# ISSUES BEYOND EXPERTISE – A HISTORY OF *DAUBERT* AND OTHER DETAILS THAT DRIVE INTERACTIONS BETWEEN LITIGATORS AND EXPERTS

Brent D. Kerger, Ph.D., DABT
Principal Scientist
Exponent
15615 Alton Parkway, Ste. 350
Irvine, CA 92618
949-242-6046
bkerger@exponent.com

*Dr. Brent Kerger is a Principal Scientist in Exponent's Health Sciences Center for Toxicology and Mechanistic Biology. A board-certified toxicologist, Dr. Kerger specializes in the study of environmental chemical fate and transport, exposure assessment, pharmacokinetics, and adverse human health effects. He has over 33 years of experience conducting and managing laboratory, field, and clinical studies of exposure, toxicology, epidemiology, and disease causation analysis. He provides scientific and strategic consultation regarding regulatory and litigation matters including 24 years of environmental chemistry and toxicology expert witness experience. He has in-depth expertise regarding asbestos, talc, dioxins and furans, PCBs, PAHs, chlorinated solvents, benzene and petroleum products, irritant gases, flavoring chemicals, and heavy metals.*

*He has over 29 years of experience as a professional toxicologist focusing on:*

- *Multi-disciplinary research in fate/transport, exposure assessment and toxicokinetics;*
- *Design and implementation of studies to characterize exposure/dose and toxicity;*
- *Human health and ecological risk assessments including complex indirect pathways;*
- *Evidence-based approaches for analysis of epidemiologic studies; and*
- *Disease causation analysis using the Hill Criteria and alternative cause assessment.*

## Daubert Considerations from the Perspective of a Toxicology Expert

The Daubert gate-keeping functions relate to proving that one's expert followed reliable scientific methods in applying his/her expertise and developing conclusions on the key scientific questions at issue—or, conversely, proving that an opposing expert did not adhere to such methods. The same gate-keeping rules are applied in evaluating admissibility of expert testimony from either plaintiffs or defendants. Simplicity and clarity of an expert opinion are probably most important in clearly communicating the expert's opinions to jurors, who can be easily overwhelmed by scientific complexity. However, an adequate showing of sophistication and complexity is often required to provide convincing proof to the judge who decides on expert testimony admissibility. One might reasonably presume that the judge is better equipped than jurors to evaluate whether all facts presented by an expert fit logically together. Yet when experts from both sides are able to exceed the 'fuzzy threshold' of adequate logic in terms of the applied

methods and associated conclusions, the ability of the judge to determine the 'better' method or the 'right' conclusions can quickly lead to subjective decision-making that on appeal may be reversed as overzealous gate-keeping. Consequently, the 'gray areas' of scientific methods and logical interpretations (even if technically incorrect) can be effectively argued to properly elude Daubert exclusion when a clear and convincing argument of expert 'abuse of discretion' cannot be demonstrated.

Decisions about Daubert exclusion tend to be centered on 'connecting the dots' between available facts and the expert's conclusions, with the scientific methods utilized being the 'glue' or the 'bridge' that allows for those conclusions to appear logical and convincing. Common bases for expert testimony exclusion include the following:

1) *Ipse dixit*- using authoritative statements rather than actual scientific methods and facts to support the expert conclusion;
2) Excessive analytical gap- using flimsy assumptions or assertions as the central feature of the expert conclusion, rather than filling that analytical gap by using valid testing data and/or fact collection in conjunction with the scientific method and logic;
3) Excessive stretching of facts to fit- using improper or highly uncertain methods as a central feature of the expert conclusion, and not disclosing the high error rate and unreliable nature of such techniques;
4) Reverse engineering of the basis for an expert opinion- relying predominantly on unfounded rationalizations instead of established scientific methods to support key conclusions; and
5) Offering opinions not within credible areas of expertise- bolstering of weak expert opinions by seemingly strong or logical assertions based on methods outside of the expert's expertise.

The case-specific facts frequently have significant information gaps that need to be filled in order to develop a strong expert opinion with respect to exposure, potential hazard, and/or disease causation. Finding those linchpin weaknesses in an expert's opinions can be made difficult by the use of generalizations or default approaches or assumptions that logically seem to fit, but actually are seriously flawed or overinflated when reality checks are done. Thus, having an appropriately experienced expert to find those chinks in the methodological armor can be critical for successful Daubert challenges.

The scientific method is the essential core for proving (or disproving) the adequacy and reliability of the expert's methodology. The steps of the scientific method include the following:

1) Purpose- Define what specific scientific questions need to be understood;
2) Research- Identify and characterize objectively the existing knowledge that is relevant;
3) Hypothesis- Form a specific prediction of the answer to the question(s) at issue;

4) Experiment- Design and implement meaningful tests to confirm or disprove the hypothesis;
5) Analysis- Record and interpret the experimental outcome;
6) Conclusion- Evaluate whether or not the observed data support the hypothesis, and how the findings fit with other existing knowledge that is relevant.

Repeated application of the scientific method to assemble a body of studies with proper design and analysis can bridge the gap between an apparently validated hypothesis or association, and a well-proven and consistent finding that might be characterized as a generally accepted theory or a causal association. In relation to Daubert and its measures of expert testimony reliability, the methodology underlying the expert opinions is evaluated with respect to the following four criteria:

1) Has the general methodology or principle been subjected to peer review and deemed to be reliable?
2) Has the specific methodology or principle been tested, or is it testable, and if so, has it been shown to be reliable?
3) Does the specific methodology or principle have an error rate that can be considered scientifically acceptable?
4) Does validation evidence for the methodology or principle exist outside the context of the litigation?

Rigorous evaluation of the above considerations can be used to establish whether or not the expert's scientific methodology underlying key conclusions can be considered reliable and generally accepted by the scientific community. Beyond establishing that reliable methodology was used, it is largely an examination of consistency and the application of logic that determines compliance with the remaining Daubert considerations, i.e., that the expert testimony is based on sufficient facts or data, and that the expert's methodology was appropriately applied to the case-specific facts or data and thereby fits the expert's conclusion(s).

In order to ensure compliance with Daubert considerations, the testifying expert must wear two hats: as a good teacher, and as an experienced scientific peer reviewer. Wearing the peer reviewer hat, the testifying expert must do the following:

1) Identify the key scientific questions that should be answered, and characterize the quality of existing information to answer those questions based on critical review of the scientific literature;
2) Discern what scientific facts are most relevant and whether they are reliably known or knowable (i.e., facts that can be developed from further inquiries or testing);
3) Identify the crucial data gaps, if any, that need to be filled in order to support strong answers for the key scientific questions, and evaluate the methodologies to be applied in accomplishing this goal; and

4) Evaluate the logical fit, strengths, and weaknesses of the answers to the key scientific questions in an objective, balanced, and transparent manner that does not stretch or overstate the existing state of knowledge.

Wearing the good teacher hat, the testifying expert must also fulfill the following:

1) Find appropriate language and illustrative techniques to clearly communicate the potentially complex methodology in a way that is understandable and engaging to the judge and jurors;
2) Explain proper and improper scientific methodology, and how the methods and principles utilized by the expert are reliable and generally accepted by the scientific community;
3) Explain how to properly apply those scientific methods and principles to the key scientific questions at issue; and
4) Explain how the sum of available facts and applied scientific methods properly fit together to support his/her conclusion in this case.

Undoubtedly, both of these skill sets are critical to making a clear case that one's expert's opinions are well supported and reliable, and/or that the opposing expert's opinions are unreliable and should be excluded.

In the areas of toxicology and disease causation analysis, proofs of general causation and specific causation can provide fertile ground to establish a basis for opposing expert exclusions under Daubert considerations. The disease cause-and-effect considerations by Sir Austin Bradford Hill (Hill AB. 1965. The environment and disease: association or causation? Proc Royal Soc Med - London 58:295-300) epitomize the diverse and rigorous set of considerations representing a thorough and generally accepted scientific methodology by which a conclusion of general causation can be reached. The Hill considerations include the following: 1) strength of association, 2) specificity of association, 3) temporal relationship, 4) dose-response relationship, 5) consistency of association, 6) biological plausibility, 7) experimental evidence, 8) analogy, and 9) coherence of association. As is the case with many scientific methodologies, the amount and quality of scientific evidence relevant to each of these considerations can vary substantially depending on the topic at issue, and thus it is often not possible—nor is it necessary—to 'check every box' in developing the final analysis and conclusions. However, a clear and logical demonstration can often be framed using these considerations to illustrate the strengths of one's expert's opinions and/or the weaknesses or fatal flaws in the opposing expert's views concerning toxicology and disease causation. Thus, the Hill considerations are well accepted as a rigorous methodology for general causation analysis that establishes whether or not there is sufficient scientific support for a particular chemical causing a particular disease.

Even in cases when general causation is established or assumed by both sides, the determination of specific causation is usually required to meet Daubert requirements on adequate methodology and proper fit to the case-specific facts. In specific causation analysis, an expert may utilize

additional details that, when properly considered, do not fit a causal relationship for the plaintiff's specific disease state and his/her specific conditions of exposure. For example, facts may show that the linchpin issue of temporality (e.g., disease onset prior to exposure) contradicts a cause-and effect-conclusion. Likewise, specific nuances regarding the disease characteristics (e.g., pathology, severity, timing) and individual characteristics (e.g., genetics, lifestyle factors, other underlying diseases) may more logically fit with alternative causes besides the alleged exposure at issue. Thus, specific causation analysis evaluates the degree of fit between the known facts about general causation and the particular facts about exposure and disease occurrence in the individual plaintiff.

I have been asked to address this question: What are the top five factors that, in your experience as a toxicology expert witness, can place an expert at greater risk of having his or her testimony partially excluded under Daubert? This is a critical question, since my potential clients often ask at interview whether or not my testimony has ever been partially or fully excluded. A positive response to this inquiry may lead the client to engage a different expert. And more serious and/or repeated occurrences of Daubert exclusions can stifle or effectively end one's career as a testifying expert.

The number one risk factor in my experience might be best characterized as 'judge issues.' More specifically, I have observed that some judges use subjective or manipulative decision-making for testimony exclusion instead of evaluating whether or not the testimony is based on scientifically reliable methods and reasonably logical connections. In some cases, the judge might choose to limit the scope of expert testimony on one or both sides in order to force settlement or shorten/simplify the issues that he or she believes should be presented to the jury. This, of course, is not the intended purpose of applying the Daubert considerations. I also suspect that sometimes the judge is unable or unwilling to learn the relevant scientific methods in sufficient detail to discern unreliable elements. In other instances, the judge may use exclusion or limitation of testimony as a bargaining tool between the parties rather than as a valid gate-keeping effort. For example, judges may curtail or limit testimony in order to offset a perceived imbalance in legal and expert skills between plaintiffs and defendants. Such manipulations are also not within the intended scope and purpose of Daubert.

The number two risk factor is perhaps best stated as 'bad schedule issues.' This is often combined with the 'bad judge issues,' where manipulation of the reasonable timeframe for case milestones can lead to insufficient time for expert (and sometimes legal counsel) preparation for deposition and trial. This factor is most damaging when there are important gaps in the facts that may require substantial time to implement strategies to address and bridge those gaps in support of key expert opinions. Accelerated timeframes also lead to missed opportunities for coordination between experts that might be necessary to improve the overall strength and clarity of the presentation in court. Also, when there are large volumes of relevant information to be considered and/or integrated into the expert analysis, time restrictions often lead to the need for

scope limitations and/or shortcuts that can weaken or potentially undermine the integrity of the expert's presentations.

The number three risk factor can be described as 'bad scope and budget issues.' As we all know, the entities that pay the legal costs are looking for the best possible cost efficiencies on all fronts. Some pre-emptive techniques for cost savings might include implementing fixed-price budgets for certain types/phases of litigation or requesting rigid budgets in advance of record review for legal counsel and/or experts. There is also a school of thought that expert preparation costs will be lowered by hiring the expert as late as possible in the case, when the possibility of settlement becomes remote. This is a flawed presumption because, like the 'bad schedule issues' described above, severe restrictions on the expert's scope of work and budget can seriously degrade the quality and clarity of analysis. In addition, anxieties related to budget restrictions may negatively influence the relationship between the expert and legal counsel. Restrictive budget and scope may correspond to less rigorous research, inability to address key data gaps, the need for shortcuts, and uncaught mistakes that together may increase risk for Daubert exclusion.

The number four risk factor can be described as 'bad information filtering issues.' This again is commonly related to time and budget restrictions that legal counsel may be attempting to address. Counsel develops a strategy to reduce the amount of information reviewed by the expert in order to save costs, but this can readily degrade the quality of expert analysis by unintentional omission of documents containing key facts or testimony. Similarly, cost-saving strategies might include not sharing certain expert reports or depositions that might have assisted the expert in developing a more powerful critique of the opposing experts for Daubert exclusion. Likewise, over-filtering may lead the expert to miss important facts that could strengthen and clarify his or her opinions. In my experience it is most convincing to judges and jurors to acknowledge that one's expert was given full freedom to investigate the facts, conduct additional investigations, and formulate his or her opinions without limitations from counsel.

Finally, the number five risk factor can be described as 'bad expert document preparation issues.' This includes the tendency of some counsel to want to write the expert's report for him or her, or to develop a script for trial presentation that does not fit with the expert's style. The core methodology and opinions should be described in the terminology most customary and comfortable for the expert in his or her scientific arena, with perhaps some added simplifications or clarifications if necessary. If the expert is unable to write or verbally communicate in a clear and effective manner, then perhaps that person should not have been hired for testifying. But if the expert is the 'good teacher' needed for the judge and jury, then having the flexibility to accept and adapt to the expert's communication style in the counsel's presentation of the expert's conclusions is very important. Counsel should also consider that good scientists will often require the inclusion of appropriate caveats that keep their testimony scientifically accurate, precise, transparent, and resistant to negative scientific critique. Such caveats might seem to be admissions of weakness from a legal perspective, but they can be quite important with respect to Daubert considerations applied to the scientific methods used. All in all, the ability of an expert

to survive Daubert challenges requires that the preparation methods allow the expert to be comfortable and confident.

It is also interesting to note that the onset of the Daubert rules in toxic tort litigation actually broadened the scope of peer-reviewed scientific publications by scientific consulting firms and individual litigation expert witnesses (including those appearing on behalf of both plaintiffs and defendants). While conducting experimental studies is sometimes perceived as a serious legal risk (since the lawyers cannot know with certainty the study outcome in advance), the appearance of such scientific studies in the peer-reviewed literature can be viewed as an endorsement of quality and general acceptance under Daubert. Hence, presenting one's expert as a scientist who has published one or more key peer-reviewed studies relevant to the scientific issues at hand can be an effective shield from Daubert exclusion, particularly for repeat litigation challenges involving the same set of scientific questions.

Even when scientific research papers have undergone peer review prior to publication in well-respected scientific journals, some attorneys and advocate groups have organized attacks directly on the authors and the publishing journals in attempts to undermine the validity of articles adverse to their own litigation interests. Through lawsuits or publicized attacks, they characterize the unfavorable articles as being 'corporate science' or 'paid-for opinions' that are no better than the 'junk science' that the Daubert rules were designed to keep out of expert testimony. Subsequently, some scientific journals began making decisions to avoid consideration of valid research papers that were perceived to have an underlying motivation to support litigation interests. In parallel, some journal editors were considered to have imposed their own personal beliefs on the selection of scientific papers that they considered suitable for publication. Thus, the Daubert rules and litigation-related research interests on both sides appear to have influenced the landscape of scientific journal peer review and decision-making that is no longer solely focused on the quality of scientific studies. The process now incorporates subjective decisions driven in part by presumed bias and monetary motivations related to litigation interests (Rothman, K. 1993. Conflict-Of-Interest - the New McCarthyism in Science. *JAMA*, *269*(21), 2782-2784).

On the other hand, the scientific literature has benefited from the participation of a diverse group of scientists who are publishing research on a broader range of topics that include direct answers to key scientific questions in toxic tort litigation. The required transparency on potential conflicts of interest, combined with adoption of more rigorous peer review standards by journal editors when considering litigation-associated research, can reasonably be expected to increase the quality and trustworthiness of such papers in quality scientific journals. On the negative side, there is a noticeable bias among some journals to avoid considering or publishing scientifically sound and important research if the funding source or perceived motivations of the authors are litigation-associated. While considering the underlying motivations of scientific researchers may offer important protections against publishing fraudulent or biased data, such judgments are

inherently subjective and can unfairly exclude valid viewpoints that should be considered in scientific debate.