#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON)TALCUM POWDER PRODUCTS)MARKETING, SALES PRACTICES AND)PRODUCTS LIABILITY LITIGATION)

MDL Docket No. 2738

Return Date: July 22, 2019

This Document Relates To All Cases

### NOTICE OF DEFENDANTS' OMNIBUS MOTION TO EXCLUDE THE OPINIONS OF PLAINTIFFS' EXPERTS FOR GENERAL CAUSATION DAUBERT HEARING

**PLEASE TAKE NOTICE** that defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. (collectively, "defendants") will respectfully move the Court on July 22, 2019, or as soon thereafter as counsel may be heard, for an Order to exclude the opinions of plaintiffs' 22 experts.

## PLEASE TAKE FURTHER NOTICE that this motion is supported by

seven briefs, described below, which are organized by topic and methodology, and collectively address the opinions of all of plaintiffs' experts.<sup>1</sup>

### 1. Memorandum Of Law In Support Of Motion To Exclude

Plaintiffs' Experts' General Causation Opinions. This memorandum addresses

<sup>&</sup>lt;sup>1</sup> Appendix A contains a table that cross-references which memoranda apply to which experts.

the opinions of 11 of plaintiffs' experts, all of whom opine – contrary to the scientific consensus – that perineal talcum powder use can cause ovarian cancer. The focus of this memorandum is on plaintiffs' experts' epidemiological opinions and the methodological flaws in their Bradford Hill analyses. Although the scientific community has studied the posited link between perineal talc use and ovarian cancer for half a century, no study has claimed to establish a causal relationship between the two (or that the body of evidence collectively has established such a relationship). At best, the association is weak or modest in some case-control studies and non-existent in the cohort studies. This inconsistency strongly suggests that the studies were affected by recall bias or confounding. In addition, no dose-response relationship has been demonstrated, and the other Bradford Hill considerations are not satisfied. For these and other reasons set forth in defendants' memorandum, the Court should exclude these opinions as unreliable.

2. Memorandum Of Law In Support Of Motion To Exclude
Plaintiffs' Experts' Opinions Related To Biological Plausibility. This
memorandum addresses the opinions of 14 of plaintiffs' experts, all of whom opine
– again without a reliable scientific basis – that: (1) talc can travel or be
transported from the external perineum to the fallopian tubes or ovaries; (2) talc

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causes chronic inflammation in the ovaries; and (3) such inflammation causes ovarian cancer. In reaching these opinions, plaintiffs' experts ignore existing knowledge regarding the etiology of the various subtypes of ovarian cancer and unreliably equate unsubstantiated hypotheses with scientific evidence. Indeed, the very sources that plaintiffs' counsel and their experts trumpet as critical support for these opinions make clear that plaintiffs' experts' theories are still merely hypotheses. For these and other reasons set forth in defendants' memorandum, the Court should exclude plaintiffs' experts' biological plausibility opinions as unreliable.

3. Memorandum Of Law In Support Of Motion To Exclude Expert

**Opinions Of Ghassan Saed**. This memorandum addresses the opinions of Dr. Ghassan Saed, an associate professor at Wayne State University. Plaintiffs' counsel retained Dr. Saed in an attempt to paper over the glaring holes in their biological plausibility theories. Dr. Saed proposed to conduct experiments involving the application of talcum powder to various cell lines (none of which, he acknowledged, replicate normal, in vivo fallopian tube or ovarian epithelial cells). Although Dr. Saed had never studied the alleged effects of talc on cells previously, he expressed an "expect[ation]" before beginning his research that talc would produce cellular effects on the balance of pro- and anti-oxidants (the "redox

balance"), induce genetic mutations and cause neoplastic transformation in cells. Dr. Saed's subsequent experiments were riddled with errors and nonsensical results; generated sloppy and unreliable lab notebooks that are rife with mathematical errors, white-out, changed dates and missing pages; and led to a manuscript that was rejected by a gynecologic oncology journal because its conclusions were not sufficiently supported before Dr. Saed ultimately published a very similar draft in a reproductive health journal. The published manuscript does not address the most serious criticisms of the original journal and falsely claims that Dr. Saed received no compensation for writing the manuscript (when he testified that he was paid by plaintiffs' counsel). Moreover, even if Dr. Saed's work were not subpar and unreliable, his claimed findings still would not establish that it is biologically plausible that talc causes ovarian cancer in living humans. Indeed, he himself admitted that further animal studies would be necessary. For these and other reasons set forth in defendants' memorandum, the Court should exclude Dr. Saed's experiments, manuscript and opinions as unreliable.

4. Memorandum Of Law In Support Of Motion To Exclude
Plaintiffs' Experts' Asbestos-Related Opinions. This memorandum addresses
the opinions of several of plaintiffs' experts that Johnson's Baby Powder and
Shower to Shower (the "Products") ostensibly contain (or at one time contained)

trace amounts of asbestos. The principal proponents of this theory are plaintiffs' experts Drs. William Longo and Mark Rigler, who use an unscientific methodology developed for litigation purposes, disregarding well established distinctions between amphibole minerals generally and the rare subspecies of such minerals that actually constitute asbestos. The brief further explains that even if talc did contain low levels of asbestos as claimed by Drs. Longo and Rigler, there is no reliable evidence that exposure to the purported levels of asbestos could cause ovarian cancer. Finally, the brief also addresses the opinions of plaintiffs' experts Drs. Robert Cook and Mark Krekeler, whose selective reading of a subset of documents cherry-picked and synthesized for the experts by plaintiffs' counsel leads them to conclude that mines from which defendants' talc was sourced could have contained asbestos. These opinions suffer from the same failure to differentiate amphibole and asbestos, as well as a failure to confirm that the deposits allegedly contaminated by asbestos are the same as those that actually sourced talc used in the Products. For these and other reasons set forth in defendants' memorandum, the Court should exclude plaintiffs' experts' asbestosrelated opinions as unreliable.

# 5. Memorandum Of Law In Support Of Motion To Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals And

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Fragrances In Johnson's Baby Powder And Shower To Shower. This

memorandum addresses the opinions of 19 plaintiffs' experts that the Products may be contaminated with some unspecified amount of chromium, cobalt or nickel and that these metals, "fibrous" talc or the Products' fragrance ingredients could cause ovarian cancer. There are no scientific articles that even suggest that any one of these things has been linked to any form of ovarian cancer, but nearly every one of plaintiffs' experts claims that some or all of them might cause ovarian cancer, resting on patently speculative extrapolations from animal studies and other data exploring links between these exposures and various *other* illnesses. For the reasons set forth in defendants' memorandum, the Court should exclude these opinions as unreliable.

6. Memorandum Of Law In Support Of Motion To Exclude Expert Opinions Unrelated To General Causation. This memorandum addresses the opinions of four of plaintiffs' experts whose reports are largely or entirely irrelevant to the general causation question that is currently before the Court. Dr. Alan Campion seeks to opine that Raman spectroscopy is a reliable technique for identifying talc particles in human tissues, including ovarian tissues, an opinion he developed for litigation on the tab of plaintiffs' counsel; Dr. April Zambelli-Weiner critiques two studies that do not form the basis of any expert's opinions in this litigation and speculates that the United States Food & Drug Administration ("FDA") was unduly influenced by the authors of those studies; Drs. David Kessler and Laura M. Plunkett both seek to opine about various legal and regulatory matters, such as the requirements of the FDA and whether defendants complied with them; and Dr. Plunkett also seeks to opine on the reasonableness of defendants' conduct and defendants' purported influence on governmental bodies. These opinions should be excluded because they are irrelevant to general causation and otherwise unreliable and/or inadmissible.

7. Memorandum Of Law In Support Of Conditional Motion To Exclude Certain Plaintiffs' Experts' Opinions For Lack Of Qualifications. This memorandum addresses the opinions of 14 experts, conditionally seeking their exclusion if the Court accepts any of plaintiffs' arguments with respect to expert qualifications. As set forth in the memorandum, many of plaintiffs' experts seek to offer opinions on a wide range of subjects that fall outside the scope of their particular areas of expertise; indeed, several admitted as much at their depositions.

As noted above, **Appendix A** is a table that cross-references which experts' opinions are addressed in each memorandum.

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#### **CONCLUSION**

For the reasons set forth above and in the seven memoranda submitted herewith, the Court should exclude: (1) plaintiffs' experts' general causation opinions; (2) plaintiffs' experts' opinions related to biological plausibility; (3) the expert opinions of Ghassan Saed; (4) plaintiffs' experts' asbestos-related opinions; (5) plaintiffs' experts' opinions regarding alleged heavy metals, fragrances and fibrous talc in Johnson's Baby Powder and Shower to Shower; and (6) expert opinions unrelated to general causation. In addition, if the Court is inclined to construe qualifications standards in the manner plaintiffs apparently intend to argue in their briefing, it should exclude any and all opinions that arguably exceed plaintiffs' experts' qualifications. Dated: May 7, 2019

Respectfully submitted,

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