CONFIDENTIAL

May 2, 1974

To: Mr. P. N. Shellenberger
Mr. W. L. Sullivan

Subject: Additional Epidemiological Studies on Workers Exposed to Vinyl Chloride

A number of industry leaders, including Diamond-Shamrock, Union Carbide, and PPG, have proposed that additional studies on the mortality of workers exposed to vinyl chloride be immediately undertaken to establish whether a showing of "no increased risk" can be shown among workers exposed at levels in the 10 - 50 ppm area. This concept has been under review within Organization Resources Counselors, one of our affiliated organizations, and has received strong endorsement from the rubber industry. It is proposed that a number of sizable plants engaged in the extrusion and/or fabrication of PVC, but not in monomer or polymer production, be enrolled in this study and that an attempt be made to include all such plants which have been in operation more than twelve years and have more than 100 - 200 people. The specific proposed protocol is attached.

An unidentified company has committed $12,000 for th exploratory phase of the study. We will shortly receive an invitation to become one of the sponsors and to advise the group whether or not we have facilities which meet the study criteria. If a sufficient number of sponsors can be enlisted, it is planne that the work will be started by ORC and then transferr d to the overall umbrella of SPI. It is likely that Allied's financial contribution would be $20,000 or less, to be equally divided between Fibers and ICD.

We are providing this advance notice so that you can be developing your thoughts on Allied's possible participation. Should you feel that we should not participate, we should carefully consider the effect of this decision on our relations with the other major companies in the industry.

ASI 00023603

W. S. F rguson

WSF:mn
c: Mr. E. W. Callahan
Mr. J. M. Quinn
Mr. T. D. K nt
Mr. R. H. Sand

Mortality Among Workers Involved in Processing PVC

The objective of this study is to review death certificates for the period 1964 to 1973 among workers who may have been exposed to PVC and died while working for or retired from the companies involved. The population under study will be limited to those for whom death certificates are available from life (insurance) underwriters of the companies in question. Two specific questions are to be investigated: (a) is there any evidence of death due to angiosarcoma and was that death possibly related to PVC exposure? and (b) are there unusual patterns of cancer mortality among the deceased workers? Because it is necessary to have some definitive results within a four-month period and since it would not be possible to complete the entire study in that time, the investigation will be carried out in a series of sequential steps.

There are an estimated 123,000 workers involved in the processing of PVC after it leaves the manufacturing plant. We assume it will be possible to identify those plants or divisions within companies where it is likely that PVC exposure could have occurred. It is further assumed that the life underwriters will be able to provide us with death certificates for workers from the plants or divisions where the PVC exposure is presumed to have taken place. If death certificates can be provided only on a company-wide basis, the number of certificates to be reviewed will be very extensive, and it is very unlikely that any substantial amount of work can be completed in four months. By limiting the death certificate review to those certificates available from life underwriters, there may be some "leakage." Such a review would not include any employee who left the company

and died without coverage provided by the life underwriters. Additionally, we would like to restrict the death certificate review to deaths occurring among all employees of the plants where PVC is used in fabrication, assuming the underwriters can provide death certificates on that basis. This could result in additional leakage if there is a tendency for employees to transfer within a company from a job in a PVC-using plant to a job in a non-PVC plant. It is hoped that some information may be available from the companies which would show that the latter leakage is minimal.

It is estimated that there would be about 11,000 deaths for a group of 123,000 workers over a 10-year period. The strategy of this study will be to review the approximately 11,000 certificates and from these select those with either cancer or liver disease mentioned on the certificate. This would amount to about 2,600. For these 2,600 deaths, it will be necessary to go to the hospital where the death occurred and review the pathology report for any mention of angiosarcoma. (The number of deaths and the number selected for further review are, of necessity, gross estimates but should give us some starting point for estimating workload. These numbers assume we can limit our review to plants involving PVC workers. If we must go to divisions or entire companies, the job will be significantly greater.) An additional element of the investigational strategy will be to contact the pathologist in any hospital visited and inquire whether there are any angiosarcoma cases in the pathology records and, if so, to determine whether or not it may be related to PVC exposure. Such a step in the investigation should cut considerably any "leakage" of the second type mentioned above (i.e., transfer of PVC plant to non-PVC plant within the same area. The hospital would provide coverage for a fairly wide

geographic area and could easily encompass workers of other company plants in a nearby geographic area.)

Investigational Procedure (Full Study)

1. Identify all plants among involved companies where PVC exposure may have occurred. These are the plants where the 123,000 workers are employed.
2. Identify life underwriters for the companies by whom these plants are owned.
3. Request all death certificates for deaths occurring from 1964-1973 among
   a. active employees who died while employed at those plants, and
   b. retired employees who worked at those plants prior to retirement.

   These certificates are to be :
   a. identified and separated from all other deaths in the covered companies,
   b. copied (Xeroxed), and
   c. sent to ORC.
4. Certificates will be reviewed by a nosologist retained for that purpose.
5. Death certificates on which cancer or liver disease is mentioned will be separated.

   [*N.B. For 1964-1967, cancer includes any of the causes of death identified by rubrics 140-205 of the 7th revision of the International List. Liver disease will include rubrics 580-586.*

   For 1968-1973, cancer is identified by rubrics 140-209 of the 8th revision of the ICDA and liver disease will include rubrics 570-576.]
6. From the information on the death certificate, hospital of death will be ascertained.

7. Hospitals will be visited to review pathology records for employee deaths identified in Step 5. It is assumed that the involved companies will be able to provide quick access to all hospital records which must be reviewed.
8. While at the hospital, the record reviewer will contact the hospital pathologist to determine whether or not the pathologist is aware of any cases of angiosarcoma.
9. Should any cases of angiosarcoma be turned up in Steps 5-8, complete occupational histories will be obtained for those workers.
10. Analyses in the form of PMR's (Proportionate Mortality Ratios) will be carried out on those deaths identified in Step 5 while the hospital review is going on.

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NOTE: We are requesting that death certificates be sent to ORC in order to take advantage of specialized talent available in Washington for death certificate review. It is unlikely that on short notice we can obtain an experienced nosologist to travel to the insurance company offices or, in fact, to train someone. Further, it is imperative that we have copies of death certificates mentioning cancer or liver disease on site at ORC. Since we do not want the underwriters doing that screeening, it is necessary that we obtain copies of all certificates as outlined in Step 3.

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Investigational Procedure (Phase I)

1. Same as 1 above.
2. Same as 2 above.

3. Select the ?-6-? largest underwriters who are likely to cover approximately 30-35% of the workers. From these, request death certificates as outlined in Step 3 above.

4. Same as 4 above.

5. Same as 5 above.

6. Same as 6 above.

7. Same as 7 above.

8. Same as 8 above.

9. Same as 9 above.

10. Same as 10 above.

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NOTE: At this point, there remain at least 2 alternatives for proceeding on to the hospital review. We can do this one insurance company at a time (which is likely, since the records are likely to come from the companies one insurance company at a time. Or, if all certificates are available at one time and very quickly, we can select a sample for initial review. This would necessitate visiting some hospitals more than once). Because of the pressing time factor, it will be necessary to select that alternative which shows promise of quickest results and we won't know that until the study is underway. There are, of course, a number of additional details for each of the above steps, e.g., abstract forms and instructions for the hospital review, and these details will follow.

Leonard Chiazze, Jr., Sc.D.

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