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January 12, 1996

Dr. Hasmukh Shah
Chemical Manufacturers Association
1300 Wilson Blvd.
Arlington, VA 22209

RE: Study of Brain Cancer in Vinyl Chloride Exposed Workers

Dear Dr. Shah:

As per our discussion and recent meeting, you will find enclosed an updated budget and more detailed outline of the timetable required for the project originally submitted (10-27-94). This proposed project will provide an analysis of the 45 year retrospective and 20 year prospective occupational surveillance data of an industrial cohort with regards to the occurrence of brain cancer in vinyl chloride exposed workers.

If there is need for any further information or questions, please feel free to call upon us.

Sincerely,



Carlo H. Tamburro, M.D., M.P.H.
Professor of Medicine
Director, Liver Research Center & Laboratory
Professor of Pharmacology & Toxicology
Chief, Division of Occupational Toxicology

CHT:njh

Enclosure

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BRAIN CANCER STUDY IN VINYL CHLORIDE EXPOSED CHEMICAL WORKERS

This proposed study will provide an updated analysis of the prospective occupational health surveillance program at the B.F. Goodrich Bells Lane plant in Louisville, Kentucky. The purpose of this study is to evaluate the relationship of vinyl chloride exposure and brain cancer occurrence. Upon completion of the six tasks outlined, each brain cancer case will be paired with all available matched controls and each brain cancer case will be evaluated as a case-control study by non-parametric rank order analysis (Greenburg and Tamburro, JOM, 1981). The study's primary aim is to ~~reaffirm our initial observations of an absence of~~ any causal relationship between vinyl chloride exposure and the development of brain cancer.

use updated data from this cohort to determine whether or not there is

In order to accomplish this in a timely fashion (within fifteen months), there are seven organizational and informational tasks that need to be completed before a comprehensive analysis can be conducted:

Task 1: Protocol Development and Review

Upon final agreement of this proposal, anticipated by March 1, 1996, a protocol committee will convene composed of University of Louisville principle investigator and staff and the CMA's working group to review the submitted protocol for concurrence of the objective aims and confirmation of the methodological approach. This will be accomplished by a meeting at the University of Louisville of the participants within two to four weeks of the study's initiation. Final protocol (by April 1, 1996), will be submitted to three external reviewers for comments and recommendations to be completed and returned by May 1, 1996. The protocol will include plans to cooperate and coordinate this study with that of Applied Epidemiological, Inc. Data will be exchanged to the extent needed without ~~breaching~~ confidentiality with either state agencies or industrial participants.

breaching

Task 2: Update of All Employee Work Histories.

Our data base indicates that approximately 3330 individuals (total cohort) were employed for one or more years at the Bells Lane plant in Louisville, Kentucky, between its initial operation in 1942 until its first offspring companies, i.e., Zeon, Inc., 1990, and Geon, Inc., 1993, were created. Work history data is available on 93% of the total cohort. Over 1400 work histories prior to 1978 are 95% completed. Some 400 to 700 employee work histories (between 1979 and 1993) need updating or verification. Approximately 1900 employees hired before and who did not work after 1974 are being added to the cohort data base. Given the full cooperation that we have enjoyed over the past years from the three existing offspring companies (B.F. Goodrich, Zeon, and Geon) we estimate that completion of Task 2 will require 480 working hours over a eight month period. Six working sessions are estimated to be needed with each of the three offspring company personnel. Each session will be spaced about three to four weeks apart to allow new data entry, data correction, validation, reanalysis for completeness, etc., for all known employees. An interim progress report will be given at seven months.

Task 3: Updating Job Titles by Activity and Plant Buildings.

All job titles and buildings for this plant for years 1942 through 1979 are 95% completed and verified. Job titles, locations, and buildings for this plant after 1979 are incomplete because of new plant construction, renovations, and manufacturing location changes. This updating is especially important due to the recent changes over the past five or six years related to the separation of the original B.F. Goodrich plant into its offspring companies. These job updates are essential for the proper assessment of exposure rankings after 1980. Given the continued cooperation of all three offspring companies, we estimate this task to take 180 working hours spread over a five month period. Approximately five sessions are estimated to be needed with past or recent personnel management and staff to acquire this information. Status reports of the progress of Task 3 will be given at five months and at its completion (seven months).

Task 4: Chemical Data.

Updating and verification of the original 22 chemicals used on a continuous or intermittent basis between 1942 and 1978 are included in this task. Area and personnel monitoring data (whichever are available) will also need to be incorporated and updated. This is essential for the quantitative confirmation of each rank order estimate. A few new or old chemicals may need to be added to this chemical list for completeness. Verification and inclusion of all such agents will require an estimated 170 working hours spread over a five month period. Status reports will be given at five months and at the completion of Task 4 (seven months).

Task 5: Exposure Rankings.

Exposure ranking updates are required for 1979 through 1994 for all previous job classifications and verifications are needed for all new jobs created between 1979 and 1994 (Task 3). We estimate Task 4 to require 510 working hours spread over an eight month period. Some participation by experienced employees will be required (estimated time 30 to 35 hours). This will be done through a number of one to two hour sessions spaced two to three weeks apart. In between sessions, new data entry, correction, validation, and some data checking will be done to avoid duplication and misclassification. Status reports will be given at the time all needed data has been obtained (five months), and after data has been computerized and validated (seven months). A final report after the cumulative exposure ranks have been calculated for each job for each year will be given at ten months.

Task 6: A Death Certificate Confirmation.

Certification and documentation of the cause of death is available in approximately 490 of the 530 known deaths in this cohort. Forty-six individuals have incomplete data which needs further verification. Some non-vested employee data will need to be confirmed and checked. This task is estimated at taking 330 working hours spread over nine months. A status report will be provided at five and seven months identifying how many employee deaths have been verified at each time interval. Final report at eleven months.