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U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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January 16, 2008

The Honorable Andrew 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 misleading statements in direct-to-consumer advertisements of prescription medications.

We are aware of television advertisements for Schering-Plough and Merck's Vytorin, a drug that has just been shown in the ENHANCE trial to provide no benefit when added to simvastatin, a low-cost, effective generic medication. The ENHANCE study ended in April 2006, yet the data were only released on January 14, 2008, almost 2 years from the study's conclusion.

We are concerned that the study's results may have been available to Schering-Plough and Merck officials, and yet the massive advertisement campaign for Vytorin was allowed to continue. Physicians and their patients should have been made aware as soon as possible, that Vytorin provided no benefit over a widely-used, cheaper, generic alternative. We are interested in whether the Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications (DDMAC) has been involved with these Vytorin advertisements.

Therefore, we ask that you provide all records relating to any print, radio, television, or internet advertisements for Vytorin. These records are to include, but not be limited to, any records relating to the review or monitoring of said advertisements, complaints received related to these advertisements, and any comments or consultations that DDMAC provided related to these advertisements.

The Honorable Andrew von Eschenbach, M.D.

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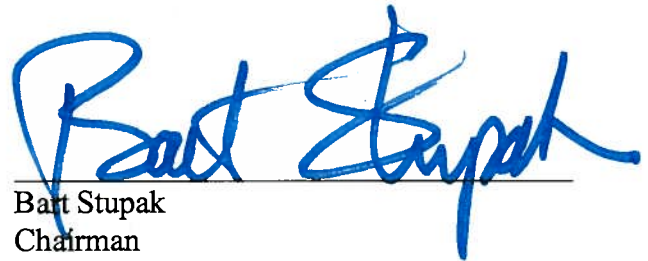
Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, by no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the 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 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 Paul Jung of 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.