Streaming Video Testimony Sheds Light on Role of Science in California Talc Litigation

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"Science Day" hearings have become commonplace in complex state and federal litigations around the country. A California state court judge recently held such a hearing in consolidated litigation dealing with the alleged link between talcum powder and ovarian cancer. With a bellwether trial scheduled for July, the closely-watched hearing was webcast and recorded by Courtroom View Network, which has also streamed three of the previous talc powder trials in St. Louis, Missouri.

Background

The major impetus for science tutorials seems to have come from the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). The holding of *Daubert*, now incorporated into, and extended by, Federal Rule of Evidence 702, requires trial judges to act as gatekeepers of the relevance and reliability of expert witness opinion testimony in their courtrooms. One of the first tests of the judiciary's performance to perform this role came in the silicone gel breast implant litigation. The federal silicone cases were consolidated before Judge Pointer Sam C. Pointer, Jr., in MDL 926. Judge Pointer believed that trial judges in the transferor courts should conduct whatever review of expert witness opinion was needed to satisfy the then recent *Daubert* decision.

Some of the first federal silicone lawsuits remanded from the MDL went to Judge Robert Jones in Portland Oregon. These cases involved complex issues of immunology, clinical rheumatology, epidemiology, toxicology, surgery, and polymer and analytical chemistry. In large measure because of Judge Jones's case management and exclusion of expert witness testimony, the silicone MDL court appointed a panel of neutral expert witnesses, in the fields of epidemiology, rheumatology, immunology, and toxicology.[1]

One of the first requests received from the Science Panel in MDL 926 was for what turned out to be a series of Science Days in which the parties' expert witnesses would present to them, and explain their interpretation of the vast array of evidence, from different disciplines. These proceedings, along with extensive submissions of articles

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1 MDL 926 Order 31 (May 31, 1996) (order to show cause why a national Science Panel should not be appointed under Federal Rule of Evidence 706); MDL 926 Order No. 31C (Aug. 23, 1996) (appointing Drs. Barbara S. Hulka, Peter Tugwell, and Betty A. Diamond); Order No. 31D (Sept. 17, 1996) (appointing Dr. Nancy I. Kerkvliet).

and briefings from the parties led to the Report of National Science Panel, on November 30, 1998.

Every Day is Science Day, Somewhere

Since the breast implant litigation, many MDL and other courts have faced complex causation claims in litigation involving pharmaceutical products, medical devices, consumer products and a host of chemical exposures. Appointment of independent, neutral expert witnesses remains unusual, but trial judges have welcomed tutorials in the form of "Science Days," to help them learn the methodologies and vocabularies of the scientific disciplines that are involved in the litigations before them. For some reason, the parties, the judges, and the legal media often reference Science Days in scare quotes, signaling that perhaps other Science takes place in these proceedings. Whether the scare quotes are warranted remains to be determined.

"Science Days" have become a tradition in mass tort litigation.[2] In the last few years, there is a Science Day somewhere, in some courtroom, going on, perhaps not daily, but with sufficient frequency that the phenomenon should receive more critical attention. Federal judges with multi-district litigation, or state judges with multi-county cases, set aside time to permit the parties a chance to educate them about the scientific and technical aspects of the litigations before them. Judges know that *Daubert* and Rule 702, or their state analogues, require them to act as gatekeepers. Furthermore, myriad motions in the discovery and trial phases of a case will require judges to make nuanced but accurate decisions about scope and content of discovery, and admissibility of documents and testimony,

Science Day – Have It Your Way

> John Milton: We negotiating?
> Kevin Lomax: Always.[3]
> *The Devil's Advocate* (1997).

There are no federal or state rules that set out procedures for science tutorials for judges or their appointed expert. The form and substance of Science Days depend upon a three-

2 *See, e.g.,* Barbara J. Rothstein & Catherine R. Borden, *Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges* at 39 & n. 54 (Fed. Jud. Ctr. 2011); Sean Wajert, "'Science Day' In Mass Torts," *Mass Tort Defense* (Oct. 20, 2008); Lisa M. Martin, "Using Science Day to Your Advantage," 2(4) *Pro Te: Solutio* 9 (2009).

3 From the screenplay of the movie, directed by Taylor Hackford, written by Jonathan Lemkin and Tony Gilroy, and based on a novel by Andrew Neiderman.

way negotiation among the plaintiffs, defendants, and the trial judge. Although the parties are often left to work out a plan for science day, most courts tend to weigh in by imposing time limits, and they may even rule in or rule out live witness testimony.

In 2007, the American Bar Association set out Civil Trial Practice Standards,[4] which included an entire section on the use of tutorials to assist the court. [The relevant standards for tutorials is set out below, as an appendix.]

Talc Science Goes Bicoastal

This year, two trial judges have entertained Science Days in talc cases, on both coasts of the United States. In the federal talc litigation, MDL 2738,[5] Judge Freda L. Wolfson conducted a Science Day on January 26, 2017. In the coordinated California state court talc cases, Judge Maren E. Nelson, of the Superior Court of California, Los Angeles County, conducted a Science Day, on March 7, 2017.[6]

Federal Talc MDL 2738

In the federal cases, Johnson & Johnson, one of the defendants, initiated the Science Day, in November 2016, when it asked Judge Wolfson to set aside a day in "which the parties and their experts can outline their positions/arguments regarding the medical and science issues at play."[7] In Case Management Order No. 1 (Jan. 23, 2017), Judge Wolfson apparently agreed, and the parties had their talc Science Day on January 26, 2017.[8] The Science Day took up over five hours of presentations to Judge Freda L. Wolfson, and Judge Lois H. Goodman.[9]

California Coordinated Docket

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4 American Bar Association's "Civil Trial Practice Standards" (August 2007 & 2011 Update).

5 *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices & Prods. Liab. Litig.*, No. 16-2738 (D.N.J.)

6 *Johnson & Johnson Talcum Powder Cases*, No. JCCP4872 (Calif. Super. Ct., Los Angeles Cty.).

7 "Johnson & Johnson Files Status Report in MDL Docket, Requests 'Science Day' to Address Causation in Talc Cases," *HarrisMartin's Talcum Powder Litigation Report* (Nov. 16, 2016).

8 "Parties in Federal Talcum Powder MDL Hold 'Science Day'," *HarrisMartin's Talcum Powder Litig. Report* (Jan. 26, 2017).

9 *Id.*

In the California cases,[10] plaintiffs' counsel filed a formal motion, in early December 2016, to request a Science Day tutorial. The plaintiffs' motion requested that each side be permitted two hours to present their views of the scientific evidence in support of their litigation positions on causation and liability in talc ovarian cancer cases. The plaintiffs argued that a Science Day would be "significant benefit to the Court and the parties."[11] Judge Nelson granted the request, and held Science Day on March 7, 2017.

Evaluation of the California Talc Litigation Science Day

Plaintiffs' Presentations

The presentation by the plaintiff lawyers was eerily reminiscent of the scientific case made by plaintiffs in the silicone breast implant ligation. Their arguments ranged from highlighting anecdotal evidence to emphasizing the implicit sinister nature of talc migration from the vaginal opening to the ovaries. Plaintiff counsel focused heavily on the alleged role of talc in the inflammatory process and strong but disputed implications that anything that enhances inflammation must necessarily cause cancer.

As one would expect, plaintiff counsel placed strong emphasis on the published epidemiological studies linking talc exposure to ovarian cancer. It is important to highlight that most of the studies demonstrating an association between talc and ovarian cancer are case-control studies by design (as opposed to a cohort design). Plaintiff counsel offered very little distinction between these two study designs and, instead tried to make the case that the sheer volume of studies made their argument.

Finally, it should be noted that at many times throughout the plaintiff presentations the attorneys made reference to industry lobbying efforts aimed at preventing a potential classification of talc as a carcinogen by regulatory agencies. Defense counsel made objections throughout that seemed to be based upon first amendment protections for the defendants' ability to speak to agencies about the scientific evidence. For example, the last presenter for the plaintiffs described alleged industry "lobbying" efforts at NTP. Defense counsel objected on first amendment grounds, and the judge semi-sustained the objection on the basis that it had little or nothing to do with the science. The plaintiffs' emphasis on "lobbying" contained no examples of misrepresentations of scientific data.

Defendants' Presentations

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10 *Johnson & Johnson Talcum Powder Cases*, No. JCCP4872 (Calif. Super. Ct., Los Angeles Cty.).

11 "Plaintiffs Ask Court to Hold 'Science Day' in California Coordinated Talcum Powder Docket," *HarrisMartin's Talcum Powder Litig. Report* (Dec. 7, 2016)

In general, the defense presentations struck a more disinterested tone. For example, many of the defense slides could stand on their own in a scientific or medical society presentation. The defense lawyers attempted to provide a solid foundation for the judge on the different types of ovarian cancer as well as the myriad uncertainties that exist in terms of the known causes of the condition. Many of the slides contained direct quotes from notable scientists and regulators on topics that were directly relevant to answering critical questions in the litigation.

Nevertheless, the defense presentations were not without their problems.

First, an important defense point was the fact that epidemiology is a measure of aggregate risk – it does not provide a measure of an individual's risk. In attempting to make this point with a quote from plaintiffs' own expert (Dr. Graham Colditz), the defense oversimplified the point. Specifically, while risk is indeed a measure to estimate the broader population it does not mean that there are no reasonable inferences that can be made from the group measure to the individual member of the sample or population. The defense seems to want to make the seemingly unreasonable point that even if an increased risk were appropriately demonstrated by the epidemiology, that that measure of risk does not tell us anything about what caused an individual claimant's ovarian cancer. This point might be correct when the magnitude of the increased risk is small (as is alleged in the talc ovarian cancer litigation), but the sweeping generality of the defense's assertion is jarring.

Interestingly, Graham Colditz has elsewhere asserted that an increased risk of disease cannot be translated into the "but-for" standard of causation:

> "Knowledge that a factor is associated with increased risk of disease does not translate into the premise that a case of disease will be prevented if a specific individual eliminates exposure to that risk factor. Disease pathogenesis at the individual level is extremely complex."

Graham A. Colditz, "From epidemiology to cancer prevention: implications for the 21st Century," 18 *Cancer Causes Control* 117, 118 (2007). Defense may have wanted to highlight this assertion even recognizing that it is somewhat controversial, and quite dependent upon the magnitude of the measured risk.

Second, the defense's claim that cohort studies are larger and therefore better than case-control studies is somewhat problematic. This is because the comparative power of a case control study and a cohort study to detect a reliable association is a complex matter and is not solely affected by the number of subjects in each of the designs. For example, the power of a case control study -- indeed, the very rationale to implement the case control study design in the first place – is highly dependent on the rate of the disease

condition in the general population. If a disease condition is sufficiently rare, then a cohort study may be entirely untenable and a case control design may be the only possible study design to consider. Other considerations about the relative power of a cohort study include how young the subjects were are study inception, and how long they were followed. At the end of the day, the key to the study's rigor and strength is revealed in the width of the confidence intervals, or power (post hoc, or pre-specified) of the studies.

Finally, it seems to us that the defense did not adequately incorporate into their presentation the important concept of causal inference (or how evidence from disparate sources is synthesized into a judgment of causation, or into a rejection of such a claim). Specifically, defense counsel never explicitly set forth the importance of the Bradford Hill factors, or the techniques of proper and rigorous systematic review methodologies. The defense did hit many of the key considerations of the Bradford Hill factors, but there was no discussion of how these factors are considered after the identification of an association that is not likely the result of bias and that is beyond the play of chance. With respect to meta-analysis, the defense, like the plaintiffs' presentation, provided no guidance or insight into the problems that arise in conducting, reporting, and interpreting quantitative syntheses of a body of epidemiologic studies.

The Trial Court's Role

Most trial judges, sadly, come to cases such as the talc ovarian cancer cases without any training in statistics, epidemiology, toxicology, or an adequate understanding of the role that clinical medicine plays (or doesn't play) in assessing important questions of causation. Judge Nelsen seemed to listen carefully, but asked few questions to suggest that Her Honor understood the discrepancy in statements made in the parties' presentation.

Perhaps a starting point for Science Day should be an Order that sets out the procedures for the Day, as well as a statement: "The Court has read and studied the relevant chapters in the *Reference Manual on Scientific Evidence* (3d ed. 2011), and all materials submitted by the parties. The parties should not recreate a tutorial that covers material in the *Reference Manual*, unless they wish to contest its contents. Specific references to the *Manual*, in connection with the parties' presentation would be very helpful to the Court."

Conclusion

Every February 28th, India celebrates National Science Day in honor of the Indian physicist Sir Chandrashekhara Venkata, who discovered the Raman effect. The United States has no equivalent celebration, but Science Day hearings play a critical role in

American mass tort litigation. Stakeholders involved in any talc-related litigation would benefit from reviewing the hearing before Judge Nelson, since the scientific information and arguments used by the parties at the hearing may provide a valuable preview of potential arguments presented to jurors in upcoming trials.

APPENDIX

American Bar Association's "Civil Trial Practice Standards" (August 2007).

7. Use of Tutorials to Assist the Court

a. Pretrial Use of Tutorials. In cases involving complex technology or other complex subject matter which may be especially difficult for non-specialists to comprehend, the court may permit or require the use of tutorials to educate the court. Tutorials are intended to provide the court with background information to assist the court in understanding the technology or other complex subject matter involved in the case. Tutorials may, but need not, seek to explain the contentions or arguments made by each party with respect to the technology or complex subject matter.

b. Selection of Type of Tutorial.

i. In any case in which the court believes one or more tutorials might be useful in assisting it in understanding the complex technology or other complex subject matter, the court should invite the parties to express their views on the desirability of one or more tutorials.

ii. Once the court decides to permit or require one or more tutorials, it should invite the parties to suggest the subject matter and format of each tutorial.

iii. If the parties cannot agree on the subject matter and format, the court should invite each party to submit a description of any tutorial it proposes and to explain how that tutorial will assist the court and why it is preferable to the tutorial proposed by another party. The court may approve one or more tutorials proposed by the parties, or the court may fashion its own tutorial after providing the parties with an opportunity to comment on the court's proposed subject matter and format.

c. Procedures for Presentation. A court may consider the following procedures for the presentation of tutorials:

i. An in-court or recorded presentation by an expert jointly selected by the parties.

ii. An in-court or recorded presentation by one or more experts on behalf of each party.

iii. An in-court or recorded presentation by counsel for each party.

iv. A combined in-court or recorded presentation by counsel and one or more experts on behalf of each party.

v. An in-court or recorded presentation by an expert appointed by the court, which may include cross-examination by counsel for each party.

vi. Recorded presentations that have been prepared for generic use in particular kinds of cases by reliable sources such as the Federal Judicial Center.

d. Trial Use of Tutorials. In cases involving complex technology or other complex subject matter which may be especially difficult for non-specialists to comprehend, the court may permit or require the use of tutorials to educate the court or jury during one or more stages of the trial. Trial tutorials are intended to provide the court or jury with background information to assist in understanding the technology or other complex subject matter involved in the case. Tutorials may, but need not, seek to explain the contentions or arguments made by each party with respect to the technology or complex subject matter.

e. Selection of Type of Tutorial. The court should use the process set forth in 7.b. above.

f. Procedures for Presentation.

i. In a bench trial, the court may consider using any of the procedures set forth in 7.b. above.

ii. In a jury trial, the court should consider the use of tutorials in connection with interim statements and arguments as provided in Standard 9.

iii. In both bench and jury trials, the court should provide parties with a full opportunity to present admissible evidence in support of their cases that may differ from or quarrel with information presented in a tutorial and to argue that the information presented in a tutorial should be rejected by the court or jury.