



CHEMICAL MANUFACTURERS ASSOCIATION

March 9, 1984

To: Vinyl Chloride Program Panel

From: C. Stack *(signature)*

Re: Epidemiology Study Update

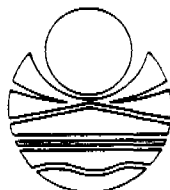
I enclose a proposal from Environmental Health Associates (EHA) to proceed with Phase II of the vinyl chloride epidemiology study update. The proposal has been reviewed and approved by the Research Coordinators.

No further funding of the project is required at this time. A Panel-approved \$300,000 budget for this project is in place (see attached). The only adjustment which needs to be made is a transfer of contingency funds into the EHA portion of the budget. Final cost for Phase I totaled \$98,595; projected cost for Phase II is \$142,223; Total: \$240,818.

Please let me know ASAP if your company approves the Phase II proposal and use of contingency funds. A response by March 23 would be appreciated. No response by that date will be considered affirmative.

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CMA 008821



Environmental Health Associates, Inc.

7 February 1984

Carol Stack, Ph.D.
Biomedical and Environmental Special Programs
Chemical Manufacturers Association
2501 M Street NW
Washington, DC 20037

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Dear Carol:

Enclosed please find the revised proposal, "An Update of the Epidemiologic Mortality of Vinyl Chloride Workers: Phase II". Our proposal has been revised to incorporate a number of helpful suggestions from Drs. Torkelson, Austin and Zavan. The revision also reflects several issues we discussed in our conference call on 3 February 1984.

Following are the major modifications in our revised proposal:

- A paragraph has been added (pp. 2-3) to address the criteria for recommending case-control studies.
- On page 3, we state the hypotheses to be tested and the references suggesting these hypotheses.
- A discussion on ICD coding is provided on page 6, explaining the reason for choosing the 7th ICD.
- A brief explanation on the calculation of SMR is provided on pages 7 and 8. As discussed during our conference call, the cohort covers a wide geographic region and many cohort members have since moved. Therefore, it would be impractical to use regional rates for comparison.
- A list of causes of death to be included in analysis is given in Exhibit 1.
- As suggested by Dr. Gaffey, we will analyze the data with and without the individuals for whom exposure status has been reclassified in the update both in the original study period and in the updated study (page 8).
- Analysis by latency and year of first exposure has been added (page 8).
- The issue of grouping plants by VCM or PVC is discussed on page 9.
- A list of criteria for interpretation of results is provided on page 9.

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- We have added a task for project management and communication (page 10).
- The budget has been modified slightly to reflect the additional analysis and the anticipated effort in communication with CMA Committee.

We are still hopeful that the study can be completed in 12 months, provided we do not run into any unusual delay with SSA or NDI. However, as Dr. Zavon pointed out, our schedule may be too optimistic. To be realistic, we propose to add a contingency of 3 months to the proposed schedule.

If you or any committee member(s) have any questions regarding the revised proposal, please give me a call.

Best regards,



Otto Wong, Sc.D.
Senior Epidemiologist

OW:jdd
Enclosure

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