HEALTH EFFECTS OF TALC EXPOSURE

Prepared by

Arthur L. Frank, M.D., Ph.D.

Professor and Chairman

Department of Preventive Medicine and Environmental Health

University of Kentucky College of Medicine

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Introduction

In 1866, Zenker coined the term "pneumonokoniosis" (dusty lungs), referring to a variety of dust diseases of the lung. This term, now known as pneumoconiosis, continues to refer to a variety of dust-induced pulmonary diseases. Among the best known of these conditions are asbestosis, coal worker's pneumoconiosis, and silicosis. Many other dusts have been reported to produce changes in the lung, and among these is talc.

In reviewing the potential for talc to produce human disease, one must consider several factors. Not least among these is the definition of the term talc. This matter will be covered in some detail.

In reviewing the scientific literature on the health effects of talc, one faces several difficulties. One of the most important is the lack of careful characterization of the talc under study in many scientific reports. As will be noted, the term talc has various meanings and various health implications. Few studies among human populations have been carried out that meet two essential factors in making a proper assessment. These two factors are (1) careful definition of the material to which the individual has been exposed, (2) the level of dust exposure that has given rise to any noted biological changes. These issues also will be addressed.

Talc Mineralogy: Nomenclature and Review of Related and Admixed Substances

Talc is a mineral entity that is defined on the basis of its chemical, structural, and physical properties. The ideal chemical formula is $Mg_6Si_8O_{20}(OH)_4$. Rarely is talc found in this ideal state and there is frequent ionic substitution in the mineral. Also, talc is commonly associated with other minerals as it occurs in natural deposits. In its ideal form, talc is 32% MgO, 63% SiO_2, and 5% bound water by weight. As a magnesium silicate, talc is found in a sheet structure with one sheet (the brucite layer) of magnesium hydroxide ($Mg(OH)_2$) sandwiched between layers of tetrahedrally linked, SiO_4 groups (the silica layers). In naturally-occuring deposits, magnesium is often substituted by other cations, such as Fe, Ni, Cr, Mn, as well as other substitutions. The silica containing portion of the structure can have substitutions of titanium and aluminum. Talc is similar to other sheet silicate minerals, such as mica and clays, because the electronic bonds holding the talc sheets together are of low energy and this leads to easy cleavage or breakage into platy fragments. It is partly because of this ready ability to cleave, its resulting high surface area, light color, and small particle size, along with its softness, that talc has been found useful as a base for cosmetics and other purposes.

Complicating this otherwise simple picture is that this "ideal" talc is rarely found as a pure mineral. Various classes of minerals are commonly found in association with naturally occuring talc deposits. These include (1) carbonates (calcite, dolomite, and magnesite); (2) amphiboles (tremolite and anthophyllite); and (3) serpentine minerals (chrysotile, antigorite, and lizardite). These amphibole and serpentine minerals include minerals that are considered asbestos, a class of fibrous magnesium silicates. Other minerals that can be found in association with talc include quartz, mica, chlorite, rutile, and pyrophyllite.

Because of this mixture of related materials, it is not uncommon to find that a material called talc may actually contain less than 50% of pure or "true" talc mineral. Many materials called talc are used for a wide variety of industrial purposes, but some care must be given to differentiating this variety of substances since there may be considerable variation. At the present time, about a million tons per year is produced in the United States, principally from the states of California, Montana, New York, Texas, and Vermont. A much smaller amount is imported into the United States from Canada, Italy, and France.

Mineralogic Classification

Since it is clear that commercial talc products may represent a variety of minerals, it is important that analytical techniques be used which can properly characterize a specimen called talc to evaluate its true and complete nature. It is also essential to be able to identify the other minerals found in talc deposits. There are a variety of ways to characterize talc dusts. These materials may be characterized according to mineral composition, chemical composition, particle shape, and particle size. Lamar has reviewed each of these methods.

Several methods have been employed to characterize the mineral composition of a substance. Among these are petrographic evaluation, x-ray diffraction, electron beam evaluation, and differential thermal analysis. X-ray diffraction is thought the most useful tool available for mineral characterization of talc dusts. Characterization for chemical composition can be useful but the information obtained is not as definitive as that obtained by x-ray diffraction in making firm mineral identification.

Particle size and particle shape analysis are also useful with particle morphology best defined by transmission and scanning electron microscopy and particle size determination by sedimentation techniques.

Quantities of silica below 1% can be detected and even lower levels of asbestos can be detected with currently available methodologies. With sufficient examination, amounts of asbestos can be found that are comparable with ambient air samples, but are not of the same biological significance as materials with a greater amount of asbestos contamination.

When considering the mineral called talc, one must be careful to dichotomize between the ideal mineral that may be contaminated with small amounts of biologically "inert" minerals and talc that contains asbestos and/or silica. When asbestos and/or silica are present the classification should either not be considered as talc, or some clarifying adjectival phrase should make clear the true nature of this material. Such phrases might be "asbestiform talc" or "fibrous talc".

Commercial Uses Of Talc

Talc is used in a variety of industrial settings because of its abundance, useful nature, and often because of its whiteness. Many of the commercial materials called talc actually contain relatively small amounts of talc mineral (sometimes less than 50%) and are used in such products as fillers and extenders for paints, in ceramics, in the rubber industry, in the manufacture of fertilizers, in refractory materials, and in the paper and textile industries. Talc is also used as a dusting agent for food products and is a major component of some pharmaceutical preparations. Among the food products containing talc are rice, chewing gum, and it is used as a polishing agent for chocolate and peanuts (Parkes).

Biological Activity of Talc

For the purposes of this review, the dichotomy suggested above will be used in evaluating the biological activity of talc. As noted above, talc is a general term that in commerce can refer to both relatively pure material or a wide range of substances that are called talc but contain other minerals, often in substantial amounts. This review will be primarily concerned with the biological activity of pure or ideal talc. Should a material that is called talc contain either asbestos or silica, it should be treated biologically, and from an industrial hygiene standpoint, not as talc but as asbestos or silica. This would also be useful when considering its handling and use. It will not be in the scope of this review to detail the biological findings associated with asbestos and silica. It is sufficient to note that asbestos has been shown to be both a carcinogen and a fibrogenic agent in the lung, and exposure to it has potentially serious biological consequences. This has been noted in deposits called talc that contain significant amounts of asbestos, generally in the form of tremolite or chrysotile. The potential to produce lung cancer is synergistic with cigarette smoking. In the case of silica, although there is no evidence of carcinogenicity, there is the

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well established disease of silicosis, another of the dust diseases of the lung. It is well documented in the scientific literature that various commercial talc deposits in the United States are relatively contaminated with asbestos and/or silica, while others contain almost exclusively the mineral talc without the mixture of these other substances. Tables 1 and 2 review the mineral composition and uses of talc from various states in which talc mining is carried out.

There are a variety of reported health effects of talc that will not be considered in this review. These include the abuses of talc as occurs with illicit drug use, or other medicinal uses of talc for unusual conditions such as the use of talc for pleurodesis. The major concern of this review will be the biological activity of talc as may occur when the material is inhaled during the course of occupational or environmental exposure.

The subject of inhalation of dust particles is a complex one, but has been recently well reviewed by Stuart. This review covers all the major facets of deposition and clearance of inhaled particles in the lung and the findings in this paper would be relevant to the deposition and clearance of talc. Although there is a relatively extensive literature on the clearance of asbestos from lungs, as well as other substances, there is less on the subject of talc clearance from the lungs. This subject has been reviewed by Wehner, who used radioactive

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talc to measure clearance from the lungs of hamsters. As is true for most substances that are inhaled, there is considerable clearance and relatively little remains in lung tissue, although some long-term deposition of virtually any substance will occur. This followed his work with commercial baby powder where he showed that the level of exposure expected in infants produced no significant effects on hamsters given these same environmental exposures by inhalation in an aerosol chamber.

Lord has reviewed the biological effects of talc in experimental animals. Not surprisingly, one of his conclusions is that the fibrotic response seen following exposure to talc appears to be a function of dose. This is consistant with much of what is known about the biology of many substances, mineral and biologic. Included in Lord's review are studies of injection, inhalation, and a limited amount of immunological studies related to talc exposure. Lord does make the distinction, as best as can be made, between studies being conducted with pure talc and those which used impure minerals. He correctly noted that in some animal studies, as will be seen with the human experience, the talc used was not adequately characterized. This makes it difficult to reach certain conclusions with regard to some of these studies, since the available information is incomplete for proper scientific judgement.

<u>Human Experience with Talc Exposure: Case Reports</u>

The first reported case of talc-associated disease was that of Thorel in 1896 (See Parkes). He described a 44-year-old woman who had been exposed in a factory setting and had nodular lesions in the lung that contained macrophages, giant multi-nucleated cells, and granulation tissue. Other case reports followed and similar findings were noted, as well as the finding of talc particles in the lung at autopsy in some individuals. These early reports did not characterize the specific talc materials to which the individuals had been exposed. It was not until 1942 that Schulz and Williams recognized that differences in mineral composition of various talcs might be responsible for the different biological responses noted. After analyzing more than 50 samples of commercial talcs, these scientists picked a small number for further testing and noted that those talcs that contained a large percentage of tremolite produced the greatest amount of fibrosis. It can be said that this was among the earliest indications that talc contaminated with asbestos might have a different biological response, and be more hazardous, than talc free of asbestos.

asbestos free or non asbestos

Over the years, additional cases of pneumoconiosis were reported among workers with exposure to talc. In some cases the talc was well characterized, but was not so in others. One such early case, that of Millman in 1947, was the report of

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pneumoconiosis resulting in an individual exposed to cosmetic talc that contained no evidence of tremolite and less than 0.5% of free silica. In this case there had been some measurements of workplace exposure and the general working environment contained approximately 16mppcf, but concentrations as high as 230mppcf were reported during particular parts of the process used. In the mid-1960s, in Sweden, five cases of pneumoconiosis were described at a rubber manufacturing plant. The talc, analyzed at the time the disease was noted, showed less than 1% quartz and no asbestos as determined by x-ray diffraction analysis. The five cases averaged 57 years of age and had worked on average 30 years. There was no information available as to the earlier composition of talc, though it was thought not to contain significant amounts of asbestos or quartz. Likewise, there was little information available as to dust counts except at the time the diagnosis was made. At that time in one operation the dust counts averaged about 60mppcf with a range of 23 to 99, whereas in another operation the average was 37mppcf with a range of 10 to 121.

Also in the mid-1960s there was a report from Italy regarding a talc that was not well classified, except for stating that it contained little free silica, and by supposition was thought not to have significant amounts of asbestos. No measurements of workplace exposure were available and the average length of exposure had been just over seven

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years. According to the results of this study, prior to three years of exposure predominantly normal x-rays were found, whereas those employed four to six years had a 50% abnormality rate, and there was an 86% abnormality rate for those employed greater than six years. Additional studies not among manufacturing workers but among miners, showed that with increasing exposure there was an increasing risk of lung abnormalities including an increased risk for emphysema and chronic bronchitis. There was evidence of a progressive decrease in vital capacity and forced expiratory volume that correlated well with duration of exposure and severity of lesions as seen on x-rays. After about 20 years of exposure, no normal x-rays were noted.

In the scientific literature one can also find individual case reports of persons with extensive exposure, either in occupational settings or from extensive personal use of talcum powders. Such individual cases of talc pneumoconiosis help little in an assessment of general workplace or environmental conditions because of the usually excessive nature of exposure and the lack of characterization of the materials used. Talcs available for personal use have been studied by Rohl and colleagues and some were noted to contain asbestos. Other reports of talc-related disease suffer from the difficulty of not having available a good characterization of the talc material to which individuals were exposed.

This review does not cover those exposures to talc that were known to contain considerable amounts of asbestos or silica since it is likely that much of the pathology noted in these cases was due to these impurities rather than to the talc itself. These cases are not instructive in making an assessment with regard to the biological effect of more mineralogically ideal talc on humans.

Epidemiologic Studies of Talc Exposed Populations

As is the case with individual reports or reports of small groups of workers, much of the epidemiologic literature suffers from the fact that the talc to which workers were exposed was not well characterized. Also, some of the best documented studies of talc exposure, such as occurred among New York State talc miners and millers, will not be reviewed here since the disease patterns are in large part related to the asbestos contamination of this material rather than to talc. The New York State talc contained tremolite and such fibers could be expected in any deposit containing this mineral because of its initial presence or from the milling process producing fibrous materials out of material not initially thought to be fibrous in nature. Such cases are more instructive for an assessment of an asbestos-related disease than they are for talc-related disease.

Another confounding aspect of any study of occupational lung disease is the affect of cigarette smoking. Few studies of talc-exposed individuals, either those exposed to ideal talc

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or impure talc, have taken into account the effect of cigarette smoking. For those few studies that have, there appears to be an effect related to talc exposure that is independent of that of cigarette smoking.

A third confounder in making an assessment about the health effects of talc is the lack of good exposure data for most populations studied. When dust counts are available, or can be reasonably constructed, exposure levels are usually high, with little information about lower levels of exposure which might now be more commonly seen in well controlled working environments.

A review of several studies is particularly useful in evaluating the epidemiological studies of talc-exposed workers. Rubino in Italy has studied talc workers exposed to a pure form of talc that contained no asbestos but did contain some free silica. The silica exposure would have been greatest at the mines where concentrations up to 12% of air samples were of silica but in the mills the total dust would have contained less than 1% of silica. Also, based on historical evidence, the maximum talc concentrations would have been close to 800mppcf in the talc mines compared with a level of 35mppcf in the talc mills in the pre-1948 era, a period which would have included some of the working time for subjects under study. Rubino's data does not show any carcinogenic effect of talc in his study population. In analyzing a series of x-ray films taken among millers exposed to talc dust that did not contain asbestos and contained 1% or less of free silica, he found that with greater exposure as measured by mppcf-years there was a greater chance of developing x-ray abnormalities. No abnormalities were noted on x-rays from individuals below 80mppcf-years exposure, but above 320mppcf-years there was definite evidence of pneumoconiosis in some of the workers. Workers at levels in between had what was called "suspected pneumoconiosis". In a later reanalysis of data available to him, Rubino suggested that one could expect abnormalities at a level of 11mppcf over an average 22 years of exposure. Without giving convincing evidence, Rubino also suggested that 160mppcf-years was a level at which pneumoconiotic changes could be expected to start occurring in a working population. One of the difficulties with such calculations is that they are based on averages rather than the variable types of exposures commonly seen at the workplace.

Selevan reported in 1977 the mortality experience of almost 400 workers from several Vermont mines and mills that produced talc which did not contain asbestos or appreciable quantities of free silica. It was probably common prior to 1970 that the concentration of talc at the workplace exceeded 20mppcf with average exposure in the mines from 28 to 122mppcf. At the mills the average concentration was thought to range from 11 to 131mppcf with some measurements in excess of 800mppcf. In addition to serving as an x-ray review, this group of workers had 90 deaths occurring during the time of observation. This compared with an expected mortality of 77 deaths. The most striking finding was the difference between 11 observed and 1.8 expected deaths in the category of non-malignant respiratory disease category. Lung neoplasms were increased with 6 observed and 3.7 expected. Complicating this finding was not only that no smoking history was available to include in the analysis but that radon daughter levels in various talc mines ranged from trace quantities to as high as one working level month, a measure of the radioactivity present.

There are several additional papers that are of interest with regard to the subject of talc and respiratory disease. Gamble and colleagues published in 1982 a study of talc workers in three talc producing regions of the United States. They studied 299 miners and millers exposed to talc in Montana, Texas, and North Carolina. Among the parameters evaluated in this cross-sectional study were respiratory symptoms, lung function, and chest x-rays. These workers came from seven mines and eight mills in these three states with the mines of Montana and Texas being open pit operations and the North Carolina facility being an underground mine. This paper is especially important to review because some of the findings were associated with exposure to pure talc. Specifically, the Montana population was handling a talc that had the lowest concentration of trace metals. The silica content of bulk samples of Montana talc were below the limit of the detection, that is, 0.8%, and no fibrous material was identified by either light microscopy or electron microscopy.

While generally of high purity, the other talcs did contain more silica, up to 2.23% in Texas and two fibrous minerals were identified in the Texas talc, namely tremolite and antigorite. Of the population studied in Montana, which numbered 177 individuals, 80% were males and the remainder females, the average age was approximately 35 with an average of 6.6 years working exposure. The cumulative exposure in this population was on average 5.9mg per cubic meter times years and the average exposure was 1.21mg per cubic meter according to the data presented. Of this group of 177, 33% were non-smokers, 21% ex-smokers, and 45% smokers. Smokers smoked on average one pack per day and had an accumulation of approximately 18 pack years. Of the groups studied, the Montana workers were younger, somewhat taller, and had worked fewer years with less cumulative exposure than those of North Carolina. In addition to rounded opacities, there was evidence of pleural thickening in each of the three groups, including 4% in the Montana group and rising to 18% in the North Carolina group. It was reported that on average those workers with pleural thickening were ten years older than those without, and on average had worked longer and had higher average cumulative exposures than other workers. Pulmonary function values were reduced in those with pleural thickening, more so if there was bilateral thickening than unilateral thickening, although this was not at that time thought clinically significant. What is significant about this study is that the talc exposure has been extremely well characterized and biological changes in humans has been noted with an extremely pure talc over a relatively short working lifetime.

Another paper of significance, also published in 1982, is that of Wegman and colleagues. A group of Vermont miners and millers of talc ore which was free from asbestos and silica was examined for respiratory effects. One hundred sixteen subjects were studied with a respiratory questionnaire, spirometry, chest x-ray, and a limited examination of the chest. One year later, 103 subjects were re-evaluated. Of note was that of the 12 x-rays that had small, round, irregular opacities of 1/0 or greater according to the ILO scale, five had not smoked cigarettes. Among the other findings was that pulmonary function values at the time of initial examination were less than predicted and the rate of loss of FEV_1 and FVC was greater than expected, although at that time not of clinical significance and not associated with then current levels of dust exposure. Some of this difference was attributed to cigarette smoking, but it was felt that this would not fully explain all the findings noted. There was evidence of an

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effect of talc exposure after adjusting for cigarette smoking for some, but not all, of the pulmonary function parameters measured. No conclusion was made with regard to safe dust levels based on this evaluation. Earlier, unpublished work by Wegman, cited in the draft of the proposed NIOSH criteria document on talc, reviews the conclusion of Wegman and colleagues that while a safe level of exposure to talc could not be reliably determined, a safe level appeared to be in the range of 1-2mg/m^3.

Fine and colleagues reported in 1976 on the respiratory morbidity of 80 rubber workers from several worksites exposed to a Vermont talc. Eighteen of twenty-one samples were reported to contain less than 1% free silica and twelve samples counted by "the standard asbestos procedure" (presumably by light microscopy) showed less than 2 fibers per cc. Levels of exposure were thought to be below 20 mppcf-years over an average working span of almost nine years. Measurements taken at the time of the study were between 0.47-3.55mg/m^3 with an average about 1mg/m^3. They controlled for other workplace exposures and for smoking. They did a regression analysis with their data including age and smoking as well as talc exposure and suggested that the decrement in FEV_1 over time was 33cc per year more than would have been expected from just age and smoking, suggesting that these changes were due to talc exposure. This was for workers with more than ten years of exposure. They suggested that FEV_1 decreased progressively as exposure to talc increased. The changes noted were of an obstructive nature, and in no case were there abnormal x-ray findings. The conclusion was to suggest a lifetime limit for 40 years of 10-20 mg-years, or a $0.25mg/m^3$ TLV.

The draft NIOSH criteria document, which has never been published, suggests a $1.5mg/m^3$ TLV.

One is then left with the need to reach some judgement about safe working levels for talc exposure. It appears on the basis of available evidence that there is little question that talc has the ability to produce biological change in humans and that with significant exposure these changes may lead to increased mortality from non-malignant respiratory disease. The evidence available to date limits a scientific judgement of what should be a "safe" workplace TLV although admittedly limited data suggests it might be appropriate below the current 20mppcf OSHA standard. Other scientific data suggest that the current ACGIH standard is adequate. The ACGIH published in 1981 a notice of intended change of 15mppcf or $2mg/m^3$.

Carcinogenic Potential of Talc Exposure

One last issue to consider briefly is the question of carcinogenicity related to talc exposure. A number of studies can be found in the literature in which there is an elevated risk of cancer, especially lung cancer and mesothelioma among talc-exposed workers. With one exception, these studies have been of populations exposed to talc contaminated with considerable amounts of asbestos including tremolite and chrysotile. There has also been put forward the suggestion that rice which has been coated with talc may explain the high incidence of cancer of the stomach among certain populations who use considerable amounts of rice in their diet. However, there appears to be little support at this time for this suggestion since additional evaluations of cancer mortality patterns and the various groups that could be considered do not support this thesis.

With regard to the question of the carcinogenicity of talc that is not contaminated with other materials there appears to be no convincing evidence at this time that uncontaminated talc should be considered a carcinogen. There is little evidence in the animal literature to suggest any causal relationship to developing cancer after talc exposure. No human experience leads to any conclusion that talc per se is a carcinogenic substance. Only one study, that of Selevan and colleagues, showed an excess of lung cancer deaths among talc exposed workers with no asbestos present, but there was no control for smoking history and there was also radon daughter exposure.

TABLE 1

Mineral Composition and Commercial Uses

of United States-Mined Talcs

	Composition	Uses
Alabama	Talc with chlorite in minor amounts and magnesite and quartz in trace amounts	Rubber, paint, textiles, cosmetics
Arkansas	Talc with dolomite, chlorite, magnesite and minor amounts of quartz and calcite	Rubber, insecticides, wall tile
California	Talc with tremolite, minor amounts of fosterite, serpentine and carbonate impurities	Rubber, pottery, paint, ceramics, textiles, pharmaceuticals
Georgia	Talc with minor amounts of magnetite, and carbonates	Crayons, paint, rubber, insecticides cosmetics, etc.
Montana	Talc with minor impurities such as chlorite, graphite, and dolomite	Cosmetics, paints, paper, ceramics
New York	Talc with a high proportion of tremolite and anthophyllite	Ceramics, paints, rubber, plastics, insecticides, foundry facings
North Carolina	Talc with traces of chlorite, dolomite, quartz, and tremolite	Cosmetics, crayons, pharmaceuticals, rubber, paint
Texas	Talc with impurities of quartz, carbonate, and oranic material	Wall tile, insecticide
Vermont	Talc with minor amounts of magnesite and sulfides	Paper, rubber, textiles, cosmetics, paint, crayons

(Adapted from draft NIOSH criteria document)

Table 2
Mineral Composition on Talc Bulk Sample
(Percentage)

	Talc	Anthophyllite	Calcite	Chlorite	Dolomite	Magnesite	Quartz	Tremolite Actinolit
Arkansas	33-55	0	2	8-10	10-20	15-25	2.4	0
California	52-96	0	.3-15	0-5	0-15	0	0-2.7	0-10
Georgia	25-84	0-12	0-5	5-50	1-10	0-10	.4-9	4-8
Montana	82-99	0	0-1	0-15	0-5	0	.2-1.5	0
New York	19-73	4.5-23	0-1	0	0-1	0	.2-5.5	13.5-57
North Carolina	75-97.5	0	0	1-20	2-5	0	0-.5	0-.5
Texas	54-95	0	0-5	0-8	10-20	0-5	1.1-12	0-2.5
Vermont	43-99	0	0-1	1-6	0-20	1-50	0-.5	0

(Adapted from draft NIOSH criteria document)

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