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Senator Grassley's December 2007 Letter To FDA Questions Agency's Approval Of Ketek

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POSTED: Wednesday, January 02, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Sanofi-Aventis Antibiotic Has Been Subject Of Controversy Since Reports of Liver Damage Surfaced In Early 2006

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

The [safety concerns about Ketek \(telithromycin\)](#) began in early 2006 after Health Canada and the European Union's European Medicines Agency (EMA) issued alerts based on the online "early" release of an article about Ketek that would later be published in the March 21, 2006 edition of the *Annals of Internal Medicine*. This article reported three cases in a North Carolina hospital where there was liver failure associated with Ketek use.

In May 2006 Senator Charles Grassley (R-Ill.) as well as Congressmen Edward Markey (D-Mass.) and Henry Waxman (D-Calf.) asked the FDA for some explanation about the agency's decision to approve the antibiotic Ketek in 2004. This scrutiny from Capitol Hill followed in the wake of a May 1, 2006 investigative piece in *The Wall Street Journal* about how the FDA approved Ketek despite knowing about some problems with a key study -- known as trial 3014 -- which was submitted to the FDA by Ketek's manufacturer, Sanofi-Aventis (SNY).

Finally, in October 2007 the FDA posted on its web site a copy of an 11-page "Warning Letter" to Sanofi-Aventis about problems with Ketek Study 3014.

Most recently, on December 19, 2007 Senator Grassley, ranking member of the U.S. Senate Committee on Finance, sent a 22-page letter to FDA commissioner Andrew C. von Eschenbach, M.D., regarding the Committee's ongoing investigation of Ketek.

In his letter Grassley reports what has been learned over the past 16 months, during which time the Committee's staff reviewed documents and information obtained from the Department of Health and Human Services (HHS), the FDA, FDA advisory committee members, and the drug company Sanofi-Aventis. The primary focus of Grassley's letter is the FDA's review of Sanofi-Aventis' Study 3014, and the FDA's unprecedented reliance on adverse-events data collected in foreign countries for evidence of Ketek's safety when approving this antibiotic for sale in the U.S.

Also in his December 19 letter to the FDA Commissioner Grassley presents the Committee's findings as regards some of the inspections and investigations

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conducted by FDA's Division of Scientific Investigations (DSI) and Office of Criminal Investigations (OCI) concerning alleged improprieties and misconduct associated with Study 3014.

As regards the FDA's approval of Ketek on April 1, 2004, from the first few pages of this December 2007 letter from Senator Grassley we learn the following:

Current and former FDA employees alleged that FDA relied solely on foreign postmarketing adverse event reports as evidence of Ketek's safety for marketing when the Agency could no longer rely on the large safety study, Study 3014. These employees questioned whether or not the use of such data as the primary basis for the Agency's safety assessment of Ketek met the standards for approval of the drug...

FDA appears to have relied primarily on foreign post-marketing safety data to

assess the safety of Ketek as a new antibiotic for marketing. Based on interviews with current and former FDA staff, heavy reliance on foreign post-marketing safety data in this context is unprecedented. A week before Ketek was approved, FDA's Division of Scientific Investigations concluded that the data from a large clinical trial were unreliable. The study was conducted to evaluate specific adverse events associated with Ketek. In place of the large clinical trial, the FDA based its assessment of the safety of Ketek on foreign post-marketing adverse event reports, despite inherent limitations with that data, including underreporting and reporting bias. When asked by Committee Staff, FDA managers and reviewers could not identify any other case where FDA relied on foreign postmarketing data as the primary basis of its safety assessment for the approval of a new antibiotic.

As the stated purpose of this December 19 letter to Dr. von Eschenbach was not only to report the Committee's findings but, also, to "request your comments and responses regarding these findings and some of the other allegations and concerns that have been brought to the Committee's attention", we will likely be reporting more about Ketek and Study 3014 in the months to come.

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