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Research & Engineering Center
AUGUST 11, 1971

MEMO FOR FILE:

FDA MEETING - ASBESTOS IN COSMETIC TALCS
AUGUST 3, 1971 - WASHINGTON, D.C.

The purpose and list of participants and discussants are given in the attached two handouts from the meeting.

Summary

Dr. Romer (NYC Department of Air Resources) set the basis for the meeting and reiterated his "demands" that the FDA:

1. specify lab procedures for evaluating talc;
2. evaluate cosmetic talcs;
3. decide on the acceptable limits of asbestos; and,
4. ban the sale of those cosmetic talcs which they deemed unacceptable.

Dr. Weissler (FDA) summarized at the end of the meeting by indicating that FDA would decide which analytical techniques should be used to evaluate cosmetic talcs, but would take no action towards banning any talcs until they had secured competent advice concerning the potential hazard of talcs containing small amounts of asbestos. He will obtain specific written comments concerning analytical techniques from the participants, specific health advice from various Government and other medical specialists, and will issue a summary memorandum on the meeting, including FDA's plans to evaluate cosmetic talcs. His outlook on the problem seemed to be reasonable and he was, at least for the moment, not stampeded by Romer's frequent interjections and demands for immediate action by FDA.

The following briefly summarizes the comments by the various speakers and associated discussion.

Dr. Malcolm Ross - U.S. Geological Survey

Described the genesis and geology of talc deposits, particularly in the New England area. New York State talcs generally characterized by high impurity contents of tremolite and quartz.

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Vermont talcs (source of J&J) generally relatively free of tremolite or other asbestos minerals.

Dr. Lewis J. Cralley - National Institute of Occupational Safety and Health, Cincinnati, Ohio

Reviewed definition of "fiber" and related the hazard to respirability and time of total exposure. Introduced again the concept of heavy metal carcinogenesis. Reviewed his published study of fibers in talc and stated emphatically that he could detect only talc by X-rays. His reference to the probable presence of asbestos fiber in these talcs was, in fact, only a "probability" based on the known geology of talc deposits.

Dr. Irving J. Selikoff - Mt. Sinai School of Medicine

Gave his usual asbestos workers story following through to his study of chrysotile in lungs of New Yorkers. He stated "that lung cancer is not necessarily dose related", but in later discussion indicated that there might be a level below which it was not harmful. He alluded to the possibility that organic and other additives in talcum powder were potentially harmful.

He noted Kleinfeld's study of talc workers (Arch. Env. Health, Vol. 14:663, 1967) but stated it was not necessarily extrapolatable to community environment. He noted excess lung cancer in talc workers in the Gouverneur, New York district of tremolite talc. He emphasized the importance of smoking habits in asbestos worker's excess lung cancer, but not in mesothelioma.

Dr. Gavin Hildick-Smith - Johnson & Johnson

Estimated total integrated exposure of a baby to talc dust as less than six days and total exposure of a man using talc several times a day during entire life as only a few months. He described use benefits of talc in open heart surgery and other techniques to secure a desired fibrotic reaction and noted that not all talcs were equally good in this respect. He showed Dr. W. E. Smith's results on hamsters, which included one sample of a tremolitic talc with no carcinogenic effect. Incidentally, the data included three cases of carcinoma with exposure to diatomaceous earth.

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Dr. Paul Gross - Industrial Health Foundation

Described animal experiments with talc (previously used on physicians' gloves) injected intentionally into bellies of animals. These produced no granulomas. He described intertracheal injections of hamsters with three types of talc (high nickel, low nickel, and off-the-shelf cosmetic talc). No fibrosis after two years, despite excessive amounts used. He noted Ian Webster's conclusions that fibers must be at least 5 microns long to be harmful.

Dr. Morris Kaplan - Consumers Union

Reiterated his interest in the safety of the consumer and that any bias introduced in the evaluation and "banning" of talc should be in the consumer's interest.

Dr. Raymond E. Barzilai - FDA

Described FDA's work on the use of particulates as drugs or as adjuncts to drugs. His review of the use of particulates in biomedical research indicated: (1) the extreme paucity of animal work; (2) no evidence or reference to mesothelioma; and (3) poor characterization of the materials used in the research work.

Selikoff noted that talcs used to take off hulls from rice may not always be removed from the rice and, in fact, talc with amphibole impurity had been noted in rice on the West Coast.

Dr. Herman F. Kraybill - FDA

Entered the political plea that FDA had indeed been active in studying health problems and had met several times with Cralley and Selikoff in 1967 and 1968. He introduced their previous interest in the "asbestos in beer" situation. He clarified the situation by noting that the beer with most asbestos in our studies had never been filtered through asbestos and owed its fiber content to water which originated in wells from the Pennsylvania Serpentine Belt.

William V. Eisenberg - FDA

Reviewed FDA's optical microscopy competence in detecting asbestos. He indicated one per cent was detectable. Nicholson introduced the

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subject of asbestos in injectable drugs and stated that more than one-half of injectable drugs in a survey at the Mt. Sinai Hospital Pharmacy contained asbestos in amounts up to 1 microgram in a vial.

S. Speil - Johns-Manville

Reviewed asbestos technology and the importance of respirable fraction vs total sample. Suggested separation into airborne sample or use of "simulated tests" with personal samplers and counting by ACGIH methods using recognized TLV with an "exposure time" factor.

Nicholson objected to using present "high" TLV limits because of "millions of people at risk" and Romer reintroduced "cloud of fiber" scare.

Indicated 0.5 per cent amphibole was detectable by X-ray as total but not specific amphiboles. Also that serpentine plus chrysotile detectable by X-ray less than 1 per cent, with post-acid treatment to distinguish between the two materials.

Emphasized need for examining for fibrous state if X-rays indicated presence. Careful petrographic techniques could detect amphiboles and chrysotile at 1 per cent limit. Downplayed use of EM because of unknown biologic effect of this size, probability of finding tiny amounts probably not biologically significant by this technique, and extreme cost. Reviewed possibility of lower detection limits by concentration with heavy liquids and a simple test for tremolite and actinolite by acid leaching, followed by calcium oxide determination.

Dr. S. Lewin - New York University
Consultant for Whittaker, Clark & Daniels

Suggested use of X-ray detection with 0.5 per cent detectable. Indicated presence of "crocidolite" in one talc sample (probably a different amphibole), but all other cosmetic talcs clean by X-rays.

Dr. Art Langer - Mt. Sinai School of Medicine

Discussed techniques used at Mt. Sinai, starting with light microscopy through microprobe, where necessary, and finally electron

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[redacted] microscopy. Indicated approximately one week work for complete evaluation of a talc sample. Showed many slides indicating presence of fibers by EM and "chrysotile" not verified by electron diffraction. Still feels identification of chrysotile by shape 90 to 95 per cent certain.

Dr. Norwood - Chas. Pfizer & Company

Pfizer talc from Montana. X-ray indicated slight chlorite impurity, but no amphiboles. Suggested X-ray followed by petrographic and chemical analysis by X-ray emission. Agreed that 8.4 Angstroms (amphibole) and 7.3 Angstroms (chrysotile plus serpentine) were sensitive X-ray detectors for approximately 0.5 per cent.

Dr. Wilson Nashed of Johnson & Johnson introduced the following group representing J&J interests.

W. T. Caneer - Colorado School of Mines Research Institute

Reviewed petrographic and electron probe studies of J&J. Showed clean fiber.

Dr. Gene Geiger - McCrone

Reviewed McCrone study of J&J cosmetic talc. Petrographic and EM determination revealed no asbestos fibers. Fibrous material identified as talc, both in the light microscope size range and in the EM size range. All EM work very detailed. Looked at 50 grid squares with micrographs. 12 fibrous particles detected corresponding to 0.03 per cent of sample. 11 fibers definitely identified by microprobe as rolled talc platelets. One fiber unidentifiable. Rolled talc fibrils often tend to unroll after a long delay period.

Very important observation by Geiger indicates that electron microprobe analysis of "chrysotile fibrils" may be necessary except where there is a known exposure to chrysotile.

1. Sodium sesquicitrate has essentially the same diameter as a chrysotile fibril with a "hole" down the center. This is sometimes added as a conditioning agent to cosmetic talcs.

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2. Hydromagnesite is fibrous in form. Diameter of 200 Angstroms with a "hole" down the center. Hydromagnesite is known to occur in some talc deposits. Geiger questions some of Art Langer's identification of chrysotile fibrils. This was a smoke screen, but a good counter offensive to Langer finding chrysotile everywhere.

Dr. F. D. Pooley - University of South Wales

Examined J&J talc by EM techniques, including heavy liquid density separation in a centrifuge. All fibrous constituents were identified as talc by electron diffraction.

Dr. R. F. Rolle - Johnson & Johnson

Showed beautiful electron micrographs of rolled up platelets of talc. Samples were made by replication using gold palladium plating.

Dr. W. E. Nicholson - Mt. Sinai School of Medicine

Sales pitch proposed a low level and high level study program for surveying cosmetic talcs. The low-level technique would include polarized light microscopy and X-ray examination, and then possibly electron microscopy plus identification, if necessary. Langer questions whether 1 per cent chrysotile in fibrillar form could be detected and showed his studies of Spex milled chrysotile with no X-ray pattern visible after intensive grinding. I countered that this material was no longer chrysotile and, therefore, not pertinent.

Nicholson's more extensive program included, in addition to the initial survey:

1. air sampling tests and complete analysis from a selected gamut of samples after preliminary screening as above;

2. statistical study of the Mt. Sinai lung survey samples of New York people to correlate fiber and talc content in the lungs with talc usage; and,

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3. a complete epidemiological study of the workers mining and producing cosmetic talcs.

C. Maggiore - Mt. Sinai School of Medicine

Reported on Mt. Sinai exploratory work towards the development of instrumentation for completely characterizing many and all fibers and particles in a sample by shape, size, chemical analysis, etc. He indicated the need for approximately $300,000 and 2 to 3 years for design and construction of a prototype unit.

S. SPEIL

SS/rs

Attachments (2)

cc:
W. P. Raines, DH
M. Swetonic, DH
C. H. Sheckler, DH
F. L. Pundsack
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