E8 Go or No Go: Screening Scientific & Technical Studies and Reports Presented in Court

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After attending this presentation, attendees will have an understanding of the factors judges and attorneys consider in screening scientific studies and expert witness report.

This presentation will impact the forensic science community by providing a better understanding of how judges scrutinize studies and reports presented by expert witnesses in court.

When Jason Daubert and Eric Schuller were born, with serious birth defects, their parents sued Merrell Dow Pharmaceuticals, Inc., the manufacturer of a prescription anti-nausea drug known as Bendectin, which was prescribed to their mothers during pregnancy to limit "morning sickness." The plaintiffs claimed that Bendectin caused birth defects in their children. Before the case was able to be tried by a jury, the defendant manufacturer made a motion for summary judgment before the judge, asserting that Bendectin did not cause birth defects in humans. In support of that assertion, the manufacturer presented the affidavit of a physician, who was also an epidemiologist that had reviewed all of the 30 plus published studies involving over 130,000 patients. The doctor concluded from his review of the studies that the use of Bendectin in the first trimester of pregnancy, when nausea is at its worst, had not been capable of causing malformations in fetuses.

While the plaintiffs did not contest the characterization of the published Bendectin studies, they opposed the motion for summary judgment and presented eight well credentialed experts in the fields of pediatrics, veterinary medicine, pathology, toxicology, developmental biology, clinical pharmacology, epidemiology, biostatistics in reproductive epidemiology, biometry, and pharmacology.

But, the trial judge rejected the plaintiffs' proffered opinions of those eight experts in favor of the sole defendant's expert, who had summarized all of the studies concerning whether Bendectin taken by pregnant mothers could cause birth defects in their children. The judge granted the defendant-manufacturer summary judgment, in essence in dismissing the case and did not allow the case to proceed to trial where a jury could evaluate all of the expert opinions. Clearly, under Federal Rule of Evidence §702, each expert was well qualified in their respective fields by education, training, skill, experience and knowledge. Yet, the trial judge found that their proposed testimony was insufficient to rebut the more than 30 studies that failed to find a causal link between the ingestion of Bendectin and birth defects in children.

Why were the plaintiffs' eight experts muzzled by the judge?

What the plaintiffs' experts presented was a recalculation of the data from some of the previous human epidemiological studies, which demonstrated no causal relationship. After the recalculation it should show a positive correlation between the drug and the cause of the birth defects. But those recalculations were never published or subjected to peer review. They also presented animal studies and pharmacological analysis to demonstrate that there was a statistically significant association between a component of Bendectin and birth defects. Others would testify that the chemical composition and physiological activity of a drug are important in ascertaining whether it is a teratogen, capable of causing birth defects. Because the plaintiffs did not present any contrary epidemiological evidence to counter the published studies in the field, the court rejected the plaintiffs' contention.

The *Daubert* case was ultimately appealed to the U.S. Supreme Court.[1] The Supreme Court outlined that judges as the gatekeepers of evidence should consider some or all of the following flexible factors to determine: (1) whether proposed expert testimony or evidence was tested or capable of being tested or refuted; (2) whether there was a margin of error; (3) whether the evidence was ever published and subjected to peer review; and, (4) whether the evidence or theory was generally accepted in the discipline to which it belongs. While scientists distinguish validity – does the principle support what it purports to show? – from reliability – does application of the principle produce consistent results – in law where a case involves "scientific evidence," the evidentiary reliability will be based upon scientific validity. Moreover, it must be relevant to the case presented. That is, the evidence or theory fits the facts of the case at hand.

The Supreme Court established or reasserted a judge's role as a gatekeeper of evidence, especially evidence concerning science, technology, and other specialized knowledge; it did not give the trial judges a definitive framework or checklist of factors to consider before admitting such evidence into a trial to be scrutinized by a jury.

The trial judge is confronted with a "go" or "no go" determination as to whether the proffered expert testimony or evidence is scientifically valid. That is, that it followed established scientific or technical methods and procedures to arrive at a conclusion that is relevant to issues of the case before the court. There is no middle ground – the evidence is either admissible, that is sufficiently reliable to go before the jury or inadmissible and will not go before the jury. Such decisions are not just another evidentiary ruling. Most decisions concerning the admissibility of scientific evidence are dispositive of the entire case. Therefore, judges need guidance in determining whether to go or not go with scientific evidence before a jury.

This presentation will provide several considerations for judges and attorneys to consider when scrutinizing scientific studies or reports. Since this is a time consuming endeavor for any judge, studies and reports asked to be admitted or

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adopted as the basis to support an expert opinion ought be presented and scrutinized well in advance of a hearing or trial with time allowed for opposing studies and reports to be submitted by the opposing side.

References:

1. *Daubert v. Merrell Dow* Pharmaceuticals, Inc., 509 U.S. 579 [1993].

Screening Studies, Expert Witness Reports, Admissibility

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