ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 28, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Secretary:

On March 22, 2007, the Food and Drug Administration (FDA) Commissioner Andrew von Eschenbach testified under oath before the Subcommittee on Oversight and Investigations regarding our investigation into the adequacy of the FDA's efforts to protect Americans from unnecessary risks of prescription drugs. At that hearing, questions were raised about the accuracy and candor of his testimony and prepared statement. As you can see from the attached news article, others who attended the hearing and had first-hand experience with some of the events described in his testimony have also raised questions about whether the Commissioner or those who helped prepare his testimony intentionally mislead the Subcommittee.

We take such allegations seriously. Accordingly, we request that you provide all documents prepared for or used in the preparation of Dr. von Eschenbach's testimony by any employee of the Department including, but not limited to, any briefing books, background memoranda and all communications between and among the senior staff of the FDA, the Offices of Legislative Affairs of the FDA and the Department of Health and Human Services (HHS), the HHS Office of General Counsel, including the Office of Chief Counsel to FDA and Commissioner von Eschenbach and his senior staff. These records must be delivered by no later than close of business on Wednesday, April 4, 2007, to room 316 of the Ford House Office Building, U.S. House of Representatives.

Further, please have all senior staff and counsels who participated in the preparation of the testimony submitted on March 22, 2007, make arrangements to be interviewed by the Committee staff in room 316 of the Ford House Office Building during the week beginning Monday, April 9, 2007. Please inform these individuals that they have a right to be accompanied by personal counsel. No employees of the Department will be allowed to participate in the interviews.

Arrangements may be made by contacting Kyle Chapman or Rachel Bleshman of the Committee staff at (202) 226-2424. If you have any questions relating to this request, please contact John Sopko, Chief Counsel for Oversight, or David Nelson, Senior Investigator, with the Committee on Energy and Commerce staff at (202) 225-3641.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

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

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

ATTACHMENT

From *FDAWebview* March 26, 2007

FDA commissioner Andrew von Eschenbach made 11 false statements and three "misleading" ones in his sworn testimony to the House Oversight and Investigations Subcommittee last week, according to a detailed critique provided by whistleblower David Ross. His allegations, to do with the Sanofi-aventis antibiotic Ketek's approval, are believed to be being taken very seriously by subcommittee chairman Bart Stupak (D-MI). A former state trooper, Stupak has already subjected von Eschenbach to grueling and skeptical questioning over his "false" testimony, and has indicated he plans calling the commissioner back to explain in the presence of Sanofi-aventis.

In a page-by-page critique he provided to the subcommittee, supported by internal FDA emails between Ketek reviewers and senior managers, including Office of New Drugs deputy director Sandra Kweder, Office of Drug Evaluation IV director Mark Goldberg and CDER's Division of Scientific Investigations, Ross counted these von Eschenbach statements he said were false:

1. Ketek's data problems were only in one large study. Emails and FDA-483s as early as a 12/19/02 face-to-face meeting with the company substantiated that at least three sites were then known by both FDA and Sanofi-aventis to have serious problems, and a fourth site with problems came in within a week of that date.

2. That study, known as 3014, "had to be disregarded." Emails substantiate that it was not disregarded, and adverse event data from it were used, according to Kweder, to "qualitatively assess patterns of toxicity."

3. The adverse findings about 3014's data were "quite preliminary" at the time of the 1/8/03 advisory committee meeting that recommended Ketek be approved. False, says Ross, because at that time FDA had issued FDA-483s.

4. At the time of the advisory committee meeting, FDA believed "based on the best information available to us, that the concerns applied to only one site out of more than 1800." Completely false, says Ross, citing seven internal emails, because at least four sites were then implicated.

5. The compromised data were too preliminary to be presented to the advisory committee. Ross, however says this testimony was also false because "the director of the review office stated that it would not be 'productive' to present the data integrity concerns to the committee, not that the findings were preliminary."

6. Von Eschenbach testified that FDA had noted that the final decision regarding approval of each indication would be made after a review of the information and analyses requested in another approvable letter sent to Sanofi-aventis after the advisory committee meeting. False, says Ross, because this letter asked for detailed data integrity information but there is no record FDA ever reviewed it.

7. Von Eschenbech repeated later in his testimony that Study 3014 was dropped for consideration in making the decision to approve Ketek, but this was contradicted by Kweder's email.

8. Von Eschenbach said limitations, such as under-reporting, were taken into account in assessing the data derived from foreign post-marketing experience reports. But Ross says the medical officer did not take them into account because their quality was too poor — he "simply ignored the problems."

9. The commissioner's sworn testimony said that although "one case of liver failure that resulted in death was found, it was not clear that this represented a signal beyond what had been seen in the data available at the time of approval." False, says Ross, because "this was exactly the signal that reviewers had been concerned about during the review."

10. Three cases of serious liver toxicity, including one death, were described by von Eschenbach as having been previously reported to FDA, "although in less detail, making conclusions about them difficult to reach until the published information was available." But Ross says a 1/23/06 email from the medical officer responsible for Ketek said the reporting physician about these cases "gave an extremely detailed report to FDA; the company gave a very sparse report."

11. Von Eschenbach testified "On February 12, 2007, FDA acted on the recommendations of the joint panel and announced revisions to the labeling and indications for Ketek designed to improve the safe use of Ketek by patients." This, Ross says, was false because FDA "failed to institute the panel's recommendation that visual adverse events receive a black box warning."

Although it is a rare step for Congress to take, and Stupak's own comments during last week's hearing suggested he is willing to blame von Eschenbach's subordinates for his false testimony under oath, perjury before Congress is a felony and can be treated as such. Sources close to the situation say the least that von Eschenbach should do now that his testimony has been so exposed is to "ream out" the subordinates who helped him prepare it and demonstrate to the subcommittee how it can't happen again.

Unfortunately, the management culture at FDA — or, to be fair, at other agencies everywhere — is not known for this kind of internal, transparent rigor when senior people have been found to have erred. In case after case over the years, going at least as far back as the Generic Drug Scandal of the late 1980s, colleagues circle the wagons and stonewall their accusers until they go away — as they usually do. Only legislative oversight and the bright light of publicity seem able to alter this syndrome, but their performances have been patchy and inconsistent, which is why the behavior continues. Different players, same game.