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INTER ORGANIZATION COMMUNICATION

Raybestos Manhattan

Corporate (DIVISION) Trumbull (LOCATION)

CONFIDENTIAL

TO. Mr. J. H. Marsh

DATE. January 3, 1977

SUBJECT. NIOSH Document Entitled: "Re-examination and Update of Information on the Health Effects of Occupational Exposure to Asbestos"

I have read the above mentioned document and feel that some comment is warranted in view of its attempt to over-simplify a complex occupational health control problem. I am astonished by the casual approach of the authors to this subject, especially as they do not have any original work of their own to put forward as evidence for altering a standard based upon a dose-response relationship in human beings and supported by circumstantial evidence. The circumstantial evidence, although some is unpublished in the literature, has all been made available to OSHA by the AIA/NA and by Johns-Manville in their respective submissions on the October 1975 proposals. If the scientific adviser to OSHA (and that is what NIOSH is) is as naive as it appears to be from this update document, then scientific logic is going to have difficulty in prevailing upon them to modify their attitude. In my opinion, NIOSH still has to grow up!

The review of animal data on carcinogenicity makes interesting reading but offers no new facts. It appears to confirm that benzo(a)pyrene and asbestos act together as co-carcinogens and that both can also cause cancers on their own.

The work of Wagner and Stanton and Wrench is quoted and it is stated: "Evidence that the response was dose-related was provided...." It is not relevant when discussing artificially induced tumors produced by extra-ordinarily high dosages (weight for weight for dust and animal dusted) to assess the effect of exposure time required to induce a response. The workers quoted were merely using animal models to reproduce a response to asbestos already noted in man in order to validate the cause and effect assumptions previously made. They inadvertently discovered an apparent dose-response relationship.

The importance of fibre diameter and length is rightly stressed as well as the fact that the animal defense mechanisms and metabollic processes can eliminate asbestos at varying rates for different fibre types.

The review of "Human Data" encompasses no fewer than 127 references.

Nobody disputes the epidemiological evidence which associates asbestos exposure with asbestosis, lung cancer, gastro-intestinal cancer and malignant

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mesothelioma. The fact that it is now recognized that the risk of contracting these diseases extends beyond the factory walls and involves users and fabricators of asbestos and products containing asbestos is not in dispute.

When dealing with the work of Newhouse and Berry regarding the projected incidence of mesothelioma it is incorrectly stated that "11% of asbestos workers" deaths in England will be from mesothelioma. In their paper on this subject published in 1976 and not reviewed by NIOSH the authors summary reads as follows:

> "Using the accumulated data on deaths from mesothelial tumors among cohorts of male and female factory workers at a London asbestos textile factory, the mortality from this cause up to the year 2000 AD has been predicted. The limitations of the methods used are pointed out, but it is estimated that for men the mortality due to mesothelial tumors will be between 7% and 11% of the total mortality and somewhat higher for women. The highest number of deaths from mesothelial tumors will occur during the 1980's, thereafter the numbers will decline because of the decreasing size of the cohort resulting from general mortality."

It is important to realize that this prediction is based upon findings in a cohort of workers from one factory using predominantly crocidolite (but where chrysotile and amosite were also used) and employed at a period of time when dust controls were changing over the years. These authors point out the importance of the lapse period and show that the mesothelioma incidence rate per 100,000 subject years at risk increases from 6 at between 10-15 years after first exposure to 318 among those with a follow-up period of 30 or more years. Also, both the degree and length of exposure are important and for men and women the rate increases both with longer periods of employment and with more intense exposure. In those with low-moderate exposure and only short periods of employment, the mesothelioma rate is about 1/6 of the rate of those with severe long exposure.

One more point with regard to this very important paper is to add the authors following statement: "Therefore the conditions responsible are not those which should be achieved today. The evidence of a dose response relationship shows that improved control of the factory environments at present and in the future should markedly reduce risks."

Had the NIOSH authors reviewed the Newhouse and Berry paper they would not have made the sweeping statement regarding mesothelioma predictions.

In reviewing the different types of asbestos and their biological effects, the authors attempt to convey the impression that all types of asbestos are carcinogenic without acknowledging the gradation of effect with regard to mesothelioma. Careful review of the literature quoted clearly indicates the more frequent association of this tumor with crocidolite, its lesser association with chrysotile and its doubtful (only 1 study) association with amosite. Anthophylite is not known to be associated with mesothelioma occurrence.

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Quoting a letter from R. A. Lemen to Vernon Rose, Director, Division of Criteria Documentation and Standards Development, the authors state that in a preliminary study on female workers employed between January 1940 and December 1967, there were 7 lung cancer deaths among 580 women when only 0.63 deaths were expected. Four of these deaths were in "never" smokers as determined from hospital admission charts and two were in women with undetermined smoking history. They attempt to conclude that because the death rates in the general population are equally affected by cigarette smoking, the excess lung cancer deaths among asbestos workers must be attributable to their occupation. In order to test this hypothesis it is necessary to prove that non-smoking asbestos workers have an incidence of death from lung cancer which is greater than that for non-smoking non-exposed workers of the same age, sex, ethnic group and region of domicile. Comparisons of death rates in a population with that for the general population may be invalid or at least very inaccurate. A study is needed to compare mortality trends for lung cancer in asbestos workers who smoke, asbestos workers who never smoked, matched controls from smoking and non-smoking non-exposed workers. It should also be remembered that retrospective studies have difficulty in determining smoking habits. A major defect of nearly all epidemiologic studies to date is a lack of definitive exposure histories and dust measurements. The crux of the matter is what risk is run by asbestos workers (whether they smoke or not, irrespective of sex) exposed in industries in compliance with the present regulations. Furthermore, whereas deaths from lung cancer in women in the general population are at a lower absolute level and have increased at a lower rate than for men, they are now increasing very rapidly. The increase has doubled in the 10 year period 1960-1970 and is still rising and is thought to be due to the increased number of women who smoke. It is a particularly unfortunate choice of population group to study in view of this, especially in the situation where smoking histories are incomplete.

I do not propose to comment on the section dealing with fibre analysis in tissue as this does not appear to be of importance with regard to setting standards, in spite of the authors' final remarks in this section.

The entire section on Sampling and Environmental Data serves to emphasize the folly of attempting to measure minute quantities accurately. At best the measurement of asbestos in the environment is a statistically based concept providing an index to exposure. Asbestos sampling with currently available equipment, no matter how sophisticated, has its greatest value as an engineering control device. When the engineers have managed to reduce asbestos dust in the environment to its lowest measurable quantity, then epidemiological studies will provide the answer as to the adequacy of their skills.

The section on the "Basis for a Standard" once again brings up the discrepancy between the 1968 BOHS Recommended Standard Data and the figures given in my paper to the Royal Society of Health published in 1972. No comment is made that dust levels were not given in my paper and no attempt was made to correlate asbestosis with dustiness. The many defficiencies in this study are ignored because it serves NIOSH's purpose to do so.

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The paper by Howard et al (1976) is the paper which was presented at Brighton in September 1975. This paper is due to be published in 1977 in the British Journal of Industrial Medicine. It indicates that a residual lung cancer risk is still demonstrable in a factory population exposed to "modern conditions" post-1950 in a large asbestos textile factory in the UK, but the NIOSH authors do not explore the possible explanations for these findings. It can be seen by studying this paper and comparing it with the three preceding papers on the same cohorts, that the cancer risk is greatest for the population exposed before dust control regulations took effect and that the risk to the post-1933 population has markedly decreased. The population followed-up post-1950 is small and the excess cancer deaths are barely statistically significant.

In reconstructing the dust exposures of this cohort it can be shown that 94 of the 255 men and 15 of the 93 women had cumulative exposure in excess of 100 fibre years/ml. All the cases of lung cancer were males and all were cigarette smokers. This report should be regarded as indicating a good prospect for the future in that dust control measures in the past 25 years are obviously beginning to eliminate both asbestosis and lung cancer in this factory. Prolonged prospective follow-up of exposure groups since new dust control measures came into effect will provide the final answer.

The recommended standard in this NIOSH document is not based on the epidemiological or biological facts. Roach has stated, with regard to the BCHS Standard that, "Open recognition should be given to the possibility that people might be adversely affected, even when the recommended standards of air cleanliness are maintained. It was recognized that to protect the hypersusceptible workers environmental control would have to be supplemented with medical examinations." To set the standard "at the lowest level detectable by available analytical techniques" ignores the substantial body of evidence which indicates:

1. a dose-response relationship for mesothelioma, lung cancer and asbestosis,

2. that fibre shape and size, in turn related to variety of raw material, is perhaps of crucial importance,

3. that cigarette smoking adversely biases statistical evaluations of dose-response relationships.

I cannot concede that the literature cited in this document in any way provides evidence of the inadequacy of the present standard, but, having special knowledge which I am not yet privileged to disclose, must put on record that a more stringent standard is almost certain to emerge in the United Kingdom. It is likely that such a standard will take account of working exposure times as well as fibre counts. The crux of the matter is that there is insufficient detailed data available as yet to allow an analysis of the effects of lower than 2 f/cc. levels of exposure over more than 20 years. Until such time as it can be decisively stated that this level of exposure does not afford protection in industry against

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all forms of asbestos-associated disease, arguments as to whether a safe level exists or not are academic, and provide hot-air to inflate the political ballon which NIOSH and OSHA are passing to and fro leaving industry to be piggy-in-the-middle!

Hilton C. Lewinsohn

/as

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