DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

By Certified Mail - Return Receipt Requested

JAN - 2 2001

Barbara Grunewald, Executive Director
Great Lakes College of Clinical Medicine
30275 West Thirteen Mile Road
Farmington, Michigan 48334

Dear Ms. Grunewald:

This letter is in reply to the Great Lakes College of Clinical Medicine (GLCCM) Institutional Review Board's (IRB's) letter dated October 26, 2000, from Dr. L. Terry Chappell, IRB Secretary. This letter is addressed to you because the GLCCM Internet web site indicates that you now represent the parent institution that is responsible for the operation of the GLCCM IRB.

In a Warning Letter dated March 9, 2000, the Food and Drug Administration (FDA) provided Dr. Chappell with written notification of violations of FDA regulations noted during an inspection of the GLCCM IRB, and immediately imposed restrictions on the operations of the IRB in accordance with 21 CFR 56.120(b)(1) and (2), namely ***no new studies*** *that are subject to Parts 50 and 56 of the FDA regulations were to be approved by your IRB, and* ***no new subjects*** *were to be admitted to ongoing studies that are subject to 21 CFR Parts 50 and 56.*

The IRB provided a written response dated March 22, 2000. FDA determined that the response was inadequate and incomplete, as described in the FDA letter to Dr. Chappell dated April 13, 2000. The IRB provided a written response dated May 26, 2000, which was also determined by FDA to be inadequate and incomplete, as described in the FDA letter dated July 21, 2000, (copy enclosed) addressed to Mr. Jack Hank, GLCCM Executive Director. Mr. Hank's written response dated August 11, 2000, provided some of the requested information, but was determined to be inadequate and incomplete, as described in the FDA letter dated September 5, 2000 (copy enclosed). In a letter dated October 26, 2000, Dr. Chappell reported that Mr. Hank is no longer the Executive Director of the GLCCM.

The FDA letter dated September 5, 2000, summarizes the information requested in the earlier letters. The IRB has not provided a substantive response to the letter dated September 5, 2000, or to the FDA comments about the IRB's written procedures as described in the FDA letter dated April 13, 2000, and July 21, 2000.

Based on the deficiencies described in the FDA's letters dated April 13, 2000, July 21, 2000, and September 5, 2000, and the IRB's inadequate responses dated March 22, 2000, May 26, 2000, August 11, 2000, and October 26, 2000, we have no assurance that the IRB is adequately protecting the rights and welfare of the human subjects of research. *For this reason, in accordance with Title 21, Code of Federal Regulations, § 56.120(b)(3), and effective immediately, the following studies are* ***terminated:***

M029 -- Roy Page, M.D. and George Kindness, M.D. — "Adjuvant Immune Therapy in the Treatment of Solid Tumors Through Modulation of Signaling Pathways Following Engagement of Humoral and Cell Mediated Responses."

M026 — W. A. Shrader, M.D. — "Evaluation of the Effect of the Immunotherapeutic Technique Enzyme Potentiated Desensitization (EPD) for a Considerable Variety of Illness/Conditions/Diagnostic Conditions."

S055 — William Kubitschek, D.O. and Gerlinde Moll — "Treatment of Sports Injuries with IBS Inductive Bio-Stimulation Therapy."

S060 — Alfredo Lopez del Castillo, M.D. — "Reconstructive Therapy for Intractable Low Back Pain."

S056 — Jack Hinkle, D.O. — "Chelation Therapy for Removal of Heavy Metals (Specifically Mercury) after DMPS Injection."

M021 — L. Terry Chappell, M.D. — "EDTA Chelation & Coronary Artery Disease Patient Registry."

S068 — D. Musnick, M.D. and D. Klinghardt, M.D. — "Low Level Laser for Treatment of Acute and Chronic Muscular-Skeletal Pain and Neurologic Symptoms."

These studies are terminated for the following reasons: (1) The IRB has determined that an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE) is required (studies M029 and M026), as described in the GLCCM letter dated August 11, 2000. No INDs or IDEs have been submitted for these studies. (2) The IRB could not determine whether an IND or IDE is required (studies S055, S060, S056, and M021), as described in the GLCCM letter dated August 11, 2000. (3) There is insufficient information for FDA to assess whether an IDE is required (S068).

Clinical investigators for these studies are required to continue monitoring study subjects for adverse events, but must immediately cease administration of investigational drugs and use of investigational medical devices by human subjects pending review and approval by another IRB.

Within fifteen (15) business days of receipt of this letter, please submit the following documentation for the studies listed on page 2, above:

1. A copy of the written notification of study termination from the IRB to each clinical investigator. The notification must include the instruction that each clinical investigator must immediately notify, in writing, all subinvestigators who participated in the study at any time. Please submit a copy of the personalized letter sent to each clinical investigator -- an incomplete or form letter is not acceptable. We will accept copies of facsimile transmissions.

2. A copy of each clinical investigator's written acknowledgment to the GLCCM IRB that the study is terminated. We will accept copies of facsimile transmissions.

3. A copy of each clinical investigator's written notification of study termination to all subinvestigators who participated in the study at any time, as described in item one (1), above. Please submit a copy of the personalized letter sent to each subinvestigator -- an incomplete or form letter is not acceptable. We will accept copies of facsimile transmissions.

4. A copy of the protocol for each study.

5. A copy of the most recent consent form approved by the IRB.

6. Please submit the letters from the following clinical investigators notifying the IRB that the following studies are inactive, completed, or are now under review by a different IRB, as described in the GLCCM letter dated August 11, 2000:

   S069 — Constantine Kotsanis, M.D. — "Intravenous Secretin to Effect Positive Behavior Changes in Autistic Individuals" — described as "completed."

   S084 — Warren Levin, M.D. — "Effects of Growth Hormone (GH) or Growth Hormone Releasing Hormone (GRF) on Age-Related Insulin Resistance, Pulmonary Function and Quality of Life" — described as "moved to another IRB due to FDA hold."

   S004 — William Mauer, D.O. -- "Phototherapy as a Modality in the Stimulation of the Immune System" — described as "terminated due to a lack of response."

S049 — Lawrence Porter, M.D. — "Chelation Therapy for Arteriosclerotic Disease (Using GLCCM Protocol)" — described as "terminated due to a lack of response."

S081 — Paula Bickle, Ph.D. — "A Protocol for Studying Mobilization of Mercury by Giving DMPS Orally to Humans" — described as "terminated due to a lack of response."

S082 — George Kindness, M.D. & Timothy Guilford, M.D. — "Use of EDTA (Extreme Dilution) Therapy for Allergy" — described as "inactivated due to FDA restrictions."

M023 — Kent Pomeroy, M.D. — "Pain Allieviation & Joint Function Improvement by Prolotherapy" — described as "inactivated due to FDA restrictions."

M010 — Bill Westendorf, D.D.S. — "Amalgam Removal and Mercury Detox" — described as "inactivated due to FDA restrictions."

M064 — Steven Ayre, M.D. — "Insulin Potentiation Therapy" — described as "inactivated due to FDA restrictions."

S077 — Gary Moore, M.D. — "Ca-EAP Therapy as an Adjunct in the Therapy of Patients with Multiple Sclerosis" — described as "inactivated due to FDA restrictions."

Studies S075, S058, and S076 may continue uninterrupted, at your option, because they do not involve products under FDA jurisdiction.

The information requested in items one (1) through six (6), above will not constitute a full response to all unresolved issues, but must be promptly submitted for FDA review to determine whether the rights and welfare of the human subjects in those clinical investigations are being protected. We will review the information submitted in response to items one (1) through six (6) and determine whether any study may be resumed. If we determine that a study does not fall within FDA jurisdiction, then we will notify you that the study may resume at your option.

In addition, the IRB has failed to respond to the IRB deficiencies described in FDA's letter dated July 21, 2000. Your failure to adequately respond to the letter dated July 21, 2000, and to this letter may result in further administrative actions against your IRB, as authorized by 21 CFR 56.120 and 56.121. These actions include, but are not limited to, the initiation of regulatory proceedings for disqualification of your IRB.

Your written response should be addressed to:

Ms. Patricia Holobaugh (HFM-664)
Division of Inspections and Surveillance
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
Telephone: (301) 827-6347

Sincerely,

Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosures
FDA letter dated July 21, 2000
FDA letter dated September 21, 2000

cc: Albert J. Scarchilli, D.O., President
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