

Monsanto

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

November 30, 1988

Dr. Hasmukh Shah
CMA
2501 M St. NW
Washington, DC 20037

Dear Has:

The update of the CMA vinyl chloride mortality study recently completed by Environmental Health Associates showed an excess of liver and biliary cancer over and above the angiosarcomas known to be associated with exposure to high levels of vinyl chloride. The excess of this non-angiosarcoma liver and biliary cancer tended to increase with increasing duration and latency of exposure.

As you know, angiosarcoma is often not coded on death certificates (the basis for the EHA study) even when it is the true cause of death. As a result, it is possible that the apparent excess in liver and biliary cancer other than angiosarcoma was in fact due to angiosarcomas that were recorded as some other less specific form of liver cancer. It is important to find out if this was in fact the case in the EHA study, since otherwise the observed excess could be interpreted as evidence that vinyl chloride causes liver cancer other than angiosarcoma.

Although I do not believe this to be the case, the only way to settle the issue is to get the most definitive possible diagnosis for all of the 37 liver and biliary cancer deaths found in the EHA study. In order to rule out angiosarcoma, that diagnosis should be based on a pathologist's examination of the liver tissue of the deceased persons. The Armed Forces Institute of Pathology has agreed to examine such liver tissue samples and to provide us with a diagnosis.

Very often, pathologists and hospitals are reluctant to provide tissue specimens to outsiders, so our best prospect for getting such specimens appears to be to seek the cooperation of the plants in the EHA study in which liver and biliary cancer deaths occurred.

RSV 0003913

Dr. Hasmukh Shah
November 30, 1988
Page 2

Specifically, we would like to do the following. EHA can prepare lists of the liver and biliary cancer deaths by company, and by plant within company for those companies that had more than one plant in the study. We would like to send those lists to the appropriate companies and plants, and to ask the company medical directors and/or plant physicians to determine, for each death, whether there was or was not a pathological evaluation of the liver tissue. If there was, we would like to obtain a block of tissue, or failing that, the slides that were made. We would then submit the material to AFIP who would tell us whether or not each such specimen was an angiosarcoma.

The exercise does not have to be completely successful in order to be useful. What we need to know is whether the total number of angiosarcomas is probably large enough to account for the observed excess in liver and biliary cancer.

I see no violation of confidentiality, since the identities of the deaths and plants are already known to EHA, and would be sent by them only to the plants from which they had originally obtained the data. No third party would be involved except for the AFIP, which would receive the pathology specimens.

I am hoping that the companies involved will agree to cooperate. They can do the required digging much more successfully than any outside contractor, and the results could resolve a question of considerable practical and legal importance.

Yours sincerely,

William R. Gaffey
William R. Gaffey, Ph.D.
Epidemiology Director

/jj