

## Dingell, Stupak Applaud Grassley's Ketek Investigation, Announce Additional Hearings

### NEWS RELEASE

Committee on Energy and Commerce  
Rep. John D. Dingell, Chairman

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Washington, D.C. — Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, have commended Senator Grassley (R-IA) for releasing the second in a series of reports on his two-year investigation into disturbing allegations regarding FDA's approval of the antibiotic Ketek. Dingell and Stupak, who have been working closely with Senator Grassley on a parallel investigation, today announced their plan to invite Senator Grassley to testify about his Ketek findings at a hearing scheduled for February 2008.

“Until the FDA and the pharmaceutical industry get serious about addressing safety in new drug applications, the American people will continue to be guinea pigs for testing new drugs,” Dingell said. “Ketek is a case study for everything that can and did go wrong in the drug approval process — fraudulent trial studies, lax or non-existent enforcement of trial study noncompliance, FDA collusion in hasty drug approvals and industry conflicts of interest in the drug approval process.”

“I applaud Senator Grassley's continuing efforts to assure our Nation's drug supply is safe,” Dingell said. “His most recent report on Ketek is another reminder that the FDA has lost sight of its foremost mission to protect the American people from unsafe drugs.”

The lawmakers plan to hold at least two additional Ketek hearings. Senator Grassley has been invited to open the next Ketek hearing where he is expected to summarize the findings of his two-year investigation into the approval of Ketek. In addition, Grassley is likely to identify institutional shortcomings in the drug approval process, which, if left unchecked, will inevitably result in the continued approval of unsafe drugs. Future Ketek-related hearings will aim to use the Ketek approval process as a microcosm of the failure by multiple stakeholders, including the FDA, pharmaceutical sponsors, and third-party monitors, to ensure the integrity of clinical trials used to support the safety and approval of new drug applications.

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