

Shanghai Health Study

Issue: Consistent with standing Executive Committee guidance regarding proposed significant changes in the Shanghai Health Study (SHS), your concurrence is sought for the Benzene Health Research Consortium (BHRC) Oversight Committee's recommendations set forth herein.

Background: During its conference call of December 18, 2006, the API Executive Committee approved an increase in the funding for the Shanghai Health Study of \$9.1 million, to a total of \$35.2 million. This increase is contingent upon: the five participating companies committing to funding levels covering the increase; amending the study parameters to include an enhanced Quality Assurance program, and tying study payments to metrics of progress towards study completion.

Since the study's inception, the University of Colorado's Health Sciences Center has been the primary research organization, and has been funded via a grant. The University of Colorado has had a sub-agreement with Fudan University in Shanghai for the use of laboratory space and personnel. Due to a shift in the lab management within Fudan University, it is necessary to execute a new agreement for the continued operation of the lab. The participating companies have now learned that, at some point in early April, there will be a critical gap in the funding of the lab for expenses such as salaries. If this funding gap is not addressed, we are told the lab might be shut down and the completion of the study jeopardized.

Dr. Richard Irons, the University of Colorado's representative and a co-principal investigator of the study, has proposed that a significant portion of the remainder of the study be completed through Cinpathogen, Inc., a US for-profit corporation established for this purpose, of which Dr. Irons and another investigator are the two principal directors. Dr. Irons has indicated that Fudan University is in favor of this new arrangement, and that he has entered into formal agreements through Cinpathogen with Fudan University to coordinate and manage the laboratory to complete the Shanghai Health Study. API is awaiting documentation from Dr. Irons. Separately, Cinpathogen and the University of Colorado have stated in a joint letter that they will cooperate to manage the research going forward and finalize the study. This approach is designed to ensure the current operation of the laboratory and its continued existence after completion of the study (one of the tangential benefits that the participating companies are hoping to achieve). Publications from the supported research would reference all institutions involved in the study.

API has yet to receive a formal, final proposal from either Cinpathogen or the University of Colorado for the completion of the study. Nonetheless, the participating companies have recommended that API work as expeditiously as possible toward executing a contract with Cinpathogen and executing an amended grant with the University of Colorado to complete the Shanghai Health Study. This recommendation recognizes