



Talc, Asbestos, and Epidemiology: Corporate Influence and Scientific Incognizance

Triet H. Tran,^a Joan E. Steffen,^a Kate M. Clancy,^{a,b} Tess Bird,^{a,c} and David S. Egilman^{a,d}

In the early 1970s, findings of asbestos in talc, and findings of talc collocated in ovarian tumor tissue, led to public controversy.¹⁻⁵ For over 40 years, talc mining and manufacturing companies attempted to obfuscate the importance of these findings by keeping exposure information behind a corporate veil and otherwise influencing medical information concerning the health effects and asbestos content of talc used in cosmetics.⁶⁻⁹ Control over information is a recognized method by which industries maintain sales and avoid regulation and tort liability.¹⁰⁻¹⁶ There are many examples when companies have concealed the presence of hazardous components in products; failed to publish study results indicating that their products presented health risks; and manipulated studies to publish false results that encouraged product use or hid side effects.¹⁰⁻¹⁶ For example, in 1971, Henderson et al. found talc in an ovarian cancer tissue sample and raised concerns about the relation between talc use and ovarian cancer.¹⁷ Johnson & Johnson hired Arthur Langer, a mineralogist at Mount Sinai, to reexamine the tissue.^{9,17} Langer confirmed the presence of talc, and also found asbestos in ovarian cancer tissue. Evidence shows that Johnson & Johnson successfully dissuaded him from publishing these findings.⁹

Furthermore, the talc mining and manufacturing companies used their industry trade organization, the Cosmetic, Toiletry, and Fragrance Association, to influence national and international public health agencies to avoid regulation and defend themselves in toxic tort litigation.^{6-9,18,19} For example, in 1976, this association developed a specification for a new “product” and named it “cosmetic talc.”²⁰ Through this specification, the association aimed to create a distinction between “cosmetic talc” and “industrial talc.” However, these two supposedly different talcs come from the same ores, in which asbestos was an accessory mineral, and the industries knew that the accessory asbestos could not be removed from the final product.^{1,2,21-23} The associations’ specification relied on an ineffective test method (J4-1) to test for the presence of asbestos.²⁴ The J4-1 method had an insensitive level of detection above 0.5% for tremolite asbestos and did not test for either chrysotile asbestos or fibrous talc,²⁴ despite company knowledge that these accessory minerals were present and had adverse health effects.^{25,26} Nonetheless, the association rushed to adopt the J4-1 as a voluntary standard to avoid the FDA’s ratification of more effective methods. The J4-1’s X-ray diffraction (XRD) is much less sensitive than transmission electron microscopy (TEM), which the talc mining and manufacturing companies described as “ultra-sensitive.”²⁷ Moreover, the association’s consultants determined pre-concentration before testing was “essential” for finding a “needle [asbestos] in a haystack [talc].”^{25,27,28} However, the J4-1 method did not specify the required preconcentration and confidential corporate documents released in the course of litigation indicate that, even using the J4-1 methodology,

From the ^aNever Again Consulting, Attleboro, MA; ^bCollege of Engineering and Mines, University of Alaska - Fairbanks, Fairbanks, AK; ^cWesleyan University, Mellon Postdoctoral Fellow, Middletown, CT; and ^dWarren Alpert Medical School, Department of Family Medicine, Brown University, Providence, RI.

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Publication of this commentary will advance D.S.E.’s credibility as an expert in this topic area and the commentary may be used in litigation, including advancing the arguments made in the commentary and as evidence of D.S.E.’s credibility. While they are not witnesses, this applies to the other authors as well.

Correspondence: Triet H. Tran, Never Again Consulting, 8 North Main St, Attleboro, MA 02703. E-mail: tranhaotriet@gmail.com.

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“cosmetic” talc powder formulations still contained considerable and detectable amounts of asbestos,²⁹ an unavoidable consequence of mine geology.

From 1965 to 2003, Johnson & Johnson “cosmetic talc” came from a Vermont mine that contained 10%–20% fibrous talc and accessory tremolite-actinolite.²³ The United States Occupational Safety and Health Administration has regulated fibrous talc as asbestos since 1972,²⁶ and the International Agency for Research on Cancer (IARC) classifies fibrous talc as a carcinogen.^{23,30–33} Avon (a direct selling company in cosmetic category) found as high as 25% tremolite in its talc products.³⁴ In 1976, the Cosmetic, Toiletry, and Fragrance Association misrepresented these concentrations to the United States Food and Drug Administration: “the summary will give you assurance as to the freedom from contamination by asbestos form materials of cosmetic talc products.”³⁵ Steffen et al. reported that 686 of 1032 tests produced in litigation revealed the presence of asbestos in talcs used in cosmetics from 1948 to 2017.^{29,36} We know of no evidence that the talc mining and manufacturing companies tested products or mined talc for fibrous talc after 1970.

At least 32 epidemiologic studies have examined the relation between talcum powder usage and ovarian cancer.^{20,37–67} Twelve out of the 32 epidemiologic studies of talc and ovarian cancer incorporated the Cosmetic, Toiletry, and Fragrance Association’s claim that “cosmetic” talc has been free of asbestos since 1976.^{38–40,43,45,47,48,56,57,59,61,64} The association between asbestos inhalation and ovarian cancer was noted in 1949, again in 1960,^{68,69} and again in 1982.^{70,71} However, possibly as a result of the Cosmetic, Toiletry, and Fragrance Association’s claims, these researchers did not consider the role of asbestos exposures during talc use. Some authors, who recognized inhaled asbestos as an established ovarian carcinogen, rejected the causal association between talc powder use and ovarian cancer because of the lack of data on mechanism for so-called “asbestos-free” talc.^{43,56,57,64} Only Rosenblatt et al. considered confounding by occupational or other asbestos exposure.⁶⁶

Deaths in infants from asphyxiation of talc during diapering and cases of consumer talcosis in adults both suggest high inhalation exposures from talc uses other than perineal application.^{70–73} Only 2 out of 32 epidemiologic studies of the association between perineal talc exposure and ovarian cancer considered the potential for exposure by nonperineal routes.^{51,66} The other published studies failed to include even obvious baby talcum powder uses, including diapering, which results in inhalation exposure and may also contribute to transvaginal talc dose in female infants.⁷⁴ Had epidemiologists had access to company information regarding actual asbestos levels in cosmetic talc and airborne exposure measurements, their studies may have been designed to account for these other exposure routes. For instance, had they known that Johnson & Johnson noted that 100 million “baby bottoms” had been dusted with talc from 1930 to 1991, they likely would have considered inhalation talc and asbestos exposures to both parents and babies as routes of exposure.⁶ In addition, the epidemiologists did not indicate any awareness of the fibrous talc content of “cosmetic talc.” These unrecorded exposures resulted in misclassification and poor sensitivity (among those truly exposed, the proportion correctly classified as exposed is low), potentially contributing to the lack of dose-response relation observed in some studies, and likely driving the rate and odds ratios toward the null. The published literature underestimates exposures by routes other than perineal use partly because the researchers relied on talc mining and manufacturing company’s false representation that talc was asbestos-free after 1976.^{43,64}

As importantly, the studies did not always adequately characterize the perineal talc exposures. Three of the investigations were

planned as prospective cohort studies and talc exposure was only evaluated once; thus, the studies did not prospectively evaluate talc exposure over time.^{56,59,67} Also, given that the induction period and latency for ovarian cancer is between 25 and 40 years,⁶⁷ none of the study cohorts had sufficient follow-up time.^{56,59,64,67} Gertig et al. (Nurses’ Health Study) stated that, “Our relatively short follow-up period may be inadequate to detect an association if the latency for development of ovarian cancer is more than 15 years.”⁵⁶ Ten years later, Gates et al. updated the Nurses’ Health Study talc use results, comparing rates of ovarian cancer between two groups of talc users (>1 week to <1 week) and found a near null rate ratio of 1.06 (95% CI = 0.89, 1.28).⁶⁴ The “Sister Study” follow-up had a median induction period and latency of 6.6 years.⁶⁷ Further, a number of studies (including all three “prospective” cohort studies) conflated cornstarch and talc cosmetic powders, leading to additional exposure misclassification.^{56,59,64,67} Customer product false recognition and recall may have led to additional misclassification. For example, there are two different types of Johnson & Johnson powder products (talcum and cornstarch) and Johnson & Johnson has had the highest share of the total baby powder market.⁷⁵ Customers are not likely to identify Johnson & Johnson talc baby powder since the bottle only lists talc as an ingredient in 6-point type on the back.⁷⁶

Talc epidemiologists may therefore have overlooked vital exposure and induction period information. Nonetheless, 18 of the 32 studies reported an importantly elevated risk of ovarian cancer among talc users, compared with nonusers, prompting public health concerns and regulatory reviews of talc carcinogenicity. The Cosmetic, Toiletry, and Fragrance Association crafted and promoted an argument that would create doubt about the causal association of “cosmetic” talc and ovarian cancer to block the US National Toxicology Program and IARC from classifying their product as a carcinogen.⁷⁷ They dubbed this the “fatal flaw” defense.⁷⁸ The Association deemed the epidemiologic studies that found an elevated risk as “fatally flawed” because talc users in the studies were exposed to asbestos from talc products sold before 1976, which they argued caused an asbestos-related but not talc-related cancer excess.

In 2000, “cosmetic” talc labeled as “not containing asbestos” was nominated to be included in the United States National Toxicology Program Report on Carcinogens. Two program scientific panels reviewed research on talc carcinogenicity and voted to list talc as a carcinogen.^{79,80} The Cosmetic, Toiletry, and Fragrance Association argued against the listing of talc in the report, asserting that the talc epidemiologic studies revealed increased rates of ovarian cancer due to the inclusion of patients who used asbestos-contaminated talcs manufactured before 1976.^{77,78,81,82} The Association argued that these results could not be applied to their “asbestos-free” talc, that the talc/ovarian cancer association was not causal because the summary risk ratio was below 2, and because many of the study results were not statistically significant.⁸² An alliance of chemical and tobacco companies successfully promoted these concepts under a campaign called “Sound Science” and “Good Epidemiologic Practices.”⁷¹⁴ Epidemiologists and some courts have mistakenly adopted this tobacco pseudoscience.^{83,84} Greenland and others have repeatedly critiqued both of these arguments.^{84–88}

Despite the Cosmetic, Toiletry, and Fragrance Association’s attempts to downplay the elevated risks of ovarian cancer associated with perineal talcum powder use reported in epidemiologic studies, both of the National Toxicology Program scientific panels voted to list talc “not containing asbestos” as a carcinogen.⁸⁹ The Cosmetic, Toiletry, and Fragrance Association then threatened the United States National Institutes of Health and National Toxicology Program Report on Carcinogens budgets,⁹⁰ and the National Toxicology Program



management overruled the science panels.^{91,92} Talc was the only one of the 21 substances nominated for the Report on Carcinogens that the National Toxicology Program withdrew.^{93,94}

The talc mining and manufacturing companies privately took credit for the National Toxicology Program decision and acknowledged that the epidemiologists had misinterpreted the studies:

“We [the talc industry] dodged a bullet in December based entirely on the confusion over the definition issue... Essentially, if the report were to be rewritten to state that the possibility of asbestos contamination of cosmetic talc prior to 1976 should simply be accounted for as an additional “confounding” factor in the epidemiology studies, a re-vote for “talc not containing asbestos fibers” would likely go the other way. ... **Time to come up with more confusion!**” [Emphasis added].⁹⁵

The Association also used the “fatal flaw” and asbestos-free arguments with the International Agency for Cancer Research when the agency reviewed talc carcinogenicity.⁹⁶ An epidemiologist who had reviewed the relation between talc and ovarian cancer for the Association co-chaired the 2009 IARC 100 meeting section pertaining to talc.^{32,97} An academic consultant to the RT Vanderbilt talc mining company was a member of the IARC 93 working group on talc over the same period (2006–2010) that she testified in talc litigation.^{98,99} Neither disclosed these conflicts.^{98,99} IARC 93 accepted the Association’s misrepresentation on the asbestos content of talc, stating that “After 1976, these powders probably did not contain anthophyllite, chrysotile or tremolite.”³² IARC 100 listed talc as a probable ovarian carcinogen.³²

Talc is one of the many examples of corporate influence on research and regulation. Tobacco and chemical companies also influenced epidemiologic methods for the determination of cause–effect relationships.^{11,14–16,100–103} There are several lessons to be learned for epidemiologists studying environmental, occupational, and consumer product hazards:

1. Epidemiologists must work with toxicologists, industrial hygienists, and other professionals. In this case, occupational health physicians and industrial hygienists could have contributed to dose estimates and elucidated possible confounding asbestos exposures. Materials scientists could have tested the talcum powder for the presence of asbestos and other carcinogenic accessory minerals, like arsenic, that are permitted to be present in “cosmetic talc”. Hygienists could have discovered that at least four of the chemicals used in Johnson & Johnson perfumes are animal carcinogens.^{104,105}
2. It is important to question and verify assumptions and information provided by industries with material interests in research findings. Regulatory capture and the problem of “revolving door” regulators can sometimes undermine the effectiveness of government oversight.^{106–109} In this case, Dr. Eiermann, the head of the United States Food and Drug Administration’s regulation of cosmetics in the 1970s, worked for Johnson & Johnson in Brazil after WWII. His successor, John Bailey, led the cosmetics division in the 1990s, then in January 2002 became the Director of Cosmetic Chemistry for the Cosmetic, Toiletry, and Fragrance Association. While leading the cosmetics division, Bailey denied the first citizen’s petition to require the United States Food and Drug Administration to label talc a carcinogen in 1995 and after leaving the administration, he lobbied in 2009 on behalf of the Cosmetic, Toiletry, and Fragrance Association against granting a second citizen’s petition on talc warnings.¹¹⁰ In 2014, the Administration denied 1994 and 2008 citizen’s petitions on talc based on the Cosmetic, Toiletry, and

Fragrance Association claim that “cosmetic” talc was asbestos free.¹¹¹

3. Researchers must be wary of scientific information gaps due to company ownership of knowledge and recognize litigation as a possible source of previously hidden scientific knowledge. Many of the documents we cite are publicly available as exhibits in court cases. There are several archives of documents and depositions produced in litigation that include important public health information, including unpublished studies.^{112–114} Over 900 medical publications have cited documents from the tobacco archives. Unfortunately, plaintiff lawyers and courts regularly permit companies to seal important public health information without forcing them to assert any claim of confidentiality. Few, if any, of these documents are trade secrets. Independent researchers can ask courts to unseal this information.
4. The Cosmetic, Toiletry, and Fragrance Association assured the National Toxicology Program that fear of litigation ensured compliance with the J4-1 method.⁸² While litigation can be a powerful agent for public health, it is reactive, so can only affect change after injuries occur. Juries who see the evidence can make appropriate scientific inferences about causation and the need for warnings or withdrawal of a product with no discernible health benefits.¹¹⁵

In 1974, Johnson & Johnson told the FDA that, “...if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.”⁷⁷ In 1994, when it became aware of the question of ovarian cancer, Carter Wallace followed this community standard and stopped using talc on its condoms.¹¹⁶ Talc safety has certainly been questioned; we agree with Johnson & Johnson: it should not be sold.

ABOUT THE AUTHORS

TRIET TRAN received his Bachelor of Science in Statistics and Quantitative Econometrics at Brown University. DAVID EGILMAN is a clinical professor of Family Medicine at the Alpert School of Medicine at Brown University. He does research on warnings and risk communication and corporate corruption of science. He is president of Global Health through Education Training and Service (GHETS.ORG), which funds the development of community oriented primary care curriculum in developing countries through South-South exchanges. TESS BIRD was trained in medical anthropology at the University of Oxford, and writing at the University of Connecticut. She is currently a Mellon Postdoctoral Fellow in Writing for the Social Sciences at Wesleyan University. JOAN STEFFEN is a student at Harvard Law School. She received her Bachelor of Arts in medical anthropology and women, gender, and sexuality studies at Washington University in St. Louis. KATE CLANCY is a senior at the University of Alaska Fairbanks studying Geological Engineering.

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