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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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January 16, 2008

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
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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 that may significantly affect the medical management of hypercholesterolemia, as well as the use of misleading statements in direct-to-consumer advertisements for prescription medications.

We are dismayed at the pace of the release of the ENHANCE study results. The trial ended in April 2006, and as of December 2007, both Schering-Plough and Merck indicated that the results had not been un-blinded and were not ready for presentation. Within a month, however, the study results were available in a press release. The results show no significant benefit in any studied endpoint from the use of Vytorin as compared to simvastatin, a less-costly generic alternative. This raises a number of troubling questions related to apparent manipulation of the study's endpoints.

Given Vytorin's large market share, we believe that the vast number of patients who have been using Vytorin could have learned of its insignificant benefits earlier than January

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2008. In addition, given the frequency of Vytorin advertisements, it concerns us that a study showing that Vytorin provides no increased benefit was not issued for nearly two years while direct-to-consumer advertisements were carried on the airwaves. This situation raises concerns that the drug companies and their advertisement agencies profited at the significant expense of patients' health.

In addition, subsequent to our letter regarding the ENHANCE trial dated December 11, 2007, we have discovered that the outside advisory panel created to provide expertise in dealing with the ENHANCE data did not include the study's primary investigator, Dr. John Kastelein. Not only was Dr. Kastelein not a member of the advisory panel, but apparently he was not even present at the meeting in which the panel recommended altering the study's endpoints.

Therefore, in addition to the request made in our initial letter, we ask that Schering-Plough and Merck provide the following:

1. All records of communications between Dr. Kastelein and Schering-Plough and Merck, as well as all communications between Dr. Kastelein and members of the outside advisory panel (namely, J. Robin Crouse, Gregory W. Evans, David G. Orloff, Michiel L. Bots, and James H. Stein);
2. All records relating to the January 14, 2008, press release announcing the ENHANCE results; and
3. All records relating to advertisements for Vytorin, including:
 - a. Scripts for all television, radio, and print advertisements for Vytorin;
 - b. All contractual arrangements relating to Vytorin advertisements, between Schering-Plough and Merck and any advertisement, communications, or public relations agencies related to the Vytorin advertisement campaigns;
 - c. All financial records related to Vytorin advertisements; and
 - d. All communications between Schering-Plough and Merck and any advertisement or communications, or public relations firms related to Vytorin or the ENHANCE 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, 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

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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.