EXPERT EVIDENCE—LAW, STRATEGIES
AND BEST PRACTICES

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§29:1 OVERVIEW

The large majority of product cases involve at least some scientific or technical evidence. The matter may be framed as whether the plaintiff was exposed at all to the product, the extent of the exposure, the nature of the harm that the exposure may cause, what aspect of the product design, manufacture, or labeling was defective (or not), what the plaintiff may or may not have been able to do to prevent harm, and a host of related questions boiling down to this issue: as a scientific matter, did the product cause the harm?

In the courtroom, juries will provide answers to these questions—whether the science or technology involved in the claims or defenses is well settled or up for grabs. Recognizing the difficulty of harmonizing real-world science with evidentiary science, our courts have developed standards for allowing scientific and technical evidence to be presented to juries, with the goal of keeping courtroom science as close as possible to real-world science. Federal and state courts have offered a variety of approaches to the use of expert evidence in the courtroom, with much of the jurisprudence influenced by product litigation.

When product liability practitioners think of expert evidence, we typically fasten onto Daubert v. Merrell Dow Pharmaceuticals, the seminal federal decision regarding the standards for admissibility of expert testimony. Indeed, it is hard to overestimate the impact of Daubert on product litigation and vice versa. "Arguably the most significant civil case in the United States in the last quarter century," the decision "is largely a child of products liability."15

The case was conceived during the explosive growth in reliance upon expert testimony that came with the equally explosive growth of products liability, and it was birthed in one of products liability's early mass tort morasses: Bendectin litigation. Without products liability, there would have been no Daubert and

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there may have been relatively little perceived need for a decision like Daubert.\textsuperscript{5}

It has been suggested that Daubert and its progeny not only reflect evolution in the law of products liability, but actually are driving how substantive common law develops in the area of product liability law. “Substance and procedure are not neatly separated in the real world of products liability. The broader goal of justice renders them inextricably intertwined, and a significant change to one must be felt by the other as well.”\textsuperscript{6}

No doubt Daubert has occupied a wide field. But as important as Daubert has become in battles over expert testimony, the world of expert evidence in product litigation extends beyond Daubert. The main reason is that states with large product litigation dockets—whether styled as negligence, strict liability, consumer fraud, or warranty claims—continue to adhere to standards arising from Frye v. United States\textsuperscript{7} or their own unique standards for admissibility of expert testimony. And, a number of factors other than the legal bases for admissibility also bear on when and whether expert evidence will be admitted and persuasive.

In this chapter, we provide an overview of the basic rules governing expert testimony and how the law impacts strategies and best practices for product litigation.

§29:2 STANDARDS FOR ADMISSIBILITY OF EXPERT OPINIONS: DAUBERT, FYRE, OR SOMETHING ELSE?

§29:2.1 Frye and Daubert

The principal hurdle for expert evidence is whether it may be admitted and presented to a jury. Initially, in the 1960s when state courts began to allow plaintiffs to pursue product liability claims, the prevailing standard for admissibility of scientific expert evidence was that set forth in Frye, which requires expert testimony to be deduced from principles “sufficiently established to have gained general acceptance in the particular field in which it belongs.”\textsuperscript{8} Decided before the adoption of either the Federal Rules of Civil Procedure or the Federal Rules of Evidence, and in the infancy of modern science, Frye involved the admissibility of data gathered from a systolic blood

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5. Id.
6. Id. at 517.
8. Id. at 1014.
pressure test, which was at the time generally relied upon to distinguish truthful statements from false ones, and was a precursor to polygraph testing. In affirming the exclusion of a scientist's testimony about the test results, the appellate court concluded:

We think the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development and experiments thus far made.

In essence, if proffered opinions were based on theories and methods that were "generally accepted" in the scientific community, then the opinions could be presented to the jury. The focus was on mainstream theories and methods as the means of separating reliable from unreliable opinions.

Although Frye was decided in a criminal context, it received widespread applicability in product liability cases, becoming the rule in federal and most state jurisdictions. In the ensuing years, many courts and scholars noted its advantages and disadvantages. Among the advantages is that judges need not spend time considering the validity of the theories and techniques underlying expert testimony. Frye "promote[s] a degree of uniformity of decision. Individual judges, whose particular conclusions may differ regarding the reliability of particular scientific evidence, may discover substantial agreement and consensus in the scientific community." Among the disadvantages, however, are "the difficulty in determining which scientific community deserved deference; the conservatism supposedly inherent in waiting for a theory's general acceptance; and the difficulty courts faced in deciding what must be accepted, what constitutes the relevant field of science, and what demonstrates acceptance." Courts have criticized Frye for being too rigid, preventing the admission of relevant, albeit innovative views simply on the ground that they are not generally accepted.

9. Id. at 1013.
10. Id. at 1014.
In 1993, the U.S. Supreme Court issued the seminal *Daubert* decision, setting forth the standards that apply in all federal cases for the admissibility of expert opinions. *Daubert* happened to be a product liability case. The parents of two children with birth defects sued the defendant drug manufacturer claiming that the children’s exposures to “Bendectin,” an anti-nausea drug taken by their mothers during the first trimester of pregnancy, had caused their birth defects. Defendant Merrell Dow submitted expert opinions showing that of the more than thirty published scientific studies about Bendectin and birth defects, involving over 130,000 patients, no study had found Bendectin to be a human teratogen (that is, a substance capable of causing malformations in fetuses). On the basis of this review, the defense expert concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.

In an effort to prove causation, the *Daubert* plaintiffs submitted opinions based on “*in vitro* (test tube) and *in vivo* (live) animal studies that found a link between Bendectin and malformations; pharmacological studies of the chemical structure of Bendectin that purported to show similarities between the structure of the drug and that of other substances known to cause birth defects; and the ‘reanalysis’ of previously published epidemiological (human statistical) studies.” Both the defense’s and plaintiffs’ experts were well credentialed.

The lower court concluded that the plaintiffs’ expert opinions were rooted in methodologies that were not generally accepted and excluded them. In granting summary judgment to the defendant, the district court looked to the large body of epidemiological data concerning Bendectin and rejected as inadmissible expert opinions about causation that were not based on epidemiological evidence, including the animal cell studies, live animal studies, and chemical structure analyses on which petitioners had relied. The plaintiffs’ recalculation of data in previously published studies did not pass muster, either, because they had not been published or subjected to peer review.

16. *Id.* at 579.
17. *Id.* at 582.
18. *Id.*
19. *Id.* at 583.
20. *Id.*
21. *Id.* at 583–84.
22. *Id.*
Circuit, affirming, also questioned the admissibility of data that were generated solely for the purpose of litigation.\textsuperscript{23}

The plaintiffs appealed, arguing, among other things, that \textit{Frye} was not the standard for admissibility of expert testimony under the Federal Rules of Evidence. In accepting review, the U.S. Supreme Court took the occasion to announce new and comprehensive standards for when expert opinions may be presented to the jury under the Federal Rules of Evidence. Rejecting \textit{Frye}, the Court emphasized that the standards for admissibility of expert testimony flow from the Federal Rules of Evidence, not federal common law, and explained the guiding factors under Rule 702, which are discussed below.

\section*{\S 29:2.2 Admissibility Under Rule 702}

\subsection*{[A] Federal Evidence Rules to Be Construed Against "Permissive Backdrop"}

The federal evidence rules are to be construed against a "permissive backdrop."\textsuperscript{24} Federal Rule of Evidence 702, admissibility of expert opinions and the basis for those opinions did not depend on general acceptance. "\textit{Frye} made 'general acceptance' the exclusive test for admitting expert testimony. That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials."\textsuperscript{25}

\subsection*{[B] Trial Court As Evidentiary Gatekeeper}

The trial court must play the role of evidentiary gatekeeper. The Court expressly assigned to the trial judge the task of ensuring "that any and all scientific testimony or evidence admitted is not only relevant, but reliable."\textsuperscript{26} This means determining "at the outset" whether the expert "is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the

\footnotesize{\begin{enumerate}
\item Id. at 584.
\item Id. at 588.
\item Id. at 589.
\item Id.
\end{enumerate}}
facts in issue.” The gatekeeping focus is on the expert’s principles and methodology, not the conclusions that are generated.

This standard is relaxed in bench trials where the judge serves as the fact-finder. The trial court’s role as evidentiary gatekeeper protects juries from “a barrage of questionable scientific evidence,” and being “awestruck by the expert’s mystique.” Those concerns are “largely irrelevant in the context of a bench trial.” As the Eleventh Circuit has stated, “[t]here is less need for a gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself.” However, the reliability “determinations must still be made at some point,” and the court must “provide more than just conclusory statements of admissibility or inadmissibility to show that it adequately preformed its gatekeeping function.”


There are multiple factors to be used in determining the reliability of expert scientific testimony, without any preconceived notion of what the factors must be or their weight. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. Nonetheless, the Court proceeded to provide a non-exclusive list of four factors—and, in practice, these following factors have been treated as akin to a checklist:

1. *Whether a theory or technique can be and has been tested empirically.*

2. *Whether the theory or technique has been subjected to peer review and publication.* While not dispositive, nonetheless,
“submission to the scrutiny of the scientific community is a component of ‘good science,’ in part because it increases the likelihood that substantive flaws in methodology will be detected."39

3. The known or potential rate of error.40 This factor is more pertinent to the testing and technical results that may be presented in court, or that underlie a theory.

4. The existence and maintenance of governing standards and controls for applying the theory or technique.41

5. General acceptance. “General acceptance,” which “can yet have a bearing on the inquiry.” At the same time, a “reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community."42

[D] Other Evidentiary Rules

Other evidentiary rules bear on admissibility of expert testimony. Considerations apart from Rule 702 come into play, including those of relevance under Federal Rule of Evidence 403, admissibility of information relied upon by the expert under Rule 703, and use of court-appointed experts under Federal Rule of Evidence 706.

§29:2.3 Daubert and Its Progeny

[A] Generally

Subsequent decisions amplified Daubert. In General Electric v. Joiner,43 the Court held that Daubert rulings are to be reviewed on appeal under an “abuse of discretion” standard. This puts a

41. Id. at 592–95.
42. Id. at 596–97 (quoting United States v. Downing, 753 F.2d 1224, 1238 (3d Cir. 1985)).
great deal of weight on the decisions made by the district judge regarding scientific methods and theories.

In *Kumho Tire Co. v. Carmichael*, the Supreme Court extended the standards to virtually all expert evidence under Rule 702, both technical as well as scientific. The *Kumho* expertise concerned tire failure analysis, with an opinion based upon a visual and tactile inspection of the tire, and the theory that in the absence of at least two of four specific, physical symptoms indicating tire abuse, the tire failure was caused by a defect. The Court upheld the exclusion of the tire failure analyst’s opinions, affirming the district court’s opinion that the expert failed to satisfy either *Daubert*’s factors or any other set of reasonable reliability criteria. In applying the *Daubert* standards to opinions outside the scope of traditional science, the Supreme Court observed that there was no clear distinction between “scientific” and “technical” knowledge. “Pure scientific theory itself may depend for its development upon observation and properly engineered machinery. And conceptual efforts to distinguish the two are unlikely to produce clear legal lines capable of application in particular cases.” In any event, we note that it is more efficient to have one test for all expert opinions, especially since both scientific and technical knowledge are typically outside the knowledge of the average juror.

These days, virtually any expert opinion offered in the federal courts must pass muster under Rule 702’s *Daubert* approach. As the Advisory Committee commented:

> The fields of knowledge which may be drawn upon are not limited merely to the “scientific” and “technical” but extend to all “specialized” knowledge. Similarly, the expert is viewed, not in a narrow sense, but as a person qualified by “knowledge, skill, experience, training or education.” Thus within the scope of the rule are not only experts in the strictest sense of the word, e.g., physicians, physicists, and architects,

45. Id. at 137.
46. Id. at 137–39.
47. Id. at 148 (citing Brief for National Academy of Engineering as Amicus Curiae at 9 (Aug. 21, 1998); Brief for Rubber Manufacturers Ass’n as Amicus Curiae at 14–16 (Aug. 24, 1998); Brief for John Allen et al. as Amici Curiae at 6 (Aug. 25, 1998)).
but also the large group sometimes called "skilled" witnesses, such as bankers or landowners testifying to land values.\textsuperscript{49}

The Supreme Court also has made clear that challenges to expert testimony may be made even after trial. In \textit{Weisgram v. Marley Co.},\textsuperscript{50} the Court held that when expert evidence has been erroneously admitted and the remaining evidence is insufficient to support a verdict, then the appellate court may direct the entry of judgment as a matter of law. Presumably, a trial court may also enter a post-trial judgment notwithstanding the verdict (j.n.o.v.).

At the time, it appeared that \textit{Daubert} might liberalize admissibility standards by providing several different avenues by which expert evidence could be judged.\textsuperscript{51} In retrospect, however, many believe that the application of \textit{Daubert} standards has made admissibility of expert evidence more rigorous,\textsuperscript{52} although this view may be affected as much by the gatekeeping role required of judges under a \textit{Daubert} regime—not typically found to the same extent in \textit{Frye} jurisdictions—as the actual standards. At least one commentator concluded: "Despite all its rhetoric about liberality, truth be told, \textit{Daubert} has undergone a rather illiberal evolution."\textsuperscript{53} Defendants have generally benefited from application of \textit{Daubert} in two respects: (1) the standards are more likely to preclude "junk science"; and (2) because of the court's gatekeeping duty, it is much more likely for a defendant to receive summary judgment on the ground that there is no admissible expert evidence to sustain a claim. One study concluded that not only were judges more likely to evaluate the reliability of expert evidence as a result of \textit{Daubert},

\begin{itemize}
\item \textsuperscript{49} Fed. R. Evid. 702 advisory committee's note.
\item \textsuperscript{50} Weisgram v. Marley Co., 528 U.S. 440 (2000).
\item \textsuperscript{52} Id. at 472–73.
\item \textsuperscript{53} D. Arthur Kelsey, \textit{Virginia's Answer to Daubert's Question Behind the Question}, 90 JUDICATURE 68 (Sept.–Oct. 2006); see also RESOCE POUND FOUND., REPORT OF THE 1997 FORUM FOR STATE COURT JUDGES, SCIENTIFIC EVIDENCE IN THE COURTS: CONCEPTS AND CONTROVERSIES 117 (1997) ("Most people thought that the \textit{Daubert} rule was initially supposed to be liberalizing the admissibility of testimony, but that has not always been true.").
\end{itemize}
they were also more likely to find the expert evidence unreliable.\textsuperscript{54} In response, parties proffering expert evidence appear to have become more adept at tailoring their evidence to the new standards, and as a result, after an initial rise in the percentage of challenged evidence found unreliable, that percentage has since declined.\textsuperscript{55} However, the study was unable to determine conclusively whether Daubert has led to improvements in the quality of evidence admitted, or if the decrease was a result of more aggressive Daubert challenges that were therefore less likely to succeed.\textsuperscript{56}

Under the federal rules, there is no presumption that an expert is competent or that her opinion is admissible simply because she is qualified to give an opinion. For example, a treating physician who is well-qualified to treat the condition at issue may not be allowed to opine as to the cause of that condition.\textsuperscript{57} Even a Nobel Prize does not give the witness a pass from judicial scrutiny.\textsuperscript{58} At the same time, the witness' own assessment that he lacks expert qualifications does not necessarily preclude the testimony. Even when the witness does not consider himself to be an expert in the particular field at issue, "that self-assessment is, standing alone, insufficient to conclude that [the purported expert witness] may not give expert testimony."\textsuperscript{59} Self-assessment serves only as a factor in determining whether the proposed testimony meets the requirements of Rule 702.\textsuperscript{60}

Federal Rule of Evidence 702, amended post-Daubert, now provides that a witness qualified as an expert may testify in the form of an opinion if:

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\textsuperscript{54} L. Dixon & B. Gill, RAND Institute for Civil Justice, Change in the Standards of Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision xiii (2001).
\textsuperscript{55} Id.
\textsuperscript{56} Id.
\textsuperscript{58} See, e.g., In re Brand Name Prescription Drugs Antitrust Litig., 1999 WL 33889, at *10–11 (N.D. Ill. Jan. 19, 1999) (excluding the testimony of Nobel Prize–winning economist because, among other defects, his opinions in the case were offered without scientific basis or economic methodological testing), aff'd in part and vacated in part, 186 F.3d 781 (7th Cir. 1999).
\textsuperscript{59} Thomas, 443 Fed. App'x 58 at 62.
\textsuperscript{60} Id.
(1) the testimony is based upon sufficient facts or data,
(2) the testimony is the product of reliable principles and methods, and
(3) the witness has applied the principles and methods reliably to the facts of the case.\(^\text{61}\)

Among other things, if the facts or data upon which an expert bases an opinion or inference are of a type reasonably relied upon by experts in the particular field in forming an opinion or inferences upon the subject, then the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.

The Federal Rules Committee identified the following five other inquiries (consistent with court decisions) to be considered in performing the gatekeeping function:

(1) whether the testimony concerns matters growing naturally and directly out of research the expert has conducted independent of the litigation or whether the expert has developed her opinions for the litigation;
(2) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion;
(3) whether the expert has adequately accounted for obvious alternative explanations;
(4) whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting; and
(5) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.\(^\text{62}\)

\(^{61}\) See also FED. R. EVID. 702 advisory committee's note (2000 Amendments).
\(^{62}\) id.
[B] **Recent Decisions About Admissibility of Expert Opinions**

While the *Daubert* product liability decision by the U.S. Supreme Court spawned the modern federal approach to expert evidence, today's opinions on expert evidence may stem from cases outside the product arena. The Court recently addressed expert evidentiary standards in civil litigation in dictum in *Wal-Mart Stores, Inc. v. Dukes*, in which it decertified a nationwide class of over 1.6 million women who sued Wal-Mart for gender discrimination. The *Wal-Mart* Court found, among other things, that plaintiff's expert sociological studies based on the new and sometimes controversial technique of "social framework analysis" were insufficient to establish that a culture of discrimination existed at Wal-Mart on a nationwide basis. The Court noted that the district court had concluded that *Daubert* did not apply in a class certification hearing, and remarked "We doubt that is so." *Daubert* challenges to expert testimony at the class certification stage have already arisen, and more are expected, as a result of this brief comment.

Lower courts are currently split as to whether a *Daubert* ruling is needed prior to class certification and if so, the extent of the review. Since *Wal-Mart*, two U.S. Courts of Appeal have issued 2-1 decisions holding that final, conclusive *Daubert* hearings are not needed at the class certification stage. The Eighth Circuit, affirming certification of a Minnesota-wide class of homeowners who purchased a defective plumbing system, rejected the defense's argument for "an early full and conclusive *Daubert* review" of plaintiffs' engineering and statistical experts in favor of a "no[n] final," "focused *Daubert* inquiry" subject to reconsideration at trial. The dissent noted that the *Wal-Mart* dictum "expressed disapproval of the position taken by the court today" and argued that the district judge should have conducted a full, conclusive *Daubert* hearing.

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63. While this section discusses some key recent developments in the product liability field, it is not an exhaustive discussion of every such decision in the past year.


65. 131 S. Ct. at 2553-55.

66. *id.* at 2554.

67. *In re Zurn Pex Plumbing Prods. Litig.*, 644 F.3d 604, 609, 611 (8th Cir. 2011).
before certifying the class. A dissenting opinion argued that the expert’s testimony should have been excluded after a full, early Daubert hearing. On June 25, 2012, the U.S. Supreme Court granted certiorari, limited to the question, “Whether a district court may certify a class action without resolving whether the plaintiff class has introduced admissible evidence, including expert testimony, to show that the case is susceptible to awarding damages on a class-wide basis.”

In contrast to this line of cases is the approach taken by two appellate courts in decisions rendered shortly prior to Wal-Mart. The Seventh Circuit now requires judges to conduct a conclusive, early Daubert inquiry in cases where an expert’s testimony is critical to class certification. After Wal-Mart, the Seventh Circuit reaffirmed its approach and held that if the trial judge is unsure whether the expert opinion may be “critical” for class certification, “the court should make an explicit Daubert ruling. An erroneous Daubert ruling excluding non-critical expert testimony would result at worst in the exclusion of expert testimony that did not matter. Failure to conduct such an analysis when necessary however, would mean that the unreliable testimony remains in the record.”

The Eleventh Circuit found the Seventh Circuit’s approach persuasive and also signaled its preference for a conclusive Daubert ruling prior to class certification. Following Wal-Mart, the Ninth Circuit, in Ellis v. Costco Wholesale Corp., appeared to have

68. Id. at 626–29 (Gruender, J., dissenting).
70. Id. at *96–101 (Jordan, J., concurring in part and dissenting in part).
72. Am. Honda Motor Co. v. Allen, 600 F.3d 813 (7th Cir. 2010).
73. Messner v. Northshore University Health System, 669 F.3d 802, 812 (7th Cir. 2012).
75. Ellis v. Costco Wholesale Corp., 657 F.3d 970, 982-84 (9th Cir. 2011).
implicitly accepted that a full Daubert inquiry is necessary at the certification stage. However, district courts in the Ninth Circuit have interpreted the holding in Ellis differently.76

One repeated theme in recent appellate decisions is the case-by-case nature of Daubert hearings and the trial judge’s primary gatekeeping responsibility. According to the First Circuit: “Exactly what is involved in ‘reliability’ was not and could not have been filled out by Daubert. Rather, the answers must come from developing case law in adjudicating individual controversies.”77 Similarly, the Seventh Circuit, affirming summary judgment against a railroad worker who brought a personal injury claim against his old employer, rejected plaintiff’s expert physician’s differential diagnosis methodology and stated that “the question of whether it is reliable under Daubert is made on a case-by-case-basis, focused on which potential causes should be ‘ruled in’ and which should be ‘ruled out.’”78 Likewise, when allowing testimony of a defense expert trauma surgeon in a Section 1983 civil rights case, the Seventh Circuit emphasized “that it is the district court’s role to act as a gatekeeper before admitting scientific testimony.”79

One case with potentially far-reaching implications for products litigation is the First Circuit’s decision in Milward v. Acuity Specialty Products Group,80 in which it admitted testimony of an expert toxicologist and molecular epidemiologist who claimed that there was a causal link between plaintiffs’ acute promyelocytic leukemia (APL) and the defendant’s benzene-containing products. The expert opined that benzene exposure caused plaintiffs’ disease based on a “weight of the evidence” approach using six “general steps”: (1) identifying association between exposure and disease; (2) considering a range of plausible explanations for the association; (3) ranking the explanations according to plausibility; (4) seeking

76. Compare Keegan v. American Honda Motor Co., Inc. 2012 W1 2250040 *4 (C.D. Cal. June 12, 2012) (“After Dukes, the Ninth Circuit approved the application of Daubert to expert testimony presented in support of or opposition to a motion for class certification.”), with Fosmire v. Progressive Max Ins. Co., 277 F.R.D. 625, 629 (W.D. Wash. October 11, 2011) (concluding that the Ninth Circuit has not yet resolved whether a full Daubert analysis is required, and adopting the Eighth Circuit’s In re Zurn Pex “focused Daubert analysis”).
additional evidence to separate the more plausible from the less plausible explanations; (5) considering all relevant available evidence; and (6) integrating the evidence using his “professional judgment” to reach his conclusion about the “best possible explanation.” The court likened this “weight of the evidence” methodology to a physician’s “differential diagnosis,” which it found a reliable basis for expert testimony. Using his “weight of the evidence” methodology, the expert reviewed five different peer-reviewed publications, picked the best explanation according to his scientific judgment, and concluded that “benzene exposure is capable of causing APL.” Overtaking the lower court’s carefully reasoned decision to exclude the testimony, the First Circuit found the expert reliable despite a “lack of statistically significant epidemiological evidence” supporting a link between benzene exposure and APL, reasoning that APL is so rare and expensive to study that it would be “very difficult” to perform any meaningful epidemiological study of its causes. Milward could make it easier for future plaintiffs’ experts to testify about causation based on “weight of the evidence” supporting the “best possible explanation” in the absence of generally accepted epidemiological evidence—particularly where the plaintiff is suffering from a newly discovered or very rare disease.

Other recent cases of interest include rulings in multidistrict litigation (MDL).

In a case within an MDL involving unintended acceleration of Toyota cars, a California federal judge denied defendants’ Daubert challenges to two of plaintiffs’ experts. The experts testified that data relating to the crash contained in the car’s Event Data Recorder (EDR) could potentially have been altered. Defendants argued that the opinions were not reliable because they were not based on scientific method or reasoning. The judge ruled that the opinions were sufficiently reliable because the experts were “clearly qualified,” and their testimony “concern[ed] only the possibility for tampering with or altering the EDR data rather than any actual alteration of

81. Id. at 15.
82. Id.
83. Id. at 22.
84. Id. at 36.
the data." In reaching its ruling, the court cited Ninth Circuit precedent for the proposition that the Daubert factors, focused on peer review, publication, and the testability of methodologies, are "neither necessarily nor exclusively" required to determine reliability, and may be "simply inapplicable" in certain contexts. A New York federal court in an MDL bellwether trial ruled on five Daubert motions in connection with plaintiffs’ claims that a prescription drug caused osteonecrosis of the jaw (ONJ). The MDL court admitted testimony of three experts: (1) plaintiff's oral surgeon who reviewed her medical records to diagnose her date of injury and opined that the drug injured the plaintiff; (2) the manufacturer's expert oral surgeon who testified about the "background rate" for ONJ and the date of onset of plaintiff's injury; and (3) a defense expert rheumatologist who conducted clinical trials, reviewed various peer-review studies, and concluded there was no link between ONJ and the drug. Two plaintiff's experts were excluded, both of whom were other physicians who relied exclusively on plaintiff's lead testifying expert.

[C] Differences Between Daubert and Frye

It is hard to overestimate the impact of Daubert on product litigation in federal courts. In our American system of justice—where it is rare for the court to retain an independent expert to advise on matters of science—plaintiffs look to their experts to sustain their case, and defendants look to their experts to defeat the claims. To some extent, the federal standard may favor defendants in product litigation, especially manufacturers. They, after all, are familiar not just with their products but are also true experts in fields bearing on the design, manufacture, and sale of products. Indeed, manufacturers may employ some of those very experts. At the same time, manufacturers may also be aware of experts who are less than rigorous in their own work. In addition, manufacturers are

86. Id. at *13 (emphasis in original).
87. Id. at *13 (citing United States v. Hankey, 203 F.3d 1160, 1169 (9th Cir. 2000); and Primiano v. Cook, 598 F.3d 558, 567 (9th Cir. 2010)).
90. Id. at *31.
often (but not always) insured for their defense costs, making retention and detailed work with an expert not an out-of-pocket expense, as it is for plaintiffs. In almost all jurisdictions, experts may not be compensated on a contingency basis, which means that there are real costs associated with expert work. Even without insurance, companies have the resources to develop expert evidence, while most plaintiffs do not (although there are very successful plaintiffs' counsels who do).

While all federal courts must follow the *Daubert* approach to admissibility of expert evidence, the states have continued to pursue their own jurisprudence. The result is a patchwork of standards. Many states have certainly been influenced by and some have expressly adopted *Daubert* standards. Other states continue to follow *Frye*, and some follow their own expert jurisprudence. The impact on product liability law is substantial, as many product cases are filed in state court. In the typical personal injury case, only if the elements of diversity jurisdiction are met may such cases be removed to federal court and enjoy the benefits of the federal procedures regarding expert evidence.

The differences between *Daubert* and *Frye* show up in a number of dimensions. First, under *Daubert*, the court plays a strong gatekeeping role in determining whether an expert's opinion will be admitted. That is not typically the case under the *Frye* standard, where the concept of "generally accepted," by its nature, places the decision about credibility and validity of an opinion in the hands of the scientific community. The expanded role of the court in assessing the reliability and validity of scientific evidence puts additional burdens on trial judges. Similar to lawyers, trial judges come with a variety of educational backgrounds, typically not scientific in nature or at least not in the specific area at issue in a given case. The *Frye* test is easier for courts to administer and requires less scientific sophistication from judges, as admissibility depends on a judgment by the expert himself and not the court as to whether a particular theory is generally accepted. On the flip side,

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91. For a state-by-state evaluation of the standards used by Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, and Texas, see infra section 29:3. For a summary chart of the admissibility standards for the fifty states and the District of Columbia, see infra Appendix 29A.
because there are fewer indicia of reliability, a Frye standard is subject to potential manipulation insofar as there are not clear-cut standards for when a theory is generally accepted.

Second, Daubert shifts the question away from whether a theory is novel or generally accepted, to whether there are sufficient indicia of the reliability and validity of the proffered scientific opinions, regardless of novelty. There are many different criteria that a court may use in its gatekeeping role to determine admissibility; none of which is mandated or dispositive. Indeed, under Daubert's "flexible" approach, each expert in each case deserves a full hearing on whether the testimony is based on sufficient facts, whether the testimony rests on reliable principles and methods, and whether the witness has applied the principles and methods reliably to the facts of the case. In that regard, the Daubert approach better tracks the evolution of scientific theory and methods. In contrast, Frye takes a relatively conservative approach to admissibility and could more readily reject innovative theories as not "generally accepted," even if there are other indicia of the new theory's reliability.

Third, Daubert imposes the same standards for evaluating opinions regardless of the field of expertise. This is different from the older Frye approach, which has no consistent standards for gauging what is generally accepted, and, therefore, what may be admissible from field to field. Some areas of science may have rigorous standards for what is generally accepted; other fields may have more lax standards. For example, the field of fingerprint analysis is generally accepted, including the notion that the technique has a zero error rate. But, as one recent report points out, the error rate may be substantially greater than zero because of the human element in interpreting real-world fingerprint impression. 92

§29:3 EXEMPLAR STATES

We provide a chart of each state’s approach to expert testimony in infra Appendix 29A. Here, we review examples of the standards that larger states use in determining the admissibility of expert evidence.

§29:3.1 Arizona

Until recently, it was clear that Arizona courts would apply the Frye standard, which the Arizona Supreme Court had reaffirmed in a 2000 decision that flatly rejected the Daubert standard and the Daubert court’s legal reasoning.93

In 2010 (largely in response to criticisms of the 2000 decision), the Arizona legislature passed a statute that expressly applies the Daubert standard to admissibility of expert testimony.94 At least one state appellate court, however, has ruled that this attempt to “codify Daubert” was an improper usurpation of the Arizona Supreme Court’s rulemaking authority that violated the separation-of-powers provisions of the Arizona constitution.95

In 2012, the Arizona Supreme Court amended Arizona Rule of Evidence 702 to adopt the Daubert standard and Federal Rule of Evidence 702.96 The new rule makes trial courts the “gatekeepers,” but leave traditional determinations of credibility and weight afforded to admissible testimony to the jury.97 The current rule allows an expert qualified by knowledge, skill experience, training, or education to testify in the form of an opinion if:

(1) “the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue”;

(2) “the testimony is based on sufficient facts or data”;

(3) “the testimony is the product of reliable principles and methods”;

(4) “the expert has reliably applied the principles and methods to the facts of the case.”98

This marks a “notable departure from Arizona’s former test for admissibility of expert testimony.”99 Arizona’s courts have looked to decisions in federal courts applying Daubert for guidance in applying the new rule.100

96. See Ariz. R. Evid. 702 advisory committee comment (2012 Amendment).
97. Id.
98. Ariz. R. Evid. 702.
100. Id. at *2.
§29:3.2 California

California has rejected Daubert and applies its own version of Frye based on People v. Kelly. The so-called Kelly/Frye test requires that the following exist:

1. "the reliability of the method must be established, usually by expert testimony";

2. "the witness furnishing such testimony must be properly qualified as an expert to give an opinion on the subject"; and

3. "the proponent of the evidence must demonstrate that correct scientific procedures were used in the particular case."

The Kelly court opined that the primary advantage of Frye "lies in its essentially conservative nature":

For a variety of reasons, Frye was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles. "There has always existed a considerable lag between advances and discoveries in scientific fields and their acceptance as evidence in a court proceeding." Several reasons founded in logic and common sense support a posture of judicial caution in this area. Lay jurors tend to give considerable weight to "scientific" evidence when presented by "experts" with impressive credentials. We have acknowledged the existence of a "...misleading aura of certainty which often envelops a new scientific process, obscuring its currently experimental nature." In the course of rejecting the admissibility of voiceprint testimony, "scientific proof may in some instances assume a posture of mystic infallibility in the eyes of a jury."

Kelly also noted that "a beneficial consequence of the Frye test is that it may well promote a degree of uniformity of decision. Individual judges whose particular conclusions may differ regarding the reliability of particular scientific evidence, may discover substantial agreement and consensus in the scientific community."

More recently, in People v. Leahy, the California Supreme Court explained why there is "no compelling reason for abandoning Kelly in

102. Id. at 1244.
103. Id. at 1245 (citations omitted).
104. Id. at 1244–45 (citing Comment, The Voiceprint Dilemma: Should Voices Be Seen and Not Heard?, 35 Mt. L. Rev. 267, 290 (1975)).
favor of the ‘flexible’ approach outlined in Daubert.” Among other things, the Kelly/Frye test, “while not perfect,” has acted to keep “unreliable evidence from the jury.” In another recent decision (which allowed testimony from a prosecution ballistics expert), the court reinforced the distinction between expert testimony based on “old technique(s)” or “basic science” and “new” or “foreign” techniques, stating that “Kelly applies only to ‘that limited class of expert testimony which is based, in whole or part, on a technique, process, or theory which is new to science and, even more so, the law.”

Application of the Kelly/Frye test may be seen in the product liability context. For example, in Roberto v. Andy’s Termite & Pest Control, Inc., involving a claim that the defendant’s pesticide caused the plaintiff’s son’s autism, the plaintiff’s experts had been excluded by the trial court, which had deemed their opinions to be “novel” and not generally accepted. Under a proper application of the Kelly/Frye test, however, the expert’s methods, not his conclusions, are the focus of the analysis. On that basis, the appellate court found that the experts’ methods were generally accepted, including such methods as analysis of peer-reviewed studies and medical examinations of the plaintiff. “It was the theory of causation, that [the defendant’s pesticide] caused plaintiff’s autism, that has not gained general acceptance in the relevant medical community. The Kelly test is not applicable even though the proffered evidence presents a new theory of medical causation.”

In O’Neill v. Novartis Consumer Health, Inc., involving a claim that the defendant’s nasal decongestant containing phenylpropanolamine (PPA) caused strokes, the plaintiffs challenged defense expert testimony on the ground that it was based on novel methodology. The experts had attacked certain clinical research by

106. Id. at 324.
107. Id. at 328.
110. Id. at 829–30.
111. Id. at 831–32.
112. Id. at 832.
113. Id. (emphasis added).
looking only at cases of exposure to the drug and not control cases.\textsuperscript{115} The appellate court, however, affirmed the ruling below that criticism of a study design, which amounts to criticism of the “professionalism” with which the study methodology is applied, is not the same as reliance on improper new scientific methods.\textsuperscript{116}

\textbf{§29:3.3 Florida}

The leading modern Florida case is \textit{Castillo v. E.I. du Pont de Nemours & Co.},\textsuperscript{117} which affirmed Florida’s continuing use of the Frye general acceptance standard. \textit{Castillo} involved a child’s \textit{in utero} exposure to a pesticide, which allegedly entered the mother’s bloodstream and caused microphthalmia (“a rare birth defect involving severely underdeveloped eyes, in her unborn son”\textsuperscript{118}). The plaintiff’s expert relied on animal and \textit{in vitro} laboratory studies to extrapolate data about the levels of exposure needed to cause birth defects. In reversing the lower court’s decision to exclude the plaintiff’s expert evidence, the \textit{Castillo} court reemphasized that the Frye focus should be on the general acceptance of the underlying scientific methods, not the opinions themselves.\textsuperscript{119}

Relatively recently, Florida reaffirmed the use of Frye in \textit{Marsh v. Valyou},\textsuperscript{120} a tort case, emphasizing that “[d]espite the federal adoption of a more lenient standard in [Daubert], we have maintained the higher standard of reliability as dictated in Frye.”\textsuperscript{121} We also note that even while adhering to Frye, some Florida courts have incorporated Daubert-like factors into their analysis.\textsuperscript{122}

\textsuperscript{115} \textit{Id.} at 558–59.
\textsuperscript{116} \textit{Id.} at 560.
\textsuperscript{117} Castillo v. E.I. du Pont de Nemours & Co., 854 So. 2d 1264 (Fla. 2003).
\textsuperscript{118} \textit{Id.} at 1265.
\textsuperscript{119} \textit{Id.} at 1276.
\textsuperscript{120} Marsh v. Valyou, 977 So. 2d 543, 547 (Fla. 2007).
\textsuperscript{121} \textit{Id.} (quoting Brim v. State, 695 So. 2d 268, 271–72 (Fla. 1997)); \textit{see also} Lbar v. State, 938 So. 2d 451, 467 (Fla. 2006) (same); Hadden v. State, 690 So. 2d 573, 578 (Fla. 1993) (same); Flanagan v. State, 625 So. 2d 827, 829 n.2 (Fla. 1993) (same).
\textsuperscript{122} \textit{See e.g.}, Ramirez v. State, 810 So. 2d 836, 849–51 (Fla. 2002) (noting that the expert’s methodology had never been formally tested, subjected to credible peer review or subject to an established error rate—all factors emphasized in Daubert).
§29:3.4 Illinois

In Donaldson v. Central Illinois Public Service Co.,\textsuperscript{123} the Supreme Court of Illinois held that "Illinois law is unequivocal: the exclusive test for the admission of expert testimony is governed by the standard first expressed in Frye v. United States."\textsuperscript{124} In a toxic tort action, the Donaldson plaintiff alleged that defendants' remediation activities caused childhood cancer.\textsuperscript{125} The plaintiff's expert witnesses offered causation opinions based on, among other things, extrapolation of medical research that did not "specifically establish a cause and effect relationship" between the defendant's activities and cancer.\textsuperscript{126} On appeal, the defendants challenged the admission of such testimony and suggested that Illinois follow "the 'Frye-plus-reliability' standard . . . adopted by some appellate court panels."\textsuperscript{127} The Frye-plus-reliability approach had included such Daubert-like questions as the following:

1. Can the scientific technique or method employed be empirically tested, and if so, has it been?

2. Has the technique or method been subjected to peer review and publication?

3. What is the technique or method's known or potential error rate?

4. Are its underlying data reliable?

5. Is the witness proposing to testify about matters growing naturally and directly out of research she has conducted independently of the litigation, or has the witness developed her opinion solely for the purpose of testifying? and

6. Did the witness form her opinion and then look for reasons to support it, rather than doing research that led her to her conclusion?\textsuperscript{128}

Because the Central Illinois Public Service Company did not formally argue for "the adoption of a new standard consistent with the United States Supreme Court decision in Daubert," the Donaldson court did

\textsuperscript{124} Id. at 323.
\textsuperscript{125} Id. at 318.
\textsuperscript{126} Id. at 329.
\textsuperscript{127} Id. at 325 (citing Harris v. Cropmate Co., 706 N.E.2d 55 (Ill. 1999), and First Midwest Trust Co. v. Rogers, 701 N.E.2d 1107 (1998)).
\textsuperscript{128} Donaldson, 767 N.E.2d at 325 n.1 (citing Harris, 706 N.E.2d at 65).
not address the issue of adopting Daubert. Donaldson rejected the Frye-plus-reliability standard, and also clarified that "[t]he determination of the reliability of an expert's methodology is naturally subsumed by the inquiry into its general acceptance in the scientific community. Simply put, a principle or technique is not generally accepted in the scientific community if it is by nature unreliable."

Kane v. Motorola took a different approach to extrapolation, reaching in the direction of Daubert. Upholding the trial court's exclusion of plaintiff's experts, the appellate court offered the following analysis:

Plaintiffs' experts were unable to state how they extrapolated their conclusions from the scientific data upon which they relied or how the numerous dissimilar studies they cited to support their conclusions. They also acknowledged they had not conducted any independent tests or investigation... Plaintiffs' experts were unable to explain what steps they took or methodologies they used to extrapolate their opinions. A court is not required to accept any conclusion an expert may reach merely because the expert claimed the conclusion was extrapolated from generally accepted scientific data. An expert must be able to show the methodologies he employed to extrapolate his conclusion were sound. Plaintiffs' experts failed to do so.

The decision in Wartalski v. JSB Construction and Consulting Co. also sidesteps a Frye analysis. The Wartalski court held that expert testimony based on the opinion of a treating physician regarding the cause of his patient's condition is not subject to exclusion under Frye. Plaintiff's causation experts, both of whom were his treating physicians, opined that exposure to UV radiation from an uncovered construction light at a work site caused him to develop facial contractions and traumatic dystonia (repetitive, involuntary muscle contractions). Affirming the trial court's ruling that the "case did not present a Frye question," the appellate court explained that "Frye

129. Donaldson, 767 N.E.2d at 325 n.1.
130. Id. at 326.
131. Id.
133. Id.
135. Id. at 128.
136. Id.
137. Id. at 124.
applies in the case of admission of novel or new scientific evidence.

Because "medical testimony is not novel," the trial court's denial of defendants' motion to bar plaintiff's causation experts without conducting a formal Frye hearing was proper. Furthermore, defendants argued that plaintiff's experts merely relied on a "temporal relationship" methodology in concluding that plaintiff's exposure to UV radiation caused his injuries, which was not generally accepted. Despite defendants' contentions, the appellate court held that "a temporal relationship is, in fact, an acceptable basis for an expert's opinion."

In a recent opinion addressing expert admissibility, State v. McKown, the Illinois Supreme Court noted that the Frye test does not include "an additional element of reliability," and stated that courts should look only to "general acceptance in the scientific community" rather than "the reliability of the [expert's] methodology."

Illinois has adopted a de novo standard of review for reviewing the admissibility of expert testimony.

§29:3.5 Indiana

For many years, Indiana courts had looked to Daubert as a persuasive, although not controlling, test for admitting scientific testimony. In Steward v. State, the Indiana Supreme Court found that "Daubert coincide[s] with the express requirement of Indiana Rule of Evidence 702(b) that the trial court be satisfied of the reliability of the scientific principles involved. Thus, although not binding upon the determination of state evidentiary law issues, the federal evidence law of Daubert and its progeny is helpful to the bench and bar in

138. Id. at 128.
139. Id. at 124, 128.
140. Id. at 127.
141. Id. at 129.
142. State v. McKown, 24 N.E.2d 941 (Ill. 2010) (reasoning that horizontal gaze nystagmus tests administered to possible drunk drivers by police are generally admissible under Frye, but also holding that the prosecution failed to lay sufficient foundation for the officer's expertise by showing evidence of training and procedure).
143. Id. at 945 n.1.
144. People v. Simons (In re Commitment of Simons), 821 N.E.2d 1184 (Ill. 2004).
applying Indiana Rule of Evidence 702(b).”146 Because the Indiana Rules of Evidence differ from the Federal Rules of Evidence in the exact wording of their “reliability” requirement, the Daubert standard is “helpful, but not controlling” in Indiana.147

An Indiana appellate court went somewhat further, and found in 2011 that scientific testimony did not need to satisfy Daubert in order to be admissible in court. In Akey v. Parkview Hospital,148 the court admitted testimony of plaintiff’s expert cardiologist who had conceded that his theory about cause of death had not been scientifically tested, discussed in medical literature, or subjected to peer review, and that he had no idea whether his theory would be accepted by the medical community at large.149 The court gave great weight to the witness’s extensive training, education, and experience as a cardiac physician and found that the “witness’s education, experience, knowledge and training is adequate to permit the trier of fact to give such weight and credence to the opinion testimony as it is inclined to do” without “opening the door to ‘junk science.’”150 The Akey court characterized its opinion as “an acceptance that reasonable expert opinions are not to be summarily excluded on grounds that the opinion has not been subjected to general acceptance by others in the field or proved by testing and peer review. Such opinions, so long as not based wholly upon speculation and conjecture, are entitled to be given due consideration.”151 The Akey court’s apparent retreat from Daubert has led some practitioners in the state to predict that, going forward, “it will be easier for parties to introduce the opinions of experts who may not pass muster under Daubert.”152

Shortly after the Akey decision, in Turner v. State,153 a criminal case in which the testimony of a firearms and tool mark expert was challenged as unreliable under Daubert, the Indiana Supreme Court held that the expert testimony was admissible. In reaching its

146. Id. at 498.
149. Id. at 544–45.
150. Id. at 546.
151. Id.
153. 953 N.E.2d 1039 (Ind. 2011).
decision, the court noted that “it is not dispositive for our purposes whether [the expert’s] theory or technique can be and has been tested, whether the theory has been subjected to peer review and publication, or whether there is a known or potential error rate, and whether the theory has been generally accepted within the relevant field of study.”\(^{34}\) Reiterating that Daubert is “helpful, but not controlling, when analyzing testimony under Indiana Evidence Rule 702(b),"\(^{35}\) the court noted that “cross-examination permits the opposing party to expose dissimilarities between the actual evidence and the scientific theory. The dissimilarities go to the weight rather than to the admissibility of the evidence.”\(^{36}\) In short, in Indiana Daubert principles have some value, but are not dispositive for expert admissibility.

§29:3.6 Michigan

As a practical matter, Michigan has shifted its approach to expert admissibility issues from a Frye standard to a Daubert standard. In Gilbert v. DaimlerChrysler Corp.,\(^{37}\) the Michigan Supreme Court noted that Michigan Rule of Evidence 702 ("MRE 702") had been recently amended to incorporate the reliability standards under Daubert.\(^{38}\) Furthermore, the court recognized that before MRE 702 had been amended, Michigan courts determined expert admissibility according to the general acceptance standard of Davis-Frye.\(^{39}\) Although the Gilbert court did not expressly reject the Davis-Frye standard in Michigan, the court noted that “this modification of MRE 702 changes only the factors that a court may consider in determining whether expert opinion evidence is admissible.”\(^{40}\) Moreover, the court explained that the modification "has not altered the court's fundamental duty of ensuring that all expert opinion testimony—regardless of whether the testimony is based on 'novel' science—is reliable."\(^{41}\)

\(^{154}\) Id. at 1051.
\(^{155}\) Id. at 1050.
\(^{156}\) Id. at 1050 (citing Lyle v. Ford Motor Co., 696 N.E.2d 465, 476 (Ind. Ct. App. 1998)).
\(^{158}\) Id. at 408.
\(^{159}\) Id.
\(^{160}\) Id.
\(^{161}\) Id.
In addition, Michigan has adopted certain expert qualification criteria by statute. Relevant to product liability cases, section 600.2955 of Michigan’s Compiled Laws relies on factors articulated in Daubert, such as whether the opinion and its basis have been subjected to scientific testing and replication, peer review publication, known or potential error rates, and other Daubert standards for reliability.

In Edry v. Adelman, the Michigan Supreme Court applied the Daubert standard in excluding testimony of a plaintiff’s expert oncologist who had failed to provide peer-reviewed literature or other support for his opinions. The Court noted that, “[u]nder MRE 702, it is generally not sufficient to simply point to an expert’s experience and background to argue that the expert’s opinion is reliable and, therefore, admissible.”

§29:3.7 Minnesota

In 1980, the Minnesota Supreme Court added a second requirement to the Frye general acceptance standard in that expert evidence also must have a scientifically reliable foundation. This established the state’s two-part Frye-Mack standard. Minnesota reaffirmed its employment of the Frye-Mack standard in Goeb v. Tharaldson, a 2000 product liability case involving the insecticide Dursban. The Goeb court noted that judges take on a gatekeeping function under both Frye-Mack and Daubert. However, the Goeb court provided various reasons for its express rejection of Daubert. For example, the court noted that Minnesota adopted a more conservative standard under Frye-Mack than under the more liberal and flexible approach of Daubert. The court also noted that Frye-Mack mandates judges

162. See Mich. Comp. Laws § 600.2169 (2010) (specifying expert qualification criteria considered in medical malpractice actions); id. § 600.2955(1) (specifying expert qualification criteria considered in actions involving “the death of a person or for injury to a person or property”).
163. See id. § 600.2955(1).
165. Id. at 571.
166. State v. Kolander, 52 N.W.2d 458, 465 (Minn. 1952) (adopting Frye).
168. Id.; Goeb v. Tharaldson, 615 N.W.2d 800, 809–10 (Minn. 2000).
169. Goeb, 615 N.W.2d at 814.
170. Id. at 814–15.
171. Id. at 812–14.
172. Id. at 812.
to defer to the scientific community in analyzing the reliability of expert evidence, whereas Daubert requires judges to be "amateur scientists."173

The Minnesota Supreme Court has described the Frye-Mack standard as a test with "two prongs."174 "Under the first prong, the court asks 'whether experts in the field widely share the view that the results of scientific testing are scientifically reliable.'... Under the second prong of the Frye-Mack test, the court considers 'whether the laboratory conducting the tests in the individual case complied with appropriate standards and controls.'"175

Minnesota has adopted a de novo standard of review for reviewing the admissibility of expert testimony.176

§29:3.8   New Jersey

In civil tort cases, New Jersey has applied the standard set forth in Rubanick v. Witco Chemical Corp.177 Under Rubanick, a "scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field."178 Rubanick involved a toxic-tort plaintiff's claim that occupational exposure to polychlorinated biphenyls (PCBs) at the defendant's chemical plant caused his cancer.179 The trial court excluded the plaintiff's expert testimony for a failure to demonstrate general acceptance by even a "substantial minority of the applicable scientific community."180 After discussing at length the "extraordinary and unique burdens facing plaintiffs who seek to prove causation in toxic-tort litigation," the New Jersey Supreme Court relaxed the standard for admissibility of expert evidence and upheld the lower court's decision to include the plaintiff's expert evidence.181

173. Id. at 813.
174. State v. Hull, 788 N.W.2d 91, 103 (Minn. 2010).
175. Id. at 103 (citations omitted).
176. Gorb, 615 N.W.2d at 815.
178. Id. at 747–48.
179. Id. at 734.
181. Rubanick, 593 A.2d at 739.
Other product decisions illustrate New Jersey's flexible approach under Rubanick. Landrigan v. Celotex Corp. involved a claim that occupational exposure to asbestos caused cancer. The trial court excluded the plaintiff's expert testimony based on epidemiology stating that while "[e]pidemiological evidence can . . . be used to show that a defendant's conduct increased a plaintiff's risk of injury to some measurable extent," it "cannot be used to predict an occurrence of health related events for a given specific individual." The New Jersey Supreme Court upheld the appellate court's reversal of the trial court's decision noting that epidemiological studies may "provide the basis for an expert's opinion" so long as they meet the standards set forth in Rubanick.

Kemp ex rel. Wright v. State was a negligence action based on administration of a vaccine to the plaintiff, who was pregnant at the time, and allegedly caused the plaintiff's child to develop Congenital Rubella Syndrome (CRS). The lower court had excluded the plaintiff's expert testimony linking the vaccination to the child's CRS, noting an "absence of any medical support or scientific evidence confirming that there is a causal connection between the rubella vaccination and CRS." Following Rubanick, the Kemp court reversed the lower court's decision to exclude the evidence and also noted that "[t]he obstacles plaintiffs generally confront concerning reasonable but unconfirmed theories of medical causation are not confined to toxic tort litigation." The Kemp court acknowledged Daubert and cited it favorably as a "flexible" approach to admissibility, but continued to rely upon its own Rubanick standard rather than adopt the Daubert approach.

§29:3.9 New York

New York's highest court looks to Frye. In People v. Wesley, while applying Frye to determine the admissibility of DNA evidence,
the court acknowledged the Daubert decision, but stated that "[Daubert] is not applicable here."191 Although Wesley was decided in the criminal context, New York has made clear that Frye applies in civil actions, as well. In Parker v. Mobil Oil Corp.,192 the court reiterated that "Frye is the current standard in New York," for novel scientific evidence, even though "some amici urge the court to adopt the federal standard (or some portions of it) as expressed in [Daubert]." Parker involved a claim "alleging that exposure to benzene in gasoline caused [the plaintiff] to develop acute myelogenous leukemia."193 The parties disputed whether the plaintiff’s expert evidence was novel and, therefore, whether the opinions should be analyzed under Frye.194 Holding that Frye was not applicable because there was "no particular novel methodology at issue,"195 the court nonetheless affirmed the appellate court's exclusion of the testimony, due to the plaintiff's failure to establish causation by any acceptable method.196

In Jackson v. Nutmeg Technologies, Inc.,197 involving a claim that occupational exposure to the defendant's chemicals caused the plaintiff's injuries, the court upheld the lower court's decision to allow the plaintiff's expert testimony despite the defendant's claim that the evidence "lacks an adequate foundation."198 The Jackson court held that the plaintiff's expert's testimony, based on epidemiological studies, was "by no means a novel methodology for demonstrating a causal relationship."199

§29:3.10 Ohio

Ohio courts reject Frye and apply the Daubert standard when interpreting Ohio Rule of Evidence 702. As set forth in Miller v. Bike Athletic Co.,200 a case in which Daubert was frequently and favorably cited, Ohio has "consistently rejected" Frye in favor of a requirement

191. Id. at 454 n.2.
193. Id. at 1116.
194. Id. at 1119.
195. Id. at 1120.
196. Id. at 1111-22.
198. Id. at 601.
199. Id.
that expert testimony be supported by guarantees of reliability.\textsuperscript{201} \textit{Miller} was a product liability case where the plaintiff was injured due to an allegedly defective football helmet, and in which the testimony of plaintiff's expert engineers concerning the helmet design was found to have been improperly excluded.\textsuperscript{202}

At least one state appellate court, excluding testimony from a plaintiff's expert physician, has recognized that “[t]he Ohio Supreme Court adopted the \textit{Daubert} analysis in \textit{Miller}” and that “a trial court's role in determining whether an expert's testimony is admissible under [Rule 702] focuses on whether the opinion is based upon scientifically valid principles.”\textsuperscript{203}

\section{Pennsylvania}

Pennsylvania courts apply \textit{Frye} in determining the admissibility of expert evidence. In \textit{Grady v. Frito-Lay, Inc.},\textsuperscript{204} the Pennsylvania Supreme Court held that “\textit{Frye} continues to provide the rule for decision in Pennsylvania.”\textsuperscript{205} \textit{Grady} involved a product liability suit brought by a consumer who suffered injuries after eating a tortilla chip.\textsuperscript{206} In affirming the trial court's exclusion of the plaintiff's expert testimony, the court cited numerous reasons for its continued adherence to \textit{Frye}.\textsuperscript{207} “One of the primary reasons we embraced the \textit{Frye} test . . . was its assurance that judges would be guided by scientists when assessing the reliability of a scientific methods.”\textsuperscript{208} Moreover, “the \textit{Frye} test, which is premised on a rule—that of 'general acceptance'—is more likely to yield uniform, objective, and predictable results among the courts, than is the application of the \textit{Daubert} standard, which calls for a balancing of several factors.”\textsuperscript{209} Although both parties preferred a \textit{Frye} approach, Justice Saylor's concurring opinion indicated an

\begin{thebibliography}{10}
\bibitem{201} \textit{Id.} at 739–40, 741 n.1.
\bibitem{202} \textit{Id.}
\bibitem{203} \textit{Plaveski v. Cleveland Clinic Found.}, 192 Ohio App. 3d 533, 540–41 (Ohio Ct. App. 2010).
\bibitem{204} \textit{Grady v. Frito-Lay, Inc.}, 839 A.2d 1038 (Pa. 2003).
\bibitem{205} \textit{Id.} at 1039.
\bibitem{206} \textit{Id.}
\bibitem{207} \textit{Id.} at 1044–45.
\bibitem{208} \textit{Id.} (citing \textit{Commonwealth v. Topa}, 369 A.2d 1277 (Pa. 1977)).
\bibitem{209} \textit{Grady}, 839 A.2d at 1045.
\end{thebibliography}
openness to reconsider the court’s position, when an “informed advocacy is presented that would favor a new direction.”

In *Commonwealth v. Puksar*, the court reiterated its adherence to *Frye* and added, “[o]f course, *Frye* is not implicated every time science comes into the courtroom; rather, it applies only to proffered expert testimony involving novel science.” “[T]he purpose of the test is merely to help the court determine when a scientific principle or discovery crosses the line between the experimental and demonstrable stages.”

The Pennsylvania Supreme Court has recently reinforced that, under the *Grady/Frye* standard, the credibility and weight of experts’ testimony “are not proper considerations at summary judgment,” and can only be raised at trial. Within the upcoming year, the Pennsylvania Supreme Court is also expected to issue a *Grady/Frye* ruling on a closely watched appeal concerning expert physicians who linked plaintiff’s mesothelioma to three defendant auto manufacturers’ asbestos-containing products on the basis that each and every exposure event was a substantial factor in causing the plaintiff’s disease.

## §29:3.12 Texas

In *E.I. du Pont de Nemours v. Robinson*, Texas accepted the *Daubert* principles. The *Robinson* plaintiffs sued the defendant fungicide manufacturer, claiming its fungicide “was contaminated [and] damaged their pecan orchard.” “[P]ersuaded by the reasoning in *Daubert*” the Texas Supreme Court held that “a trial court may consider in making the threshold determination of admissibility” a non-exclusive list of factors which are similar to the factors stated in *Daubert*. These factors include, but are not limited to: (1) the extent to which the theory has been or can be tested; (2) the extent to which the technique

210. *Id* at 1052.
212. *Id* at 274 (quoting *Commonwealth v. Dongler*, 890 A.2d 372, 380 (Pa. 2005)).
217. *Id* at 551.
218. *Id* at 557.
relies upon the subject interpretation of the expert...; (3) whether the
to the relevant scientific
community; and (6) the non-judicial uses which have been made of the
theory or technique.\textsuperscript{219}

Robinson is regularly applied in product liability cases. For example, Cooper Tire & Rubber Co. v. Mendez\textsuperscript{220} involves a product liability claim against a tire manufacturer and a challenge to the admissibility of plaintiff's experts' testimony that the failed tire caused a fatal accident.\textsuperscript{221} After applying the six Robinson factors, the court reversed the lower court's decision and held the first expert's testimony to be inadmissible, adding that "[h]is explanation for the tire failure was a naked hypothesis untested and unconfirmed by the methods of science."\textsuperscript{222} The court also held the second expert's testimony inadmissible because his testimony was "subjective, and unsupported by any measurements, testing, references to peer-reviewed studies, proof that [his] observational techniques are generally accepted in the relevant scientific community as a valid method of identifying a manufacturing defect, or evidence that his techniques are employed in non-judicial contexts."\textsuperscript{223}

In Volkswagen of America, Inc. v. Ramirez,\textsuperscript{224} involving a negligence claim that a car defect caused a fatal accident, Volkswagen complain[ed] that [the expert] failed to conduct tests, cite studies, or perform calculations in support of his ... theory.\textsuperscript{225} The court held that the expert's testimony was inadmissible because he did not "close the 'analytical gap'" through his explanation of how the supposed defect caused the accident.\textsuperscript{226}

More recently, Whirlpool Corp. v. Camacho\textsuperscript{227} involved a design defect claim against the manufacturer of an electric clothes dryer and a challenge to the legal sufficiency of expert evidence proffered by

\begin{itemize}
\item \textsuperscript{219} Id.
\item \textsuperscript{220} Cooper Tire & Rubber Co. v. Mendez, 204 S.W.3d 797 (Tex. 2006).
\item \textsuperscript{221} Id. at 805.
\item \textsuperscript{222} Id.
\item \textsuperscript{223} Id. at 806.
\item \textsuperscript{224} Volkswagen of Am., Inc. v. Ramirez, 159 S.W.3d 897 (Tex. 2004).
\item \textsuperscript{225} Id. at 904.
\item \textsuperscript{226} Id. at 906 (citing Gammill v. Jack Williams Chevrolet, Inc., 972 S.W.2d 713, 727 (Tex. 1998)).
\item \textsuperscript{227} Whirlpool Corp. v. Camacho, 298 S.W.3d 631 (Tex. 2010).
\end{itemize}
plaintiffs.\textsuperscript{228} Plaintiffs alleged that the defectively designed dryer caused the fire that resulted in the death of their child.\textsuperscript{229} Whirlpool asserted that the appellate court conducted an improper legal sufficiency review by not “considering both Robinson-type factors and examining for analytical gaps” in the testimony of plaintiffs’ defective design expert.\textsuperscript{230} Although the appellate court affirmed the $14 million jury verdict in favor of plaintiffs, the Texas Supreme Court reversed.\textsuperscript{231} The court held that because the testimony of plaintiffs’ design defect expert was unreliable under Robinson and did not account for analytical gaps, the evidence was legally insufficient to support the verdict.\textsuperscript{232}

\section*{Virginia}

In \textit{Spencer v. Commonwealth},\textsuperscript{233} the Supreme Court of Virginia rejected the \textit{Frye} standard in favor of a hybrid approach. Today, the Virginia rule governing admissibility of scientific evidence, as reiterated in \textit{Billips v. Commonwealth},\textsuperscript{234} requires a trial court to “make a threshold finding of fact with respect to the reliability of the scientific method offered.” The trial court has “wide discretion” in making such findings.\textsuperscript{235} However, admissibility of expert testimony is “subject to certain fundamental requirements,” such as the requirement that the expert take into account all relevant variables, and that the expert opinion be based on an “adequate foundation.”\textsuperscript{236} In \textit{CNH America LLC v. Smith},\textsuperscript{237} a plaintiff's expert testified that the product (a disc mower hose) had a defect because it “failed young.”\textsuperscript{238} The Virginia Supreme Court rejected that opinion because “the only basis for [the expert's] opinion testimony that the hose had a manufacturing

\begin{footnotesize}
\begin{itemize}
\item[228.] \textit{Id.} at 633–34.
\item[229.] \textit{Id.} at 635–36.
\item[230.] \textit{Id.} at 640.
\item[231.] \textit{Id.} at 636, 643.
\item[232.] \textit{Id.} at 639–40, 642–43.
\item[234.] \textit{Billips v. Commonwealth}, 652 S.E.2d 99 (Va. 2007) (citing \textit{Spencer}, 393 S.E.2d at 621).
\item[235.] \textit{Spencer}, 393 S.E.2d at 621.
\item[238.] \textit{Id.} at 374.
\end{itemize}
\end{footnotesize}
defect was the failure of the hose itself."239 The expert had not performed any tests except a visual borescope examination of the hose, which had not revealed any defects. The court held that this was not an adequate foundation for the expert’s opinion about the purported product defect.240

The only exceptions to this threshold finding of fact requirement are [1] if the scientific evidence is “of a kind so familiar and accepted as to require no foundation to establish the fundamental reliability of the system,” [2] if the evidence is “so unreliable that the considerations requiring its exclusion have ripened into rules of law,” or [3] if “its admission is regulated by statute.”241

In essence, the threshold finding of fact requires the trial court to decide “whether the evidence is so inherently unreliable that a lay jury must be shielded from it, or whether it is of such character that the jury may safely be left to determine the credibility for itself.”242 At least one court has interpreted this standard to “arguably [set] a lower threshold for the admission of scientific evidence” than Daubert, barring only “inherently unreliable” evidence.243 This approach is supported by the holding in Spencer that “[e]ven where the issue of scientific reliability is disputed...the court may, in its discretion admit the evidence with appropriate instructions to the jury to consider the disputed reliability of the evidence in determining its credibility and weight.”244

Even though Virginia has not formally adopted all of the Daubert standards,245 some Virginia trial courts have described their role as a “gate-keeper” of evidence.246 In those cases, however, the courts still

239. Id. at 375.
240. Id. at 375-76.
241. Id.
242. Id.
244. Spencer, 393 S.E.2d at 621.
245. John v. Im, 559 S.E.2d 694, 698 (Va. 2002) (“We have not previously considered the question whether the Daubert analysis employed by the federal courts should be employed in our trial courts to determine the scientific reliability of expert testimony.... [W]e leave this question open for future consideration.”).
consistently adhered to those "certain fundamental requirements" in admitting expert testimony.\textsuperscript{247}

\textbf{§29:3.14 Wisconsin}

Wisconsin had previously rejected \textit{Daubert}\textsuperscript{248} in favor of a state-specific "relevancy test." Under this test, "admissibility of scientific evidence is not conditioned upon its reliability. Rather, scientific evidence was admissible if: (1) it is relevant; (2) the witness is qualified as an expert; and (3) the evidence will assist the trier of fact in determining an issue of fact."\textsuperscript{249} This standard limited the trial judge's role. The trial judge "merely require[d] the evidence to be an 'aid to the jury' or 'reliable enough to be probative.'\textsuperscript{250} The trial judge may exercise "limited gatekeeping functions" by excluding relevant testimony that was superfluous, was a waste of judicial time, had greater prejudicial than probative value, was inherently improbable, or was not suitable for expert opinion.\textsuperscript{251} In practice, this standard has been characterized as "a wide-open gate for the receipt of expert testimony."\textsuperscript{252}

In \textit{State v. Fisher},\textsuperscript{253} the Wisconsin Supreme Court reiterated that in the "established Wisconsin "limited gatekeeper" approach... reliability of evidence is a matter for the finder of fact." Because Wisconsin allowed "substantially unlimited cross-examination," the "underlying theory or principle on which admissibility is based can be attacked by cross-examination or by other types of impeachment."\textsuperscript{254} The Wisconsin Supreme Court, therefore, "decline[d] to adopt a \textit{Daubert}-like approach to expert testimony and make the judge the gatekeeper."\textsuperscript{255}

Where Wisconsin courts did not go, the Wisconsin legislature did. In 2011, the legislature amended Wis. Stat. section 907.02 to adopt

\begin{itemize}
\item \textit{Spencer}, 393 S.E.2d at 621.
\item \textit{State v. Fisher}, 778 N.W.2d 629, 633-34 (Wis. 2010).
\item \textit{Peters}, 534 N.W.2d at 873 (citations omitted).
\item \textit{State v. Fisher}, 778 N.W.2d 629, 633-34 (Wis. 2010).
\item \textit{Walstad}, 351 N.W.2d at 519.
\item \textit{Fisher}, 778 N.W.2d at 633-34.
\end{itemize}
the *Daubert* reliability standard now embodied in Federal Rules of Evidence 702. The amendment added the requirements that expert testimony must be “based upon sufficient facts or data,” that the testimony must be “the product of reliable principles and methods,” and that the expert must have “applied the principles and methods reliably to the facts of the case.”

§29:4  **DAUBERT/FRYE IN PRACTICE**

§29:4.1  **Establishing Causation Through Expert Testimony**

The careful practitioner should know what standard applies to the admissibility of a retained expert’s testimony long before trial begins. Expert witnesses often are critical to the prosecution or defense, and a successful challenge to the admission of an expert’s opinion can end the case before it ever reaches a jury. For example, experts often are the sole causation witnesses in product cases, and a well-aimed *Daubert*- or *Frye*-based motion for summary judgment can deprive the plaintiff of proof that a product caused the plaintiff’s injury. Likewise, if a plaintiff’s causation expert survives such a challenge, it can set the stage for settlement, as well as the filing of subsequent lawsuits by other plaintiffs claiming to suffer from the same or similar injuries caused by the product. Particularly where the product in question is alleged to have caused a systemic disease, causation experts are likely to be closely challenged as to whether there is a scientific basis for claims of general causation, that is, the claim that a substance can cause a particular disease. Such challenges now are commonplace in product liability cases—especially so in the mass tort and multidistrict litigation (MDL) context.

Indeed, courts increasingly establish test cases (also called “bellwether cases”) in pattern litigation (such as mass tort MDLs or a cadre of joined cases) to test the validity of causation theories relatively early in the life cycle of these disputes. A recent example

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256. *See* 2011 Wis. Act 2, §34m. *See also,* State v. Kandutsch, 799 N.W.2d 865, 872 n. 7 (Wis. 2011).
257. *See* 2011 Wis. Act 2, §34m, and Wis. Stat. § 907.02.
is Snyder ex rel. Snyder v. Secretary of Human Services, 259 which was selected as one of three test cases before the U.S. Court of Federal Claims Office of Special Masters to manage disposition of 4,700 claims alleging that childhood vaccines caused the petitioners’ autism or similar neurodevelopmental disorders. 260 Snyder was specifically selected “to test the first theory of causation advanced by the Omnibus Autism Proceeding Petitioners.” 261 As the Snyder opinion details, a panel of special masters heard testimony from a wide array of experts and ultimately concluded, in all three cases, that the petitioners could not establish general causation. These three decisions followed a number of rulings in state and federal courts excluding plaintiffs’ general causation experts who opined that administration of vaccines and thimerosal-containing medical products resulted in the development of autism in children. 262 It is expected that these decisions effectively will quash any substantial future litigation in this area.

The same issues can arise in the single product liability case. Where a particular injury claim does not reach the level of a mass tort, questions of general causation can be very thorny, and the careful practitioner should prepare the expert case assuming there will be a challenge to any novel theories presented in the case. The scientific basis for claims of causation may be limited to early and perhaps weak studies or anecdotal reports; there may be no known (or only a poorly understood) mechanism by which the product or an ingredient therein can be said to cause the injury in question; and the techniques used by the expert may not have been widely tested for their validity. How a court will react to any one of these factors—especially where there is not significant precedent from other courts facing the same admissibility question—is often very difficult to predict, and what is inadmissible to one judge may well be acceptable to another. In some jurisdictions, the distinction between general causation and specific causation is not necessarily recognized, which in a given case can mask what is novel and unreliable from what is generally accepted or reliable.

260. Id. at 708.
261. Id.
In some instances, courts have ordered, or parties have agreed, to move expert discovery ahead of other discovery. This approach is especially useful when the scientific issues will dispose of the matter of causation, as in cases where the plaintiff alleges that a specific medical condition was caused by exposure to a specific chemical substance. Focusing early on whether the causal connection is generally plausible as a scientific matter or plausible in the specific case, and getting the scientific issues heard early by the court, may be a cost-effective way for both sides to approach the litigation—by avoiding the time and expense of other fact discovery. Of course, many factors other than the desire to reach the merits of the causation issue may affect whether or not parties or the court agree to an early focus on expert testimony.

§29:4.2 Preparing for Daubert/Frye Challenges

What, then, should the practitioner keep in mind in preparing for Daubert- or Frye-based challenges in a products case—whether brought by or against her experts? The suggested answers may be elementary, but they bear stating.

First, be careful in the choice of expert. Has the expert testified before? Has he or she been qualified as an expert in the field about which the expert is expected to testify? Has the expert been excluded from testifying before? Has the expert made earlier statements that contradict his testimony in your case? Is the expert engaging in an activity that contradicts the position she is taking in your case? Especially where the expert’s testimony may be critical to the elements of the case, the last thing the attorney wants is to be confronted by a scathing critique of that expert from a judge in a different case, or a critique of the expert’s position in the instant case from his own earlier publication, opinion, or statement.

Second, educate the expert about the standards for admission of expert testimony in the jurisdiction of the case. An early understanding of the terms on which the expert’s opinions will be admitted can avert later disasters. This is especially important if the practitioner or the expert works in a variety of jurisdictions. Frye states, for example, vary in subtle but important ways regarding their emphasis on underlying methods and other bases for admissibility. Not only does the lawyer want to avoid an opinion from the expert that is ruled inadmissible for failure to comply with the proper standards, the expert needs to know the proper standards to help the attorney prepare for the examination of opposing experts.
Third, if a written report is submitted in the case—which is required in almost every jurisdiction—make sure the expert uses terminology that echoes the standards for admissibility in the jurisdiction. For example, it can be useful to have the expert describe the methodologies employed to reach his or her conclusions, and perhaps even offer some citations demonstrating the general acceptance and/or reliability of that methodology in the written report. By contrast, if an expert is challenging another’s conclusions, the lawyer should ask that he or she frame at least part of the challenge in terms of the methodologies used and not focus solely on the conclusions. Particularly in Frye states, focusing on conclusions alone could seriously undermine a pre-trial challenge to the admissibility of the opposing expert’s testimony.

Fourth, attorneys must become well-versed in the disciplines of their experts, as well as the opposing experts. The better the lawyer understands the science, the better she will be able to explain to the judge the flaws in the opposing expert’s methodology. It goes without saying that for many of us, the science is difficult to learn and even more difficult to ask questions about. However, it is worth the time (and it will take plenty of time!) to learn and understand the scientific vocabulary, concepts, and methods, as well as the scientific strengths and weaknesses. After all, ultimately the attorney will have to explain the science to a jury, and it is hard to present compelling explanations of why she is on the right side of the science without fully understanding the mechanisms and limitations of her scientific position and that of her opponent.

Fifth, in depositions, it is critically important to frame questions based on the standard in the jurisdiction and, where useful, on prior cases that have resulted in exclusion of an expert’s testimony. If the opponent has not prepared the expert on buzzwords, the expert may well make admissions that are devastating to the proponent’s case.

All of the above considerations lead to the actual Daubert- or Frye-based challenge to expert testimony. Among the first questions to ask is what are the jurisdictional practices and requirements for a Daubert or Frye challenge? The timing of the challenge can vary—best practices may be to prepare a Daubert or Frye motion to strike the expert, coupled with a motion for summary judgment contending that without the expert, causation (or some other critical element of the plaintiff’s or defendant’s case) cannot be established. Some courts, particularly federal courts, may explicitly schedule a time for Daubert or Frye motions to be filed, and often there are different
deadlines for dispositive motions as opposed to Daubert or Frye motions. Some courts treat Daubert or Frye motions as motions in limine, to be filed long after the deadline for dispositive motions. Even other courts will entertain a Daubert- or Frye-based challenge during trial, right before an expert testifies. In addition, a practitioner should consider whether to renew a Daubert- or Frye-based challenge at trial if testimony raises new grounds for that attack.

Of course, an attack on an expert’s opinion and a ruling about its admissibility can come even after the testimony has been admitted, such as in a motion for directed verdict, a post-trial motion, or at appeal. In the same vein, be aware of the appellate standard for reviewing the trial court’s decision about admissibility. Some jurisdictions review admissibility using a de novo standard, while many others approach the matter with an abuse of discretion standard.

Whenever the motion comes (at the summary judgment phase, right before trial, or during trial), the next question is what kinds of proofs the court will entertain from the parties. A tactical and procedural series of questions to ask is whether to demand a full hearing on the evidentiary challenge; what sort of evidence to provide on either side of the challenge; and the effect of a court’s decision not to hold a hearing. From the perspective of the challenger, if there is a strong basis for opposing admission of an expert’s testimony, it almost always will be best to seek a hearing on the issue. Having a developed record of the challenge is likely to highlight the importance of the issue, and gives the appellate court a substantial basis on which to examine the trial court’s determination, whichever way it goes. On the other hand, presenting Daubert or Frye arguments in written form may be more persuasive than through testimony at a hearing, and certainly, briefs are more easily controlled than testimony, where a proffering or challenging witness will be subject to cross-examination with all of the implied uncertainties.

The question of whether a hearing is required is one that a number of courts have addressed, at least at the federal level—finding that the trial court has substantial discretion in deciding whether to

263. See, e.g., Weisgram v. Marley Co., 528 U.S. 440, 445–46 (2000) (affirming appellate court’s grant of j.n.o.v. because the testimony of the plaintiff’s expert—the sole evidence supporting product defect claim—was speculative and not shown to be scientifically sound).
hold a formal *Daubert* hearing.\textsuperscript{264} State courts are subject to more variation. In *Smith v. Clement,*\textsuperscript{265} the Mississippi Supreme Court reversed the trial court’s exclusion of a plaintiff expert’s testimony without a *Daubert* hearing. The best practice, the majority observed, was to permit litigants to be heard via briefs and a formal hearing before such testimony is excluded.

If and when a court decides to hold a hearing, the question of what that hearing will consist of will vary widely by judge, jurisdiction, and subject matter. Special attention should be paid to the parties’ burdens and whether they have been met in the hearing. For example, if the challenged expert does not testify—by affidavit or live—it may be possible to argue later that the trial court lacked an evidentiary basis on which to admit the evidence. The hearings can be mini-trials or simply oral arguments by the lawyers with perhaps one or two live witnesses. In an interesting recent development, courts increasingly are ordering *Daubert* hearings as part of class certification proceedings.\textsuperscript{266} It is unclear whether and to what extent such hearings will be applied in the product liability context in light of the general unavailability of class treatment of such claims, but with the rise of consumer fraud class actions, such tandem *Daubert*-class action inquiries may well develop in this related area.

\section*{§29:5 2010 Amendments to Federal Rule of Civil Procedure 26}

Since publication of the first edition of this treatise, amendments to Federal Rule of Civil Procedure 26 have been adopted. These amendments will affect some of the traditional strategies employed with experts, both by their proponents and in cross-examination.

The amendments to Rule 26 took effect on December 1, 2010. Amended Rule 26(a)(2)(B) extends work-product immunity to drafts of expert reports and to some communications between testifying experts and attorneys that previously were subject to discovery by opposing counsel.

\begin{footnotes}
\footnoteref{264} See, e.g., *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 532 (6th Cir. 2008) (applying an abuse of discretion standard in reviewing decision not to hold a formal hearing); *United States v. Kenyon*, 481 F.3d 1054, 1060-61 (8th Cir. 2007) (same).
\footnoteref{265} *Smith ex rel. Smith v. Clement*, 983 So. 2d 285 (Miss. 2008).
\end{footnotes}
Amended Rule 26(b)(4)(C) extends work-product immunity to communications between attorneys and experts, except for those that fall into one of the following three categories:

(1) compensation for an expert's testimony;
(2) facts or data provided to the expert by the attorney that the expert considered in forming her opinions; and
(3) assumptions provided to the expert by the attorney that the expert relied upon in forming her opinion.

This change makes the flow of information and ideas between counsel and a retained expert less circumscribed than it traditionally has been. Some commentators also believe that the change will do away with the common practice of retaining consulting experts, as opposed to testifying experts.

In addition, if an expert is not required to provide a report under 26(a)(2)(B), amended Rule 26(a)(2)(C) requires retaining counsel to state in its Rule 26(a)(2)(A) disclosures the following: "(i) the subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705; and (ii) a summary of the facts and opinions to which the witness is expected to testify," unless otherwise stipulated by the parties or ordered by the court.

The Judicial Conference Committee on Rules of Practice and Procedure (the "Committee") noted the positive effects of similar rule changes that had occurred in New Jersey state courts. The Committee concluded that extending work-product immunity to draft expert reports and certain categories of attorney-expert communications may decrease litigation costs and create a more open dialogue between expert and attorney.

The amendments to Rule 26 did not apply retroactively.

§29:6 CONCLUSION

Challenges to the admissibility of expert testimony can be a blessing or a curse. Whether you are leading the attack or defending against it, the critical tools for the practitioner are to know the rules, pick the experts carefully and learn as much as you can about the science.