23 September 2016

Practice Group(s):

Toxic Tort

Product Liability

New Jersey Court Rules Talcum Powder Claims Not Supported by Science

By Michele C. Barnes, Clifton T. Hutchinson

Talcum powder has been widely used as a cosmetic and bath product by Americans for well over a century. In recent years, claims have been asserted that talcum powder causes certain forms of ovarian cancer. This has resulted in litigation and two verdicts of $72 million and $55 million in state court in St. Louis, Missouri. But on September 2, a New Jersey state court, in a comprehensive and thoughtful analysis, found significant gaps in the methodology and analyses of two of the same plaintiff's experts who provided opinions in Missouri. Carefully applying its gatekeeping function, the New Jersey court rejected the expert opinions and granted summary judgment for defendants. This decision is a signal victory for the application of rational and well-founded science in the courtroom. *Carl v. Johnson & Johnson*, and *Balderrama v. Johnson & Johnson*, Civil Action No. 300 (MCL) (N.J. Super. Ct. Sept. 2, 2016).

The talcum powder cases continue the line of mass tort litigation that illustrate the difficulty and cost of dealing with toxicological claims based more on advocacy and emotional fact patterns than on a reliable application of the scientific method. The Bendectin and breast implant claims exemplify this life cycle, consisting of an initial highly publicized wave of lawsuits, large early jury verdicts, followed ultimately by recognition that the allegations were all along unfounded. The first wave in this life cycle is dependent on persuasive expert testimony, such as the plaintiffs' experts in *Carl/Balderrama*, one of whom was described by the trial court as a "dazzling witness," whose "vocal inflection, cadence and adroit use of histrionics" were extremely effective. Fortunately, the New Jersey court looked behind the histrionics to the science.

In toxic torts, the expert must establish general causation, that a substance can generally cause a toxic effect, and specific causation, that the substance did cause the effect in the specific plaintiff. In the mass tort paradigm, general causation is the most significant prong of the calculus because if the substance cannot cause the ailment at all, then it cannot be implicated in any individual case. Conversely, a finding of general causation can lead to an overwhelming wave of new filings.

The building blocks required to establish general causation in toxic tort are well-recognized, as discussed in scientific literature, laid out in legal treatises such as the Federal Judicial Center's Reference Manual on Scientific Evidence,[1] and as discussed by Judge Johnson in the New Jersey case. Scientists look at human data from epidemiologic studies and laboratory studies in which cells and laboratory animals are exposed to the alleged toxic substance. Human epidemiologic studies differ in the strength and accuracy of their proof of association between disease and exposure. Cohort studies measure and compare the incidence of disease in an exposed and unexposed population. Another type of study, a case-control study, starts with a population of persons who have the ailment, then tries to

[1] REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (3d ed. Federal Judicial Center 2011) ("FJC Manual").

determine what percentage of persons were exposed. Case-control studies are less informative in that they rely on the subjects' recall and are prone to recall bias and selection bias. "In general, patients have greater motivation (e.g., to explain their disease) and thus are more likely to remember and/or report certain past exposures than are healthy individuals who are selected as control subjects."[2]

Only after an epidemiological study finds an association between agent and disease do scientists apply the guidelines for inferring whether there is a causal relationship.[3] A number of factors, known as the Koch or Bradford Hill postulates, are considered. An important factor is the strength of the association, measured by the relative risk. Relative risk is a cornerstone of causal inference.[4] Relative risk is the ratio of risk of disease among people exposed to an agent to the risk among the unexposed. Relative risks of 1.0 show no association and relative risks below 1.5 indicate only a weak association. A number of leading epidemiologists require a study to have a relative risk of at least 3.0 to show a possible causal link.[5] The three large cohort studies of talcum powder use, involving over 191,000 participants, showed no cancer risk, with relative risks near 1.0.[6] The Plaintiff's causation expert's own research, based upon case-control studies, showed an odds ratio of 1.29, which is admittedly weak.[7]

Another important factor is the consistency of epidemiological studies. Results should be replicated in different populations by different investigators before causation is accepted.[8] In the case of talcum powder, the only consistency is the showing of weak or nonexistent association with ovarian cancer. Scientists should also consider potential alternative causes for the disease. A confounding variable, when another causal factor confuses the relationship between the agent and the disease, is a major reason for error in epidemiologic studies.[9] In the New Jersey cases, each of the plaintiffs had significant risk factors for ovarian cancer, but their experts did not account for or eliminate these risks.

Perhaps the most important factor in the causation analysis is biologic plausibility: Is there a plausible explanation of the mechanism by which the agent causes disease? In the New Jersey case, plaintiffs' experts postulated that talcum powder particles traveled to the ovaries, causing inflammation, which led to cancer. But talc is inert, does not cause cell mutations, and, in fact, has anti-cancer properties.[10] Most significantly, there was no evidence that either plaintiff had inflammation in her ovarian tissues. There was simply no explanation of the chain of events leading from talcum powder use to cancer. "Uttering the term inflammation does not explain the etiology of ovarian cancer. . . ."[11] This was true of the general causation inquiry, as well as the specific causation question for both of the plaintiffs.

---

[2] Paolo Boffetta, et al., *False-Positive Results in Cancer Epidemiology: A Plea for Epistemological Modesty*, 100 J. NAT'L CANCER INST. 988, 991 (2008).

[3] FJC Manual at 598–99.

[4] *Id.* at 602.

[5] Gary Taubes, *Epidemiology Faces Its Limits*, 269 SCIENCE 164 (1995).

[6] *See* Order, Appendix A.

[7] Order at 29–30. The odds ratio in a case-control study is quite similar to risk ration from a cohort study. FJC Manual at 625.

[8] FJC Manual at 604.

[9] *Id*. at 591.

[10] Order at 21–22.

[11] Order at 32–33.

Finally, though the trial court found the experts were generally qualified to testify on the subject matter, their conclusions were unsupported by their own research. The court commended both experts for their prior research and their peer-reviewed publications on the risks of talc use. The court noted, however, that their conclusions in those prior publications — namely, that there was insufficient evidence to conclude that talc was a risk factor for ovarian cancer — showed their trial opinion that talcum powder caused the two plaintiffs' ovarian cancer was merely a "made-for-litigation" presentation.

How does one explain the conflicting results in these cases? The standards for gatekeeping in Missouri and New Jersey state courts are not far apart. Missouri Code section 490.065 governs the admissibility of expert opinion and generally tracks Federal Rules of Evidence 702 and 703. The Missouri Supreme Court has advised that cases interpreting the federal rules "provide relevant and useful guidance in interpreting and applying section 490.065."[12] But the Missouri trial court did not conduct special expert gatekeeping proceedings, nor hear expert testimony, before making his rulings.

Like Missouri, New Jersey's expert evidence rules generally track the federal rules. New Jersey Rule of Evidence 702 is identical to Federal Rule 702 as it existed when *Daubert*[13] was decided. Accordingly, New Jersey courts apply gatekeeping to assure that experts are presenting reliable science. "The court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs."[14] In contrast to the procedure followed in Missouri, the New Jersey court conducted an evidentiary hearing over seven days before reaching his decision.

Application of a similar evidentiary standard to the same expert opinions should yield similar results. The New Jersey and St. Louis cases provide a cautionary demonstration, however, of the consequences when trial courts fail to adequately scrutinize the foundation of proposed expert testimony. Hopefully, the New Jersey Court's comprehensive analysis will provide guidance for courts considering these and similar mass tort claims in the future.

Authors:

Michele C. Barnes
michele.barnes@klgates.com
+1.415.249.1011

Clifton T. Hutchinson
cliff.hutchinson@klgates.com
+1.214.939.5444

[12] *State Bd. of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 146, 155 (Mo. 2003).
[13] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).
[14] *Landrigan v. Celotex Corp.*, 127 N.J. 404, 414 (1992).

K&L GATES