

FILE NAME: Colgate (COL)

DATE: 1976 Mar 17

DOC#: COL020

DOCUMENT DESCRIPTION: Memo from Dr. Langer RE The Ongoing Talc Study in the Environmental Sciences Laboratory

of The City University of New York

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To Dean Thomas C. Chalmers

Date: March 17, 1976

From: Dr. Arthur M. Langer

Subject: The ongoing Talc Study in the
Environmental Sciences Laboratory.

Following our telephone conversation of Wednesday, March 17th, I am herein submitting to you, as accurately as memory permits, the involvement of our Laboratory with the analysis of talc-containing consumer products.

In December of 1968, Dr. Selikoff and I were invited to the Food and Drug Administration to participate in a seminar before the Division of Pharmacology and Toxicology. We presented materials under the title "Current studies on pulmonary fibrous mineral microparticles - potential contribution of talc." At the seminar we discussed our studies involving the fiber content of lung tissues obtained from 3,000 consecutive autopsies in New York City; the biological hazards associated with the inhalation of asbestos; preliminary data which suggested that some of these lung fibers were asbestos fibers; the natural contamination of talcum products with fibrous minerals (including asbestos); the potential hazards associated with inhalation of talc dust. If memory serves me correctly this was not the first time this subject matter was broached with FDA. Some members of Food and Drug were present at a meeting a year earlier, in Cincinnati, Ohio, in which the asbestos problem was openly discussed at a governmental meeting. It was because of this meeting, and the ensuing discussions, that we were invited to Washington for the seminar. (See Appendix No. 1.) Talc research, for us, was put on a "back burner" for future study. We continued at intervals to examine consumer products and observed that they contain fibrous minerals which when analyzed demonstrated them to be asbestos.

In August, 1971, our group was invited to a discussion at the Food and Drug Administration concerning the asbestos content of consumer talcs. A number of individuals were present representing various areas of society. Dr. Selikoff spoke on the biological significance of asbestos and I presented some information concerning the analytical methodology required for asbestos analysis. (See Appendix No. 2.) On page 5 of this document, paragraph 4 reflects our findings concerning asbestos contents of Johnson & Johnson talcs.

In September, 1971, we began, in a more formal manner, the study of the asbestos content of consumer talcs. We prepared a study proposal for the Environmental Protection Administration outlining a study for the determination of the fiber contents of consumer talcs sold in New York City. (See Appendix No. 3.) No funds were available for this study and we were so informed. However, we formulated in our own minds the outlines of a consumer talcum study.

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In February, 1972, our group was invited down to the Food and Drug Administration to discuss a number of problems. Ostensibly, we discussed the occurrence of asbestos in parenteral drugs. It is my belief that at this meeting we again broached the subject of asbestos contamination of consumer talcs. (See Appendix No. 4.)

In late 1972 and early 1973, I was approached by Dr. Morris Kleinfeld, of the N.Y.S. Department of Labor, who had been studying talc miners and millers in New York State. He is a recognized authority in this area and his publications have received wide attention. He and his colleagues were the first to epidemiologically establish the association between fibrous talc exposure and excess human malignancies. He approached me to study the mineral content of talcs mined from the Balmat-Edwards mining area of New York State. I collaborated with him and one of his colleagues and a joint publication resulted from our efforts. (See Appendix No. 5.) During this study we developed the methodology for x-ray diffraction analysis of talc, and the electron beam instrumentation required for the analysis of submicroscopic fibers in talc samples.

During this time, we began to purchase samples of talc products in New York City. We were not funded to do this research so that we had an extremely limited budget for "cash outlay." We requested individual members of our Laboratory to bring in any "talcs that they might have in their medicine cabinets at home" to supply us with some materials. At this time I submitted to the Public Health Service a grant application entitled "Asbestos content of consumer talcum products." (See Appendix No. 6.) We again outlined in very great detail an analytical procedure for the analysis of consumer talcs for their asbestos contents. The methodology for talc analysis was worked out at this time and we believe the research warranted support because of its importance. Unfortunately, although the grant was approved (favorably recommended) the relative priority number was not great enough to have it funded.

We continued with our work concerning the analysis of consumer talcum products. In May of 1973, several of my colleagues and I were invited to a symposium on talc in Washington, D.C. This was sponsored by the Bureau of Mines and pertained to various aspects concerning the biological hazards associated with the talc mining industry. I presented materials concerning the nature of talc mineralogically and reported the occurrence of asbestos fibers in the lung tissues of a workman exposed to talc dust. This circular of the Bureau of Mines has been used by the news media many times and from it many inquiries had been directed to us. (See Appendix No. 7.)

Still without significant research support, other than "stealing time" from other projects, we continued our analyses of consumer talcs. In the spring of 1974, my colleagues and I were invited to a microscopy symposium in New York City to discuss the identification and quantitation of asbestos fiber in a range of media. Dr. Rohl and I have reported results concerning the identification and quantitation of asbestos in talc. (See Appendix No. 8.) These papers were submitted for publication

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in the Environmental Health Perspectives. This paper has become a standard methodology in that we have had requests from the Philips Electronics Corporation for reprints to be used in their teaching seminars in Mt. Vernon. This paper represents almost one year of "bench" time. This is one of our basic techniques in the analysis of consumer talcum products.

In order to properly "round out" our studies we invited several of our colleagues in Great Britain to join with us in mutual collaborative efforts. We decided that our studies would be strengthened if we knew more about the bulk chemistry and trace metal contents of these materials. Dr. Donald R. Bowes, Professor of Petrology and Geochemistry from The University, Glasgow, consented to work with us. His laboratory furnishes our studies with complete chemical analyses of materials we send to him. Complete analyses of British consumer talcum products may be found in the paper included in Appendix No. 9. Some ten major oxides and 17 trace metals are routinely analyzed. The samples are run in duplicate and triplicate and if "mismatches" are obtained, the analyses are thrown out and done over again. Dr. Bowes has 20 years of experience in the geochemistry field and his reputation is excellent.

My colleagues and I were invited to present a paper at the British Occupational Hygiene Society's meeting, held in Edinburgh in September of 1975. (See Appendix No. 9.) In the session called "talc" Dr. Pooley and I were listed to present a paper entitled "Chemical, physical and mineralogical characteristics of talcs." The authorship and titles were later changed, in which Dr. Pooley was made senior author and the title was amended to "Mineralogy and chemistry of British talc and consumer talcum products." This paper was withdrawn by Dr. Pooley two days prior to the conference start. We enclose an 18-page paper which was to be presented. The reasons for Dr. Pooley's withdrawal of this paper are many and I shall be happy to discuss these with you in private. He was subjected to personal and professional pressures and industry harassment. We respected Dr. Pooley's wishes at the time of the conference and allowed him to withdraw it. This manuscript is being resubmitted to a different British journal for publication. Dr. Rohl has the correspondence connected with the withdrawal of the paper and the subsequent request for its submission to an appropriate journal in Great Britain.

These documents, and the above statements, more or less outline our interest in talc and consumer talcum products. My colleagues and I have been studying this problem area for a number of years. A number of press releases have appeared over the past several years generally as the result of widespread interest in this subject area. I cannot count the number of times I have been approached by individuals in the journalism field with questions concerning asbestos contents of consumer talcs. Many occasions, both in personal contact and by telephone, have presented themselves in which this subject area was broached. My colleagues find this to be "old hat" not necessarily reflecting that it is unimportant, but rather it is just not new to us.

Dean Thomas C. Chalmers

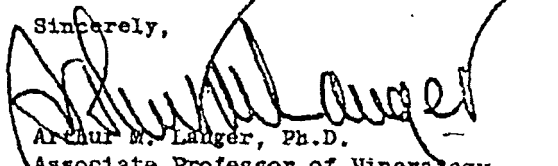
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The consumer talcs (United States) have been studied with identical methods as the British talcs. The paper has been accepted for publication in Environmental Research. A revised pre-publication manuscript will be shortly forwarded to your office.

If you have any further questions concerning these materials I shall be very happy to answer them.

Sincerely,



Arthur M. Langer, Ph.D.
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Head, Physical Sciences Section

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