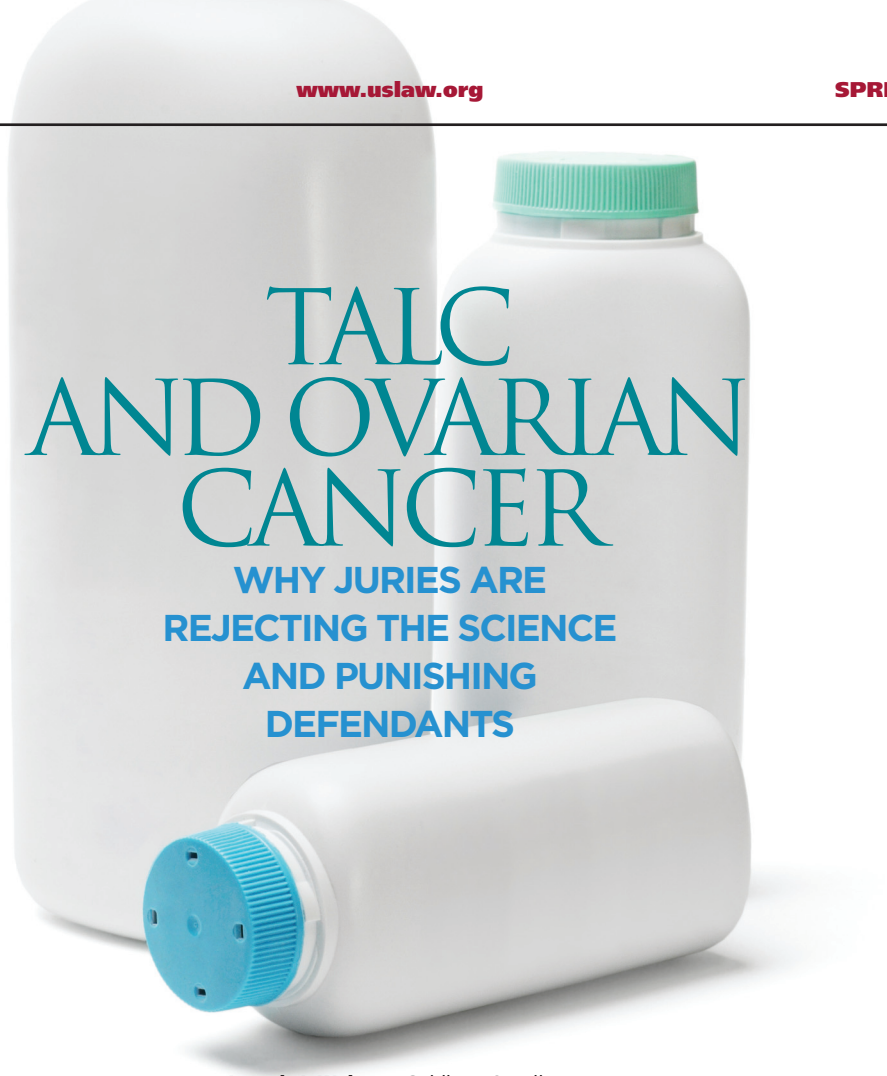

TALC AND OVARIAN CANCER

WHY JURIES ARE REJECTING THE SCIENCE AND PUNISHING DEFENDANTS

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According to the Food and Drug Administration (FDA), the Center for Disease Control (CDC), the National Cancer Institute, the National Toxicology Program, the U.S. Department of Health and Human Services, the American Conference of Industrial Hygienists, the American Cancer Society, and a host of healthcare associations, current scientific literature does not support the conclusion that perineal use of cosmetic talcum powder causes ovarian cancer. Nevertheless, juries in St. Louis City have returned exorbitant verdicts of $72 million, $55 million, and $70 million this past year. Why are these juries repeatedly rejecting strong, well-grounded (and well-presented) scientific defenses?

THE SCIENCE

While studies of the hypothesized link between cosmetic talc and ovarian cancer go back for decades, there is little scientifically sound support in the literature. Plaintiffs in this litigation rely on a small subset of retrospective case-control studies finding a weak and inconsistent correlation. These include studies noting slight purported increases in relative risk factor of 1.85 (Cramer, 1982), 1.3 (Green, et al., 1997), 1.4 (Chang, et al., 1997; Gertig, et al., 2000), 1.5 (Harlow, et al., 1992; Ness, et al., 2000), and 1.6 (Crook, et al., 1997; Cramer, et al., 1999). Six additional meta-analyses, which largely rely on these original studies, also concluded an increased risk (between 24% and 70%) of ovarian cancer with perineal talcum powder use.

These studies are rife with methodological problems. First, they suffer from "recall bias." Second, the studies do not control for confounding variables, such as obesity. Third, although statistically significant, the increased risks identified in the research are both practically insignificant and misleading given the small sample sizes, the confidence intervals suggest that relative risks may actually be closer to 1.0 (i.e., no association), and the actual incidence of ovarian cancer is so small (1.4%) that an increased risk of even the most generous finding (85%) results in an incidence rate of 2.6%, only slightly above the general population.

The research cited by the defense includes three prospective cohort studies following tens of thousands of women who did not have ovarian cancer, over several decades. Though approximately half reported contemporaneous talcum powder use, the incidence of ovarian cancer at the end of the studies was no greater for women who used talc than those who didn't, and incidences in both groups were consistent with the general population (Gertig, et at., 2000; Gates, et al., 2010 [a follow-up of Gertig]; Houghton, et al., 2014; Gonzalez, at al., 2016).

The vast majority of regulatory agencies and healthcare associations declined to include cosmetic talc as a potential carcinogen or as a risk factor in developing ovarian cancer. For instance, the FDA rejected Citizens' Petitions to require a warning on talc products due to "insufficient evidence," the National Cancer Institute notes "inadequate evidence" of an associated risk, and the CDC even recommends talcum powder to treat genital warts. The U.S. Department of Health & Human Services specifically explained that the studies have been "misinterpreted statistically," have "several biasing factors," and have been "strongly contradicted" by other studies. In 2006, the International Agency for Research on Cancer (IARC), listed perineal use of talc-based body powder as "possibly carcinogenic to humans," but also has recognized the same methodological problems with the studies discussed above.

THE LITIGATION

Talc and ovarian litigation has been around for a number of years, but little attention was paid until February 2016 when a St. Louis City jury rendered a verdict of $72 million ($62 million in punitive damages) against two Johnson & Johnson companies. In May 2016, another St. Louis City jury handed down a second verdict for $55 million ($50 million in punitive damages) against the same two companies.

In September 2016, the New Jersey state court litigation was brought to an abrupt halt when Judge Nelson Johnson issued a decision precluding plaintiffs' causation expert's opinions as not scientifically reliable and dismissed the first two cases that proceeded to trial in that jurisdiction. In October 2016, a third case went to trial in St. Louis City, which resulted in a $70 million verdict ($67.5 million punitive damages) against the Johnson & Johnson companies and, for the first time, the talc supplier, Imerys Talc America.

These disparate results in St. Louis and New Jersey raises the question of how the science can be so unreliable that cases do not even reach the jury in New Jersey, yet three juries in St. Louis City have rejected the same scientific evidence and related arguments.

WHY ARE JURIES BUYING PLAINTIFFS' "SCIENCE?"

Jury research conducted on methodological and statistical reasoning skills suggests that laypersons have great difficulty differentiating between valid and flawed research. Most people fail to understand the importance of a control group and have difficulty applying statistical concepts to human behavior. Laypersons fail to recognize that larger sample sizes produce more reliable results than smaller sample sizes. In a trial setting, McAuliff & Kovera (2001) studied the reactions of real jurors to variations in the methodological quality of expert evidence and found that expert evidence quality did not appear to influence jurors' liability decisions or their evaluations of the expert evidence.

This is particularly true in the talc/ovarian cancer cases, where plaintiffs' experts have cherry picked small – albeit "peer-reviewed and published" – retrospective case-control studies that are of questionable reliability due to recall bias and confounding variables, and yet ignore larger, more reliable prospective cohort studies involving hundreds of thousands of women. Juries hear a Harvard Medical School professor discussing studies showing a slight increase in risk and have no sufficient frame of reference to weigh it against an equally credible defense expert. In some respects, our jury system is designed to eliminate people with this specialized relevant knowledge, leaving jurors with an uninformed perspective on the importance and nuances of scientific issues. The average juror may simplistically believe that experts cancel each other out.

COMBATTING THE "SIMPLE" THEORY

Plaintiffs' strategy in the talc and ovarian cancer cases is "keep it simple." Johnson & Johnson made talc products. Studies show a link between talc use and ovarian cancer. Johnson & Johnson knew it. Additional studies show women were at increased risk of developing cancer through use of talc products. Johnson & Johnson knew it and provided no product warnings. Mrs. Smith used Johnson & Johnson products for years and has cancer caused by Johnson & Johnson. It is really that simple. Plaintiffs do not have to dig deep into the scientific weeds to prove their case, assuming the judge permits their medical causation experts to testify. Defendants are put in the position of having to dissect the scientific studies and explain nuances, creating the misimpression that companies are trying to explain away their knowledge of a potential link.

In this context, juries struggle with when a company should warn of a potential risk. Can and should companies wait until there is an established scientific causal connection before warning? Should companies warn of potential risks based on a case report, a case series, or one epidemiological study? Realistically, juries are more inclined to hold a company liable for failing to share even *questionable* scientific evidence of a product risk.

A GOOD COMPANY STORY

A jury's willingness to accept a scientific defense starts with credibility. In the talc and ovarian cancer cases, Johnson & Johnson had seemingly damaging company documents, which factored into the jury's consideration of the science defenses. By contrast, Imerys was the company that supplied the talc. It was not the decision-maker for warnings. It merely sold the talc to Johnson & Johnson and it included the IARC listing as a "2B possible carcinogen" on its MSDS, which it supplied to its customers. This defense worked in the first two St. Louis City trials but not the third. Plaintiffs' tactics has been to incense jurors early with "bad documents" and baseless allegations, such that jurors are pre-disposed to mistrust the defense presentation of the science.

The "good company" story is made even more difficult by documents suggesting an intent to influence regulatory decision-makers. Another impediment is jurors' belief that regulatory agencies within the U.S. are heavily influenced by industry. Mistrust of government and awareness of political influence makes jurors more likely to discount the conclusions of U.S. regulatory agencies that support the companies' case.

The documents presented in the talc litigation only seem to support this belief, as the industry trade association formed a "Task Force" to develop a strategy to defend the use of talc, noting "regulatory challenges" that could cripple the industry. Although the Task Force and company documents note that these efforts are grounded in scientific literature, the impression is that the agencies were unfairly influenced or "bullied" into not listing talc as a potential carcinogen. When the National Toxicology Program initially voted to list talc as a carcinogen (a 13-2 vote in the first two formal reviews), and then voted 7-3 not to list talc following the public commenting period, jurors could easily surmise that undue industry influence, and not the scientific evidence, was the reason.

While jurors' inability to critically evaluate scientific research and their feelings about companies and government agencies can result in a plaintiff verdict, it is their sympathy for those suffering from cancer and anger at companies that drive massive damage awards. Once they are sold on liability, jurors seek to punish the defendants for "manipulating the evidence," "bullying the agencies," and putting on the face of a company that cares while simultaneously refusing to place a warning on its product. Defendants must strategize new techniques for defending these cases, which should include winning the credibility war and developing demonstratives and arguments that can aid jurors in understanding and assimilating the underlying scientific research.

Joseph J. Welter is chair of Goldberg Segalla's Toxic Tort and Environmental Practice Group and has over 25 years of experience representing clients in mass tort, toxic tort and product liability litigation. He works to develop effective scientific and medical defenses, including extensive vetting and retention of expert witnesses and effective use of Daubert and Frye motions to preclude plaintiffs' experts.