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Ms Susan Brager
ERG
110 Hartwell Avenue
Lexington, Mass.

Dear Ms. Brager:

As you know, it will not be possible for me to participate in the peer review workshop on PCBs dealing with cancer dose response due to a previous international commitment. As encouraged by you and Bill Farland I would like to offer several brief comments for the Workshops consideration.

1. What is the appropriate data base for use in PCB risk assessment?

While I strongly support the position that all data should be used in a weight of evidence process it would appear to me that there is a new data base that dominates. I refer to the recently completed Battelle studies in rats where four specific Aroclors were studied in parallel adhering to a similar protocol. It provides the only meaningful data on the long term effects of Aroclor 1016 and 1242. Further, it does not suffer the limitations of group size that compromised the interpretation of the NCI study with Aroclor 1254. The studies with Aroclor 1260 provide the first opportunity to assess response to more than one dose and carry the additional benefit of temporal relevance to the other Aroclor studies. The Battelle studies have the additional benefit of being conducted in a manner that was fully compliant with EPA Good Laboratory Practices. Finally, there is the additional, powerful advantage of congener specific analytical chemistry data which permits determination of dose to target site. In my opinion, the previous studies should now be relegated to a secondary utility, including the "re-read data" that I published a little over a year ago. There is one gold standard - the Battelle study - from which to derive any type of quantitative estimates of potency; the other data sets are not remotely of the same quality.

2. How to derive quantitative estimates of potency?

Were I able to participate at the meeting I would have argued strongly for consideration of a BMD approach with an appropriate MOS for each Aroclor. There is much evidence to suggest that the non coplanar congeners promote rather than induce carcinogenesis. The data from the Battelle study indicate that Aroclor 1254 is not leading to the same type of

response seen with other Aroclors. Current belief would tend to account for this by invoking a duality of response due to the relative concentrations of coplanar congeners in this mixture in addition to the non coplanar promotion.

Should one not opt for BMD plus MOS it is assumed one will favor the estimation of an ED10 with a line then drawn to 0. Given the unsettled nature of the discussion regarding use of the lower 95% confidence bound for the line drawing it would be my hope that the central estimate and the lower bound data be presented.

The total value of the Battelle study has not been realized given that there is a plethora of analytical data that has yet to be published. Such data may provide the opportunity to propose different model considerations for potency estimation of the Aroclor 1254 data in particular. It would be my hope that the Workshop formally recognize this and encourage the consideration of such data should it become available.

What potency values should be used for field data?

I am sure this topic will provoke lively discussion. Rather than offer my own "potency recipe" let me make one recommendation. In those instances where there is credible field data encourage its use in a risk assessment in lieu of a default assumption. Encourage the comparison of their analytical results with Aroclor congener profiles to determine the most relevant Aroclor from which to estimate cancer potency. In other words, foster the use of data and the application of common sense. Where appropriate analytical data are not available at a site the default approach would be recommended.

Sincerely,

John A. Moore