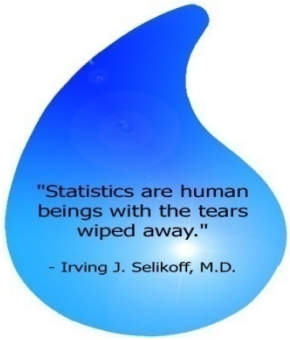

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December 9, 2019

Chairman Raja Krishnamoorthi
The Committee on Oversight and Reform
Subcommittee on Economic and Consumer Policy
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Krishnamoorthi:

Thank you for holding hearings on the issue of asbestos in talc. I am submitting comments on the issue of test methods for asbestos in talc.

Summary

Test methods

There is no test that can ensure that a can of talc is asbestos-free. This is because every test has a limit of detection, an amount of asbestos in a can that will not be detected. In addition, asbestos is not evenly distributed in talc. Thus any sample can easily miss asbestos. This is especially true for the most sensitive tests for asbestos, which are based on visualizing asbestos in an electron microscope. Unfortunately, the more sensitive the test, the smaller amount of talc that can be examined. For example, to examine most of the talc in a 1.5 once (42 gm) travel size talc container using the current TEM method employed by J&J would take 630,000 days. Each test examines less than 100 nanograms of talc, and J&J claims it tests 4 times a year. (See below)

This is a J&J slide on detection limits. It shows that J&J's best test method would allow a can to contain .01% asbestos, which would result in exposure to millions of fibers per can.

Analytical Detection Limits

Source – RJ Lee Group

Analytical Method	Detection Limit	Comment
XRD	0.1 – 1 %	Depends on particle size, matrix interference Cannot differentiate morphology
PLM	1% 100/Points Counted %	Visual estimation Variable, depends on the number of particles counted (i.e., 400 pts = 0.25%, 1000 pts = 0.1%) PLM limited to particles 0.5 – 1 µm and wider
TEM	0.01 – 0.1 %	May be much lower if matrix particles can be removed. Capable of detecting PPM given adequate sample size. TEM limited to particles shorter than 50 µm or thinner than 5 – 10 µm

6/16/2011 CONFIDENTIAL - Draft for Discussion 7

In 2018, J&J's corporate representative admitted that "not detected" is different from "not quantifiable," stating "So the requirement is not detectable. The requirement is not 'not-quantifiable.' There's a huge difference between the two."[75] J&J's corporate representative testified that "Our standard is not detectable. Even a single fiber would cause that to be an issue."[75]

Since asbestos has been found in all talc ores, the only way to ensure that cosmetic are asbestos free is to ban the use of talc in cosmetics. Talc has no health benefits and consumers prefer corn starch to talc

powders. In addition, many babies who are overexposed to talc (but not cornstarch) during diapering have died from asphyxiation.

History of testing and hiding tests that found asbestos in talc

Introduction

Beginning in the late 1960s, government and university laboratories began to report the presence of asbestos in cosmetic talc products. In 1973, the Food and Drug Administration (FDA) proposed regulations that required that cosmetic products containing talc contained less than .01% asbestos. The talc mining and product manufacturing companies (TM&MCs) objected to government regulation and declared that they would self-regulate asbestos content in talc. In 1976, the talc industry proposed voluntary testing for asbestos in talc and asserted that they adopted a "zero tolerance" standard for asbestos in talc. The FDA acceded to the company request to self-regulate and withdrew the proposed talc regulation. This research reviews corporate documents and laboratory tests performed by TM&MCs and others to evaluate the claim that consumer talc was ever "asbestos free."

TM&MCs have since repeatedly deceitfully claimed that their cosmetic grade talcs are asbestos-free. Recent product testing and previously-secret TM&MC test results from 1950 to 2019 disclosed in litigation reveal that cosmetic talc products were never asbestos-free. The TM&MCs provided falsified asbestos test results to the FDA indicating that their talcs were asbestos-free. The TM&MCs developed a test method that could detect low levels of asbestos but rejected it because it was "too sensitive." Instead they published an insensitive test method that had an 86% failure rate. Even using insensitive test methods, TM&MCs' tests still identified asbestos in talc mines and in talc products. Independent laboratories also found asbestos in talc. Over 1,000 tests performed between 1950 and 2019 indicate that talc used in cosmetics from the 1950s to the present contained asbestos.

Talc-based cosmetics and powders contain asbestos. Talc companies cannot assure a "zero tolerance" standard for asbestos in talc due to the fact that all test methods have a limit of detection and the fact that random sampling cannot test presentative sample because asbestos is not uniformly distributed in talc ores. IARC has classified inhaled asbestos as a Group 1 ovarian carcinogen, and epidemiologic studies have shown an association between talc use and ovarian cancer. Talc use has also caused mesothelioma in users. The presence of asbestos in talc and the inhalation of fibers from the expected use of talc-containing cosmetics provide evidence that this association is causal.

Early History of Asbestos in Talc

TM&MCs have since repeatedly claimed that their cosmetic grade talcs are asbestos-free. This research reviews corporate documents and laboratory tests performed by TM&MCs and others to evaluate the claim that consumer talc was ever "asbestos-free." I focus on two main areas: 1) inadequate testing methods and protocols used by the TM&MCs to avoid asbestos detection and 2) evidence of asbestos in talc despite these efforts.

Geology of Asbestos in Talc

By the 19th century, geology texts recognized asbestos as an accessory mineral in talc formations.[1] In 1872, the Annual Report of the Vermont State stated "Asbestos may be seen in the seams of almost every outcrop of the rock" in the serpentine belt where the Vermont talc mines are located.[2-4] In 1898, Dana's Textbook of Mineralogy noted that talc "frequently contains … asbestos" and that fibrous talc was a "pseudomorph (an altered form of a mineral in which the internal structure and chemical composition are changed but the external form remains) of tremolite asbestos."[1] Jacobs 1914 concurred that "fibrous talc is pseudomorphous after the anhydrous enstatite or tremolite."[5] The following asbestiform minerals have since been found in association with talc: actinolite, anthophyllite, chesterite, chrysotile, clinojimthompsonite, jimthompsonite, tremolite, and winchite.[6-11] Several forms

of asbestos (anthophyllite, tremolite, amosite) may form in solid solution with talc due to the fact that they have similar chemistry and crystal structures.[12] The metamorphic process even generates "transition fibers" that comprised of both talc and asbestos constituents at opposite ends.[13] Fibrous (asbestiform) talc has also been found in talc deposits.[14] Dufresne (1995) and McDonald (1989) noted that fibrous talc and asbestos anthophyllite are so similar that "no differentiation between talc and anthophyllite can be made simply on the basis of the composition of the elements without using electron diffraction; exposure to anthophyllite must definitely also be assumed."[15]

Van Gosen et al. (2004) found that "the talc-forming environment directly influenced the amphibole and amphibole-asbestos content of the talc deposit" and reported "consistent associations of amphibole-rich talc deposits with contact metamorphism versus amphibole-poor talc with hydrothermal processes."[16] Dr. Edward McCarthy of Luzenac, a U.S. talc producer, listed four different types of talc formation processes: ultramafic, mafic, metasedimentary, and metamorphic origin.[17] Various forms of asbestos are generated as an accessory mineral in one or another of these formations.[18]

Historical Reports of Asbestos in Cosmetic Talc Products

As early as 1958, Battelle Memorial Institute, a private nonprofit applied science and technology development company, found tremolite and other amphiboles in talc ores used in J&J Baby Powder.[19] In 1968, Gross and Cralley reported that injected cosmetic talcum powders generated fibrous asbestos tremolite ferruginous bodies in hamster lungs.[20] The observation that cosmetic talcum products generated asbestos bodies stimulated a study to determine the extent of asbestos content in cosmetic talcum powders.[7] Cralley et al. (1968) tested 22 talcum products and found "The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile as these are often present in fibrous talc mineral deposits."[11, 21, 22] Cralley et al. reported fiber contents

ranging from “8 to 30% by count of the total talcum particulates with an average of 19%” and defined a fiber as “a particulate having at least a 1:3 ratio of diameter to length.”[11]

In 1971, Harold Romer, the assistant commissioner of Air Resources for New York City, notified J&J and the FDA that Dr. Selikoff’s group at Mount Sinai Hospital had found a significant amount of asbestos in J&J talc.[23] Through the 1970s, Drs. Rohl, Langer, Selikoff and others at Mt. Sinai continued to publish analyses of asbestos identified in cosmetic talc products.[9, 10] In 1972, the National Institute for Occupational Safety and Health (NIOSH) studied asbestos fiber exposures to mothers and infants during the process of diapering with various talc powder. NIOSH found that during diaper changing, J&J Baby Powder exposed mothers to 2.2 asbestos fibers/cubic centimeter (f/cc) and babies to 1.8 f/cc.[24]

In 1973, the FDA proposed regulation of asbestos in talc, allowed 0.1% tremolite and 0.01% chrysotile content.[25] In response to industry objections, in 1976, the FDA withdrew the regulation allowed the industry to establish voluntary testing procedures for identifying asbestos in talc used in cosmetics.[26, 27]

Inadequate Testing Methods

Due to the fact that every test has a limit of detection, no test can assure that talc is asbestos free. Many company, government and private tests have failed to detect asbestos in talc.

Reports of non-detection of asbestos occurred for at least five reasons:

1. Companies hid the existence of more sensitive methods
2. Companies failed to use more sensitive test methods.
3. Companies manipulated the definition of asbestos to claim positive results were non-detects

4. Sample sizes were small and sampling did not account for the fact that asbestos is dispersed non-homogenously in talc
5. Companies altered positive results

Hiding more sensitive detection methods: Omission of concentration techniques

In 1973, Dr. Pooley developed "two techniques for preconcentration of chrysotile and tremolite in talc followed by X-ray diffraction (XRD) analysis" involving "two heavy liquid separations to concentrate any chrysotile and tremolite-actinolite which may be present."[28] Dr. Pooley found 0.05% tremolite in J&J Vermont talc by this method. J&J disapproved of this method because "it may be too sensitive" in detecting asbestos in talcum powders.[29] Later in 1991, J&J consultant, Alice Blount stated that it would be necessary to review 4,000 fields of view by the FDA proposed microscopic method to detect asbestos in talc, noting "This is clearly beyond what could be expected of any sane microscopist for a routine analysis."[30, 31] In 1977, the National Bureau of Standards also noted that it was necessary to examine at least 6,000 fields of view to find a fiber.[32] In 1991, Dr. Alice Blount published an asbestos concentration method for talc analysis. She described this concentration procedure as "a more rapid and equally accurate method … based on concentrating the amphibole particles by density difference."[30] Colorado School of Mines (CSMRI), Dartmouth and International Organization for Standardization (ISO) separately recommended that concentration method is "essential" because finding asbestos in talc is akin to "finding a needle in a haystack."[28, 33, 34] In 1973, CSMRI stated to J&J that:[28]

> Based on past experience with detecting and identifying minerals when present at low levels, a concentration of the phases to be detected was considered **essential** to the success of any suggested procedure. Once concentrated, the impurities could be detected by conventional methods of examination. [Emphasis added]

Despite CSMRI's recommendation of the more sensitive concentration method, J&J William Ashton responded: "there is substantially no interest regarding the proposal ideas [concentration method] per your letter of January 31."[35] The industry instead developed less-sensitive test methods that did not use concentration techniques. In 1974, Wallace Steinberg, the Director of Development in J&J's Health Care division, wrote that "we believe in is critical for the CTFA to now recommend these methods to the FDA before the art advanced to more sophisticated techniques with higher levels of sensitization."[36] IN 1975, J&J UK wrote to J&J USA that they "deliberately have not included a concentration technique [to test for asbestos in talc] as we felt it would not be in worldwide company interests to do this."[37] When the FDA considered the concentration method in 1976, Ashton characterized it as "disturbing" and "there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation [concentration] techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals."[27] The FDA never developed these methods and instead allowed TM&MCs to self-regulate.

Adoption of insensitive methods

Instead, in 1976, the CTFA created voluntary method CTFA J4-1 to test for "amphibole" asbestos in "cosmetic grade" talc.[26] This called for screening with slow-scanning XRD followed by light microcopy if asbestos was detected by XRD. Having told the FDA that their talc never contained chrysotile, the CTFA and TM&MCs relied on the J4-1 method, which did not test for chrysotile, and thereby assuring that chrysotile would never again be found in their talcs. The J4-1 method, being XRD, could not distinguish and test for the presence of fibrous talc.[26, 38] While developing the J4-1 method, J&J recommended that the detection limit be set at 0.9%-4% fibrous tremolite and anthophyllite.[39]

In 1973, Walter C. McCrone Associates, a lab that many TM&MCs used to test for asbestos in talc, stated that XRD was "less sensitive" than transmission electron microscopy (TEM), but that the asbestos (level of detection) "sensitivity can be increased from 0.5 - 1% to 0.1 - 0.5%" by step-scanning rather than slow-scanning.[40] Another J&J and FDA consultant, Dr. Lewin of New York University (NYU), recommended the same step-scanning methods and the use of an internal standard to improve the level of detection by XRD.[41] Nonetheless, the TM&MCs did not adopt this recommendation and used slow-scanning XRD to screen talc for asbestos using CTFA J4-1.[26]

Although the TM&MCs claimed the J4-1 method tested for all amphiboles, spiked tremolite was the only benchmark specified for a test talc sample to be compared to.[26] In 1976, the CTFA performed a round robin test to evaluate the J4-1 method. They sent samples spiked with 0.5% tremolite to the FDA, Avon, Chesebrough-Ponds, McCrone, Colgate-Palmolive, Cyprus, Mennen, and Johnson & Johnson. Only one lab (the FDA's) was able to detect the tremolite using CTFA J4-1.[42] Thus, the round robin results demonstrated a false negative rate of approximately 86%. The CTFA recognized this problem, noting that the objectives of "Determin[ing] whether or not any 1976 production of major commercial talc products contain asbestiform amphibole contaminants" and gaining "assurance that method is accurate, reliable and practical" had not been achieved.[42] The CTFA also acknowledged that the proposed (but withdrawn) FDA method was 5 times more sensitive for the detection of tremolite asbestos than the J4-1 method.[43] In 1977, following the failed round robin results, the CTFA called for a change in the J4-1 method.[44] However, the CTFA never adopted these changes.[26] In fact, although the TM&MCs cited the J4-1 method as the basis for claiming that talc used in cosmetics was asbestos-free, the CTFA never formally codified, monitored or enforced the J4-1 method.[45-47]

TM&MCs also relied at times on the US Pharmacopeia (USP) method for detecting asbestos in talc. Like the CTFA method, the USP talc monograph called for a screening step with slow-scanning XRD

following by optical microscopy to confirm the presence of asbestos; the USP method, however, allowed for an alternative screening step by IR spectroscopy.[48] In 2014, a panel of industry experts and consultants evaluated the USP methods which included the same XRD procedure as the J4-1 method. The group found that the "Limit of detection may be too high for public health and regulatory purposes" and that the XRD step "may give false-negative result[s] if used as a screening method."[49] Nonetheless the USP method remains unchanged.

Neither the CTFA J4-1 method nor the USP method specified the magnification power used for Optical Microscopy Analysis.[26, 48] Colgate-Palmolive stated that they used 125X power to test the talc.[50] The Occupational Safety and Health Administration (OSHA) specified phase contrast microscopy (PCM) power at 400-450X and cannot detect fibers <0.25 microns in width.[51] A magnification of 125X cannot detect asbestos fibers thinner than 0.9 microns and would generate even higher rates of false negative results.[52]

Manipulation of asbestos definitions

The 1974 Glossary of Geology quotes Humpty Dumpty to describe the poor state of geologic definitions of minerals. The TM&MCs took advantage of the lack of consensus for the definition of asbestos to avoid reporting asbestos in talc. For example as recently as this year Julie Pier, the Imerys' microscopist and chair of the ASTM working group developing test methods for asbestos in talc, testified that fibrous tremolite was "not necessarily asbestos" depending on "the definition of a fiber…We use the term 'tremolite asbestos.' We determine whether it's asbestiform or not. 'Fibrous' has had different meanings in the past so that's not an accurate term to use."[53] This definition allows Imerys to state that previous reports of fibrous tremolite were not necessarily asbestos. The CTFA J4-1 limited counting to fibers with aspect ratios >5:1, in opposition to OSHA which required counting fibers with aspect ratios > 3:1.[48, 54, 55]

In certain cases, TM&MCs claim that the tremolite, anthophyllite, and/or actinolite present in their talc is not asbestos because these particles do not meet requirements for a geological definition of asbestos. For example, Dr. John Hopkins, J&J's legal corporate representative, claimed that the following tremolite findings are not asbestos: "cleavage fragment," "rod," "fiber-form," "needle," "particle," "acicular" and even "asbestiform" and thus safe to use in a consumer products.[56] Contradictorily, he claimed in previous testimony that J&J testing for acicular fibers were tests for asbestos fibers.[57] The TM&MCs went further by controlling the American Society for Testing and Materials (ASTM) testing standard for asbestos. J&J's Ashton took charge of the ASTM committee on the definition of asbestos and arranged to have the definition exclude asbestiform fibers in talc. [55, 58-60]

In 1994, OSHA modified the definition of asbestos at the urging of RT Vanderbilt, a talc mining company, and their consultant geologist, Ann Wylie. Although OSHA removed "cleavage fragments" from the regulatory definition of asbestos fibers, OSHA never changed the counting rules. [60] Therefore "cleavage fragments" that meet the asbestiform criteria are still counted as asbestos. TM&MCs' representative Richard Zazenski recounted: "I closely followed the OSHA Vanderbilt debate during the 1980's and early 1990's. 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."[61]

Imerys' Julie Pier adopted Wylie's definition for an asbestos fiber in order to make the claim that their products are free from asbestos, including a claim that not all fibrous tremolite was asbestos.[53, 62] Wylie substituted a geologic definition for asbestos rather than a definition based on the health effects of asbestos determined by the size and shape and physical properties of asbestiform fibers. For example Wylie's definition excludes most asbestos fibers found in the pleura of patients who died for mesothelioma. [63-65] Wylie distinguishes "cleavage fragment" of the same size and shape as asbestiform

fibers from asbestiform fibers which she claimed had to be formed as in an asbestos habit as bundles of fibers.[66] However, these "cleavage fragments" have the same chemical formula, length, width, aspect ratios and surface properties of asbestiform fibers.[67] The "Wylie Definition" incorrectly interpreted Stanton's 1981 paper to claim that to be called asbestos a fiber had to have a minimum 20:1 aspect ratio; otherwise, it was a "cleavage fragment."[68] However, OSHA defined as asbestos fibers that had a 3:1 aspect ratio or greater, and determined that cleavage fragments that met this definition were indeed fibers.[60] Moreover, exposure to "cleavage fragments" has been shown to be harmful to humans.[69] Prior to recent litigation, TM&MCs had determined that "rods," "needle" and "acicular" shaped particles were asbestos fibers.[70, 71]

TM&MCs also required finding a 'population' of fibers in order to report the presence of asbestos in talc. In 1977, J&J first proposed a TEM procedure stated that a single asbestos fiber would result in a positive test result.[72] In 1989, J&J changed the procedure to require the presence of five asbestos fibers of the same type to trigger a positive result.[73] Under this new procedure finding as many as 16 asbestos fibers (four for each type) was to be recorded as "non-quantifiable" and thus safe for consumer use.[73]

McCrone reported their findings of anthophyllite and chrysotile fibers as "Examination found no quantifiable amounts of asbestiform minerals."[74] In 2018, J&J's corporate representative admitted that "not detected" is different from "not quantifiable," stating "So the requirement is not detectable. The requirement is not 'not-quantifiable.' There's a huge difference between the two."[75] Despite the minimum 5 fiber of the same type requirement for a positive finding, J&J's corporate representative testified that "Our standard is not detectable. Even a single fiber would cause that to be an issue."[75]

Sampling errors

Talc ores contain a variety of accessory minerals including asbestos. These are not uniformly distributed in the mines or the ore.[76] Because asbestos is not homogenous in talc mines or ore, TM&MCs' sampling is inherently inaccurate. [77] Minnitt et al. noted that non-homogenous distribution of accessory minerals results in a "Sampling Fundamental Error." [77] Minnitt et al. noted, "Fundamental Error" arises "because of the compositional and distributional heterogeneity, both factors acting to prevent the sample being representative of the whole rock pile."[77] Compositional heterogeneity represents "a reflection of the differences in the internal composition between individual fragments of sampled ores," while distributional heterogeneity is "the difference in average composition of the lot from one place to the next in the lot."[77] Moreover, Minnitt et al. noted that "Contrary to the popular belief that errors are self-compensating, sampling variances are additive." [77] The distribution of asbestos in talc has both of these characteristics.

The "fundamental error cannot be removed" and eliminating the sampling errors "is not possible."[77, 78] In 1975, McCrone conceded that, "Homogeneity is a problem. The size of the resulting error is inversely proportional to the sample size."[79] In 1977, the National Bureau of Standards also noted that testing a talc sample with asbestos could still yield negative results due to "inhomogeneity and/or subjectivity in deciding fiber morphology."[32]

J&J and Imerys employed composite testing for talc quality control.[80] Imerys and J&J noted that testing "a composite taken from all floated production from the last quarter – hence [sic] not exactly traceable to an individual lot."[80] Moreover, the British Columbia Ministry of Environment that asbestos in talc is not "sufficiently homogeneous to warrant compositing."[81]

After the late 1970s, TM&MCs only conducted TEM analysis for asbestos in consumer talc products once every three to six months.[82, 83] J&J sent a single composite sample weighing 100

nanograms for every 650 tons to McCrone/Julie Pier for quarterly TEM testing.[83] During at least one four-year period (2001-2004), Julie Pier failed to test these samples.[84] An independent auditor told Imerys that their sampling techniques would not produce representative results: "Samples for the incoming raw material are taken from the large rocks and are not representative for the incoming raw material lot. Samples for the finished product are taken from the distribution line before product bagging and are not properly representing the microbiological level of the finished product."[85]

A TEM analysis only analyzed a drop from the tip of a micropipette.[86] As a result, without pre-concentration a TEM was not representative of even a fraction of the 650 tons of talc. Julie Pier testified that in 30 years, she had only tested 0.0002 grams of talc.[87] In other words, without preconcentration it would take TM&MCs 630,000 years to completely test an ounce-and-a-half J&J Baby Powder bottle.

Manipulation of test results - some examples

Historically, TM&MCs have relied on manipulated asbestos definitions to avoid regulation. TM&MCs hired McCrone Associates to carry out asbestos test on their talc products.[88] Since 1973, McCrone Associates had found chrysotile asbestos fibers in J&J Medicated powder, J&J Shower to Shower and Hammondsville (VT) cosmetic ores.[89, 90] After discussing these results on the phone with J&J, McCrone concluded that these chrysotile fibers were due to background contamination.[91, 92] However, in 1995, J&J reviewed the issue of "contamination" and concluded that "As of the time of this writing, background correction has not been necessary. The amount of background asbestos detected has been insignificant in comparison to the levels of asbestos found in contaminated samples."[73]

J&J also hired McCrone Associates Inc. to test a variety of their products, including 344L baby powder in 1971 and 108T and 109T baby powders (Lewin samples 133 and 134) in 1972.[93, 94, 95] In the original, unpublished report to J&J, McCrone found 0.2-0.5% tremolite in the 108T and 109T samples.[93] These results, however, were quashed by J&J: McCrone's original report, dated October 27, 1972, had a

handwritten note: "DO NOT USE THIS REPORT. REPLACED BY ANOTHER VERSION."[93] McCrone issued a re-written second report on the same tests on November 15, 1972 with their "modified thinking" on the samples.[95] Their report (which was dated October 27, 1972) claimed that there was no asbestos in J&J products. J&J submitted this version to the FDA on November 29, 1972.[96] In 1990, McCrone Associates found anthophyllite and chrysotile fibers in Cyprus talc, J&J's supplier at this time. However, McCrone changed the standard report language that was required by J4-1 from "no asbestos detected" to asbestos content that was "non-quantifiable."[74]

Some talc that was known to contain asbestos was sold

Shipping product that contained asbestos

Some TM&MCs shipped their talcs before testing for asbestos. For example, Imerys tested a "grab" sample of every five tons of talc for asbestos.[97, 98] Imerys procedures called for testing after the ore was shipped.[99, 100] Colgate-Palmolive tested and found asbestos in ores and products that had been shipped.[101-103] WCD shipped talc ores that had been found to contain asbestos.[104, 105]

Backlogged testing

In 2004, KCRA-TV, an NBC-affiliated television station licensed to Sacramento, California, detected anthophyllite asbestos in J&J Baby Powder.[106] In response, "J&J called us [Julie Pier] frantically, because some outside lab apparently found asbestos in off-the-shelf baby powder."[84] Julie Pier admitted that talc shipped to J&J had not been tested for asbestos for four years: "I was supposed to be doing quarterly samples by TEM, but they were all in the backlog. Since 2001. Oops ... I had to scramble and try to catch up."[84]

Test results showing asbestos in talc

686 of 1,032 tests produced in litigation revealed the presence of asbestos in talcs used in cosmetics from 1948 through 2017.[107] (See Figure 1.) Asbestos was found in talc by at least 11 major

TM&MCs and 10 different mines. A number of asbestos types have also been found in TM&MCs' talc: anthophyllite, tremolite, chrysotile, antigorite, amphibole, richterite and fibrous talc.

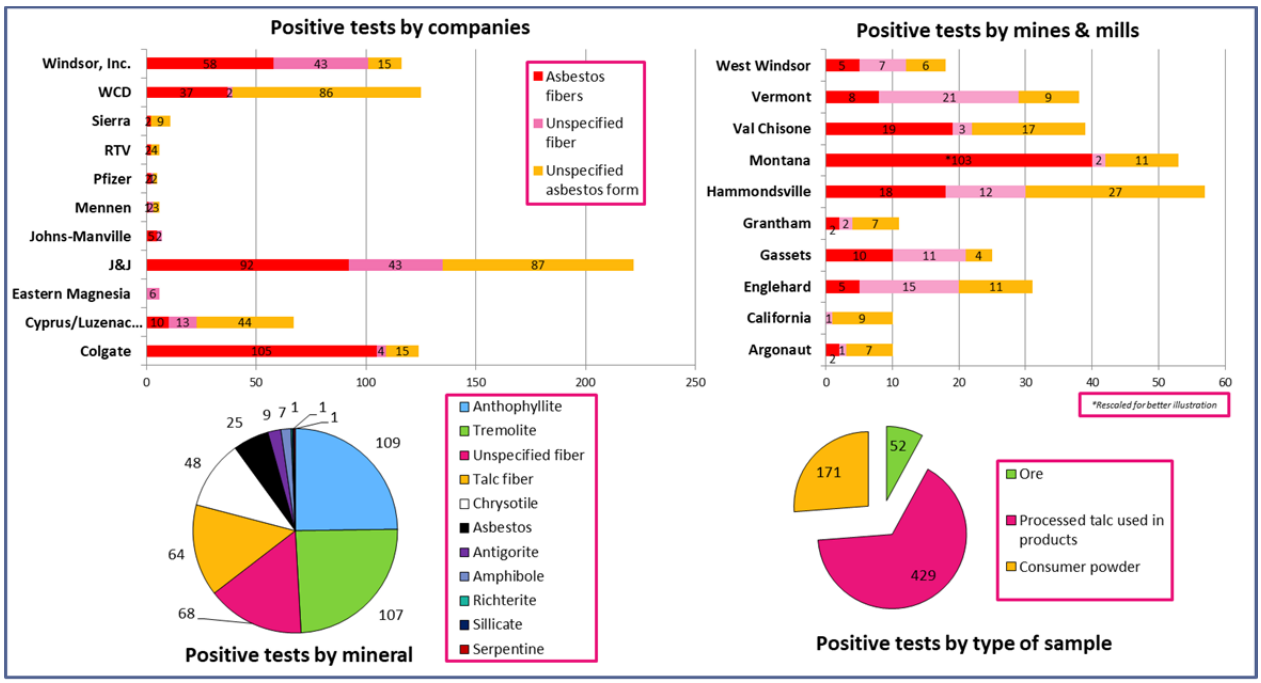


Figure 1: Results of tests showing the presence of asbestos in talc

Presence of asbestos revealed in corporate documents

TM&MCs claimed that their talcum powder was "pure," asbestos–free talc that came from "clean mines" that did not contain asbestos.[108] In 1989, with the aim of quashing potential lawsuits, William Ashton, head of the Research Division at Johnson & Johnson (J&J) Baby Products Company, swore in an affidavit that, "From the 1940s through the 1980s, talc mined in Vermont and specifically, the talc mined by Engelhard Corporation (and its predecessors) from the talc mine located in Johnson, Vermont has been considered to be talc free from contamination by asbestos" to quash potential lawsuits.[109] However, J&J and others had found asbestos in all Vermont talc.[110, 111] (See Table 1) J&J consultants, Dr. Fred Pooley and Dr. Alice Blount, also confirmed these findings of asbestos in Vermont talc mines.[30, 112]

Table 1: Evidence of asbestos in Vermont talc mines.

Mine	Asbestos found	Description of Geology	Location (County)
Hammondsville	Chrysotile, tremolite, amosite, antigorite, actinolite[30]	Country rock consisting of quartz-mica schist. Steatite in contact with foliated/bedded schist[113]	Windsor
Argonaut	Tremolite Chrysotile	Quartzite and quartz-plagioclase granulite with greenish quartz-sericite-chlorite phyllite and schist, and minor carbonaceous phyllite[113]	Windsor
Greeley Quarry	Actinolite[113]	Altered basic igneous intrusion altered to serpentine in contact with quartz-muscovite schist Masses of actinolite in serpentine[114]	Windsor
Waterbury Mine	Chrysotile[113]	Irregular band of schist country rock in contact with serpentine mass. Serpentinization of talc from non-schistose intrusion[113]	Washington
Johnson Mine	Chrysotile	Ultramafic mass altered to grit and steatite with remnants of serpentine. Larger part of steatite zone derived from serpentine[3]	Lamoille
Carleton Quarry (Chester Talc mine)	Anthophyllite, Actinolite[113]	Ultramafic units with 10 unnamed subdivisions with amphibolite and hornblende gneiss and schist, amphibolite, and quartzite[113]	Windsor
Ludlow	Chrysotile[113]	Ultramafic Rocks consisting of dunite,	Windsor

		peridotite, and serpentinite[113]	

In the introduction to its study of the Vermont talc mines, NIOSH claimed that "geological studies dating from the early 1900's have shown that the Vermont talc deposits contain no asbestos…[115] They based this conclusion on the misleading assumption that "geological studies dating from the early 1900's have shown that the Vermont talc deposits contain no asbestos."[115] However, as noted in Table 1, geologists had repeatedly reported the presence of asbestos in association with talc mine locations beginning in 1872. Moreover, J&J exerted considerable influence over NIOSH's understanding of the mine geology. Vern Zeitz, the Windsor mill manager, described how he swayed NIOSH:[116]

> *Numerous preliminary meetings were held involving both Harvard and NIOSH on the pretense of protocol reviews; while in reality were structured as a "crash course" in ultramafic and serpentine mineralogy, including lectures on geochemistry directed at the metamorphic pathways, through which talc, and its accessory minerals are formed….*
>
> *A great deal of effort was expended by representatives of Windsor Minerals and Johnson and Johnson to develop defensive and offensive opportunities through this approach, which relied upon low keyed but highly persuasive intellectual arguments. The process was extremely effective and allowed the subtle development of a strong strategic position with respect to this study and, if properly utilized, will have far reaching, positive long term corporate implications.*

J&J did not tell NIOSH that they had repeatedly found chrysotile and tremolite asbestos and fibrous talc in their Vermont mines and tried but failed to develop a reagent system to remove the chrysotile.[19, 117, 118] In 1973, Nashed of J&J told the Department of HEW that "asbestos-form particles

cannot be removed from talc" and that the "Johnson & Johnson process for beneficiating Vermont talc, which we believe to be the most advanced in the field, will not guarantee a zero tolerance for elongated particles."[119]

NIOSH noted that PLM methods were not sensitive enough to detect asbestos in talc. Employing SEM NIOSH found level of asbestos as high as 1 f/cc in worker breathing zones. In addition, after meeting with J&J, NIOSH deleted references to finding trace metals and chrysotile in the ore. NIOSH noted that the NIOSH/USPHS method for counting fibers is invalid for a talc environment" because PLM cold not detect thin fibers.[120]

TM&MCs also had reports of asbestos in the Val Chisone mine in Italy, which supplied talc for use in cosmetics in the US. In 1974, in response to concerns about the presence of asbestos and other accessory minerals in talc used in cosmetics, the Societa Talco e Grafite Val Chisone (SVC), the owner of the Val Chisone mine, began distribution of a pamphlet titled, "Practical Guide to the Recognition of Impurities in Talc." The pamphlet stated that the Val Chisone talc ore used in cosmetics contained trace amounts of chrysotile and tremolite asbestos. [121] When J&J became aware of this admission they met with the owner of SVC and convinced them to withdraw the pamphlet.[122] SVC complied.[123] Dr. Edward McCarthy of Luzenac, a major US talc producer, listed tremolite and actinolite as the accessory minerals in the talc formations of Val Chisone, Italy.[17]

Although the TM&MCs never systematically tested for fibrous talc, episodic tests found fibrous talc concentrations that ranged from 0.1% to 20% in talc ore and cosmetic powders.[19, 124] From 1975 to 2003, J&J "cosmetic talc" came from a mine that contained 10-20% fibrous talc.[125, 126] As early as 1966, J&J learned of tremolite and fibrous talc in their products when they tested the quality of historic cosmetic talcs taken from their museum, but these findings remained internal.[127] Fibrous talc is formed by asbestos fibers chemically transitioning to talc, is regulated as asbestos, and is a Group 1 IARC

carcinogen.[128-130] Asbestiform minerals like fibrous talc have the same health effects as "asbestos."[131] Since 1972, OSHA has regulated fibrous talc as asbestos.[55, 132] In addition, J&J acknowledged that the presence of fibrous talc might drive government regulation of talc and eliminate its use.[133]

> *If the FDA Food Division, which 1s moving more rapidly than the Cosmetic Division, publishes a standard, it will probably be to ban asbestos-form or fibrous material in talc. That could eliminate the current uses of talc in packaging materials. These tales contain widely varying amounts of tremolite or fibrous talc.* ***Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (optical Microscope) and these might be classified as asbestos fiber.*** *[Emphasis added]*

Additionally, in 1973, J&J privately acknowledged that there were no "clean mines": [133]

> *It is our joint conclusion that we should not rely on the 'Clean Mine' approach as a protective device for Baby Powder in the current Asbestos or Asbestos-Form controversy. …we are also confident that fiber forming or fiber type minerals could be found. The usefulness of the 'Clean Mine' approach for asbestos only is over.*

The TM&MC trade organization, The Cosmetic, Toiletry, and Fragrance Association (CTFA), also admitted that asbestos could not be removed from talc ores, and that all talc ores have been shown to contain asbestos.[134]

Previously secret company testing and misrepresentations to the FDA

In March 1976, the CTFA sent the FDA a packet of eleven letters from talc mining and manufacturing companies which purportedly summarized their tests for asbestos in talc.[135] These letters urged the FDA not to regulate asbestos in talc and assured the Agency that cosmetic talc

products were asbestos-free. McCrone – who tested talc for Avon, Bristol-Myers, Chesebrough-Ponds, Colgate-Palmolive, Faberge, Johnson & Johnson, Windsor Minerals, and Whittaker Clark and Daniels – falsely claimed that cosmetic talc had never contained chrysotile, and no longer contained other asbestos minerals.[135] (See Table 2 below.) By this time, J&J was aware that at least five laboratories had found chrysotile in their talcs from Val Chisone (Italy) and Vermont.[136, 137] Pfizer, Fulham, and McCrone found chrysotile in Whitaker, Clark, and Daniels talc ore from Montana and Val Chisone (Italy).[138, 139] In 1973, Johns-Manville found chrysotile in Val Chisone talc ores.[140] From 1946 to the early 1980s, J&J, Colgate-Palmolive, Avon, Cyclax, Yardley, Coty, Gala, Shulton, and Elizabeth Arden used talc from the Val Chisone mine in their consumer talc products.[141] McCrone also found chrysotile in Cashmere Bouquet.[138] TEM is much more sensitive a method than XRD for detecting asbestos in talcum powder. By March 1976, McCrone found chrysotile (using an electron microscope) in 22 tests performed for cosmetic talc companies, and reported, from 1973 to 1976, findings of asbestos in 124 tests for cosmetic talc companies. In 1972, TEM tests on Shower to Shower (performed at the University of Minnesota Space Science Center and commissioned by McCrone and Johnson & Johnson) reported that "crysotile [sic] asbestos does exist in the specimens of Shower to Shower."[142] Despite having found chrysotile in many of their talcs, the TM&MCS told the FDA that chrysotile had not been found, stating that they "questioned the need for a regulation on chrysotile since no sample has yet to be confirmed as containing this material [chrysotile]."[143]

Table 2: Findings of chrysotile in talc used in cosmetics prior to 1976.

Date	Laboratory	Company	Findings
8/6/1971	Colorado School of Mines Research Institute (CSMRI)[136]	J&J	Chrysotile in Val Chisone talc
9/3/1971	Walter C. McCrone	J&J	Chrysotile fibers in J&J medicated

	Associates, INC.[144]		powder and Shower to Shower
6/12/1972	ES Laboratories[139]	Pfizer	Chrysotile in Pfizer talc
10/19/1972	Dr. Lewin report to the FDA[137]	J&J	2-3% Chrysotile in J&J Baby Powder and Shower to Shower
9/4/1973	Johns-Manville[145]	Johns-Manville	1880 fibers/mg in Val Chisone talc
10/16/1973	Ernest F. Fulham, INC.[146]	WCD	Chrysotile in WCD talc
2/5/1974	Walter C. McCrone Associates, INC.[138]	Colgate-Palmolive	Chrysotile fibers in Colgate-Palmolive powder

In the same March 1976 submission to the FDA, the CTFA and TM&MCs made various other misrepresentations about the presence of asbestos in their talcum powder products; these are summarized in Table 3 below.

Table 3: Summary of misrepresentations in March 1976 CTFA submissions to the FDA.

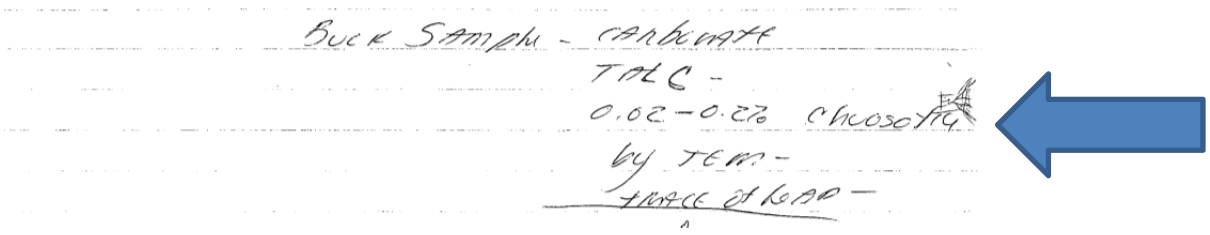
Company	**1976 misrepresentation to the FDA**[135]	**One contradictory finding to TM&MCs' claim***	**Date**
Avon	"A total of 170 samples of talcs used in our products were examined [for chrysotile] by McCrone and can be reviewed by authorized people… The results were negative…We have analyzed about 250 samples of talc receipts in-house by DTA for chrysotile and IR for tremolite…The	20-25% tremolite in antiseptic talcum powder[147]	3/14/1972

	results were negative."		
Chesebrough-Pond's	"The last 84 reports, covering a three-year period, are, without exception, negative for chrysotile and negative for fibrous amphiboles."	5% tremolite, trace chrysotile in Vaseline Intensive Care, Beloved Perfumed Dusting Powder, Prince Matchabelli[148]	10/1/1973
Colgate-Palmolive	"The results of these analyses indicate to us that talc products produced by the Colgate-Palmolive Company since 1972 are free of asbestos minerals when subjected to the most sophisticated methodology available."	Chrysotile fibers in Colgate-Palmolive powder[138]	6/12/1972
J&J	"No amphiboles or serpentine minerals were detected in any sample."	Chrysotile in Val Chisone talc, 2-3% Chrysotile in J&J Baby Powder and Shower to Shower,[136] Chrysotile fibers in J&J medicated	1971-1972

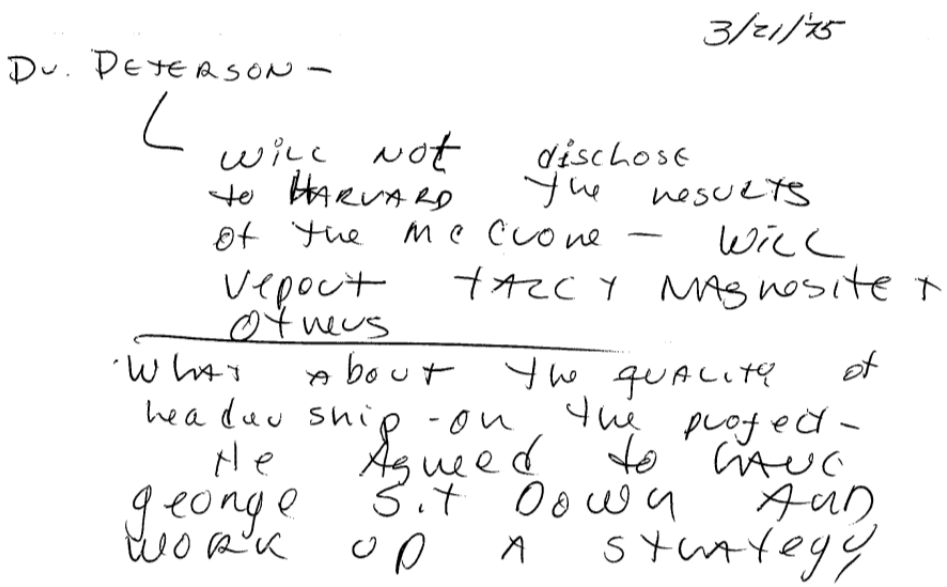
		powder and Shower to Shower[144]	
McCrone Associates	"No chrysotile asbestos was found in these [J&J] talcs."	Chrysotile fibers in Windsor Minerals talc 66 used in J&J Baby Powder[89, 90]	5/14/1974
	"Since 1973 none of the talcs which we have examined and which have been identified to us as production materials have shown any detectable levels of either chrysotile or asbestiform amphibole."	McCrone changed tremolite findings to "a few isolated crystals," "a few individual crystals" or "a few tremolite rods."[149]	10/27/1972
Sterling Drug	"There was no detectable asbestiform minerals present in these samples."	2% tremolite, 3% chrysotile in ZBT Baby Powder[148]	10/1/1973
Whittaker, Clark & Daniels (WCD)	"In August 1971 a test program was instituted by our company to insure customers using our cosmetic grade talcs that they are free of fibrous asbestos…show non-detectable amount of fibrous asbestos form minerals."	Chrysotile in WCD cosmetic talc found by Ernest F. Fulham laboratory[146]	10/16/1973

**There are more positive test results of finding asbestos in cosmetic talcum products summarized in the next section.*

In 1975 NIOSH and Harvard did a study of some Vermont mines. J&J had McCrone test ore (bulk) samples and found chrysotile asbestos.



J&J deleted this finding and did not give it to NIOSH or Harvard. As a result the published study claimed the J&J mine was asbestos free.



Published studies on asbestos content of cosmetic talc after 1976

Many published papers have reported the presence of asbestos in consumer cosmetic talcs.[17, 24, 30, 106, 150] In 1991, Dr. Alice Blount - a mineralogist who tested for asbestos in talc at the request of many talc mining and manufacturing companies including J&J - examined "High -grade talc products from five deposits in Montana, three in Vermont, and one each in North Carolina and Alabama" and found

tremolite fibers in J&J Baby Powder made from talc from the Hammondsville Vermont mine processed at the Windsor Vermont mill.[30]

Paoletti et al (1984) found tremolite in two of six Italian cosmetic talcum powders and tremolite, anthophyllite or chrysotile in 6 of 14 talc samples provided by the European Pharmacopeia.[151] From 1996 to 2005, Mattenklott (2007) found asbestos in 13 of 57 talcum powder samples from on the German market.[152] Jehan, using PLM, XRD, AA and SEM found tremolite, anthophyllite and chrysotile in cosmetic grade baby and body powder used in Pakistan.[153]

Ilgren et al. (2017) found 3.687 x 10^6 [tremolite asbestos] fibers/gram in cosmetic talc that came from the Val Chisone mines of Italy manufactured in 1971.[154] In response to recent litigation, several laboratories have been retained by plaintiffs and T&MCs to test current and historical cosmetic talcs. Gordon et al. (2014) reported average airborne fiber concentrations of 4.8 f/cc during use of Cashmere Bouquet talc powder. Gordon reported that 1.9 f/cc of the fibers were asbestos; the remaining 2.9 f/cc were fibrous talc.[155]

TM&MCs' litigation-related testing

J&J and Colgate-Palmolive commissioned ChemRisk to evaluate the presence of asbestos in cosmetic talc. [156] The investigators concluded that asbestos could not be detected in the tested talcs. However, Pierce et al. (2017) used insensitive methods and failed to use the pre-concentration method.[156] Pierce et al. utilized the EPA "Method For The Determination Of Asbestos In Bulk Building Materials."[62] Talc is not a bulk building material. An asbestos test method and counting criteria must be adapted to meet both the specific setting in which the asbestos is found and its concentration in that environment. Pierce's formula to convert dust to fiber concentration is based on a study by Kleinfeld et al. (1973) who explicitly stated "In both talc plants there was no correlation between the fiber count and mean dust count."[157] Pierce et al. assumed a 0.1 % concentration of asbestos in talc and used their

faulty mathematical model to conclude that exposures were below "background." However, Addison et al. actually tested airborne exposures from soils containing 0.1% asbestos and found 1.17 - 2.29 asbestos f/cc in the air, 10,000 times above background.[158]

Moreover, TM&MCs' expert witnesses manipulated another experiment that measured actual fiber exposures from using cosmetic talc.[159] Study authors had the microscopist change his interpretation of fiber that he had identified from "anthophyllite" to "no fibers were found."[159] Steffen & Egilman (2018) also noted that "Deviations from the referenced analytical methods, however, would account for the small number of fibers counted relative to the limit of detection."[159] Additionally, the authors did not concentrate asbestos in the talc before testing. Without pre-concentration, it is virtually impossible to correctly identify asbestos in talc.[30] With respect to light microscopy, Johns-Manville recommended that a minimum of 200 fields should be viewed where fibers were not found, "For this reason all of the earlier low number chrysotile counts based on only 20 fields must be disregarded."[160]

Dr. William Longo used an Eppendorf micro-centrifuge (Model No. 5415D) to concentrate talcum powder before analyzing the samples under the JEOL 1200EX TEMs equipped with either a Noran or an Advanced Analysis Technologies (light element). By adopting a proper testing method, Dr. Longo detected asbestos in both J&J Baby Powder and Colgate-Palmolive Cashmere Bouquet.[161, 162]

FDA 2010 talc survey

In December 2009 John Gasper, FDA, presented a PowerPoint to PCPC titled "Talc - FDA's Perspective" which alerted the industry to the FDA talc survey (IMERYS246773 - IMERYS246781). From September 2009 to September 2010, the FDA conducted a survey to test for the presence of mineral fibers in cosmetic grade raw talc.[163] The FDA commissioned AMA Analytical Services Inc. (AMA) to test 34 cosmetic talcum materials. AMA Analytical performed a total of 204 analyses on these samples using PLM and TEM.

Following a meeting at the Regulatory Science Summit in December 2009, Julie Pier of Rio Tinto Minerals told John Gasper, FDA, that AMA Analytical Services Inc. is "very reputable in the analysis of building materials" but "is not experienced in the analysis of mineral materials."

The FDA reported, "[AMA] found no asbestos fibers or structures in any of the samples of cosmetic grade raw material talc or cosmetic products containing talc." The FDA concluded that "the survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc of cosmetic products containing talc" but the results were "limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested.. There is no evidence AMA spiked any samples with tremolite or chrysotile that would be representative of chrysotile levels in cosmetic talc to determine an actual level of detection.

The AMA used an incorrect mathematical model to calculate the analytic sensitivity of the method. The analytical sensitivity in weight by the ATEM method is based on the theoretical mathematical calculation of one fiber which can give a computed analytical sensitivity in the millions of a percent. However, in order to find the fiber during the ATEM analysis, the real numerical fiber-bundle concentration per gram of talc for the analysis must be known, otherwise the ATEM theoretical analytical sensitivity expressed in weight percent is meaningless.

The FDA claimed the ATEM method had a limit of detection of 0.0000021% or 2.1×10^{-6}. 15 However, when the calculated ATEM analytical sensitivity based on the actual AMA TEM bench sheets, indicate that the numerical fiber concentration needed to find the single fiber was 13,500,000 fibers per/gram of talc. Thus the LOD was much higher than the FDA reported.[161] Recently both the FDA and J&J's testing laboratory RJ Lee Company found chrysotile in current off the shelf J&J cosmetic talc powders. As is par for the course, as described above, J&J's testing laboratory claimed the results were due to "contamination" despite the fact that the control samples were negative. In 2016 J&J audited RJ

Lee. J&J noted that RJ Lee found chrysotile in J&J cosmetic talc but reported the result as no asbestiform minerals detected.

> The Laboratory report stated that for each Talc Sample number, there was no asbestiform minerals detected. The report is signed and dated by Craig Huntington, Analyst on 2/11/2016. The Tracking sheet listed that final proof reading by Manager was done on 2/11/2016. Point Count Data Sheet for the samples indicated that there were no asbestos (chrysotile, amosite, crocidolite, anthophyllite, tremolite, actinolite) or non-asbestos fibers (cellulose, fiberglass, hair, mineral wool, synthetic fibers, wollastonite)…The samples were re-prepped and it indicated that Sample in ID# 3138494 had multiple chrysotile particles. Repreparation could not duplicate the original results. This issue was just noted in the J&J Project Report and there was no investigation into whether this was analyst error or was this chrysotile inherent in the sample itself.

Discussion

In a 2004 submission to the National Toxicology Program regarding the question of talc's carcinogenicity, the CTFA claimed that their talc products have been asbestos-free since the creation of CTFA method J4-1, even though the method was not finalized until 1977: [108]

> *In 1976, CTFA promulgated a specification for cosmetic talc to ensure that it is* ***free of asbestos****. As a practical matter, that specification is self-enforcing. Asbestos has been listed as a known human carcinogen, is highly regulated, and no consumer products company would knowingly run the risk of asbestos being present in its product, even in minute quantities. This is a matter both of public perception and potential litigation exposure. Therefore, both suppliers and end users go to great lengths to assure that the*

CTFA specification is met. In some cases, cosmetic talc producers augment the quality assurance process by utilizing additional detection precautions such as transmission electron microscopy. [Emphasis added]

Prior to this unfounded 1976 claim that there was no asbestos in talc, Colgate had no official certification from anybody that their product was asbestos-free.[97]

In 2016, Johnson and Johnson reiterated this asbestos-free claim as Fact #1 on their website page, *Facts About Talc*:[165]

> Since the 1970s, talc used in consumer products has been required to be asbestos-free, so JOHNSON'S® talc products do not contain asbestos, a substance classified as cancer-causing. JOHNSON'S® Baby Powder products contain only U.S. Pharmacopeia (USP) grade talc, which meets the highest quality, purity and compliance standards. The company's sources for talc are routinely evaluated using a sophisticated battery of tests designed to ensure compliance with all global standards.

Talc company corporate representatives testify that they have a "zero tolerance" policy for asbestos in talc. J&J even asserted that "Zero means zero" regarding their "zero tolerance policy for asbestos minerals in its baby powder."[166, 167] Colgate-Palmolive and Johnson & Johnson have taken a public position that they have a "zero tolerance" for asbestos in talc used in cosmetics.[166, 168] As a result, medical researchers and epidemiologists who have published on this issue have interpreted these industry assertions to be correct and assumed that cosmetic talc has been asbestos-free since 1976.[169-179]

Conclusions

Talc-based cosmetics and powders contain asbestos. Ironically, in a 2004 submission to the National Toxicology Program, the CTFA admitted that talc products manufactured before they developed this test (but sold and used *after* 1976) contained asbestos: "the inference that after 1976, exposure was to non-asbestiform talc, may not be justified. All that can be assumed is that at some unknown time after 1976, the ratio of the use of asbestiform to non-asbestiform talc presumably declined."[108] They dubbed this the "fatal flaw" defense. The CTFA deemed the epidemiologic studies that found a statistically significant association between perineal talc use and ovarian cancer as "fatally flawed." The CTFA claimed that these talc users in the studies were exposed to asbestos, which could have caused the cancer excess, because they purchased talcum products sold before 1976. However, talc companies cannot ensure that talc used in cosmetics is asbestos-free. There are no known test methods with a limit of detection of zero. Despite having high limits of detection, some tests have found asbestos in cosmetic talc products. IARC has classified asbestos as an ovarian carcinogen and epidemiologic studies have shown as association between talc use and ovarian cancer.

Sincerely yours,

David Egilman MD, MPH

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