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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. ROTHSCCHILD, CHIEF COUNSEL

Mr. M. Cass Wheeler
Chief Executive Officer
American Heart Association
7272 Greenville Avenue
Dallas, TX 75231

Dear Mr. Wheeler:

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 Heart Association (AHA) released a statement indicating that Vytorin "does not appear to be unsafe." We are concerned that the AHA has strong financial ties to Merck/Schering-Plough (MSP) such that the decisions related to AHA's position on Vytorin and the ENHANCE trial may be compromised. For example, the AHA's web page on cholesterol¹ includes a prominent link to a sponsor, indicating "Merck/Schering-Plough is a proud sponsor of the American Heart Association's Cholesterol Web site." It appears that MSP is the only sponsor of the AHA's cholesterol education web page.²

¹ Cholesterol. American Heart Association. Accessed at <http://www.americanheart.org/presenter.jhtml?identifier=1516> on January 22, 2008, at 1:45pm.

² Meet Our Sponsors. American Heart Association. Accessed at <http://www.americanheart.org/presenter.jhtml?identifier=1521> on January 22, 2008, at 1:45pm.

The AHA Web site also includes a page titled, "The Two Sources of Cholesterol,"³ which seems identical to Merck/Schering-Plough's advertising campaign for Vytorin. A link on that page, which reads "Links to Other Sites: Learn more about the sources of cholesterol," directs visitors to a Merck/Schering-Plough Web site for Vytorin.⁴ We are concerned that the AHA's educational campaign for cholesterol is merely an advertising campaign in disguise for Merck/Schering-Plough's Vytorin.

Therefore, we ask the American Heart Association to provide the Committee with the following:

1. All records relating to the American Heart Association's association with Merck/Schering-Plough, including any contractual arrangements related to MSP's sponsorship of the AHA Web site or any AHA products, including, but not limited to, publications, educational materials, and programs;
2. All financial records related to the AHA's association with MSP, including the amount of money AHA has received from MSP, by year, since 2002;
3. All conflict of interest records related to MSP's association with individual leaders of the AHA, including the amount of money any AHA Officer, Director, Delegate, Council, or Committee member has received from MSP, by year, since 2002;
4. All records related to the statement of January 15, 2008, on Vytorin / ENHANCE, including the names of the authors and editors of the statement, as well as all officers of the AHA who approved the statement; and
5. Please provide a written description of how decisions are made at the AHA with regard to how educational materials are selected, prepared, and presented on the AHA Web site.

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 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, 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 AHA officials.

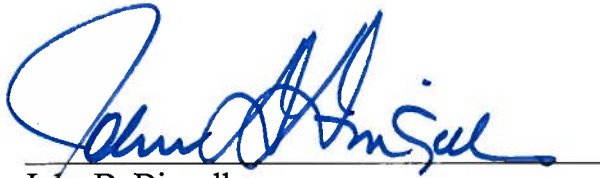
³ The Two Sources of Cholesterol. American Heart Association. Accessed at <http://www.americanheart.org/presenter.jhtml?identifier=3046105> on January 22, 2008, at 1:45pm.

⁴ Food and Family: The Two Sources of Cholesterol. Merck/Schering-Plough Pharmaceuticals. Accessed at http://www.2sourcesofcholesterol.com/high_cholesterol/2sourcesofcholesterol/index.jsp on January 22, 2008, at 1:45pm.

Mr. M. Cass Wheeler
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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.