

Dingell, Stupak Assert that FDA Letter to Sanofi-Aventis Vindicates Whistleblowers; 'Warning Letter'

Reps. John D. Dingell (D-MI), Chairman of the Energy & Commerce Committee, and Bart Stupak (D-MI), Chairman of its Subcommittee on Oversight and Investigations, announced that FDA's release of a 12-page "warning letter" yesterday to Sanofi-Aventis is a vindication for the whistleblowers who testified before the Committee at a February 13, 2007, hearing.

NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

For Immediate Release: October 25, 2007

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Dingell, Stupak Assert that FDA Letter to Sanofi-Aventis Vindicates Whistleblowers
& "Warning Letter"; Shows FDA Knew Ketek Safety Study Was Compromised

Washington, DC — Reps. John D. Dingell (D-MI), Chairman of the Energy & Commerce Committee, and Bart Stupak (D-MI), Chairman of its Subcommittee on Oversight and Investigations, announced that FDA's release of a 12-page "warning letter" yesterday to Sanofi-Aventis is a vindication for the whistleblowers who testified before the Committee at a February 13, 2007, hearing. During the hearing, witnesses alleged that Sanofi-Aventis was complicit in scientific misconduct in a safety study of the antibiotic drug Ketek.

"The Committee's investigation, along with the work led by Senator Grassley in the last Congress, substantiated allegations that the manufacturer of Ketek and the FDA had knowledge of falsifications in the pivotal safety trial conducted before January 2003, when Ketek was presented to an Advisory Committee," said Dingell. "The warning letter issued to Sanofi-Aventis confirms that the company was aware that data it presented to FDA

was compromised. Even more troubling is the fact that, although the FDA was fully aware it received distorted information, the agency decided to present the study as valid to an Advisory Committee.”

The lawmakers noted that only after the Congress began investigating serious adverse events associated with Ketek, including liver failures that resulted in 13 deaths, did the FDA change the labeling and add a “black box” warning for its use.

“The Administration should know that whenever it puts the interest of drug companies above that of the public health, this Subcommittee will investigate and expose such conduct. Unfortunately, the truth comes too late for some victims,” added Stupak. “With this warning letter to Sanofi-Aventis, FDA’s last excuse for blocking our committee’s investigation has been stripped away. We now intend to obtain FDA’s entire closed criminal case file. We will interview the case agents who FDA has thus far refused to let us talk to as well as other key FDA employees. Our Committee will also determine if there are other current or former FDA and corporate officials who were involved in corrupting the approval process of this drug.”

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Prepared by the Committee on Energy and Commerce

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