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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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February 11, 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 investigating the withholding of clinical trial data in the ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) trial.

We have recently learned of messages posted to a Web site, Cafepharma.com, in which anonymous posters apparently reveal knowledge of ENHANCE trial results as early as March 13, 2007, nine months before Merck/Schering-Plough (M/SP) released the unblinded data. Examples of Web site entries include:

- March 13, 2007: "have a buddy at [Schering-Plough Research Institute]. He says that the study is a bust. Adding Zetia to already maxed-out statin is useless"
- June 3, 2007: "Heard it crashed and burned!"

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- July 24, 2007: "If ENHANCE indeed is negative, and I have heard from [sic] sources close that it is, then IMPROVE-IT is definitely at risk."
- September 20, 2007: "One of my docs is a very good friend of the study PI overseas. I'm told that the study IS negative in that there is absolutely no difference in carotid IMT between simva 80+placebo vs simva 80+Zetia 10."
- November 14, 2007: "word of mouth from investigators involved in running the trial is that it is a negative study. We and Merck both talked up this study publicly a bunch before the results were known internally, now both are stone cold silent."

These Web site entries are obviously troubling and raise again the question of whether anyone within Merck or Schering-Plough knew the results of the ENHANCE trial prior to the official release of data in the January 14, 2008, press release. In addition, the timeline released by M/SP indicates that Schering-Plough biostatisticians began "conducting routine data quality reviews of the initial blinded ENHANCE data" in "Summer through end of 2005."

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

1. A written explanation as to when and how Merck and Schering-Plough officials first became aware of these Cafepharma.com posts;
2. A written explanation as to what Merck and Schering-Plough plan to do or have done with regards to investigating the source(s) of these posts; and
3. All records relating to the Cafepharma.com posts.

In addition, we ask that you do not destroy, dispose of, or tamper with any records relating to the Cafepharma.com posts or records relating to the biostatisticians and their work in conducting the routine data quality reviews of ENHANCE at any time during and after the study.

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 M/SP 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 with the Committee on Energy and Commerce staff at (202) 226-2424.

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Mr. Richard T. Clark  
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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.