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ATTACHMENT J

Environmental Health Associates, Inc.

January 15, 1980

Joseph T. Seawell
Chemical Manufacturers Association
1825 Connecticut Avenue, NW
Washington, D.C. 20009

Dear Mr. Seawell:

This will confirm and summarize the points discussed in our telephone conversation concerning the vinyl chloride mortality study data and the work desired by the Chemical Manufacturers Association. For additional detail, reference should be made to our letters of May 15 and May 25, 1979, to Dr. T. R. Torkelson (copies to you).

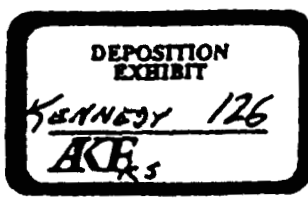
For ease of reference I will number the points we discussed.

1) Environmental Health Associates, Inc., has adequate and secure working-storage facilities to accomodate the vinyl chloride study files. This space will be made available for a reasonable period of time at no charge while CMA and EHA formulate a scope of work to be performed. If CMA selects EHA to undertake a follow-up study, no storage charges will be involved. If CMA elects not to proceed with a follow-up study, a reasonable charge for storage will be established at the time.

2) EHA is prepared to proceed immediately with a follow-up study of the 12 cases identified as "brain cancer" in the Equitable Environmental Health final mortality study report of 1978. Available information indicates that these 12 cases came from four or five separate plants. EHA will require early assistance from CMA in order to identify a contact person at each plant who will be responsible for expediting EHA requests for information.

EHA proposes to obtain copies of the following files for each case:

- a) Company medical file,
- b) Company personnel file,



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- c) Company or Insurance carrier Workers' Compensation file,
- d) Additional information from supervisors or fellow workers concerning work history, previous employment, hobbies, etc. The extent to which this can be done depends on information obtained from the company's files.

If adequate information is available from the above sources, EHA will attempt to obtain:

- a) Pertinent medical history from personal physician
- b) Surgical and/or autopsy histopathology results

When possible, this information will be obtained from sources which can be identified in the subsequent report. Where the information is obtained on a confidential basis, no source citation will be provided.

At CMA's option, EHA will contact the deceased's family for additional details. This may be decided on a case by case basis in consultation with the company involved. If a particular case has been adjudicated, there is little reason to avoid family contact as this can be a valuable information source.

On the basis of the data collected for each case, EHA will establish to the extent possible:

- a) verification of diagnosis;
- b) histologic diagnosis;
- c) complete job history including:
 - 1) nature of vinyl chloride exposure (length, relative level, time since first exposure, time between last exposure, and onset of clinical illness (latency);
 - 2) likelihood of exposure to other chemicals;
 - 3) employment before and after vinyl chloride exposure; and
- d) other sources of confounding exposures such as hobbies, etc.

Information concerning the validity of the association between these 12 deaths and exposure to vinyl chloride will be

evaluated by Drs. Whorton and Milby. The investigators will examine these data for commonality of exposure variables, time between onset of exposure and disease development, cell type, association with exposure to other agents, and other related matters.

Conclusions will be reported to CMA in a final technical report. No information will be submitted by EHA for publication without consultation with CMA on the manner in which the data are to be reported.

No work can proceed on this study until the vinyl chloride study files reach EHA. Subject to timely response on EHA requests for information from the plants involved, the work will require approximately 6 weeks to complete from the time authorization by CMA is received.

Based on all of the assumptions stated and implied above, the cost of the study will approximately \$10,000. This assumes no travel on the part of EHA personnel. EHA proposes the following budget on which a time and materials contract can be developed.

<u>Personnel</u>	<u>Time</u>	<u>Rate</u>	<u>Costs</u>
D. Whorton, M.D.	60hrs.	\$85	\$5,100.00
T. Milby, M.D.	40hrs.	\$85	\$3,400.00
R. Davis	20hrs.	\$50	\$1,000.00
Research Assistant	10hrs.	\$14	\$140.00
Secretarial	<u>10hrs.</u>	\$14	<u>\$140.00</u>
Total Personnel	140hrs.		\$9,780.00

Other Direct Costs

Telephone	\$700.00
Computer, Postage, etc.	<u>\$100.00</u>
Total Other Direct Costs	\$800.00

Total Estimated Project Costs \$10,580.00

If CMA desires a meeting with EHA personnel to discuss matters pertaining solely to the brain tumor study, the meeting will be attended by Drs. Milby and Whorton. The following estimate assumes a one-day meeting in Dallas, Texas. (Washington, D.C. will add approximately \$500 to the cost.)



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T. Milby, M.D.	16 hours @ \$85/hr.	\$1,360
D. Whorton, M.D.	16 hours @ \$85/hr.	<u>\$1,360</u>
Total EHA Staff		\$2,720
Travel Costs		<u>\$1,050</u>
Total Meeting Costs		\$3,770

Examination of this new information may serve to clarify a number of questions regarding the presence or absence of a positive correlation between exposure to vinyl chloride monomer (VCM) and the development of brain tumors, hence would be of extreme value to the literature on this subject. However, it would be excessively optimistic to expect even the most assiduous reconstruction of exposure and effect data on these 12 cases to establish or deny beyond doubt the existence of a statistically and biologically plausible relationship between VCM exposure and brain tumor induction. This final level of proof must await the application of other research strategies, including further follow-up of the five year old vinyl chloride cohort and well planned studies in experimental animals. EHA would be hesitant to undertake the follow-up study of the 12 brain tumor cases without reasonable assurance that a five-year follow-up of the existing vinyl chloride cohort will take place.

3) EHA's letter to Dr. Torkelson of May 15 outlines some of the imponderables affecting the development of a protocol for the follow-up of the vinyl chloride study cohort. EHA proposes to evaluate the existing data base in order to develop a study protocol acceptable to CMA. A budget for that evaluation includes:

<u>Personnel</u>	<u>Time</u>	<u>Rate</u>	<u>Costs</u>
T. H. Milby, M.D.	20hrs @	\$85	\$1,700
R. L. Davis	60hrs @	\$50	\$3,000
J. Schulman	20hrs @	\$21	\$420
Secretary	8hrs @	\$14	<u>\$112</u>
Total Personnel			\$5,232
W. C. Cooper, M.D.	1 Day @	\$680	\$680
H. Stubbs, Ph.D.	1 Day @	\$185	<u>\$185</u>
Total Consultants			\$865
Other Direct Costs			<u>\$100</u>
			\$6,197

