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Nancy Newkirk; Lorraine Twerdok; George Woodall
Subject: China Benzene - Public Relations Invitation

<<File: DABT Lorraine E Twerdok Ph D .vcf>>
To the China Benzene Risk Research Group:

One of the major items for discussion at the upcoming August 31 meeting for the China Benzene Research Consortium is how we will conduct the project in a manner that would be considered responsible from a bioethics perspective. Adequately addressing bioethics issues are not only critical to ensure confidentiality, informed consent and benefit to the study participants but also will positively affect the acceptance of the research findings and public opinion of the study and its sponsors. Because of this latter aspect it may be desirable for participating companies on the 31st to include attendance by a representative of their public relations/public affairs staff. We apologize for the tardiness in raising this issue but wanted to issue the invitation and make sure that participating companies understood that attendance of Public Relations or Public Affairs representatives is encouraged.

In the next few days premeeting materials addressing the bioethics issues will be sent out. Whether or not you will be attending the meeting on the 31st, we would like to encourage you to make sure that these materials are distributed to appropriate individuals in your companies.

Regards,
Lorraine Twerdok
Manager, Health Sciences

<<DABT Lorraine E Twerdok Ph D .vcf>>

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From: Paula Podhasky [podhaskyp@api.org]
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Subject: China Benzene Consortium
DATE: September 5, 2000
TO: Potential Members of the China Research Consortium

Once again, I would like to thank those of you who attended the second development meeting for the Benzene Research Consortium. I believe that the meeting was a very constructive step on the road to the actual formation of the consortium. I received useful input on a possible committee structure to manage the consortium and I think that we all have a better appreciation of the ethical issues that need to be woven into the scientific protocols. I was gratified by the willingness of several individuals to step forward and volunteer to form a committee to propose a funding formula for the consortium. I believe that we have a group that represents all major categories of potential members from the petrochemical industry.

From where we left off on Thursday we have three major issues for the path forward: development and acceptance of a funding formula; assurance that we have identified and addressed issues for the ethical conduct of the research; and continue progress on finalization of the research protocols.

The first issue is being addressed by the committee that formed on the 31st. The 2nd and 3rd issues, as we learned during discussions on Thursday, are tightly interwoven. Many ethical issues must be adequately addressed before the scientific protocols will pass the reviews by the University of Colorado IRB (Institutional Review Board) and the Chinese equivalent in Shanghai. This means that a core group of 2-3 bioethicists should be formed to assist the principal investigators in this area. Working with the bioethicists and the Chinese investigators, Drs. Wong and Irons need to finalize development of the protocols for the planned research. All of this and the necessary approvals must be in place prior to the initiation of any research activities.

Up to this point the API Benzene Task Force has funded feasibility studies and protocol development activities. These have included salary support for Dr. Irons, and his visiting research associate, Dr. Bao; support for Dr. Irons and Dr. Wong to present at the June 12 consortium development meeting; initial discussions with Dr. Fu and other Chinese collaborators; and the help of Dr. Brody to begin to identify the bioethical issues. The Benzene

Task Force is also funding Dr. Irons' travel to Shanghai in two weeks to assist in designing the space that Dr. Fu has reserved for the consortium laboratory.

To support further protocol development an initial sum of \$15,000 was requested from each company at the August 31 meeting to support further protocol development activities. Additional support is needed for development of the detailed scientific protocols for the proposed research (including some method development for tissue preparation and transport overseas), and for formation of the core bioethics group to assist in this protocol development activity. This bioethics group will also lay the groundwork for industrial hygiene monitoring activities that will be included in the epidemiological and clinical research plans. Travel to Shanghai is necessary to ensure adequate input from the Chinese scientists and to plan for administrative issues. Although not required for further participation in consortium activities, this \$15,000 sum is requested as an indicator of continuing interest in consortium development. More importantly, a significant number of companies contributing money to consortium development will be a powerful indication to the Chinese that we are sincere in our efforts and will ease any reluctance on their part to participate. This symbolic commitment may also increase the likelihood of participation by non-US companies.

We have asked that companies indicate their willingness to participate financially in protocol development activities by September 18 to Lorraine Twerdok of API.

Thank you for your past support. I believe that this research represents a quantum leap in our ability to generate credible scientific data that can make a significant change in how the health risks of benzene are assessed.

Shanghai Health Study

Benzene Health Research Consortium - Business Sponsors

Company	Oversight Committee	Business Sponsor	Business
Sponsor Contact Person			
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