U.S. SENATE COMMITTEE ON
Finance
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Grassley: Drug-Safety Agency Withheld Key Information From Expert Panel

WASHINGTON — As panelists prepare to meet regarding the risks and benefits of a relatively new antibiotic on the American market, Sen. Chuck Grassley said the Food and Drug Administration intentionally withheld key information from its own advisory panel in January 2003 about the integrity of a pivotal clinical trial used to support the safety of the drug and dismissed concerns expressed by staff-level officials before the advisory panel meeting.

Grassley has been conducting a lengthy review of the way the nation's drug-safety agency handled the approval and conducted post-market surveillance of the drug Ketek. Today, he released statements made by a number of members of the 2003 board in response to a survey he conducted about the FDA's posture on Ketek during those deliberations. Grassley reported his findings in a letter to the newly confirmed commissioner of the Food and Drug Administration. Grassley's letter report also includes detailed information about internal FDA communications and decisions that led to the agency's presentation of highly suspect information at that 2003 meeting.

"The Food and Drug Administration can't be in the business of misleading the public and hiding the truth," Grassley said. "I agree with these experts who say the agency was wrong for withholding information from them and to present a flawed study. The integrity of the agency is at stake. The new commissioner has promised to improve the way the FDA operates. If he lives up to his word, maybe something good will come out of this."

A newly formed FDA advisory panel will meet tomorrow and Friday to review the FDA's actions on Ketek, assess the risks and benefits of the drug, and make recommendations about the antibiotic's FDA-approved status. Grassley remains concerned that the FDA approved Ketek relying largely on foreign post-market data, reportedly an unprecedented step, after the pivotal safety study demanded by the agency proved to be useless for regulatory purposes.

A copy of Grassley's letter report is posted at http://finance.senate.gov.

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