DRAFT – May 11, 2001

Benzene Consortium Call
May 3, 2001

Participants:

Paula Podhasky
Lynn Russo (Exxon)
John Wagner
Otto Wong
Tom Armstrong
Lorraine Twerdok
Patsy Clegg (Shell)
Chris Raythorne (BP)
Stuart Cagen (Shell)
Patrick Beatty (Chevron)

Roll Call of Companies:

Company	Shares	Commitment level
Exxon	3	No decision yet (will follow-up with Carol Fairbrother)
BP	3	Positive outlook, hopefully a decision next week
Chevron	2	Yes, letter should be out next week
Shell	2	Yes, with conditions
Conoco	1	(Relayed by Patrick Beatty) Tentatively yes, no official letter yet
Phillips	1	Not likely to decide until the Tosco merger is complete
Marathon/Ashland	2	Not seen as very likely

Issues to Consortium Formation:

- Agency Involvement - EPA or other agency could "nominate" a member to review the protocols, or they could be invited to join the independent scientific review committee with representation either by a qualified agency scientist or by an outside scientist. For other issues, a "Stakeholder" Committee for agencies, labor , other NGOs, etc. may be formed.
- Critical Mass - Shell would like a "critical mass" of shares before proceeding. The suggestion was to have 15 shares or scale back the protocols to meet whatever lower funding is available.
  - The question was asked, when do we need to get 15 shares committed? No firm date was fixed, but it was stated that it should be sometime in the future to avoid scaling back now then trying to add back capabilities if and when additional funding partners are found. Action was for Patsy Clegg to identify the dollar amount approved for Shell participation since a maximum of 14 shares was anticipated.
  - Is there a potential for tiering the studies to address funding availability?
- Interim Funding – An estimated $100K in additional funding (split on a share basis among the interested companies) will be needed to cover 2 months (to the end of June) until the consortium actually forms or not.
- Potential Other Funding Sources

- Dow and Dupont may be approached - Dow originally said no
- Eastman
- Dupont
- Total/Final/Elf
- Equistar – showing some interest early on
- Leukemia Foundation funds $45M in research and may also be a candidate
- Robin Rorick of API has been investigating potential leads from searches on the internet. The results of those searches will be shared on the consortium web site soon.

Action Items:

- To continue funding for the University of Colorado staff for next 2 months (until the end of June)
- Companies should have a legal review of the proposed project name - "Benzene Health Research Consortium"

Review of Minutes from April 24 call:

- Concern with growing tensions over Taiwan (Communications Issue)
- Guarantee for the University of Colorado = contract on May 15th date
- $25K is anticipated to cover independent protocol reviews and no additional funds would be anticipated for any reviewers from governmental agencies; they usually perform these types of tasks as a part of their normal work duties – however, that may also delay their availability.

Next Call Monday, May 14th – 9:00am

SHELL QUESTIONS FOLLOW BOLDED TEXT AND ARE IN CAPS. APRIL 24, 2001

REPORT TO API

Results of Ethics Review of Protocols

April 24 Conference Call

This document serves to summarize the results of the ethics review process for both Dr. Wong's NHL-AML protocol and Dr. Irons's DP and ME studies. Although there are two major issues to be dealt with at a later stage (as indicated below), we feel that these three protocols now meet very high standards.

This document is organized by major issues and protocol responses:

benefits to the subjects and to the community– the combined projects will leave in Shanghai a state of the art clinical laboratory with trained staff ready to run it (there are **provisions for modest consultation after the projects are over).**
COST AND WHO IS RESPONSIBLE????

There are clear commitments from local officials that the data from the study will be used to strengthen as appropriate local standards for benzene exposure. So there will be considerable benefit to the community from the research. In the DP study, attending physicians will be identified at clinic visits and notified about clinically relevant findings. Patients found to have developed **BP**
What is BP?

will be followed to insure that they are removed, as per Chinese law, from the benzene exposure workplace. The ME protocol deals with the investigator working closely with the authorities on research identified worker protection issues. So the individual subjects will also benefit considerably from participation.

protection of confidentiality - the clinical database from the diagnostic laboratory, the research database for Dr. Wong's study, and the research database for Dr. Irons's studies will be kept separate. Data from the first will be transferred to the second or the third only after the subject consents to be in the relevant study. Only a limited number of individuals (specified in Dr. Irons's protocol) will have access to all databases, and the justification for their access is spelt out in the protocol. At the end of the studies, an additional database will be constructed containing the cell cultures, linked research data, and linked clinical data, but this database will contain no

identifiers. It will be a powerful tool for future research without any risks of breaches of confidentiality.

WHO WILL OWN THESE DATA BASES AND WHERE WILL THEY RESIDE???????????

avoiding exploitation and coercion of subjects- the schedule of payments for subjects was developed to minimize these types of ethical issues. We decided to put greater emphasis on not exploiting subjects by underpaying them rather than on offering them excessive inducements. Therefore, Dr. Wong will pay his subjects $30 for completing a questionnaire, the same amount he pays in the U.S. Dr. Irons has a complex payment schedule, reflecting different demands on different subjects; it takes into account US payment standards, but also is somewhat more generous with blood draw and bone marrow collection payments, to reflect Chinese practice of payments for blood donation

WHO WILL ISSUE THE CHECKS????? WHO IS THE PAYOR?????????????

control of publication of results- although there will be an opportunity for comments both by the sponsors and the scientific advisory board, the investigators have final control over all results to be presented or published.

informed consent- each study will have a series of consent forms, one for each type of subject in the study (e.g., Dr. Wong has one for the cases and the others for the controls; Dr Irons has many). The detailed consent forms will be developed by the investigators, in consultation with a Chinese bioethicist, to insure cultural sensitivity and appropriateness. **These forms will be reviewed by the ethics review group when they are finalized.**

questionnaire development- each of the studies requires asking the subjects questions about social history, exposures to other risk factors etc. Some of these questions may be very sensitive in that cultural setting. The detailed questionnaires will be developed by the investigators, in consultation with a Chinese bioethicist, to insure cultural sensitivity and appropriateness. **They will be reviewed by the ethics review group when they are finalized.**

Baruch A. Brody, Ph.D.