

Energy and Commerce Subcommittee Subpoenas FDA Witnesses, Documents

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NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

For Immediate Release: Tuesday, January 29, 2008

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ENERGY AND COMMERCE SUBCOMMITTEE SUBPOENAS FDA WITNESSES, DOCUMENTS

In a bipartisan vote today, the Energy and Commerce Committee's Subcommittee on Oversight and Investigations unanimously approved the issuance of subpoenas for the testimony of two current and one former criminal investigator of the Food and Drug Administration (FDA) for a hearing on February 12, 2008. The Subcommittee is seeking testimony regarding the agency's ability and willingness to protect Americans from excessive risk from prescription drugs. The drug involved is Ketek, an antibiotic produced by Sanofi-Aventis (formerly Aventis), which had two of its three indications removed by the FDA for safety concerns just before the Subcommittee's first hearing on the matter last February.

At the same business meeting, the Subcommittee also unanimously approved a subpoena to the Secretary of the Department of Health and Human Resources (HHS) for documents related to the briefing book and other materials used to prepare FDA Commissioner Andrew von Eschenbach for his testimony before the Subcommittee on March 22, 2007.

“The Committee gave HHS and FDA every opportunity to produce these witnesses and documents voluntarily,” said Rep. John D. Dingell, Chairman of the Committee on Energy and Commerce. “The Commissioner and Department officials failed to identify a single legal argument to support their attempt to limit the Committee’s ability to conduct a thorough and fair investigation of the Ketek matter. There is unanimous sentiment on the Committee that HHS and FDA must fully cooperate with our investigations.”

“I regret that subpoenas were necessary, but I was pleased to see Republicans on the Subcommittee are as committed as we are to this investigation,” said Rep. Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations. “It is important for the Subcommittee to ascertain what the FDA and Aventis knew and when they knew it regarding fraud in the pivotal safety trial for Ketek. The integrity of the drug approval process is at stake. Questions about the accuracy of testimony by Commissioner von Eschenbach last year regarding the approval of Ketek must also be answered. One would think the Commissioner would be eager to discover the truth, but instead, he has resisted our request for his briefing documents since March 28, 2007.”

A fourth subpoena for testimony was issued to a private sector witness who had relevant information for this inquiry. Three other document requests were removed from consideration for subpoenas after the FDA delivered the material last night. These requests dealt with records related to the Ketek investigation, ongoing investigations of salary and bonus abuses by HHS employees, and FDA’s lack of oversight over Institutional Review Boards.

January 29, 2008 Subcommittee Motion

- 30 -

Prepared by the Committee on Energy and Commerce

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