



Engineering Sciences Section – 2011

C16 Establishing Causation in Environmental Toxin Cases – Optimal Interaction Between Lawyers and Experts

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After attending this presentation, attendees will have an overview of the methodology for establishing general and specific causation in cases of individuals exposed to environmental carcinogens. These cases are unique in their requirement for a team of experts with widely differing areas of expertise each of whom must rely on the one before him.

If one of the expert's reasoning is found to be flawed by the court, it can result in a *Daubert* challenge against all the subsequent experts who relied upon that one expert. This presentation will impact the forensic science community by providing an understanding of the newly-evolving scientific and legal requirements for these cases which will allow a better understanding of the interpretation of the results, how much the case will cost and it will allow the experts to evaluate the validity of each other's testimony.

The tools available to establish general causation are largely in the form of animal studies performed by regulatory agencies such as the Centers for Disease Control (CDC) or compiled and discussed by agencies such as the Institute of Medicine (IOM), together with human studies which are essential to support general causation. Except for a few chemicals such as the dioxins which have been followed in exposed populations prospectively, proper controlled studies are not available since it is not ethical to expose humans to carcinogens. In the absence of controlled studies on carcinogen exposure, published exposure studies are primarily at the workplace. The rate of cancer in workplace studies is *always* underestimated because of the methodology by which the studies are conducted. Judges have adopted the rule that a chemical cannot be legally found to cause a cancer unless there is a report showing a relative risk of 2.0. In addition, if the confidence interval crosses 1.0, then the study can be excluded from evidence as not being statistically significant. The usual result of this is that the plaintiff presents a barrage of appropriate studies, the defendant counters with another onslaught of epidemiologic studies that do not meet the statistical requirements, and then the expertise, preparation, and quick wittedness of the expert comes to the fore in his/her ability to point out the flaws in the studies. These flaws are predictable and will be discussed.

Probably the greatest challenge in establishing general causation is identifying the chemical and, therefore, the disease(s) in which it could be implicated. The safest way to find a good case is probably to follow on the studies performed by the regulatory agencies that are mandated to identify and quantify the environmental chemical, usually carcinogens, once a superfund site is identified. In these studies, the raw data is usually accurate although the scientific interpretation may be politically dictated.

Specific causation is very much a matter of precise, careful histories to exclude other causes of the target illness, and optimally to identify a mechanism of action by which the targeted chemical caused the disease. This is routine medical practice, and a competent physician who is experienced in the range of chemicals which may cause the disease should handle it well. However the devil is in the details, and in the case of specific causation, the devil is in the dose.

The EPA holds that a dose which increases risk of cancer by $>1/10^5$ in a population can be considered significant. Although workplace exposure is helpful, most environmental toxic exposures are domestic. A large number of methods must be utilized to determine what the dose of a suspect chemical was at the time that critical exposure occurred, made more difficult by the long latency period of most cancers. Most physicians will agree that there is a range of carcinogen exposure which can cause a significant increased risk of cancer (usually considered to be

$>1/10^5$ /year) in a population. Because of the enormous biological variability in exposed humans, many will refuse to opine on what was a cancer dose for a given individual. As judges and defendants have come to realize that the difficulty in establishing causation they have crafted a series of questions which can quickly reduce the expert who refuses to play the game to idiot status. Those questions will be discussed, as will the many ways that a dose can be established.

Environmental Toxins, Domestic Exposure, Dose