# RELEVANCE OR FIT: THE MEANING AND USE OF THIS IMPORTANT ELEMENT OF DAUBERT

## How experts misuse scientific literature

A critical element of Daubert, specifically stated, is that scientific literature used by experts to support their opinions must be relevant (or, fit) the situation extant in the case. Frequently, experts provide such "support" with long bibliographic lists or stacks of authoritative-seeming articles from scientific journals. This sheer mass of material ostensibly supports your opponent's opinion. The list may be impressive and daunting. When we do *relevance checks*, however, we commonly find that many of those citations are irrelevant because they fail to support either general or specific causation in the case at hand. Some of the reasons they fail include:

- Conclusions drawn from animal, not human, studies;
- The quantitative doses or exposure levels in the literature are not comparable to the levels in the case;
- The literature cites the wrong disease;
- The published regulatory data are not applicable to a specific individual;
- The latency period in the literature is inconsistent with the matter;
- The clinical course of treatment in the matter is different; and
- There are many other possibilities as well.

Here's a simple, non-scientific, example. Assume a man died after being hit by a truck. The operator of the truck was accused of contributing to the death. Plenty of research could be produced to support the proposition that trucks can kill. But wait! This was a child playing with a toy Tonka truck. Clearly, his toy truck could not have been responsible. Thus, all of the vast evidence that trucks can kill is irrelevant in this case. It is often equally irrelevant in cases involving allegations of chemically-induced injuries. However, in these latter cases, the lack of relevance is less apparent to the non-scientist.

#### Don't be intimidated by a long reference list or a box of literature

In a case currently pending before a State Supreme Court, the claimant's attorney, attempting to salvage her disqualified expert, argued that her expert used a "weight of evidence" approach. In that matter, she intended "weight" to mean "fully considered." What it actually meant was numbers of pounds. The hundreds of articles weighed a great deal, but they were, in totality or individually, inadequate to support the claim. Most were irrelevant.

On almost any medical or scientific subject, it is possible for an expert to produce dozens, if not hundreds, of articles which are offered to support his/her position. Some may be right on point. Often, many are extraneous or irrelevant, even when they have the name of the chemical, or of the disease, in the title itself. They are simply provided to bolster a poorly-supported position. Attorneys may do the same thing when they compare the facts of their case to a prior precedent, but there are differences. First, the number of legal citations offered is generally less. Second, because they are being used by lawyers to bolster legal arguments against other lawyers' positions, a critical analysis and response is anticipated. Thus, while the citations may not be directly on point, they either come close, or are readily attackable by opposing counsel. By contrast, attorneys and the Court are in no position, without help, to dissect the hundreds of impressive scientific papers when assessing their relevance. Because of these circumstances, medical and scientific experts are better positioned to mislead.



# Case Example

Under Daubert, supporting literature must be "relevant" or "fit" the circumstances at issue, but there are many reasons why imposing stacks of articles may fail the relevancy test. For example:

In certain situations the chemical is known to cause the disease at issue as is the case with Benzene and Leukemia.

Certain relatively high levels of occupational exposures to benzene are clearly connected to a specific form of leukemia: AML (acute myelogenous leukemia). AML is not a terribly rare disease and can arise with no known cause. In fact, most do. It is common for patients who develop leukemia to be asked about "chemical exposures." Some may have worked with or around some chemicals that contain either benzene or other chemicals that contain the name "benzene." This finding alone may then generate either a workers' compensation claim, or a liability claim alleging that "benzene" in the workplace caused the leukemia.

A voluminous stack of articles dealing with all aspects of benzene and leukemia accompanied by MSDS's (the manufacturer's material safety data sheets--the product information sheets) of chemicals at the workplace containing the word "benzene" will be put forth to support the claim. A closer look at those information sheets, a **relevance check**, commonly finds them to be irrelevant. Why? Many chemicals which are not benzene contain the name benzene, for example, ethyl benzene, methyl benzene, dichlorobenzene, and many others. These do not cause leukemia. Also, all chemicals derived from petroleum, including paints, paint thinners, and even furniture polish, contain low levels of residual benzene (0.1 % or less) and must, by law, have benzene on the label. Exposures to these products containing small amounts of benzene are not connected to leukemias. Again, these MSDS's may appear persuasive, but they are irrelevant.

#### **General Causation not met**

Articles can be used to allege almost any relationship between numerous chemicals and equally numerous diseases. Animal studies may link specific cancers to certain agents. Regulatory agencies may even regulate those agents as carcinogens, based on those studies. Those studies, however, may not prove that the disease at issue, cancer, brain damage or others, is actually causally-connected to those diseases in humans. Therefore, the literature may be irrelevant for supporting the requirement for general causation: that it is scientifically known that this agent can cause this disease.

## **Specific Causation not met**

Dose insufficient: The benzene example above is one of many instances in which links between an agent and a disease may be known, *if the dose is sufficient*. Another example we deal with quite often relates to alleged claims that indoor exposure to mold mycotoxins caused a disease, yet this is unsupported scientifically because of insufficient dose. This "DID it cause this person's disease?" question -- the essence of specific causation -- is rarely answered by scientific literature. Another example would be that just because elevated lead levels in a child may lead to IQ or behavioral changes -- hundreds of articles deal with that -- does not mean that this particular child's disorder is related to lead. All of that lead literature may be irrelevant to the specifics of this child's disorder.

# Wrong kind of disease

The fact that a chemical may cause a kidney or liver or respiratory disorder does not mean that it can cause **any** kidney, lung, or respiratory disorder. Often chemical effects are quite specific, affecting certain cells in a specific pathological manner. Thus, if a person has a peripheral neuropathy and has been exposed to n-hexane (a known cause of a specific type of peripheral neuropathy), both the exposure dose and the pathological type must fit the known outcome of n-hexane toxicity. The hundreds of articles and book chapters that discuss the effects of n-hexane, while impressive, are irrelevant, if the claimant has the wrong disease. The same can be said for most benzene claims other than AML. Benzene does not cause injuries to most organ systems.

### Performing a relevancy check

When we perform a relevancy check of opposing experts' literature, we examine a number of critical questions:

- 1. Are the studies sufficiently robust and replicated to support a general causation argument?
- 2. Do the studies establish the potential for the types of clinical effects alleged in the claim? Or, for example, do they investigate subtle biochemical changes which, at present, have no direct clinical applicability?
- 3. How much effect do the studies show? For example, if a risk is increased by 5%, it is rarely possible to use such studies to allege specific causation in an individual.
- 4. Were the studies performed in human beings under circumstances similar to those at issue in the case? Agents injected into a mouse's abdomen are not the same as lower-level materials inhaled by people.
- 5. What doses were used or observed in those studies? Occupational exposures to a chemical are rarely equivalent or directly applicable to low-level consumer product exposures.

These are just a few of the numerous types of relevancy issues with which we deal daily in our causation analyses. The simple take away message is that daunting lists or piles of scientific and medical articles may be worrisome to attorneys, but they are meaningless to a claim, if they are irrelevant to the specific facts of the case.

## **ICTM Expertise**

Again, Daubert mandates that the trial judges act as "gatekeepers" and allow a jury to hear and consider only evidence that is deemed to be both relevant and reliable. Prior to Daubert, many claims did not involve good evidence of a causal relationship. I testified at one of the first Daubert hearings in 1993, in which the defense won a favorable decision and the plaintiff experts were excluded. Since that time, ICTM has done a tremendous amount of work on Daubert matters, both working on individual cases where we have provided affidavits and brought together scientific information, accumulated various experts to help our clients, as well as succeeded in getting experts excluded on the other side, when they did not have good scientific support for their positions. I have written chapters in books on Daubert, including all of the elements and the scientific applications. I have also signed on to successful amicus briefs that have been submitted to both state supreme courts and the U.S. Supreme Court.