



FDA to Sen. Grassley: Go Home

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By BRIAN ROSS AND JOSEPH RHEE REPORT:

Sen. Charles Grassley, R-IA, was sent home empty-handed today by federal health officials who refused the powerful Republican access to information on a controversial drug approved by the FDA.

"I smell a cover-up," Sen. Grassley said as he emerged from the headquarters of the Department of Health and Human Services.

Grassley has been investigating why FDA officials approved the sale of the antibiotic Ketek even after the government learned safety tests on the drug had been forged. Grassley wanted to speak with the FDA investigator who uncovered the fraud.

According to an FDA document obtained by ABC News, there have been reports of four deaths and 35 liver failures or serious injuries among people taking the drug, which is used to treat bronchitis and other respiratory infections.

"I can say without a doubt that this drug should have been withdrawn," Grassley told ABC News.

The study with the forged test results was conducted at a former weight loss clinic in Gadsden, Alabama. Dr. Maria Anne Kirkman-Campbell is serving five years in prison for falsifying safety test results on Ketek.

A former nurse, Michelle Snedeker, told ABC News she was ordered to forge documents and report data on people who had not even been given Ketek. The doctor was paid \$400 for each of the 407 subjects that she enrolled for the study.

The maker of Ketek, Sanofi-Aventis, says "the benefit of Ketek outweighs any known risk." Along with the FDA, the company insists Ketek is safe, based on tests that were done in Europe.

The FDA would not comment on Sen. Grassley's investigation but says there are no plans to take Ketek off the market, despite the recent death and injury reports.

An FDA spokesman said the agency was considering the addition of a warning label on the outside package of the prescription drug.