

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

MDL NO. 16-2738 (FLW) (LHG)

PLAINTIFFS' STATUS REPORT

Pursuant to this Court's directive, Counsel in the above-referenced MDL submit the following Status Report to inform the Court of the status of the litigation.

I. Factual Background of the Cases

Johnson & Johnson's Baby Powder was introduced to the market in 1893. Since that time, Johnson & Johnson and its subsidiaries have marketed Baby Powder as a safe, mild product intended for use by both mothers and babies. Johnson & Johnson's Baby Powder is composed, almost exclusively, of pure talc, a soft mineral comprised of magnesium, silicon, oxygen, and hydrogen. In 1966, Johnson & Johnson developed Shower to Shower, another talc-based body powder. Each of these products is marketed for feminine hygiene use, including perineal (genital) application, to limit perspiration, chafing, and other discomfort. Imerys Talc America, Inc. ("Imerys") provides all of the talc used in Johnson & Johnson's talc-based body powders.

In 1971, the first study to indicate a possible association between the perineal application of talcum powder and ovarian cancer was conducted by W.J. Henderson in Cardiff, Wales.¹ In 1982, Dr. Daniel Cramer conducted the first case-control study of perineal talcum powder use and ovarian cancer and found a significant increased risk of ovarian cancer among women who use

¹ W.J. Henderson, et al., *Talc and Carcinoma of the Ovary and Cervix*, 78 J. Obst. Gyn. Brit. Common. 266 (March 1971).

talcum powders in the genital area.² Since 1982, numerous studies (27+ studies through October 2016)³, involving many of the most esteemed epidemiologists in the world, have consistently shown an increased risk of ovarian cancer associated with perineal talc use. Out of these 27

² Cramer et al., *Ovarian Cancer and Talc: A Case-Control Study*, 50 *Cancer* 372 (1982).

³ Henderson, W.J., Joslin, C.A.F., Turnbull, A.C., and Griffiths, K., *Talc and Carcinoma of the Ovary and Cervix*, *The Journal of Obstetrics and Gynaecology of the British Commonwealth*, March, 1971. Vol. 78. pp. 266–272; Cramer, D. W., W. R. Welch, R. E. Scully, and C. A. Wojciechowski, *Ovarian Cancer and Talc: A Case-Control Study*, *Cancer* 50, no. 2, (July 15, 1982): 372–76.; Hartge, P., R. Hoover, L. P. Leshner, and L. McGowan. *Talc and Ovarian Cancer*, *JAMA: The Journal of the American Medical Association* 250, no. 14, (October 14, 1983): 1844.; Whittemore, A. S., M. L. Wu, R. S. Paffenbarger, D. L. Sarles, J. B. Kampert, S. Grosser, D. L. Jung, S. Ballon, and M. Hendrickson, *Personal and Environmental Characteristics Related to Epithelial Ovarian Cancer. II. Exposures to Talcum Powder, Tobacco, Alcohol, and Coffee*, *American Journal of Epidemiology* 128, no. 6 (December 1988): 1228–40.; Harlow, B. L., and N. S. Weiss, *A Case-Control Study of Borderline Ovarian Tumors: The Influence of Perineal Exposure to Talc*, *American Journal of Epidemiology* 130, no. 2 (August 1989): 390–94.; Harlow, B. L., D. W. Cramer, D. A. Bell, and W. R. Welch, *Perineal Exposure to Talc and Ovarian Cancer Risk*, *Obstetrics and Gynecology* 80, no. 1 (July 1992): 19–26.; Tzonou, A., A. Polychronopoulou, C. C. Hsieh, A. Rebelakos, A. Karakatsani, and D. Trichopoulos, *Hair Dyes, Analgesics, Tranquilizers and Perineal Talc Application as Risk Factors for Ovarian Cancer*, *International Journal of Cancer. Journal International Du Cancer* 55, no. 3 (September 30, 1993): 408–10.; Chang, S., and H. A. Risch, *Perineal Talc Exposure and Risk of Ovarian Carcinoma*, *Cancer* 79, no. 12 (June 15, 1997): 2396–2401.; Cook, Linda S., Mary L. Kamb, and Noel S. Weiss, *Perineal Powder Exposure and the Risk of Ovarian Cancer*, *American Journal of Epidemiology* 145, no. 5 (March 1, 1997): 459–65.; Cramer, D. W., R. F. Liberman, L. Titus-Ernstoff, W. R. Welch, E. R. Greenberg, J. A. Baron, and B. L. Harlow, *Genital Talc Exposure and Risk of Ovarian Cancer*, *International Journal of Cancer, Journal International Du Cancer* 81, no. 3 (May 5, 1999): 351–56.; Wong, C., R. E. Hempling, M. S. Piver, N. Natarajan, and C. J. Mettlin, *Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: A Case-Control Study*, *Obstetrics and Gynecology* 93, no. 3 (March 1999): 372–76.; Gertig, D. M., D. J. Hunter, D. W. Cramer, G. A. Colditz, F. E. Speizer, W. C. Willett, and S. E. Hankinson, *Prospective Study of Talc Use and Ovarian Cancer*, *Journal of the National Cancer Institute* 92, no. 3 (February 2, 2000): 249–52.; Mills, Paul K., Deborah G. Riordan, Rosemary D. Cress, and Heather A. Young, *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, *International Journal of Cancer, Journal International Du Cancer* 112, no. 3 (November 10, 2004): 458–64 [doi:10.1002/ijc.20434].; Gates, Margaret A., Shelley S. Tworoger, Kathryn L. Terry, Linda Titus-Ernstoff, Bernard Rosner, Immaculata De Vivo, Daniel W. Cramer, and Susan E. Hankinson, *Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer*, *Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology* 17, no. 9 (September 2008): 2436–44 [doi:10.1158/1055-9965.EPI-08-0399].; Wu, Anna H., Pearce, Celeste L., Tseng, Chiu-Chen, Templeman, Claire, and Pike, Malcolm C., *Markers of inflammation and Risk of ovarian cancer in Los Angeles County*, *Int J Cancer*. 2009 Mar 15; 124(6): 1409–1415.; Rosenblatt, Karin A., Noel S. Weiss, Kara L. Cushing-Haugen, Kristine G. Wicklund, and Mary Anne Rossing, *Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer*, *Cancer Causes & Control: CCC* 22, no. 5 (May 2011): 737–42 [doi:10.1007/s10552-011-9746-3].; Houghton, Serena C., Katherine W. Reeves, Susan E. Hankinson, Lori Crawford, Dorothy Lane, Jean Wactawski-Wende, Cynthia A. Thomson, Judith K. Ockene, and Susan R. Sturgeon, *Perineal Powder Use and Risk of Ovarian Cancer*, *Journal of the National Cancer Institute* 106, no. 9 (September 2014) [doi:10.1093/jnci/dju208].; Cramer, Daniel W., Allison F. Vitonis, Kathryn L. Terry, William R. Welch, and Linda J. Titus, *The Association between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, *Epidemiology (Cambridge, Mass.)*, December 17, 2015 [doi:10.1097/EDE.0000000000000434].; Schildkraut, Joellen M., et al., *Association Between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES)*, Published Online with the American Association for Cancer Research, May 12, 2016; Gonzalez, Nicole L., et al., *Douching, Talc Use, and Risk of Ovarian Cancer*, *Epidemiology Publish Ahead of Print*, June 20, 2016.

studies, all but one of them found a statistically significant increased risk of ovarian cancer from talc use.

Beginning in September 1971, Johnson & Johnson developed a strategy to refute or discredit the Henderson findings. This included criticizing the Henderson study's techniques, validity, tissues, and references. Johnson & Johnson also focused on trying to prove the purity of the talc they used in their products, rather than performing research to determine if talc itself had any adverse effects when embedded in ovarian tissues. This effort continued for the next ten years and only intensified after the 1982 study performed by Dr. Cramer. Numerous Johnson & Johnson and Imerys internal documents acknowledge the increasing health concerns involved with genital talc use and ovarian cancer.

In 2005, the International Agency for the Research on Cancer ("IARC"), an organization that is part of the World Health Organization, voted in favor of declaring perineal use of cosmetic grade talc a group 2B carcinogen, i.e., "possibly carcinogenic to human beings." IARC's rationale for this ruling was: "For perineal use of talc-based body powder, many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out." Since the IARC pronouncement, Imerys has placed a warning on the talc Material Safety Data Sheets ("MSDS") that it sends to Johnson & Johnson, acknowledging that genital talc use may increase the risk of ovarian cancer.

Internal documents from Johnson & Johnson and Imerys demonstrate that, despite their knowledge of the risk of harm to women, these companies, along with their trade association, the Personal Care Products Council ("PCPC"), actively concealed information regarding the dangers of genital talcum powder use from consumers. Both companies have actively attempted to influence regulatory agencies in an effort to prevent governmental regulation of talc use. This has

included the formation of the Talc Interested Party Task Force, formed under the auspices of the Cosmetic, Toiletry, and Fragrance Association, for the purpose of defending talc-based products. Over the years this task force and other industry-sponsored groups have worked to influence the National Toxicology Program, U.S. Food and Drug Administration, National Institutes of Health, National Institute of Environmental Health Sciences, and other regulatory agencies.

Despite consistent evidence of a causal connection between perineal application of talcum powder and ovarian cancer, neither Johnson & Johnson's Baby Powder nor Shower to Shower have been removed from the market or altered to remove talc as a main ingredient. Johnson & Johnson continues to sell these talc-based body powders without a consumer warning.

As a direct result of the Defendants' actions, untold numbers of women continue to use these products on a daily basis, and thousands of women have been diagnosed with cancer. Over the past few decades, this has led to countless avoidable deaths from ovarian cancer caused by the genital use of talcum powder.

II. Discovery in Federal Court

As of the date of this letter, 60 cases have been transferred to MDL No. 2738. In all but one case, discovery has not commenced.

In *James Chakalos, as Personal Representative on behalf of the Estate of Janice Chakalos v. Johnson & Johnson, et al.*, Docket No. 3:14-cv-7079, discovery has begun. In *Chakalos*, the following represents the status of discovery in relation to Johnson & Johnson and Imerys Talc America, Inc.:

- A. Johnson & Johnson, et al.
 - i. Johnson & Johnson has produced approximately 88,519 documents.
 - ii. The production is substantially similar to the disclosures in various state court cases in the Superior Court of the District of Columbia, the Circuit Court of the City of St. Louis, Missouri, and the Superior Court of the Atlantic County, New Jersey.

- iii. Plaintiffs will seek additional documents relating to sales and marketing, clinical investigations, adverse event reporting, regulatory affairs, third party communications, as well as other areas that have not yet been the subject of discovery.
- iv. Johnson & Johnson has not signed a certificate of completeness in relation to the document production.
- v. Johnson & Johnson has served a privilege log in relation to 1,149 documents. Plaintiffs expect to assert objections to certain privilege designations. Challenges to privilege designations are being considered in other jurisdictions.
- vi. To date, the depositions of two corporate witnesses have been taken, John Hopkins and Lorena Telofski. These two depositions were taken in *Berg v. Johnson & Johnson, et al.* (D.S.D. 2013).

B. Imerys Talc America, Inc.

- i. Imerys has produced approximately 76,920 documents.
- ii. The production is substantially similar to the disclosures in various state court cases in the Superior Court of District of Columbia, the Circuit Court of the City of St. Louis, Missouri, and the Superior Court of the Atlantic County, New Jersey.
- iii. Imerys has not signed a certificate of completeness in relation to the production.
- iv. Imerys has served a privilege log in relation to 1,865 documents. Plaintiffs expect to assert objections to certain privilege designations. Challenges to privilege designations are being considered in state court jurisdictions.
- v. The depositions of two corporate witnesses have been taken, John Poston and Shripal Sharma. These two depositions were taken in *Berg v. Johnson & Johnson, et al.* (D.S.D. 2013).

PCPC has been named as a defendant in numerous federal cases. Discovery has not commenced in relation to PCPC in any of the cases pending in the MDL. Discovery is ongoing in relation to PCPC in cases pending in the Superior Court of Atlantic County, New Jersey and the Superior Court of the District of Columbia.

Third-party discovery has also not yet begun in cases pending in federal court. Third-party discovery will be a significant aspect of pre-trial preparation. Third party discovery is ongoing in other jurisdictions in relation to the following third parties: i) Cosmetic Ingredient Review; ii) Center for Regulatory Effectiveness; iii) Industrial Materials Association; and iv) Dezenhall Resources.

III. Settlement

The Parties have not entered into settlement discussions.

IV. Pending Motions

Counsel in individual cases will report on the status of pending motions and motions previously decided by a transferor judge.

V. Related State Litigation

There are currently cases pending before five state court venues listed below:

- A. Superior Court for the District of Columbia – Hon. Brian Holeman, Hon. Marisa DeMeo: There are 3 filed cases.
- B. Missouri Circuit Court, St. Louis City – Hon. Rex Burlison, Special Master, Hon. Glenn Norton:
 - i. 20 dockets, approximately 1,800 cases filed; and
 - ii. 3 cases tried to verdict (*Fox, et al. v. Johnson & Johnson*, No. 1422-CC09012-01 (Feb. 2016); *Ristesund v. Johnson & Johnson*, No. 1422-CC09012-01 (May 2016); and *Giannecchini v. Johnson & Johnson*, No. 1422-CC09012-01 (Oct. 2016).
- C. Superior Court of Atlantic County, New Jersey – Hon. Nelson Johnson
 - i. Approximately 400 cases filed and consolidated;
 - ii. *Kemp* Hearing in August 2016; and
 - iii. Two cases (*Carl* and *Balderrama*) dismissed following the *Kemp* Hearing.
- D. Superior Court of California, County of Los Angeles, Central Judicial District, – Hon. Maren E. Nelson (who will be substituted by Jan. 2017): Approximately 240 Plaintiffs are currently coordinated in the Judicial Council Coordinated Proceedings.
- E. Superior Court of the State of Delaware – Hon. Charles E. Butler: There are 5 filed cases. A motion to consolidate these 5 actions for pre-trial discovery is pending.

VI. Proposed Lead and Liaison Counsel

Counsel for all Plaintiffs with cases pending before this Court have met and conferred. There is unanimous agreement that Michelle A. Parfitt and P. Leigh O'Dell serve as Co-Lead Counsel of the MDL. Counsel propose that Christopher M. Placitella be appointed as Liaison Counsel.

Ms. Parfitt and Ms. O'Dell will represent the interests of Plaintiffs who have alleged personal injury claims during the Organizational Conference. Timothy G. Blood will represent the interests of the Plaintiffs who have brought consumer protection class actions.

Plaintiffs have met and are prepared to submit to the Court proposed leadership that has the support of a majority of Plaintiffs' counsel.

VII. Proposed Agenda Items

Counsel for Plaintiffs propose the following agenda items that may be discussed during the Organizational Conference:

- A. Appointment of the Plaintiffs Steering Committee
 - i. Appointment of Committee Chairs and Members
 - ii. State/Federal Liaison
- B. Service of Papers
 - i. Generate Corrected Service List
 - ii. Potential for Use of a Counsel Contact Information Form
 - iii. Potential for Stipulation Related to Waiver and Electronic Service Defendants
- C. Direct Filing Order
- D. Master Complaint/Short Form Complaints
- E. Master Answer/Short Form Answers

- F. Protective Order
- G. ESI Protocol
- H. Document Production Protocols
- I. Preservation/Extremis Depositions
- J. Tissue Preservation Protocol
- K. Plaintiff Fact Sheets/Defendant Fact Sheets
- L. Role of Magistrate Judge

Dated: November 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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