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From Hao Shuk
Ref. No. VC 1422 E
Date 4/19/88

Dear Ms. Jones:

I had an opportunity to review the draft of the ATSDR Toxicological Profile for vinyl chloride and have the following comments which may be helpful in developing the final profile. Since I am not competent to review the material on animal and metabolic studies I have confined myself to epidemiology.

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The section on human carcinogenicity (Sec. 4.3.6, pages 54-59) pretty much accepts earlier EPA evaluations of the principal studies. Criticisms of these evaluations are really criticisms of various EPA documents, and are not appropriate here. However, on page 54, at the end of the second paragraph, the present report offers what appears to be an independent comment on the study by Heldaas et al. [1984] to the effect that incidence of malignant melanoma may not be reflected in mortality, thus explaining the discrepancy between this incidence study and other mortality studies. The five year survival rate for malignant melanoma is about 50 percent, so I doubt that this explanation would be accepted by many epidemiologists. In addition, no comments are made on the discrepancies among the mortality studies, which creates the impression that the Heldaas study is being singled out for special (and charitable) attention.

I also have substantive comments on two other parts of the document.

1. Hepatotoxicity. Section 4.3.2.1 (page 40). The text lists several epidemiology studies as showing an association between occupational exposure and impaired liver function. I had immediate access to only one of the cited reports (Lee et al. 1972) and found that it was in fact a negative study whose conclusions were precisely the opposite of what they were stated to be in this document. This is serious, because it calls into

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question the interpretation of the remaining references which I could not readily obtain. There should be an independent scrutiny of the references.

2. Developmental toxicity. Section 4.3.3.1 (page 46). The document describes five studies of the association between fetal loss and exposure to vinyl chloride. Two are positive and three are negative. One of the negative studies [Edmonds et al. 1975] was done in a population that was part of one of the positive studies [Infante et al. 1976]. The authors reach conclusions directly contradictory to those reached by Infante et al. Nevertheless, this document concludes that there is evidence of developmental toxicity and cites the two positive studies in the Health Effects Summary (page 13) while ignoring the three negative studies. The authors of the document have in effect evaluated the five studies and decided that the three negative studies are of no importance, but there is nothing of that evaluation in the text. I doubt if the results of their evaluation will be accepted without some justification.

I'm not at all sure that the conclusions of the document in the areas of hepatotoxicity and developmental toxicity would change if my comments were taken into account, but it seems to me that those conclusions are not supported by the data that are now presented in those sections.

I do appreciate the opportunity to comment on the draft.

Yours sincerely,

William R. Gaffey

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