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RESEARCH ARTICLE

The Definition of Asbestos - A Manufactured Defense to Avoid Regulation and Victim Compensation

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* tranhaotriet@gmail.com ABSTRACT

Background: The Occupational Safety and Health Administration (OSHA) first identified asbestos as a regulated workplace hazard in 1971. In the half century since, OSHA has fully rescinded only one of its hundreds of regulations, one that happened to regulate a form of asbestos found as an accessory mineral in cosmetic talc. This extremely rare action grew out of a 20-year campaign by Talc Mining and Manufacturing Companies (TM&MCs) to redefine some of the asbestos routinely found in talc as “non-asbestos” to keep talc out of the regulation. Under this new definition, at least 50% of the products sold as asbestos became “non-asbestos.”

Methods: We used systematic search techniques and grounded theory to review published studies, government records, corporate documents and public statements.

Results: Current asbestos regulations and test methods rely heavily on asbestos geologic definition which determine the majority of asbestos fibers as “non-asbestos.” In essence, this geologic definition defined some asbestos out of existence. However, asbestos regulations should be driven by the health effects of asbestos.

Conclusions: TM&MCs funded experts and lobbied OSHA to promote an overly restrictive definition of asbestos and to support inadequate test methods in place of more effective procedures. These companies subsequently relied on these same restrictive definitions and inadequate tests to falsely claim that their cosmetic talcs are free of asbestos. Replacing the restrictive geologic definition of asbestos with a health definition is needed to protect the public from the well-known dangers of asbestos.

Keywords: regulation; asbestos; asbestiform; non-asbestiform; talc; cancer

Background

In May 1990, the Occupational Safety and Health Administration (OSHA) held five days of hearings regarding a request by RT Vanderbilt (RTV), a talc mining company, to reconsider regulation of “non-asbestiform” asbestos. William L. Kitchen, the only worker to testify at the hearings, posed the key regulatory question: “Should we ...be listening to the mineralogists or be listening to the medical experts, particularly when a number of the mineralogists have very strong financial ties to the companies that are going to be regulated under these standards.” His question aptly reflected two sides of the debate around asbestos: one that protected the health of workers by recognizing the health hazards of all forms of asbestos, or one that served the financial interests of the Talc Mining and Manufacturing Companies (TM&MCs). For over 100 years, asbestos and talc companies have relied on manipulating the definition of asbestos in order to prevent regulation and avoid compensation of people who have developed asbestos caused disease.^{1,2}

In 1971, OSHA issued a regulation that defined asbestos as chrysotile and amphibole fibers longer than 5 μ m.³ Talc products contained hazardous materials that this OSHA regulation would classify as asbestos. We describe the TM&MCs 20-year lobbying effort to limit the definition of asbestos so as to maintain the appearance of safety in their products. The companies convinced OSHA to limit the definition of asbestos to chrysotile and amphibole fibers that had “grown” as fibers (asbestiform habit).⁴ As a result, in 1992, OSHA rescinded the regulation of “non-asbestiform” fibers (cleaved from larger rocks with the same size and shape of asbestiform fibers), the first and only OSHA regulation that has ever been withdrawn. This change made “non-asbestiform” fibers disappear from OSHA regulations, although

there is no medical evidence that such “non-asbestiform” fibers are non-hazardous to exposed workers and consumers.⁵

For many companies, creating a lenient, easily-met standard, whether it protects public health or not, is far cheaper than developing safer products or providing adequate safety recommendations which may reduce sales.⁶ TM&MCs have successfully blocked regulation of asbestos-containing talc by controlling the definitions for asbestos and lobbying agencies to rescind regulation of their products.⁷ The companies relied primarily on consultant geologists rather than medical experts to assert the claim that “non-asbestiform” fibers did not cause cancer.⁸ However, workers had been exposed to both asbestiform and “non-asbestiform” asbestos, which were present in every bag of asbestos. In addition, neither epidemiologic nor pathologic studies could distinguish the health effects of either form of asbestos.⁵

Asbestos is a commercial term used to describe certain amphiboles and one serpentine rock.³ Bags of asbestos contain fibers that form as fibers (asbestiform) or cleave into fibers (non-asbestiform).⁹ (See Figure 1) 100% of the minerals (including both forms) in these bags were and are sold as asbestos.^{10,11} Single fibers fitting either definition can and often do have the same length and length/width (aspect) ratio (See Figure 1).⁹ In fact, although RTV’s redefinition effort was driven by its desire to rescind regulation of its talc by claiming it only contained “non-asbestiform” tremolite, its main witness Ann Wylie had found asbestiform fibers in RTV talc years before the OSHA hearing. The whole re-definition effort was a cynical effort to protect talc companies from the scrutiny and liability that attached to sales of a product that contained fibers that caused cancer.¹²

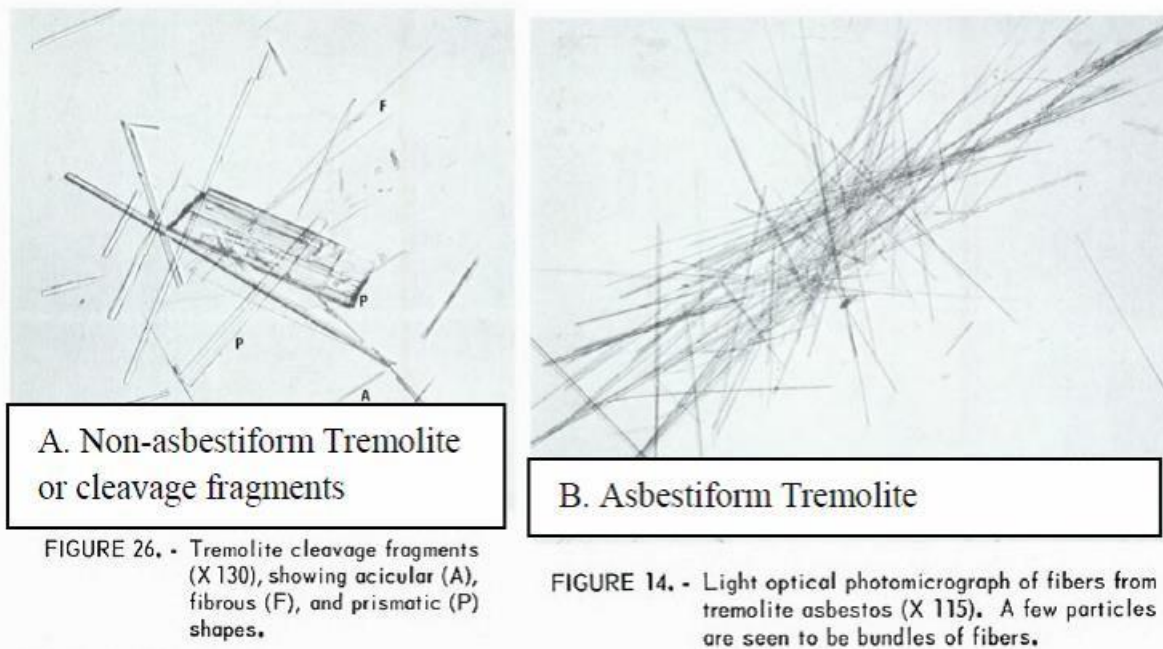


FIGURE 26. - Tremolite cleavage fragments (X 130), showing acicular (A), fibrous (F), and prismatic (P) shapes.

FIGURE 14. - Light optical photomicrograph of fibers from tremolite asbestos (X 115). A few particles are seen to be bundles of fibers.

Figure 1: Non-asbestiform Fig. 26 & B Asbestiform Asbestos Fig. 14 from Campbell et al. (1977)

Methods

The authors described and analyzed the various changes of the definition of asbestos in the past 100 years. The study design employs a “Grounded Theory” approach, or an “inductive methodology,” which is a systematic generation of knowledge from systematic research. This synthesis of historical and scientific evidence typically consists of comparing public vs. corporate knowledge over time.

We reviewed primary source material consisting of corporate documents uncovered in litigation and government documents released through FOIA requests. Talc-related documents were deposited in a searchable database that was accessible to researchers during Gail Ingham, et al. v. Johnson & Johnson, et al., a personal injury/product liability lawsuit in District Court in St. Louis, Missouri (2018) regarding the use of commercial talcum powder. This document database included records produced by the numerous TM&MCs.

The authors also reviewed depositions of individuals connected to talc litigation. These findings are combined with a review of the published literature. We provide a narrative review of meetings, events, newspaper reports, tests and research conducted, and FDA and industry decisions. The review is organized

chronologically, with some exceptions to facilitate reader understanding of the issues uncovered.

In recent litigation, the CTFA, J&J, and Luzenac have claimed that many of the documents we cite were “confidential trade secrets.” Our review of documents is limited to the documents made available to us, as well as those released to the public domain.

Ethical Issues/Statement

Ethics approval and informed consent were not necessary as this is a review of historical documents. All cited documents were released from confidentiality by various courts.

Aim and Scope

Our paper adds a critical health perspective to the discussion of risks of the accessory mineral asbestos found in talc. The current asbestos/talc policy issue is mired in erroneous assumptions and technical limitations related to the definition of asbestos. By narrating the history of asbestos definition with regards to talc, we aimed to clarify the assessment of risks associated with asbestos as found in talc. In addition, we discuss how the asbestos definitions have impacted on the regulation of asbestos content of construction materials and everyday consumer products. A

correct definition should be based on health and epidemiology data instead of arbitrary geologic terms is needed to protect the public from the well-known health risks of asbestos exposure. Our study aims to 1) Provide policy-makers a more balanced understanding of the toxicity of different types of asbestos fibers than the information provided by the asbestos industry (which government agencies have historically relied on) and 2) Provided policy-makers a better understanding of the difference between the geologic and the health definitions of asbestos. Geologic definitions of asbestos are arbitrary while health definitions are driven by epidemiology. Policies should focus on the health definition of asbestos to best protect the well-being of the public.

Results

The original definition – includes all asbestos fiber forms

Asbestos disease became a major public health problem for industry in the 1930's when workers began to successfully sue for compensation.^{13,14} In 1938, companies that manufactured asbestos brakes funded animal studies at Saranac Laboratory in New York. The studies determined that asbestos fibers, rather than non-fibrous round particles with the same chemistry, caused lung fibrosis.¹⁵ Unfortunately, the exposure measurement technology used until the mid-1960s could only count the total number of particles, both fibers and non-fibrous in air samples.¹ Thus, epidemiological studies of workers exposed prior to the 1970s relied on total particle counts (millions of particles per cubic foot MPPCF) to assess exposures.¹ In 1974, Canadian researchers who conducted studies of asbestos mining workers found that particle counts could not be converted to fiber counts.¹⁶ Researchers, therefore, had little basis for distinguishing the health effects of different sizes and shapes of asbestos mineral particles.

In 1971, OSHA adopted the American Conference of Governmental Industrial Hygienists (ACGIH) TLV of 12f/cc for "all asbestos" as its first permissible exposure limit (PEL).³ In 1972, OSHA issued the first specific regulation designed to limit worker exposure to *all forms of asbestos*.¹⁷ OSHA used four geologic terms— anthophyllite, tremolite, chrysotile and actinolite— and the names of two commercial asbestos products— amosite (cummingtonite-grunerite) and crocidolite (riebeckite) - to define the applicability of the

standard. OSHA set length as the only criterion to define fiber: "Asbestos fibers' means asbestos fibers longer than 5 micrometers."¹⁷ In 1973, the Food and Drug Administration (FDA) defined asbestos as "a generic term for a number of hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils."¹⁷ The FDA has never changed this definition. In 1974, Judge Miles Lord, in the first legal case concerning federal regulation of corporate pollution, defined asbestos as follows: "Asbestos is a generic term for a number of hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils."¹⁸

In 1986, OSHA established counting rules which limited fibers to those with a length width aspect ratio greater than 3:1 and longer than 5 microns.¹⁹ The United States Environmental Protection Agency (EPA) established an aspect ratio of 5:1 for asbestos with length longer than 0.5 microns.²⁰ At the time, there was no specific geologic definition for the term asbestos fiber.²¹

An opportUNE void

It was easy to formulate a debate over definitions since geologists had never agreed to any specific definition of asbestos (which historically had been a commercial and not a geologic term). A 1987 book on the subject of asbestos fibers noted that: "A search of more than 50 technical and scientific texts, glossaries and dictionaries produced no authoritative definition of fiber or fibrous that is applicable to asbestos and appropriate for use by health professionals."²² The 1974 Glossary of Geology quotes Lewis Carroll to describe the state of geologic definitions of minerals, implying that the definitions used were subjective: (p. vii)²³

"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean—neither more nor less." "The question is," said Alice, "whether you can make words mean so many different things." "The question is," said Humpty Dumpty, "which is to be master— that's all."

In the early 1970s, Pfizer and Johns Manville (JM) began to warn customers of the presence of asbestos in their talc products. RTV complained in a letter to JM and Pfizer that these warning were hurting their talc sales and a bitter dispute ensued between the companies. RTV asked Pfizer to stop

warning its customers that talc contained asbestos: (p. 1)²⁴

It's a crazy world isn't it? Here we have been producing and selling tremolitic talc for 30 years and we see from a recent advertisement of your Minerals Division (enclosed) that tremolite is an undesirable impurity in talc -- like asbestos. I'll bet your West Coast ceramic customers are surprised to learn this.

In the minds of many, talc and asbestos are one and the same. The more your Minerals Division continues to muddy the water by discussing talc and asbestos and asbestiform minerals in their advertising copy, the more firmly this misconception will be implanted in the minds of Government regulators and others who have a vested interest in the hazards of asbestos. Already NIOSH talks of a "talc alert" and the WALL STREET JOURNAL runs a leading article (enclosed) on the hazards of "pure talc."

This is a critical time for the talc industry. Your Minerals Division can help by giving more careful consideration to the consequences of their talc advertising copy.

In response to this letter, Pfizer summarized RTV's strategy for defending their talc from regulation: (p. 2)⁶

R. T. Vanderbilt has been the largest producer in the United States of "industrial talc" with high amphibole content.... Prior to the publication of the original standard, they launched a massive effort to block the standard and later to overturn it. Initially their thrust was that the amphiboles were not asbestos and should not be included in the asbestos standard. Later they took the position that the amphiboles involved, especially tremolite, existed in both "asbestiform" and "non-asbestiform" varieties and that Vanderbilt talc contained of the non-harmful variety. ALTHOUGH their

position has never been supported by any scientist of renown or any other talc company, Vanderbilt has remained adamant in that defense of it. Their lobbying efforts were successful in obtaining certain letters... [from OSHA]. Although these letters were ambiguous, Vanderbilt used them to certify the safety of their product until the labor department rescinded the letters on January 19, 1977. [Emphasis added]

Pfizer warned about the presence of asbestos in their talc products and acquiesced to OSHA regulation: (p. 3)⁶

JM, another major talc producer, with considerable expertise and asbestos took a radically different approach. On September 30, 1974, they issued a letter stating that their Grantham talcs contained amphiboles of asbestos and placed asbestos warning labels on their talc packages. In June 1976, they officially shut down the Grantham talc operation in Death Valley and went out of the talc business.

...MPM [Pfizer's] scientists believe that after grinding, tremolite particles either meet the OSHA definition of a fiber or failed to meet it. If the fiber definition is met, tenderness best the form particle exists.

Based on the above, Pfizer has chosen not to attempt to challenge the OSHA regulations.

JM feared that RTV's refusal to acknowledge the health risks of asbestos in their talc products would undermine the industry's ethical and professional credibility. JM's director of environmental services, Edward Fenner, in a memo to coworkers stated his objections to a published paper written by RTV's geologist CS Thompson: (p. 1)²⁵

...[I] disagree with almost everything said by Thompson. I object strongly to an earlier statement ...Re: "Misinformation" supplied by competitor. Furthermore, in all of Thompson's gobbledygook regarding the mineralogy of Vanderbilt's "talc" at no point does he admit to the

fact that their "talcs" contain not only fibrous tremolite but chrysotile and anthophyllite as well. This we have proved by every available technique. These findings are well documented in numerous R&D reports. I am afraid that Dr. Thompson long ago gave up any professional ethics he might have had and is now persisting with a program that is not only technically false but even more tragic morally and ethically wrong. He totally ignores the medical consequences of his immorality. [Emphasis in original]

Unfortunately, RTV and other talc companies continued to supply the same "misinformation" in the years to come. Neither asbestos mining and manufacturing companies nor geologists had ever used any definition that distinguished "asbestiform" from "non-asbestiform" until OSHA began to regulate all forms of asbestos in 1972.²⁶ (In fact, in 2002, the United States Geological Survey (USGS) created a 75-page "Tabulation of Asbestos-Related Terminology" and "asbestiform" does not appear in any asbestos definition until 1977).²¹

In 1973, the FDA proposed regulation of asbestos in talc.⁷ As a result, RTV, which sold "tremolitic" talc (50-70% tremolite and anthophyllite), and J&J, whose iconic product was talcum baby powder that contained asbestos, faced a considerable problem.²⁷ In response, RTV and Johnson and Johnson (J&J) took advantage of the vacuum of geological definitions of asbestos to defend the safety of their talc products by beginning a campaign to restrict the definition of asbestos to only those fibers that could be shown to have originally formed in bundles like hairs on a brush. The asbestos definition propounded by RTV and J&J excluded single fibers of the same size. The two companies began a campaign to have OSHA restrict the definition of anthophyllite, tremolite, and actinolite (ATA) asbestos to only fibers that originated in an asbestiform habit. However, both forms are found in all asbestos deposits and products and it is impossible to determine the origin of a single fiber after processing (e.g., talc used in cosmetics is processed by milling and sieving, which destroys many of the asbestos bundles).^{28,29}

Deleting non-asbestiform fibers from the definition of asbestos

Using Geologists to Influence Government Regulatory Bodies. Beginning in the 1960s, the National Institute for Occupational Safety & Health (NIOSH) and others had found asbestos fibers (with an aspect ratio of 3:1) in cosmetic talc products.^{30,31} Facing the threat of FDA proposed regulation and OSHA regulation of asbestos found in cosmetic talcs, the TM&MCs began a campaign to redefine asbestos.

In 1973, the Congressman who represented RTV's mining district wrote to OSHA on their behalf supporting deregulation of RTV talc because it was his "...understanding that there was no evidence that tremolite was carcinogenic."³² In July 1974, RTV met with the Secretary of Labor Stender, to request that OSHA rescind regulation of its talc.³³

"RTV...requested relief from the Asbestos Standard for our non-fibrous or non-asbestiform tremolite, anthophyllite and actinolite "pending thorough investigation by NIOSH which was then estimated to be concluded in one (1) year. Secretary Stender at this meeting stated that the R. Vanderbilt Company, Inc. was being held "Hostage" without documentation on tremolite, anthophyllite and actinolite." (p.1)

On August 6, 1974 Stender wrote to Vanderbilt that "...non-asbestiform minerals such as non-asbestiform tremolite are not within the scope of the existing Asbestos Standard." This was not enough for Vanderbilt who wrote back: (p.1-2)³³

*"This was a step forward but the lack of a definition for of fibre still holds us 'Hostage.' We are therefore now losing a considerable amount of business and suffering irreparable economic harm...We meet today not to decide **what is or what is not carcinogenic**, but only to ask that our industrial talcs containing tremolite, anthophyllite and actinolite be excluded from the Asbestos Standard immediately pending results of the NIOSH investigation now in progress. We are suffering financially as a result of not being excluded pending*

documentation, we ask most sincerely for a quick exclusion. As we mentioned on July 2, this is the course of action EPA and MESA have taken while awaiting results of the same NIOSH study.”³³ [Emphasis added]

In the 1980's, RTV's consultant geologists began to lobby OSHA to adopt a geologic rather than a health-based definition of asbestos that would rescind regulation of non-asbestiform asbestos. The geologists argued that non-asbestiform asbestos was not asbestos because it was not developed or formed in a fibrous habit. RTV consultant, Dr. Ann Wylie, Associate Professor in the Department of Geology at the University of Maryland, first promoted this geologic definition asbestos in a 1983 legal opinion provided to RTV.³⁴ Later, Wylie presented this geologic definition in a 1984 presentation co-authored with John Kelse of RTV, Vanderbilt, Richard J. Lee (another RTV consultant) and Kelly F. Bailey, a geologist employee of Vulcan Materials Company.⁸ They claimed “difference exists mineralogically and biologically” between “elongated non-asbestiform cleavage fragments” and asbestos fibers.⁸

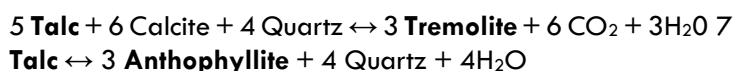
Wylie's participation was crucial to RTV's efforts. In 1985, Slim Thomson, RTV's mineralogist, reciprocated Wylie's contribution to RTV in a letter endorsing her application for tenure.³⁵ Her department chair thanked Thomson, noting that RTV's recommendation “...will constitute the most important piece of document to be used in the entire promotion and tenure process.”³⁶

In 1984, Wylie testified as a representative of RTV at OSHA hearings and promoted the adoption of her geologic definition of asbestos:³⁷

Asbestos is a commercial name and it has been applied to a group of highly fibrous silicates specifically chrysotile and several of the amphibole minerals. These minerals are characterized by very unique physical properties that include high tensile strength, resistance to acid and heat, flexibility enough to be woven into cloth and unique optical properties.

Two of these requirements (those asbestos fibers must have a mean aspect ratio of at least 20:1 and appear in bundles) would eliminate OSHA regulation of much of the asbestos found in talc used in cosmetics. The talc companies were aware that microscopy, when applied to cosmetic talcs, generally only detected individual fibers whose derivation could not be determined.^{28,29,38} Further, tremolite, actinolite, anthophyllite, and harsh chrysotile have low tensile strength and poor flexibility³⁹⁻⁴¹ Non-asbestiform fibers have just as much flexibility as “true asbestos”. There is nothing unique, diagnostic, or special about the flexibility of asbestiform fibers.⁴²

In the same month, Wylie asserted that the term asbestos should be limited to fibers that had “grown” or formed in a fibrous habit (group of fibers) with aspect ratios greater than 20:1.⁴ (See Figure 1) However, many minerals form in a fibrous habit; fibrous tremolite and anthophyllite naturally chemically convert to talc and vice versa while maintaining the same fibrous structure: (See Figure 2)



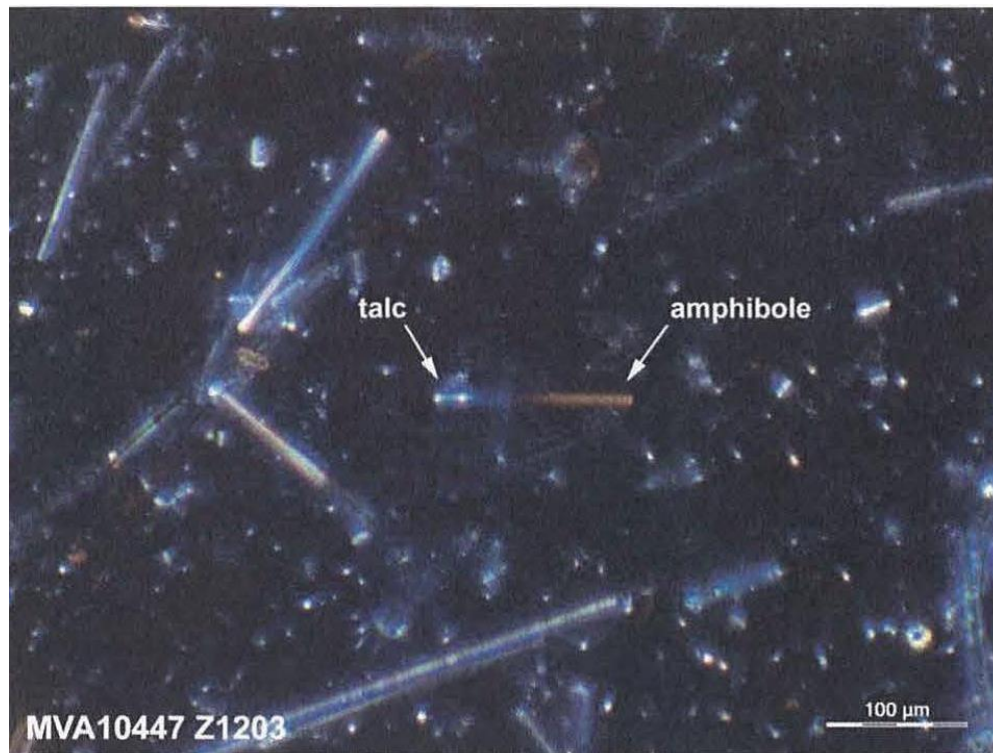


Figure 2: Talc and amphibole ends in a single fiber (Compton and Millette 2004)

In 1987, RTV reviewed a draft of a Wylie paper on asbestos definition.¹² John Kelse of Vanderbilt was concerned about the paper and suggested “several **embellishments.**” [Emphasis added] Kelse asked Wylie to emphasize the fact that the aspect ratio should be used only as a “screening tool only – as one of many variables which helped distinguish non-asbestiform particles from asbestiform particles. As for health effects, the possible role of many other variables to be recognized, (e. g. hardness, surface charge, durability, etc.) When you say on page 6, for example, the particles with aspect ratios greater than 15:1 are the particles ‘known to be carcinogens’, we know what you mean but fear others will not.”¹² The “known to be carcinogens” language does not appear in Wylie’s papers published in this time period.⁴³⁻⁴⁷

In August 1990, Wylie presented a more extensive test method criterion to define asbestos at a NIOSH meeting which was published in a non-peer review summary of the meeting papers:(p. 1)⁴⁴

ASBESTOS FIBERS. Asbestiform mineral fiber populations generally have the following

characteristics when viewed by light microscopy:

1. Mean aspect ratios ranging from 20:1 or greater for fibers longer than 5 μm,
2. Very thin fibrils, usually less than 0.5 μm in width,
3. One or more of the following:
 - a) Parallel fibers occurring in bundles,
 - b) Fiber bundles displaying splayed ends
 - c) Fibers in the form of thin needles
 - d) Matted masses of individual fibers
 - e) Fibers showing curvature

Wylie’s definition hinged on the mean aspect ratio, but she did not report any mean aspect ratio for any asbestos variety in this paper.⁴⁴ However, in 1984 she reported that the 20:1 aspect ratio was too high: “Aspect ratios between 8:1 and 19:1 are characteristic of fibers of amosite and anthophyllite.”⁴⁴ In 1985, Wylie reported that a 20:1 cut off would fail to account for 50% of commercial amosite fibers.⁴⁸ Puffer and Germaine (2019) found the mean aspect ratio of amosite to be 11.7.⁴⁹ In addition, PLM cannot identify fibers less than 0.3 μm wide and in many fibers are

thinner than that. Campbell et al. (1977) also showed that neither length nor aspect ratio could distinguish habit from cleavage formed asbestos fibers since they overlapped. (See Figure 3) Shedd (1985) measured the dimensions of crocidolite asbestos and found that the majority of crocidolite asbestos fibers would be considered “non-asbestiform” by the Wylie criteria.⁵⁰ Millette (2015) commented on the Wylie’s criteria: “Trying to use two or more of those mineralogical characteristics would result in misclassifying up to 80% of the asbestos fibers.”⁵¹

At OSHA, Wylie conceded that her 20:1 criterion could not distinguish asbestiform from non-asbestiform asbestos:

“The use of a 20 to 1 aspect ratio that I am suggesting is not cast in stone. I do not mean to imply that if an amphibole article has an aspect ratio of greater than 20 to 1 it is asbestos, and if it has an aspect ratio of less than 20 to 1 it is not. I do not believe that you can find an ADEQUATE criterion which WOULD allow us to UNEQUIVOCALLY place a particle in one camp or the other.” (p.7)³⁷ [Emphasis added]

Population is another key point of demarcation between “cleavage fragments” and asbestiform fibers. The term “population” is the gravamen of defense geologist arguments because during milling bundles of fibers (populations) are broken- up and only single fibers are visible in any field of view. However, neither Wylie nor other defense experts can define “population.”^{52,53} “Reproducibility is the ‘Touchstone’ of Scientific Method.”⁵⁴ A criterion that is undefined cannot be reproduced and is therefore not a scientific method. The geologists assign various meanings to the population requirement which suit the particular need of the day or testimony. In addition, the terms “parallel” and “matted” are also contradictory. “Matted” means “tangled into

a thick mass;” parallel means “side by side and having the same distance continuously between them.”

Julie Pier, who was in charge of testing for asbestos in talc for Rio Tinto Minerals and J&J, summarized the problems related to the limiting the identification of asbestiform fibers beginning with the concern that “It is not known whether cleavage fragments of similar dimensions to asbestiform fibers pose the similar health risks”: (p. 11)⁵⁵

- Amphiboles are naturally elongated; when ground consistently produce “cleavage fragments” that meet 3:1 and 5:1 criteria
- On a microscopic scale, one cannot distinguish between asbestiform and cleavage fragment
- Deposits can contain both asbestiform and non-asbestiform particles
- Therefore, it is nearly impossible to characterize individual amphibole fibers as truly asbestiform or non-asbestiform.

Moreover in 1980, Schiller and Payne of the USGS found that asbestiform and non-asbestiform fibers had the same surface properties thus eliminating the main argument that non-asbestiform fibers were nontoxic.^{56,57} They

examined samples of asbestiform amosite, crocidolite, tremolite, and cummingtonite; massive tremolite and actinolite; acicular and riebeckite; and fibrous (but non-asbestiform) tremolite and actinolite. Their results indicated no significant difference in surface properties between cleavage fragments and fibers: (p. 22)⁵⁶

Surface charge does not appear promising as a basis for distinguishing fibers and cleavage fragment. Non-asbestiform amphibole particles were found to have essentially the same surface charge as amphibole asbestiform fibers of the same dimensions.

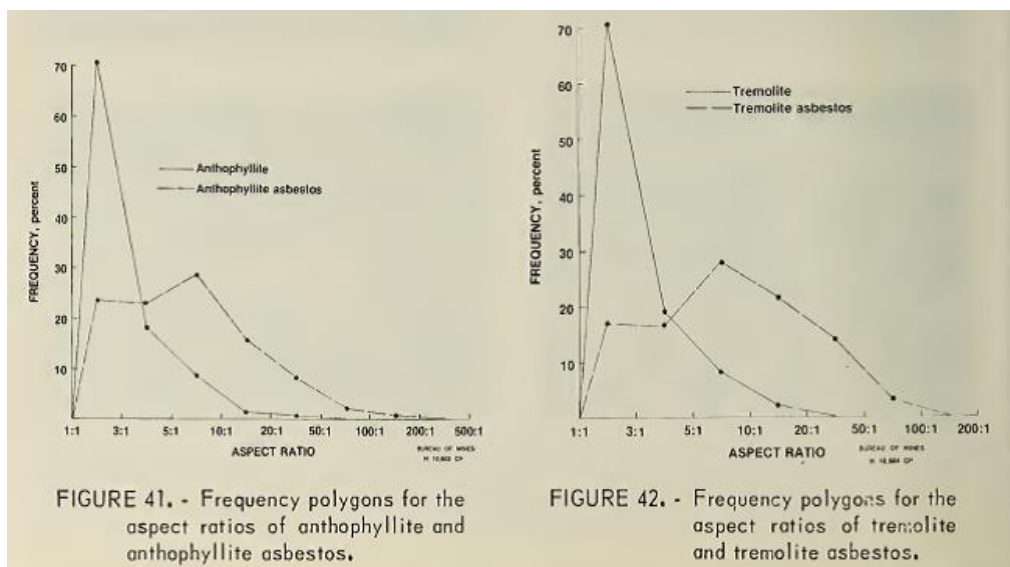


FIGURE 3: Overlapping aspect ratio of habit formed and cleaved fibers from Campbell et al. 1977 (Campbell, Blake et al. 1977)

OSHA responded to RTV's geologists by holding hearings 1984. In 1986, RTV sued OSHA and challenged to OSHA's regulation of non-asbestiform asbestos.⁵⁸ The court rejected the industry motion because OSHA had already agreed, at industry request, to reconsider its 1986 standards as they apply to non-asbestiform minerals.⁵⁹ In 1973, OSHA rescinded regulation of RTV talc pending the completion of the NIOSH study expected within a year.⁶⁰ Three years later, NIOSH informed OSHA that they had found an elevated rate of lung cancer in RTV New York talc mine workers and OSHA renewed regulation of all forms of ATA.⁶¹ As of 2020 there are ten mesothelioma in RTV miners in workforce of less than 1000.⁶²

OSHA repeatedly cited RTV consultant Wylie's testimony (as described above) and written submissions as a basis for withdrawal of regulation of non-asbestiform asbestos. However, as a federal regulatory body responsible for occupational health and safety, OSHA should have been most concerned with the health-effects of asbestos. In deposition testimony, Wylie agreed that she "... was not an expert in [the] biological activity of substance's effect on the human body." (p.17)⁵² Indeed, a geological definition of asbestos does not define toxicity.

Geologic definition of fibers does not define toxicity. Wylie claimed that her definition was based on Stanton's and other animal data.^{8,43,46} In 1981, Stanton published a series of animal studies exposed to a variety of fibers but his analysis was

limited to considerations of fiber length and width; he did not consider any of the geologic properties of the fibers he studied, including aspect ratio or the origin of the fibers.^{57,63-65} Wylie (1987) evaluated Stanton's crocidolite fibers and concluded that the correlation coefficients between fiber width and length and carcinogenicity "...were low enough to suggest the possibility that factors other than size and shape play a role in mineral fiber carcinogenicity." She did not evaluate aspect ratio or any of her other proposed criteria.⁶⁶ Dunnigan (1984) criticized Stanton's sample preparation method which included milling, and produce false negative results: "...most original studies claiming that short fibers lack fibrogenic activity used traumatic ball-milling preparatory steps. Studies using less vigorous preparatory techniques, such as flotation, have yielded positive results."⁶⁴

The toxicologists, physicians and physician organizations who were not compensated for their testimony who testified at the 1990 OSHA hearings asserted that that cleaved fibers (non-asbestiform) asbestos was a health hazard and should be regulated. For example, OSHA described a published letter by Bruce Case MD, a pathologist who had been funded by Quebec Asbestos Mining companies: (p. 24320)⁶¹

The major flaw in the substitution of mineralogical definitions for microscopical characteristics is a reliance of the former on gross morphology. For regulatory and

health assessment purposes, it is microscopical morphology that counts: there is no evidence that potential-affected ceils can distinguish between "asbestiform" and "non-asbestiform" fibers having equivalent dimensions.

OSHA also summarized the view of the American Thoracic Society in favor of continued regulation of non-asbestiform fibers:(p.24311)⁶¹

The Agency acknowledged that certain public health organizations have recommended that OSHA continue to regulate non- asbestiform ATA under the asbestos standards. Thus, the American Thoracic Society (ATS) concluded that "(a)t present, the prudent public health policy course is to regard appropriately sized (non-asbestiform) tremolite fibers" in sufficient exposure dose (concentration and duration), as capable of producing the recognized asbestos related diseases, and they should be regulated accordingly.

OSHA summarized the National Occupational and Safety Administration's (NIOSH) position in favor of continued regulation of non-asbestiform fibers: (p. 24311)⁶¹

NIOSH also recommends that OSHA continue to regulate non-asbestiform ATA under the asbestos standards. Its major rationale is similar to the ATS's, i.e. "NIOSH concludes for regulatory purposes that cleavage fragments of the appropriate aspect ratio and length from the non-asbestiform minerals should be considered as hazardous as fibers from the asbestiform minerals."

OSHA cited NIOSH's findings of an occurrence of lung cancer in RTV mine workers: (p. 24322)⁶¹

According to NIOSH the SMR for lung cancer was uniform across tenure strata and increased with increasing latency. There was a statistically significant excess in lung cancer in those with 20 years of more latency and with less than one year employment. Those in this latency group with greater than

one year duration also exhibited an increased risk but it was not statistically significant. The increased risk of lung cancer among those with short duration also was observed in the 1989 analysis.

As noted above, Wylie claimed that these mines only contain non-asbestiform asbestos.⁶⁷

John Addison, a geologist testified on as yet incomplete animal studies (conducted with Dr. Davis, of both asbestiform and non-asbestiform tremolite), claimed the non-asbestiform tremolite had not caused mesothelioma.⁶⁸ Dr. Spooner, a consultant geologist, cited a letter quoting Dr. Davis as writing that he would be "...extremely worried if tremolite fibers with step sides [cleavage fragments] were not subject to the strictest dust regulations."⁶⁹ Indeed when completed, Davis et al. (1991) concluded that, "...the present study has demonstrated that all forms of the mineral tremolite have some carcinogenic potential."⁷⁰ RTV never corrected the record.

Nonetheless, OSHA acceded to the company lobbying.⁶¹ Apart from Campbell, OSHA only cited company consultant geologists.

Despite rescinding regulation of non-asbestiform asbestos mineral, OSHA failed to change the microscopic definition of a fiber in its test method for fiber determination published in 1995.^{71,72} While OSHA limited measurements to fibers "in the asbestos growth habit," the OSHA test method did not included any of Wylie's proposed criteria for determining how to classify a fiber as having originated in the asbestos growth habit.⁷² OSHA still regulated all fibers or particles greater than 5 microns in length, with aspect ratio's greater than 3:1, contrary to Wylie's criteria.^{71,72} The ambiguity of the standard is evident in OSHA's PCM method which states:

...only if a fiber is obviously not asbestos should it be excluded from the count...If there is a question whether a fiber is asbestos or not, follow the rule:

"WHEN IN DOUBT, COUNT." [Emphasis in original]

In 2008, the head of safety for Imerys admitted misgivings with OSHA's de-regulation of cleavage fragments: (p. 2)⁷³

I cannot agree with the position. We just don't have enough facts. Geologically, it doesn't make sense to me that you can have a mineral

deposit that just contains "non-asbestiform" tremolite. I believe the USGS study of talc from Death Valley, California, nailed it correctly that if a deposit contains "non-asbestiform" tremolite, there is also asbestiform tremolite naturally present as well. And since tremolite was never really a large commercial mineral such as chrysotile or crocidolite, there is not enough medical data to conclude that "blocky" tremolite is simply a nuisance dust. But that has been the story line for Vanderbilt for years and they're sticking to it.

Essentially, OSHA "threw in the towel" rather than expend their limited resources any longer on this issue. Their decision by no means should be interpreted as a vindication of Vanderbilt's arguments. [Emphasis added]

In 2009, Gregory Meeker, of the United States Geological Survey (USGS), objected to attempts to create a "geologic" definition of a fiber as a basis for health protection. He noted that the definition should rely on toxicological evaluation of risk to health, and not geologic properties per se: (p. 270)⁷⁴

The job of Earth scientists is not to decide what is toxic; our job is to assist the health community and regulators by carefully describing the physical and chemical properties of natural materials, understanding their occurrence, and providing scientifically rigorous terminology when needed.

Ultimately, Wylie's definition made the asbestos in talc magically disappear from the OSHA regulation and allowed TM&MCs to successfully defend against some tort lawsuits filed by talc user who claimed that asbestos in talc has caused their ovarian cancers or mesotheliomas.

Other agencies reject the geologic definition

In 1987, the World Health Organization (WHO)'s International Agency for Research on Cancer (IARC) declared that "for talc containing asbestiform fibres...[there is] sufficient evidence for carcinogenicity to humans," without a including a growth habit requirement⁷⁵ Wylie, in violation of IARC conflict of interest rules, failed to disclose her

industry consulting, and became a member of the 2006 IARC talc panel.(p. 4)⁷⁶ Unsurprisingly, after Wylie became a member, the IARC revised its definition of asbestiform, distinguishing it from "elongated mineral fragments that are not asbestiform."⁷⁶ IARC did not adopt any of Wylie's criteria for demarcating fiber origin.^{77,78}

Although "non-asbestiform" appeared in a single 1993 EPA test method, EPA's regulation established an aspect ratio of 5:1 for asbestos.^{20,79} In 2006, the EPA soundly rejected the argument that geological definition should be considered for health-based regulations:⁸⁰

...relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.

In 2000, Dorland's Illustrated Medical Dictionary defined asbestos as "any of several fibrous, incombustible materials, forms of magnesium and calcium silicate, used as thermal insulation; the two major types are amphibole a. and serpentine a. Its dust causes asbestosis and acts as an epigenetic carcinogen for pleural mesothelioma and possibly bronchogenic carcinoma."

Harper (2008) reported that "NIOSH concluded there is no scientifically valid reason to exclude cleavage fragments from regulation, and doing so may compromise the protection of workers exposed to mixed fibers."⁸¹ In 2011, NIOSH stated that "NIOSH makes clear that such non-asbestiform minerals are not 'asbestos' or 'asbestos minerals.'"⁸² However, NIOSH did not make any conclusion on the health effects of "non- asbestiform" minerals and acknowledged "By analogy to asbestiform amphiboles, there is reason to be concerned about potential for health risks associated with inhalational exposure to EMPs not covered by asbestos policies."⁸² NIOSH reaffirmed that "Clarification of the REL in this way does not change the existing NIOSH occupational health policy for asbestos" which included "counting those EMPs having: (1) an aspect ratio of 3:1 or greater and (2) a length

greater than 5 μm .”⁸² NIOSH asked for “development of a deeper understanding of the determinants of toxicity” of these minerals.⁸² Since 2011, studies have shown that non-asbestiform tremolite would cause lung cancer and pulmonary fibrosis.^{83,84} In addition, Militello et al. (2020) showed an increase in chromosomal aberrations triggered by exposition to non-asbestiform amphiboles in vitro.⁸⁵

In 2015, the French Agency for Food, Environmental and Occupational Health & Safety concluded that “In the current state of knowledge **concerning their health effects**, cleavage fragments from non-asbestiform amphiboles of actinolite, anthophyllite, tremolite, grunerite and riebeckite meeting the WHO’s dimensional criteria for fibres (L > 5 μm ; D < 3 μm and L:D > 3:1) should not be distinguished from their asbestiform counterparts (actinolite-asbestos, anthophyllite- asbestos, tremolite-asbestos, amosite and crocidolite).”⁸⁶

Discussion

The TM&MCs successful use of “gobbledygook” to influence regulation can also be measured in cancer cases in mine workers and users of its industrial and cosmetic talcs. However, ten miners and at least one ceramic worker who used their talc have died from mesothelioma.⁸⁷⁻⁸⁹ As RTV consultant Mickey Gunter agreed in testimony, if RTV talc is asbestiform free then non-asbestiform talc caused the mesotheliomas.⁹⁰ In either case the company lobbying paid off and as a result OSHA failed to protect the public’s health.

As noted above, Wylie, in violation of IARC conflict of interest rules, failed to disclose her industry consulting, and became a member of the 2006 IARC talc panel.⁷⁶ Wylie had testified as a representative of RTV at the July 1984 OSHA hearings (p.1).⁹¹ Similarly when she testified at Senate hearings in 2007 Senator Boxer asked, “Have you worked or businesses that make money selling products that may have caused diseases associated with asbestos?” She answered “No.” When confronted with her bills, Wylie claimed she had meant she never worked for an asbestos manufacturer or fabricator. However, she had worked for Celotex and GAF manufacturers of asbestos insulation products the year before.⁴⁵ In 2000, she testified at the NTP hearing on talc carcinogenicity and was asked who she represented. She answered, “I represent no one. I represent the mineralogical community. I’m from

the University of Maryland.”⁹² However, the CTFA newsletter thanked her and others for being “speakers for industry who were instrumental in educating the Subcommittee members to the deficiencies of the NTP position.”⁹³

The TM&MCs continue to argue that because cleavage fragments do not originate from an asbestiform habit, these elongated particles are harmless.⁹⁴ However, Egilman et al. (2019) reviewed the evidence and concluded that non-asbestiform fibers are carcinogenic.⁵ The gravamen of the question of toxicity is the fact that workers, miners, and others (talc users) were exposed to the material in asbestos bags or products contained both asbestiform and non- asbestiform fibers. All epidemiologic studies of asbestos and talc exposed population have inhaled both fiber types.^{4,49,76,95} In fact human pathologic studies have not and cannot address this question since pathologist do not access tissue for the presence of populations of fibers.⁹⁶ Since pathologists have never followed the Wylie definition, all human and animal studies that examined lung or pleural tissues for asbestos only reported single fibers.^{89,97-116} If the definition was applied, all these fibers would be called non-asbestiform fibers (“cleavage fragments”) and all asbestos disease would be attributed to non-asbestiform fibers (“cleavage fragments.”) The lung and pleura can only distinguish size shape and surface properties and the mineralogical definitions do not distinguish particles based on these biologic characteristics.

Three years after the 1990 OSHA hearing, Langer published an analysis of the tremolite fibers found in the Canadian mines where Canadian researchers had attributed mesotheliomas to tremolite exposure.¹¹⁷ He found that “...the morphology of the [tremolite] particles found, and selected area electron diffraction characterization, **showed that they were cleavage fragments, not asbestos fibres.**”⁴⁰ [Emphasis added] In 1995, McDonald attributed the mesothelioma excess in Canadian to tremolite rather than chrysotile.^{117,118} Williams-Jones et al. (2001) studies the largest Canadian mine and found, “Although most of the amphibole is fibrous, only a small proportion (tremolite) qualifies as asbestiform according to criteria developed by the U.S. Occupational Safety and Health Administration.”¹¹⁹ In 2014, Puffer and Germaine examined tremolite- actinolite fibers in the lungs of workers who had died from mesothelioma and found that, “Fibers found in lung samples and in a bulk comparison

sample are produced primarily by splitting of thicker crystals and, as such, might not be considered asbestos fibers on the basis of certain mineralogical criteria.”¹²⁰ The same authors studied the lungs of asbestos miners and found the average aspect ratio was 15.6 and mean length was less than 10 and thus would not meet Wylie’s definition of an asbestiform fiber yet these miners had increased rates of lung cancer and mesothelioma.^{121,122} Recently, Puffer and Germaine examined commercial amosite (cummingtonite-grunerite) and determined that most of the fibers were cleavage fragments noting that “Our findings indicate that amosite would not be regulated under current asbestos regulations, which define amphibole asbestos as whole crystals that are not split and that form fibril bundles, not found in our [OSHA] standard.”⁴⁹ They concluded that “Our findings therefore contradict the following assertions: 1) that carcinogenicity of asbestos fibers is related to special surface properties of crystal faces, 2) that when a fiber splits it ceases to be carcinogenic, 3) and that amphibole fibers not formed by crystal growth are harmless “cleavage fragments.” Thus human epidemiologic studies cannot distinguish the health effects based on the genesis of the fiber since both asbestiform and non-asbestiform particles are present in commercial products.⁶¹ The current agency criteria for fiber determination vary by agency but only the EPA bulk asbestos method which cannot apply to talc incorporates the Wylie definition.

Conclusions

Asbestos is a commercial product comprised of any of five minerals sold as tremolite, anthophyllite, amosite, crocidolite, or chrysotile, and actinolite. Bags of asbestos contain both asbestiform fibers that split from bundles and non-asbestiform fibers that split from larger rocks and chrysotile, tremolite, anthophyllite and actinolite are accessory minerals found in talc. “Non- asbestiform” fibers are sometimes referred to as “cleavage fragments” but both forms actually cleave or split from their original form. Workers who inhaled the contents of the bag as sold, which included both “asbestiform” and “non-asbestiform” asbestos, contracted mesothelioma, lung and

ovarian and other cancers and lung fibrosis (asbestosis) from the exposure. **When defined according to its health effects**, current FDA, OSHA and EPA asbestos regulations further define an asbestos fiber as having length greater than 5 microns and length to width ratio >5:1 when using light microscopy and length greater than 0.5 microns and length to width ratio >3:1. Both “asbestiform” and “non-asbestiform” asbestos can have the same size and shape. Chrysotile is often serpentine (curved) and amphiboles are straight. Crocidolite and amosite are product names that contain “asbestiform” and “non-asbestiform” asbestos fibers whose geologic names are riebeckite and cummingtonite-grunerite. Other amphibole fibers with similar dimensions include winchite-richterite, jimthomsonite, arfvedsonite, eckermannite, and chesterite.

TM&MCs funded experts and lobbied OSHA to promote an overly restrictive definition of asbestos and to support inadequate test methods in place of more effective procedures. In essence, this geologic definition defined asbestos out of existence. Despite the fact that NIOSH and most medical experts disagreed, OSHA relied on the testimony of company funded mineralogists, to withdraw regulation of non-asbestiform asbestos. Based on the same definitional confusion, courts have annulled jury compensation of mesothelioma patients sickened by their use of asbestos contaminated baby powder.¹²³ These companies subsequently relied on these same restrictive definitions and inadequate tests to claim that their cosmetic talcs are free of asbestos.

Conflict of Interest Statement

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: D.S.E. serves as an expert witness in litigation at the request of people who claim injuries resulting from the use of talcum powders. T.H.T. works for D.S.E. T.B. worked for D.S.E. during the initial phases of research and writing. Dr. Egilman was not compensated for work on this article. T.H.T., T.B., K.C. were not compensated by law firms for work on this article. Parts of this paper were previously submitted as an affidavit in a legal case.

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