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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

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GREGG A. ROTHSCHILD, CHIEF COUNSEL

Mr. Jack Lewin  
Chief Executive Officer  
American College of Cardiology  
2400 N Street, N.W.  
Washington, D.C. 20037

Dear Mr. Lewin:

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) released a statement reporting that "The overall incidence rates of cardiac events were nearly identical between both treatment groups, and both medicines were generally well tolerated. There should be no reason for patients to panic." We are concerned that the ACC has strong financial ties to Merck and/or Schering-Plough (MSP) such that the decisions related to ACC's position on Vytorin and the ENHANCE trial may be compromised. For example, the ACC Foundation and Merck have jointly sponsored the ACC Foundation/Merck Adult Cardiology Research Fellowship Awards that fund six young cardiologists to conduct cardiovascular research for one year. According to

the ACC Web site,<sup>1</sup> “The Merck Company Foundation has underwritten the entire program, investing millions of dollars during the past 25 years. The American College of Cardiology Foundation has administered all aspects of this program...”

Therefore, we ask that the ACC provide the Committee with the following:

1. All records relating to the American College of Cardiology’s association with Merck/Schering-Plough, including any contractual arrangements related to MSP’s sponsorship of the ACC Web site or any ACC products, including, but not limited to, publications, educational materials, Continuing Medical Education, and other programs;
2. All financial records relating to ACC’s association with MSP, including the amount of money the ACC has received from MSP, by year, since 2002;
3. All conflict of interest records relating to MSP’s association with individual leaders of the ACC, including the amount of money any ACC Trustee, officer, or member involved in College governance has received from MSP, by year, since 2002;
4. All conflict of interest records relating to any trials sponsored by MSP that had as its principal investigator or study director a Trustee, officer, or member of the ACC involved in College governance during the time of the study’s trial or analysis; and
5. All records relating 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 Trustees and officers of the ACC who approved the statement.

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.

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 ACC officials.

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<sup>1</sup> ACCF/Merck Awards. Accessed at [http://www.acc.org/about/award/award\\_merck.htm](http://www.acc.org/about/award/award_merck.htm) on January 22, 2008, at 2:45pm.

Mr. Jack Lewin  
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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.