ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

January 22, 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 continuing their investigation into Vytorin and the ENHANCE trial.

Since the Committee's initial letter dated December 11, 2007, we have discovered that, in addition to the ad hoc advisory board convened after the trial's conclusion, there may have been a scientific advisory committee or advisory board created at the outset of the ENHANCE trial that was to periodically meet to discuss the ENHANCE trial, and that it may include a European and U.S. component. We wish to determine whether such an advisory board exists and also whether there was a Data Safety Monitoring Board associated with the ENHANCE trial.

We have also discovered that a Schering-Plough officer, Carrie Smith Cox, sold significant numbers of shares of Schering-Plough in the time between the end of the ENHANCE study and the release of the results on January 14, 2008. This raises questions as to whether this sale was related to any knowledge of the study's results.

Your press release of January 14, 2008, stated, "Key secondary imaging endpoints showed no statistical difference between treatment groups." The press release did not, however, provide specific data related to these secondary endpoints.

Therefore, in addition to our prior requests, we ask that Schering-Plough and Merck provide the Committee answers to the following questions:

1. Was there an advisory committee, board, or panel of any sort, either within the United States, Europe, or both, with the charge of meeting periodically to discuss the ENHANCE trial?

2. Was there a Data Safety Monitoring Board associated with the ENHANCE trial?

3. Have you decided to discontinue direct-to-consumer advertisements for Vytorin, or have you decided to reduce your advertising for the drug?

4. Did any corporate officer have knowledge of the results or any preliminary results of the ENHANCE trial prior to the public release of results on January 14, 2008?

We also ask that Schering-Plough and Merck provide the following:

1. Names and qualifications of all persons on any aforementioned committee created to discuss the ENHANCE trial;

2. All records, including but not limited to, minutes and transcripts relating to all meetings of any advisory committee, board, or panel created to meet periodically to discuss the ENHANCE trial;

3. All records of communications between the members of any aforementioned committee to Schering-Plough, Merck, or Dr. John Kastelein;

4. Names and qualifications of all persons on a Data Safety Monitoring Board for the ENHANCE trial;

5. All records, including but not limited to, minutes and transcripts relating to all meetings of a Data Safety Monitoring Board;

6. All records of all briefings to corporate officers of Schering-Plough or Merck relating to the ENHANCE trial;

7. All records of stock sales by Schering-Plough and Merck corporate officers between April 2006 and January 2008, inclusive;

8. All financial and contractual records relating to the division of revenue from Vytorin between Schering-Plough and Merck, including, but not limited to, the percentage of revenue allocated to Zetia versus simvastatin;

9. Results of secondary analyses of the ENHANCE trial, specifically the secondary endpoints detailed in "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."; and

10. The original ENHANCE trial protocol.

Please deliver the responses to our questions and 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, by 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 John F. Sopko or 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.