Court of Appeals
of the
State of New York

APL-2020-00122

FRANCIS NEMETH, Individually and as the Personal Representative of the Estate of FLORENCE NEMETH,

Plaintiff-Respondent,

- against -

BRENNTAG NORTH AMERICA, et al.

Defendants,

- and -

WHITTAKER, CLARK & DANIELS, INC.,

Defendant-Appellant.

BRIEF ON BEHALF OF CONCERNED PHYSICIANS AND SCIENTISTS REGARDING CAUSATION OF ASBESTOS-RELATED DISEASE FROM EXPOSURE TO ASBESTOS-CONTAMINATED COSMETIC TALCUM POWDER, AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-RESPONDENT

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STATEMENT OF INTEREST

It is our[1] understanding that Appellant Whittaker Clark and Daniels, Inc. ("WCD") disputes the scientific reliability of Dr. Jacqueline Moline's testimony that exposure to asbestos-contaminated cosmetic talcum powder products was a substantial contributing factor in the development of Ms. Nemeth's peritoneal mesothelioma. In doing so, WCD and its *amici curiae* incorrectly suggest that there is a minimum threshold level of exposure to asbestos sufficient to cause peritoneal mesothelioma, and erroneously claim that a medical expert must quantify an individual's asbestos exposure to a particular product to properly assess its role in disease causation. As discussed herein, these contentions are contrary to the scientific principles and methodology widely accepted by the relevant scientific and medical communities.

As physicians and scientists, we are concerned with asbestos disease that causes several thousand preventable deaths each year in the United States alone, and the extent to which asbestos exposure from use of cosmetic talcum powder has contributed to these deaths without adequate acknowledgment from public health agencies. The signers of this paper collectively possess hundreds of years of experience researching, diagnosing, and treating asbestos-related diseases. We have

[1] A list of the signatories and their affiliations is attached as Exhibit A. Their titles and affiliations are given for identification purposes only.

published extensively in this field for more than 40 years and have conducted epidemiological and other investigations into the relationships of talc, asbestos, and disease. Many of us have testified before legislative and regulatory bodies regarding talc, asbestos, and disease, as well as in court proceedings at the request of individuals suffering from mesothelioma and other asbestos-related diseases.

Our interest in this matter is not whether Ms. Nemeth's mesothelioma was specifically caused by her exposure to asbestos-contaminated talc supplied by WCD but, rather, whether a reliable scientific foundation exists for an expert such as Dr. Moline to proffer that opinion. The geological and biomedical literature demonstrates that cosmetic talcum powder products are contaminated with asbestos, and that exposure to asbestos through the regular use of these cosmetic talcum powder products increases the risk of developing malignant mesothelioma. The causative link between exposure to asbestos and mesothelioma has been firmly established by multiple epidemiological studies, and no safe threshold to exposures above background has been established either within the medical literature or by regulatory agencies in both the U.S. and Europe. As with any other asbestos-containing product, attributing causation to an asbestos-contaminated cosmetic talcum powder does not require an expert to quantify the amount of exposure an individual experienced. It is unreasonable to expect an exposed individual or a scientific expert to accurately reconstruct exposures in either the remote or recent

past. The claim that an opinion attributing mesothelioma causation to asbestos exposures above background ambient air levels from cosmetic talc is unscientific, or somehow "junk science," is contrary to what is widely accepted in the medical/scientific literature and, thus, incorrect.

The review of the available medical and scientific literature summarized herein demonstrates that Dr. Moline's opinions are based upon sound and generally-accepted scientific knowledge. Insofar as Dr. Moline assigned causation based upon her review of the decedent's diagnosis, medical and occupational history, generally-accepted scientific and medical data derived from relevant case reports, case series, and epidemiological studies published in peer-reviewed literature, and her nearly 30 years of experience in evaluating and treating patients with asbestos-related illness, her causation opinion accords with generally-accepted scientific methodology. While there may be scientists who, despite what is accepted by the scientific mainstream, hold different opinions, there is no generally-accepted basis to find that an opinion assigning causation for an individual's mesothelioma to asbestos-contaminated cosmetic talcum powder is not reliable.

ARGUMENT

I. Generally-Accepted Scientific Principles and Conclusions Support that Exposure to Asbestos-Contaminated Cosmetic Talcum Powder Products Causes All Forms of Mesothelioma.

1. All Types of Asbestos Fibers Cause Disease

Asbestos is a commercial and regulatory term that has been designated to a group that includes six different fibrous silicate minerals occurring naturally in the environment.[2] These fibers can be subclassified into two mineral groups: serpentine (chrysotile), and amphibole (amosite, crocidolite, anthophyllite, tremolite, and actinolite). The predominant fiber type used commercially in the United States has been chrysotile asbestos.[3] Based on peer-reviewed, scientific literature from a range of disciplines, including epidemiology, toxicology, medical research, and industrial hygiene, there is a consensus within the scientific and medical communities that exposure to all forms of asbestos can cause mesothelioma and lung cancer.[4]

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[2] Agency for Toxic Substances and Disease Registry, *Public Health Statement Asbestos*, 1.1 (2001); World Health Organization ("WHO"), *Chrysotile Asbestos* (2014), at 2-3; Virta, *Asbestos: Geology, mineralogy, mining, and uses.* U.S. Dep't. of the Interior: U.S. Geology Survey. Open-File Report No. 02-149 (2003).

[3] WHO (2014), *supra*, at 3.

[4] WHO, International Agency Research on Cancer ("IARC"), *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, A Review of Human Carcinogens, Part C: Arsenic, Metals, Fibres, and Dusts* Vol. 100C (2012); Joint Policy Committee of the Societies of Epidemiology, *Position Statement on Asbestos from the Joint Policy Committee of the Societies of Epidemiology (JPC-SE)* (June 4, 2012); WHO, IARC, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, A Review of Human Carcinogens, Part C: Arsenic, Metals, Fibres, and Dusts* (2009); WHO, *Elimination of asbestos-related diseases* (2006); Dodson, Atkinson and Levin, *Asbestos Fiber Length as Related to Potential Pathogenicity: A Critical Review*, 44 AM. J. INDUS. MED. 291-297 (2003); Egilman, Fehnel, and Rankin Bohme, *Exposing the "Myth" of ABC, "Anything But Chrysotile": A Critique of the Canadian Asbestos Mining Industry and McGill University Chrysotile Studies*, 44 AM. J. INDUS. MED. 540-557 (2003); WHO, IARC, *IARC*

2. Asbestos and Talc Geologically Co-Exist, Inevitably Leading Cosmetic Talcum Powder Products to Contain Asbestos and, Thus, Be Carcinogenic

Like asbestos, talc is a naturally occurring silicate mineral.[5] And like asbestos, it is formed by water-rock interactions in which pre-existing rock formations, called protoliths, are subjected to changes in temperature, pressure, and the infiltration of hydrothermal fluids (hot water).[6] Over millions of years, these physical changes drive reactions in which minerals inside the protolith break down to form a complex mixture of new stable minerals, including talc and asbestos.[7]

For over a century, geologists have known that talc is found in geologic fault lines often contaminated with tremolite, anthophyllite, and chrysotile.[8] Because the formation of asbestos and talc is linked by common geologic processes, this is not surprising. Indeed, although some "refer to asbestos as a 'contaminant' in talc as if it is an introduced foreign substance, asbestos occurs as a relict component of the natural talc-forming geologic processes" and its presence in raw talc ore can

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Monographs on the Evaluation of the Carcinogenic Risks for Humans, Chemical and Industrial Processes Associated with Cancer in Humans: IARC Monographs, Volumes 1 to 20, *Supplement 1* (1979).

[5] IARC (2012), *supra*, at 230.

[6] Testimony of Rodney V. Metcalf PhD, Congressional Subcommittee on Economic and Consumer Policy Hearing Examining Asbestos in Talc, Dec. 10, 2019, https://www.congress.gov/116/meeting/house/110311/witnesses/HHRG-116-GO05-Wstate-MetcalfP-20191210.pdf; Deer, Howie, Zussman, *An Introduction to the Rock-Forming Minerals* (2d Ed. Longman: Harlow) (1966), at 227-230.

[7] Metcalf, *supra*.

[8] Rohl, *et al.*, *Consumer talcums and powders: mineral and chemical characterization*, 2 J. TOXICOL. ENVIRON. HEALTH 255-284 (1976), at 257; Dana and Ford, *Dana's Textbook of Mineralogy* (1932), at 677-678.

therefore be expected.[9] Asbestos remains in talc after it has been extracted from the earth because the natural complexity of the mineral deposits in which asbestos and talc co-exist makes selective mining or the extrication of asbestos from mined talc virtually impossible.[10] The presence of asbestos in finished consumer talcum powder products was demonstrated by studies as early as the 1960s.[11] In 2020, the U.S. FDA expressly recognized that, in talc-containing consumer products, the talc is "the presumptive source of asbestos."[12]

It is a widely accepted scientific fact that talc containing asbestos is a human carcinogen capable of causing mesothelioma.[13] Recent peer-reviewed case studies discussed in further detail below have linked malignant mesothelioma at all sites to asbestos exposure from cosmetic talc use.[14] Asbestos in cosmetic talc is considered a health hazard to consumers at levels below 0.5%, which, under the cosmetic talc

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[9] Metcalf, *supra*.

[10] Rohl and Langer, *Identification and Quantitation of Asbestos in Talc*, 9 ENVT'L. HEALTH PERS. 95-109 (1974), at 96-97; Deer, Howie, Zussman, *supra*, at 159, 228-230.

[11] *See e.g.* Cralley, *et al.*, *Fibrous and Mineral Content of Cosmetic Talcum Products*, 29 AM. IND. HYG. ASSOC. J. 350-354 (1968); Rohl, *et al.*, (1976), *supra*.

[12] FDA, Interagency Working Group on Asbestos in Consumer Products, *Executive Summary, Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc* (Jan. 6, 2020).

[13] IARC (2012), *supra*, at 38, 219, 293.

[14] Emory, Maddox, and Kradin, *Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients*, 63 AM. J. OF INDUS. MED. 6, 484-489 (2020); Moline, *et al.*, *Mesothelioma Associated with the Use of Cosmetic Talc*, J. 62 OCCUP. & ENVT'L. MED. 1, 11-17 (2020); Gordon, Fitzgerald, and Millette, *Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women*, 20 INT'L. J. OF OCCUP. & ENVT'L. HEALTH 4, 318-322 (2014).

industry's "J4-1" asbestos testing standard, are labeled as "non-detect."[15] As Dr. Arthur Rohl of Mount Sinai School of Medicine observed in 1974, asbestos levels of 0.25% in talc represents *billions* of particles of asbestos per milligram of talc.[16]

In the legal setting, it has become a matter of controversy whether asbestos fibers that meet the geologic criteria for "cleavage fragments" or "non-asbestiform" cause disease. There is no evidence to suggest that human cells differentiate between fibers that have identical chemistry, shape, size, charge, *etc*. To the contrary, evidence exists that so called "cleavage fragments" have similar cytotoxic effects as asbestos fibers, leading to changes on the cellular level that can lead to cancer.[17] Accordingly, as has been recognized in countless pronouncements and recommendations of health and regulatory bodies, as well as peer-reviewed scientific literature, an asbestos fiber classified by some investigators as a "non-asbestos cleavage fragment" by geologic criteria can still cause mesothelioma.[18]

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[15] Bird, *et al.*, *A Review of the Talc Industry's Influence on Federal Regulation and Scientific Standards for Asbestos in Talc*, NEW SOLUTIONS 1-18 (Feb. 27, 2021), https://journals.sagepub.com/doi/10.1177/1048291121996645; Rosner and Markowitz, *"Nondetected": The politics of measurement of asbestos in talc, 1971-1976*, 109 AM. J. OF PUB. H. SCIENCE & PUB. HEALTH CONSCIENCE 7, 969-974 (2019).

[16] Rohl, *Asbestos in Talc*, 9 ENVT'L. HEALTH PERS. 129-132 (1974), at 130.

[17] Khaliullin, *et al.*, *Differential responses of murine alveolar macrophages to elongate mineral particles of asbestiform and non-asbestiform varieties: Cytotoxicity, cytokine secretion and transcriptional changes*, 409 TOXICOLOGY AND APPLIED PHARMACOLOGY (2020).

[18] *See e.g.* Egilman, *et al.*, *Health Effects of Censored Elongated Mineral Particles: A Critical Review*, in *Detection Limits in Air Quality and Environmental Measurements*, ed. M. Brisson (ASTM International 2019), 192-239; Oyarzun, *et al.*, *Restrictive Definition of Asbestos and the Assessment of Potential Health Hazards: Insights from Northern Chile*, 52 INT'L. GEOLOGY REVIEW 9, 955-963 (2010); Kahkonen, *et al.*, *Asbestos Risk Management Guidelines for Mines*, Finnish Institute of Occup. Health (2019); Environmental Protection Agency ("EPA"),

Therefore, for purposes of evaluating the health risks associated with asbestos in consumer talcum powder products, no distinction should be made between minerals that meet the morphological criteria of an asbestiform fiber.

3. Mesothelioma is a Signal Tumor for Exposure to Asbestos

Mesothelioma is a rare cancer that develops from the thin layer of cells that line the internal organs of the body, *i.e.* the mesothelium.[19] Recognition that asbestos was the cause of malignant mesothelioma followed Wagner's discovery that mesothelioma, a previously extraordinarily rare cancer, occurred with markedly increased frequency in individuals who worked or lived in the vicinity of a South African asbestos mine.[20] Sixty years later, there is no debate that asbestos is the primary known cause of malignant mesothelioma.[21] For this reason, mesothelioma is considered a "sentinel" or "signal" tumor for asbestos exposure.[22]

In challenging the epidemiology of peritoneal mesothelioma in relation to asbestos and asbestos-contaminated cosmetic talc, defendants generally ignore the

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Region IX, *Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group, Inc. "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project*" (April 20, 2006).

[19] Kanarek and Mandich, *Peritoneal Mesothelioma and Asbestos: Clarifying the Relationship by Epidemiology*, 6 EPIDEMIOLOGY (Sunnyvale) 2, 1-7 (2016).

[20] Wagner, Sleggs, and Marchand, *Diffuse pleural mesothelioma and asbestos exposure in the North Western Cape Province*, 17 BR. J. IND. MED. 260-271 (1960).

[21] Checkoway, Pearce, and Crawford-Brown, *Research Methods in Occupational Epidemiology* (2d Ed. 2004), at 248.

[22] Kanarek and Mandich, *supra*; Rutstein, *et al.*, *Sentinel health events (occupational): a basis for physician recognition and public health surveillance*, 73 AM. J. PUB. HEALTH 9, 1054-1061 (1983).

consensus of the non-aligned scientific community that *all forms of mesothelioma* are causally linked to asbestos exposure.[23] Such consensus is based on the full body of the scientific evidence, including epidemiological studies, human fiber burden testing, animal studies, in vitro studies, as well as case series and case-control studies showing that all types of asbestos cause cellular changes that lead to mesothelioma, including peritoneal.[24]

Although the scientific community has historically labeled some mesotheliomas as "idiopathic," *i.e.* of unknown origin,[25] this may reflect incomplete exposure histories or immediately unavailable information about a patient's product use or a product's asbestos content, and not necessarily because a mesothelioma is unrelated to asbestos exposure. In many cases, individuals do not know when or how they were exposed, or they die before an exhaustive inquiry into potential exposures can be conducted.[26] Many epidemiologic studies are limited because they assess occupational exposures for which there is information available from existing work

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[23] *See* Magnani, *et al.*, *III Italian Consensus Conference on Malignant Mesothelioma of the Pleura Epidemiology, Public Health and Occupational Medicine Related Issues*, 106 MED. LAV. 5 (2015); Wolff, *et al.*, *Consensus Report: Asbestos, asbestosis, and Cancer, the Helsinki Criteria for Diagnosis and Attribution 2014: Recommendations*, 41 SCAND. J. WORK ENVIRON. HEALTH 1, 5-15 (2015); Tossavainen, *et al.*, *Consensus Report: Asbestos, asbestosis, and cancer: the Helsinki criteria for diagnosis and attribution*, 23 SCAND. J. WORK ENVIRON. HEALTH 4, 311-316 (1997).

[24] Kanarek and Mandich, *supra*.

[25] Roggli, *et al.*, *Pathology of Asbestos-Associated Diseases* (3d Ed. 2014), at 308.

[26] Welch, *Asbestos Exposure Causes Mesothelioma, But Not This Asbestos Exposure: An Amicus Brief to the Michigan Supreme Court*, 13 INT. J. OCCUP. ENVIRON. HEALTH 3, 318-327 (2007).

records, but do not include potential para-occupational or environmental exposures.[27] However, it is well known that non-occupational exposures are a significant source of asbestos exposure, and just as dangerous to human health as their occupational counterparts.[28] This is corroborated by the growing body of reliable scientific data indicating that millions of men and women were unwittingly exposed to asbestos from cosmetic talc products (mostly women as they are the more likely users of these powders), and that these exposures were not considered by the historic medical literature.[29] As recognized by Dr. George Wright, who served as a consultant to Johns-Manville (once the world's leading manufacturer of asbestos-containing products), at a presentation before the American Thoracic Society in 1969, "[i]t is difficult to conceive of a better way of having fibers inhaled than the use of cosmetic talcum powders."[30]

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[27] *Id*.

[28] Mazurek, *et al.*, *Malignant mesothelioma mortality – United States, 1999-2015*, HHS/Center for Disease Control and Prevention 66 MORB. MORTAL WKLY. REP. 214-218 (2017); Marinaccio, *et al.*, *The epidemiology of malignant mesothelioma in women: gender differences and modalities of asbestos* exposure, 75 OCCUP. ENVT'L. MED. 4, 254-262 (2017); Lacourt, *et al*., *Occupational and non-occupational attributable risk of asbestos exposure for malignant pleural mesothelioma*, 69 THORAX 532-539 (2014); Selikoff and Lee, *Environmental Science: An Interdisciplinary Monograph Series – Asbestos and Disease* (1978); Bradford Hill, *The Environment and Disease: Association or Causation?* PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE (1965).

[29] Stoiber, Fitzgerald, and Leiba, *Asbestos Contamination in Talc-Based Cosmetics: An Invisible Cancer Risk*, 14 ENVT'L. HEALTH INSIGHTS 1-3 (2020); Finkelstein, *Letter to the Editor: Malignant Mesothelioma and Its Nonasbestos Causes*, 143 ARCH. PATHOL. LAB. MED. 659-660 (2019).

[30] Wright, *Asbestos and Health in 1969*, 100 AM. REVIEW OF RESPIRATORY DISEASE 4, 467-479 (1969), at 476.

Simply put, the existence of mesotheliomas labeled "idiopathic" does not support that there are large numbers of "spontaneous," *i.e.* non-asbestos related mesotheliomas. In fact, studies intended to scientifically prove this belief have failed to do so,[31] and examinations of mesothelioma cases around the world have generally found either a history of exposure or evidence of asbestos in tissue analyses.[32] When conducting exposure assessments of mesothelioma patients, greater consideration must be given to potential non-occupational exposures, including possible exposures to cosmetic talcum powder.[33] Clearly, a complete and accurate accounting of all potential asbestos exposures, including cosmetic talcum powder use, will result in fewer "idiopathic" mesotheliomas.

4. Mesothelioma is a Cumulative Exposure Disease to Which All Sources of Asbestos Exposure Contribute, Even at Low Levels

Mesothelioma is caused primarily by inhaling asbestos fibers, although other routes of entry, *e.g.*, transvaginal in women, must be considered. For purposes of understanding the causative relationship between mesothelioma, asbestos, and talc,

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[31] Mark and Yokoi, *Absence of evidence for a significant background incidence of diffuse malignant mesothelioma apart from asbestos exposure*, 643 ANN. N.Y. ACAD. SCI. 196-204 (1991).

[32] *See e.g.* Panou, *et al.*, *Malignant mesothelioma in 91 danish women: the environmental asbestos exposure*, 35 J. CLIN. ONCOL. 15, 8560-8565 (2017) (non-occupational exposure main cause of mesotheliomas studied); Leigh, *et al.*, *Malignant Mesothelioma in Australia 1945-2000*, 9 INT. J. OCCUP. ENVT'L. HEALTH 3, 206-217 (2003) (90% of mesothelioma cases had history of exposure or asbestos in lung tissue); Heller, *et al.*, *Presence of asbestos in peritoneal malignant mesotheliomas in women*, 9 INT. J. GYNECOL. CANCER 452-455 (1999) (asbestos in tissue of six women with peritoneal mesothelioma and no recorded exposure).

[33] *See generally* Mazurek, *supra*.

it must be said that it makes no scientific difference as to the product from which the asbestos originates. What matters is whether asbestos fibers can enter the body and be transported to a mesothelial-lined surface.[34]

Mesothelioma, like other diseases caused by the inhalation of asbestos, occurs on the cellular level with each exposure potentially contributing to the onset of disease, even at low cumulative exposure levels.[35] Indeed, mesothelioma is dose-responsive, with the risk of developing disease correlated directly with the dose.[36]

There is no recognized threshold of exposure to asbestos above "normal" ambient background (0.0001-0.00000001 fiber/cc air) that does not increase the risk of disease for those exposed to asbestos generated by product use.[37] The scientific

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[34] *See* IARC (2012), *supra*, at 283-294.

[35] *See generally* Hammar, *et al.*, *Neoplasms of the Pleura,* in 2 Dail and Hammar's Pulmonary Pathology Volume II: Neoplastic Lung Disease (3d Ed. 2008), 579-599 (describing multi-stage progress in which asbestos infiltrates body and causes malignant transformation of cells); *see e.g.* Pairon, *et al.*, *Pleural mesothelioma and exposure to asbestos: evaluation from work histories and analysis of asbestos bodies in bronchoalveolar lavage fluid or lung tissue in 131 patients*, 51 OCCUP. ENVIRON. MED. 244-249 (1994).

[36] Jiang, *et al.*, *Hand-spinning chrysotile exposure and risk of malignant mesothelioma: A case-control study in Southeastern China*, 142 INT'L. J. OF CANCER 514-523 (2018); Wolff, *supra*; Tossavainen, *supra*; Hillderdal, *Mesothelioma: cases associated with non-occupational and low dose exposures*, 56 OCCUP. ENVT'L. MED. 8, 505-513 (1999); Neumann, *et al.*, *German mesothelioma register 1987-1999*, 74 INT'L. ARCH. ENV. HEALTH 6, 383-395 (2001).

[37] *See* Linton, *et al.*, *The ticking time-bomb of asbestos: Its insidious role in the development of malignant mesothelioma*, 84 CRITICAL REVIEWS IN ONCOLOGY/HEMATOLOGY 2, 200-212 (2012); WHO, *Position on Asbestos* (May 5, 2006); British Thoracic Society Standards of Care Committee, *Statement of Malignant Mesothelioma in the United Kingdom*, 56 THORAX 250-265 (2001), at 252; EPA, *Evaluation of the Potential Carcinogenicity of Asbestos*, Report No. EPA/600/8-91/065 (June 1988); Nat'l. Inst. Occup. Safety & Health ("NIOSH"), HHS, *Workplace Exposure to Asbestos, Review and Recommendations*, Pub. No. 81-103 (1980), at 25; Consumer Product Safety Commission, Ban of Consumer Patching Compounds Containing Respirable Free-Form Asbestos, 16 C.F.R. Ch. 11 § 1304.5 (1977), at 351; Greenberg and Davies, *Mesothelioma*

mainstream views efforts "to deduce a 'threshold' by identifying the lowest estimated dose received by any observed case is a logical nonsense."[38] It is well-established that brief or low exposures to asbestos have caused mesothelioma. The medical literature is replete with case reports of mesotheliomas caused by as little as months, weeks, or even a few days of asbestos exposure.[39] This is true regardless of fiber type (*i.e.* low doses of both amphiboles and chrysotile have triggered the onset of mesothelioma)[40] and for both pleural and peritoneal mesothelioma.[41] Indeed,

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Register 1967-68, 31 BRIT. J. IND. MED. 2, 91-104 (1974); Hills, *Economics of Dust Control: Discussion*, 132 ANNALS OF THE NEW YORK ACADEMY OF SCIENCES 322-337 (1965), at 335.

[38] Hodgson and Darnton, *Quantitative risks of mesothelioma and lung cancer in relation to asbestos exposure*, 44 ANN. OCCUP. HYG. 8, 565-601 (2000), at 583.

[39] *See e.g.* Skammeritz, *et al.*, *Asbestos Exposure and Survival in Malignant Mesothelioma: A Description of 122 Consecutive Cases at an Occupational Clinic*, 2 J. OCCUP. & ENVIRON. MED. 4, 224-236 (2011) (exposure for some was "a few days"); Greenberg and Davies, *supra*, at 96, 98 (reporting exposures of three weeks and one day); Borow, *et al.*, *Critical Review, Mesothelioma following Exposure to Asbestos: A review of 72 Cases*, 64 CHEST 5, 641-646 (1973) (two mesotheliomas after working in areas "not heavily contaminated with asbestos" for ten and eighteen months); Lieben and Pistawka, *Mesothelioma and Asbestos Exposure*, 14 ARCH. ENVT'L. HEALTH 4, 559-566 (1967) (mesothelioma after exposure of "a matter of hours"); Newhouse and Thompson, *Mesothelioma of Pleura and Peritoneum Following Exposure to Asbestos in the London Area*, 22 BRIT. J. INDUS. MED. 4, 261-269 (1965) (two mesotheliomas with exposure of two months or less); 20 U.S.C. § 3601 (1980) ("medical science has not established any minimum level of exposure to asbestos which is considered to be safe to individuals exposed to the fibers").

[40] *See e.g.* Mirabelli, *et al.*, *Excess of mesotheliomas after exposure to chrysotile in Balangero, Italy*, 65 OCCUP. & ENVT'L. MED. 12, 815-819 (2008) (updated study of miners and area surrounding chrysotile-only mine shows increase in mesothelioma among miners and residents); Piolatto, *et al.*, *An Update of Cancer Mortality among Chrysotile Asbestos Miners in Balangero, Northern Italy*, 47 BRIT. J. IND. MED. 12, 810-814 (1990) (two miners of chrysotile-only mine developed mesothelioma); Wagner, Skidmore, and Timbrell, *The Effects of the Inhalation of Asbestos in Rats*, 29 BRIT. J. OF CANCER 3, 252-269 (1974) (animal studies involving exposure to amphibole and chrysotile show one day of exposure can cause disease).

[41] *See e.g.* Kradin, Eng, Christiani, *Diffuse peritoneal mesothelioma: A case series of 62 patients including paraoccupational exposures to chrysotile asbestos*, 60 AM. J. IND. MED. 11, 963-967 (2017); Welch, *Asbestos and Peritoneal Mesothelioma among College-Educated Men*, 11 INT'L. J. OF OCCUP. ENVT'L. HEALTH 3, 254-258 (2005).

medical literature has documented that all fiber types are capable of translocating, or physically transferring, from the lung to the pleura where cancer occurs.[42]

The universally-accepted scientific principles and methodology dictating the requirements for an expert to attribute a given mesothelioma to asbestos exposure were set forth by internationally recognized asbestos disease experts in 1997,[43] and reaffirmed in 2014,[44] in a peer-reviewed consensus report that includes the so-called "Helsinki Criteria." Given the irrefutable causative link between asbestos and mesothelioma, the Helsinki Criteria agreed with what was already widely accepted within the relevant scientific community – that "a history of significant occupational, domestic or environmental exposure will suffice for attribution."[45] Moreover, with the specific focus of providing guidance to determining attribution of a given mesothelioma to asbestos exposures, the Helsinki Criteria counseled that:

- "The great majority of mesotheliomas are due to asbestos exposure;"
- "Mesotheliomas can occur in cases with low asbestos exposure. However, very low background environmental exposures carry only an extremely low risk;"

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[42] Suzuki, Yuen, and Ashley, *Short, thin asbestos fibers contribute to the development of human malignant mesothelioma: pathological evidence*, 208 INT. J. HYG. ENVIRON.-HEALTH 3, 201-210 (2005); Suzuki and Yuen, *Asbestos Fibers Contributing to the Induction of Human Malignant Mesothelioma*, 982 ANN. N.Y. ACAD. SCI. 160-176 (2002); Dodson, *et al*., *Asbestos content of omentum and mesentery in nonoccupationally exposed individuals*, 17 TOXICOL. IND. HEALTH 4, 138-143 (2001); Dodson, *et al.*, *Asbestos in extrapulmonary sites: omentum and mesentery*, 117 CHEST 2, 486-493 (2000).

[43] Tossavainen, *supra*.

[44] Wolff, *supra*.

[45] Tossavainen, *supra*, at 313.

- "About 80% of mesothelioma patients have had some sort of occupational exposure to asbestos (necessitating a carefully obtained and detailed occupational history for proper diagnosis);"

- "An occupational history of brief or low-level exposure should be considered sufficient for mesothelioma to be designated as occupationally related;"

- "A minimum of 10 years from the first exposure is required to attribute the mesothelioma to asbestos exposure, though in most cases the latency interval is longer (*e.g.* in the order of 30-40 years)."[46]

These generally accepted principles serve as the basic framework for occupational medicine and public health professionals making determinations of both whether the total cumulative exposure was capable of causing mesothelioma, and whether some subset of the total exposure was a significant or appreciable exposure.

Significantly, *neither the Helsinki Criteria, nor any other credible medical or scientific authority, include the necessity of making a quantitative estimate of a patient's asbestos "dose."* Not only would such an estimate be impossible given the challenges with reconstructing specific exposures from indirect sources decades after they were experienced,[47] but it is also unnecessary given what is currently accepted by the medical/scientific community regarding asbestos and the biological

[46] *Id*.

[47] Goldstein and Henifin, *Reference Guide on Toxicology,* in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Federal Judicial Center, 3d Ed. 2011), at 640 ("usually difficult, if not impossible, to quantify the amount of past exposure").

mechanisms by which it causes disease. What *is* required for an expert to conclude that mesothelioma is asbestos related is evidence based on patient interview or direct testimony that the patient breathed levels of asbestos in an occupational, para-occupational, domestic, or similar setting with regularity.[48] Exposures occurring in *all* these settings, from *all* sources, must be viewed as causative of a patient's mesothelioma.

5. Asbestos Exposure Resulting from Cosmetic Talcum Powder is a Cause of Mesothelioma

The hazards of exposure to asbestos in consumer talc have been known for over fifty years. By the mid-1960s, miners of talc had been identified by occupational health researchers as having an increased risk for lung diseases.[49] Over the next ten years, interest in exploring whether impurities in talc placed users of consumer talcum powder products at risk of the same diseases led to robust research confirming the widespread presence of asbestos in talc. In 1968, Cralley, *et al.*, reported the "probable presence" of tremolite, anthophyllite, and chrysotile in 22 of 22 consumer talcum powder products tested.[50] Asbestos manufacturers testing consumer products at the time identified tremolite in some "body talcum powders."[51]

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[48] Tossavainen, *supra*, at 313; Wolff, *supra*, at 9.

[49] Kleinfeld, *et al.*, *Mortality Among Talc Miners and Millers in New York State*, 14 ARCHIVES OF ENVT'L. HEALTH 5, 663-667 (1967).

[50] Cralley, *supra*, at 352.

[51] Johns Manville Research and Engineering Center, "Body Talcum Powders – Petrographic Examination," Oct. 31, 1968.

In 1972, Snider, *et al.*, examined a range of 18 commercial talcum powders, used as baby powders, shave talcum powders, and spray talcum powders, and found chrysotile, tremolite, and/or anthophyllite in all.[52] By 1976, Rohl and Langer, detected tremolite and anthophyllite in 10 out of 20 products labeled talc or talcum powder, including body powder.[53] In 1991, Blount reported asbestiform tremolite in talc ore that was used to manufacture cosmetic talcum powder products.[54] Manufacturers continued to mass produce consumer talcum powder products in spite of these findings. In 2014, Gordon, *et al.* revisited the Rohl and Langer study by testing 50 containers of a cosmetic talcum powder product, produced over a 50-year timespan, that Rohl and Langer had tested four decades before.[55] Gordon, *et al.*, found anthophyllite and tremolite in all 50 containers.

Meanwhile, as prominent researchers were developing reliable data reflecting the extent of the asbestos contamination in cosmetic talc, medical doctors were documenting a growing incidence of asbestos-related diseases arising out of cosmetic talcum powder exposures. In 1970, Moskowitz published a case report of a 31-year-old woman suffering from pneumoconiosis who, as a quality control inspector for cosmetics manufacturer Revlon for 11 years, inspected talcum powder

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[52] Snider, Pfeiffer, and Mancuso, *Asbestiform Impurities in Commercial Talcum Powders*, 49 THE COMPASS OF SIGMA GAMMA EPSILON 65-67 (1972).

[53] Rohl (1974), *supra*; Rohl and Langer (1976), *supra*.

[54] Blount, *Amphibole content of cosmetic and pharmaceutical talcs*, 94 ENVIRON. HEALTH PERS. 225-230 (1991).

[55] Gordon, Fitzgerald, and Millette, *supra*.

products on a regular basis.[56] A lung biopsy confirmed asbestos bodies in the patient's lung tissue. In 1990, Andrion, *et al.*, described a case of a 17-year-old boy with malignant peritoneal mesothelioma who, from the age of 9 until the age of about 12, "used large quantities of cosmetic talc daily," and was found to have chrysotile and tremolite fibers in his lung tissue.[57] In 2002, Roggli found five mesotheliomas with anthophyllite and tremolite in lung tissue and deduced that they came from talc exposures.[58] In 2012, Finkelstein updated a cohort study of talc miners and millers from New York by incorporating data concerning additional cases of mesothelioma that had previously been unavailable.[59] Based on this information and applying assumptions that would lead to an underestimate of the risk of mesothelioma, Finkelstein found there were at least five new cases of mesothelioma in the cohort and mesothelioma incidence rates were five (1.6-11.7) times the rate in the general population. Given these results, Finkelstein concluded that dusts from New York State talc, which contained fibers of tremolite and anthophyllite, are capable of causing mesothelioma in exposed individuals.[60]

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[56] Moskowitz, *Talc Pneumoconiosis: A Treated Case*, 58 CHEST 1, 37-41 (1970).

[57] Andrion, *et al.*, *Malignant Peritoneal Mesothelioma in a 17-Year-Old-Boy with Evidence of Previous Exposure to Chrysotile and Tremolite Asbestos*, 25 HUMAN PATHOLOGY 6, 617-622 (1994).

[58] Roggli, *et al.*, *Tremolite and Mesothelioma*, 46 ANN. OCCUP. HYG. 5, 447-453 (2002).

[59] Finkelstein, *Malignant Mesothelioma Incidence Among Talc Miners and Millers in New York State*, 55 AM. J. OF INDUSTRIAL MED. 10, 863-868 (2012).

[60] *Id*.

Experts practicing generally-accepted scientific principles and methodologies have confirmed that exposure to the levels of asbestos found in cosmetic talcum powder products can cause mesothelioma through regular use. In 2007, Mattenklott found that low or trace levels of asbestos by weight in talcum powder (0.1%) released millions of asbestos fibers upon use.[61] In 2014, Gordon, *et al.*, evaluated the ability of the cosmetic talcum powder product in which it found anthophyllite and tremolite to release asbestos fibers into the breathing zone of the direct user and bystander.[62] Through a "shaker container test" and "puff application test," Gordon, *et al.*, measured asbestos exposure in conditions that are substantially similar to those in which cosmetic talcum powder is typically applied. The shaker container test showed a measurement for the user of 4.8 f/cc, with an actual asbestos fiber measurement of 1.9 f/cc. Bystander measurements showed a lower, but still significant exposure of 1.35 f/cc, and 0.5 f/cc of actual asbestos fibers. After using a puff applicator, the direct user's measurements were 23.6 f/cc and 16.5 f/cc, with actual asbestos fiber measurements of 5 f/cc and 3.5 f/cc.[63] These results reflect that a cosmetic talcum powder user regularly experiences a significant and substantial

[61] Mattenklott, *Asbestos in talc powders and soapstone – the present state*, Gefahrstoffe – Reinhart. Luft 67 (2007) no. 7/8 pp. 287-291 (by courtesy of Springer-VDI-Verlag, Dusseldorf).

[62] Gordon, Fitzgerald, and Millette, *supra*, at 323.

[63] *Id*.

exposure to asbestos that is well above background levels, and is sufficient to cause mesothelioma.[64]

In addition to looking at bulk and air samples, Gordon, *et al.*, analyzed the lung tissue and lymph node tissue of a woman who died of mesothelioma and whose only known source of asbestos exposure was cosmetic talcum powder.[65] The tissue digestion revealed the presence of anthophyllite and tremolite fibers – the same as those found in the talcum powder the subject used in conditions replicated through the study's application simulations.

Recent case studies of women who died of mesothelioma after exposure to consumer talcum powder products, *and no other identifiable sources*, strengthen the scientific foundation supporting the causal connection between asbestos-contaminated talc and mesothelioma. In 2019, Moline, *et al.*, described the exposures to cosmetic talcum powder leading to mesothelioma among 33 individuals referred for medico-legal evaluation.[66] Tissue digestion was done for six cases according to generally-accepted methodology. The same types of asbestos found in talcum powder were found in all six cases: there were two cases with anthophyllite fibers; one case had anthophyllite and tremolite fibers; one case had anthophyllite,

[64] OSHA's current permissible exposure limit for asbestos, which is based on a feasibility assessment designed for industrial occupations and does not represent a safe level for asbestos-induced cancer, is "0.1 fiber per cubic centimeter of air as an eight (8)-hour time-weighted average…" 29 CFR 1910.1001(c)(1).

[65] Gordon, Fitzgerald and Millette, *supra*, at 321-326.

[66] Moline, *supra*.

tremolite, and actinolite fibers; one case had chrysotile fibers; and one case had tremolite fibers. Cosmetic talcum powder usage was the only source of asbestos for all 33 cases.

In 2020, Emory, *et al.*, as a follow-up to Dr. Moline's study, described a case series of 75 malignant mesothelioma cases gathered from medico-legal consultations, whose only known exposure to asbestos was to cosmetic talcum powders.[67] Nine of the cases were examined for asbestiform fibers by analytic electron microscopy. All had anthophyllite. Of those, six also had tremolite fibers, and one additionally had amosite and chrysotile fibers.

6. Epidemiological Studies Specific to Talc and Mesothelioma Are Not Conclusive

It is suggested by some in litigation that an expert cannot offer a scientifically-reliable opinion that exposure to asbestos-contaminated talc was a cause of disease without the direct support of an epidemiological study of talc-exposed individuals. Defendants often point to certain epidemiological studies claiming that they show no correlation between talc and mesothelioma. In addition to ignoring many problems that compromise the results in these existing studies, these claims overstate the value of epidemiological studies in scientifically determining attribution, especially for a signature disease such as mesothelioma. Placing an inordinate

[67] Emory, Maddox, and Kradin, *supra*.

emphasis on "epidemiological studies" has been criticized by the esteemed expert Sir Bradford Hill who set out the criteria for determining causation.[68] In addition to epidemiological studies, Bradford Hill's guidelines incorporate the totality of the science on a given issue including cell biology, animal studies, and mechanistic studies. As Bradford Hill stated, "[n]one of [his] nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*."[69] Recently Kanarek and co-workers have suggested that cosmetic talc meets the Bradford Hill criteria for establishing causation of malignant mesothelioma.[70]

As discussed above, there is overwhelming consensus in the medical and scientific communities that exposure to all forms of asbestos fibers cause mesothelioma.[71] This consensus is firmly grounded in decades of peer-reviewed epidemiological studies.[72] Because mesothelioma is caused by asbestos fibers, not by job classification or product type, there is no rule in any relevant field of science that requires a product specific positive epidemiology study to attribute asbestos exposure to this disease. It is simply an irrefutable scientific fact that asbestos fibers,

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[68] Bradford Hill, *supra*.

[69] *Id*. at 299.

[70] Kanarek, *et al.*, *Asbestos in Talc and Mesothelioma: Review of the Causality Using Epidemiology*, 8 MEDICAL RESEARCH ARCH. 5, 1-13 (2020).

[71] IARC (2012), *supra*; JPC-SE (2012), *supra*; WHO (2006), *supra*.

[72] IARC (2012), *supra*.

even at low levels of exposure, can increase the risk of developing mesothelioma.[73] This is as true for asbestos in a cosmetic talcum powder product as it is for any other asbestos-containing product.

The claim that there are epidemiological studies that effectively disprove a causal link between cosmetic talc and mesothelioma is without merit. Four of the studies most commonly cited for this proposition are of Italian talc miners, which have significant shortcomings.[74] The size of the cohorts studied were too small to detect an increased risk of mesothelioma; the researchers did not follow-up the workers for a sufficient length of time (it takes on average more than 25 years for mesothelioma to develop following exposure to asbestos) and workers over the age of 85 were not included.[75] Three of these studies were conducted before the International Classification of Disease developed a code for mesothelioma in 1999 (Rubino 1921-1979, Pira and Coggiola 1946-1995), so there is a high probability that mesotheliomas were misclassified as other cancers including "lung cancer."[76] In the 1976 Rubino study, this problem was potentially exaggerated by the authors'

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[73] Wolff, *supra*; Hammar, *supra*; Pairon, *supra*.

[74] Rubino, *et al*., *Mortality study of talc miners and millers*, 18 J. OCCUP. MED. 3, 187-193 (1976); Rubino, *et al.*, *Mortality of chrysotile asbestos workers at the Balangero Mine, Northern Italy*, 36 BRIT. J. IND. MED. 3,187-94 (1979); Coggiola, *et al.*, *An Update of a mortality study of talc miners and millers in Italy*, 44 AM. J. IND. MED. 1, 63-69 (2003); Pira, *et al.*, *Mortality of talc miners and millers from Val Chisone, Northern Italy: an updated cohort study*, 59 J. OCCUP. ENVIRON. MED. 7, 659-664 (2017).

[75] Finkelstein, *Re: Mortality of Talc Miners and Millers from Val Chisone, Northern Italy*, 59 J. OCCUP. ENVIRON. MED. 10, e194 (2017).

[76] Kanarek, *et al.*, *supra*, at 4-5.

primary reliance on death certificates that often fail to provide a cause of death with accuracy.[77] The results of at least two of the studies (Rubino and Coggiola) are compromised because the studies were conducted and controlled by interested parties.[78] Notably, even though Rubino did not report mesotheliomas among Italian talc workers, he attributed fibers in the workers' air to talc ore containing a "little amount of tremolite."[79] After the Coggiola study was published, Mirabelli, a highly respected non-aligned scientist, identified a case of mesothelioma at the Italian talc mill that Coggiola had examined, but that had not been reported in the study.[80]

The Finley, *et al.*, study sometimes cited by defense experts is similarly problematic.[81] To reach the conclusion "that there is no epidemiological evidence to support the hypothesis that exposure to cosmetic talc is associated with the development of pleural mesothelioma," Finley, *et al.,* performed "a statistical power analysis" using national and regional mesothelioma rates as comparisons for cosmetic talc mining populations. As explained by Finkelstein, *et al*., the conceptual

[77] Rubino (1976), *supra*, at 187-188.

[78] *See e.g.* Johnson & Johnson ("J&J") Letters re: Epidemiological Study of Workers in Italian Talc Mines (Oct. 18 and 26, 1973) (J&J defined nature of Rubino study and covered cost).

[79] Rubino (1976), *supra*, at 193.

[80] Mirabelli, *Letter on "Cosmetic talc as a risk factor for pleural mesothelioma: a weight of the evidence evaluation of the epidemiology"*, 29 INHALATION TOXICOLOGY 8, 341 (2017).

[81] Finley, Benson, and Marsh, *Cosmetic talc as a risk factor for pleural mesothelioma: a weight of evidence evaluation of the epidemiology*, 29 INHALATION TOXICOLOGY 4, 179-185 (2017).

design of this study was deeply flawed.[82] The national and regional mesothelioma rates would be dominated by the mesothelioma risk of workers in industries such as manufacturing, ship yards, and construction. The levels of asbestos exposure that these workers experienced would have generally been significantly higher than those experienced by cosmetic talc mining populations and, therefore, did not provide an appropriate comparison.

Other studies referenced by scientists testifying for the defense of cosmetic talc manufacturers, when viewed in their entirety, actually support the mainstream opinion that there is a causal connection between asbestos-contaminated talc and disease. In the 1982 Gamble study,[83] scientists examined 299 miners and millers exposed to talc from Montana, Texas, and North Carolina in a cross-sectional study of respiratory symptoms, lung function, and chest x-rays and found a significantly increased prevalence of pleural thickening in the talc workers lungs—a characteristic objective sign of previous asbestos exposure. In 2019, Fordyce, *et al*., updated a cohort study of Vermont talc workers and, although they determined that there was no evidence of increased risk of respiratory cancer within this group, they

[82] Finkelstein, *Letter to the Editor Re: Brent L. Finley, Stacey M. Benson & Gary M. Marsh (2017): Cosmetic talc as a risk factor for pleural mesothelioma: a weight of evidence evaluation of the epidemiology*, 29 INHALATION TOXICOLOGY 9, 387-388 (2017).

[83] Gamble, Greife, and Hancock, *An Epidemiological-Industrial Hygiene Study of Talc Workers*, 26 ANN. OCCUP. HYG. 8, 841-859 (1982).

inexplicably failed to factor two acknowledged deaths from mesothelioma into their analysis.[84]

In addition to the various issues with epidemiological studies often relied on by defendants and their experts, the general overarching flaw in their litigation-oriented views is that a non-positive study – one that does not dispositively prove a statistically significant increased risk – is proof that there is no association between the exposure to asbestos-contaminated talc and mesothelioma. As noted, a product-specific positive epidemiology study is not required to determine a link between asbestos exposure and disease. Answering the question as to whether a substance can cause disease requires a consideration of all scientific disciplines and all available evidence. Epidemiologic evidence may, in some cases, be sufficient to determine causation but, in its absence, other scientific evidence may allow for the same conclusions. Based on the body of scientific evidence that currently exists, it is widely accepted that talc containing asbestos is a human carcinogen capable of causing mesothelioma.[85]

CONCLUSION

It is generally-accepted within the scientific community that asbestos is the primary cause of mesothelioma. There is abundant evidence that cosmetic talc

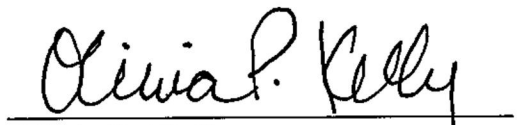
[84] Fordyce, *et al.*, *A 37-year Update on Mortality Patterns in an Expanded Cohort of Vermont Talc Miners and Millers*, 61 J. OCCUP. ENV. MED. 11, 916-923 (2019).

[85] IARC (2012), *supra*.

contains asbestos and there is a growing literature linking malignant mesothelioma to repeated exposures to cosmetic talc. It is also generally accepted that a threshold requirement of exposure to asbestos for the development of mesothelioma has not been established. For these reasons, any expert who, in accordance with generally-accepted methodology, attributes causation for an individual's mesothelioma to their use of asbestos-contaminated cosmetic talcum powder products is fully supported by generally-accepted scientific principles set out in an extensive body of scientific and medical literature.

Dated: September 15, 2021

Respectfully Submitted,



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NEW YORK COURT OF APPEALS CERTIFICATE OF COMPLIANCE WITH PRINTING SPECIFICATIONS

Olivia P. Kelly, an attorney duly admitted to practice law before the Court of the State of New York, affirms the truth of the following pursuant to CPLR 2106:

1. I am an associate of Simmons Hanly Conroy, LLC, attorney for Proposed Amicus Curiae for Dr. Richard L. Kradin and Other Concerned Physicians and Scientists.
2. This brief is in compliance with 22 N.Y.C.R.R. Part 500.1(j). It is 27 pages long and contains 6,996 words, counting all printed text on each page of the body of the brief. It was prepared using Microsoft Word. The typeface is Times New Roman, set in 14 point type, double spaced, throughout the body of the brief and in the headings. Footnotes are set in 12 point type, since spaced.

Dated: September 15, 2021

Olivia P. Kelly

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AFFIDAVIT OF SERVICE

STATE OF NEW YORK)
)
COUNTY OF WESTCHESTER)

Ivan Diaz, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age, and resides at 2160 Holland Avenue, Bronx, New York 10462.

That on the 16th day of September, 2021, deponent served the within:

BRIEF ON BEHALF OF CONCERNED PHYSICIANS AND SCIENTISTS REGARDING CAUSATION OF ASBESTOS-RELATED DISEASE FROM EXPOSURE TO ASBESTOS-CONTAMINATED COSMETIC TALCUM POWDER, AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-RESPONDENT

upon designated parties indicated herein at the addresses provided below by means of Federal Express Standard Overnight Delivery of 2 true copies of the same at the addresses of said attorney/parties with the names of each represented party:

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Sworn to before me this
16th day of September, 2021

Notary Public

Ivan Diaz

ERIC R. LARKE
Notary Public, State of New York
No. 01LA5067236
Qualified in Westchester County
Commission Expires March 5, 2023

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