

GREAT LAKES COLLEGE OF CLINICAL MEDICINE

Institutional Review Board

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October 26, 2000

**Ms. Patricia Holobaugh, (HFM-650)
Division of Inspections and Surveillance
Food And Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448**

Dear Ms. Holobaugh:

This letter is to update you on the GLCCM IRB. Jack Hank is no longer our Executive Director, so I am writing you directly. For reasons that we do not fully understand, we have not been able to satisfy your many requests for changes, despite our best efforts. From the comments we have heard and received, we believe that you are trying to shut us down.

If we are correct, we are greatly disappointed because we feel we are providing an important service that no other IRB offers. We are also disappointed that the FDA is no longer as supportive and helpful to IRB's as they were prior to the last year or so.

We believe that our only chance to satisfy you is to form a partnership with a prestigious organization. We are trying to accomplish this. If we are unsuccessful, we will read your handwriting on the wall and shut down operations.

Sincerely,



L. Terry Chappell, M.D.

Secretary

LTC/bra