



The Dow Chemical Company
Midland, Michigan 48674

1803 BUILDING
January 5, 1995

Hasmukh C. Shah, Ph.D.
Vinyl Chloride Panel
Chemical Manufacturers Association
2501 M Street NW
Washington, D.C. 20037

Dear Dr. *Shah* *Has* Shah:

In response to your request, I am writing to explain in detail the reasons for my and the other research coordinators' endorsement of the proposal by Applied Epidemiology Inc., Amherst MA, for the updated industry-wide vinyl chloride workers mortality study. I am expressing my opinions here as the current Chair of the Vinyl Chloride Panel research coordinators group.

To evaluate and compare the three proposals received for the update study, we used a set of criteria which I organized into an "evaluation matrix" (attached). Most of these criteria were derived directly from the Scope of Work document sent out from CMA as the request for proposals. Not all research coordinators were able to employ this matrix to the full extent, of course, since some of the criteria fell outside their areas of professional expertise. All were able to arrive at a "bottom-line" conclusion about the relative merits of the three proposals received, however.

The proposal from New York University appeared to reflect a substantial misunderstanding of the Scope of Work and of the previous studies of the CMA cohort. This proposal requested nearly 1.5 million dollars for the study, proposed a study duration of 42 months from start to completion, and indicated that additional analytical studies would be included as well as the cohort mortality update. The magnitude of this effort was clearly beyond that suggested by the Scope of Work. In addition, the proposal called for longitudinal regression analysis of mortality in the cohort by estimated exposure intensity, when it should have been clear that the existing data will

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not support this type of analysis. I and the rest of the coordinators felt strongly that we could not seriously consider this proposal because of these factors.

The proposals from Applied Epidemiology Inc. and Applied Health Sciences Inc. were similar in many respects, including their estimated costs and study duration. Both proposals addressed all of the points outlined in the Scope of Work. The proposal from Applied Health Sciences (AHS) had some inherent advantages in the the Principal Investigator had conducted the previous mortality update study and had immediate access to all relevant existing data. However, in the end it appeared that the proposal from Applied Epidemiology Inc. (AEI) was the superior one, for the following reasons:

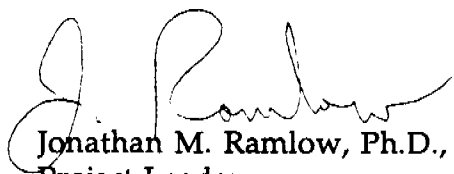
- 1) the AEI proposal was much more detailed than the proposal from AHS; for example, AEI estimated the large number of additional deaths to be expected in this update, thus highlighting the substantial increase in the power of this study;
- 2) the AEI proposal contained provisions for conducting the study under the Good Epidemiology Practice (GEP) guidelines developed for CMA; specifically, it called for the development of an acceptable protocol prior to the actual conduct of analyses;
- 3) the AEI proposal took more seriously our concerns about possible inter-regional differences in mortality;
- 4) the AEI proposal took more seriously our concerns about standardizing all cause-of-death data to the most current revision of the International Classification of Diseases.

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- 5) the AEI proposal, in my professional judgment, displayed more insight into the fundamentals of epidemiologic analysis; for example, in response to our inquiry about the potential value of regression modeling techniques in this update, AEI indicated that this would depend on the results of the standard SMR analysis, rather than simply stating in advance an intention to use such methods.

I hope that this letter clarifies the results of the proposal comparison process for you. Please let me know if there is anything else that I can do in this regard.

Sincerely yours,



Jonathan M. Ramlow, Ph.D., M.P.H.
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Epidemiology, H&ES
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Attachment

**Evaluation Matrix For VCM Industry-Wide
Cohort Study Update Proposals**

	Proposal		
Criterion	Applied Health Sciences	Applied Epidemiology	New York University
Verify dataset completeness			
Obtain death certificates from previous update			
Follow-up vital status ascertainment to 1992			
Obtain death certificates through 1992			
Mortality analysis completeness			
Update employment history to 1992			
Apply regression modeling			
Update coding of cause of death			

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**Evaluation Matrix For VCM Industry-Wide
Cohort Study Update Proposals**

	Proposal		
Criterion	Applied Health Sciences	Applied Epidemiology	New York University
Use state and local mortality rates			
Include race-specific analysis			
Prepare written protocol			
Time frame for study			
Total study cost			
Other			
Overall			