

Johnson & Johnson

BABY PRODUCTS COMPANY

May 25, 1976

Dr. Robert M. Schaffner
Bureau of Foods, HFF-400
Food and Drug Administration
200 "C" Street
Washington, DC 20204

Raf 5/28/76

Dear Dr. Schaffner:

In follow-up to our June 2, 1975 letter to you, we append three final reprints of the article, "Mortality Study of Talc Miners", by Rubino, et al., published in the Journal of Occupational Medicine in March, 1976. This is the material presented by Dr. Rubino before the American Industrial Health Conference on April 15, 1975.

Thank you.

Respectfully yours,

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Manager
Medical and Regulatory Affairs

clj
Enclosures

cy of reprint to HFF-440 5-28-76

Mortality Study of Talc Miners and Millers

Giovanni F. Rubino, M.D.; Giovanni Scansetti, M.D.;
Giorgio Piolatto, M.D.; and Canzio A. Romano, M.D.

The purpose of this research is to ascertain the causes of death in talc miners and millers. Special attention is paid to the incidence of pulmonary, mesothelial and gastrointestinal tumors.

Our study was conducted on a talc which is mineralogically very pure in its natural state. This is the type of material used in the pharmaceutical and cosmetic industries. All the subjects of our study have worked in the mines and the mills of the talc operation in the Germanasca and Chisone Valley (Piedmont). This particular talc has been mined for many decades and has continued to be recognized to be of the highest standard of purity (see Appendix).

An epidemiological study which can be taken as reference for our investigation was conducted by Kleinfeld et al., and recently reviewed with additional informations (1974), on talc miners and millers in the State of New York.^{1, 2} The incidence of carcinoma of the lung and pleura in those workers was found to be about four times that which is observed in the general population.

This New York Study was on workers exposed to an industrial talc which is a mixture of talc and other materials. Kleinfeld points out that the talc to which his workers were exposed "contained not only mineral talc but also other silicates such as serpentine, tremolite, anthophyllite, and other ingredients predominately carbonates. Moreover free silica was present in the dust in variable amounts, usually averaging not more than three percent".

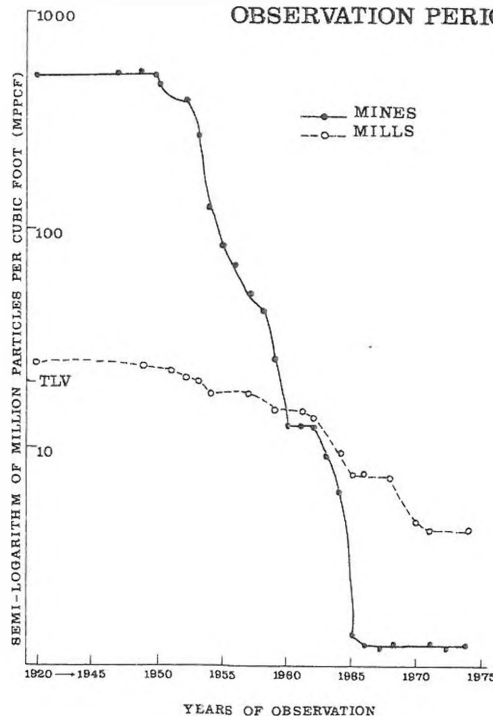
Therefore, our present epidemiological study provides a basis for comparing subjects exposed to an impure industrial type of talc (e.g. Kleinfeld Study) to subjects exposed to a very pure type of talc.

Type of Study and Data Collection

An historic prospective study has been employed consisting in the follow-up of a cohort of male subjects who began work at a definite time and including retired as well as active workers. We have been able to do so because we had at our disposal a group of subjects fit for this type of investigation.

Data were collected for each worker who began work in the years between 1921 and 1950 and who has been employed for at least one year in a job involving exposure to talc in the mines or in the mills. Necessary informations such as birth date, place of birth, last known address, type and duration of all works performed, were abstracted from pay rolls and

DUST CONCENTRATION IN AIR ALONG
OBSERVATION PERIOD



Decreasing trend of total dust in respirable range, following the adoption of technical preventive means from 1950.

Presented at the 60th Annual Meeting of the American Occupational Medical Association, American Industrial Health Conference, April 15, 1975, San Francisco

Dr. Rubino is Professor of Occupational Medicine and Director, Institute of Occupational Medicine, Turin University. Drs. Scansetti, Piolatto and Romano are assistants, Institute of Occupational Medicine, Turin University.

Reprint requests to Dept. of Occupational Medicine, University of Torino, C.T.O. — Via Zuretti 29, 10126 Torino, Italy.

Johnson & Johnson

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

June 2, 1975

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert M. Schaffner, PhD
HFF-400
Bureau of Foods
Food and Drug Administration
200 "C" Street, S. W.
Washington, DC 20204

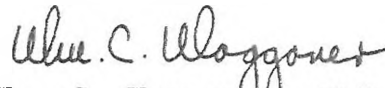
Dear Dr. Schaffner:

Pursuant to our April 3, 1975 letter we enclose a copy of Professor Rubino's paper, Mortality Study of Talc Miners and Millers, as prepared for presentation at the American Industrial Health Conference in San Francisco on April 15, 1975.

We trust this information will be useful.

Respectfully yours,

JOHNSON & JOHNSON
Baby Products Company



Wm. C. Waggoner, PhD
Administrator
Medical and Regulatory Affairs

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BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

April 3, 1975

CERTIFIED MAIL

RAV 4/21

Robert M. Schaffner, PhD
HFF-400
Bureau of Foods
Food and Drug Administration
200 "C" Street, S. W.
Washington, DC 20204

Dear Dr. Schaffner:

In continued cooperation with the Food and Drug Administration on informational exchange regarding the talc question, we have learned that a paper on Dr. G. F. Rubino's epidemiological study with Italian cosmetic talc miners and millers will be presented on April 15, 1975 at the San Francisco Hilton during the American Industrial Health Conference. As soon as a copy of the paper, which contains the main epidemiological data, is made available to us, we will forward it for your review.

We also note that during the same conference Dr. L. J. Fine of Harvard will be presenting a paper, "Respiratory Morbidity in Talc Workers", providing data on pulmonary function of industrial rubber workers who have been exposed to a combination of industrial grade talc and organic solvents. Discussions with the Harvard group enabled us to have a sample of the mineral powder analyzed and this was shown to contain only 42 percent talc.

Concerning these studies we point out the vast differences in the nature of material, to which the populations of each, respectively, were exposed. From the program there appear to be no other talc related papers other than the two described above. We trust this information will be useful.

Respectfully yours,

JOHNSON & JOHNSON
Baby Products Company

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Administrator
Medical and Regulatory Affairs

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