

# Effective Strategies for Closing the Door on Junk Science Experts

*The Daubert decision offers defense counsel an excellent vehicle for excluding junk science, but there are many alternatives to consider*

By Bruce R. Parker

MUCH has been written about the legal standards announced by the U.S. Supreme Court in *Daubert v. Merrill Dow Pharmaceuticals*<sup>1</sup> and *Joiner v. General Electric Co.*,<sup>2</sup> but relatively little attention has been afforded to the practical implications of both decisions with respect to deposing and cross-examining at trial an expert whose testimony is subject to a *Daubert* challenge. This article examines what approaches should be used when deposing or cross-examining at trial experts who have survived a *Daubert* challenge. For simplicity, let's call such a person a "Daubert expert" and the cross-examination a "Daubert cross."

## PRACTICAL ASPECTS

### A. Deposing a Daubert Expert

The Supreme Court's invitation to challenge the admissibility of expert testimony by demonstrating the unreliability of the expert's methodology has made it even more imperative that trial counsel develop expertise on the scientific principles relevant to the expert's testimony. The expertise must be developed—at least substantially so—before the expert is deposed in order to maximize the opportunity to elicit testimony that will support a *Daubert* challenge.

Counsel knowledgeable on the relevant scientific principles often will have an advantage at an expert's deposition, particu-

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larly when the expert is deposed early in the case. Plaintiffs' attorneys often will not have spent the time to learn the science before their experts are deposed, also particularly when the deposition occurs early in the case. They will not be in a position to have prepared their experts for depositions. In addition, because experts know that most cases settle, many will not prepare for a deposition as thoroughly as they will for trial testimony. These factors create a unique opportunity for deposing defense counsel to extract concessions from the expert that will be critical in having the testimony stricken under *Daubert*.

The following discussion is not intended to be an all encompassing outline for deposing *Daubert* experts. Rather, it's intended to highlight several issues that need to be addressed when deposing *Daubert* experts.

#### 1. Have the experts subscribe to the scientific method

The scientific method is the means by which scientific knowledge is developed. If experts are to survive a *Daubert* challenge, they must establish that their opinions were formed consistent with the scientific method. The scientific method involves the formation of a hypothesis or theory—re-

1. 509 U.S. 579 (1993).  
2. 118 S.Ct. 512 (1997).

ferred to as the "null" hypothesis—which is then subject to rigorous controlled testing. Data generated by the testing are statistically analyzed to determine if they are statistically meaningful. If data are statistically meaningful, additional factors must be evaluated to determine their biological importance.

Experts who subscribe to the scientific method will be hard pressed to argue credibly that data not statistically significant or generated by uncontrolled studies provide an adequate basis on which to reach scientific conclusions.

### **2. Demonstrate that experts' opinions are unreliable because of their unfamiliarity with the underlying theory**

It often is a judgment call whether to explore certain issues with an expert on deposition or to wait until a Daubert hearing. Many experienced defense trial counsel would prefer to leave to the Daubert hearing and not address in a deposition the degree (or lack thereof) of experts' knowledge in the substantive area relevant to their opinions. These lawyers view the deposition as a means to have experts state all their opinions, leaving for trial a challenge to the validity of the opinions. If, however, counsel can get experts to concede at deposition that they do not understand the scientific theory underlying the test that generated the data on which they rely, then their testimony should not be admissible.<sup>3</sup>

### **3. Demonstrate that the theory has not been subject to adequate and/or objective scientific testing**

Experts who subscribe to the scientific method will be forced to concede that an opinion lacking empirical validation is not supported by scientific data. In most cases, however, experts will contend there has been some degree of testing that has generated data to support their theory. In those cases, defense counsel must obtain the raw data on which the opinion is predicated. In

matters involving sophisticated and complex testing, defense counsel should get an order requiring the expert to produce the data in advance of the deposition so that it can be reviewed by defense counsel's expert. If the data is not produced before the deposition, defense counsel should consider having their expert attend the deposition. The expert may be able to analyze the data at least preliminarily during the deposition and provide counsel with advice regarding deficiencies in the data.

### **4. If the experts' theories have been tested, show that the data have not been validated by others**

A fundamental principle of science is that before data can be considered valid, they must be reproducible. It is important to ascertain if others have attempted to validate the assay or technique and, if so, the results. Experts often evade this inquiry by emphasizing the highly statistical significance of the data. It is not, however, a substitute for reproducibility of data for experts to argue that the data are statistically significant at the 99 percent level. Meaningless data can be "statistically significant."

In addition, defense counsel should not accept at face value experts' testimony that the data were validated by "independent" laboratories. Deposing the "independent" labs often reveals evidence of bias, poor study design and questionable lab techniques.

### **5. Determine whether the data were properly statistically analyzed**

With few, if any, exceptions, scientific data that have not been properly statistically analyzed should not be admissible

3. See *United States v. Kilgus*, 571 F.2d 508 (9th Cir. 1978) (prosecution witness's inability to explain theory behind forward looking infrared (FLIR) system was basis to exclude his interpretation of results of FLIR data). See also E.J. IMWINKELRIED, *THE METHODS OF ATTACKING SCIENTIFIC EVIDENCE* 91 (1997) [hereinafter Imwinkelried].

under *Daubert*. The scientific method requires that the results produced by an experiment be statistically significant. By convention this is set at a probability (P) level of 5 percent. In other words, the difference between two or more results must be such that the odds of obtaining the results by chance alone are not greater than 1 in 20 (i.e.,  $\leq .05$ ).

Questioning experts on the statistical significance of data on which they have relied is often a fruitful area of examination. Because of the complexity of statistical testing, most investigators rely on a biostatistician to evaluate their data. When data have not been subjected to peer review and the expert has not performed the statistical analysis, the expert will not be able to lay the proper foundation under *Daubert* to rely on the data.

It is beyond the scope of this paper to offer a primer on biostatistics, but statistical evidence is often misused by experts in drug and medical device litigation and is a fertile area for cross-examination. Areas include poor study design, inappropriate statistical analysis of the data and statistical manipulation of data to create statistical significance.<sup>4</sup>

#### **6. Determine whether the assay or equipment is accepted within the scientific community**

There are several lines of inquiry that can produce testimony that an assay or technique has not achieved general acceptance in the scientific community. The following questions highlight areas that, depending upon the nature of the experiment, instrument or assay, may be helpful in demonstrating that opinions based on the

data generated by an instrument, assay or experiment do not constitute "scientific knowledge" under *Daubert*.

#### **(a) Has the assay been approved by the appropriate government agency?**

Immunoassay kits that are sold or otherwise used for diagnostic purposes are subject to FDA regulation. Manufacturers of unapproved assays often receive FDA regulatory letters. These letters typically describe the assay as experimental and not suitable for diagnostic purposes. An assessment by the FDA that the assay is experimental should help counsel convince a court of its unreliability under *Daubert*.

#### **(b) Has the expert modified a standard assay to develop the data?**

Experts often claim that their testimony is admissible under *Daubert* because it is predicated on tests that have been accepted for many years. Footnote 11 of Justice Blackmun's opinion in *Daubert* strongly suggests, however, that, although *Frye*<sup>5</sup> applied exclusively to novel scientific techniques, *Daubert* principles apply to all scientific knowledge. As one commentator has noted, "scientific techniques cannot be 'grandfathered' in under *Daubert*."<sup>6</sup> In some cases, experts derive data from conventional assays that have been modified. Modifying an assay to test something for which it was not developed renders the data as unreliable as if the assay had just been developed.

Explore in the deposition how the assay was modified, the purpose for the modification, whether preliminary experiments to optimize the kinetics of the assay were performed, the results of the preliminary assays and whether internal controls or standards were used when the assay was run.

#### **(c) Was the experiment properly designed and performed?**

There are many factors that are essential to a well-designed and performed experiment. A critical feature of a well-designed

4. Several key statistical concepts are discussed by the author in *Understanding Epidemiology and Its Use in Drug and Medical Device Litigation*, 65 DEF. COUNS. J. 35 (1998). See also the discussion of biostatistical principles in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 147-57, 335-468 (Federal Judicial Center, 1994) [hereinafter Reference Manual].

5. 293 F. 1013 (D.C. 1923).

6. See Imwinkelried, *supra* note 3, at 97.

study is the appropriate selection and number of controls. An experiment that is not properly controlled will not produce reliable data. Experts should be able to identify the variables the investigators sought to control and how the controls were selected. The greater the number of uncontrolled variables, the less reliable is the data. Experts should not be permitted to rely on experimental data to express an opinion if they cannot explain how (1) the study was designed, (2) the controls were selected and (3) the experiment was performed.

An experiment, to the extent possible, should be done "blind"—that is, one in which the investigators do not know who are the test subjects and who are the controls. It is particularly important to perform studies blind when the study is based on subjective evaluations. A "double-blind" study is one in which, during the study period, the subjects and controls do not know whether they have received the treatment or a placebo.<sup>7</sup>

Depending on the nature of the experiment, several other factors may be important to assess the validity of an experiment's design, execution and analysis of results. For example, determining whether multiple or single data points were used to develop response curves is important. Multiple data points are preferred since they provide greater assurance that the results are real and not the result of aberrant responses (e.g., outliers). For most toxicological and immunological assays, there also should be a dose-response if the causal relationship between an exposure and effect is real.

**(d) Was the instrument or assay studied pursuant to institutional review board (IRB) approval?**

Under federal law,<sup>8</sup> institutions that sponsor medical experiments must establish institutional review boards that are responsible for approving study protocols. When experts rely on data generated in an IRB-approved study, counsel should obtain

copies of the protocol and all reports submitted by the investigators to the IRB committee. Most important, counsel should get the informed consent document used for the study. Almost invariable, this document will characterize the assay as experimental and/or not for diagnostic purposes. It is extremely rare to find that the IRB took steps after the experiment was completed to validate the assay for clinical use. It is persuasive evidence that the assay does not meet *Daubert's* standards when the expert's institution has not validated the assay for clinical use.

**(e) Is the instrument or assay used in the expert's clinical practice?**

With disturbing regularity, experts in drug and medical device litigation develop biological assays that the experts claim generate diagnostically relevant data. However, these experts often do not use the assay in their clinical practice. The cost of performing an assay that has not been validated for clinical use is rarely reimbursable by health insurers. It is persuasive to show at a *Daubert* hearing that the assay on which the expert relies is not used by the expert in the expert's practice.

**(f) Have medical societies accepted the assay or data?**

Many medical associations issue reports or position statements on controversial procedures, drugs, biological assays and medical devices. For example, position papers have been issued by the American Medical Association and other medical groups on "silicone antibody" assays and plaintiffs' claims of silicone-induced autoimmune disease. Contrary position statements are very useful when examining experts who contend that their opinions are generally

7. Because of ethical constraints, it is very difficult to conceive of an experiment involving medical devices in which the subjects and controls are blind to whether they received a medical device or a "sham" (control) operation.

8. 45 C.F.R. § 46.01 et seq.

accepted within the scientific community. Position statements would demonstrate that the relevant medical or technical society does not endorse the expert's opinion.

**(g) Is the rate of error either unknown or too high?**

The phrase "rate of error" can mean different things depending on the nature of the instrument or assay. In general, the rate of error of a biological assay refers to its degree of sensitivity, specificity and negative or positive predictive value. The sensitivity of an assay is the percentage of patients who have a disease or condition and test positive for the condition. It is calculated by the following formulas:

$$\frac{\text{\# of true pos. responders}}{\text{\# of true pos. + (\# of false neg. responders)}} = \% \text{ sensitivity}$$

A test with high sensitivity has a low false negative rate.

Specificity is the percentage of subjects who do not have the disease or condition of interest and who test negative. The specificity of an assay is computed by the following formula:

$$\frac{\text{\# of true neg. responders}}{\text{\# of true neg. + (\# of false pos. responders)}} = \% \text{ specificity}$$

An assay with high specificity has a low false positive rate.

The positive predictive value of an assay reflects the probability that a patient with a positive test result has the disease or condition in question. Conversely, the negative predictive value is the probability that a patient with a negative test result does not have the disease in question.

Virtually all biological tests produce a background rate of positive results in a segment of the unexposed population. Experimental assays are often performed on only a small cross section of the population. In such cases, there will be an insuffi-

cient database on the background level from which to accurately calculate the assay's specificity and sensitivity. Assays that do not have a known specificity and sensitivity have little, if any, clinical value. Finally, most assays have inter- and intra-laboratory variability. The larger the rate of error, the more persuasive the Daubert challenge.

**7. Has the study been peer reviewed?**

Counsel should never assume that simply because an article has been published in a medical journal that it has been subjected to peer review. Not all medical journals are peer reviewed. In addition, journals that are typically peer reviewed have different standards for peer review. For example, scientific journals often print articles as a "quick communication" as a means to communicate new research in an area of current interest. Because of the need for quick publication, these articles are generally not subject to the same peer review process as are other research articles.

Experts should be compelled to produce copies of the peer reviewers' or editors' comments. Not infrequently, experts may decline to alter their articles in accordance with the suggestions of a peer reviewer and opt to have the article published in a journal of lesser quality. The peer reviewers' criticisms can be a very effective tool in cross-examining experts on the reliability of their data at the Daubert hearing. Finally, ask an expert to identify all journals that rejected the article and to produce the reviewers' and editors' comments.

Another area to pursue is whether the subject matter of the journal in which the study is published is relevant to the subject of the article. For example, a research immunological study should ordinarily be published in a journal read by research immunologists. When such an article appears in a clinical journal, it may be an indication that the article did not survive, or would not have survived, the peer review of a high-quality immunology journal. Experts should be pressed to explain why a more

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relevant journal was not selected, or, as is often the case, why the relevant journals rejected the article.

Establishing that the expert or the expert's academic department or private office does not subscribe to the journal that published the article is additional evidence to help demonstrate that the peer review and publication of the expert's article should not be accepted as an indication of its reliability. It also can be effective to show the court that the journal that published the expert's litigation-related study is not one in which the expert normally publishes non-litigation related research. Finally, whether the expert is a current member of the editorial board of the journal that published his article and, if so, whether the expert disclosed a potential conflict of interest are also important facts to support a Daubert challenge.

#### 8. Is the data reliable?

The "fit" requirement of *Daubert* is, in part, a test of relevance. An expert who is not qualified to offer an opinion cannot offer testimony that "fits" the case. Consequently, counsel must closely question experts on their qualifications to render opinions in the areas for which they have been proffered.

Experts whose reasoning departs from conventional scientific principles are not expressing scientific knowledge. When experts opine on the pathogenesis of a chronic latent disease, they should be questioned on the Bradford-Hill criteria. Standard scientific methodology requires causation data for latent diseases to be analyzed pursuant to these criteria.

The Bradford-Hill criteria were originally proposed in 1965 as an interpretive framework for analyzing whether an association existed between cigarette smoking and lung cancer. The criteria are:

- strength of association (epidemiological evidence);
- consistency of association (are the epidemiological studies consistent?);
- specificity of association (are one or

more diseases implicated with exposure to the agent?);

- temporality (did the disease occur following exposure?);
- biological gradient (does the exposure produce a dose-response?);
- biologic plausibility;
- coherence (are the data consistent?);
- experiment (does the effect disappear in experimental animals when the suspected agent is removed?); and
- analogies (do analogies suggest causal inferences?).

Under the Bradford-Hill criteria, if there is no epidemiological evidence of an association, one cannot reach conclusions on causation (as distinguished from association) by relying on animal and other *in vitro* data.

#### 9. Show that the data are not the type on which experts typically rely pursuant to Rule 703 in rendering opinions

Courts are beginning to address the interplay between Federal Rules 702 and 703. Counsel should not overlook Rule 703 when deposing experts. Information obtained from such questioning may yield concessions to supplement a Daubert challenge. For example, ego-driven experts in unrecognized disciplines—for example, clinical ecology—are often willing to boast that they are at the forefront of the scientific community and for that reason the information on which they rely is not the type of information relied on by other, "less enlightened" scientists. This sort of testimony should not survive a Daubert challenge.

#### 10. Is the expert's practice consistent with the expert's opinions?

Experts often testify that a drug or medical device caused a disease or injury because of a flaw in the design, testing or manufacture of the product. The logical extension of that testimony, consistent with a physician's ethical obligation, is that the physician/expert ought not use other phar-

maceuticals or devices that arguably share the same defect and should warn others of the alleged danger. When pressed, many experts are forced to concede that they have not advised their colleagues, patients and/or hospital administrators of the dangers presented by the product in question or by other products containing similar chemical compounds or properties.

What experts say in the courtroom often bears little relationship to how they comport themselves in their professional practice. If they have not acted on their alleged beliefs and warned their colleagues and patients, such evidence suggests that they may not believe that the danger or causal link is as real as they would have the court and jury believe.

### JOINER'S EFFECT ON PRETRIAL STRATEGIES

Prior to the Supreme Court's decision in *Joiner*, defense counsel facing Daubert experts instinctively filed motions in limine challenging the admissibility of the testimony and seeking pre-trial evidentiary hearings under Federal Rule 104 or its state counterparts, typical of those conducted by Judge Jones in *Hall v. Baxter Healthcare Corp.*<sup>9</sup> and Judge Weinstein in *In re Breast Implant Cases*.<sup>10</sup> While a request for a Rule 104 hearing to challenge admissibility is still advisable in most situations post-*Joiner*, there are circumstances that may require alternative approaches.

Before *Joiner*, some state and federal appellate courts reviewed Daubert rulings under a de novo standard.<sup>11</sup> In those jurisdictions, the record at a Rule 104 hearing is developed as much, if not more, for the benefit of the appellate court than the trial court, because the appellate court is the ultimate fact finder. There is every reason in

a jurisdiction with a de novo standard for defense counsel to develop a comprehensive record in a pretrial Daubert hearing. The same may not be true in a jurisdiction in which the trial court's ruling is reviewed under an abuse of discretion standard.

*Joiner* holds that trial court rulings are to be reviewed under an abuse of discretion standard. This standard requires the appellate court to give great deference to the district court's findings. Although the goal of defense counsel challenging the admissibility of a Daubert expert's testimony is the same whether the standard is de novo or abuse of discretion, there may be situations in which an abuse of discretion standard of review calls for different tactical decisions to be made.

The starting point in analyzing how, if at all, the standard of review may affect tactical decisions begins with the fact that the proponent of junk science carries the burden of persuasion under Rule 104.<sup>12</sup> In some circumstances, a defendant is arguably better served by waiting until trial to challenge the Daubert expert's testimony. For example, if prior experience with the trial judge leads defense counsel to conclude that there is virtually no chance of a pretrial challenge being successful, it may not be in a defendant's best interest to give the plaintiff the opportunity to develop, pretrial, a full record on the challenge. That record, depending on the science, could make it very difficult to have the trial court's decision reversed as an abuse of discretion.

If it is reasonable to presume that there are trial judges whose understanding of the law or philosophy is such that a successful challenge is most unlikely, then it follows that counsel should carefully consider in the post-*Joiner* era whether a client is best served by seeking a pretrial Rule 104 hearing.

### BENEFITS OF PRETRIAL HEARING ON CHALLENGES

Aside from the considerations discussed in the preceding section, experienced trial

9. 947 F.Supp. 1387 (D. Or. 1996).

10. 942 F.Supp. 958 (S.D. N.Y. 1996).

11. See, e.g., *Bradley v. Brown*, 42 F.3d 434 (7th Cir. 1994); *Craddock v. Bennett L. Watson and Barbourville Transfer Inc.*, 475 S.E. 2d 62 (W. Va. 1996).

12. See *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 n.9 (3d Cir. 1994).

lawyers who have not had to make a Daubert challenge might instinctively conclude that there are no situations in which a pretrial challenge should be made. This conclusion is predicated on the belief that a pretrial challenge prematurely reveals to the plaintiff and the Daubert expert how one plans to attack the testimony.

While such a conclusion may be valid in some circumstances, it must be carefully weighed against the benefits of having a challenge resolved in a pretrial Rule 104 hearing. Before a jury is impaneled, a trial judge is more likely to spend the time necessary to read and learn the science introduced by the defendant than if the challenge is made during the trial. A challenge during trial delays the trial and inconveniences the jury, which many trial judges go to great lengths to avoid.

In addition, because the Rules of Evidence are not applicable in a Rule 104 proceeding, defense counsel has considerable freedom to introduce a variety of probative evidence demonstrating the unreliability of the Daubert expert's testimony. This evidence generally would be unavailable during the trial cross-examination. For example, it is entirely permissible (and probably advisable) in a Rule 104 hearing to introduce affidavits, letters from non-trial expert witnesses, medical and scientific treatises and other forms of evidence not otherwise admissible in a trial.

Since most judges are not schooled in science, counsel needs time to educate them. That often is not possible if the challenge is made during trial. It has been the author's experience that judges who take the time to learn the science often take an active role in the pretrial Rule 104 hearing and question the experts in order to get a better understanding of the scientific principles in dispute. It is unrealistic to expect that a trial judge will have the same ability to review and understand complex scientific data if it is initially introduced during the voir dire of the expert immediately before the expert is to testify.

Another benefit of a pretrial Daubert

hearing is that defense counsel is able to cross-examine the expert with evidence that may not have been available at the time of the expert's deposition. Such information can be critical to demonstrating that the expert's testimony is not "scientific knowledge."

Pretrial cross-examination allows defense counsel to pin down experts on their explanation of the new science. A pretrial cross-examination will also give defense counsel time to research any new wrinkles in experts' theories discussed during the pretrial hearing.

### REASONS TO FORGO PRETRIAL CHALLENGES

As previously mentioned, there are reasons not to ask for a pretrial Daubert hearing, particularly after *Joiner*. If the pretrial challenge fails, the plaintiff will have time to correct the now-revealed deficiencies in the expert's testimony before trial. In addition, the element of surprise is lost if strongly conflicting scientific data are shown to the expert in a pretrial Rule 104 hearing. It is not unusual for the same experts who had no knowledge of critical conflicting data at the Rule 104 hearing to have become quite knowledgeable on the issues by the time of trial. Such experts have no difficulty between the pretrial hearing and their trial appearance to develop an explanation of how defense counsel misinterpreted the data during the pretrial hearing and that when properly interpreted (as they have done for the jury), the data actually support their testimony!

Finally, as discussed, a pretrial Rule 104 hearing will give the plaintiff the opportunity to develop a record in support of the trial court's denial of the Daubert challenge, and this may be very difficult to reverse during trial and/or on appeal as an abuse of discretion.

### STRATEGIES FOR OBTAINING A DAUBERT HEARING

Rule 104 case law offers little guidance



as to whether parties are entitled to a Daubert hearing at which testimonial evidence can be presented. According to the Ninth Circuit, the trial court does not have to hold a Rule 104(a) hearing, "but rather must merely make a determination as to the proposed expert's qualifications."<sup>13</sup> There is no case law (known to the author) that imposes on the trial court an obligation to conduct Daubert hearings before the trial begins. Some courts, however, have recognized that in order for the trial court to exercise its "gatekeeping" function effectively, rulings should be made before the trial begins.<sup>14</sup>

Daubert challenges also can be raised at trial. In *Hose v. Chicago Northwestern Transportation Co.*,<sup>15</sup> the defendants had not filed a motion for summary judgment or pretrial motions to exclude the scientific testimony of plaintiffs' expert. On the first day of trial, defense counsel moved in limine to exclude the testimony of plaintiff's expert. The circuit court concluded that defense counsel's objection to that testimony was timely, despite the fact that counsel had not raised the motion until the first day of trial.

Although there may be situations in which tactical considerations favor having a Daubert hearing immediately before an expert is to testify during the course of the trial, the generally preferred practice is to have Daubert hearings on all of the challenged evidence before the trial begins.

One important benefit of having Daubert hearings before trial is that counsel may be able to obtain additional concessions from the experts that can be used during their cross-examination if the Daubert chal-

lenge fails. When trial counsel are assigned to a case after the expert has been deposed or when new information is learned after the expert's deposition has been taken, the record may be incomplete for trial preparation purposes. A pretrial hearing offers the opportunity to confront the expert with the new information. Moreover, since the court is the fact finder during the hearing, it is often more willing to become active in the examination.

This is particularly beneficial with evasive witnesses. When evasive experts find themselves confronted by a judge who has no patience for their evasiveness, concessions may be given that previously were impossible to obtain. The additional concessions often are quite helpful during the trial if the experts are permitted to testify.

Courts, however, may be reluctant to issue pretrial Daubert rulings for any one or more of the following reasons:

1. Courts may be reluctant to make pretrial rulings before it has a better understanding of how the experts' testimony will fit in the case.

2. Courts may be reluctant to exclude critical causation testimony and risk creating reversible error before the trial has begun.

3. Courts without much experience with complex scientific testimony in product liability cases may feel uncomfortable when suddenly thrust into the role of fact finder on scientific issues and may lack the confidence to issue pretrial rulings.

4. Courts may favor the plaintiff's position and feel that it would be unfair to deprive the jury of the opportunity to hear the case.

Except for those courts whose attitudes are consistent with No. 4 above, counsel can improve their chances of convincing the court to conduct a pretrial Daubert hearing by using one or more of the following suggestions:

1. Convince the trial judge that judicial economy favors pretrial hearings. The court must be reminded of the substantial inconvenience that the jurors will experi-

13. *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124 (9th Cir. 1994).

14. See *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 973 n.3 (8th Cir. 1995) (citing *Gier v. Educ. Serv. Unit No. 16*, 66 F.3d, 940, 942 (8th Cir. 1995): "An early evidentiary challenge allows the trial judge to exercise properly the 'gatekeeping role' regarding expert testimony envisioned under *Daubert*."

15. 70 F.3d 968, 973 (8th Cir. 1995).

ence if the hearings are conducted during trial.

2. Give examples of other courts that have conducted similar hearings. The court may not be as hesitant if it feels it is not the first to have conducted pretrial hearings.

3. For those judges who view themselves as judicial leaders, show that the issues are novel and complex, and that guidance is necessary for other courts struggling with the same issues.

4. Provide the court with realistic time estimates for the hearing. This can allay concerns that the hearings will delay the trial excessively. Because of the impatience most courts have with delaying trials, counsel should be conservative with their estimates—and stick to them.

5. To help the court understand the complex scientific issues, consider suggesting that the court retain scientific advisors under Rule 104. A good example of this procedure is seen in *Hall*, cited above, in which the court retained a rheumatologist, immunologist, epidemiologist and chemist to hear testimony presented by both the plaintiffs and defendants. These experts rendered reports to the court explaining whether the plaintiffs' experts satisfied the Daubert criteria.

6. Convince the court that without pretrial rulings, there is little chance for pretrial settlement.

#### **PRACTICE POINTERS FOR A DAUBERT HEARING**

##### **A. Determine Scope of Issues**

Since time is generally limited, counsel must exercise discretion in deciding which aspects of the experts' testimony to challenge. A shotgun approach to questioning experts on each opinion has little chance of success.

##### **B. Educate Court about Scientific Method**

To have a reasonable chance of success, it is imperative that counsel educate the court about the scientific method. Several

issues that the court must understand include:

- The scientific method involves the formation of a hypothesis and the generation of data to support or refute the hypothesis by reproducible, well controlled and statistically significant data.

- Scientific data considered to have scientific significance are data that have been reported at a 95 percent confidence level or which has a P value of less than or equal to .05 percent. Plaintiffs typically argue that because the civil burden of proof is 51 percent (that is, a preponderance of the evidence), data on which their experts rely need not meet the rigorous scientific standard of 95 percent. This argument is specious.<sup>16</sup> The legal "preponderance of the evidence" standard has nothing to do with assessing whether data is scientifically reliable. Since *Daubert* seeks to exclude scientifically unreliable evidence, the scientific evidence must conform to the accepted convention of 95 percent probability to be admissible. Once all scientifically reliable evidence (that is, that meeting the 95 percent threshold) is introduced, the fact finder will determine by the preponderance of all admissible scientifically reliable evidence, whether the plaintiff has met the burden of proof.

- Biological data from poorly controlled experiments are not good scientific evidence just because they are statistically significant.

- The fact that data are produced by a well-controlled study and are statistically significant does not necessarily mean that the data have biological significance.

##### **C. Cross-examining Plaintiffs' Experts**

Since Federal Rule 104 and its state counterparts permit the trial court to consider inadmissible evidence in reaching its decision, counsel need not spend time lay-

16. For a discussion of this issue, see Reference Manual, *supra* note 4, at 153 n.80 (1994) (calling this claim "incorrect").

ing a foundation to use learned treatises in cross-examining experts. Using standard medical textbooks on cross is an excellent way to demonstrate that the experts' theories are inconsistent with, and perhaps unsupported by, scientifically reliable evidence.

Demonstrating experts' biases by showing that they have earned considerable income from litigation is often an effective way to impeach their credibility. This form of bias, however, is generally not relevant in a Daubert hearing, but other forms of bias may be relevant. For example, if experts base their opinions on their clinical experience, the fact that their patients were sent to them by their lawyers creates referral or selection bias, which is a highly relevant factor in assessing the quality of the clinical data. Trial courts also will look to see whether the experts' opinions were developed for litigation purposes or represent legitimate scientific investigation. Counsel should demonstrate, whenever possible, that the opinions were developed for litigation.

Since the nature of Daubert challenges is varied, so will be the cross-examination of experts. In general, cross-examination should be planned with the goal of incorporating *Daubert's* legal framework into the cross in order to develop the points needed to exclude the testimony. As a general rule, it is always helpful to have the expert concede the importance of the scientific method and the Bradford-Hill criteria in reaching opinions on causation.

Although experienced practitioners would not hesitate to use audio-visual aids to enhance the clarity of their presentation to jurors, there often exists an unwarranted assumption that the court will not need demonstrative aids to understand the evidence. Given the complexity of the information that the court is being asked to comprehend in a relatively short period of time, the use of demonstrative aids is prob-

ably more important in a Daubert hearing than during trial. Charts that summarize complex bodies of scientific evidence are important in helping the court not lose the forest for the trees.

Beyond visual aids, the greatest assistance that a court can receive in resolving complex scientific issues is advice from independent scientific experts. There is no prescribed formula or structure as to how advisors are to be used by the court in a Rule 104 hearing. If a court appoints experts pursuant to Rule 104, those experts can serve as independent advisors to the court and ordinarily will not be subject to deposition or subpoena for trial purposes.<sup>17</sup>

Experts appointed under Rule 706, on the other hand, may be deposed and called to testify at trial by the court or the parties. Because court-appointed experts' role in the ongoing litigation varies depending on the authority under which they are appointed, careful consideration by counsel is necessary when deciding what recommendation should be given to the court. If the court appoints experts *sua sponte*, counsel should seek prompt clarification regarding which type—Rule 104 or 706—of experts are to be selected. Rule 706, unlike Rule 104, sets forth several procedural guidelines for the use of court-appointed experts.

In the Daubert hearing conducted by the court in *Hall*, both the court and the court-appointed experts actively questioned the parties' experts. Following the presentation of the court-appointed evidence by plaintiffs and defendants, each of the experts submitted a report to the court and parties. The parties were given an opportunity to question each of the court-appointed experts regarding his report. Having read the experts' reports and having heard the experts' responses to counsel's questions, the court then decided the Daubert issues.

#### WHAT TO DO IF JUNK SCIENCE IS ADMITTED

Denial of a pretrial Daubert challenge is not the only opportunity counsel has to have the trial court exclude the Daubert

17. See *Hall*, 947 F.Supp. at 1392 n.8.

expert's testimony. In some jurisdictions, a denial of a motion in limine (with or without a hearing) does not preserve the objection unless the objection is renewed during trial. Counsel should renew the objection before the expert testifies and, if no pretrial hearing was conducted, request a Rule 104 hearing.

If a Daubert challenge has failed, regardless of when it was made, counsel must make some difficult decisions in planning the trial cross-examination. Although there are general issues common to all cross-examinations, there are issues that go to the heart of a Daubert challenge that would not be relevant to a cross-examination of a non-Daubert expert. In addition, the trial cross-examination of a Daubert expert can be an important part of the record from which counsel will later argue, in the event of a plaintiff's verdict, that the trial court abused its discretion in permitting the Daubert expert to testify.

In preparing the trial cross-examination, counsel should recognize that the substantive issues that must be developed for a successful challenge may not lend themselves to an effective jury cross-examination of the Daubert expert. Whether to cross on the Daubert issues and risk losing the jury should be carefully considered, with input from the client. Among the hard questions counsel must answer are whether there is a realistic chance of winning the case before the jury or whether the case is being tried for the appellate court. If there is a realistic chance of a defense verdict, counsel must consider whether a Daubert cross would be too complex or confusing for the jury? If the trial court did not permit evidence to be introduced on the Daubert issues before denying the Daubert motion, counsel must consider whether a sufficient record can be developed through the testimony of the defense experts before excluding Daubert issues from the cross-examination of the Daubert expert at trial.

An experienced trial lawyer may conclude that a cross-examination designed to demonstrate the unreliability of the Daubert

expert's methodology would be lost on the jury—and therefore ineffective. Counsel may conclude that a far more effective approach before the jury might be simply to cross-examine the Daubert expert on the expert's litigation bias, weak qualifications and ignorance of case-specific issues, such as the plaintiff's medical history.

Courts increasingly are imposing stringent time limitations on the examination of witnesses to reduce the length of trials. In some cases, even if counsel would prefer to cross-examine the expert on Daubert issues, time limitations may force abandonment of the Daubert cross and dictate a more traditional and limited cross. In a recent case in which the author was trial counsel, cross-examinations were limited to 75 percent of the time spent on direct examination. Under such circumstances, the length of the defendant's cross-examination is controlled by the plaintiff. As any experienced trial lawyer knows, a number of critical issues can be covered by an experienced expert who offers broad conclusory opinions in a reasonably short period of time. An effective cross-examination of such an expert almost certainly will exceed the length of the direct examination. Time limitations of this type make it all but impossible to conduct an effective Daubert cross-examination.

Variables such as the cross-examiner's skill, the evasiveness of the Daubert expert, and the degree of complexity of the Daubert issues make it very difficult to offer general rules regarding the cross-examination of a Daubert expert. There are points, however, that are relevant and that can be established with reasonable safety. The deposition outline discussed above and as refined below provides a framework from which counsel can develop a Daubert cross-examination.

1. Educate fact finders so that they understand the scientific method. Admissions by Daubert experts that they do not follow the scientific method make it almost impossible for a trial court not to strike the testimony under *Daubert*. Consequently, a

reasonably safe point to establish in the trial cross-examination is whether the expert subscribes to the scientific method. In follow-up questions, counsel should attempt to demonstrate that the expert has not complied with the scientific method in reaching opinions.

2. Obtain a concession that the expert's theory has not been subject to objective scientific testing.

3. If the expert's theory has been tested, have the expert acknowledge that the data have not been validated by other investigators.

4. Demonstrate that the data were not properly statistically analyzed and therefore do not support the expert's conclusions.

5. Demonstrate that the assay or equipment that produced the data relied on by the expert has not been accepted by the scientific community.

(a) Show that the assay has not been approved by an appropriate governmental agency.

(b) If experts claim that they have "only" modified a standard methodology," demonstrate that the manner in which the test, equipment or assay was modified no longer renders the assay "standard."

(c) Show that the expert's experiment was not properly designed and/or performed.

(d) If the data were generated through testing at a university, demonstrate that the assay was not validated pursuant to the university's institutional review board.

(e) If an expert's testimony is based on data derived from an assay, point out that the expert does not use the assay in the expert's clinical practice.

(f) Have the expert concede that medical societies have criticized the assay or data.

(g) Have the expert acknowledge that the assay or equipment's rate of error is either unknown or too high.

6. Show that the study has not been subject to peer review.

7. Demonstrate that the expert's causa-

tion opinions are unreliable since they fail to meet standard scientific methodology as embodied in the Bradford-Hill criteria.

8. Show that the data are not a type on which experts typically rely pursuant to Rule 703 in reaching opinions.

9. Show that the expert has not conducted himself in his clinical practice consistent with his opinions.

Although most Daubert experts will have made some concessions in their depositions that can be established at trial on cross-examination with relative safety, there are circumstances in which counsel should not attempt a full Daubert cross-examination. For example, it is a recipe for disaster for counsel to attempt a Daubert cross-examination of an evasive and experienced expert who is testifying before a judge who will not force the expert to answer direct questions. Under these circumstances, the complexity of a Daubert cross-examination will be ineffective at best and at worse benefit the plaintiff's case.

Not only will the Daubert cross give the expert an opportunity to build a record to support the trial court's rejection of the Daubert challenge, the jury may become more impressed with the expert as a result of the cross. Jurors expect witnesses on direct examination to be impressive and persuasive. When the expert has withstood cross-examination, it only serves to enhance the persuasiveness of his testimony.

If a Daubert motion has been denied and if, after an evaluation of the variables discussed here, counsel concludes that a full Daubert cross is unwise, the examination should be conducted as if Daubert were not a factor. In these cases, counsel should have the defense experts explain to the jury, judge and appellate court why the plaintiff's experts' testimony fails to meet the Daubert criteria.

#### **DIRECT EXAMINATION OF DEFENSE EXPERTS**

Rarely will the trial cross-examination of

a Daubert expert generate a sufficiently compelling record that will lead a trial court to re-consider its decision at the conclusion of the cross-examination or allow an appellate court to find an abuse of discretion. In most cases, points made in the cross-examination will need to be amplified and explained by defense experts. It is beyond the scope of this article to discuss practice pointers on how to conduct an examination of the defense expert witness. However, certain points must be made by the expert in order to have any chance of convincing the trial judge, jury or appellate court that the Daubert expert's testimony does not constitute "scientific knowledge."

Because the goal of a Daubert challenge is to demonstrate that the expert's testimony does not constitute scientific knowledge, the presentation of the attack by the defense expert often begins with an explanation of the scientific method. This task is deceptively difficult. Judges are trained to accept, as evidence, what witnesses say. Jurors are instructed before trial that evidence is what they read, see (demonstrative exhibits), and hear from witnesses. Consequently, jurors may readily accept, as scientific fact, the testimony of a Daubert expert that is simplistic and logically appealing. Judges and juries must be made to understand that a Daubert expert's "scientific opinion" is as unreliable as a lay witness who has no personal knowledge of an event and admittedly is guessing or speculating what happened.

Defense experts must be able to have the judge and jury understand that the hallmark of a good scientific study is controlled testing. It helps jurors understand this when they are given examples to which they can relate. For example, there are numerous instances in medical history in which physicians rendered ineffective and, in some cases, harmful treatment because of a lack of empirical controlled testing demonstrating the efficacy of the treatment. Jurors begin to understand why case reports and other types of uncontrolled "evidence" relied on by the Daubert expert are of little

scientific importance when they are reminded that for centuries people were subjected to a bizarre array of medical treatments, including bloodletting to treat the common cold. The asserted efficacy of bloodletting treatment was based on the observation that from five to seven days after treatment, the cold symptoms would abate. Scientists eventually compared the results of a group of treated patients to an untreated group. When they found that symptoms in the untreated group abated in five to seven days, they realized the treatment was not efficacious. This simple experiment highlighted the importance of controlled testing.

Daubert experts often rely on experimental data claimed to be highly important when, in fact, the results are nothing more than a chance occurrence. Jurors often believe that because a scientific test, which is made to sound quite sophisticated by the Daubert expert, produced a result, the result must be scientifically meaningful, when in fact the test producing the result may be completely bogus. To make the jurors and judge understand that the experimental effect claimed is nothing more than a chance occurrence, the defense expert must be able to explain statistics in a way that is understandable and overcomes jurors' distrust of statistics.

Analogies that are helpful in explaining statistical concepts can be drawn from everyday experiences. For example, jurors will understand that an expert who claims that Batter A, who hit .400, is "much better" than Batter B, who hit "only" .250, is misleading them if the expert fails to tell the jury that A had only five plate appearances, while B had 500.

As with experts in non-Daubert situations, it is very important to use demonstrative exhibits that jurors can either see or feel and that help them understand why the Daubert expert's testimony is unreliable. In some instances, it may be helpful to have the defense expert point out the absurdity of the Daubert expert's testimony if taken to its logical extension.

Most important, the defense expert should be particularly adept at explaining the rationale of the Bradford-Hill criteria and their acceptance within the medical community as the standard methodology for reaching conclusions regarding causal relationships between environmental exposures and chronic diseases.

#### **MOTIONS FOR RECONSIDERATION AND/OR TO STRIKE**

When an appellate court is asked to consider whether the trial court abused its discretion in admitting the testimony of a Daubert expert, the court will look at the entire record. In most cases, the defendant will want to rely on the evidence introduced by its experts to argue that the plaintiff's expert's testimony was unreliable and therefore inadmissible. In order to be able to make this argument on appeal, it is prudent for defense counsel to move for reconsideration or to strike the Daubert expert's testimony before closing the defense case. This motion gives the trial court one last opportunity to evaluate the expert's testimony in the light of all of the evidence.

By not moving to strike, defense counsel invites the appellate court to find that the defense waived that portion of the Daubert challenge that relies on evidence admitted after the challenge was denied.

#### **CONCLUSION**

*Daubert* offers counsel facing junk science testimony an excellent opportunity to have the testimony excluded. To be successful, counsel must first lay a foundation in the expert's deposition that the testimony does not comport with the scientific method for one or more of the reasons outlined in *Daubert*.

Varying circumstances affect whether pretrial Daubert hearings are tactically advantageous. The key to obtaining a favorable ruling is being able to teach the court effectively about the scientific method and demonstrate that the expert's opinion is based on data that were not derived consistent with sound, reliable scientific principles. If trial counsel does not give the court the knowledge it needs to reach the correct decision, there is little chance that the trial court can fulfill its "gatekeeper" function.

If a Daubert challenge is unsuccessful, counsel must consider the necessity of conducting a Daubert cross of the expert during trial or whether the record made during the hearing, as amplified by defense experts later in the case, will be sufficiently strong to allow counsel to eliminate cross. The potential for confusing the jury with a Daubert cross is real and must be considered carefully before beginning the cross-examination.