ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

February 11, 2008

Mr. Fred Hassan
Chairman and CEO
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Mr. Richard T. Clark
Chairman, President, and CEO
Merck & Co., Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889

Dear Mr. Hassan and Mr. Clark:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the withholding of clinical trial data in the ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) trial.

We appreciate your partial responses to our initial queries. Your responses, however, have raised further questions. For example, the timeline released by Merck and Schering-Plough (M/SP) indicates that Schering-Plough biostatisticians began "conducting routine data quality reviews of the initial blinded ENHANCE data" in "Summer through end of 2005." In addition, it is not clear whether the protocol or statistical analysis plan (SAP) for ENHANCE was ever modified, or whether the U.S. Food and Drug Administration (FDA) or institutional review board(s) for the ENHANCE trial were notified properly about such modifications.

Therefore, we ask that Merck and Schering-Plough provide the following:

1. All names and contact information for all the biostatisticians involved in this "routine data quality review";

2. All records relating to the data reviewed by the aforementioned biostatisticians, including but not limited to, any communications relating to the data and the data analysis, both within the group of biostatisticians and to anyone outside the group;

3. All records of any and all versions of ENHANCE protocols, SAPs, Operator Manuals, and Reader Manuals, including but not limited to, any amendments or modifications to either the protocols, SAPs, or Manuals, and any records relating to these amendments or modifications;

4. All records of communications with FDA relating to the ENHANCE protocols, SAPs, Operator Manuals, Reader Manuals, and their amendments;

5. All records relating to any Institutional Review Board's review of the ENHANCE protocol and SAP, including but not limited to, the dates and versions of the protocol and SAP used for each review;

6. The names and contact information for all members of the Cholesterol Development Committee as well as all members of any standing scientific advisory boards used by Merck and Schering-Plough to discuss the ENHANCE trial; and

7. Any records of abstracts relating to the ENHANCE trial submitted to either the American Heart Association or American College of Cardiology for any scientific meetings between 2006 and 2008, inclusive.

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 M/SP officials.

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 John F. Sopko or Paul Jung with the Committee on Energy and Commerce 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.