

Environmental Health Associates, Inc.

April 3, 1987

Hasmukh Shah, Ph.D.
Program Manager
Biomedical and Environmental
Special Programs
Chemical Manufacturers Association
2501 M Street, NW
Washington, DC 20037

Dear Has:

We are pleased to learn that CMA has decided to further investigate the problem of liver cancer and angiosarcoma in the vinyl chloride study. We agree that the first step should be a pathology review of all deaths coded as liver and biliary cancer in the study. Dr. Ishak at the Armed Forces Institute of Pathology is certainly well known for his expertise in hepatic pathology, and will contribute significantly to this stage of the investigation. As you indicated during our recent phone discussion, CMA is interested in receiving a proposal from EHA for retrieving pathologic materials for Dr. Ishak.

There were 37 liver and biliary cancer deaths in the study. It is my understanding that CMA is interested in reviewing the pathologic materials for all 37 cases. In addition to these liver and biliary cancer deaths, I am aware of at least two angiosarcomas which are not specifically identified as occurring in the liver, and were therefore coded as connective tissue tumors. It is likely that they were angiosarcomas of the liver. We suggest that these two cases be reviewed as well, bringing the total to 39 cases.

There are 29 different hospitals at which the deaths of the 39 cases occurred. These hospitals are likely to have pathology materials from autopsies. However, only 17 cases are known to have had autopsies conducted. The remaining 22 cases will most likely require additional investigation to identify the location of biopsy specimens. We will contact the appropriate hospital or physician for each case, and request all the pertinent pathology materials.

Since the pathology materials are confidential, we will need the approval from the Institutional Review Board. It will be necessary for us to prepare a brief protocol for IRB's review. We feel that an IRB approval will facilitate our request. Dr.

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Lowengart, a physician on our staff, will write a letter to the appropriate hospitals or physicians. She will briefly explain the purpose of the request as well as provide reassurance for protecting confidentiality. We estimate that we will obtain approximately 20% of the pathology materials requested in response to our first request. We will follow-up our original requests in order to obtain the remaining 80%. I anticipate that repeated requests will be needed in some cases. Once we receive the materials, we will put appropriate identifiers on them and ship them to Dr. Ishak at the Armed Forces Institute of Pathology.

Dr. Lowengart, Dr. Whorton and I will be responsible for this project. In addition, other EHA support staff will also be involved. The following is our budget estimate:

Otto Wong, ScD	2 hours @ \$155	\$310
Donald Whorton, MD	2 hours @ \$155	\$310
Ruth Lowengart, MD	20 hours @ \$115	\$2300
Research Analyst	35 hours @ \$45	\$1575
Administrative Asst	8 hours @ \$38	\$304
IRB fee		\$250
Telephone		\$500
Copying (200 pages @ 15 cents)		\$30
Postage and express mail		\$50

TOTAL ESTIMATED BUDGET = \$5,629

Since it is difficult to anticipate exactly how much time it will take to retrieve all the necessary materials, the above budget is only an estimate. Furthermore, most hospitals or physicians will require reimbursement for shipping and handling the materials. Therefore, we propose to conduct the project on a time and material basis. We will bill CMA for the actual labor and direct expenses on a monthly basis. We estimate the entire project will take approximately 3 months.

If you have any questions regarding this proposal, please give me a call. I look forward to working with you again in this project.

Sincerely yours,



Otto Wong, Sc.D., F.A.C.E.
President, Scientific Affairs