ONE HUNDRED EIGHTH CONGRESS

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

December 9, 2004

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The Committee on Energy and Commerce is investigating drug safety issues related to Vioxx, as well as broader issues raised at Committee hearings and elsewhere about the adequacy of the Food and Drug Administration (FDA) to address concerns related to the safety of prescription drugs approved by the FDA. At the request of this Committee, the Government Accountability Office (GAO) is examining how the FDA Center for Drug Evaluation and Research (CDER) manages internal disagreements over the handling of drug safety issues.

We note that at your press conference on December 3rd you stated that the Administration will present a plan to reform FDA's regulation of drug safety. Further, you suggested that this initiative could feature the creation of a drug safety entity with greater independence from FDA's review functions.

We write to express our appreciation for your comments and interest in this issue. While the Committee is actively investigating issues that bear directly on FDA's drug safety program, we are eager to work with you on sensible and pro-active reforms you are considering regarding the drug safety program concerns at FDA.

To enhance the credibility of this initiative, we recommend that the drug safety review include interviews with appropriate FDA management officials at CDER as well as FDA scientists who have concerns about the drug safety program. The review, including personnel interviews, should be conducted by staff independent of CDER. We emphasize that the Department take all necessary steps to assure that no negative employment consequences attach to staff that express concern about the FDA's handling of drug safety issues. If the review is already proceeding this way, we would appreciate that assurance from the Department.

Although you indicated at the press conference that the Administration would present its plan in the next two weeks, we would be supportive of the Administration if it took a few extra weeks to strengthen the quality and enhance the credibility of the review, and presented its findings by January 19, 2005.

We commend you for your willingness to take quick action, but emphasize this drug-safety review be conducted with objectivity, independence, and fairness. Public confidence in the safety of our drug supply as well as the regulatory ability and independence of the FDA is at stake.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member