ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

August 21, 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 to investigate the safety and effectiveness of Vytorin, a prescription drug marketed by a joint venture of Merck and Schering-Plough (henceforth the joint venture).

We were concerned to learn from your own press conference that Vytorin was associated with significantly higher rates of cancer and cancer deaths than the placebo group in the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study, completed in June 2008. Although we appreciate the timely release of study results, we are troubled by the confusing nature of the information you released to the public.

For example, the SEAS press release from Monday, July 21, 2008, indicated that there were 93 cancer cases among those taking Vytorin and 65 among those taking placebo. The consultant's press release from Oxford University's Clinical Trials Service Unit (CTSU), however, indicated that there were 102 cancer cases among Vytorin users and 67 in the placebo group. Moreover, while the SEAS release provided a probability value (p-value) for statistical significance, the CTSU release did not.

Your counsel briefed Committee investigators about these results on July 22, 2008. During that briefing, your counsel asserted that the increased cancer deaths were an anomaly and that a report provided to the Food and Drug Administration (FDA) by Sir Richard Peto, co-director of the Oxford University Clinical Trials Service Unit, would support this position. Furthermore, your counsel advised that Dr. Peto's report was not underwritten by the companies or the joint venture, and that it was submitted to FDA directly by Dr. Peto. Your counsel also informed the staff that the joint venture would not provide a copy to the Committee without assurances that it would not be released to the public. Furthermore, they encouraged the Committee to obtain a copy from FDA, which we have requested.

We are concerned that the analysis of Vytorin data conducted by Sir Richard Peto may not be as "independent" as expected, given that his Clinical Trials Service Unit is conducting the Study of Heart and Renal Protection (SHARP) trial of Vytorin, also funded by Merck, Schering-Plough, and/or the joint venture. In addition, Dr. Peto has apparently submitted a copy of his full report directly to FDA, but has not made it public, an action we deem questionable.

Therefore, we ask that you provide answers to the following questions:

1. How much is Dr. Peto and his institute, the Clinical Trials Service Unit of Oxford University, being paid directly or indirectly by Merck, Schering-Plough, the joint venture, or their agents, attorneys, or lobbyists to conduct the SHARP trial?

2. Which data referenced above (SEAS or CTSU) are the correct data from which health care providers should base their clinical judgment?

3. What are the complete data for the number of randomized patients, as well as the number of cancers and cancer deaths, in each treatment arm of the SEAS, SHARP, and IMPROVE-IT trials?

4. Upon completion of the SHARP and IMPROVE-IT trials, will Merck, Schering-Plough, or its joint venture, conduct another full analysis of the relationship between Vytorin and cancer and cancer deaths based upon complete versus preliminary data?

Finally, please provide all records since January 1, 1998, relating to the following:

1. All payments by Merck, Schering-Plough, the joint venture, or any of their agents, attorneys, or lobbyists to Dr. Peto or the Oxford University Clinical Trials Service Unit for any work related to Vytorin or for any other reason;

2. Any and all contracts or agreements between Merck, Schering-Plough, or the joint venture and Dr. Peto or the Oxford University Clinical Trials Service Unit for any work related to Vytorin or for any other reason;

3. All communications between Merck, Schering-Plough, the joint venture, or any of their agents, attorneys, or lobbyists and Dr. Peto or the Oxford University Clinical Trials Service Unit; and

4. All communications between Merck, Schering-Plough, the joint venture, or any of their agents, attorneys, or lobbyists and any Government officials related to the SHARP, IMPROVE-IT studies, or any work done by or on behalf of Dr. Peto or the Oxford University Clinical Trials Service Unit or any of their agents or contractors.

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 company 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.