ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

April 24, 2007

Curt D. Furberg, M.D., Ph.D.
Professor
Department of Public Health Sciences
Wake Forest University School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157-1063

Dear Dr. Furberg:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, March 22, 2007, at the hearing entitled, "The Adequacy of FDA to Assure the Safety of the Drug Supply - Part II." We appreciate the time and effort you gave as a witness before the Subcommittee.

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's questions along with your response. In the event you have been asked questions from more than one Member of the Committee, please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business on **Wednesday, May 9, 2007.** Your written responses should be delivered to **2125 Rayburn House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov** in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman with the committee staff at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

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

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Bart Stupak

1. What problems do you see in connection with the restricted use of fees contained in Prescription Drug User Fee Act (PDUFA) IV?

2. Do the deadlines in PDUFA contribute to an excess of unrecognized safety problems in connection with new drug applications?

3. Has PDUFA affected the "culture" of the Food and Drug Administration (FDA)?

4. What changes in FDA's drug safety structure would be most likely to obviate another "Vioxx" tragedy?

5. Should the Office of Surveillance and Epidemiology *share* authority with the Office of New Drugs in postmarket setting?

6. What is your opinion of direct-to-consumer marketing of new drugs?

7. How can the use of new drugs, with relatively unknown safety records, be reduced?

8. What are the problems associated with post marketing safety studies?

9. Does the FDA have sufficient authority to sanction pharmaceutical companies that suppress or delay submission of unfavorable trial information?