methodological reliability of the expert's theory in general[307] and not with its application in the particular case.[308] At some point, however, as *DeLuca* recognizes, an expert whose opinion is derived from faulty data combined with types of data not reasonably relied on is obviously using a skewed methodology, thereby implicating Rule 702 concerns. At other times, however, courts are willing to leave possible errors in data as questions of weight for the jury.[309]

In part the evidentiary issues may be defined by what is discoverable. In civil cases in which the mandatory expert disclosure provisions are in effect, experts must reveal data underlying their conclusions and are subject to deposition.[310] In a criminal case, the lessened opportunity for discovery undoubtedly decreases the likelihood of detecting actual errors in underlying data. In civil cases as well, however, discovery may not always produce the relevant data. When an expert

that the three employees were smokers and that it was impossible to determine if their cancers were caused by asbestos).

303. DeLuca v. Merrell Dow Pharmaceuticals, Inc., 791 F. Supp. 1042 (D.N.J. 1992), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 114 S. Ct. 691 (1994).

304. 791 F. Supp. at 1048–50.

305. *Id.* at 1059.

306. *See In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *149–54, *152 n.39 (defendants argued that experts would not rely on a nationwide study of PCBs in fat to calculate background level of PCBs in blood; plaintiffs countered that defendants' argument was that experts would not reasonably rely on data from this particular study and not that experts would not reasonably rely on this *type* of data, and that the language of Rule 703 makes it permissible to rely on particular data "even if the particular data was imperfect"; court declined to "rest upon this difficult distinction, for defendants' argument is easily recharacterized as attacking expert reliance on fat data reported in broad ranges (a type of data) rather than as an attack on particular data"; court found that trial court had abused discretion in excluding testimony based on fat study data).

307. *See* discussion *supra* § III.

308. Professor Edward Imwinkelried has suggested that expert testimony has a syllogistic structure, the constituent parts of which are a major premise embodying the expert's explanatory theory, a minor premise constituting the case-specific data to which the expert applies the major premise, and a conclusion, which is the opinion the expert proffers. According to this analysis, Rule 702 addresses deficiencies in the major premise, and Rule 703 addresses deficiencies in the minor premise. *See* Edward J. Imwinkelried, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 2–3, 5 (1988). As the discussion below indicates, however, in practice it is difficult to discern a bright line between a theory and its application.

309. *See* discussion of DNA laboratory procedures *supra* § III.C.3.e.

310. *See* discussion *supra* § I.C.1.

relies on a study done by someone else, as Rule 703 clearly allows, the data underlying that study may not be readily available.[311]

4. *Expert's opinion does not rest on a foundation that experts would generally find reliable.* Prior to *Daubert*, the First Circuit excluded plaintiff's expert testimony in a Bendectin case pursuant to Rule 703,[312] and the District of Columbia Circuit suggested in two cases that the expert's testimony in a Bendectin case was inadmissible pursuant to Rule 703, although both cases arose in the context of rulings on the sufficiency of the evidence.[313] The courts seemed to conclude that a court was justified in excluding under Rule 703 testimony contrary to a scientific consensus.

In *Daubert*, the Supreme Court stated in the course of interpreting Rule 702: "The focus, of course, must be solely on the principles and methodology, not on the conclusions that they generate."[314] The Court also acknowledged that a directed verdict or a grant of summary judgment is appropriate "in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true."[315] After a "*Cf., e.g.,*" cite, the Court referred to two Bendectin cases, *Turpin v. Merrell Dow Pharmaceuticals, Inc.,* 959 F.2d 1349 (6th Cir. 1987), *cert. denied*, 113 S. Ct. 84 (1992), and *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir.), *and modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990).[316] In *Turpin*, the appellate court affirmed the district court's grant of summary judgment; in *Brock*, the appellate court reversed a jury verdict for the plaintiffs.

The Supreme Court's opinion in *Daubert* raises but does not answer several valid questions: May a court rely on Rule 703 to exclude an expert's opinion that reaches a conclusion that is inconsistent with a scientific consensus or that lacks a scientific foundation? Does such a reading constitute a back-door resurrection of the *Frye* "general acceptance" test, which was rejected by the Court as incompatible with the Federal Rules of Evidence?[317] Should a court use a sufficiency analysis rather than an admissibility analysis when an expert uses an ap-

311. *Cf.* Fed. R. Civ. P. 45(c)(3)(B)(ii) (obtaining disclosure of unretained expert's opinion or information).

312. Lynch v. Merrell-National Lab., Inc., 830 F.2d 1190, 1196–97 (1st Cir. 1987) ("[T]he district court's firm rejection here of foundationless expert testimony was necessary, admirable, and entirely within the discretion of the court under Federal Rules of Evidence 403 and 703.").

313. Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1162, 1164 (D.C. Cir.) ("[U]nder Rule 703, an opinion refuting this scientific consensus [that Bendectin is not teratogenic] is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion"; court reversed trial judge's refusal to grant judgment n.o.v.), *cert. denied* , 498 U.S. 950 (1990); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 829 (D.C. Cir. 1988) (court stated that Rule 703 "lays the foundation for our consideration of what constitutes adequate expert testimony"; case arose in the procedural posture of the trial court's grant of a judgment n.o.v.), *cert. denied*, 493 U.S. 882 (1989).

314. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2797 (1993).

315. *Id.* at 2798.

316. *Id.*

317. The Court stated: "Nor does respondent present any clear indication that Rule 702 *or the Rules as a whole* were intended to incorporate a 'general acceptance' standard." 113 S. Ct. at 2794 (emphasis added).

propriate methodology and relies on data that experts reasonably rely upon but nevertheless reaches an opinion at odds with the scientific community?

Two questions that surface with some regularity in toxic tort cases illustrate issues the appellate courts may have to address pursuant to Rule 703. First, may a court reject as inadmissible an opinion based on a study that fails to meet a certain level of statistical significance?[318] Second, may a court reject an expert's causation testimony based on animal studies?[319] Both of these issues have been discussed in connection with methodological concerns.[320] These questions indicate that the interrelationship between Rules 702 and 703 and between admissibility and sufficiency questions requires further consideration by the appellate courts.[321]

318. *See, e.g.*, Wade-Greaux v. Whitehall Lab., Inc., No. 30/1988, 1994 U.S. Dist. LEXIS 7649, at *126 (D.V.I. Mar. 1, 1994) (rejecting testimony pursuant to Rule 703 based on epidemiological studies that do not show a statistically significant increase in the risk of limb reductions associated with the use of defendant's product because the experts "used data that experts in the field would not use in reaching conclusions on the subject").

319. *Id.* at *12–13, *117–18 (experts in teratology would not reasonably rely upon animal studies in the absence of positive epidemiological data); *In re* Paoli R.R. Yard PCB Litig., No. 86-2229, 1992 U.S. Dist. LEXIS 16287, at *15–16 (E.D. Pa. Oct. 21, 1992) (same).

320. *See supra* § III.

321. *See* discussion of *In re* Paoli R.R. Yard PCB Litig. (Paoli II), *supra* note 221 and related text, questioning the viability of the distinction between a methodology and its application after *Daubert*.

V. Is the Expert's Opinion Subject to Exclusion Under Rule 403?

A. The Interplay Between Rules 702, 703, and 403

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* the Supreme Court acknowledged in passing that Rule 403[322] may also be used to control scientific expert testimony. The Court stated:

> Finally, Rule 403 permits the exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . . " Judge Weinstein has explained: "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses."[323]

The Court's recognition that Rule 403 is a source for the exclusion of expert testimony states a proposition with which most judges have generally agreed. Nevertheless, the range of Rule 403's operation in connection with the Article VII rules was somewhat unclear before *Daubert,* when the circuits differed in their understanding of the scope of Rules 702 and 703. Now that *Daubert* has shed some light on the proper role of Rule 702, questions still remain about how Rule 403 fits into this analysis, and the appropriate boundary with Rule 703.

Potential uses for Rule 403 in excluding expert scientific testimony raise complex issues implicating the relationship between judge and jury. Particularly because the exclusion of the plaintiff's expert proof will often result in summary judgment for the defendant, courts will undoubtedly exercise sparingly their power to exclude scientific evidence that is sufficiently trustworthy to pass the test of Rule 702 but would nevertheless confuse or prejudice the jury.[324]

322. Fed. R. Evid. 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

323. 113 S. Ct. 2786, 2798 (quoting Jack B. Weinstein, Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)).

324. *In re* Paoli R.R. Yard PCB Litig. (Paoli II), 1994 U.S. App. LEXIS 23722, at *58 n.16 (3d Cir. Aug. 31, 1994) ("exclusion under Rule 403 should be rare").

Whether some issues should be handled pursuant to Rule 702, 703, or 403 is not yet clear. For instance, may a court exclude evidence based on animal studies on the ground that extrapolating from the studies to humans is confusing or prejudicial? Is this an admissibility issue or a sufficiency issue? Does it matter whether the court relies on evidentiary principles or on rules governing sufficiency?

Prior lack of unanimity about the role of Rule 403 stemmed from some courts' view that the Rule 403 balancing test is built into Rules 702 and 703.[325] For instance, the "assist the trier" standard of Rule 702 led some courts to weigh the probative value of expert proof against the countervailing considerations of prejudice and confusion specified in Rule 403.[326] Similarly, the "reasonably rely" language in Rule 703 suggested to judges who take a broad view of the rule that evidence may be excluded without having to turn to Rule 403.[327]

B. Examples of Situations in Which Courts Apply Rule 403

Some issues regarding expert testimony, such as the admissibility of cumulative testimony, raise questions precisely analogous to those that arise in the nonscientific evidence context. A few examples are discussed below.

1. Prejudicial language

Courts rely on Rule 403 to exclude opinions which are couched in terms that a judge views as overly prejudicial even though the gist of the opinion is admissible.[328] A judge might, for instance, find the terms "voiceprint" or "DNA print" objectionable as suggesting an analogy to fingerprints that might cause a juror to overvalue the worth of the expert's opinion.

325. *See* Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1112, 1120–22 (5th Cir. 1991) (en banc) (per curiam) (while all the judges seemed to agree that expert witness testimony is subject to a Rule 403 analysis, the majority excluded the expert testimony in question without reaching Rule 403; the concurring opinion found that the testimony satisfied the expert rules but should have been excluded pursuant to Rule 403, and the dissent found that the testimony satisfied the expert rules and Rule 403), *cert. denied*, 112 S. Ct 1280 (1992). *See also* discussion *supra* § IV.B.2.a.

326. *See* United States v. Vance, 871 F.2d 572, 577 (6th Cir.) (listing as a factor that makes testimony admissible under Rule 702 that probative value outweighs prejudice), *cert. denied*, 110 S. Ct. 323 (1989); American Bearing Co. v. Litton Indus., Inc., 540 F. Supp. 1163, 1170–71 (E.D. Pa. 1982) ("It is apparent that when considering the admissibility of expert testimony, Rules 703 and 403 somewhat overlap, in that an opinion which is deemed inadmissible under one of the rules may also be deemed inadmissible on the basis of the other." Economist in antitrust action included figures from outside the defined market which thus could be misleading and speculative; court cited both Rule 403 and Rule 703).

327. See the dispute between the majority and concurring opinions in Christophersen v. Allied-Signal Corp., 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1280 (1992), as to the appropriateness of this approach. *See also* discussion *supra* § IV.B.2.a.

328. *See, e.g.*, Scott v. Sears, Roebuck & Co., 789 F.2d 1052, 1055–56 (4th Cir. 1986) (not an abuse of discretion for plaintiff's expert, testifying about various elements of the defendant's grating that made it dangerous, to opine that a yellow curb causes human eye to fill in the discontinuities; court granted a new trial because the expert had also stated that the scene was an "accident waiting to happen"; testimony was rejected pursuant to Rule 403 as overly prejudicial).

2. "Aura of scientific infallibility"[329]

Taken literally, the charge "aura of scientific infallibility" would lead to the exclusion of scientific evidence of the highest probative value. What courts mean when they use this phrase is that the "aura" is somewhat deceptive, but that jurors might be overwhelmed by the seeming "infallibility."[330]

Courts have relied on Rule 403 when they fear that statements of statistical probability might be overpersuasive and thus prejudice the jury. In *United States v. Massey*,[331] for example, the court reversed on the basis of plain error. The prosecution's expert witness who identified a hair sample as identical to one taken from the defendant testified to some statistical probabilities as to which no foundation had been established. In addition, the trial judge engaged in a colloquy with the expert concerning mathematical probabilities which was speculative and confusing. Prejudice was exacerbated by the prosecution's closing argument, which misstated what the expert had said and then dwelled on these misleading mathematical odds.[332]

3. In-court demonstrations or evidence of experiments

Courts will at times rely on Rule 403 to exclude visual evidence, such as videotaped demonstrations or computer-generated evidence. Evidence of this kind is so vivid and compelling that jurors may disregard its true value if it is at all misleading. Judges therefore scrutinize this type of evidence carefully to ensure that it is relevant and not improperly influential. Limiting instructions by the trial judge may help to obviate the dangers.

Two cases are illustrative of how courts analyze these cases, and how inextricably Rule 403 evaluations are tied to the particular facts of a case. In *Shipp v. General Motors Corp.*, the plaintiff claimed that a defect in the roof of a car manufactured by the defendant caused her more serious injuries than she would otherwise have suffered. Both the plaintiff and the defendant wanted to offer films into evidence.[333] The court admitted the plaintiff's film and photographs of a car similar to that involved in the accident being dropped on its roof, but excluded all tapes of drop tests performed on other model cars. The defendant

329. The quotation is from Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 Colum. L. Rev. 1197, 1237 (1980). *See* Barefoot v. Estelle, 463 U.S. 880, 926 (1983) (Blackmun, J., dissenting); United States v. Anderson, 851 F.2d 384, 393 (D.C. Cir. 1988), *cert. denied*, 488 U.S. 1012 (1989) (prejudicial impact of expert testimony offered against the accused); United States v. Amaral, 488 F.2d 1148, 1152 (9th Cir. 1973) (prejudicial impact of expert testimony offered by criminal defendant in support of a defense).

330. Polygraph evidence has often been excluded on a Rule 403 analysis. *See* United States v. Alexander, 526 F.2d 161, 168 (8th Cir. 1975) ("polygraph evidence . . . is likely to be shrouded with an aura of near infallibility, akin to the ancient oracle of Delphi"), quoted in United States v. MacEntee, 713 F. Supp. 829, 831 (E.D. Pa. 1989). In *MacEntee*, the court relied on Rule 702 in excluding expert testimony that the government's witness was untruthful based on a failed polygraph but stated that it could also have excluded under Rule 403. *Id.* at 832.

331. 594 F.2d 676, 680 (8th Cir. 1979).

332. *See also* discussion of statistical problems with regard to DNA evidence *supra* § III.C.3.d–e.

333. 750 F.2d 418, 422 n.4, 427 (5th Cir. 1985).

sought to admit a film of rollover tests with dummies that showed how a body is tossed in an accident when seat belts are not worn. The defendant argued that this film was relevant to show general principles of occupant movement and was not being offered as a simulation of the accident.[334]

After expressing its distrust of demonstrations involving vehicles other than the model involved in the accident, the trial judge concluded that the jury "would likely consider it as more than a simple demonstration of general principles."[335] The appellate court found no abuse of discretion.[336]

In contrast, in *Harvey v. General Motors Corp.*, a case in which the plaintiff was seeking damages for injuries sustained when thrown through the roof of his car, the trial court admitted films of rollover tests offered to illustrate vehicle dynamics and not to re-create the accident.[337] The trial judge clearly and in detail instructed the jury not to ignore the distinctions in the model of cars.[338] The appellate court affirmed, noting that *Shipp* was not to the contrary: "Evidence properly excluded in one context is not automatically admitted erroneously in a separate context."[339]

Although some courts may continue to rely on Rule 403 in responding to fact patterns that other courts view as controlled solely by Rule 702 or 703, the dispute will probably not affect outcomes. Furthermore, it is often difficult to tell to what extent a particular decision rests on Rule 403, rather than on the expert rules, because courts frequently cite Rule 403 in addition to one of the expert rules.[340] If after *Daubert* the circuits insist on more uniformity in how trial judges must handle certain recurring issues pursuant to Rules 702 and 703, then Rule 403 may become correspondingly more important as a vehicle for the trial courts' exercise of discretion. The trial courts' resort to Rule 403 may also be af-

334. *Id.* at 427.
335. *Id.*
336. *Id.*
337. 873 F.2d 1343, 1355 (10th Cir. 1989).
338. *Id.*
339. *Id.* at 1356. *See also* Swajian v. General Motors Corp., 916 F.2d 31, 36 & n.2 (1st Cir. 1990) (court affirmed the exclusion of videotaped testimony showing what occurs when an axle fractures, but allowed oral testimony about the experiments); Edwards v. Liz Claiborne, Inc., 17 Fed. R. Evid. Serv. (Callaghan) 1316, 1320 (E.D. Pa. 1984) (not officially reported) (defendant allowed to burn fiber in court which was used to show only a limited part of accident; jury would not be misled into believing it was an exact replication of the accident); Shekell v. Sturm, Ruger & Co., 14 Fed. R. Evid. Serv. (Callaghan) 1634, 1637 (9th Cir. 1983) (unpublished opinion) (new trial ordered in product liability action where gun accidentally discharged; a live drop demonstration using a different gun was done only for effect and was probably too prejudicial); Raymond v. Riegel Textile Corp., 484 F.2d 1025, 1028 n.8 (1st Cir. 1973) (dicta) (may have been prejudicial to permit in-court exhibition of burning fabric in a jury trial, but not in a bench trial); Patterson v. F.W. Woolworth Co., 786 F.2d 874, 880 (8th Cir. 1986) (court admitted expert testimony concerning a demonstration that took place under different conditions; appellate court stated that test need not be conducted under exactly similar conditions and noted that trial court had limited prejudice by permitting the plaintiff's expert to remain in the courtroom and offer rebuttal); Wolf v. Procter & Gamble Co., 555 F. Supp. 613, 626–27 (D.N.J. 1982) (toxic shock syndrome case; court permitted plaintiff's expert to perform in-court experiment to explain the expert's testimony; any distinctions between the testing conditions and the human body could be explored on cross-examination).
340. United States v. Long, 917 F.2d 691 (2d Cir. 1990) (expert testimony on structure of crime family excluded; would not be helpful to jury; unclear as to which test was applied).

fected by the appellate courts' choice of standards for reviewing determinations pursuant to Rules 702 and 703.[341] If courts adopt stringent standards, then trial courts may tend to bolster their conclusions with a Rule 403 analysis that will be governed by an abuse-of-discretion standard of review.

341. *See* discussion *supra* § I.D.