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ONE HUNDRED TENTH CONGRESS

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

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CHAIRMAN

December 13, 2007

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The Honorable Andrew von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

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 Electro Physiological Feedback Xrroid (EPFX) biofeedback device, and 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.

Therefore, we ask that you provide the following:

1. All records relating to the EPFX biofeedback device;
2. All records relating to William Nelson, the manufacturer of the EPFX;
3. All records relating to Ecllosion, the company that markets the EPFX;
4. All records relating to the PAP-IMI machine;
5. All records relating to Panos Pappas, manufacturer of the PAP-IMI; and
6. All records relating to Charles "Chuck" Wallach, a marketer of the PAP-IMI.

The Honorable Andrew von Eschenbach, M.D.
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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 Ed Whitfield, 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.