

CMA - VINYL CHLORIDE PROJECT PANEL MEETING

March 18, 1980 Washington, D.C.

1. General Remarks

- a. Meeting chaired by Ed Frost, CMA General Counsel. Also present was David Zall, CMA Attorney.
- b. The Busey Report (EPL - Vinyl Chloride Pathology Report of the IBT data) was evaluated by an attorney of Union Carbide, Mary Manette, and concluded that there is a possible 8(e) consideration here. This was determined on March 13, 1980, but Mr. Wheeler of Union Carbide stated that Carbide's position has not been crystallized yet. In particular, Carbide is concerned with the rat brain data and the incidence of Neuroepithelioma (primary brain tumor).
- c. Initially, there was no consideration of an 8(e) report when the Busey Report was submitted. Also, no consideration was given at that to it being submitted to the governmental agencies. In addition, this report, for some reason, was not widely distributed beyond the audit group??

2. Background: IBT/CMA vinyl chloride inhalation study.

- a. Project began in 1973 with three species and three dose levels. An interim report "IBT-23 months Status Summary to MCA Chronic Vapor Inhalation Toxicity Study with Vinyl Chloride in albino rats, albino mice, and golden hamsters. September 23, 1975 IBT 663-03222" was made to CMA and later disclosed to a lower level EPA employee on January 14, 1977. (Copy to be obtained). This interim report only indicated suspected gross lesions. For male rats three brain lesions were reported in the high dose group (T-3). For female rats and male and female mice, no brain gross lesions were reported. There is question as to whether the interim report clarifies that the three gross brain tumors were found in only six observed rats. It was felt by those present who had looked at the interim report that this could not be determined.
- b. An audit of the IBT study by Experimental Pathology Laboratories (Dr. Busey) indicated that:
 - 1) Angiosarcoma effect in all species at all levels
 - 2) Primary lung tumor effect in mice
 - 3) A carcinogenic effect on the Zymbal's gland of the rat.

Besides the above, this audit indicated that in the high dose male rats (T-3), only 23 brains were counted with six examined microscopically. Of the six, three indicated primary brain tumors (neuroepitheliomas). Also, for the middle dosed male rats (T-2), 23 brains were counted with 18 examined microscopically with 1 of the 18 determined to have a neuroepithelioma.

It was noted that in this particular rat strain, primary brain tumors occur from 0% to 3%. In the IBT study, there was 100 animal/doses/sex, if no more than three brain tumors per sex/dose level are determined then they would fall within a statistical norm. This problem can only be resolved by histopathological

evaluation of all the brain tissues, as indicated by several of the individuals present. However, it appeared that some individuals were not particularly in favor of the approach.

3. Disposition of Busey Report.

- a. Initially Dr. Busey recommended in the EPL Vinyl Chloride Pathology Report, January 9, 1979, that no further pathology work be done on this study. This was because of the serious deficiency in the number of tissue saved. However, in a meeting with CMA-VC audit task group on March 21, 1979, Dr. Busey reversed his recommendations and indicated that in light of recent epidemiological data further pathology work should be performed.
- b. It was mentioned at this time by Ed Frost that he had heard that Joe Wagoner had evidence that he believes will sink CMA. Dr. Wagoner is the last speaker at the two day government vinyl chloride meeting, representing EDF.
- c. Ed Frost pointed out what he, as the CMA representative, considered the two critical issues to be addressed.
 - 1) The disposition of the Busey Report should be made available to government agencies in a low-keyed way as soon as possible. He recommends to draft a letter this afternoon and send out the report tomorrow to the six government agencies that received the IBT interim report: OSHA, CPSC, EPA, HEW, FDA, and NCI.
 - 2) Additional treatment and disposition of the IBT data should be considered, particularly the remaining brain tissues.
- d. It was motioned, seconded, discussed and approved that a letter be drafted as discussed and be sent along with the Busey Report (EPL - Vinyl Chloride Pathology Report) to the six indicated government agencies.
- e. Mr. Wheeler of Union Carbide stated that there are no working connections between any brain tumors observed at Texas City and VC working conditions.
- f. Question raised concerning 8(e) reporting and whether this sending of the Busey Report eliminated a company's obligation, if any, to report. It was suggested by counsel (Ed Frost) that all companies need to consider 8(e) reporting.

4. Additional treatment and disposition of IBT data and tissues.

- a. Stated that since January, 1979 there have been problems and a lot of discussion concerning what to do.
- b. Dr. Hatfield stated that we need to look at other tissues besides the brain. He feels that it is difficult to just single out the brain if you suspect all the data reported by Dr. Busey.

- c. After much discussion, Dr. Zeb Bell motioned that we proceed to look at all the available brain tissue in the entire study, as recommended by Dr. Busey in March, 1979. This motion was seconded and carried with one exception of a No vote by Dr. Torkelson. Ed Frost stated that this would be done in all haste and requested that Dr. Bell coordinate this effort. Dr. Bell agreed along with the consensus of the rest of the members present.

5. Termination of IBT contract and our legal claim.

CMA has made a claim to IBT for a breach of contract. Despite a number of calls and requests by Ed Frost, IBT has not yet responded. It is not advised that we sue at the present time. CMA has asked for \$600,000 from IBT, but it is not believed that this amount will be refunded. It is hoped that a modest amount, probably in the neighborhood of \$100,000 can be obtained from IBT without recourse to a law suit.

6. Other follow-up work.

There was discussion as to what to ultimately do with the archived material at IBT. It was suggested that the same procedure be used as was used with the CMA/IBT trichloroethylene study. The procedure entails notifying the government that all materials will be kept at their disposal for a period of six months. After that time, IBT is to retain this material, but without any financial support. No action was taken by the panel on this matter.

7. Meeting adjourned.