

THE UNIVERSITY OF MICHIGAN

SCHOOL OF PUBLIC HEALTH

ANN ARBOR, MICHIGAN 48104

Department of Environmental
and Industrial Health

March 8, 1973

Dr. Kenneth D. Johnson
Assistant Technical Director
Occupational Health
Manufacturing Chemists Association
1825 Connecticut Avenue, N.W.
Washington, D.C. 20009

Dear Dr. Johnson:

Based on the need expressed at your recent meeting in Washington, D.C., we are submitting a proposal for an epidemiological study of industrial workers engaged in the manufacture of vinyl chloride. This relies basically on available data and assumes that records do exist and will be made available to us as required. As you will note, we urge strongly that this study should coincide with the initiation of an industry-wide plan to collect all the information needed for a prospective analysis of the questions at some future date. We are prepared to begin the study as soon as the contract is approved, and estimate that the work should be completed in two years, though every effort will be made to report the findings to you as much in advance of that time as possible. It may be that 75 percent of the follow-up could be completed in one year. A provisional analysis at this stage could be presented, but we have no means of estimating with any certainty what proportion of the work could be completed in 12 months.

In outline, the proposal consists of the following:

- (1) A retrospective study of all workers (approximately 5,000) engaged in the manufacture of vinyl chloride. Definition of the study group will be through personnel and medical records, follow-up through a variety of mechanisms, and additional essential information will be collected by questionnaire, either from the employees themselves or from next of kin.
- (2) A concomitant limited environmental study consisting of visits to several plants by industrial hygienists for the purpose of obtaining data by direct sampling, or making arrangements with qualified industry personnel to obtain such data. Every effort will be made to collect all existing environmental data but it is our understanding that such data are quite limited. In addition, the industrial hygiene survey will describe the various classes of jobs and their attendant exposures, so that it should be possible to define the degree of exposure of all individuals included in the study. It is expected that our efforts in this regard will be helped considerably by the prior experience of University of Michigan personnel with the Acroosteolysis Study.

CMA 009527

March 8, 1973

- (3) No medical examination of workers is planned for the present study. Within the time available it is not felt that an appropriate study could be completed, but it is our recommendation that industry-wide discussions should commence, leading to improved examination procedures which could be valuable in the next several years in reassessing the extent of the problem.
- (4) We understand that animal toxicological studies are to be performed elsewhere. We should appreciate being kept informed of the findings of these and other studies such as those thought to be underway in Europe. Conceivably, new findings in research could influence the direction of the proposed study, and it would be particularly important to be appraised of any epidemiological data which might become known.
- (5) Our budget is of necessity approximate. The magnitude of certain aspects of the study cannot be completely defined at this time. It is, for example, almost impossible to estimate travel expenses. We should suggest an agreement whereby actual travel expenses would be reimbursed, with some limitation on the extent of travel agreed upon in advance and subject to approval by the MCA. One of the largest unknown factors is the difficulty and expense of location information regarding employees who have retired or otherwise dropped out of the exposure group. Here again we would expect that as the magnitude of the effort became better defined, agreement between the MCA and ourselves could easily be reached concerning the necessary level of expenditures.
- Several of the key personnel included in the budget would be available to the extent indicated as soon as our proposal is accepted and it is believed that others could be acquired very quickly.
- (6) As discussed in Washington, the budget has not yet been approved by the University. If The University of Michigan is selected to perform this study, a formal proposal will be written and will bear the signature of the proper officials in the University. The official proposal will be essentially the same as this informal proposal, with variations limited to those which arise from discussions between MCA and ourselves.

Our proposal has deliberately been kept short. It does not include Curricula Vitae for staff members, etc., on the assumption that at present these are not required. The Department of Environmental and Industrial Health, and the Department of Epidemiology are thoroughly experienced in this type of investigation, and can be expected to follow in general the procedures previously used in the Acro-osteolysis Study as well as other industrial studies of a related nature. We shall be most pleased to meet and amplify or clarify any aspects of our proposal or budget at your convenience.

Very truly yours,

R. G. Smith

Ralph G. Smith, Ph.D.

I. T. Higgins

Ian T. Higgins, M.D.

RDS/ITH/gs

CMA 009528