**Daubert in Drug and Dietary Supplement Cases: The Recipe Matters**

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It is a well-tread maxim that the human body is a highly complex machine. It should come as no surprise, then, that drug products (both prescription and over-the-counter), dietary supplements and other ingestibles the substances created to maintain or improve that complex machine’s smooth running are often equally complex. Behind each tablet, capsule or liquid dose lies a network of active ingredients, co-ingredients, and other substances.

Over the years, many of these products have been the subject of numerous product liability lawsuits across the country. These cases are frequently marked by a parade of expert witnesses of varying qualifications and experience. Not surprisingly, parties often seek to exclude or limit expert testimony through *Daubert* motions.

**Daubert and Its Progeny**

Before *Daubert*, courts typically applied the *Frye* standard, *i.e.*, expert testimony was only admissible if it was “generally accepted” by the relevant scientific community. The premium on consensus within the scientific establishment governed for decades. The need for such “general acceptance” among a body as diverse as the scientific or medical community made it difficult to admit expert testimony based upon newly emerging scientific principles. Scientific advances could only earn the necessary “general acceptance” through the passage of time, scrutiny, and peer review. In theory, this ensured that a jury only heard bedrock solid scientific principles, at the cost of excluding valid but novel science.

In 1993, when the Supreme Court issued its decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, it adopted a more nuanced view of expert testimony. *Daubert* announced that trial courts have the power and obligation to act as gatekeepers and screen out unreliable expert testimony. First, the testimony must “fit” the facts of the particular case. Stated differently, the expert testimony must be sufficiently connected to the facts of a case. Second, the expert testimony must use reliable methods, not speculation or subjective belief. To evaluate the reliability of an expert’s methods, *Daubert* took *Frye’s* rigid “general acceptance” standard and made it just one of many considerations that courts must weigh, namely: (1) whether the expert’s analysis evaluates each individual product, as well as each specific active ingredient in each product. Rather than consider the effect of every active ingredient, courts have generally evaluated only the most well-known ingredient, without regard to the possible impact that co-ingredients may have. However, when products contain active co-ingredients, a thorough analysis of each of the ingredients should be conducted to determine what effect each ingredient has, or what role each ingredient plays, if any, in the outcome. Courts should be mindful of the fact that each ingredient could have an additive, synergistic, or perhaps even a neutralizing effect on another active ingredient. In this context, fulfilling the principles behind *Daubert* cannot be accomplished without a thoughtful and painstaking analysis of each individual ingredient.

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method has been or can be tested; (2) whether it has been subject to peer review and publication; (3) its known or potential error rate; and (4) whether it has been generally accepted by the relevant scientific community. No single one of these broad factors is dispositive, further expanding the trial court’s ability to exclude or admit expert testimony based on the facts of the particular case.

The current “lawsuit crisis” has resulted in a number of so-called mass torts. These cases have resulted in an explosion of “expert” testimony, with an accompanying potential for the jury’s confusion, obfuscation, and distraction away from the core issues in any lawsuit.

**Daubert in Mass Tort and Multiple Defendant Litigation**

In the context of mass torts, MDLs and other litigation involving multiple defendants alleged to have manufactured, sold and/or supplied various similar, but not identical products, the Daubert analysis presents a unique challenge for the court and the parties. Certain ingredients may present a potential for an outcome that is only realized through interactions with other ingredients. For example, in products such as PPA or a variety of dietary supplements, the ingredients vary from product to product. Therefore, for these type of “unique recipe” ingestible products that are the subject of an MDL or consolidated state court proceedings, courts would need to review each of the products sold by various manufacturers, and analyze the specific ingredients (and amount of each ingredient) present in each product. This would be necessary to determine the role, if any, that the individual ingredients played in the alleged outcome, and to determine if that particular product could have caused or contributed to the alleged outcome.

The presence or absence of certain co-ingredients in products supplied by different defendants makes a “one size fits all” Daubert analysis untenable. For example, certain products containing ephedra can also contain one or more of 40 co-ingredients. Each ingredient for each of these different branded products must be evaluated independently for a proper Daubert analysis to be performed. Does a particular active ingredient have an effect only when combined with a second specific ingredient? Does the presence of a third ingredient counter the effect of the second, thereby minimizing or eliminating any claimed potential risk? Are the effects of certain ingredients additive, synergistic, neutralizing, or perhaps even irrelevant as to the claim being evaluated by the court?

Formulation is likewise critical because an active ingredient may have no effect at a particular level (or dose), but a significant impact at a different level. If Company A supplies an ingredient in a product at a far different level than does Company B, should not the court scrutinize these products separately, rather than simply identify the mere presence of an ingredient and, without more, consider the products to be the same in a Daubert analysis? These are some of the issues and questions that should be addressed for the Daubert analysis to be conducted properly in a multiple ingredient ingestible case.

All parties to such litigation are better served when courts acknowledge that when there are different ingredients in varying amounts, this can—and often does—result in fundamentally different products with a different risk/benefit profile. The mere fact that these products share some of the same ingredients is not sufficient to justify the “one size fits all” approach. Specific, focused, and exacting expert testimony is necessary to identify, let alone tackle or resolve, causation questions in this context. Experts should, where appropriate, review the product in question and scrutinize its particular ingredients and their effects, side effects and potential interactions. Such an evaluation should help address, with greater precision, any causation issues by helping to: (1) isolate the allegedly harmful ingredient(s); (2) evaluate the dose at which such ingredient(s) may cause side effects; and (3) evaluate interactions between these ingredients.

Some courts are unwilling, or unable, to wrestle with and gain command of scientific principles. Too many experts fail to discuss ingestible products with this type of rigor. Worse yet, too many courts often do not require it at either the Daubert stage or at trial. Instead, courts sometimes permit experts to address the product and its alleged harms too broadly, with only general, vague, and conclusory opinions. The result?

Product liability lawsuits, especially involving drugs and dietary supplements, often proceed like runaway trains, without satisfying meaningfully the threshold question did the product, and not something else, specifically cause plaintiff’s claimed harm?
A Better Application of Daubert

Daubert instructed courts to admit only scientific evidence and testimony that: (1) is based upon reliable methods; and (2) fits the specific facts of the case. Any abdication of these principles is a disservice, because it only engenders unnecessary time, expense, and effort. Therefore, courts must recognize and require scientific rigor at the Daubert stage.

The need for scientific rigor is particularly striking in litigation dealing with ingestible products that presents complicated causation issues. An expert should not be permitted to rely only on broad notions that an ingredient is harmful without considering the precise interrelationship between each product's formulation and co-ingredients. Conclusory or generalized opinions fail to “fit” the particular circumstances of case. For example, it is ultimately irrelevant whether one active ingredient, taken in large doses, can generally be harmful. The pertinent question for a lawsuit is, and can only be, whether that particular active ingredient, taken in accordance with the labeling instructions, actually led to the specific harm that a plaintiff suffered. This question can only be answered after careful scrutiny of the product and the relationship and impact of the product's co-ingredients.

To address these causation issues, courts should examine the expert opinions from both sides to see whether the role of other ingredients in some products may have an effect, if any, on the cause (or possible prevention) of the alleged harm. In the proper case, experts should: (1) articulate how and why each active ingredient plays a role in increasing or decreasing any claimed causative effect; and (2) cite reliable scientific data in support of any claim concerning the effect of each ingredient evaluated. This approach reflects the traditional notions in the scientific method. Science does not stop at the mere formulation of hypothesis or theory. It soldiers on towards validation through actual observation, testing, and study. More importantly, it ensures that a jury only hears, considers, and bases decisions upon expert testimony that is not only reliable, but actually pertinent to the precise issues that it must decide.

Opponents to this approach may argue that any inquiry about the thoroughness of an expert’s analysis goes to the evidence’s weight, not its admissibility, and is appropriate grist for cross-examination at trial, not a Daubert motion. However, these arguments ignore a practical reality every “expert” who testifies at trial may carry, in essence, a judicial stamp of approval. This imprimatur of “credibility” can affect the jury’s evaluation of the evidence. Therefore, a more searching inquiry at the Daubert stage is a safety measure to ensure that any expert status is earned and not dispensed freely.

Conclusion

Courts should and must enforce their Daubert obligations with rigor. In cases involving ingestible products, jurors are likely to rely upon experts to guide them through scientific principles and their application to the particular issues and questions that they must resolve at the end of the day. Vague, amorphous, or suspect expert testimony should not be able to slide its way before the jury. Courts and counsel must insist that experts be able to connect the alleged defect and the alleged harm with valid science, not speculation and conjecture.

In the context of mass torts and MDLs with numerous or different defendants that are alleged to have manufactured, sold and/or supplied various products at issue, courts must resist the temptation to group all of these products together when there are similar products with multiple and sometimes different co-ingredients and different formulations. To best serve the ends of justice, courts must recognize that each product needs to be scrutinized individually. Experts who fail to consider the intricacies of each product at issue should not be permitted to testify. Anything less fails to honor Daubert or elementary scientific principles.

1 Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).
3 Daubert, 509 U.S. 579, 599 (1993) (“reliable” scientific knowledge “connotes more than subjective belief or unsupported speculation”); Goebel v. Denver and Rio Grande Western RR Co., 215 F.3d 1083, 1088 (10th Cir. 2000) (“It is axiomatic that an expert, no matter how good his credentials, is not permitted to speculate.”).
4 While some courts have recognized the complexities within products like pharmaceuticals, noting that even the slightest change can yield drastic results, this recognition does not often enough extend to expert testimony or Daubert proceedings. See, e.g., Schudel v. General Electric, 120 F.3d 991, 996–97 (9th Cir. 1997) (“[S]mall differences in molecular structure may produce substantial differences in physiological effects.”); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 791 F. Supp. 1042, 1054 (D.N.J. 1992) aff’d 6 F.3d 778 (3d Cir. 1993) (“Small changes in chemical structure can cause very different human effects.”).
5 See DePape v. General Motors Corp., 141 F.3d 715, 720 (7th Cir. 1998) (“District courts must be careful to keep experts within their proper scope, lest apparently scientific evidence carry more weight with the jury than it deserves.”).