United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

http://finance.senate.gov
Press_Office@finance-rep.senate.gov

M E M O R A N D U M

To: Reporters and Editors
Re: Grassley letter to FDA Commissioner regarding timing of investigation into Ketek sponsor
Da: Thursday, Dec. 20, 2007

Sen. Chuck Grassley, ranking member of the Committee on Finance, today released a letter that he sent to the commissioner of the Food and Drug Administration regarding the antibiotic Ketek. The letter reports in detail additional information that Grassley's staff investigation has learned from internal FDA communications and decisions related to the review of the drug maker's large safety study, Study 3014, and FDA's primary reliance on adverse-events data collected in foreign countries for evidence of Ketek's safety for marketing in the United States. Today's report follows a letter report made a year ago by Grassley about how the FDA intentionally withheld key information from its own advisory panel in January 2003 about the integrity of Study 3014. That study was used to support the safety of the drug despite concerns expressed by staff-level officials prior to the advisory panel meeting. Major finding from Grassley's new review include the following:

- Based on interviews with FDA employees responsible for the review of new drugs, heavy reliance on foreign post-marketing adverse events data as the basis for FDA's assessment of Ketek's safety in place of a large clinical trial is unprecedented. FDA officials could not identify any other case where FDA relied on foreign post-marketing data in this context for the approval of a new antibiotic.

- Based on a review of information provided to Senator Grassley's Finance Committee staff, the FDA lacks a system for tracking concerns and recommendations from its Office of Criminal Investigations. The FDA also lacks a formal policy or guidance that specifies which branches of the agency are responsible for monitoring or following up on matters that are referred to the agency's review divisions of the agency from criminal or regulatory investigators. In the case of Ketek, the lead agent recommended to his supervisors and to FDA management that a task force be formed to explore the scope of fraud in the conduct of Study 3014 and the extent of the drug company's involvement and/or knowledge of the fraud. However, the FDA did not form a task force or follow up on the agent's recommendation, and the agent's supervisors believed that once the matter was referred to FDA management, this safety matter would be addressed. It was not.

Here is a comment from Senator Grassley about the findings described in his December 2007 letter to the FDA Commissioner:

"The new information described in this letter raises additional questions about the way things happen inside the Food and Drug Administration. Why did FDA approve Ketek based on foreign data? Why did the FDA initiate its criminal review of the maker of Ketek around the same time I started asking questions? What's behind the disconnect between the right hand and the left hand of the FDA? How is the FDA to be held accountable to the American people, who rely on the agency for drug safety? The only conclusion I can draw right now is that I need to keep asking questions and scrutinizing what's going on at the FDA."

Grassley's letter is posted with this memo at http://finance.senate.gov.