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Center for Interdisciplinary Research in Immunology and Disease (CIRID)

October 17, 2002

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Steven Peckman Associate Director-Human Subjects Research Office for Protection of Research Subjects 2107 PVUB MC 169407

Dear Mr. Peckman,

This is written as a response to your letter of October 8, 2002 concerning "Complaint About Human Research Collaboration on Malariotherapy".

- Item 1) I am <u>not</u> acknowledged as a co-author of "three scientific articles" and have <u>no</u> knowledge of being cited on any manuscripts, articles or abstracts "[that] have been submitted to international AIDS conferences describing research" related to malariotherapy in collaboration with Dr. Henry Heimlich.
- Item 2) I have <u>not</u> been "working in conjunction" with the Heimlich Institute.
- Item 3) I did <u>not</u> receive human biological samples from this project. When Dr. Xiao Ping Chen, the Principal Investigator for the project in China, came to UCLA for the Fogarty International AIDS Training and Research Program (AITRP) (5-T22 TW00003) in 1997, he brought serum samples obtained during a malarial study conducted in China before any contact with UCLA. Dr. X.P. Chen performed several immunological tests on his samples and took his remaining samples back to China when he returned.

Contrary to Dr. Heimlich's statement, we did <u>not</u> (and do <u>not</u>) measure "the actual virus".

- Dr. X.P. Chen was trained to do ELISA tests for neopterin, β_2 m, sTNF RII and IL-2. HIV p24 antigen measurements were demonstrated by Dr. Pari and Hripi Nishanian. The UCLA Fogarty AITRP did provide reagents for testing of Dr. X.P. Chen's samples at UCLA as a part of the immunology laboratory training.
- a) I am <u>not</u> acknowledged in scientific presentation, papers or articles for the work Dr. Heimlich refers to in the interview.
- Item 4) Dr. Xiao Ping Chen was a Visiting Scholar at UCLA from 03/24/97 to 05/31/97, receiving training in AIDS research under an existing Fogarty AIDS International Training and Research Program (AITRP) at UCLA. In addition to AIDS epidemiology,

pathogenesis and clinical design classes, Dr. X.P. Chen was particularly interested in learning the immunologic methods used in AIDS research.

- We did <u>not</u> "carry out independent verification of the immunological results obtained in China".
- "Technical support" included instruction in immunologic laboratory methods, and reagents for practice testing and quality control.
- I had <u>no</u> contact with patients and could <u>not</u> have reported that patients' treatments were progressing extremely well.
- The "nature of the work" at UCLA was training in immunologic laboratory methods, clinical trial design, ethics of patient recruitment and information, necessity to have approval of all applicable Institutional Review Boards before undertaking a clinical research project, and quality control and quality assurance procedures. Similar training was provided to all Chinese Fogarty AITRP trainees who came to UCLA and contact was maintained with them during the two years following return to China. We did supply reagents for setting up quality control procedures for immunologic testing in Guangzhou.
- Item 5) I did <u>not</u> collaborate in the pilot malariotherapy research as indicated in the article. Dr. Heimlich's account mixes two research studies they did—one of which (1994) used a poor method to measure CD4 T cell levels. Thus, the claimed changes in CD4 T cell levels are not reliable. I did offer training in immunologic laboratory methodologies to Dr. X.P. Chen in 1997.
 - a) I did <u>not</u> participate in fundraising for the Heimlich Institute's malariotherapy research.
 - b) I did <u>not</u> ask to join the Heimlich Institute research project in 1996. I did offer training in research on AIDS, mainly immunologic laboratory methodology, to the Chinese scientists of the Center for AIDS Control and Research, Municipal Health and Anti-Epidemic Station of Guangzhou, Guangzhou, People's Republic of China. Similar training was conducted for other Chinese scientists from other research institutions in China.
 - c) If the deleted names refer to visits by John L. Fahey to the Municipal Health and Anti-Epidemic Station of Guangzhou, I can say that I was obtaining information on the value of the training program provided by the Fogarty AITRP at UCLA. There was no "independent corroboration" of the results.
 - i) I and individuals from my laboratory did <u>not</u> "make regular trips to the research site in Guangzhou to provide independent evaluation of the quality of the research" or provide "independent corroboration of results". I did make trips to China in 1998 and 1999 to visit seven Chinese trainees in their home institutions as a normal follow-up to the International AIDS Research Training acquired at UCLA. Guangzhou was included.
 - ii) There was <u>no</u> activity in any capacity resulting in co-authorship on scientific articles, papers or presentations.

- Item 6) I did not provide financial support for the referenced research. We did supply kits for establishing immunology laboratory capacities and for establishing quality control procedures.
 - a & b) Funding was from the Fogarty training grant 5-T22-TW00003 for supplies which are allowed by Fogarty International Center policy to be sent for continued in-country training. UCLA funds were not provided for the research.
- Item 7) I did not assist in the research design of the clinical trial "Impact of Acute Vivax Malaria" beyond the feedback provided to all international scholars for the hypothetical research project description they are required to prepare during the training period at UCLA.
 - We did donate reagents for flow cytometry and cytokine quality control a) measurements as part of the in-country training. My colleagues and I performed no laboratory tests for this research.
- Item 8) I did not receive any research materials from subjects in malariotherapy research. The samples from a prior study that were independently brought by Dr. X.P. Chen to UCLA and tested by Dr. X.P. Chen were identified only by serial numbers (1, 2, 3, etc.) and could not be linked back to the subjects.

Item 9) None.

- Item 10) I did not visit China in order to provide services, information or guidance related to malariotherapy research. My two follow-up training visits to Dr. X.P. Chen and other Fogarty International trainees elsewhere in China were funded by a Fogarty grant 5-T22-TW00003. Dr. Najib Aziz's visit in 1999, for Immunology laboratory personnel training related to AIDS research, was in response to an invitation and was paid for by the Municipal Health and Anti-Epidemic Station, Guangzhou.
- Item 11) Dr. Xiao Ping Chen was appointed as a Visiting Scholar, not as a postdoctoral student or an employee. He was one of eight international AITRP scholars at UCLA, who trained in my laboratory for two months in 1997.
 - He was at UCLA 03/24/97 to 05/31/97.
 - He did not work with the Heimlich Institute while under my supervision. Dr. X.P. Chen included Chinese serum samples from a prior malariotherapy study in the laboratory training exercises at UCLA.
 - c) See 11b above.

L. Jakey John Z. Fahey, MD