ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN



July 5, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with prescription drugs.

As part of that inquiry, we have been examining the activities of senior FDA officials in the Avandia matter. Our current inquiry concerns FDA's Deputy Director for Drug Risk Evaluation in the Center for Drug Evaluation and Research Office of Surveillance and Epidemiology, Dr. Rosemary Johann-Liang, who last year approved a black box warning on both rosiglitazone (Avandia) and pioglitazone (Actos) for congestive heart failure and also added macular edema as a serious adverse event. For this action, she was reportedly reprimanded by the Director for Drug Risk Evaluation, Dr. Mark Avigan, ordered to retract her approval of the black-box warning, stripped of her authority to approve any other safety assessments, and relieved of her duties with regard to Avandia and Actos.

If true, these actions would not only be reprehensible, but possibly criminal. We require an explanation as to why such actions were taken and how they were prompted.

We note that, in the past, Dr. Mark Avigan has been accused of being a party to the suppression of a crucial FDA safety study. In a Subcommittee hearing on September 23, 2004, "FDA's Role in Protecting the Public Health," the record indicates that Dr. Avigan suppressed a study by FDA reviewer, Dr. Andrew D. Mosholder, which showed a high risk of suicidality among teenagers taking anti-depressant medications. Dr. Mosholder's work was withheld from an FDA Advisory Committee convened to assess such risk. Given these two cases, the

Committee seeks to learn if Dr. Avigan is acting on his own to limit the ability of FDA staff to conduct proper scientific reviews and management decisions with regards to drug safety or is doing so on behalf of other officials or private parties. Dr. Avigan's actions are especially troubling, since in both cases he appears to have acted either in concert with or at the behest of officials of the Office of New Drugs—officials who are outside of his direct reporting line.

We also note that in past testimony before the Subcommittee, you clearly stated your position on FDA policies regarding scientific inquiry, open discussion, and whistleblower protection. Specifically, in the Subcommittee hearing on March 22, 2007, entitled "The Adequacy of the FDA to Assure the Safety of the Nation's Drug Supply," you stated that FDA should "be a science-based and science-led academic-like organization" with "an environment in which people with diverse points of view, completely different perspectives on an issue or problem can come together with mutual respect and vigorously, even aggressively, debate and discuss those issues, and do that in the comfort of being respected and supported and even encouraged – even, quite candidly, from my standpoint, expected." We are curious as to why Dr. Johann-Liang was both reprimanded and stripped of her authority based on her scientific assessment, since these actions are counter to the environment that you stated you would create and encourage at FDA.

We believe that you share our concerns regarding this apparent breach of your own expressed policies and will support the Committee in its inquiry. Therefore, we request that you provide the following documents:

1. All records—including, but not limited to, e-mails and memoranda—related to Dr. Rosemary Johann-Liang's performance, including, but not limited to, her performance reviews, personnel actions, disciplinary actions, award nominations, or considerations from January 1, 2001, to the present;

2. All documents, e-mails, and memoranda from or to Dr. Johann-Liang related to rosiglitazone (Avandia) and pioglitzaone (Actos);

3. All documents, e-mails, and memoranda from or to Dr. Mark Avigan related to rosiglitazone (Avandia) and pioglitazone (Actos); and

4. All records including, but not limited to, notes of conversations and memoranda, regarding the removal of Dr. Johann-Liang's authority to approve or disapprove any safety assessments from the Office of Surveillance and Epidemiology.

In addition, we have directed Committee staff to interview Dr. Mark Avigan and the individuals within the Office of New Drugs who communicated with Dr. Avigan regarding rosiglitazone and pioglitazone. We may also need to interview other staff members of both the Office of Surveillance and Epidemiology and the Office of New Drugs.

The Committee asks that you provide the requested records and arrange for the initial interviews no later than the close of business two weeks from the date of this letter. If you have any questions regarding these requests, please contact us or have your staff contact David Nelson or Paul Jung with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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

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