U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Tuesday, Dec. 19, 2006

Grassley: Drug-Safety Agency's Statements Under Scrutiny

WASHINGTON – Sen. Chuck Grassley, chairman of the Committee on Finance, has expressed concern that the Food and Drug Administration may have misled a joint advisory panel on the antibiotic Ketek. Grassley requested a transcript of the panel's proceedings as part of the committee's ongoing investigation of how the FDA handled data integrity problems with a pivotal Ketek safety study. Before the advisory panel met last week, Grassley issued a report showing the agency intentionally withheld key information from an advisory panel in January 2003 and dismissed concerns expressed by staff-level officials about presenting the troubled study to the advisory panel.

"It's unfortunate that the FDA misled its expert advisors and the public regarding Ketek once already," Grassley said. "Further scrutiny may show that some agency officials misled the public yet again. Convening the joint advisory panel was a step toward greater transparency and accountability, but the FDA appears to have taken another step back in the attempt."

The text of Grassley's latest letter follows here.

December 18, 2006

Via Electronic Transmission
The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to oversee the proper administration of these programs, including the payment for prescription drugs regulated by the Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

Last week, the FDA convened a joint meeting of the Anti-Infective Drugs Advisory Committee and

the Drug Safety and Risk Management Advisory Committee (Joint Ketek Advisory Committee) to reconsider the risks and benefits of the antibiotic Ketek. As the Committee continues to investigate several allegations relating to the approval and post-market surveillance of Ketek by the FDA, I am troubled by a number of statements made on the record by agency officials, and other participants, before the Joint Ketek Advisory Committee, which appear to be factually inaccurate and/or misleading. It appears the FDA did not ensure that an expert advisory panel and the public received accurate information regarding Ketek. Pursuant to the Committee's ongoing investigation, I respectfully request a copy of the draft transcript of the proceedings of the Joint Ketek Advisory Committee as soon as a draft copy is made available to FDA. Please have your staff contact the Committee by no later than the end of this week, December 22, 2006, to identify the company that transcribed the Joint Ketek Advisory Committee proceedings and when FDA expects to receive a draft transcript. If you anticipate any difficulty in complying with the deadline, please immediately contact my Committee Staff.

Sincerely,

Charles E. Grassley
Chairman

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