Environmental Sciences Laboratory

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Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
MD-EC-14
Post Office Box 12233
Research Triangle Park, NC 27709

May 2, 2001

Re: National Toxicology Program/RoC/Talc(Asbestiform and NonAsbestiform)

Dear Dr Jameson:

I am writing concerning the request for public comments in the above referenced matter. The Environmental Sciences Laboratory has made two submissions regarding the nomination:

- Mineralogy and Experimental Animal Studies of Tremolitic Talc. G.L. Nord, C.W. Axten and R.P. Nolan.
- An evaluation of the Epidemiological Evidence concerning "Talc" and Respiratory Cancer in Humans with Specific Attention to "Talc" as Produced by the Gouverneur Talc Company at its Mines in New York State and Factors to Consider in Evaluating Causation. G.W. Gibbs

The authors of these reports reviewed the Background Document for the nomination prepared by Technology Planning and Management Corporation and attended the nomination meeting. Two oral presentations were made describing the conclusions of the reports. I appreciate this further opportunity to make a public comment.

The meeting left us with a "through the NTP Looking Glass" feeling with regards to the nomination of talc asbestiform to be listed in the Report on Carcinogens (RoC). The document did not define talc asbestiform in a manner that distinguished between asbestos and other fibrous minerals that may be found in talc. The Background Document contained an extensive discussion of the health hazard of asbestos minerals, that are

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known to be human carcinogens and already extensively regulated to control human exposure, and implied that similar effects can be expected from the minerals found in tremolitic talc. What actual mineral(s) NTP intended to nominate was not specified in the Background Document nor was it made clear until the opening of the Board of Scientific Counselors'(BSC) meeting. The two earlier review groups (RG1 & RG2) - which decided that talc asbestiform was either known to be or reasonably anticipated to a human carcinogen -remind us of what the Queen said to Alice, first the verdict than the trial.

The Chairperson opened the part of the BSC meeting addressing the nomination of talc with an impromptu discussion of how to define what they were proposing to list as a carcinogen. This should have been done prior to the meeting's beginning and reflected in the Background Document. Instead the Chairperson called on individuals present to address the BSC about what is and what is not asbestos and how to define the kind of talc that would be voted on the following day for listing in the RoC. This discussion went on for over an hour and confusion among the Board members was clearly evident. The terminology developed that morning –nonasbestos asbestiform fibers- is not appropriate for describing the fibers found in talc. Furthermore, the minerals found in talc should be defined using the science of mineralogy and the results of relevant studies for their health hazards evaluated, not - the make-it-up as you go along and let someone else figure it out - approach of the NTP. If the NTP wishes to list minerals in the RoC it should describe the minerals it intends to list using the mineralogical criteria needed to define any mineral. The conclusions of the RG1 and RG2 are understandable in light of the fact that it is obvious the authors of the talc asbestiform Background Document had little or no knowledge of the mineralogy of talc as it is found in nature or in the various commercial products it is used to fabricate. Using talc as a surrogate for asbestos in the Background Document is highly misleading and the scientific and medical basis for the NTP decision-making is incorrect.

The two earlier review groups (RG1 & RG2) did not recognize the shortcomings in the Background Report where the talc asbestiform fibers were either considered to be asbestos or something so similar they might as well be the same. Even though genotoxicity studies indicate that neither asbestiform or non-asbestiform talc is genotoxic or clastogenic while asbestos has been shown to be clastogenic. By using asbestos and asbestiform interchangeable in the Background Document it is not possible to know what the two review groups voted to list in the RoC as a carcinogen. At the NTP Board of Scientific Counselors' meeting it became somewhat clear that the intent of the NTP was to nominate something else besides asbestos which has yet to be defined and written down on a piece of paper. The NTP staff continues to give merit to the evaluation of RG1 and RG2 rather than dismiss the opinions of these groups after it became apparent that they relied on a Background Document in which the substance nominated was not correctly identified and falsely assumed to be a surrogate for asbestos. Although workers exposed to tremolitic talc in underground mines have increased risk of lung cancer those who work in the mill do not. The lung cancer risk does not increase with tenure or cumulative exposure and the reason for the excess lung cancer in the cohort has not been conclusively identified. No link has been established between exposure to tremolitic talc and mesothelioma further weakening the argument that talc asbestiform is a surrogate for

asbestos. In no less than two experimental animal studies of fibrous talc and transitionals - which NTP is proposing to list as carcinogens – were negative and clearly lacked the carcinogenic potency of asbestos which cautions us not to be adventurous in interpreting the epidemiology.

The manner in which this nomination was handled created a spectacle that brings the US Federal Government efforts to identify carcinogens into disrepute. The large attendance at the meeting representing both US scientists and many from foreign countries should encourage NTP to do a better job. The contracted Background Document was not up to the standards we would expect for a RoC Report, put simply, they did not do their homework and the two earlier review groups did not notice or chose to accept the information without further clarification. The Board of Scientific Counselors' split on the recommendation with five members supporting and five members opposing the listing of talc asbestiform as reasonably anticipated to be a human carcinogen. The Chair did not vote and a tie in this case would be equivalent to a do not list vote. We are supportive of the Scientific Counselor's conclusion that the scientific and medical information available for both the talc fibers and transitionals found in tremolitic talc does not meet the criteria for being included in the RoC.

Repectfully Yours;

Cc: Kenneth Olden
Director, National Toxicology Program