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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 24, 2008

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

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.

On December 11, 2007, the Committee began an investigation into the delayed release of results from the "Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia" (ENHANCE) trial. Data subsequently released to the public via a press release on January 14, 2008, revealed that Vytorin did not significantly reduce plaque formation when compared to Zocor (simvastatin) alone.

On January 15, 2008, the American College of Cardiology (ACC) and the American Heart Association (AHA) both released separate statements related to Vytorin and the ENHANCE trial. We are concerned that both Merck and Schering-Plough have financial ties to

Mr. Fred Hassan
Mr. Richard T. Clark
Page 2

the AHA and the ACC such that their advisories related to cholesterol medications may be compromised. We are also curious as to whether Merck and/or Schering-Plough (MSP) may have had direct input into the AHA and ACC statements.

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

1. All records relating to MSP's association with the AHA and the ACC, including any contractual arrangements related to MSP's sponsorship of Web sites or any products of either the AHA or ACC, including, but not limited to, publications, educational materials, continuing medical education, and other programs;
2. All financial records relating to MSP's association with the AHA and the ACC, including the amount of money the AHA and the ACC have received from MSP, by year, since 2002;
3. All financial records relating to MSP's association with individual leaders of the AHA and ACC, including the amount of money any AHA or ACC Officer, Trustee, Director, Delegate, Council, or Committee member has received from MSP, by year, since 2002; and
4. All records relating to the AHA and ACC press releases of January 15, 2008, including, but not limited to, communications between any officer of MSP and any officer or representative of the AHA and/or ACC.

In addition, we ask that you do not destroy, dispose of, or tamper with any records relating to Merck/Schering-Plough and their association with the American College of Cardiology and/or the American Heart Association.

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 accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with MSP officials.

Mr. Fred Hassan
Mr. Richard T. Clark
Page 3

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact John F. Sopko or Paul Jung with 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.