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

Raymond L. Woosley, M.D., Ph.D.
President and CEO
The Critical Path Institute
4280 N. Campbell Ave. #214
Tucson, AZ 85718

Dear Dr. Woosley:

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. In an article you co-authored in 1998 entitled "Making Medicines Safer," you cited figures indicating that adverse effects of drugs is one of the top six causes of death in this country. Is that still the case?

2. In the same 1998 article, you noted that, given the state of information technology in 1998, it was remarkable that the Food and Drug Administration (FDA) lacked a systematic program of post-marketing drug surveillance. Does it exist today?

3. How does FDA's voluntary reporting system (AERS – Adverse Event Reporting System) compare with France's post approval drug safety surveillance system?

4. How does FDA's voluntary reporting system compare with the United Kingdom?

5. The article you co-authored entitled "A New System for Moving Drugs to Market," contains your recommendation that newly-approved drugs should be given to a defined population under observed conditions only. Would this require an initial ban on most direct-to-consumer marketing since a newly approved drug would be approved for a carefully defined population?

6. How would the FDA enforce such a limitation on drug prescriptions given that States regulate medical practice, not the FDA?

7. Does providing warnings, product labels, or package inserts adequately protect patients from adverse events?

8. In your 1998 article, entitled "Making Medicines Safer," you called for establishment of a post-marketing drug-safety program independent of the FDA to assure objectivity and to avoid conflicts of interest. Do you still recommend the creation of an independent body responsible for oversight and investigation of post-market drug safety?

9. Given that the FDA permits the same reviewers in the Office of New Drugs who approve a drug to make the final decision on post-market status of the drug, is this not an inherent conflict of interest?