

Food and Drug Administration
Center for Biologics Evaluation and
Research
1401 Rockville Pike
Rockville MD 20852-1448

By Certified Mail - Return Receipt Requested

Henry J. Heimlich, M.D., Sc.D. President
The Heimlich Institute
311 Straight Street
Cincinnati, Ohio 45219

JUN - 8 2000

Dear Dr. Heimlich:

This letter will not discuss the scientific merits of the referenced study. FDA did not conduct a complete review of the research project; rather, we assessed how the IRB evaluated proposed research. In the case of this study, among other matters, the FDA's letter noted that the IRB did not distinguish that the proposed research fell outside its jurisdiction.

As part of an IRB's responsibility to protect the rights and welfare of the human subjects involved in research, it must have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. A U.S. IRB does not have the authority to suspend or terminate studies in other countries because human subject protection is the responsibility of the country where the research is conducted.

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Your letter to Dr. Henney states that the research is conducted under the oversight of the appropriate regulatory authorities in the ______ That is the appropriate authority for oversight of such foreign research, not a United States based IRB.

We hope this information is helpful.

Sincerely,

Colóteven A. Masiello

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation

and Research

cc: Great Lakes College of Clinical Medicine

122 Thurman Street Post Office Box 248 Bluffton, Ohio 45817