United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
for Sen. Chuck Grassley
RE: FDA warning letter on Ketek study
DA: Wed., Oct. 24, 2007

Sen. Chuck Grassley issued the comment below about the warning letter (posted at http://www.fda.gov/cder/warn/warn2007) sent yesterday by the Food and Drug Administration to Sanofi-Aventis U.S. LLC regarding "objectionable conditions" found with the drug manufacturer's conduct of the large safety study (3014) it submitted to make the case for FDA approval of the antibiotic Ketek.

Sen. Grassley's comment:

"This warning vindicates the courageous FDA insiders who stuck out their necks to let the public know about the flawed safety study that was submitted to FDA to get Ketek approved. The letter starts to hold the drug maker accountable for failing to conduct its clinical trial in a legal way. Now it's time to hold the FDA accountable for its own failures to be a check on this process. I intend to make sure that happens."

Background information:

More than a year ago, Sen. Grassley began conducting extensive oversight of the way the Food and Drug Administration approved Ketek, even issuing a congressional subpoena for documents and directly confronting officials at the Department of Health and Human Services. He began his oversight of the FDA more than three years ago and has put pressure on the drug safety agency to act with more independence and transparency than it has demonstrated in recent years in order to build public confidence and strengthen public safety. Sen. Grassley has called the FDA's relationship with the drug industry "too cozy" and criticized the way that agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations. He has pursued legislative reforms of the agency's post-market surveillance operation and to require that all clinical trials be publicly registered.