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TALC

COSMETIC, TOILETRY and FRAGRANCE ASSOCIATION, D.C.

CTFA REPORT ON ASBESTOS AND TALC MEETING

A discussion on "asbestos and talc" was held on Tuesday, August 3rd, 1971 at the Food and Drug Administration laboratories, 200 C Street, N.W., Washington, D.C. Those in attendance were:

Dr. Raymond E. Barzilai, FDA
Dr. Murray Berdick, Chesebrough-Pond's, Inc.
Mr. W.T. Cancer, Johnson & Johnson
Dr. Armand R. Casola, FDA
Mr. William Cook, FDA
Mr. Paul Corneliusson, FDA
Dr. Lewis J. Cralley, National Inst. of Occupational Safety and Health
Mr. William V. Eisenberg, FDA
Dr. Norman F. Estrin, CTFA
Mr. Hyman R. Gittes, FDA
Dr. A. Goudie, Johnson & Johnson
Dr. Gene Grieger, Johnson & Johnson
Dr. Paul Gross, Medical University of South Carolina
Mr. Keith Heine, FDA
Dr. Gavin Hildick-Smith, Johnson & Johnson
Mr. Morris Kaplan, Consumers Union
Dr. Charles Kokoski, FDA
Dr. Alfred Kolbye
Dr. Herman F. Krayhill, FDA
Dr. Jule K. Lamar, FDA
Dr. Arthur M. Langer, Mt. Sinai School of Medicine
Dr. Seymour Z. Levin, New York University
Dr. L.J. Maggiore, Mt. Sinai School of Medicine
Dr. Denis J. McGrath, FDA
Mr. S.R. Mountsier, Jr., Whittaker, Clark & Daniels
Dr. Wilson Mushed, Johnson & Johnson
Dr. Sylvan B. Norbunger, FDA
Dr. William J. Nicholson, Mt. Sinai School of Medicine
Dr. Norwood, Charles Pfizer & Company
Dr. Pooley, Johnson & Johnson
Dr. R.I. Polle, Johnson & Johnson
Col. [illegible], N.Y.C. Dept. of Air Pollution
Dr. [illegible], U.S. Geological Survey

Dr. Robert H. Schaffner, FDA
Dr. Irving J. Selikoff, Mt. Sinai School of Medicine
Dr. T.H. Shelley, Johnson & Johnson
Mrs. Manjeet Singh, FDA
Dr. Sidney Speil, Johns-Manville
Dr. Herold Stanley, Charles Pfizer & Company
Dr. Ian Stewart, Johnson & Johnson
Dr. George Thompson, FDA
Dr. Alfred Weissler, FDA
Dr. John A. Wenninger, FDA

Dr. Weissler opened the meeting by noting Mr. Kretchmer's suggestion that a survey of cosmetic talcs should be done to ascertain their possible asbestos content. Dr. Weissler felt the first step towards such a survey must be a discussion of available methods and the properties of asbestos and talc. With that introduction, Dr. Weissler introduced the first speaker, Dr. Malcolm Ross.

1. Asbestos and Talc Mineral Deposits, Dr. Malcolm Ross, U.S. Geological Survey

Dr. Ross discussed the chemical composition of asbestos and talc materials:

Talc - $Mg_3 Si_4 O_{10} (OH)_2$

Serpentine - $Mg_3 Si_2 O_5 (OH)_4$

Anthopyllite $(Mg, Fe)_7 Si_8 O_{22} (OH)_2$

Tremolite - $Ca_2 Mg_5 Si_8 O_{22} (OH)_2$ (also called actinolite)

Cunningtonite - $(Fe, Mg)_7 Si_8 O_{22} (OH)_2$ (also called grunerite)

Hornblende - $Na_4 (Ca, Na)_2 (Mg, Fe, Al)_5 (Si, Al)_8 O_{22} (OH)_2$

Crocidite - $Na_4 (Mg, Fe, Al)_7 (Si, Al)_8 O_{22} (OH)_2$

Dr. Ross stated that with the exception of the first two minerals, the remainder were in a fibrous habit and are termed "asbestos." Other terms often used for these materials are "amphiboles" and "metabasalt minerals." During the discussion, Dr. Speil offered a definition of asbestos: "Asbestos is a generic term for a variety of hydrated silicate minerals which have one attribute - the ability to separate into soft fibers (often silky) minerals." Dr. Ross noted that serpentine minerals include chrysotile and that there are many types of asbestos.

2. Fibrous Content of Cosmetic Talcum Products, Dr. L.J. Cralley, National Institute of Occupational Safety and Health, Cincinnati, Ohio.

Dr. Cralley noted that his area of interest was the study of talc workers and the fibers found in autopsy. He discussed in detail his paper entitled, "Fibrous and Mineral Content of Cosmetic Talcum Products" which appeared in the American Industrial Hygiene Association Journal, Volume 29, July-August, 1968, pp. 350-354. (Copies are available from CTFA upon request.) Dr. Cralley discussed four major areas of concern:

A. Features of talc which may relate to health and exposure. The areas of concern here are the nature and extent of respirable fibers and the nature and extent of trace metals.

B. Sources of potential contamination. The ore itself, contamination from the processing of the ore, and additives during formulation are possibilities.

C. Presence of fibers and trace elements. In a study of 22 cosmetic talcum products, chromium, cobalt, nickel and manganese were found in low levels in most cases. One talc had 53% free silica. A range of 8-30% fibers were found in these talcs.

D. Methods of measuring exposures. Atomic adsorption, emission spectography, and microscopy were Dr. Cralley's tools. Dr. Cralley concluded that there are sources of talc available that have a low trace metal content and that trace metal content should be considered further in assessing the safety of talcs.

3. Biological-Medical Significance of Asbestos and Other Fibers; Dr. I.J. Selikoff, Mt. Sinai School of Medicine; Dr. G. Hildick-Smith, Johnson & Johnson; Dr. Paul Gross, Medical University of South Carolina

Dr. Selikoff opened his discussion with the observation that the problem under discussion today could not have been discovered earlier or acted upon earlier by the Food and Drug Administration, so that no criticism could properly be leveled at the FDA. Dr. Selikoff chronologically traced the evolution of the problem by quoting extensively from the literature:

A. Industrial Bulletin, W. Siegel, Volume 22, pp. 436, 1943. [illegible] talc miners and millers in St. Lawrence Co., New York were examined by x-ray. Light [illegible] of 30, six (7%) had fibrosis. Of 92 [illegible] the age of ten to 29, 26 (28%) had fibrosis. 91 [illegible]

recently, as with the asbestos worker, the problem was considered only as occupationally related.

The biological potential for talc was well recognized, but perspective has now changed because people exposed to asbestos have now had the opportunity to develop lung cancer.

Insulation workers were examined in 1943. The total deaths of asbestos workers were as follows:

	1943-47	1948-52	1953-57	1967
Observed	28	54	85	94
Expected	39.7	50.8	50	47.5

Thus, peritoneal mesothelioma (cancer of the lining of the lung), normally rare, increased dramatically in people exposed to asbestos. By June 30th, 1971 in a study of 425 deaths among 632 men, 85 (20%) died as a result of lung cancer. Twenty (4.8%) were due to peritoneal mesothelioma. Thus, a new dimension has been added -- cancer which may or may not be dose related.

Dr. Selikoff emphasized a long lapse period for action by asbestos. Most effects occured between 25 to 40 years from the onset of exposure.

In the last several years it has been demonstrated that the effects are not only found in asbestos workmen. In a study of 1,117 persons, 57.9% showed calcification 40 years after onset of exposure.

B. Kivilvoto reported in Acta Radiologia. Suppl., Volume 194, p. 1, 1960, the following:

	Total X-Rayed	Asbestostic Pleural Calcification
Asbestos Mine Workers	6,312	499
Non-Mine Workers	7,101	0

Dr. Selikoff found that many different types of mineral fibers can produce this effect.

C. Thompson, South African Medical Journal, Volume 37, p. 77, 1963, reported similar results on 500 consecutive autopsies. Dr. Selikoff, during the period of 1966 to 1968, found similar results in 3,000 consecutive autopsies. In 28 out of 28 consecutive lungs examined, fibers of chrysotile were found in New York City. In every case plating particles were found in the lungs. Dr. Selikoff added that the biological potential of plates and fibers are not known at this time. What is known, however, is that our lungs are being contaminated. Dr. Selikoff found three cases of mesothelioma in 30 years of practice corresponding to one in 10,000 of the general population.

D. Wagner, reported in the British Journal of Industrial Medicine, Volume 17, p. 260, 1960, 47 cases of mesothelioma. All the subjects had prior asbestos contact. Some were workers, others were not. In a study from a London hospital, 76 cases of mesothelioma were found. Of the 76, asbestos workers accounted for 31 cases, their relatives nine cases, people living within a half a mile of the asbestos plant 11 cases, and 25 who had no known exposure to asbestos. Lieben and Pistawka reported in 1967 observations of 42 cases of mesothelioma during the period 1958 to 1963. Twenty occured in industrial workers. The statistics of mesothelioma cases, or the ones in hospitals, during the years 1917 to 1964 were equally alarming. Before 1950, ten cases were observed. Between 1950 and 1959, 33 cases were observed. And between 1960 to 1964 some 40 cases were observed. Similar results were observed in Scotland where an increase of one case in 1950 to 20 cases in 1970 were observed. Harries, reporting in Anals. of Occupational Hygiene, Volume, p. 125, 1968, similarly reported a large number of cases from people who have no direct contact with asbestos. Whitwell, in Thorax, Volume 26, p. 6, 1971, reported similar findings. Thus, cases other than occupational exposure are beginning to be associated with cancer.

E. Kleinfeld, reported in the Archives of Environmental Health, Volume 14, p. 653, 1967, four times the expected rate of cancer for talc workers. This raises the question of whether less than occupational exposure to talc can be associated with lung cancer. Dr. Selikoff cautioned that little is known about actual talcs used in cosmetics. The cause of cancer is based on extrapolation and extrapolation only. This does not mean that the concern is [illegible]. Dr. Selikoff also [illegible] that asbestos workers who [illegible] of getting lung cancer. Dr. Selikoff also [illegible]

as well as in other organs and considered that their biological effects are unknown at this time.

Dr. Wildick-Smith noted that absence of complaints and literature reports over a period of 70 years has shown that tales are not a problem. In addition, he pointed out that an adult might use tale for a total of two months of chronic exposure in a lifetime. He added that this was just an estimate and that better data is needed. He also noted that cases of misuse of cosmetic tales are rare and that acute animal studies are also rare. He did find that when 50 hamsters were exposed to translite tale for 700 days, no tumors were found. During the discussion period, Dr. Roman took exception to Dr. Wildick-Smith's talk and spoke of the hazard to babies which could not be tolerated. Dr. Cralley observed that he was taking a great leap in discussing effects on users of tale where actual studies were performed on tale workers.

Dr. Paul Cross, of the Medical University of South Carolina, noted that there was very little hard data available on biological assays. He studied the behavior of various dusts in animals. Thirty rats were injected in the belly with tales of the type used in gloves. No adhesions were found, however, other types of tale can produce an effect. Injection of tales (including cosmetic tales) into hamsters showed no evidence of pulmonary fibrosis of the lungs after two years, although the dose was substantial. He inclued that the fibrogenicity and pathogenicity of tales depends on the percent of fibrous particles.

Dr. Cross noted that a controversy rages as to what is the critical size of the fibrous particle. Dr. Ian Webster (S. African Med. J.) reported that fibers less than five microns in length are capable of producing scar tissue. Thus, many fibers observed in tale would have little or no biological significance. However, much more work needs to be done in this area. During the discussion period, Dr. Selikoff was assured by Dr. Norwood, of Charles Pfizer and Company, that there is much tale available that contains no fibers.

4. Current FDA Interests in Asbestos; Dr. R.E. Parzild, Bureau of Drugs; Dr. O.K. Lewis, Bureau of Drugs; Dr. L.F. Pragnell, Bureau of Foods

Dr. Parzild reported that the Bureau of Drugs is concerned with mineral particles as possible contaminants of both prescription, [illegible] creams and dental drugs. He advised the group to consider [illegible] presented points of entry as well as the [illegible] of [illegible] tale. Dr. O.K. Lewis, of the Bureau of Drugs, [illegible] specific [illegible] data. Dr. L.F. Pragnell, [illegible]

question as to the asbestos content of beer was raised. It was poi[illegible] out that less than .001 micrograms per gallon of fiber is found in beer. This is of the same order of magnitude as found in water.

5. Consumer Interest in Asbestos, Morris Kaplan, Consumers' Union

Mr. Kaplan observed that apparently the data necessary to deal with this problem is not available at this time. He called for an interim decision on the basis of existing information, as well as long range action plans. He concluded that existing knowledge should be applied on the side of the consumer -- rather than the producer.

6. Cosmetic Industry Interest in Asbestos, Dr. Norman F. Estrin, The Cosmetic, Toiletry and Fragrance Association, Inc.

Dr. Estrin pointed out that the cosmetic industry has pursued aggressively a program of consumer protection and congratulated the FDA for organizing a seminar program where scientists from the industry, the FDA, and the academic world could join forces to explore methodolog[illegible] for the determination of asbestos in talc in order to learn whether or not a problem exists.

7. Analytical Methods for Asbestos; William Eisenberg, FDA; Dr. S. Speil, Johns Manville; S.R. Mountsier, Jr., Whittaker, Clark & Daniels; Dr. A.M. Langer, Mt. Sinai School of Medicine; Dr. Norwood, Charles Pfizer & Company; Dr. W. Rashed et al, Johnson & Johnson

Mr. Eisenberg presented a table of refractive indices:

	α	β	γ
Talc	1.539	1.589	1.589
Serpentine	1.542	?	1.885

He observed that all a[illegible] have [illegible] indices higher than the numbers for talc. [illegible] have refractive indices of [illegible] 1.6[illegible] [illegible] for talc. Dr. [illegible]

Dr. S. Speil, of Johns Manville, noted at the start that if a talc l a large number of amphiboles, it is certain that it would not be u in cosmetic products. Therefore, we must address ourselves to the d tection of small amounts of asbestos in talc. Dr. Speil observed t x-ray screening test can tell whether there is one half of one perc amphibole content in the talc. One percent serpentine and chrysotil be detected by this method. He added that petrographic procedures, well as electron microscopy, can also be used. Also, an examination metal content may be helpful. Tremolite has a 10-12% lime content w will not dissolve upon treatment with acid. Dr. Speil stated that i order to determine the exposure of a person to talc one must look at the airborne sample. One must first separate a respirable sample and then do a particle size analysis. Finally, a simulated test must be run to define exposure to the fiber. A discussion of the relative utility of "TLV" followed.

S.R. Mountsier, Jr., Whittaker, Clark & Daniels, introduced Dr. Seymour Z. Lewin who contributed x-ray diffraction data on eight commercial tales. Dr. Lewin found that his samples varied from almost pure talc to those containing a material on the order of one half of one percent which could be asbestos. Dr. Lewin concluded that one can quickly screen those materials which contain clearly objectional materal to those which may be safe. He added that sensitivity can be increased by as much as a factor of 10 or 100 by prefractionation or improved instrumental methods. Next, x-ray diffraction is a good screening technique which must be followed up by observation of the fibers.

Dr. A.M. Langer, Mt. Sinai School of Medicine, stated the problem as to how to determine whose talc is contaminated with asbestos. He reported that the following methods were used at Mt. Sinai:

A. A polarized light microscope which he termed an excellent screening technique.

B. X-ray diffraction, either by the powder or diffractometry.

C. Electron microscopy which can differentiate serpentine from amphiboles and easily detect fibrous talc. He added that electron microscopy could be used to detect chrysotile with a 90% certainty.

D. Electron microprobe which can be used to chemically differentiate the fibers.

E. Fractionation of the samples to ascertain the relative proportion of fibers and plates.

F. Bulk density studies and tree metal work. He added that respirable fraction should be studied to determine whether they dissolve in vivo. If talcs are found to dissolve in vivo, solubilization techniques should be used. To quantify [illegible] Dr. Langer suggested use of the high resolution [illegible] electron microscopy, and X-ray [illegible]

which utilized a spectrum stripping device.

Dr. Speil commented that the techniques suggested by Dr. Langer were much too sophisticated for the problem at hand. Dr. Langer showed photos of fibrous talcs not necessarily in cosmetics. It was generally recognized that many of the fibers found were fibrous talcs, rather than asbestos.

Dr. Norwood, Charles Pfizer & Company, suggested the following techniques:

A. X-ray diffraction as the main scanning technique.

B. Electron microscopy where small amounts of other minerals are found.

C. Bulk analysis for iron, aluminum, etc., including x-ray fluorescence methods and fusion techniques. Dr. Norwood showed photomicrographs with and without fine grained asbestos added at a one percent level.

Dr. Norwood failed to find fibrous materials in the talcs he studied by these methods. He noted that step scanning integration can be used to detect levels as low as 0.1%. Dr. Norwood concluded that after observation of over 300 different types of talcs, he has not found asbestos.

The general consensus was that x-ray diffraction should be used for preliminary screening and that optical microscopy and electron microscopy should also be used. Optional use of step scanning integration or time counts were mentioned.

Dr. W. Nashed, Johnson & Johnson, agreed that initally optical microscopy should be used. Dr. Grieger and Dr. Stewart, Johnson & Johnson, described in detail their electron microscopy study of Johnson & Johnson talcs. In this study 0.1 grams of talc were suspended in isopropyl alcohol, shaken and put in a low power ultrasonerator for ten minutes. Some 75-80% of the heavy particles were lost in the process. The sample was then placed on an electron microscope grid coated with carbon. Photomicrographs were taken without preselection and x-ray diffraction was done on the fibers where possible. Results were that a total of 12 fibers were found in the 50 plates, 11 of which were identified as rolled talc. Thus, 0.035% of the talc consists of fibers. Of this amount, 0.0252% accounts for the 11 identified fibers. The remaining fiber, accounting for 0.005% of the talc, was tentatively identified as quartz, calcite or hydromagnisite. Hydromagnisite is found in talc areas and has a similar morphology to chrysotile. Dr. Langer admitted that his claim that chrysotile was found in small amounts in Johnson & Johnson talcs was based solely on morphological examination without confirmation by electron diffraction. The conclusion of the Johnson & Johnson scientists was that electron microscopy is a superb tool for the definitive identification of asbestos. The fibers thought to be talc which are in fact chrysotile after confirmation by electron diffraction to be nothing [illegible]

Professor Pooley, Johnson & Johnson, described an experiment in which nine samples were studied for amphibole and chrysotile content. The dust was dispersed in distilled water and the wetting agent and dispersing agent was added. The resulting sample was diluted to 0.02% and allowed to stand in order to remove particles greater than ten microns in size. Examination of the particles on a carbon grid showed that one of the nine samples exhibited a small chrysotile fibril. Dr. R.F. Rolle, Johnson & Johnson, described problems in utilizing the scanning electron microscope at 10,000 times magnification to show definitively that fibers are asbestos. Dr. Rolle found that powder x-ray diffraction could detect 0.5% chrysotile in spiked samples. He suggests the following scheme for analysis of asbestos in talc:

> First utilize optical microscopy for a quick scan. If many fibers are seen, utilize x-ray diffraction. If very few fibers are seen, utilize electron microscopy in conjunction with electron diffraction.

Dr. Weissler found that this suggestion represented the consensus of the group present.

GENERAL DISCUSSION

Dr. Levin expressed the view that an x-ray diffraction examination for amphiboles and chrysotile, in concentrations of 0.05 to one percent, is a reasonable type of screening for cosmetic talcs. He added that if there is a detectable quantity of amphibole in a talc, the burden of proof of safety should be on the manufacturer. Dr. Nicholson suggested that one should follow the x-ray diffraction analysis with electron microscopy and selected area electron diffraction to be sure that the talcs with the lowest possible levels are used. Dr. Levin responded that if the x-ray examination discloses a set amount of suspect material, the material should be held until the manufacturer shows it is o.k. If the material is found not to be suspect, it could be used provisionally while further studies are done. Dr. Langer then presented Dr. Selikoff's suggested program for analysis of asbestos in talc:

1. Basic analysis of consumer talc products

   A. Polarized light microscopy.

   B. X-ray diffraction.

   C. [illegible] microscopy.

   D. [illegible]

2. A detailed study of the characteristics of talc for cosmetic use.

   E. Electron microprobe analysis with non-dispersive x-ray determination.

   F. Bulk chemical analysis.

   G. Trace metal analysis.

   H. Particle size.

   I. Literature search.

   J. Geological evaluation.

3. Development of surveillance capabilities. This would involve automation of essential parameters for talc for both qualitative and quantitative characteristics.

4. Mineral dust exposure in use of consumer products.

   A. Air sampling for selected groups of representative talcs during consumer usage.

   B. Analysis by light microscopy and electron microscopy.

5. Talc (and asbestos) content of the human lung in relation to talc utilization.

6. Epidemiological investigation.

   A. Working men producing cosmetic talcs.

   B. Others

Dr. Weisslar responded by stating that it is not clear from FDA's limited resources just what part of this comprehensive program could be done. He concluded that FDA will attempt to develop a laboratory procedure which will be checked with the participants. A survey will then be carried out if money can be made available. Dr. Kaplan had the last word in requesting feedback on FDA progress.

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