Update 2005, Issue 3
With permission from FDLI
www.fdli.org

# Expert Witnesses in Product Liability Litigation: Boon or Bust?

*by Thomas N. Tiedt, Ph.D.*

Product liability litigation necessitates recruitment of competent medical, research and development (R&D), epidemiological, manufacturing, labeling, advertising, managerial, and regulatory experts. Such expertise—deployed via expert reports, affidavits, and testimony—usually is critical to the successful development and outcome of litigation pertaining to pharmaceuticals, medical devices, and dietary supplements.

The quality and preparation of expert witnesses hardly can be overemphasized. Hundreds of thousands of pages of medical and technical documents may need to be analyzed and shared with experts and the opposing party. Certain documents may require substantial resource investment, rebuttal, and/or further investigation. While some experts may have limited case participation, others will be tasked across various aspects of the case.

Ultimately, the court and the jury must find that the presentation of expert opinions and highly technical subject matter is cohesive and credible. Details and themes must interweave so the expert testimony will be more credible, thus increasing the likelihood of successful case resolution.

## Suggestions and Cautions

All expert witnesses should prepare for their testimony, and be prepared by their managing counsel as to the expert's role in the case and the likely evolving case-critical issues relevant to the expert's case opinions. An expert's credibility is not bolstered by admitting that he/she did not prepare for testimony or is oblivious to the scientific basis for their opinions as proffered by counsel.

An important point is that expert opinions may be deemed to represent the views of the party proffering the expert witness; experts are proffered as surrogates for the party. Therefore, what an expert opines can help—and damage—a party in the litigation.

An expert cannot defend the purported safety of a product without reviewing the product formula, ingredient pharmacology, labeling, advertising, R&D package, record of adverse event reports, critical regulatory reviews, medical literature pertaining to the product, and brand management history and planning. Sometimes, investigational new drug, new drug application/approval, institutional review board, and informed consent form documents also need to be reviewed.

Some experts effectively self-destruct during their depositions by testifying that they have little or no relevant expertise in the scientific or technical areas for which they are being provided. Or, during cross-examination they may reveal that they effectively support the opposing party more than the hiring party. Or, without credible explanation, they may establish for opposing experts scientific hurdles that they did not rely upon in their own research.

Preferably, expert witnesses will be independent—they will formulate their case opinions without any commercial ties to parties in the litigation (e.g., employment, family relationship, marketing/sales collaboration). Expert opinions, as well as the expert's professional fees, should not be linked to a case's outcome. The expert's expertise—other than for case-specific testing or opinions based on medical information and case discovery—should be formulated prior to the litigation.

A difficult area presented by corporate defense experts is the degree to which the expert is supplied internal R&D and brand management packages that may demonstrate the defendant's prior knowledge of product hazards and/or questionable response to this damaging information. Such information generally is supplied to the plaintiff by court order in the discovery process, but a defense expert can be placed at a significant disadvantage if this expert did not review those potentially-problematic internal records. To the jury, any perceived lack of candor or lack of appropriate pre-opinion

*Dr. Tiedt is Director, Med-Tox Group, Bradenton, FL.*

investigation from the expert may suggest noncredibility, or even dishonesty.

Expert opinions will be tested during cross-examination, so attention should be given to the rationality and prudence of that process as conducted by opposing counsel. Purported scientific standards not routinely relied upon in the "real world" (i.e., outside of the litigation bubble) generally are recognized by triers of fact. The application of such standards may convince the court or jury that the expert witness (or worse, the party in the case) is not credible. An unwanted case dismissal or default judgment could follow.

The purpose behind the *Daubert*,[1] *Frye*,[2] and *Havner*[3] standards of evidence apply to plaintiff and defense expert opinions and are fundamental to product liability litigation—to ensure that only good science and scientific methodology are presented to the jury or admitted into the record. There can be a distorted reliance, however, on these rules of admissibility for scientific evidence. Large amounts of time and money can be wasted in needless challenges of generally recognized science; even more can be lost in punitive damage assessments.

One important example of misplaced reliance is the strategy of focusing on an *ad hoc* notion of "epidemiology"—one that would be almost unrecognizable in the medical community. As noted in the federal reference manual on scientific evidence, epidemiology cannot objectively prove causation; rather, causation is a judgment.[4]

Epidemiology is the study of the distribution and causes of disease in populations using a wide range of tools, and it is utilized typically for public policy decisions by government. Epidemiology itself is only one tool in assessing disease causation, and it often addresses specific risks and patients rather imprecisely; epidemiological analysis is much broader in its methodologies than the case-control study that is overemphasized in many product liability lawsuits. Real-world epidemiology involves pharmacology, pathophysiology, differential diagnosis, case reports, case series, post-marketing surveillance, analysis of societal trends impacting patient sensitivities, observational odds ratio and relative risk studies (e.g., case-control studies), and randomized clinical trials—all in the context of several overlapping factors that guide causation judgments.[5] "No one of them is absolutely necessary for an observation to be a causal association. Analogously, no one of them is sufficient for an association to be considered a causal association."[6]

Corporate defendants face special challenges in defending product liability lawsuits. Employees (typically testifying under subpoena, and often videotaped) may be subject to the same considerations for credibility and expertise as expert witnesses. Few employees, however, have access to or responsibility for the array of information that their employer submitted to the plaintiff in discovery. Thus, employee testimony can elicit very negative responses from juries if they present a picture of corporate indifference, hiding material facts, or insufficient due diligence in product marketing and risk-control planning. Undoubtedly, juries expect employees to withstand the same kinds of cross-examination as expert witnesses.

Furthermore, although the burden of proof rests upon the plaintiff, juries expect more substantial scientific evidence and opinions from corporate defense experts because they expect the product marketer to be the most knowledgeable resource for product risk and benefit analyses. If this is not the case, disaster for the corporate defendant in the form of punitive damages could be large.

It is not effective for a defense expert to simply opine that "little is known" when cross-examination reveals that the expert himself knows little about the particular field, relevant medical literature, or the general medical consensus. Likewise, it is not helpful for an expert to simply "disagree" with virtually all of the evidence normally considered by experts in disease causation, or with a block of medical organizations, peer-reviewed medical studies, secular organizations, or diverse and well-respected medical texts.

Corporate defendants also face the minefields of internal company studies and documents that may span decades of records from multiple departments or business and technical operational divisions. Such information may suggest a disregard for consumer health as well as unethical conduct.

Another Pandora's box waits for corporate defendants who delegate defense tactics and strategies with insufficient analysis and oversight to external defense counsel, who in turn may have "oversold" their trial expertise or may be more interested in a lengthy and expensive menu of billable activities than in providing genuine assistance for a successful defense. Common examples of how this may play out include: recruitment of egregiously-inadequate expert witnesses; mounting futile challenges of scientific evidence; filing hopeless motions for summary or default judgment; creation of *ad hoc* trade associations to produce thinly-veiled "independent" reports; strategizing to simply exhaust plaintiff resources; and misrepresentation of internal and published evidence.

It is likely that juries assess expert witness credibility more on preparation and delivery than on their technical accuracy on matters that jury members may not understand. In other words, it may come down to a jury's assessment of which experts' testimony is most comprehendible and convincing.

## "Closing Argument"

Product liability litigation is complex and expensive. Documentary evidence can be voluminous and contradictory. Diligent oversight and attention to detail is important to avoid wasting resources and to improve the prospects for success. Above all, credibility is critical.

The selection and cultivation of expert witnesses will channel case execution. Appropriate and cost-effective utilization of experts demands that the expert witnesses be qualified and independent (i.e., their opinions are not *ad hoc* to the litigation except in isolated circumstances), as well as prepared with insights on the issues identified during the litigation process. Fundamental to the successful utilization of expert witnesses is the process by which they are managed. For example, the opinions of an expert witness should be known before they are deposed or testify at trial.

## Conclusion

These are trying times in product liability litigation. The explosion of lawsuits and deepening public concern about drug and dietary supplement risks and benefits perhaps has begun to reverse the "deregulatory" swing of the public policy pendulum. The Food and Drug Administration (FDA) recently announced the creation of a Drug Safety Oversight Board and finally has begun serious implementation of the Dietary Supplement Health and Education Act of 1994[7] (e.g., with the 2004 ephedra ban). Medical associations and journal editors are sharpening their criticism of FDA's oversight duty as well as corporate product support and promotion practices. The Director of the National Institutes of Health (NIH) recently banned NIH scientists from accepting compensation from the biomedical industry and called for an "ethics summit."[8] Members of Congress are beginning to consider FDA shortcomings in protecting consumers. At least some of the motivation for these initiatives stems from troubling insights revealed during litigation.

Accordingly, the spotlight on product safety is intensifying. The stakes for better use of expert witnesses and for renewed reflection on product development are enormous. There can be no doubt, in light of current events and deepening publicity about product safety, that the existing litigation paradigm needs to be modified. Improvement in expert witness planning is a step in the right direction. Lessons from product litigation successes and failures should be seriously considered as part of the product development process—i.e., sooner rather than later—so that R&D and brand management packages can better accommodate product support needs and better deflect potential problems later in the product life cycle.

---

1 *See* Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993).

2 *See* Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

3 *See* Merrell Dow Pharm., Inc. v. Havner, 907 S.W.2d 535 (Tex. App. 1994).

4 M.D. Green, D.M. Freedman & L. Gordis, *Reference Guide on Epidemiology*, *in* Reference Manual on Scientific Evidence (2d ed. Federal Judicial Center 2000).

5 The Bradford-Hill criteria for causation include: temporal relationship, strength of association, dose-response relationship, replication of findings, biological plausibility and variation, consideration of alternate explanations, effects of exposure cessation and re-challenge, specificity of the risk, and consistency with other kinds of medical knowledge.

6 Pharmacoepidemiology (Brian Strom ed., John Wiley & Sons 3d ed. 2002).

7 Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified in multiple sections of 21 U.S.C.).

8 David Willman, *NIH Chief Calls for Ethics Summit*, L.A. Times, Feb. 12, 2005, *at* http://www.latimes.com/features/health/medicine/la-na-nih12feb12,1,6572319,print.story?coll=la-halth-medicine (last visited May 5, 2005).

**Expert Witnesses**

| Do | Don't |
|---|---|
| • Link qualifications with opinions. | • Proffer unreliable opinions. |
| • Insist on preparation. | • Create *ad hoc* scientific standards. |
| • Ensure adequate basis for opinions. | • Needlessly challenge medical consensus. |
| • Cross-examine your expert. | • Speculate. |
| • Retain certain expert(s) with R&D experience (including long before litigation). | • Assert different evidence standards for product marketing and product litigation. |