

Client Alert **Product Liability Law**

New Jersey Court Excludes “Made-For-Litigation” Causation Expert Opinions In Talc-Based Powder Products Litigation

Introduction

On September 2, 2016, the Honorable Nelson C. Johnson excluded the testimony of Plaintiffs’ key causation experts in the Talc-Based Powder Products Litigation, a Multi-County Litigation (“MCL”) pending in the Superior Court of New Jersey, Atlantic County. See *Carl v. Johnson & Johnson*, 2016 WL 4580145 (N.J. Super. Law., Sep. 2, 2016). Under New Jersey’s expert testimony standard, plaintiffs must demonstrate that both the factual basis and underlying methodology used by their expert(s) are scientifically reliable. See *Kemp v. State of New Jersey*, 174 N.J. 412 (2002). New Jersey’s *Kemp* standard is considered by some to be less demanding than the federal *Daubert* standard. In this case, however, the Court performed an exhaustive review of the underlying factual information relied on by Plaintiffs’ experts and the methodologies used by the experts to assess whether their opinions were scientifically reliable. Specifically, the Court reviewed approximately 100 reports, abstracts, epidemiology studies, and peer reviewed articles (collectively “treatises”) relied upon by the experts, along with the parties’ legal briefs, and heard seven days of testimony at a *Kemp* hearing. After reviewing all of the evidence, the Court concluded that the opinions of Plaintiffs’ causation experts suffered from multiple deficiencies, and that the scientific community would not rely upon the same limited information. Describing the experts’ analysis as “narrow and shallow,” the Court granted Defendants’ motions for summary judgment dismissing the Complaints of two plaintiffs.

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Background

Plaintiffs Brandi Carl and Diana Balderrama filed separate lawsuits claiming that Defendants' talc-based products caused each of them to develop ovarian cancer. At the conclusion of discovery, Defendants moved to exclude the testimony of Plaintiffs' expert witnesses on causation, Dr. Graham A. Colditz and Dr. Daniel W. Cramer,¹ and for summary judgment in the event that the motions to exclude testimony were granted. Defendants argued that the hypotheses used by Plaintiffs' experts as to general and specific causation were flawed and that Plaintiffs' experts' opinions were not supported by reliable scientific evidence. In response, Plaintiffs argued that their experts were qualified and offered reliable opinions based on scientific methodologies relied on by experts in their respective fields.

Court's Decision

In analyzing the motions, the Court noted that the inquiry at the *Kemp* hearing needed to be "flexible" and that its gatekeeper role was to determine whether the experts' opinions were "derived from a sound and well-founded methodology." The Court further noted that it was Plaintiffs' burden to "demonstrate that the methodologies used by their experts [were] consistent with valid scientific principles accepted in the scientific and medical communities." Importantly, the Court relied heavily on the *Reference Manual on Scientific Evidence (3d Edition)* issued by the Federal Judicial Center and the National Research Council of the National Academies ("Reference Manual"). Against this backdrop, the Court framed the key question to be decided as follows: "Have Plaintiffs shown that their experts' theories of causation are sufficiently reliable as being based on a sound, adequately-founded scientific methodology, *to wit*, that they are based upon methods upon which experts in their field would reasonably rely in forming their own (possibly different) opinions about the cause(s) of each of Plaintiffs' ovarian cancers?"

In answering this question, the Court reviewed all treatises cited by the experts and heard testimony from five of Plaintiffs' experts and four of Defendants' experts. The Court also extensively reviewed what it called the "building blocks" of the scientific method in evaluating the methodologies utilized by Plaintiffs' experts. These building blocks included a review of epidemiological studies (cohort studies and case-control studies); laboratory studies (*in vitro* and *in vivo* studies); the biology of cancer and the status of current research; animal studies; the findings of agencies that study cancer (National Cancer Institute, U.S. Food and Drug Administration, American Cancer Society, World Health Organization, International Agency Research on Cancer, and The

1. Among other things, Drs. Colditz and Cramer are both epidemiologists.

American College of Obstetricians and Gynecologists); and the Bradford Hill Criteria (strength of association, consistency, specificity, temporality, biological gradient, plausibility, experiment, and analogy).

Although the Court found that Plaintiffs' experts were "eminently qualified," the Court expressed disappointment that Plaintiffs' experts largely ignored the findings of three large cohort studies and relied on small retrospective case-control studies.² Moreover, Plaintiffs' experts' reluctance to consider anything but epidemiological studies made the Court feel as if the Plaintiffs' expert were saying "Look at this, and forget everything else science has to teach us." As a result, the Court determined that "their areas of scientific inquiry, reasoning, and methodology [were] slanted away from objective science and towards advocacy" and that their opinions failed to "demonstrate 'that the data or information used were soundly and reliably generated and [were] of a type reasonably relied upon by comparable experts.'"

With regard to Dr. Colditz, the Court held that his report deviated from the scientific method, his opinion was nothing more than *ipse dixit* (meaning the only proof of the fact is that this person said it), and it had all the "earmarks for a made-for-litigation presentation." For example, on the issue of biologic plausibility (*i.e.*, whether there is a biologically plausible mechanism by which talc-powder could cause ovarian cancer), the Court noted that none of the four articles relied on by Dr. Colditz set forth a biologic mechanism by which talc-powder could cause ovarian cancer. Dr. Colditz also admitted at the *Kemp* hearing that more studies were needed to understand the mechanism by which talc-powder could cause ovarian cancer. Moreover, Dr. Colditz failed to analyze the strength of association and how such association rises to the level of general causation, let alone specific causation.

The Court had similar issues with Dr. Cramer. Despite his exceptional credentials, Dr. Cramer "totally ignored laboratory research regarding the biology of cancer and the ameliorative effects of talc on cancer." With regard to general causation, Dr. Cramer relied on upon case-control studies, in which he admitted demonstrated a "weak" association and could not explain when or how the association rises to the level of causation. With regard to specific causation, Dr. Cramer relied on epidemiology, but such studies are not designed to and do not address the question of the cause of an individual's disease. Dr. Cramer also failed to account for Plaintiffs' significant risk factors for ovarian cancer. In addition, Dr. Cramer's opinions were found to be litigation

2. As noted by the Court, "[c]ohort studies compare the incidence of disease among individuals exposed to a substance with an unexposed group", whereas "[c]ase-control studies examine the frequency of exposure in individuals who presently have the disease and compare them to a group of individuals who presently have the disease and compare them to a group of individuals who do not have the disease."

driven because in all of his prior articles from 1982 to 2007, he always concluded that a causal relationship (general and specific causation) between ovarian cancer and talc had not been proven.

Analysis

Despite two prior verdicts in Missouri awarding over \$125 million in lawsuits claiming that talc-powder products caused two women to develop ovarian cancer, Judge Nelson determined that the data and information used by Plaintiffs' experts were not soundly and reliably generated, were not of the type reasonably relied upon by experts in this field, and, as a result, were inadmissible under New Jersey's *Kemp* standard. The Court, therefore, granted Defendants' summary judgment motions because Plaintiffs, as a matter of law, could not establish through expert testimony that talc-powder products cause ovarian cancer or that the talc-powder products used by Plaintiffs caused their ovarian cancer. With over 100 additional cases pending in this New Jersey MCL, Plaintiffs will most likely file an appeal. It will be interesting to see whether this Court's thorough and extensive decision will be sustained on appeal, or whether New Jersey's appellate courts will reject or modify Judge Nelson's application of New Jersey's *Kemp* standard. If nothing else, the Court has correctly put the guidance of the Reference Manual front and center in the *Kemp* analysis.

We will continue to keep you apprised of further developments in this area.

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