

Stupak Calls for FDA Resignation

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By Ken Thomas, Associated Press Writer

Key House Democrat Says Head of FDA Should Resign

WASHINGTON (AP) -- A key House Democrat said Thursday that the head of the Food and Drug Administration should resign in the wake of a probe over an antibiotic and news of a blood thinner linked to allergic reactions and four deaths.

Rep. Bart Stupak, D-Mich., who heads an investigative panel that conducts oversight of the agency, said in an interview with The Associated Press that FDA Commissioner Andrew von Eschenbach should step down because "it's just a total lack of leadership."

Stupak, chairman of the Subcommittee on Oversight and Investigations, said he had lost confidence in the commissioner and other top FDA officials over the handling of inspections and oversight by the agency.

FDA spokeswoman Heidi Rebello said that "there isn't really anything to say beyond we've been responsive to the congressman as much as possible."

Stupak's panel has investigated a Sanofi-Aventis antibiotic called Ketek which was linked to death and liver failure in 2006. Stupak has alleged that the FDA approved the antibiotic despite knowing a key safety study of the drug was plagued by faulty data.

Earlier this week, Stupak and Rep. John Dingell, D-Mich., the chairman of the House Energy and Commerce Committee, threatened to hold Health and Human Services Secretary Michael Leavitt in contempt for refusing to turn over FDA briefing documents subpoenaed by the committee in the probe. Leavitt oversees the FDA and other health care agencies.

The documents in question were used to prepare von Eschenbach for his appearance before House lawmakers last year. The commissioner testified that FDA did not use the flawed safety study to approve Ketek. But Stupak has called that statement untrue and subpoenaed von Eschenbach's notes to determine if he lied under oath.

The agency has said there was no intention to deceive the public.

Sanofi-Aventis SA has said one of its predecessors, Aventis, was not aware of fraud connected with a key Ketek study until after the study was submitted to the FDA.

Additionally, Stupak said he was dismayed to learn this week that U.S. health officials had not inspected a Chinese factory that may be the source of problems with a Baxter International blood thinner tied to hundreds of reports of allergic reactions and the four deaths.

Stupak said in a conference call with Michigan reporters earlier Thursday that the panel had asked for briefings on the drug heparin "and they've told us they're too busy. They can't brief us on what's going on. Maybe it's time that we replace the leadership there at the FDA."

Rebello said late Thursday that the FDA would brief members of Stupak's staff on the situation on Friday.

The FDA wants to inspect the facility as soon as possible and has requested its inspection data and other reports.

Baxter has said it buys the active ingredient for heparin from a supplier that manufactures it at the Chinese factory and at a U.S. facility. The company said it inspected both facilities last year and found no quality issues but it plans to re-inspect the facility as part of its own investigation.