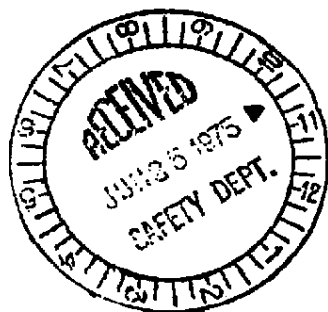






XB

INTEROFFICE
MEMORANDUM

Date 12 June 1975

Subject MCA - VCM

To Richard Fleming

Valley Forge

(Location, Organization, or Department)

From W. Mayo Smith

T-Town

(Location, Organization, or Department)

cc: A. Rose Adams

W. L. Ball

J. T. Baker

T. L. Carey/H. L. Watson

E. Donley

J. V. Heider

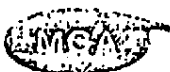
G. J. Mantell

Dr. M. Kushner (via ARA)

This is the reply to Science (see memo WMSmith to Richard Fleming, 23 May 1975, MCA Meeting - 22 May 1975) which four of us prepared to go over Al Clark's signature (MCA) during our meeting.

W. M. Smith
cmw

WMS:CMW



MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6125

ALBERT C. CLARK
VICE PRESIDENT
TECHNICAL DIRECTOR

June 2, 1975

RECEIVED
RESEARCH & DEVELOPMENT
JUN 6 1975
W. M. SMITH

Philip H. Abelson, Editor
"Science"
1515 Massachusetts Avenue, N. W.
Washington, D.C. 20005

Dear Dr. Abelson:

The Edsall article, "Scientific Freedom and Responsibility" (J. T. Edsall, "Science," May 16, 1975) requires comment. I presume Dr. Edsall is not responsible for the content of the article, but merely prepared it from the AAAS committee report. However, scientific freedom and responsibility are as important for AAAS committees as they are for other scientists. The "case of data suppression concerning the carcinogenicity of vinyl chloride" (pg. 690) is a melange of omissions and untruths inconsistent with scientific freedom and responsibility. Since so much pertinent information has been omitted concerning this matter readers may be misled into believing Dr. Edsall's report.

Edsall states that, "up to that time (May 1970) there had apparently been no research in the plastics industry concerning the possible hazards of vinyl chloride...". This is untrue. In fact, the basic published data on vinyl chloride toxicity came from American industry. (references 1-7) The information in references 4, 5, 6, and 7 had been publicly disclosed and presented prior to their publication dates. Furthermore, the investigations of Dr. P. L. Viola and Dr. Maltoni have been supported by European industries.

Edsall correctly states that Manufacturing Chemists Association (MCA) member companies entered into an agreement with the European sponsors of Maltoni's work not to reveal preliminary Italian data. The agreement was not dissimilar to that between American sponsors (Government, Industry, and Academic) and research institutions that new data remain the property of the institution and not be disclosed until the study is completed and evaluated prior to disclosure of final results in proper scientific channels. There was no intention to withhold adverse data. Under MCA rules, all data developed under its auspices must be promptly reported publicly. Without exception, this has been done with all data on vinyl chloride.

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Philip H. Abelson, Editor
"Science"

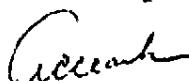
June 2, 1975
page 2

U. S. Government scientists knew of Maltoni's preliminary results early in 1973 but considered it as preliminary as did U. S. industry. At the Second International Symposium on Cancer Detection and Prevention in Bologna, April 9-12, 1973, Dr. Maltoni showed a table of preliminary results linking vinyl chloride with cancer formation⁸ (not published until 1974). Dr. Umberto Saffiotti, Associate Director of Carcinogenesis, National Cancer Institute, was present at the meeting and subsequently discussed the results with Maltoni at his Italian laboratory.⁹ Saffiotti felt that the work needed to be included in "a well documented report" to be assessed by the World Health Organization (Review Panel of the International Agency for Research on Cancer of which the United States is a member). This committee also considered Maltoni's data preliminary at that time and "decided to postpone compilation of the definitive review to the next meeting of the committee."⁹

Following a period in which epidemiological and animal studies were being established, MCA on April 17, 1973 asked the Europeans to jointly make presentations to United States and European Government authorities. The Europeans readily agreed, and on June 15, 1973 MCA called the National Institute for Occupational Safety and Health (NIOSH) and requested an opportunity to bring new information to that agency's attention. The appointment was set by NIOSH for July 17. Five European and American industry representatives presented to NIOSH the information that tumors had been observed at concentrations below that reported by Viola. At that time, human cases had not been reported; therefore, no special significance could be attached to the types of tumors observed by Maltoni.

The MCA suggested label referred to by Edsall was illustrated in the Chemical Safety Data Sheet (SD56) on vinyl chloride, revised April 1972. Section 10.1 on Health Hazards refers to Viola's published studies. The Data Sheet states "Recent research studies reported from Italy indicate that repeated, long-term high level exposures of rats to vinyl chloride monomer vapor can result in the development of malignant tumors. However, many years of industrial experience with human exposures to concentrations frequently far above current standards have not demonstrated any carcinogenicity to humans." Thus the statement by Edsall that MCA "...appears to have deliberately deceived NIOSH regarding the true facts." is inaccurate and misleading.

Sincerely,



References:

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- (2) Wilson, R. H., W. E. McCormick, C. F. Tatum, and J. L. Creech. Occupational Acroosteolysis, report of 31 cases. The Journal of the American Medical Association, 201(8), 577-581. 1967.
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- (8) Maltoni, C. Occupational Carcinogenesis. Proceedings of the Second International Symposium on Cancer Detection and Prevention. Bologna, April 9-12, 1973. Excerpta Medica, Amsterdam. 1974.
- (9) Hearing before the Subcommittee on Environment of the Committee on Commerce, United States Senate, August 21, 1974, (Serial No. 93-110) on Dangers of Vinyl Chloride, pages 54-56.