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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 11, 2008

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Mr. Fred Hassan
Chairman of the Board, Chief Executive Officer
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Mr. Richard T. Clark
Chairman of the Board, President, Chief Executive Officer
Merck & Co., Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889

Dear Mr. Hassan and Mr. Clark:

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 continuing to investigate the withholding of clinical trial data related to the ENHANCE trial. Although the ENHANCE data were presented at the American College of Cardiology meeting on March 30, 2008, our investigation is by no means concluded.

The primary purpose of our investigation is to determine why Merck/Schering-Plough delayed the reporting of the ENHANCE trial, completed in April 2006, until January 2008. This nearly two-year delay is unusual for a clinical trial, and although the companies have argued that poor data quality is the primary reason for the delay, we continue to have serious concerns related to the conduct and reporting of this study. Based on the documents produced to date (see attachments), our investigation has uncovered some unusual circumstances related to the ENHANCE trial that raise new questions.

Therefore, we ask that you respond to the following:

1. Why were the minutes of the ad hoc Expert Panel meeting created after the fact, and after the participants were told that there would be no minutes or transcript of the meeting (attachment pages 1-17)?

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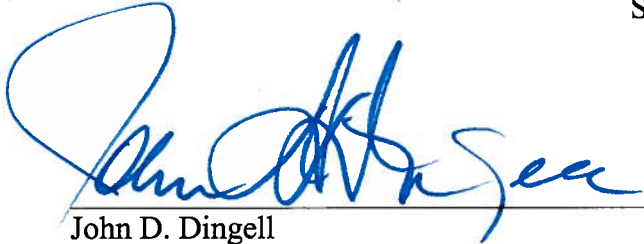
2. For what purpose is the Expert Panel meeting summary (attachment pages 18–24) now being used?
3. Why was Dr. Kastelein not informed about the specifics related to the Expert Panel meeting? (attachment Page 52.)
4. Why was Dr. Kastelein’s signature not required for any of the study protocol amendments?
5. What was the purpose of hiring an independent consultant to review ENHANCE data, and why did Merck/Schering-Plough not proceed with data analysis after Dr. Bots’s independent consultation report indicated that the ENHANCE data were, in his own words, “fine”? (attachment pages 53-65.)
6. Why did Merck/Schering-Plough convene an Expert Panel in light of an already completed independent consultant’s report to assess the quality of ENHANCE data?
7. Did the ad hoc Expert Panel review Dr. Bots’s report from January 2007?
8. Who created the slides and graphs for presentation to the Expert Panel? (attachment pages 25-51.)
9. Why is there no mention of the 2005 data “routine data quality reviews” in the ENHANCE Study Protocol?
10. Why did Merck/Schering-Plough generate the Statistical Analysis Plan after completion of the study in spring 2006?
11. Who decided that company statisticians would review data in 2005, prior to completion of the study?
12. Did the Food and Drug Administration’s (FDA) Division of Drug Marketing, Advertisement, and Communications contact Merck/Schering-Plough prior to their January 23, 2008, letter (attachment pages 66–70) to inform you of their decision that Vytorin television advertisements were misleading? If so, who from FDA contacted Merck/Schering-Plough?
13. Did Merck/Schering-Plough suspend their television advertisements on January 22, 2008, due to FDA/DDMAC’s determination or for another reason?
14. Does Merck/Schering-Plough plan to reinstate the Vytorin “Food & Family” television ads in the near future?

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Given the outstanding questions above, we believe that our investigation into ENHANCE and Vytarin is far from concluded. We intend to continue our investigation and fully explore all possibilities related to Merck/Schering-Plough's conduct of the ENHANCE trial. We appreciate your cooperation to date, and we hope this cooperation will continue throughout the full course of our investigation.

Please deliver your responses to the Subcommittee on Oversight and Investigations, Room 316, Ford House Office Building, by no later than two weeks from the date of this letter. If you have any questions related to this letter, 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

Attachments

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations