Conference Call Summary
July 23, 2001
Technical Review Committee
Benzene Health Research Consortium

Participants:

Patrick Beatty (Chevron)
Shan Tsai (Shell)
Stuart Cagen (Shell)
Bill Broddle (Conoco)
Don Burnett (BP)
George Woodall (API)
Lorraine Twerdok (API)

Issues

1) Selection of a Chair for the Committee – Patrick Beatty was chosen unanimously.

2) Role of the Committee in the Consortium – Several roles for the Technical Review Committee within the consortium were suggested. For many of those roles, the level of involvement needs to be determined. The roles and the options for the level of involvement for each of those roles as listed below were deemed appropriate for presentation to the Executive Oversight Committee, which will be meeting this Thursday (July 26, 2001).

Interaction with the Executive Oversight Committee

- Liaison between the Independent Scientific Review Panel and the Oversight Committee, serving to foster clear communications but not to act as a filtering mechanism. The Oversight Committee will make all final decisions over the financing of the study, and the Scientific Review Panel will have final decision authority over technical issues.
- Consultant in Technical and Financial decisions – final decisions would be made by the Oversight Committee
    1) Passive Option – keep the Oversight Committee informed but not actively participate in the decision process
    2) Active Option – participate in some level of decisions (e.g., what parts of the project need to be scaled back if financing becomes an issue) as determined by the Oversight Committee.
- Chair of the Technical Review Committee will serve as an ex-officio (non-voting) member of the Oversight Committee. The same would also apply to the Chair of the Communications Committee.

Review of Manuscripts and Reports

- No Comment Option – Receive copies of reports and other documents to keep informed but no comments given.
- Advisement Comments – Comments given but with no binding obligation upon the Investigators to accept them.

Interactions with the Investigators

- Passive Option – Keep informed on issues and needs for decisions to pass along to the Oversight Committee and/or the Scientific Review Panel, bringing critical issues to their attention for action.
- Active Option – There are several tiers of activity that are listed below.
  - Serve as a resource for the Investigators during periods between meetings of the Scientific Review Panel (making some decisions and providing advisement)
  - Monitor progress on the project, ensuring that the Investigators meet milestones and stay within budget. (This would be in concert with the role of API as administrator for the project and the Scientific Review Panel as oversight for the technical progress of the project.)

Other

- Attend portions of the meetings of the Scientific Review Panel meeting where the Investigators are presenting their findings, then withdrawing for the Panel to deliberate.
- Serve as a panel of experts from the sponsor companies for the rest of the consortium committees and panels.
- All decisions by the Committee will need to be appropriately documented.

3) Composition of the Scientific Review Panel and Nominees – Each of the nominees in order of preference are listed under their area of expertise. The composition of the Scientific Review Panel, as suggested below, consists of one or more members from each area of expertise (numbers in parentheses indicates preferred number of experts from each field).

Epidemiology (2)

- Nancy Mueller (Harvard) - A specialist in epi of lymphomas and NHL. One of the original reviewers. Made a strong contribution to the review at that time.
- Martha Linet (NCI) - She was part of the original NCI team in China, but seems to be more objective about their work than Hayes or Rothman. My understanding is that she has left that project. Her presence on the Panel would bring significant credibility.
- Robert Millikan (U. North Carolina) - Originally a Ph.D. in Biochemistry/Molecular biology with subsequent return to school for Public Health degree. Would be useful reviewer of Molecular Epi and epi aspects of the Disease Progression study.
- Elizabeth Delzell (University of Alabama at Birmingham) - Also one of the original reviewers, but with a stronger tie to the industry that may make her seem less independent to outside view.

Industrial Hygiene/Exposure Assesment (2)

- Robert Herrick (Harvard) - Extensive experience and credentials. Credibility as former NIOSH adminsitrator. Has consulted as reviewer for an EMBSI study.

- Robert Harris (U. North Carolina) - Lots of experience. Participated in early Pliofilm work. Not sure if he is retired. Recommended by Dennis Paustenbach as non-aligned and respected
- Lance Wallace (USEPA Ret'd) - Not an IH'er but well known name in exposure monitoring, although predominantly not occupational. Could meet the requirement for a regulatory representative
- Neil Zimmerman (Purdue) - Second tier name from Paustenbach. Younger than the 2 above. Experience with occupational epi and solvents.
- Steve Rappaport (U North Carolina) - This one is controversial. He has published on benzene-related hydroquinone aducts to protein. He has one paper arguing that the benzene PEL is not protective for workers. Paustenbach says that he disagrees with PEL development process in general and used benzene as an example, but that he would be an objective reviewer. Biggest value is his credibility with regulatory agencies and NGOs. Rob Schnatter says that he is a perfectionist, critical of everyone's work, including his own.

Statistics/Study Design (1)

- Louise Ryan (Harvard) - Experience with clinical studies. She has been on advisory boards for NTP and EPA as well as NAS committees. Fellow of the American Statistical Society. She is a coauthor on a couple studies of reproductive effects of benzene/solvent exposure in China.
- Kenneth Kopecky (U Washington/Fred Hutchinson Cancer Center) - Extensive bibliography on AML, both clinical trials and basic research. Involved in epi studies of radiation effects in Hanford WA and Chernobyl.
- Nicholas Jewell (UC Berkeley) – Suggested as being non-aligned. He does work with epi studies including diseases.

Hematology (2)

- Richard Larson (U. Chicago) - Clinical Hematologist/Oncologist. Participated in Ottawa Conference and on previous review of China protocols. He was very useful in that first review. Good solid reputation.
- Mark Minden (Ontario Cancer Institute) - Molecular hematologist. Publications in area of leukemia progression and molecular biology of leukemia (especially AML) induction and regulation. Could be an excellent person to review the disease progression study.

Hematopathology (1)

- James Brunning (U Minn.) - Recommended by Larson. Currently emeritus professor, but active. Involved in recent WHO reclassification of MDS.
- (The two really big names, John Bennett and Harold Vardiman are wanted by Irons for a pathology working group to review tissue slides as needed. This may make them ineligible as reviewers of their own work.)

Genetic Toxicology (1)

- Richard Albertini (U. Vermont) - Big name in genetic biomarkers. Participated in Butadiene study of Czech workers. Participant in initial review of China

protocols. Was not a strong participant. Will participate in 2nd review upcoming.

- Need a 2nd candidate to discuss in this category.

General Biochemistry (1)

- Jerry Rice (IARC) - Rice is the head of the group in IARC which develops the Monographs. He has agreed to review the protocols and to participate on the ongoing Panel. Having IARC participation is a very big score for the consortium. If we don't use him in this category, he should be added in a quasi regulatory slot. He is a keeper.
- David Eastmond (UC Riverside) - Some will consider him controversial. He has consulted for USEPA and Cal/EPA on benzene. He takes a conservative stance on risk issues. However, this gives him great credibility with these agencies. He has published extensively on benzene and the research is well done. Rob Schnatter thinks he would be an objective, fair reviewer.
- Donald Reed (Oregon State U.) - Former SOT president and Director of OSU Center in Environmental Toxicology (NIEHS funded). Reed is very well known and respected in mechanistic toxicology and metabolism. He has not published on benzene but would be a good general reviewer. He does not have the specific credibilities with regulatory agencies, but would make a good candidate if the other two are not available or interested.