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April 24, 1974

Honorable John H. Stender
Assistant Secretary of Labor
U. S. Department of Labor
Occupational Safety and Health Administration
Washington, D. C. 20210

D ar Mr. Stender:

Supplementing information, which has been supplied to you and which you have gathered in your own vigorously pursued visits, about business reaction to the newly discovered hazards of vinyl chloride, this is to bring you and Lou Cox up-to-date on some projected research being undertaken. This deals with the study subject of my letters of April 17 and 18, copies of which Wayne T. Brooks supplied to you through Lou Cox last Friday.

The situation in which employers-employees and government find themselves calls for the most balanced quality of judgment we can muster. No judgment, however, can be any better than the facts on which it is based.

There are only two ways in which facts can be brought to bear on the vinyl chloride issue. One is by way of animal experiments. The other is an evaluation of human exposure and results.

Animal experimentation had, until recently, indicated that no angiosarcoma had resulted from exposure corresponding to the present emergency standard level of 50ppm. However, the recent MCA announcement of Bio-Tech Laboratory experiments indicated that at least one strain of white mice had developed angiosarcoma at 50ppm.

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The incidents of angiosarcoma occurring at that concentration of vinyl chloride lead to the probability that there is a concentration level somewhat below 50ppm which would probably not be harmful to white mice. However, the actual test results under lower concentrations, to be obtained as a result of Bio-Tech Lab tests we believe are now being undertaken, will not be available for 7 to 9 months.

Not much information is now available regarding the effects of low concentration exposures on workers. We know of the cases uncovered in recent months, all of which are presumed to have been exposed to very high concentrations for varying periods of daily exposure and extending over substantial numbers of years. This tells us very little about the experience of employees (such as those involved in certain polyvinyl chlorid processes and fabricator processes) in which the present exposure is in the order of 10-20ppm, with possible short-time excursions beyond that range.

In order to obtain human fatality experience in this field of low vinyl chloride monomer concentration, we have been asked by a number of ORC companies to make an epidemiology mortality study among employees of polyvinyl chloride users (fabricators). Such a study normally takes a couple of years to do. We have been casting about for ways to condense the time frame in order to get some results within as little as four months. To make sure that we are on the right track, we have retained Dr. Leonard Chiazze, Director, Division of Biostatistics & Epidemiology, Georgetown University School of Medicine, to develop a protocol for the mortality study and to advise us as to its conduct.

At a meeting of the ORC PVC Task Force on April 23, with Dr. Chiazze in attendance, it was concluded that the most productive approach would be to undertake a review of all death certificates of employees who had worked for PVC users or fabricators for the last 10 years; select from those, the ones listing cancer or liver diseases as cause of death; follow-up at hospitals where death occurred, pathological findings or other things that looked suspicious; and check with employers occupational background and workplace environment if angiosarcoma of the liver were suspect.

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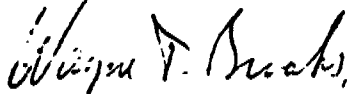
The first phase of the study will cover the 15 largest PVC users (which would probably cover over one-half the employment in the industry) so that some results would be available in time for consideration before the final standard had been adopted. It is the intention, however, to continue the mortality study to cover substantially the entire industry.

It is our hope that the results of this mortality study will contribute to a more informed judgment as to the level at which the permissible vinyl chloride concentration will be set in the final standard.

Another imminent source of new information is likely to be the New York Academy of Sciences Symposium scheduled to be held in New York on May 10 and 11. This Symposium will include reports of animal experiments by European researchers (including Dr. C. Maltoni's latest results); as well as the results of epidemiologists in Germany, Rumania and Japan, and U. S. reports by Doctors Selikoff, Tabershaw and Wagoner among others. A draft copy of the program is enclosed. These presentations and discussions should provide additional information that should contribute to a more balanced judgment than is now possible.

The question of zero exposure level inevitably will be raised some time during discussions of vinyl chloride. At the time of the hearing on the Carcinogen Standards last Fall, ORC filed a statement, which we believe has relevance to the present considerations. A copy of that statement is enclosed. The statement discusses zero concentration in the context it arises: that is as a policy or philosophic question.

Sincerely,



Wayne T. Brooks
Director Occupational
Safety & Health Services



Leo Teplow
Special Consultant

WTB/LT:cs
Enclosure

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