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Ms. Susan Howe
Chemical Manufacturers Association
2501 M St. NW
Washington, DC 20037

Dear Susan:

This is a summary of the activities of the Vinyl Chloride Panel with respect to the update of the old CMA sponsored vinyl chloride mortality study.

When I was asked to chair the panel, its principal responsibility was to oversee an update of the above study, whose results were first reported in 1974. ENSR, a company in Oakland, California, was awarded the contract and did in fact complete the update in 1987.

We had hoped to settle some outstanding issues that some people saw in the earlier study, where for some causes of death (other than liver cancer) there were so few deaths that we couldn't really rule out the possibility that there might be an excess risk.

The update settled these issues favorably. However, there was a residual excess of deaths from liver and biliary cancer over and above those known, either from death certificates or from the ICI angiosarcoma registry, to have been angiosarcomas. The excess was positively related to duration and latency of employment in vinyl chloride related jobs. Since this phenomenon had not been seen in the earlier study, we were at a loss as to whether the excess was (a) due to chance, (b) due to the presence of undiagnosed angiosarcoma hidden among the other liver cancers, or (c) due to vinyl chloride exposure.

We decided to tackle (b) above by getting slides of tissue specimens for all the liver and biliary cancers, if available, and having them diagnosed by the Armed Forces Institute of Pathology. In this way we hoped to find the hidden angiosarcomas, if any. Our further reasoning was that, even if

slides were not available for all of the deaths, we could get some idea of what proportion of the liver cancer deaths were really hidden angiosarcomas.

ENSR got the job of doing the follow back. The results were disappointing because, although ENSR got a few pathology reports, they were unable to get any slides, so we were not really any further ahead.

In many cases the physician or hospital in question refused to provide any information at all without permission from the next of kin. Unfortunately the only source of information on next of kin was on the death certificate, and ENSR had obtained most of the death certificates by agreeing not to contact anyone named on the death certificate. Dr. Wong of ENSR refused to go back to all of the original health jurisdictions and to the National Death Index to ask that this restriction be removed, because in his opinion that major effort would not materially improve his ability to get slides. He offered to give us a written statement to that effect.

Our next thought was the following. Although there were about 1500 deaths in the updated study, there were only 37 deaths due to liver and biliary cancer. If we sent each of those death certificates back to the company for which the deceased had worked, those companies might have better luck in getting slides or in establishing that slides did not exist. This seemed reasonable because individual plants and companies might have a better rapport with the local physicians and hospitals.

The difficulty was that ENSR, as part of its confidentiality agreements, had agreed not to furnish copies of the death certificates to any third party. The best they could do was to identify for each of the 1500 deaths the company that the deceased worked for, and send back to each company a list of the total deaths from that company. Each company would then have to (a) get the death certificates for the people on its list, (b) identify those due to liver and biliary cancer (c) get permission to follow back those deaths, and (d) do the follow back. Since only 37 deaths were involved, it was clear that some companies would be requesting hundreds of death certificates only to find that one or two of them, or perhaps none of them, were liver cancers.

In addition, each company would almost certainly have to set up an Institutional Review Board to satisfy the requirements of the health jurisdiction and of the NDI.

All of the above would be a formidable job, even for a company with an in-house capability in epidemiology.

Dr. Wong's pessimism about the whole enterprise was buttressed by the experience of one large company with an extremely competent in-house epidemiology staff. Having cleared all of the above hurdles in another study, that company found that not only was it impossible to get slides, it was not even possible to find out whether slides had ever existed!

The cumulation of all these difficulties led the majority of the Vinyl Chloride Panel, in a conference call on September 6, 1989, to conclude that the probability of even modest success was so minute that no effort should be made to obtain the company listings of deaths or to persuade the companies involved to do the tasks required.

I have gone into great detail in this account because I wanted to make it clear that the Vinyl Chloride Panel did everything possible to resolve the situation, and that we can see no other way to determine the true diagnoses of the liver cancers in this study. If the issue is still up in the air, it is not for lack of effort on the part of the study sponsors.

Yours sincerely,

William R. Gaffey

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