NJ COURT RULES PLAINTIFFS' EXPERTS' OPINIONS ARE INADMISSIBLE, GRANTS SUMMARY JUDGMENT FOR DEFENDANTS

*By: Eli Granek, Esq.**

Departing from the rulings of judges in other jurisdictions, a New Jersey court Friday barred the plaintiffs' causation experts from testifying and entered summary judgment for the defendants. The decision, which is the first to be issued in New Jersey's *In re Talc Based Powder Product Litigation* MCL, will affect the remaining 203 lawsuits filed in New Jersey and could prove influential in other jurisdictions.

The Lawsuit

The court's September 2, 2016 Order and Opinion was issued in *Brandi Carl v. Johnson & Johnson, et al.* and *Diana Balderrama v. Johnson & Johnson, et al*., the two cases selected to serve as bellwethers in New Jersey's talcum-powder MCL. According to the plaintiffs, they developed ovarian cancer after applying Johnson & Johnson talcum powders to their perineal area for many years. The plaintiffs alleged that defendants Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., and Imerys Talc America, Inc., knew that perineal-talc use could cause ovarian cancer yet failed to warn their customers. They further alleged that these defendants, in conjunction with defendant Personal Care Products Council, a cosmetics trade association, conspired to suppress and undermine research suggesting that perineal-talc use could cause ovarian cancer.

New Jersey law requires plaintiffs pursuing toxic-tort product-liability claims to prove that reliable scientific evidence supports their assertions. Recognizing that scientific debate can take years, and that, in the toxic-tort context, claims often may be based on new or emerging theories of causation, the law does not require that expert opinions supporting a plaintiff's claim already are generally accepted in the relevant scientific community. It does, however, require that the expert's approach is scientifically sound—*i.e.*, that the methodology the expert employed to reach his or her conclusions and the data on which he or she relied is the same methodology and data that other researchers exploring the issue would use.

For the plaintiffs in *Carl* and *Balderrama* to be able to prove their claims, therefore, they had to show that reliable scientific evidence supported both: (1) that perineal-talc use could cause ovarian cancer (general causation); and (2) that the plaintiffs' use of the defendants' product caused them to develop ovarian cancer (specific causation). According to the defendants, no such evidence exists, and to the extent the plaintiffs' experts alleged otherwise, their opinions were unreliable "junk science," reached using unorthodox and unsound methodologies and data.

The Parties' Arguments

The plaintiffs sought to satisfy their burden of proof through the testimony of Dr. Graham Colditz and Dr. Daniel Cramer, both of whom are medical doctors and epidemiologists. According to these experts, case-control studies conducted over the last thirty years reveal that women who used talc in their genital region were thirty-percent more likely to develop ovarian cancer than those who did not, and that this reported association between perineal-talc use and ovarian cancer (OR 1.3) is sufficient to establish a causal relationship. To explain *how* talc might cause ovarian cancer, they further opined that, after entering the body, talc particles could flow upstream through the vagina, cervical canal, uterine cavity, Fallopian tubes, and peritoneal cavity before somehow attaching to an ovary's surface. Once there, the talc particle would irritate the cells of the ovary, stimulating an inflammatory reaction which, when chronic, causes immunosuppression which could cause cancer.

The defendants asked the court to preclude Dr. Colditz and Dr. Cramer's opinions, arguing that they were inherently unreliable, resulted from flawed methodologies, were contrary to the conclusions held by the relevant scientific community, and were fabricated for the purpose of this litigation. Although they acknowledged that causation could be established by an analysis of the Hill criteria,[1] the defendants contended that the plaintiffs' experts applied these factors erroneously.

The Court's Discussion Regarding General Causation

In ruling that the plaintiffs' experts' opinions are inadmissible, the court found that the plaintiffs' experts failed to employ a scientifically-sound methodology and failed to evaluate the type of data on which scientists conducting a comparable study would rely. The plaintiffs' experts first strayed beyond the bounds of the scientific process when they artificially limited the pool of data from which they drew their conclusions. Not only did they fail to consider relevant data from lab studies, animal studies, and the field of cancer biology, the court explained, but even within the realm of their chosen source of data—epidemiology—they "confined their analysis to evidence derived from small[,] retrospective[,] case-control studies," ignoring contradictory data from larger, cohort studies.[2] This "narrow and shallow" approach rendered their opinion unreliable and thus inadmissible.

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[1] Named after Sir Austin Bradford Hill, the Hill criteria are factors researchers must evaluate when trying to determine whether an observed association between exposure to a substance and a disease is sufficiently strong to conclude that the substance can be said to cause—as opposed to merely be associated with— the disease. These criteria include: (1) strength of the observed association; (2) whether the association is consistently observed in multiple subjects; (3) whether the incidence of disease increases or decreases in accordance with the degree of exposure; and (4) whether there exists a biologically plausible mechanism by which the substance could cause the disease.

[2] Case-control studies examine the frequency of exposure in individuals who have a disease and compare them to a group of individuals who do not have the disease. Cohort studies compare the incidence of disease among individuals exposed to a substance with the incidence of the disease among individuals who

The court also faulted the manner in which the plaintiffs' experts analyzed the artificially-limited data they did evaluate. Despite purporting to have applied the Hill criteria to reach his conclusions, the court found that Dr. Colditz's analysis "blithely passes over most of the Hill criteria," including a failure to evaluate the strength of the association linking talc to ovarian cancer and how it militates in favor of finding causation. The court found that rather than explain why an observed association of < 2.0 was sufficient to demonstrate a causal relationship between perineal-talc use and ovarian cancer, Dr. Colditz merely repeated buzzwords like "significant." Repeated buzzwords, the court held, did not constitute assessing of the strength of an observed association as required by the scientific process.

Similarly, despite opining "that the causal association between ovarian cancer and the use of talc has been 'significant' and consistent for thirty years," Dr. Cramer admitted that the 1.29 odds ratio he reported was "weak," and failed to explain why a "weak" association nevertheless was sufficient to find a casual relationship. Like Dr. Colditz, Dr. Cramer's reliance on buzzwords like "significant" instead of a scientifically-valid explication led the court to hold that Dr. Cramer's methodology fell short of the analysis required by the scientific process.

Having found that the manner in which the plaintiffs' experts selected data to evaluate and the manner in which they analyzed that data was inconsistent with the scientific process, the court next highlighted the plaintiffs' experts' failure "to provide a coherent explanation to support their hypothesis for biological plausibility." Dr. Cramer, the court noted, never offered an opinion on the subject. Dr. Colditz, on the other hand, opined that "it is established that talc can travel to the ovary … cause[] an inflammatory response, and this mechanism is consistent with the increase of ovarian cancer that is observed," and cited four peer-reviewed articles in support. But after reviewing the sources Colditz cited, the court found that none "discuss[ed] the means by which talc can travel to the ovary, [or] the means by which talc causes an inflammatory response in the cells of the ovaries." And without a basis in peer-reviewed literature, lab work, or another authoritative source, Dr. Colditz's unsupported opinion constituted inadmissible speculation.

These "significant deficiencies" in the plaintiffs' experts' methodology and analysis led the court to hold that the plaintiff's experts' general-causation opinions were inadmissible.

The Court's Ruling Regarding Specific Causation

The plaintiffs extended two arguments to prove specific causation—*i.e.*, that their use of the defendants' product caused them to develop ovarian cancer. First, as discussed

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were not exposed to the substance. Case-control studies, which involve asking individuals who have been diagnosed with an illness whether they have been exposed to a substance that may have caused that illness, are particularly susceptible to recall bias and are considered less reliable than a prospective cohort study.

above, the plaintiffs' experts suggested that talc could enter the vagina and flow upstream before lodging in an ovary, causing inflammation which, if chronic, causes immunosuppression which could lead to cancer. As noted above, the court found that the plaintiffs' experts failed to provide any scientific support for this hypothesis. Equally fatal, the court found that this theory is incongruent with plaintiffs' allegations: "A cornerstone of the 'talc causes cancer' hypothesis is 'inflammation,' yet none was present in any of the [plaintiffs'] tissue samples studied."

Second, Dr. Cramer sought to prove that the plaintiffs' use of the defendants' product caused the plaintiffs to develop ovarian cancer through statistical analysis of epidemiological data. The court took exception to Dr. Cramer's diagnosis-"by-the-numbers" approach for several reasons, including that epidemiology—even when done properly—is too blunt a tool to establish specific causation in a particular plaintiff. The court also found Dr. Cramer's methodology wanting, noting that "re-analyzing old studies and subjectively mingling the various risk factors for each Plaintiff" comprised "an incomplete/irregular methodology unlike anything on which his peers would rely."

Once again, therefore, the court held that the deficiencies in the plaintiffs' experts' methodology and analysis rendered their opinions inadmissible.

Conclusion

The decision's impact will likely be felt locally and nationally. In New Jersey, the attorneys representing the remaining 200+ plaintiffs will have to find new causation experts or change their current experts' approach. Going forward, plaintiffs will have to answer the questions Drs. Cramer and Colditz failed to answer in *Carl* and *Balderrama*—namely, why the plaintiffs' lacked evidence of inflammation in plaintiffs' pathology; why the plaintiffs' failed to present evidence linking talc use to other types of gynecological cancer; whether a valid scientific basis exists to support plaintiffs' hypothesis regarding the biological mechanism through which perineal-talc use could cause cancer; and why the multi-disciplinary body of research contradicting the plaintiffs' theory does not—if not entirely nullify plaintiffs' theory of causation—prevent science from concluding that there is evidence of a causal relationship between perineal-talc use and ovarian cancer. Some of these questions will be easily answered as materials on which plaintiffs' experts likely can rely already exist. Other questions will require more effort and creativity.

Beyond New Jersey, Judge Johnson's detailed and well-reasoned opinion provides a roadmap for other jurists who will be tasked with conducting a similar analysis. Whether these judges will follow the path Judge Johnson blazed, however, will turn on the particular laws and personalities involved. This decision may also lead to an increased number of filings in Missouri, California, and other fora that have held that they may assert jurisdiction over non-resident plaintiffs' claims against non-resident defendants. While plaintiffs may stop filing these claims in New Jersey, counsel will likely bring the claims in other jurisdictions.

Swartz Campbell's attorneys have experience counseling and defending material suppliers, product manufacturers, distributors, premises owners, and employers in cases involving product-liability and toxic-tort exposure. If you have any questions or would like to discuss this article further, feel free to contact the author or any of the attorneys in Swartz Campbell's Environmental & Toxic Torts Department.

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