J. Sapko
P. Jung
RHOB

BioMed•IRB

December 21, 2007

John D. Dingell, Michigan
Chairman
Paul Jung, Committee Staff
U.S. House on Representatives
Committee on Energy and Commerce
Washington DC 20515-6115

Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
on the Committee on Energy and Commerce
Room 316
Ford House Office Building

In response to your request from your correspondence faxed December 13, 2007, attached please find the documents requested of BioMed IRB with regard to your investigation of the Pap-Ion Inductor (PAP-IMI) device study.

The documents that are extant are in the form of submittals from proposed investigators as well as reports from investigators who sought continual approval but were either disapproved or terminated from the study.

All submittals to the IRB have been scanned and included on the enclosed computer disk as per a conversation with Mr. Jung, on your staff; we believe this to comply even though you had requested hard copy by mail. Please note that in accordance with FDA regulations, the information retained by the IRB relating to a clinical trial is only required to be retained for three (3) years post study closure and that limited information relating to the protocol in question is retained in our records.

There were confidential whistleblower conversations with the IRB chairman for which no paper records have ever been created. Follow up testimony to your staff during your ongoing investigation can address this topic further. Conversations, for which no written records are extant, together with internal working documents of the IRB staff or its citizen volunteers in the oversight of clinical studies, are disclosures under appropriate safeguards for the public interest and will be the subject of further discussions to be coordinated with FDA representation.

BioMed formally submits the following written responses additionally requested on your correspondence.

1. BioMed does retain records of its IRB Committee Members. I have included the BioMed IRB Membership Rosters from the date of the initial approval in May 2001 through the termination date of the study.

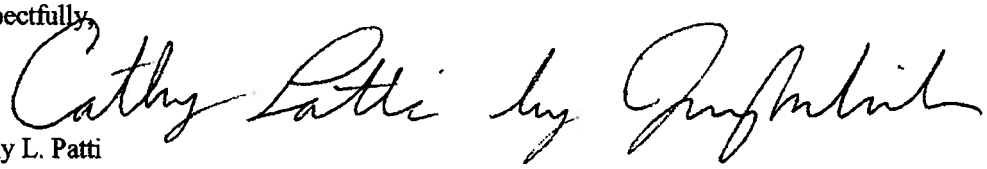
2. BioMed IRB does maintain a registration number with Office of Human Research Protection (OHRP). The number is 00000773 and all associated information relating to our organization can be located by searching our institution name on the OHRP website site http://ohrp.cit.nih.gov/search/irbdtl.asp?IRBID=727). Your question is phrased as if you are seeking and Assurance Number filed by the IRB. The IRB registration number is recorded on a Federalwide Assurance (FWA) application being filed by the individual or entity applying for a grant. So far as known to BioMed IRB, none of the purported research for the PAP IMI was federally funded while under oversight consideration here.

3. The approval for this study is no longer in effect. BioMed IRB terminated this study in June 2002 and reported the findings to the FDA in accordance with applicable regulations.

I have also included an invoice for the research time as Mr. Jung was not aware of whom BioMed should bill directly.

Should you have further questions or require additional information, please contact our offices. Thank you.

Respectfully,



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