HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
DIANA DEGETTE, COLORADO
VICE CHAIRMAN
LOIS CAPPS, CALIFORNIA
MIKE DOYLE, PENNSYLVANIA
JANE HARMAN, CALIFORNIA
TOM ALLEN, MAINE
JAN SCHAKOWSKY, ILLINOIS
HILDA L. SOLIS, CALIFORNIA
CHARLES A. GONZALEZ, TEXAS
JAY INSLEE, WASHINGTON
TAMMY BALDWIN, WISCONSIN
MIKE ROSS, ARKANSAS
DARLENE HOOLEY, OREGON
ANTHONY D. WEINER, NEW YORK
JIM MATHESON, UTAH
G.K. BUTTERFIELD, NORTH CAROLINA
CHARLIE MELANCON, LOUISIANA
JOHN BARROW, GEORGIA
BARON P. HILL, INDIANA

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER
RALPH M. HALL, TEXAS
J. DENNIS HASTERT, ILLINOIS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
NATHAN DEAL, GEORGIA
ED WHITFIELD, KENTUCKY
BARBARA CUBIN, WYOMING
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
STEVE BUYER, INDIANA
GEORGE RADANOVICH, CALIFORNIA
JOSEPH R. PITTS, PENNSYLVANIA
MARY BONO, CALIFORNIA
GREG WALDEN, OREGON
LEE TERRY, NEBRASKA
MIKE FERGUSON, NEW JERSEY
MIKE ROGERS, MICHIGAN
SUE MYRICK, NORTH CAROLINA
JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

December 13, 2007

Ms. M. Joyce Heinrich
Texas Applied Biomedical Services
12101 Cullen Blvd., Suite A
Houston, Texas 77047

Mr. Fred Fox
Chairman
Biomedical Research Institute of America
2525 Camino Del Rio South, Suite 300
San Diego, CA 92108

Dear Ms. Heinrich and Mr. Fox:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the ability of Institutional Review Boards (IRBs) to protect human subjects in biomedical research.

In particular, we are interested in the potential misuse of IRB approval to market questionable medical devices such as the Pap-Ion Magnetic Inductor (PAP-IMI). This misuse of IRB approval in marketing materials may provide consumers with a false sense of security by implying that the devices meet the U.S. Food and Drug Administration's safety and efficacy standards.

It is our understanding that Panos Pappas and Charles "Chuck" Wallach, the inventors and marketers of the PAP-IMI device, applied for and received IRB approval for clinical trials involving the PAP-IMI device from both the Biomedical Research Institute of America, as well as Texas Applied Biomedical Services.

Therefore, we ask that you provide the following:

1. All records relating to the PAP-IMI machine, specifically the initial application for IRB approval, and any communications between your IRBs and any persons responsible for the IRB application;

2. All records relating to Panos Pappas, manufacturer of the PAP-IMI device; and

3. All records relating to Charles "Chuck" Wallach, a marketer of the PAP-IMI device.

We also ask that you provide written responses to the following questions from the Committee:

1. Who are the members of your IRB? Please provide a list of all members and their professional qualifications.

2. Are you registered with the U.S. Department of Health and Human Services Office of Human Research Protections? If so, please provide your Federal-Wide Assurance number. If not, please explain why not.

3. Is your IRB's approval of a clinical trial for the PAP-IMI device still in effect? If not, please explain why your IRB's approval was withdrawn.

Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with study investigators.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact Paul Jung of the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.