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Sent: Tuesday, May 6, 2003 6:21 PM (GMT)
To: Paula Podhasky <Podhaskyp@api.org>
Subject: benzene
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PROGRESS REPORT
JUNE 2002

**I. ANALYSIS OF DISEASE PROGRESSION FOR APLASTIC ANEMIA,
MYELO-DYSPLASTIC SYNDROME, ACUTE MYELOGENOUS LEUKEMIA
AND BENZENE POISONING IN SHANGHAI, CHINA**

**II. MOLECULAR EPIDEMIOLOGY OF BENZENE-EXPOSED WORKERS IN
SHANGHAI, CHINA**

A MULTICENTER INTERNATIONAL STUDY

**Molecular Toxicology and Environmental Health Sciences Program
Dept. of Pharmaceutical Sciences, School of Pharmacy
Department of Pathology, School of Medicine
University of Colorado Health Sciences Center, Denver, CO.**

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**School of Public Health, Hua Shan Hospital, Cancer Hospital,
Fudan University Medical Center, Shanghai, China**

I Introduction

A Executive summary

1. Overall Status of the Budget

NOTE: this is the Semiannual Report of Progress as it Relates to the Budget set forth in our contract and is separate and distinct from the University of Colorado Health Sciences Report of Expenditures and Financial Statement, the Quarterly Report on Field Expenses and the Supplemental Summary Requested by API and the Technical Committee, each of which will be forwarded separately. Unless otherwise stated, actual budget numbers are "as of" May 30, 2002.

The overall status of the budget for this fiscal year is as follows: As of May 30, 2002 we have received \$4,099,505 against a current approved budget of \$4,870,330 exclusive of field expenses. We have expended \$1,566,248 as of May 30. At the end of this fiscal year (August 31, 2002) we estimate total expenditures, both encumbered and projected, to be \$3,061,859. This will leave a balance of \$1,808,471 that includes \$1,041,238 in sequestered funds originally earmarked for subject and clinical costs in Year 1.

We have been able to maintain an overall positive cash flow in the face of the budgetary shortfall described above that is due to several factors: salary and supply savings achieved as a result of delays in project funding and start-up, exercise of extended budgetary authority and cost shifting in multiple categories, successes in the negotiation of equipment and reagent contracts, and deferral of the payment of incremental increases in EMBSI expenses as part of the revised budget. Because of the delay in project funding, many of the hires and non-capital equipment and reagent purchases scheduled for Fiscal Year 1 (FY1) are being expensed in the last half of the fiscal year. As a result, most of the expenditures estimated for the second half of FY1 are actually encumbered at this time. The progress and budgetary status of each project component will be discussed in subsequent chapters.

B FY2 Costs and Cash flow

1. Projected

Based on the original contract, we will receive \$3,416,254 in FY2 against a currently approved budget of \$3,284,446. We estimate actual expenses for FY2 to be \$4,009,037. The projected differences here are primarily the result of expenses deferred from FY1 as a result of the delay in funding, and include charges against training, equipment, database and personnel. By the end of FY2 we estimate the cumulative deficit will be \$592,783. In terms of cash flow (not balances) this is more than offset by the subject-related costs sequestered in FY1. It should be noted that the actual subject-related expenses encountered in FY2 and beyond will depend on the number of cases recruited to the studies: the more cases recruited, the less the balance we will

have on hand. Whether in fact we are able to maintain a positive cash flow in FY2 will depend on subject recruitment. However, it is also obvious that funds originally budgeted to cover subject-related costs that are expensed to cover cash shortfalls will necessarily have to be replaced, probably in early FY3.

C Budgetary and contractual issues

1. UCHSC contract

At present we have committed to equipment and supply purchases and payment schedules to Chinese entities that reflect the budget approved by the Consortium in December 01/January 02. This is being achieved by modifications that reflect realized salary savings and cost shifting at the expense of personnel and operating budgets as discussed in this document. To date, API has not provided UCHSC with any letter of intent or contract addenda to reflect the modified budget changes. In the absence of this, UCHSC will consider the project in default the moment we encounter a negative cash balance. Therefore, under our current contractual arrangements we will not be able to bridge any negative cash balance even for a short period of time. Alternatively, if we are provided a contract modified to reflect the current budget, short term bridging is possible. It is impossible to accurately estimate the timing of these impacts in the absence of being able to predict actual subject accrual rates, but our best estimates suggest a crisis is possible in the latter half of FY2/first half of FY3. Independently, even given a positive cash balance during FY2 we will not be able to modify our payments to EMBSI to reflect their increased costs without a contract addendum.

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still true -
yes

2. Fudan API contract

It appears that API does not yet have a contract with Fudan University to support Case Control Study operation. As a consequence, Fudan has been charging all Project-related expenses, including Case Control Study expenses, against the UCHSC account. To date the impact has been minimal (i.e. we estimate approximately \$14,000 of expenses that should be borne by the Case Control Study will be charged against UCHSC during FY1). In order to facilitate project development and for humanitarian reasons we will continue to support personnel assigned to the Case Control Study. However, this issue is becoming an ongoing management problem with almost daily requests to authorize expenditures that relate to Case Control Study activities. The additional costs for the management of this activity have not yet been built into our budget, and we estimate that these will escalate significantly in FY2. It is our understanding that this practice will continue unless or until API has finalized a contract and funded an account at Fudan University or decides to expense these funds through UCHSC.

II Equipment