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March 20, 2003

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, MD 20852

Re: Boston University Medical Center
FWA No. 00000301

Research Publication: Barnett EB, Levatin JL, Chapman EH, Floyd LA, Eisenberg D, Kaptchuk TJ, Klein JO. Challenges of evaluating homeopathic treatment of acute otitis media. *Pediatr Infect Dis J.* 2000; 19:273-5.

Dear Dr. Borrer:

I am writing in response to your letter dated February 13, 2003, regarding allegations of noncompliance that the Office for Human Research Protections received about the above mentioned research publication. We understand that these allegations were made to you in the form of the anonymous letter that you included with your letter.

David Eisenberg, MD, a staff member of Beth Israel Deaconess Hospital was the principal investigator of this study, and thus the study was submitted to and approved by the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center, his institution. Boston University's involvement in this matter stems from the fact that Elizabeth Barnett, MD and Jerome Klein, MD (co-investigators in the study and co-authors on the published paper) are faculty members at Boston University School of Medicine. Our Institutional Review Board was not involved in the review and approval of this study.

Drs. Barnett and Klein participated with their colleagues at Beth Israel Deaconess in preparing the response to your letter (submitted by Dr. Lisbon, attached). I concur with the findings as detailed in Dr. Lisbon's letter.

I wish to address one point in the allegation that relates directly to the Boston University Medical Center IRB. The published article states that this study "was approved by the Human Studies Committee at Boston Medical Center." This statement is an error. The Beth Israel Deaconess Committee on Clinical Investigations was the only IRB that reviewed this study. The protocol was not submitted to the IRB at Boston University Medical Center based on the December, 1996 understanding of Drs. Klein and Barnett that their roles in the study did not meet the definition of "engaged in research": namely, they did not interact with any research subjects. Thus they thought that the Beth Israel

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approval was all that was needed. However, based on the OHRP guidelines for Engagement in Research published on January 26, 1999, Drs. Klein and Barnett have agreed that in the future they will submit such studies to the IRB at Boston University Medical Center because, as your guideline clarifies, they were obtaining individually identifiable private information for research purposes.

In summary, we have worked closely with our colleagues at the Beth Israel Deaconess Medical Center Committee on Clinical Investigation to assess this situation and are in support of their findings.

Sincerely,

A handwritten signature in black ink, appearing to read "Aram Chobanian". The signature is fluid and cursive, with a long horizontal stroke at the end.

Aram Chobanian, MD
Institutional Official, Boston University Medical Center Institutional Review Board
Provost, Boston University Medical Campus