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Dr. Welsh

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20 May 1974

Memorandum For: MEMBERS

Subject: Answers to Questions addressed to Irving J. Selikoff, M.D., Mount Sinai School of Medicine

Reference:

A. Minutes of Special Board of Directors Meeting, February 21, 1974, New York City, forwarded March 6, 1974

B. Executive Director letter to Dr. Selikoff dated February 26, 1974

C. Executive Director letter to Dr. Selikoff dated March 6, 1974 (not to all)

Enclosed are answers from Dr. Selikoff with regard to the 13 questions included with Ref. A and submitted to Dr. Selikoff by Ref. b.

R. H. Mereness
Executive Director

Enclosure

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PLAINTIFF'S EXHIBIT
UC-1344

MOUNT SINAI SCHOOL OF MEDICINE
of The City University of New York
FIFTH AVENUE AND 100TH STREET • NEW YORK, N.Y. 10029

Department of Community Medicine

May 14, 1974

Mr. R. H. Mereness, Executive Director
Asbestos Information Association
1660 L Street, N. W.
Washington, D. C. 20036

Dear Mr. Mereness:

I regret we didn't have time to discuss outstanding questions at our recent meeting; clarification of such outstanding problems is often the most useful part of a meeting.

I have briefly commented below concerning the several questions raised:

1. I know of no comparable studies which provide information concerning the relative occupational hazard of crocidolite, chrysotile, amosite. I am aware that Dr. Enterline's study of Johns-Manville asbestos cement workers exposed to crocidolite in addition to chrysotile provided data interpreted by him as suggesting that exposure to these fibers was associated with additional hazard. I consider that such interpretation is insecure, in view of many uncertainties and variables.

2. There is very little information, especially in humans, concerning the relative toxicity of asbestos fibers identical in all respects except for "size" (? length, ?diameter, ?surface area). Dr. Langer of our Laboratory has found, for example, that the overwhelming number of fibers in the lungs of asbestos workers who die of asbestosis or mesothelioma are very small, most in the submicron range. Relatively few are visible by light microscopy. Huth and his colleagues found approximately as many experimental mesothelioma with chrysotile fibers shorter than 3μ as with those longer. These results have not been controverted.

   Further evidence on this matter can be extensively provided, but this is hardly the occasion for it.

3. I see no reason not to use asbestos-containing filter media, provided the end-product does not contain more asbestos than the initial ingredients. I would not support the use of such materials, however, if they added to the concentration of asbestos.

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4. There are no reliable data on the total number of mesotheliomas in the United States each year. Data are currently available only for occupationally exposed asbestos workers where studies indicate that approximately 5% of deaths are due to pleural or peritoneal mesothelioma. Some measure of the annual number of mesothelioma deaths among these workers can be obtained by reviewing data concerning newly hired asbestos workers each year 1930-1960. Calculations could even include such variables as age distribution, duration of employment.

   The Public Health Service has estimated that there are now some one million workers who are currently employed in asbestos trades or who were previously employed but who are now either retired or working elsewhere. Without knowing their age distribution and year of onset of asbestos work, only rough projections are possible 1970-2000.

   Although mesothelioma may occur as a result of neighborhood or family exposure, or as the result of "bystander" exposure in shipyards or the construction industry, few data are available that would allow reliable quantitative estimates to be made in such circumstances.

   Should any studies be planned to provide information concerning the number of mesothelioma cases in the United States, I would hope that an appropriate design would be used. Otherwise, results would be questionable and conclusions potentially misleading, as has been the case in some studies that have been made.

5. There are no reliable data one way or the other concerning cancer hazard that might be associated with the ingestion of asbestos fibers in water, beverages, food or in fluids used for the administration of drugs. The question is an important one and it is, in my opinion, wrong to state that there is no cancer hazard present. We simply don't know, one way or the other, and the phrasing of the statement as it now stands, is misleading.

6. It would not be at all surprising that an asbestos filter would sharply decrease the amount of asbestos in a liquid which had been deliberately heavily loaded with fiber. I fail to see why an experiment had to be done to document such an obvious conclusion.

   The pertinent experiment would be whether or not asbestos-free liquid passed through an asbestos filter becomes contaminated with fiber from the filter. Such experiments have been done in Dr. Langer's laboratory and they show that the filtrate becomes contaminated.

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The question submitted suggests that uncertainty still exists on this point. We had thought it sufficiently obvious that we were reluctant to publish what seemed self-evident. Perhaps we were wrong and should record the data.

7. The suggestion inherent in this question - that other filter materials might add carcinogenic potential to the filtrate - is an interesting one and data should be obtained. Thus, if vinyl chloride monomer were to be leached from PVC-containing filters, I suspect that FDA would wish to investigate the matter. I am unaware of the levels of polycyclic aromatic hydrocarbons that might be derived from activated carbon. This, too, would be of interest. Finally, I am unaware of data concerning the carcinogenic potential of diatomacious earth.

8. I have seen asbestos-associated disease following occupational exposure for one or two days thirty years before. However, this was not minimal exposure, since it occurred in an asbestos factory with few controls and with what we now consider very heavy exposure. Thus, the exposure might have been brief, but not necessarily minimal.

   Dr. Hammond and I have recently published data indicating a serious increase in lung cancer risk (age, year and sex specific) among individuals exposed to such uncontrolled conditions for three months or less, and traced some thirty years later. This, again, is not "minimal" exposure. Rather, it is better categorized as exposure of limited duration.

   Thus, uncontrolled exposure, in my opinion, poses a serious problem, wherever it exists.

9. I do not believe that asbestos is the only cause of mesothelioma. Review of cases in the South Africa Mesothelioma Registry by Dr. Webster and his colleagues indicated that approximately 15% of cases studied by them had no recorded history of either environmental or occupational asbestos exposure. Experimentally, of course, other agents can produce mesothelioma, as well.

   We have considered investigating other possible causes of mesothelioma, but the press of priorities and limited resources have so far not allowed us to investigate this interesting question.

10. We are now regularly seeing cases of mesothelioma with occupational history of employment in shipyards during World War II. These are random cases, however, and happen to be referred to us because physicians know of our interest in the disease. We did make inquiry at the Norfolk shipyard to see whether records there could be made available for an appropriate population-based study but this came to naught. Similarly, we have proposed that an investigation be undertaken by the U. S. Navy and this, too, has been

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implemented. However, the navy, through the Federal Bureau of Employees Compensation now compensates all cases of mesothelioma who worked in navy shipyards in World War II, provided that they had no asbestos employment since.

Very worrisome data were reported several months ago by Dr. John R. Edge of the High Carley Hospital in Lancashire. He found in a male autopsy study in Barrow, where a very large majority of the male population has worked in shipyards, that approximately one-third had pleural plaques and that approximately 6% had radiologically visible pleural plaques (of the current shipyard workforce). Prospective observation of a group of 235 men with pleural plaques, starting in 1970, showed that 70 had died by 1973. 17 died of mesothelioma.

These new data give added cause for concern (as do Dr. Harries' most recent data) especially since we still have no successful treatment for this condition.

If you have access to appropriate industry sources that would allow us to trace a large cohort of 1940-1945 shipyard workers, we would be pleased to undertake such an investigation and will be able to provide useful data concerning the expected incidence of mesothelioma among such people.

11. I thoroughly agree that peak exposures may be of considerable importance, and that time weighted averages may not at all tell the whole story. We have made a series of measurements concerning peak exposures, and have reported these.

12. We have not investigated asbestos-associated lung cancer other than in asbestos workers. We would therefore expect to find concurrent asbestosis, at least histologically, in cases of lung cancer that we see. However, lung cancer may occur among workers who have very little or no radiological evidence of pulmonary asbestosis. As you know, not all occupationally exposed asbestos workers develop radiological evidence of pulmonary fibrosis.

It is of interest, further, that Dr. Churg found varying levels of pulmonary fibrosis (asbestosis) among cases of asbestos-associated lung cancer studied by him, and recently reported. Some cases ha very little fibrosis, and others had a good deal.

13. We are now investigating this question, prospectively. In 1963, we examined over 1,100 asbestos insulation workers and recorded the extent of radiological pulmonary fibrosis among them. These men have remained under observation and all deaths have been recorded. We intend to analyze the experience of these men, in relation to the extent of fibrosis in 1963. Analyses will take age, cigarette smoking, total exposure and duration from onset of exposure, into account.

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Sincerely yours,

Irving J. Selikoff M.D.

QUESTIONS

1. In recent months, some reports in the press indicate that you now feel crocidolite is more hazardous than chrysotile. In your opinion, is this true? Should there be different standards for chrysotile and crocidolite, as well, perhaps, as for amosite?

2. Statements have been made by individuals from the Environmental Sciences Laboratory at Mount Sinai that EM-sized asbestos fibers are as harmful as light-sized fibers. Do you have any solid evidence that this is true, considering Stanton's research indicating that fibers in the sub-micron range are not harmful?

3. What is your position with reference to the continued use of asbestos-containing filter media, such as filter sheets, used in both parenterals and ingested products?

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4. What is your estimate of the yearly total of mesothelioma cases in the United States? How many of these do you think are asbestos-related?

5. What is your opinion of the position taken by the Advisory Committee on Asbestos Cancers of the International Agency for Research on Cancer of the World Health Organization to the effect that "There is no cancer hazard resulting from the ingestion of asbestos fibers present in water, beverages, food, or in the fluids used for the administration of drugs."?

6. Would you comment on the two recent reports issued by the FDA with reference to the use of asbestos filters, both of which would indicate that asbestos filters do not add asbestos fibers to the filtered liquid? The first report was by Mr. Philip McGrath to Dr. Armand Casola, dated July 10, 1973, showing that an asbestos filter, far from adding to the contamination, almost eliminated asbestos from a liquid which had been deliberately heavily loaded with the material. The second report, from Dr. J. Richard Crout to the Acting Director, Bureau of Drugs, would indicate that the use of asbestos-containing filters bears no relationship to the presence of asbestos fibers in finished parenteral products.

7. Would you comment on the possible carcinogenic effects of other filter media, such as the polymers in membrane filters, diatomaceous earth, and activated carbon?

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8. You have been quoted as saying that asbestos-related disease can be contracted from very minimal exposure to asbestos -- one or two days, for example. Do you have evidence that this is really a serious problem or has your position been exaggerated in the press?

9. Do you believe that asbestos is the only cause of mesothelioma? Are other possible causes being investigated by the Mt. Sinai Environmental Laboratory?

10. You have predicted an epidemic of mesothelioma among World War II shipyard workers. How many actual cases are you finding or are you aware of per year in this industry?

11. You have talked of the two- or three-fiber Time Weighted Average of the insulation workers, but have said little about peak exposures. Isn't it likely that these are of even greater importance in the causation of disease than the medium or low average exposures? Are you undertaking any investigations in this area?

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12. You have stated that lung cancer can develop from lower levels of exposure than asbestosis, yet most cases of lung cancer occur among workers who already have asbestosis. How is this explained?

13. What percentage of the lung cancer deaths in the insulation workers whom you have studied occur among those workers who don't have asbestosis?

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