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August 12, 2020

VIA ECF

Honorable Freda L. Wolfson, Chief Judge
United States District Court- District of NJ
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street, Court Room 5E
Trenton, NJ 08608

Re: *In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation - MDL 2738*

Dear Chief Judge Wolfson:

I am writing to request leave to file a motion asking that the Court name independent, Court-appointed expert witnesses in the areas of epidemiology and cancer biology, pursuant to Fed. R. Evid. 706, to assist the jurors in understanding some of the epidemiological, biological and other complex scientific issues that will be addressed in the first bellwether trial. Defendants believe that the use of Court-appointed experts will assist the jurors in better understanding scientific issues – and that appointing such experts can be accomplished without delaying the Court’s schedule. Specifically, once the experts are appointed, our experience indicates that they could complete their work in a six- to nine-month period.

At trial, jurors will be presented with two diametrically opposite scientific positions about whether talc use can cause ovarian cancer. As was evident in the *Daubert* proceeding, defendants’ experts will testify (consistent with numerous cancer organizations and governmental organizations) that the evidence does not show that talc can cause ovarian cancer. This testimony will be based on well-established principles of cancer biology as well as the overall body of epidemiology presented to the Court during the

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Daubert proceeding, augmented by the recent JAMA study.¹ The JAMA study, which was not part of the *Daubert* record, pooled the cohort studies and incorporated previously unpublished data (thereby increasing the power of the cohort studies), and concluded that there is no concern over the alleged risk of talcum powder. Defendants' experts will also testify that the Bradford Hill criteria are not satisfied in this matter and that no reasonable scientist could conclude otherwise, because the criteria of strength, consistency and dose-response are not remotely satisfied by the epidemiological evidence and that plaintiffs' evidence of biological plausibility is based on speculation.

By contrast, plaintiffs' experts will presumably testify that the case-control studies, which they contend are more reliable, generally show a positive association between talc exposure and ovarian cancer; that the rules of statistical significance should be revamped to accommodate their view of the science; that strength of association should not be assessed numerically; and that it is biologically plausible for externally applied talc to migrate up through the reproductive system in significant amounts and cause inflammation in the fallopian tubes and ovaries, despite the many scientific and common-sense problems with these theories.

In its 141-page *Daubert* ruling, the Court evaluated the complicated medical and scientific opinions of plaintiffs' general causation experts and held (with certain exceptions) that they were admissible as a matter of law because "the body of relevant scientific evidence is inconclusive and may be open to different interpretations." (Op. at 118.) The Court thus concluded that the scientific validity of those opinions would ultimately have to be reviewed and tested by juries tasked with resolving plaintiffs' claims at trial. (*Id.*) In so ruling, the Court identified a number of scientific questions central to the validity of plaintiffs' claims that would turn on a "battle of the experts" presented by each party at trial, with the lay jurors required to determine which party's experts' interpretation of complicated scientific evidence was the most reliable. (See, e.g., *id.* at 81, 87.) Some of the highly complex questions identified in the Court's order as issues that the jury will need to decide are whether the relative risk identified in certain case-control studies is "weak" or "strong" as an epidemiological matter (*id.* at 71, 73-74, 78, 88);

¹ O'Brien KM, Tworoger SS, Harris HR, et al. Association of powder in the genital area with risk of ovarian cancer. *JAMA*. 2020;323(1):49-59. doi: 10.1001/jama.2019.20079.

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whether the relative risk identified in certain case-control studies may be affected by recall bias and confounding (*id.* at 81); whether plaintiffs' or defendants' experts employ the correct and most scientifically reliable approach for considering "statistical significance within the [relevant] studies in determining" the consistency of the relevant epidemiological data (*id.* at 87); what "weight to ascribe to [plaintiffs'] scientific hypothesis" that it is "biologically plausible that talc can lead to chronic inflammation, which in turn increases the risk of ovarian cancer" (*id.* at 94-95); and which of the parties' "different interpretations" of the "inconclusive" "body of evidence with respect to dose-response" is most accurate and whether the science "support[s] a dose-response relationship" (*id.* at 105).

As the Court's *Daubert* order makes clear, these are science-based inquiries that will turn on complex scientific issues, particularly with respect to biological plausibility. Moreover, these complicated scientific questions will have to be answered by lay jurors without any specialized education in epidemiology, statistics, biology or any other relevant scientific field, after hearing diametrically opposed opinions offered by the parties' retained experts. Accordingly, the jurors would benefit strongly from the assistance of Court-appointed scientists with experience in the relevant fields in sifting through the relevant scientific standards, data and other evidence necessary to reach a verdict.

To assist jurors in that task, we would propose that a Rule 706 panel be appointed to answer the following three questions (and any related or subordinate questions they believe should be separately addressed):

- Whether the scientific evidence, analyzed pursuant to the Bradford Hill framework or any other scientifically accepted methodology for assessing general causation, supports the conclusion that cosmetic talcum powder use can cause any subtype of ovarian cancer, and if so, which subtypes and at what dose;
- Whether plaintiffs' biological mechanism theory that talc promotes inflammation and/or oxidative stress that leads to the development of epithelial ovarian cancer is consistent with what is known about the development of the various subtypes of ovarian cancer, and

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particularly what we know about ovarian cancer precursors such as STIC cells; and

- Whether it is possible to say that a particular woman's talc use caused her to develop ovarian cancer, and if so, the method by which that causal conclusion can be reached.

As other courts have recognized, appointment of a neutral expert or panel of experts under Rule 706 is particularly appropriate in cases involving “unusually complex” questions and “starkly conflicting expert testimony.” *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 558 F.3d 1341, 1348 (Fed. Cir. 2009); see *In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 665 (7th Cir. 2002) (recommending that district court appoint neutral expert panel “rather than leave [it]self and the jury completely at the mercy of the parties’ warring experts”); *Walker v. Am. Home Shield Long Term Disability Plan*, 180 F.3d 1065, 1070-71 (9th Cir. 1999) (appropriate “to appoint an independent expert to assist the court in evaluating contradictory evidence about an elusive disease of unknown cause”); *E. Air Lines, Inc. v. McDonnell Douglas Corp.*, 532 F.2d 957, 999-1000 (5th Cir. 1976) (recommending that district court appoint neutral expert to “provide an objective insight into the . . . difference of opinion between the parties’ experts”); *Norwood v. Zhang*, No. 10 C 3143, 2013 WL 5162202, at *3 (N. D. Ill. Sept. 13, 2013) (“Rule 706 is often employed to provide the jury with neutral assistance where the parties’ competing experts discuss technically complex issues outside the understanding of an average layperson.”); 29 Charles Alan Wright & Arthur R. Miller (“Wright & Miller”), *Federal Practice and Procedure Evidence* § 6304 n.14 (2d ed.) (discussing courts that appointed their own experts when “each party offered apparently competent expert testimony that was in direct opposition”); see also, e.g., *Soldo v. Sandoz Pharm. Corp.*, 244 F Supp. 2d 434, 503 (W.D. Pa. 2003) (utilizing court-appointed experts in reviewing *Daubert* motions and motions for summary judgment). As one judge has explained, in circumstances like these, “an independent court-appointed expert can be tasked with the responsibility of conducting a comprehensive survey of available research in order to provide the . . . finder of fact with an untainted summary of all available information.” Bradford H. Charles, *Rule 706: An Underutilized Tool To Be Used When Partisan Experts Become “Hired Guns”*, 60 Vill. L. Rev. 941, 953 (2015). And although the procedure is not widely used, one study showed that “judges who appointed experts

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[under Rule 706] were almost unanimous in expressing their satisfaction.” Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706* at 79 (F.J.C. 1993).

The expert panel appointed in the nationwide breast implant litigation is especially instructive. In that case, the MDL court granted the plaintiffs’ motion to appoint a panel of “experts, whose testimony might be potentially usable” in subsequent federal court trials. *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1996 WL 34401813, at *1 (N.D. Ala. May 31, 1996). The court appointed a series of experts in different scientific disciplines to study “issues of ‘general causation’” and provided that their opinions would be presented at trial through “initial . . . examination” by the court or another neutral party followed by cross-examination by plaintiffs and defendants. *Id.* at *3, *5; see *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1996 WL 34401764, at *1 (N.D. Ala. Aug. 23, 1996); *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1996 WL 34401766, at *1 (N.D. Ala. Oct. 31, 1996) (defining precise general causation questions). The parties maintained the right to “call[] expert witnesses of their own” to supplement or contradict the court-appointed experts. See 1996 WL 34401813, at *5; Fed. R. Evid. 706(e). The *Breast Implant* model thus preserves both the role of the jury as finder of fact and the parties’ control over the litigation, while also ensuring the most complete and fulsome presentation of the facts and “promot[ing] accurate factfinding.” Wright & Miller § 6302.

Defendants respectfully urge that the same approach would be helpful here to ensure that jurors receive a fulsome presentation on the science by respected scientists who have conducted a “comprehensive survey” of the literature and can provide the jury with an assessment that is not tied to either party.

We look forward to submitting a motion that spells out our proposal in more detail or discussing this proposal and the practical issues that would be involved in appointing Rule 706 experts at the Court’s convenience.

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Respectfully submitted,

/s/ Susan M. Sharko

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cc: All Counsel of Record (via ECF)
Hon. Joel A. Pisano (ret.)