ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

December 11, 2007

Mr. Fred Hassan
Chairman of the Board, Chief Executive Officer
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Mr. Richard T. Clark
Chairman of the Board, President, Chief Executive Officer
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 the Subcommittee on Oversight and Investigations are investigating the withholding of clinical trial data that may significantly affect the medical management of hypercholesterolemia.

In particular, we are interested in Schering-Plough and Merck's delay in making complete data available from the "Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Subjects With Heterozygous Familial Hypercholesterolemia" trial (ENHANCE, ClinicalTrials.gov Identifier: NCT00552097). The ENHANCE trial was completed in April 2006, and yet no data from the trial have been published or presented in their entirety. In fact, it appears that the study itself was not registered with ClinicalTrials.gov until October 31, 2007, a full 18 months after completion of the study. In addition, the endpoint indicated in the ClinicalTrials.gov web site[1] appears to differ from the endpoint described in the initial study design.[2]

[1]Effect of Ezetimibe Plus Simvastatin Versus Simvastatin Alone on Atherosclerosis in the Carotid Artery (ENHANCE)(P02578AM3). U.S. Department of Health and Human Services, National Institutes of Health clinical trials registry. Accessed at http://clinicaltrials.gov/ct2/show/NCT00552097 on December 6, 2007.

[2]Kastelein JJ, Sager PT, de Groot E, Veltri E. Comparison of ezetimibe plus simvastatin versus simvastatin monotherapy on atherosclerosis progression in familial hypercholesterolemia. Design and rationale of the Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression (ENHANCE) trial. Am Heart J. 2005 Feb;149(2):234-9.

Recent news reports indicate that ENHANCE data may be presented at the American College of Cardiology conference in March 2008, but only after using partial results and after changing the trial's primary endpoint. According to Schering-Plough spokesman Lee Davies, a panel of outside scientists recommended changing the trial's primary endpoint. We are concerned with the delay in releasing the results of the study, the timing of ENHANCE trial registration, and the apparent manipulation of trial data.

Therefore, we ask that Schering-Plough and Merck:

1. Make available ENHANCE study director Dr. Enrico P. Veltri, as well as principal investigator, Dr. John Kastelein, for interviews with Committee staff;

2. Make available corporate officials from both companies for interviews with Committee staff to discuss the ENHANCE trial;

3. Provide the identities and professional qualifications of each member of the outside panel that recommended changing the primary endpoint of the ENHANCE trial;

4. Provide copies of records relating to the ENHANCE trial generated by members of the outside panel;

5. Provide a written explanation why the ENHANCE trial was not registered with ClinicalTrials.gov until October 31, 2007, 18 months after the completion of the trial;

6. Provide a written explanation why the ENHANCE trial's primary endpoint was changed from its initial study design; and

7. Retain all primary data and records relating to the ENHANCE trial and refrain from destroying or altering any data and records related to the trial.

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 and corporate 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 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.