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February 19, 2009

Mr. Fred Hassan
Chairman of the Board, Chief Executive Officer
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Mr. Richard T. Clark
Chairman of the Board, President, Chief Executive Officer
Merck & Company, Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889

Dear Mr. Hassan and Mr. Clark:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are continuing an investigation into the safety and effectiveness of Vytorin, a prescription drug manufactured jointly by Schering-Plough and Merck.

On September 5, 2008, your counsel provided a briefing to Committee staff on a clinical trial called the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial. Your counsel stated that in January 2008, the Data Safety Monitoring Board for this trial, which is responsible for ensuring the safety of patients participating in the trial, requested that the Data Safety Monitoring Boards for two other large, ongoing Vytorin trials "unblind," or release, their study data prior to the conclusion of the studies. According to your counsel, the Data Safety Monitoring Boards for both of those trials — the Study of Heart and Renal Protection (SHARP) trial and the Examining Outcomes in Subjects with Acute Coronary Syndrome: Vytorin vs. Simvastatin (IMPROVE-IT) trial — agreed to do so.

We are writing to request information about the decisions by the Data Safety Monitoring Boards to unblind the interim data from the SHARP and IMPROVE-IT trials. Accordingly, we

request that Schering-Plough, Merck, and the joint venture of Schering-Plough and Merck produce the following documents and information by March 6, 2009:

1. The names, affiliations, and current contact information for all members of the Data Safety Monitoring Boards for the SEAS, SHARP, and IMPROVE-IT trials;

2. The names, affiliations, and current contact information for all members of the steering committees for the SEAS, SHARP, and IMPROVE-IT trials;

3. All documents relating to Institutional Review Board (IRB) approval and any subsequent IRB deliberations relating to the SEAS trial;

4. All minutes of Data Safety Monitoring Board meetings for the SEAS trial;

5. All communications relating to the SEAS trial between or among:

    a. Any members of the SEAS trial's Data Safety Monitoring Board;

    b. Any member of the SEAS trial's Data Safety Monitoring Board and any members of the SEAS, SHARP, or IMPROVE-IT steering committees;

    c. Any member of the SEAS trial's Data Safety Monitoring Board and any investigators for the SEAS, SHARP, or IMPROVE-IT trials;

    d. Any member of the SEAS trial's Data Safety Monitoring Board and any officers or employees of Merck, Schering-Plough, or the Merck/Schering-Plough joint venture;

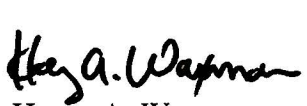
6. All documents relating to the submission of the SEAS manuscript to the New England Journal of Medicine; and

7. All minutes of Data Safety Monitoring Board meetings for the SHARP and IMPROVE-IT trials no later than two weeks after the completion of those trials.

We request that Schering-Plough, Merck, and the joint venture of Schering-Plough and Merck retain without alteration, until further notice, all minutes, records, communications, and other documents relating to the Data Safety Monitoring Boards for the SEAS, SHARP, and IMPROVE-IT trials.

An attachment to this letter provides additional information on how to respond to the Committee's request. If you have any questions regarding this request, please contact Paul Jung of the Committee staff at (202) 226-2424.

Sincerely,



Henry A. Waxman
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Enclosure

cc: Joe Barton
Ranking Minority Member
Committee on Energy and Commerce

cc: Greg Walden
Ranking Minority Member
Subcommittee on Oversight and Investigations