



INTERNAL
CORRESPONDENCE

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To (Name) Mr. T. E. Lawrence
Dist. Section K1467
Location Danbury
Area

Date June 24, 1983

Originating Dept.

Area

Copy to Mr. T. W. Carmody - P2595
Mr. L. A. Crisorio - P2598

Subject Chemical Regulation Reporter,
May 27, 1983 - "OSHA Vinyl
Chloride Case Was Lesson
To Heed Animal Data, Infante
Maintains"

Dr. Infante states that Dr. Viola's studies were kept confidential to avoid over-reaction by the Department of Labor and NIOSH. He cites the source as being from internal Union Carbide Corporation correspondence.

Attached is the correspondence he refers to. This was provided to the law firm of Levinson, Conover, Fink and Axelrod in the case of Maliko, et al. versus Union Carbide Corporation during discovery and production of documents. They, in turn, made it available to Dr. Samuel Epstein. Contrary to normal rules of confidentiality, Dr. Epstein used it in his other work as professional expert witness and author. I have objected to our attorneys Pitney, Hardin and Kipp about this use, but to no apparent avail.

Considering that the memorandum is now in the hands of the "scientists" it will be quoted eternally.

R. N. Wheeler, Jr.

RNWJr./rhw

Attachment

UCC
005611

MEMORANDUM

November 23, 1971

TO : Dr. C. U. Dernehl, NYO-4
Mr. M. E. Eisenhour, 515
Mr. R. J. Hanna, 511
Dr. E. Q. Hull, 514
Mr. G. R. Kraft, 514
Dr. K. S. Lane, NYO-4
Dr. W. R. Manning, 511
Dr. A. B. Steele, NYO-28

SUBJECT: Manufacturing Chemists Association
Occupational Health Committee -
Vinyl Chloride Conference

Companies with interest in vinyl chloride were invited to send representatives to consider the following:

1. Continuation of the Acroosteolysis Registry Program.
2. Review the reports of Dr. P. L. Viola on the development of tumors in rats exposed to vinyl chloride monomer gas.
3. Consider sponsoring a research program in the U. S. to confirm and to provide additional data in Doctor Viola's study area. The proposed program would cost approximately \$100,000 per year.

The meeting attendance was light with about 30 people present. A full list of those attending will be issued later by MCA.

Continuation of the Acroosteolysis Registry Program was estimated to cost \$300 to \$500 per month, depending on the case load. The program has cost \$4,000 for eighteen months operation to date. A firm budget for future operation was not available at this time.

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Essentially all those present expressed a desire to continue the program now supported by about ten companies. Individual companies will be contacted for further authorization of funds. Union Carbide should continue to participate in this program at least until the physiological effects of vinyl chloride are better defined.

Dr. P. L. Viola, et al of the Regina Elena Institute for Cancer, Research, Rome, Italy, sponsored by Solvay M. C. started out to study acroosteolysis and its attendant Raynaud's phenomena. He originally started working with monkeys and later switched to rats because of cost and other factors. Doctor Viola exposed rats to varying concentrations of acetylene derived vinyl chloride and noted the following incidence of tumors:

<u>Vinyl Chloride Concentration</u>	<u>Incidence of Tumors</u>
30,000 ppm	65%
20,000 ppm	50%
10,000 ppm	25%
5,000 ppm	10-15%
<5,000 ppm	Some tumors

(Dr. M. J. LeFevre, Solvay M. C., stated later that the incidence of tumors in control groups of this strain of rats was 5%.)

Doctor Viola's initial work involving exposure of rats to 30,000 ppm VC was reported at the Tenth International Cancer Congress, Houston, Texas in May 1970 and was later published in Cancer Research, May 1971. The remaining data is unpublished at this time. After the appearance of Doctor Viola's paper at the Houston meeting interested companies, including UCC, paid Doctor Viola's expenses for a meeting in Washington on May 5, 1971.

Publishing of Doctor Viola's work in the U. S. could lead to serious problems with regard to the vinyl chloride monomer and resin industry. These are as follows:

1. The Delaney amendment bans the use of any material in food that can cause cancer.
2. A law exists in Pennsylvania banning carcinogens from the air; i. e., the allowable threshold limit is zero.

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3. The present political climate in the U.S. is such that a campaign by Mr. R. Nader and others could force an industrial upheaval via new laws or strict interpretation of pollution and occupational health laws.

There has been no Government reaction to Viola's work, to date. The ACGIH plans to discuss it this week at their meeting.

Dr. T. R. Torkleson reviewed the proposed MCA-sponsored animal study. This program involved exposure of rats and mice to three levels of vinyl chloride gas concentration - 5,000, 1,500, and 500 ppm. The vinyl chloride would be derived from ethylene and from acetylene. The rat study would cover 24 months while the mouse study would cover 12 months. The cost of the study was estimated to be \$183,000 by Industrial Biotest, Chicago, Illinois.

Depending on the results of this study, an epidemiological study of the industry could be required. If vinyl chloride were exonerated in the proposed animal study, then a study of the effects of the material on progeny might be required.

The need for two sources of vinyl chloride and the chosen exposure concentrations was questioned, but no action was taken at this time.

Dr. M. J. LeFevre, Solvay M. C., discussed the work of his Company in Europe as well as his own knowledge regarding physiological effects of vinyl chloride. Items of interest are as follows:

1. Rumanian work showed 10% liver enlargement as well as acroosteolysis. Workers in Spain showed unnatural weariness, possibly indicating liver involvement. This was not noted in French or Belgian workers.
2. Doctor Viola found 29 impurities in his vinyl chloride including methyl chloride. This could be a major factor.

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3. The bone tumors noted by Viola were probably acroosteolysis. Doctor LeFevre has seen lesions in the knees and in the pelvic area of the back.
4. No acroosteolysis has been found in monomer and compound plant workers. No tumors in reactor cleaners at Solvay M. C. plants.
5. Doctor LeFevre theorizes that vinyl chloride is absorbed in body fats and is carried to the brain. It acts on the centers controlling circulation of blood to the extremities. Restriction of the blood flow causes the pH of the bone structures to move from a normal basic condition where minerals are deposited to an acidic condition causing removal of minerals from the bones. Acroosteolysis is caused by general exposure and inhalation of vinyl chloride; not just exposure of the hands.
6. Doctor Viola's work is being checked and expanded. European studies underway involve exposure of animals to concentrations of 20,000, 10,000, 5,000, 2,000, 500, and perhaps 100 ppm. Vinyl chloride used will be a mixture of 50% acetylene and 50% ethylene derived.

The afternoon discussion originally planned to organize industry support for the MCA program showed that many questions existed and would have to be answered before a program could be presented for industry support. Some of the principal items discussed were:

1. Acetylene-based vinyl chloride monomer could possibly be cut from the study except to confirm Doctor Viola's work at the 5,000 ppm exposure level.
2. Lower concentration exposure levels, such as 50 ppm, should be checked.
3. The animal study proposal was still not completely set and it should not overlap the European study mentioned by Doctor LeFevre.
4. Human epidemiological studies should be made.

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5. All industry sponsors should pay their pro rata share, but what is a pro rata share?
6. The Government should sponsor the study. Even if unfavorable, they wouldn't shut down an industry of this size.
7. Vinyl chloride monomer is full of impurities, and one of these must be a carcinogen.

When it became evident that more study was required, an industry subcommittee was appointed to study the problems and make recommendations to the Occupational Health Committee of MCA. The committee consists of:

R. N. Wheeler, Jr., Chairman
Union Carbide Corporation

Norman G. White, Ph. D.
Shell Chemical Company

M. V. Anthony
Stauffer Chemical Company

The Committee is to seek opinions and data from industry members and to meet with Dr. K. D. Johnson, MCA Assistant Technical Director, Occupational Health, on December 14, 1971 to prepare a program. The Committee is to recommend a program industry will support and recommend procedures for funding the program. Questions of study scope, acetylene vs ethylene derived vinyl chloride, and significant impurities in vinyl chloride will be resolved.

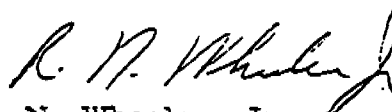
The MCA will survey members of the industry regarding their willingness to support a \$100,000 per year study with costs allocated to sponsors based on published capacities of monomer and polymer. Monomer producers will be asked for representative analyses of their monomer and their methods of analysis.

Assuming 100% industry participation, Union Carbide's share of the program cost should be approximately \$5,000 per year. This cost should be either borne directly by the Corporation or charged to Vinyl Resins, Dymel, and Fluorocarbon profit centers on the basis of their vinyl chloride consumption.

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Union Carbide's general support for the MCA's program has been pledged, based on the following:

1. The industry has a responsibility to its employees and customers to take any necessary action to protect them. Union Carbide Corporation is a responsible member of that industry and will bear its share of the cost.
2. Union Carbide has a large stake in the areas most likely to be affected such as food, food packaging, fibers, and aerosols and would be seriously hurt by arbitrary or panic-induced government restrictions.
3. Union Carbide has a plethora of knowledge and experience that can add to the success of the proposed study and that can guide such a study to reasoned conclusions.


R. N. Wheeler, Jr.

RNWJr/ra

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