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Subpoenas Issued For Witnesses To Appear At February 2008 U.S. House Committee Hearing On Ketek

Tuesday, January 29, 2008

Congress Wants To Know When Sanofi-Aventis And The FDA Learned About Fraud Involved With Ketek Study 3014

(Posted by Tom Lamb at DrugInjuryWatch.com)

Soon after noon on January 29, 2008 Ed Silverman posted on his Pharmalot blog an article, "[House Committee Will Subpoena FDA Over Ketek](#)", which reported this breaking news about the Congressional investigation into Ketek, Sanofi-Aventis, and the FDA:

At its hearing this morning, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations voted unanimously to approve a motion to subpoena FDA officials and investigators over clinical trial data for the Sanofi-Aventis antibiotic [Ketek], which has been linked to liver failure.

This same Pharmalot post about Ketek provided access to a [January 25, 2008 memorandum sent by the committee's chairman, John Dingell, and Bart Stupak, the head of a subcommittee, both from Michigan, which had](#)



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previewed the actions that would be taken at this January 29 meeting.

More detail came soon thereafter in this CQ Today Midday Update article, "[House Energy Panel OKs Subpoenas in FDA Probe](#)", published January 29 online:

The subcommittee is seeking testimony from:

- FDA special agent Douglas Loveland.
- FDA special agent Robert West.
- Robert Ekey, former special agent at the FDA.
- Ann Marie Cisneros, a clinical researcher who was involved in the testing.

The panel also authorized a subpoena to Health and Human Services [(HHS)] Secretary Michael O. Leavitt for records related to FDA Commissioner Andrew C. von Eschenbach's testimony before the House Energy and Commerce Committee on March 22.

Stupak, who offered the motion, said "the FDA has been less than forthcoming with either witness or document production in connection with our drug safety investigations."

The Michigan Democrat added that the panel requested briefing books and related documents six days after the March hearing, but the agencies refused to provide them, and "no legal authority has been provided to the committee to support this refusal."

And not much later the same day we got reactions to this latest development in the Ketek investigation from a *Reuters* January 29 article, "[US panel OKs subpoenas in Sanofi antibiotic probe](#)", by reporter Lisa Richwine:

FDA spokeswoman Karen Riley said the agency had provided more than 80,000 pages of Ketek information to House investigators and would continue to cooperate with the probe.

"We also have made staff available who have met with the committee, and we have made every effort to be responsive to the committee's requests," she added.

HHS spokeswoman Christina Pearson said the health department had "worked hard to be responsive to congressional requests related to Ketek" for the past two years.

"We will continue to work with the House toward a solution that is responsive but will not compromise investigations or the ability of senior officials to obtain accurate information and frank advice from their staffs," she said.

Sanofi-Aventis spokeswoman Julissa Viana repeated earlier comments saying Aventis was not aware of the fraud in Study

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3014 until after it was submitted to the FDA.

"We have critically reviewed the record of the clinical study being reviewed and have identified important lessons learned to improve policies and procedures," she said.

Elsewhere on Capitol Hill, as some may recall, in [December 2007 Senator Charles Grassley wrote a letter to the FDA that raised questions about the agency's approval of Ketek in 2004.](#)

We look forward to the meeting of this House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, currently scheduled for February 12, 2008. According to the January 29 *Reuters* article, their Ketek investigation will continue in this manner:

The panel wants to question the witnesses about "their knowledge of whether Aventis was aware of substantial data integrity problems in Study 3014 at the time of submission to FDA," Stupak said.

Be assured that we will report out what is learned at this February 12 Congressional hearing about the who-knew-what-and-when as regards this now infamous Ketek Study 3014.

P.S. According to a February 13, 2008 *Bloomberg News* article, "[White House rejects subpoena](#)", yesterday HHS Secretary Leavitt refused to comply with that subpoena issued by this investigative subcommittee of the House Energy and Commerce Committee regarding papers used to prepare FDA Commissioner von Eschenbach for testimony that he had given at a hearing on Sanofi-Aventis' antibiotic Ketek in March 2007. (2/13/08)

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