ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

April 25, 2007

Bruce M. Psaty, M.D., Ph.D.
Professor, Medicine & Epidemiology
University of Washington
Cardiovascular Health Research Unit
1730 Minor Avenue, Suite #1360
Seattle, WA 98101-1448

Dear Dr. Psaty:

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 **Friday, April 27, 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. Were there recommendations to which the Food and Drug Administration (FDA) was especially responsive?

2. You listed a number of "incomplete" responses to the Institute of Medicine's (IOM) recommendations. Are there others?

3. Why is the public-private partnership recommended by the IOM necessary?

4. You mentioned that 899 post-market commitments are still pending. Why are so many pending?

5. You referred to the value of scientific disagreement. How is it that disagreement helps the FDA in its mission?

6. You have raised the question of transparency at the Agency. If you could look at internal FDA documents, which ones would you like to see?

7. One of the IOM's recommendations concerned risk-benefit. What did you think of the FDA response to this recommendation?

8. What is your view of direct-to-consumer (DTC) advertising?

9. Is there a conflict-of-interest problem on FDA Advisory Committees?

10. You referred to the industry's lack of interest in safety. Can you provide any examples?

11. Why did the IOM recommend clinical trial registration?

12. Do you favor the continuing appropriations from user fees?