

that appropriate supporting agreements, including those between API and the five participating companies to increase the funding, would need to be executed as well.

Also, the participating companies have recommended that the API Executive Committee approve up to a \$2 million advance from API to Cinpathogen for the operation of the laboratory through June, 2007, prior to final contracts being executed. The Oversight Committee believes that this is a compelling, time sensitive situation due to the laboratory funding issues in Shanghai, and that immediate attention is required. Without this advance, Dr. Irons informed API that the lab will be closed or the study interrupted. Additional payments would be provided subsequently under contract to keep the study sufficiently funded, consistent with the approved budget and commitments from the participating companies.

Given time pressures in the study, concurrence of the API Executive Committee is sought at this time for proceeding down this new funding path, contracting with both the for-profit corporation, Cinpathogen, and the University of Colorado, rather than exclusively through the University. Contracting with Cinpathogen to complete the study may raise questions about the appropriateness of a for-profit entity replacing much of the University of Colorado effort in the conduct of such health research. Further, the addition of a newly formed, for-profit entity to the research effort would be administratively more complex than simply extending the existing contractual arrangement with the University of Colorado. However, Dr. Irons has informed us that this new administrative arrangement is supported by Fudan University and necessary under the current situation. While a new for-profit company will now become involved, there will be no change in personnel, and there are already for-profit entities involved in other parts of the study. Considering the options, the participating companies have recommended proceeding to engage Cinpathogen to help complete this study.

Action Requested

Your concurrence in the BHRC Oversight Committee's recommendations, as follows:

1. Approval for API to contract with the for-profit corporation, Cinpathogen, to complete a substantial portion of the remainder of this study. The Cinpathogen contract would be executed once fully developed proposals from the investigators and recommendations from the participating companies regarding those proposals are all received and once the participating companies have committed to funding the study.
2. Approval for API to advance up to \$2 million to Cinpathogen for the operation of the laboratory through June, 2007, prior to final contracts being executed, so long as this funding is consistent with the approved budget and commitments from the participating companies.

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