United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

January 24, 2008

Via Electronic Transmission

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

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

Dear Messrs. Clark and Hassan:

As the Ranking Member of the United States Senate Committee on Finance (Committee), I have an obligation to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to ensure that taxpayer and beneficiary dollars are spent in a fiscally sound manner. This also includes the responsibility to conduct oversight of the medical and pharmaceutical industries to ensure that Medicare and Medicaid dollars are spent appropriately on safe and effective drugs and devices. The American people expect elected officials to guard their tax dollars as if it was money out of their pockets.

I have been disturbed by reports regarding delays in releasing the results of the ENHANCE trial by Schering-Plough and Merck. [1] This study examines whether Vytorin provides better health benefits than generic simvastatin. Vytorin is a pill that combines the statin, simvastatin, with a drug called ezetimibe that decreases absorption of cholesterol by the digestive tract.

According to a report in TIME magazine, your companies have had the ENHANCE study results since April 2006, more than 20 months ago. [2] However, your companies failed to release the ENHANCE results until January 14, 2008. According to your own press release, there is no apparent gain in health benefits from using Vytorin over the much cheaper generic statin, simvastatin.[3] Even more disturbing is an article in *The New York Times* stating that your companies have failed to release several studies on ezetimibe.[4] It is this type of behavior that has caused the American public to lose trust in drug companies.

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[1] Alex Berenson, "Cardiologists Question Delay of Data on 2 Drugs," *The New York Times*, November 21, 2007.
[2] Alice Park, "Is Vytorin a Failure?" TIME, January 15, 2008.
[3] Schering-Plough News Release, "Merck/Schering-Plough Pharmaceuticals Provides Results of EHANCE Trial," released on company Website on January 14, 2008.
[4] Alex Berenson "Date About Zetia Risks Was Not Fully Revealed" *The New York Times*, December 21, 2007.

While the health benefits of Vytorin appear similar to a cheaper generic, the cost difference to the citizens of Iowa is certainly another matter. At a Wal-Mart pharmacy in Iowa City, generic simvastatin costs $54.54 for a month's supply while Vytorin costs $112.46. I am confident that the citizens of Iowa would have appreciated knowing that a cheaper drug works just as well. Instead, Iowans and other Americans paid out their hard-earned dollars unnecessarily for almost two years, while waiting for Schering-Plough and Merck to announce the scientific results of ENHANCE.

I am also disturbed by reports on CBS News that Carrie Smith Cox, President of Global Pharmaceuticals at Schering-Plough, sold 900,000 shares of company stock last year worth $28 million. There have also been reports that other executives sold large amounts of stock during this same time period. These stock sales occurred during the time when executives at the company were delaying the release of the ENHANCE results.

Accordingly, I would appreciate responses to the following questions and requests for documents, communications, and records. In responding to these questions, please repeat each enumerated question and follow it with the appropriate response.

1. The FDA approved Vytorin back in July of 2004. Please provide quarterly sales figures for Vytorin, Zetia (ezetimibe), and Zocor (simvastatin). This request covers the period of July 2004, to the present.

2. If your company negotiates separate contracts with Pharmacy Benefit Managers (PBMs) for Medicare Part D, please provide quarterly sales figures for Vytorin as received from these PBMs. If not, please provide an estimate of sales attributable to the Medicare Part D program. This request covers the period of July 2004 to the present.

3. Please state the first date that the ENHANCE trial was unblinded. Provide all names and documents regarding the unblinding of the ENHANCE trial.

4. Please provide a copy of company documents, communications, telephone messages and records on news reports, lawsuits, and federal investigations regarding the ENHANCE trial. This request covers the period of January 2007 to the present.

5. Please provide a list of all medical studies completed by Schering-Plough and Merck on Vytorin or ezetimibe. This request covers the period of January 2000 to the present. For each study, please provide the following information:

    a) Study name
    b) Brief synopsis
    c) Completion date of study
    d) Date of public release of results (please specify whether all results were made public or only a portion of the study).

e) If the study was not publicly released, please provide any drafts of that study or other documents regarding the results.

6. Please provide a list of all payments made to the American Heart Association. This request covers the period of January 2004 to the present. For each payment, please provide the following information:

    a) Date of payment
    b) Payment description (CME, meeting support, research support, etc.)
    c) Amount of payment

7. Please provide a list of all payments made to the American College of Cardiology. This request covers the period of January 2004 to the present. For each payment, please provide the following information:

    a) Date of payment
    b) Payment description (CME, meeting support, research support, etc.)
    c) Amount of payment

8. Please provide a list of all payments, if any, made to the members of the panel that chose to change the endpoint goal of ENHANCE. This request covers the period of July 2004 to the present. For each payment to a panel member, please provide the following

    a) Name of physician
    b) Date of payment
    c) Payment description (CME, honorarium, research support, etc.)
    d) Amount of payment

9. Please provide a list of all payments for continuing medical education (CME) regarding cardiovascular risk management, and/or cholesterol control, and/or Vytorin. This request covers the period of January 2004 to the present. For each payment, please provide the following:

    a) Topic of CME
    b) Name of group hosting the CME
    c) Date of CME
    d) Amount of payment to organization hosting the CME.

In cooperating with the Committee's review, no documents, records, data, or other information related to these matters, either directly or indirectly, shall be destroyed, modified, removed, or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than February 8, 2008. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Angela Choy and/or Paul Thacker at (202) 224-4515.

Sincerely,

Charles E. Grassley
Ranking Member

GENERAL INSTRUCTIONS

1. The terms “Schering- Plough Corporation” and “your company” mean its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which “Schering- Plough Corporation” entered into a partnership, joint venture or any other business agreement or arrangement.

2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.

3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.

5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).

6. In the event that a document is withheld on the basis of privilege, provide the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.

7. Each document produced shall be produced in a form that renders the document susceptible of copying.

8. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same document.

9. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.

10. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.

11. All documents shall be Bates stamped sequentially and produced sequentially.

GENERAL DEFINITIONS

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. 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.

3. The terms “relate,” “related,” “relating,” or “regarding” as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.

4. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The masculine includes the feminine and neuter genders to bring within the scope of this document request any information that might otherwise be construed to be outside its scope.

5. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a “communication” include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.