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Chemical Manufacturers Association

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Record of Meeting

DEC 26 1979

VINYL CHLORIDE RESEARCH COORDINATORS R. L. Gibson, M.D.

November 28, 1979

CMA Offices, Room 407

Washington, D. C.

MEMBERS PRESENT

R. T. Torkelson, Chairman	Dow Chemical Company
T. J. Benya	Ethyl Corporation
Z. G. Bell, Jr.	PPG Industries, Inc.
W. D. Harris	Uniroyal, Inc.
M. N. Johnson	The BFGoodrich Company
V. L. Kirkland	Shell Chemical Company
W. M. Smith	Air Products & Chemicals, Inc.
R. N. Wheeler	Union Carbide Corporation
J. T. Seawell	CMA Staff

PRESENT BY INVITATION

J. Stafford	Imperial Chemical Industries, Limited (ICI)
W. Adams	ICI
C. P. Duffield	ICI
J. Lawrence	The Society of the Plastics Industry

1.0 Approval of Record of Last Meeting

The record of the September 20, 1979 meeting was approved as recorded.

2.0 Recommendation on Distribution of Records of Meeting of the Research Coordinators

The Research Coordinators recommended that their records of meetings be sent to the "original" thirty sponsors of biological research programs and to the sponsors of the ongoing epidemiological study.

CUSAROSS 01061

3.0 Procedure Developed for Handling the Settlement Proposed by the General Counsel for Industrial BIO-TEST Laboratories (IBT)

The settlement to be proposed by IBT Counsel within the next several weeks is to be sent first to the Vinyl Chloride Audit Task Group (VC/ATG). After taking the action required, the VC/ATG will send their recommendations to the Research Coordinators. The Research Coordinators will then, in turn, prepare recommendations to be submitted to the Panel.

4.0 Epidemiological Study of Workers Exposed to Polyvinyl Chloride Dust

Drs. John Stafford and William Adams of ICI, England presented a thorough-going review of the study sponsored by ICI and conducted by the Institute of Occupational Medicine (IOM) in Edinburgh. This prestigious research organization made it crystal clear to ICI in the very beginning that, although it was sponsoring the study, ICI would have no voice in the conduct of the study at any point. IOM also made it clear that the study would be conducted primarily for the benefit of the industrial worker.

As far as can be ascertained there are no other studies of "nuisance dusts" with which this study can be compared. This presents somewhat of a problem.

Eight hundred and eighteen men selected from the present and past work force of a plant manufacturing polyvinyl chloride (PVC) were studied to determine whether PVC dust caused any measurable effects on the lungs of workers exposed to it. Respiratory symptoms such as cough or breathlessness and the results of breathing tests and appearances of the chest x-rays were compared with estimates of the amount of fine PVC dust to which each man had been exposed during his employment at the plant. When studying the effects of PVC dust, allowance was made for the known effects of aging, smoking, and physique on the lungs.

It was found that men who smoked cigarettes and who had also been exposed to higher amount of PVC dust reported slight shortness of breath on exertion more often than smokers who had been exposed to lower amounts of dust. This symptom was associated more strongly with aging than smoking as such. The dust effect was not seen among non-smokers and ex-smokers. Exposure to PVC dust was not associated with chronic cough or sputum production (chronic bronchitis), acute chest illnesses, acute bronchitis, pneumonia, pleurisy, or asthma.

There was a relationship between exposure to PVC dust and the complaint of breathlessness when hurrying on level ground or walking up a slight hill, but this relationship was found only in cigarette smokers and not in non-or-ex smokers.

4.1 Chest Radiographs

The chest radiographs were read independently by recognized experts using the ILO U/C International Classification of Radiographs of Pneumoconiosis (International Labor Office, 1972). The medically qualified readers were chosen to represent a range of interpretations of the presence of small radiographic opacities and on the basis of systematic inter-reader differences recorded in previous work. None of the radiographic experts were employed by IOM.

One of the three experts detected small, round opacities more commonly in the radiographs of men with higher exposure to PVC dust than in those with lower or no exposure. The other two readers did not detect an effect of PVC dust although they observed small, round opacities in a few cases. The opacities seen by these readers were not more common in those with higher exposures to dust than in those with lower or no exposure. Prevalence of small, round opacities was not related to the presence of chronic cough or sputum, or histories of chest illness.

The IOM report concludes with the opinion that the effect of PVC dust inhalation on lung function is of the same order of magnitude as that of cigarettes and approximately one-seventh that of aging. They also conclude that while these results are not unduly alarming, they do indicate that further measures to reduce individual dust exposure would be prudent.

4.2 Recommendations of the Research Coordinators

4.2.1 The Research Coordinators recommended that ICI send a copy of the IOM report to NIOSH. This recommendation was contingent on subsequent advice given to the ICI representatives by their legal counsel in Wilmington.

4.2.2 The Chairman of the Research Coordinators, Dr. E. R. Torkelson appointed Mr. R. N. Wheeler to prepare a summary statement containing salient findings presented in the IOM report. On completing his statement, Mr. Wheeler is to forward it to SPI and to the Project Administrator. Upon receiving it, the Project Administrator is to

it immediately to CMA's General Counsel who, in turn, is to collaborate with SPI's Counsel, Mr. Joseph Hadley, on the preparation of the final statement. After joint agreement of SPI and CMA counsels, the document will be sent to the Research Coordinators to secure their approval of technical content. After the Research Coordinators have approved the document in final form, it will be distributed to all Panel members

5.0 Extension of Basic Epidemiological Study, Five-Year Update

Dr. Torkleson presented a status report on preparatory work in progress. His review included the document recently prepared by the Project Administrator entitled "Specifications on which Proposals and/or Bids are to be Based for a Five-Year Epidemiological Update on Vinyl Chloride and Critique of Factors Relevant to the Study". These bid/proposal specifications emphasize that an evaluation of data currently being archived by Equitable Environmental Health, Inc. (EEH) is a necessary prerequisite to both the "brain study", should it be conducted as a separate entity, and to the larger investigation, the five-year epidemiological update.

The cohort data used in the basic epidemiological investigation of VC workers is stored at the Rockville, Maryland offices of EEH. These consist of unit files and computer cards for each cohort member, a series of computer print-outs on study analyses, and pertinent correspondence with participating plants.

The unit files contain the raw data collected from plant records with the data reduced to the study format. The computer cards are punched with the data so reduced. The computer print-outs contain the data from which the comparative tables were prepared for the reports. Review of these data in detail is necessary to the development of a definitive study protocol, a responsibly valid cost, and a performance time estimate.

The epidemiological update is to extend from December 31, 1972 to December 31, 1977.

- 1) An effort will be made to determine the vital status as of December 31, 1977 of the eight thousand nine hundred and seventy cohort members who were determined to be alive on December 31, 1972.
- 2) An attempt will be made to determine the vital status of the four hundred and ninety-six cohort members who were lost to follow-up during the previous study.

- 3) Efforts will be made to retrieve death certificates for cohort members identified as deceased based on the follow-up effort.
- 4) The complete study population will be analyzed using the expanded life table program, for example, Monsons's program (Harvard) or Enterline's Program (University of Pittsburgh).

After deliberating on factors relevant to the brain study and to the overall epidemiological update it was VOTED:

To request commitment of \$30,000 to cover:

- 1) A study or assessment of the data currently in storage at EEH,
- 2) A case control study of brain tumors, and
- 3) The preparation of a protocol for the five-year epidemiological update.

6.0 The Vinotex Study

Dr. William Adams reported very briefly on a study conducted within the Vinotex Group in England. This research is an attempt to correlate dose-related VC exposure and coronary disease. Among other phases, are subsidiary investigations on triglycerides. Following Dr. Adams' review, Dr. M.N. Johnson will follow-up with Dr. Tamburro (Director of Research at the University of Louisville) on observations made by Dr. Tamburro and his associates on triglycerides and their possible relationship with VC exposures and coronary incidences.

7.0 Evaluation by Dr. J. M. Norris of the Edgewood Arsenal Study on Vinyl Chloride Monomer

At the request of the Panel Chairman, Dr. T. R. Torkelson, Dr. J. M. Norris evaluated the final report issued on the so-called Edgewood Arsenal "Single-Hit Study" sponsored by the Consumer Product Safety Commission (CPSC) under an inter-agency agreement with the Chemical Systems Laboratory (formerly Edgewood Arsenal).

Dr. Norris reported that the final Edgewood report contains the same deficiencies as did the draft report. Specifically, the report contains discrepancies both in the reporting of the number of animals per test group, that were placed on the various studies, relative to the numbers that were evaluated. Further discrepancies were found in the numbers of animals observed with tumors as reported in various tables. Further, the months in which the studies were terminated were incorrectly reported.

Data in the report indicate that both the ICR and A/J mice had relatively high background incidences of pulmonary adenomas. The ICR mice also had either a chronic pneumonic condition or developed pneumonitis during the study. The marked body weight loss in the mice, both the vinyl chloride exposed and control animals, during the twenty-eighth and forty-second weeks of the studies suggest that external factors may have contributed to the pneumonic conditions. Except for the male ICR mice in the group exposed to 50,000 ppm vinyl chloride, the incidence of pneumonitis is roughly proportional to the incidence of pulmonary adenomas. However, since the handling/housing of the control mice relative to the exposed mice is not reported and since no statement is made as to whether medications were administered, the significance of the apparent association cannot be concluded.

8.0 Proposed Action Pertinent to the Edgewood/CPSC "Single-Hit Study"

Appropriate follow-up action will be taken to that outlined under Section 14.0 in the Record of Meeting, September 20, 1979.

Dr. Torkelson, Dr. Hatfield, and Mr. Wheeler will pursue additional data on the respective study categories listed under section 14.0. CMA's action will be contingent on the results of the efforts of these gentlemen.

9.0 An Update on Dr. John Stafford's Worldwide Registry of Angiosarcoma of the Liver Vinyl Chloride Polymerization Workers

Dr. Stafford presented the most recent data on his widely respected registry of angiosarcoma cases. These data are as follows:

<u>Country</u>	<u>YEARS</u>		
	<u>1977</u>	<u>1978</u>	<u>1979</u>
Canada	1	0	0
France	2	2	2
Germany	3	4*	0
Sweden	1	0	0
United Kingdom	0	0	2
United States	1	2	0

*Plus two unconfirmed

10.0 VCM/PVC Symposium

A symposium on Vinyl Chloride monomer and polyvinyl chloride is to be held in Washington, D.C. "sometime during the last part of February". It is currently anticipated (by representatives of Dr. Enfant's office) that it will be a two day

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symposium having as its theme "Reevaluation of the Toxicity of Vinylchloride and Polyvinylchloride and Structural Analogs." Dr. Infant's office said further that it is in the early planning stages and that our (CMA and the Panel's) participation will be welcomed. No information other than the above is available at this time.

11.0 Angiosarcoma Over-Diagnosed in England

Dr. David Duffield reported that a Panel of pathologists in England have "thrown out" (invalidated) the readings on about one half of the slides on which angiosarcoma diagnoses were based. Action of these expert pathologists results in the number of angiosarcoma cases in England during a five year period being reduced by approximately one half.


J.T. Seawell
Project Administrator
Vinyl Chloride

JTS:tab

Record Subject to Approval
12/14/79