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## N.J. court sets evidence standards in talc/cancer case, tosses lawsuit

**T**he New Jersey Superior Court recently held in the talc-based powder products litigation that “courts are experts in the law, not science.”

The litigation is a consolidated case of two plaintiffs who brought claims which alleged that a talc-based product manufactured by the defendant had caused each of them to develop ovarian cancer. *Carl, et al. v. Johnson & Johnson, et al.*, No. ATL-L-6546-14 (N.J. Sup. Ct.) (2016).

The issue for the court to decide was whether the plaintiffs had shown that their experts’ theories of causation were “sufficiently reliable as being based on a sound, adequately founded scientific methodology, to wit, that they [were] based upon methods which experts in their field would reasonably rely in forming their own ... opinions about the cause(s) of each of plaintiffs’ ovarian cancers.”

Specifically, the court was ruling on the defendants’ motions to bar testimony of each of the plaintiffs’ several expert witnesses. In the event that the court ruled in favor of the defendants’ motions, the defendants also filed companion motions for summary judgment. The motions were received by the court at a plenary hearing conducted pursuant to the standards articulated in *Kemp v. State of New Jersey*, 174 N.J. 412, 430-32 (2002).

The court granted the motions to bar testimony and, as a consequence, granted the defendants summary judgment.

Until 1991, New Jersey’s test for the admissibility of expert testimony based upon a body of knowledge peculiar to a field of scientific study was that it had to be generally accepted or had been accepted by at least a substantial minority of the scientific community.

In *Rubanick v. Witco Chemical Corp.*, 125 N.J. 421, 432 (1991), the New Jersey Supreme Court modified that test with regard to evidence proffered for use in toxic tort cases.

“Pursuant to *Rubanick*,” the court noted, “the key to reliability is the determination that the expert’s opinion is based on a sound,

adequately founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field.”

Thus, New Jersey courts recognize that there are situations in which a theory of causation that has not yet reached general acceptance in the scientific community may still be found sufficiently reliable to support submission of such a claim to a jury.

In *Kemp*, the New Jersey Supreme Court suggested that an N.J.R.E. 104 hearing is the preferred procedural practice in every case involving an expert’s theory that has not yet achieved “general acceptance,” finding that the trial court has an obligation, sua sponte, to conduct such a hearing and that the failure to do so is plain error.

The talc litigation court noted that the focus of the hearings must be on principles and methodology and not necessarily on the conclusions or opinions that such scientific methodology may generate.

“This court’s role is that of a ‘gatekeeper,’” explained the court, “who — based upon the proofs presented by the parties — must assess whether or not the hypotheses of causation advanced by plaintiffs’ experts are sufficiently reliable to be presented to a jury.”

In anticipation of the parties’ experts, the court solicited from counsels the submission of all reports, abstracts, epidemiology studies and peer-reviewed articles that were relied upon by the witnesses in formulating their opinions. Of particular importance, the court pointed out, was The Reference Manual on Scientific Evidence (3rd Edition). “Because [The Reference Manual] is indicative of what the scientific community deems to be reasonable,” noted the court, it “provides excellent guidance to trial judges in sifting through and prioritizing the information generated at a *Kemp* hearing.”

A “*Kemp* hearing is the intersection of the scientific method and the rule of law,” said the court. “If our court system is to be respected by the scientific community, then we must respect the sci-

### TOXIC TORT TALK



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entific process.” Thus, in evaluating the plaintiffs’ experts’ methodologies in arriving at their conclusions and opinions, and whether the same are “reliable,” the court noted that it must consider six “building blocks” of the scientific method: (1) epidemiological studies; (2) laboratory studies on talc and cancer; (3) cancer biology and research; (4) animal studies; (5) agencies which study cancer; and (6) Bradford Hill criteria.

#### Epidemiological studies

These provide “the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease.” The typical use of large population-based studies, noted the court, is in connection with general causation. As noted in The Reference Manual, general causation is concerned with “whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual’s disease.”

#### Laboratory studies on talc and cancer

The court noted that, to confirm a possible cause-and-effect relationship suggested by epidemiological studies, an exposure assessment can be conducted in order that the findings of those studies may be compared to the ad-

verse health impacts predicted from exposure estimates and toxicological data from laboratory experiments.

Here, the court said, regarding the plaintiffs’ claim of a specific causal relation between talc-based powder and ovarian cancer, laboratory studies can be performed on both human and animal cells to assess the impact of talc upon tissue and cells removed from both women and animals.

#### Cancer biology and research

The court noted that scientists now have the ability to analyze many thousands of genes, and to study how a particular gene responds to various substances. As a result, the biology of cancer and the research being done are all relevant to any scientific inquiry into the alleged causal connection between talc-based powder and ovarian cancer.

#### Animal studies

Studies on animals, the court noted, are another means by which to measure the toxicity of an agent in humans. Agencies which study cancer and those agencies’ findings are also useful.

#### Bradford Hill criteria

Sir Austin Bradford Hill, a respected scientist and pioneer in medical statistics, advised that scientists should be guided by various factors in determining whether an observed association between a chemical and a disease is causal. These factors are referred to as the Hill criteria and include (1) strength of association; (2) consistency of the relationship; (3) specificity of association; (4) temporality; (5) biological gradient; (6) plausibility; (7) coherence; (8) experiment; (9) analogy.

The court “was disappointed in the scope of plaintiffs’ presentation” of its experts, describing the proceedings as “narrow and shallow,” in that much of the testimony ignored other building blocks.

Having applied the standards established in *Rubanick*, the court held that significant deficiencies in the plaintiffs’ two principal experts’ methodology and analysis render their opinions inadmissible; therefore, the defendants’ motions to bar testimony and for summary judgment were granted.