PLAINTIFF'S EXHIBIT AIA-26

AIA NORTH AMERICA ASBESTOS INFORMATION ASSOCIATION
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MAR 15 1976

M E M O

To: - Participants in Asbestos Industry Response to the Proposed Asbestos Regulation

Subject: Task Force Status Report -- Forwarding of Comments by Hans Weill, M. D. on Proposed Revision to OSHA Asbestos Standard

The Association's Executive Committee will meet with Mr. Guy G. Gabrielson, Jr., Chairman, AIA/NA OSHA Standard Task Force, Thursday, March 25 for review of documents to be submitted to OSHA by the announced comment deadline April 9. On Friday, March 26, the "comment package" will be presented at a meeting of the Association's directors following which the documents, including the comprehensive report of the Roy F. Weston, Inc. technological feasibility and economic impact study, and specific recommendations for changes to the proposed revision to the standard, will be mailed to all participants for endorsement. It is recognized that little time will be available for review of the documents by those not attending the Board of Directors meeting. The time requirements of the task offer no alternative if we are to meet the April 9 deadline.

Because of the significance of the comments prepared by the Association's medical consultant, Dr. Hans Weill, on the medical science issues raised in the proposed revision to the OSHA standard to those participants who are preparing company or trade association response to OSHA in addition to endorsement of the AIA/NA task force presentation, Dr. Weill's statement is forwarded with this memorandum.

We are pleased to advise that the Association continues to increase its membership and a number of non-member companies and associations have contributed to the extraordinary expense of consultant fees and task force administrative costs. We are appreciative of the splendid cooperation of participants in the Association's efforts to assist the Department of Labor in the development of a practicable standard for the protection of asbestos workers.

MAR 18 1976

R. H. Mereness
Executive Director

RHM:v
Enclosure

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I would like to make clear my role in submitting these comments on the proposed new standard for occupational exposure to asbestos. I was asked to prepare an objective, scientific assessment of the literature cited by OSHA in support of its proposed standard change by the Asbestos Information Association of North America. I accepted this consultative task because I firmly believe that industry, in order to meet its occupational health responsibilities, must have available to them outside advice from academic and other sources. It is my objective in the following discussion to provide scientifically-based and dispassionate judgments on the issues raised and in no way assume an advocacy or adversary position.

There should be no doubt or confusion concerning the reasons or indeed justification for the setting of occupational health standards by regulatory agencies: these standards are set to protect workers exposed to environmental hazards in the work place. The standard-setting process should begin with a scientific data base providing quantitative information on the relationship between the environmental exposures and any associated health effects. Without data for both sides of this equation for a particular health hazard, resulting information is incomplete in terms of the important function of setting standards for safe levels of occupational exposures. Although these requirements have now been recognized by both government and non-governmental scientists, the fund of hard data of this type which is

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back to 1907, do not relate to the central issue, that being at what level (if any) of exposure do such effects fail to occur. Documenting that these health effects have occurred in workers who have had years of exposure to asbestos dust without relating measurement or reasonable estimates of past exposures to these effects has been of great importance, but does not materially assist in the standard setting process. It is respectfully suggested that the great majority of the 42 references cited in the proposal must be classified in this way.

Because of the emphasis placed by the writers of this proposal on a few, mainly unpublished, recent reports, these will be reviewed in some detail. Few studies have received as much attention and imputed importance in this standard setting process than the epidemiologic investigation of a cohort of workers employed in an asbestos textile plant in the industrial midlands of England. However, it is with some dismay that our British colleagues view the current use of their data, which is in many ways incomplete, by scientists and regulatory agencies in the U.S. Certain facts seem indisputable. The initial report published by Professor Doll in 1955 demonstrated a clear excess in respiratory cancer and pulmonary fibrosis in workers who had previous exposure for 20 or more years in this plant (1A). Follow-up of mortality data published in 1968 provided evidence that workers having their initial exposure since the asbestos regulations

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dust exposure data were presented nor were claims made in regard to the utility of these results in setting safe standards or in generating dose-response relationships between asbestos exposure and risk of developing respiratory cancer.

Because of the importance placed on this study and the recent orally presented (but not published) report, and the requirements outlined above for the scientific basis of rationally promulgated occupational health standards, I undertook a visit to this plant during the week of January 12, 1976, with the hope of obtaining specific dust exposure data during the period since 1951, with the view of correlating level of exposure to asbestos dust with the demonstrated mortality results. Exceptional cooperation by the medical director, industrial hygienist, and management of this plant resulted in their providing extensive exposure information for this cohort, which formed the basis for the following comments. Dust data between 1951 and 1960 are based on sampling using the Casella Thermal Precipitator giving particles per milliliter, and since 1961 are based on static or area sampling using the membrane filter method and providing fibers per milliliter. For the decade prior to 1961 (when fiber counts first became available), the particle counts were converted to fiber levels. Using these data, an individual exposure estimate was reconstructed for each member of the mortality cohort for the period 1951 through 1974, using yearly average data

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1972 reveal mean values in some job areas ranging as high as 26 fibers per ml., with standard deviations close to that number, indicating that some individual counts would have to have been many times the current standard in either country. Again, it must be emphasized that in the main these very high values were obtained prior to the 1969 asbestos regulations (U.K.). However, in carding and several other job sites, more recent sampling data continued to show some average values of 4, 5 and 6 fibers per ml., with standard deviations around the mean again indicating individual fiber counts at higher levels.

Among those individuals first exposed to asbestos dust in this plant since 1951, ten have now been certified by the Pneumoconiosis Medical Panel as having asbestosis. The minimum exposure period of this group was 10 years, maximum 18 years, mean of 14 years; and the cumulative mean group exposure was 170 fiber-years per ml. All of these workers were men and entered the plant between 1951 and 1956. Their individual cumulative exposure calculations ranged from 66 to 280 fiber years per ml.

Six individuals in the cohort first employed since 1951 have died of respiratory cancer, five of these whose time from initial exposure to death was greater than 15 years. These persons were all cigarette smokers whose year of first exposure ranged from 1952 until 1956. In each of these six individuals, the average yearly exposure to asbestos while employed exceeded

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sub-population have been below 75 fiber years per ml. in workers first exposed since 1951. It is of interest that in this population, there have been no cases of certified asbestosis or lung cancer, encouraging preliminary evidence in regard to the safety of a 2 fiber per ml. average exposure.

There have been no cases of mesothelioma in the post-1951 cohort of this plant.

The conclusions to be drawn from the biologic and exposure data from this asbestos textile plant since 1951 are reasonably straightforward. It is probable that an excess risk for the development of respiratory cancer exists in the post-1951 cohort being studied by the Oxford group. The numbers are small and Professor Doll indicated to me in January, 1976, that this excess has not yet been firmly established. In addition, asbestosis has appeared in members of this cohort. In this population, asbestos exposures during the past 20 or more years have on average clearly exceeded the current 2 fibers per ml. standard and these studies in no way invalidate that standard in regard to its adequacy in protecting from asbestos-related health effects. The use of this report (30) in supporting a change from a standard (2 fiber per ml.) which has not yet become operational in the U.S. to 0.5 fibers per ml. must be considered at best invalid and at worst misleading.

Often not recognized, particularly in the U.S., is the fact that the current British asbestos standard of 2 fibers per ml. is not based on the Doll

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ities with respect to their significance to asbestosis was not attempted in the Lewinsohn paper. Equating the lowest category of radiographic change with the disease, asbestosis, is obviously of questionable merit and as previously indicated, the x-ray appearance was not the primary basis for the establishment of the BOHS standard. In view of the described dust exposure levels in this plant since 1951, the controversy concerning differences in interpretation of morbidity data is less relevant in assessing the safety of a 2 fiber per ml. average exposure standard. The BOHS subcommittee has for the past several months been reviewing the asbestos standard in the U. K. Updated dust exposure data similar to those described previously are being correlated with the various indicators of a biologic response in exposed workers, including clinical, radiographic and physiologic information. A recent meeting of this subcommittee (mid-January, 1976) failed to result in even a preliminary position concerning the asbestos standard and it appears that it will be some months before a report to the full BOHS standards committee will be completed. It is only after the BOHS committee has approved the final report that it will become generally available.

Considerable attention has also been directed toward the report of an investigation by NIOSH presented at the Conference on Occupational Carcinogenesis, New York Academy of Sciences, in March, 1975 (41). This study entitled "Morbidity and Mortality among Hard Rock Miners exposed to an

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micrograms per cubic meter were measured in this mine in 1974. Although the authors preclude the possibility that arsenic (a known carcinogenic material) may have played a role in any excess respiratory cancer risk, a NIOSH investigator added to the list of authors in the last draft presented a separate paper on inorganic arsenic at the same New York Academy of Sciences meeting in March with the following statement included in the published abstract of this report: "the only quantitative epidemiological study, reported in 1974, revealed a dose-response demonstrating an increased lung cancer mortality risk at arsenic concentrations above 1 microgram per cubic meter, calculated as the average occupational exposure over a 40-year work life". The conclusions of these NIOSH investigators in this same meeting seemed contradictory, and it is difficult to understand why specific reference to the arsenic levels have been deleted from the final gold mine study draft.

Two of these same NIOSH investigators have previously pointed out the pulmonary carcinogenic effect of radon daughter exposures in the uranium mining industry (3A). Dr. Wagoner also authored a paper entitled "Unusual Cancer Mortality among a Group of Underground Metal Miners" published in the New England Journal of Medicine in 1963 showing a respiratory cancer excess of a magnitude similar to that claimed in the gold mine study (4A). No etiologic factor was firmly established, although trace metals,

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both of which exceed the TLV for silica". These airborne silica data are excluded from the last draft. This is of particular interest since the authors claim that a statistically significant excess in non-malignant respiratory disease was noted in this cohort. In the earlier draft, this excess is entirely explained by a diagnosis of "silicosis" in four of these miners. It would be difficult to associate the finding of silicosis at death with past exposures to small asbestos fibers. This subject is further confused when in the last draft the term "pneumoconiotic disease" is substituted for silicosis as the cause of death in the non-malignant respiratory disease category.

Smoking analysis, which was included in earlier drafts, is no longer present in the pre-publication or last draft. Additionally, the single paper which was presented orally at the conference was divided into two papers after the second draft, the additional paper now entitled "Asbestos Fiber Exposures in a Hard Rock Gold Mine". It describes the amphibole fiber measurements indicating an average concentration of 0.36 fibers per ml. greater than 5 micron in length, and an average total fiber concentration of 4.82 fibers per ml., with 94% of the fibers being less than 5 microns in length. The conclusions of this second paper, however, include broad statements concerning the health effects of this exposure, none of which are supported or even dealt with in the results reported in the manuscript.

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based is forthcoming in this latest report presented at the International Conference on Biological Effects of Asbestos, in Lyon, France, in 1972. At this same meeting, Dr. Selikoff's group again confirmed the interaction between asbestos exposure and cigarette smoking and the risk of developing carcinoma of the lung (20). It was suggested that this risk may also extend to asbestosis but again in the absence of exposure information, it is difficult to justify the inclusion of this report in the literature purporting to support the asbestos standard change. Also made available in the recent past is a paper reporting the presence of asbestosis, lung cancer, and mesothelioma in a cohort of workers who have had past exposure in an amosite insulation manufacturing operation (18). It is clearly stated that "no information is available concerning dust levels in this plant" and this interesting study is hardly useful in the setting of safe asbestos standards. A study of insulation workers in Belfast, published in 1971, confirmed the New York insulation experience and found excess mortality in asbestos-exposed insulators for the specific causes of lung fibrosis, lung cancer, mesothelioma, and gastro-intestinal malignancy (26). Of interest is that the lung cancer cases had associated pulmonary fibrosis (asbestosis) while those individuals who died of mesothelioma did not. This result speaks to the controversy concerning whether asbestos-related lung cancer is associated with a level of exposure which has also resulted in pulmonary fibrosis. Again, in the absence of

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A number of cited references concern themselves with the association between asbestos exposure and the risk for the development of pleural or peritoneal mesothelioma (21, 22, 23, 25, 32, 33, 34, 37, 38). As no environmental dust data are reported in any of these studies, dose-response relationships can to date not be established for these malignant tumors. Considerable credit should be given to Wagner (21) for recognizing and reporting this association in 1960. These tumors have been reported in cases where the exposure had been occupational but also where contact had been in the household or in the vicinity of an industrial or mining asbestos source. It should be recognized, however, that these non-occupational sources of exposure are not necessarily low but probably of the "intermittent high level" type, perhaps similar to those exposures experienced by individuals in factory maintenance jobs. In the absence of more precise information, the demonstration of these associations does not help in setting safe levels of asbestos exposure. Certainly, there is no scientific basis for concluding that household or other non-occupational exposures have been in the range of 2 fibers per ml. or less. Newhouse and Berry (25) reported on a statistical model designed to predict future mesothelioma rates in a cohort of workers previously employed in an asbestos textile factory near London. Past exposures had been admittedly high prior to the closing of the plant in 1968. Dust levels, however, were not available and this

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amosite plant previously discussed. Both pleural and parenchymal changes were found but the association of these radiographic abnormalities with asbestos exposure must be studied further and the x-ray readings should be confirmed. Assuming the changes to be present, the past level and intermittency of exposure in these households is completely unknown. Considerable asbestos dust must have been brought to the homes by workers returning from a factory without significant dust control, since the same New York group of investigators have recently found evidence of significant asbestos fiber accumulation in these homes up to the present time.

An interesting and provocative paper presented at Brighton by Nicholson (19) reviews the factors involved in arriving at a threshold limit value (TLV), particularly the limitations of this approach. While this review or editorial provides stimulus for further scientific and philosophical discussion concerning the standard setting process, it does not claim to present evidence supporting the proposed change in the asbestos standard to an average of 0.5 fibers per ml. I agree with the statement in Dr. Nicholson's summary: "in the case of asbestos, current exposures can only be described crudely at any level of exposure, and health effects are only known for past high, but ill-defined, exposures." Finally, in another thoughtful paper cited by OSHA, Berry (11) stresses the importance of acceptable risk as balanced by the benefits of using the particular material

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cannot finally conclude at this time that this level is "safe" in regard to all health effects recognized to be associated with asbestos exposure, in all exposed individuals. However, it is also impossible to state that the proposed average exposure of 0.5 fibers per ml. for a working lifetime is free of these health hazards. However, the limited information available from studies on both sides of the Atlantic, which attempt to define dose-response relationships, is encouraging in regard to a 2 fiber per ml. standard.

The other alternative depends upon the following argument. Occupational exposure to asbestos at some level has been shown to be associated with a carcinogenic risk. Since a safe threshold level of exposure cannot be scientifically proven at this time, the standard must require that all exposures be at or below the lowest technologically feasible level. The implications of this approach, vis a vis the multitude of carcinogenic materials in our environment, are far-reaching and must be faced. Those who favor this alternative must vigorously support a uniform approach and defend the resulting consequences on life in our society. I favor the first alternative as being prudent and protective of the worker's health in light of the best available current scientific information. The 2 fiber per ml. standard, which is to take effect in this country in mid-1976, has not yet become a reality in either the U.S. or U.K. This standard should be given

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CURRICULUM VITAE

Hans Weill, M.D.

Education

Tulane University, 1951-54, B.A., June, 1955
Tulane University School of Medicine, 1954-58, M.D., June, 1958

Post-Graduate Medical Training

Intern, Mt. Sinai Hospital, New York City, 1958-59
Resident, Charity Hospital of Louisiana, New Orleans, Tulane Medical Unit, 1959-60
Research Fellow, Department of Medicine and Pulmonary Laboratory, Tulane University School of Medicine, 1960-61
Chief Resident, Charity Hospital of Louisiana, New Orleans, Tulane Medical Unit, 1961-62

Teaching and Research Appointments

Instructor in Medicine, Pulmonary Diseases Section and Pulmonary Laboratory, Tulane University School of Medicine, 1962-64
Assistant Professor of Medicine, Tulane University School of Medicine, 1964-67
Associate Professor of Medicine, Tulane University School of Medicine, 1967-71
Professor of Medicine, Tulane University School of Medicine, 1971-present
Director, Specialized Center of Research (SCOR) in Occupational Respiratory Disease, NHLI, 1972-

Hospital Appointments

Visiting Physician, Charity Hospital of Louisiana at New Orleans, Tulane Unit
Chief, Pulmonary Function Laboratory, Veterans Administration Hospital, New Orleans, 1963-present
Consultant in Pulmonary Diseases and Medicine, USPHS Hospital, New Orleans, 1964-present

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Hans Weill, M. D. - CV cont'd

Honors and Societies

Phi Beta Kappa, 1955
Alpha Omega Alpha, 1958
American Thoracic Society, 1962
Orleans Parish Medical Society, 1963
Diplomate, American Board of Internal Medicine, 1965
Fellow, American College of Chest Physicians, 1965; Governor for La., 1970
Fellow, American College of Physicians, 1967
Certified in Pulmonary Diseases, American Board of Internal Medicine, 1966
American Federation for Clinical Research, 1967
Southern Society for Clinical Investigation, 1969
Chairman, Post-Graduate Course, Pulmonary Function in Health and Disease, 1970-72
Fellow, Royal Society of Medicine, 1971
New York Academy of Sciences, 1971
Society for Occupational and Environmental Health, 1972
Councilor-at-large, American Thoracic Society, 1973 -
President-elect, American Thoracic Society, 1975

Consultant and Committee Assignments

Member, Task Force on Environmental Lung Diseases, National Heart and Lung Institute, NIH, 1972
Consultant, National Institute of Occupational Safety and Health, TDI Criteria Document, 1973, Phosgene Criteria Document, 1975
Planning Committee, Occupational Lung Disease post-graduate course, Annual Meeting of American Thoracic Society, 1973
Program Committee, American Lung Association, 1973
Faculty Advisory Committee, Tulane University School of Medicine, 1973 -
Secretary-Treasurer, New Orleans Academy of Internal Medicine, 1973 -

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