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File: Vinyl Chloride
V C M

September 26, 1974

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

Dear John:

You may recall that on April 24 we wrote you concerning a mortality study seeking to determine the effect of exposure to low levels of vinyl chloride monomer. Being conducted under ORC management, the study is based on the examination and analysis of death certificates for employees who worked in the fabrication of products that contain polyvinyl chloride resins, and who died in the years 1964-1973 inclusive. These employees have unquestionably been exposed to varying concentrations of polyvinyl chloride, estimated to be in the range of 10-15ppm or less.

In conducting the study, we contacted fabricators known to us, solicited the assistance of trade associations, and obtained the cooperation of resin producers to identify major customers.

As a result we have been in contact with 35 companies, of whom 10 declined to participate because they had been fabricating polyvinyl chloride products substantially less than the time required for inclusion in the mortality study. There was evidence of active interest and desire to participate on the part of every company we contacted. The search for the facts seems to generate a common desire to help.

We have studied death certificates supplied by eight companies with 34 plants in 14 states (the combined total employment of these plants being approximately 16,000 as of December 31, 1973).

In order to verify that we had all of the death certificates, where possible, we have requested confirmation of the list on the part of the life insurance companies involved. Additional companies are now making their data also available to us. Upon receipt of death certificates, they are studied by a nosologist who classifies them in the broad categories of cancer, liver disease, or neither. Those in the cancer and liver disease category are then assigned to a field investigator who is a Registered Medical Records Administrator for further investigation. The field investigator checks the cause of death on the death certificate against the pathology records in the hospital (after overcoming the reluctance of many hospitals to make records available). If final illness was not in the hospital, the treating physician is contacted. At this point, field investigators have visited ten hospitals and one state tumor registry. About 350 abstracts have been completed with respect to such deaths.

Our experience to this date leads us to conclude that the records maintained by insurance companies were never designed to support epidemiology studies (we have in fact formed a new task force designed to develop a uniform system of maintaining health records in the hope that in the future epidemiology studies may be facilitated).

Under present circumstances, gathering data is a slow, tedious, and laborious process. It is impossible to collect meaningful data and to provide meaningful analysis during the brief six-month statutory period of an emergency standard. The time span between the discovery of vinyl chloride problems in January and the time when the temporary emergency standard must be promulgated is so short that even accelerated research cannot be completed. However, our study will continue and progress will be reported to you periodically, even though it is impossible to make a definitive report in time for consideration with respect to the permanent standard.

At this stage we can only say that, of the limited number of death certificates processed, no case of angiosarcoma has been found. In fact only two pathologists contacted by us have ever seen a case of angiosarcoma.

Aside from the matter of angiosarcoma, the incidence of cancer and liver disease do not appear to be disproportionate to what might be expected. However, at this stage the data is so limited that these results must be considered as highly tentative. We are now making determined efforts to complete as much of the study as possible by the end of 1974. As new information becomes available, it will be shared with you.

While we can understand the reason why the law provided a limited duration for an emergency temporary standard during the past three years, this experience makes it clear that so short a period imposes an almost impossible burden on OSHA as well as those who are helping it to determine the facts. Certainly there is very little time in which to do essential research.

Sincerely yours,

Leo Teplow
Special Consultant