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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 18, 2008

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Weems:

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 cholesterol medication Vytorin and the ENHANCE clinical trial, which compared Vytorin to the cheaper, generic version of Zocor.

The ENHANCE trial ended in April 2006, and the results were only released on January 14, 2008. The results show that Vytorin has no significant effect when compared to a cheaper, generic version of Zocor. We are concerned that Merck and Schering-Plough officials may have known the results of the study and purposely delayed release of the results so as not to affect Vytorin's market share. Given Vytorin's large market share, we believe that the vast number of physicians who prescribe Vytorin and their patients could have been notified of its insignificant benefits earlier than January 2008. We are seriously concerned that while the manufacturers may have known that Vytorin was ineffective, huge sums of taxpayer dollars may have been spent on this expensive drug.

Therefore, we request that the Centers for Medicare and Medicaid Services (CMS) provide to the Committee the dollar amount spent by both the Medicare and Medicaid programs on Vytorin since April 2006. We request that the data be provided by month, program, and State (e.g., Medicare Part D, Medicaid per State, etc.).

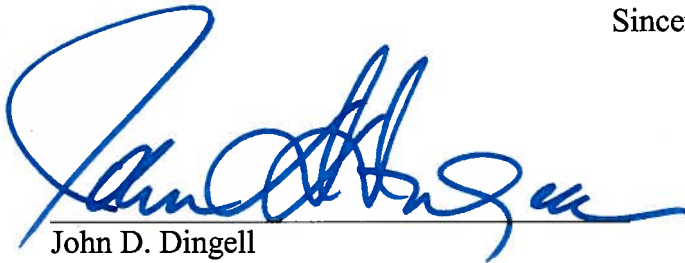
Mr. Kerry N. Weems
Page 2

We also request a briefing for Committee staff on whether CMS has considered withdrawing payment for Vytarin based on its apparent lack of increased efficacy when compared to Zocor (simvastatin) alone, as well as how CMS makes decisions regarding payment for prescription medications that may be subsequently found to have little efficacy.

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 CMS employees.

Thank you for your prompt attention to this matter. If you have any questions related to this request, and to arrange the requested briefing, please contact us or have your staff contact John F. Sopko or 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.