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April 25, 2000

L. Terry Chappell, M.D.
Secretary
Great Lakes College of Clinical Medicine
Institutional Review Board
122 Thurman Street
Bluffton, OH 45817

Dear Dr. Chappell,

In response to your letter of April 19, 2000 regarding GLCCM IRB and its approval of our project "Heimlich Maneuver for Asthma," the following has been done:

1. Enrollment in this project has been suspended until the FDA has lifted your restrictions.

2. We spoke to Barry Poole, Supervisor of Consumer Safety, of the FDA's Drug Information Center on April 25, 2000. He has advised us that we do not need an IDE or an IND for the asthma project since it does not involve a drug or a device. Furthermore, he was of the opinion that this project would not be under FDA jurisdiction because it is not a drug or a device. We have asked for a letter confirming this and will forward a copy of this when we receive it.

3. Attached is a copy of the latest consent form. If this is inadequate, please let us know so that we can make the appropriate changes.

4. We have not solicited enrollment into this project through advertisement or announcement. This project is described briefly on our web site (www.heimlichinstitute.org); however, no mention is made of GLCCM IRB approval. Attached is a copy of the pertinent material from the web site.

Again, please note that this project is most likely not under FDA jurisdiction; consequently, it would seem that the GLCCM IRB would not be bound by FDA strictures in this particular case.

Sincerely,

Henry J. Heimlich, M.D., Sc.D.
President

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