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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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April 25, 2008

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The Honorable Andrew C. von Eschenbach, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. von Eschenbach:

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 misleading statements in direct-to-consumer (DTC) advertisements of prescription medications.

Thank you for responding to our January 16, 2008, letter about television advertisements for the Merck/Schering-Plough drug Vytorin. We have noticed, however, a new series of print advertisements for Vytorin, including several full-page ads in major newspapers, which raise new concerns about the accuracy of direct-to-consumer advertising.

The ads in question were released subsequent to the presentation of the results of the ENHANCE trial, which showed that Vytorin did not significantly reduce cholesterol plaque build-up when compared to generic Zocor. Based on these study results, numerous scientists have begun to question the use of surrogate endpoints such as low-density lipoprotein (LDL), or "bad" cholesterol, in determining the effect of a drug on a patient's health. We are concerned that these print ads are misleading since they do not adequately reflect the effect of the ENHANCE study results on the use of Vytorin in particular, or cholesterol therapy, in general.

Therefore, we ask that you provide all records relating to any print or Internet advertisements for Vytorin since January 16, 2008. These records are to include, but not be limited to, any records relating to the review or monitoring of said advertisements, complaints received relating to these advertisements, and any comments or consultations that the Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications has provided relating to these advertisements.

The Honorable Andrew von Eschenbach, M.D.  
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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 FDA 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 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.