Plaintiffs' Attack on Cosmetic Talc Epidemiology

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Epidemiology is the branch of medical science that examines the incidence and prevalence of disease among certain populations to determine the source and cause of diseases or lack thereof. Epidemiology is the gold standard for assessing disease causation. Employing epidemiologic studies, scientists established over 50 years ago that exposure to asbestos increases the risk of developing of mesothelioma among occupationally exposed males. Such studies firmly establish a causal connection between cohorts of people occupationally exposed to asbestos and mesothelioma. Unlike the link between occupational levels of exposure to asbestos and mesothelioma, there are no epidemiological studies demonstrating such an increased risk of mesothelioma even among cohorts of people with the highest levels of exposure to cosmetic talc. *See* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 93 at 318-333.

The goal of this paper and corresponding presentation is to help provide an understanding of the epidemiological studies conducted to investigate the potential association between exposure to cosmetic-grade talc and mesothelioma, plaintiffs' key points of attack on the design and results of such studies and their reliance on case reports purporting to support this association.

I. COSMETIC TALC EPIDEMIOLOGY

Cohort studies of talc miners and millers have investigated cancer risks in populations exposed to cosmetic talc. These studies do not show any association, i.e., there is zero epidemiological proof that exposure to cosmetic talc causes mesothelioma. As a result, plaintiffs' response is to launch a series of attacks on these epidemiology studies and counter with case reports largely written by plaintiffs' experts.

A. Can Exposure to Cosmetic Talcum Powder Cause Disease?

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Epidemiology Study	Exposure Assessment Details	Type of disease	Number of cases / deaths	Other Details
Rubino et al. (1976) – Italy	Occupational history and estimation of cumulative exposure	Respiratory cancers / All cancers	Miners 9 Millers 8 (100, 42)	No observed cases of mesothelioma
Rubino et al. (1979) - Italy	Mortality follow-up, 1946-1974	Lung	Miners 8 Millers 4	No observed cases of mesothelioma
Selevan et al (1979) - Vermont	Total exposure not calculated - limited historical information	Respiratory cancers	Miners 5 Millers 2	No cases of mesothelioma reported Limited smoking
Wergeland et al (1990) - Norway	Exposure subjective	All cancer	Miners 9 Millers 17 Follow-up: Miners 2	No observed cases of mesothelioma

			Millers 4	
Wild et al (2000) - France	Exposure (binned) subjective	Lung Cancer	Unexposed 6 Exposed < 100 5 100-400 6 400-800 3 > 800 3	No cases of mesothelioma reported
Wild et al. (2002) - France, Austria	Exposure (binned) Nested case-control exposure estimates from company records	Lung Cancer	French 21 Austrian 7	No cases of mesothelioma reported Limited smoking info
Coggiola et al. (2003) - Italy	Job histories from plant records (1244 miners, 551 millers)	Lung cancer	Total 44 Miners 33 Millers 11	No cases of mesothelioma identified
Finley (2017)	Data pooled via systematic review		99,022 person-years of observation	No cases of mesothelioma identified
Pira (2017) - Italy	Death certificates and ICD-10 codes	Lung cancer Pleural cancer Non-neoplastic respiratory disease		Talc noted as free of asbestos / No cases of mesothelioma identified
Wergeland et al. (2017) - Norway	94 miners, 296 millers	Malignant neoplasms	Total 71 Miners 17 Millers 54	No cases of mesothelioma or cancer of the pleura or peritoneum recorded
Fordyce et al. (2019) - Vermont	Death certificates and ICD-10 codes	Malignant neoplasms Mesothelioma, lung cancer		1 mesothelioma death (Death certificate indicated asbestos exposure)
Marsh et al. (2019)	Meta-analysis - Data pooled total of 113,344 person-years			No reported mesothelioma or pleural cancer cases
Marsh and Ierardi (2020)	Updated – pooled total of 130,514 person-years			1 mesothelioma death (Fordyce 2019 – death certificate indicated asbestos exposure)

B. Key Points of Attack

1. Plaintiffs argue that there are no epidemiology studies of end users of cosmetic talcum powder to attack the fact that there is zero epidemiological proof that exposure to cosmetic talc causes mesothelioma.

   Rebuttal: Occupational exposures and epidemiology are often studied because people who work with a given substance are the most exposed to it. In other words, even if there was a study of consumer end users, their exposure to cosmetic talc would still be significantly less than the talc miners and millers studies where there was virtually not a single mesothelioma.

2. Criticisms from experts that are not epidemiologists – plaintiffs' experts argue that the Italian miners and millers studies (Rubino 1976 and 1979, Coggiola, and Pira) are underpowered and insufficient to prove that talc does not cause mesothelioma [Egilman, Smith, Madigan].
   Rebuttal: Criticizing the power is problematic for the following reasons:

   a. Calculation of statistical power can be useful when planning a study, for the purpose of determining whether the hypothetical study will be large enough to find a statistically significant result under certain theoretical scenarios. However, once a study has been conducted, statistical power is no longer a meaningful concept. Instead, one should evaluate the actual results to determine what magnitude of association is consistent with the real, observed findings. *See* Cox 1958, Smith and Bates 1992, Hoenig and Heisey 2001, Levine and Ensom 2001, Senn 2002, Greenland et al. 2016.

   b. With regard to human studies, there is a hierarchy of evidence to consider. Meta-analysis (an analysis grouping multiple underlying studies) is the strongest type of evidence followed by randomized controlled trials, then observational studies (case control and cohort), followed by case reports, case series and descriptive studies. *See* Fed. Judicial Ctr., Reference Manual on Scientific Evidence (3rd ed. 2011) at 723-24. Marsh and colleagues performed a systematic review and meta-analysis for the Rubino cohort and three others, i.e., a pooled statistical power analysis of mesothelioma incidence in the Italian, Norwegian, Austrian, and French cosmetic talc miner and miller cohorts. There was a pooled total of 113,344 person-years in the cohorts. *See* Marsh et al (2019). Occupational exposure to cosmetic talc and risk of mesothelioma: an updated pooled cohort and

statistical power analysis with consideration of latency period. *Inhalation toxicology*, 31 (6), 213-223.

c. If plaintiffs' theory held true, and the cosmetic talc mines were contaminated with asbestos and consumer use of cosmetic talcum powder causes mesothelioma, people would be getting sick in troves.

3. Plaintiffs also argue selection bias, specifically that the loss to follow-up ratio is huge in these studies ("healthy worker effect").

Rebuttal: It occasionally happens but irrespective, if the cosmetic talc mines were contaminated with asbestos all of this is totally academic because there would be a higher incidence of mesothelioma.

4. Plaintiffs generally undervalue these studies from a methodological point of view arguing that they provide no meaningful scientific evidence with regards to mesothelioma.

a. Exposure histories are reconstructed from indirect sources such as job categories and years of working in a certain setting. Industry records are not adequate for exposure estimates.

b. Epidemiology is an observational science and therefore susceptible to bias (i.e., not reflective of the true population).

Rebuttal: Epidemiological studies are essential to establish causal links between exposures and human chronic disease. Cohort mortality studies in particular can be critical for identifying causal effects of occupational exposure. Where randomly assigning exposures in interventional studies is not feasible (as in the case of most environmental and occupational exposures) only observational epidemiological studies can determine whether disease risk differs between comparable groups with unequal levels of exposures (i.e. whether an exposure is associated with a given health outcome).

II. COSMETIC TALC CASE STUDIES

The cosmetic talc epidemiology is largely problematic for the plaintiffs. In addition to launching a series of attacks on the cohort studies of talc miners and millers, plaintiffs also rely on three recent case reports written by plaintiff experts to counter the epidemiology and support their purported link between consumer use of cosmetic talcum powder and mesothelioma.

A. Can Case Studies Establish Causation?

1. Plaintiffs argue that reports of multiple cases of mesothelioma among women whose only known exposure to asbestos was from their use of talcum powder can demonstrate a causal link between cosmetic talc and mesothelioma.

    a. Gordon, R., et al. Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women, Int'l J. of Occup. and Environ. Health, Vol. 20, No. 4 (2014).

    b. Moline, J., Mesothelioma Associated with the Use of Cosmetic Talc, J. of Occup. and Environ. Med., Vol. 62, No. 1 (Jan. 2020).

    c. Emory, Y., et al., Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients, Am. J. of Indust. Med., Vol. 63, No. 6 (Mar. 16, 2020).

2. The Bradford Hill criteria is widely accepted for assessing causality in epidemiological studies. The criteria for establishing a causal inference include consistency, strength of association, specificity, dose-response relationship, temporality, biologic plausibility, coherence of the association, and experimentation. Available evidence can be assessed and graded according to its sufficiency (or lack thereof) to establish a causal link.

    Rebuttal: Case reports do not compare a study population to a control group to determine whether the difference in incidence of mesothelioma is statistically significant. Moreover, case studies of reporting mesothelioma in women who used talcum powders for decades fail to establish a causal link because such case reports fail to compare disease incidence to a control group. Further, the case studies on which their opinions are based hinge on the premise that the subjects' *only* potential exposure was through the use of cosmetic talcum power products. Finally, each of the case reports involves a litigation referral (selection bias).

CONCLUSION

Cohort studies of talc miners and millers have investigated cancer risks in populations exposed to cosmetic talc. Simply put, the data does not support a causal relationship between cosmetic talc and mesothelioma. These studies represent distinct populations of men, spanning five countries, and over a wide range of years (1940 to 2013), yet have a common occupational exposure agent and consistently report no increased risk of mesothelioma. Despite plaintiffs' attacks on cosmetic talc epidemiology, the fact that there is no increase in mesothelioma incidence among talc miners and millers supports the conclusion that cosmetic talc is not related to the development of mesothelioma.