

# Liver Failure Warning Upgraded for Telithromycin

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The Food and Drug Administration has determined that the antibiotic telithromycin (Ketek) may be associated with serious liver injury and liver failure, and has been linked to four deaths and one liver transplant. The drug's maker, Sanofi-Aventis, has upgraded a caution in the drug's label on the potential for liver injury to a bolded warning that serious he-

patic injury has been "observed during or immediately after treatment." Injury has progressed rapidly after just a few doses, according to the company.

Ketek has not received a black box warning, and both the FDA and Sanofi say the drug's benefits outweigh its risks.

"We are advising both patients taking Ketek and their doctors to be on the alert for signs and symptoms of liver problems," Dr. Steven Galson, director of the FDA's Center for Drug Evaluation and

Research, said in a prepared statement.

However, the drug maker has stopped enrollment in five pediatric trials investigating use of Ketek in acute otitis media, community-acquired pneumonia, and tonsillitis in children 6 months to 18 years old.

The new warning is based partly on an FDA analysis that found that Ketek may be associated with 12 cases of liver failure and four deaths since its approval in 2004. "We're engaged in ongoing discussions with the FDA regarding a detailed medical

evaluation of hepatic events reported in connection with Ketek use," confirmed Sanofi spokeswoman Melissa Feltmann, who would not comment further.

Ketek is currently approved for use in adults to treat community-acquired pneumonia, sinusitis, and acute exacerbation of chronic bronchitis.

"We still believe that the benefit of Ketek outweighs any known risks of the drug when used for its FDA-approved indications," said Emmy Tsui, another Sanofi spokeswoman.

Ms. Tsui said therapy will continue according to protocol in children already enrolled in the five pediatric trials, but that Sanofi would not enroll any new trial participants until it was certain that its development program "remains consistent with the current thinking of the FDA regarding the structure and design of antibiotic drug development in pediatrics."

The Senate Finance Committee has been investigating Ketek's approval, as well as a postmarketing safety study that was later found to be fraudulent.

For several months, committee chairman Charles Grassley (R-Iowa), has been complaining that he's been stonewalled by the FDA in his attempts to meet with the agency's special agent who investigated the fraud. In mid-June, he visited the Department of Health and Human Services headquarters to demand such a meeting. Vince Ventimiglia, assistant secretary for legislation at HHS, said the agency has a policy of prohibiting access to lower-level investigators. Sen. Grassley, however, pointed out numerous instances of such investigators talking to the legislative branch, said a spokeswoman for the senator. ■

## Anthrax Vaccine Stockpile Will Reach 10M Doses

The Department of Health and Human Services is buying 5 million additional doses of Anthrax Vaccine Adsorbed from the BioPort Corp., Lansing, Mich.

The purchase modifies an existing HHS contract with BioPort awarded in May 2005, also for 5 million doses, the agency said in a statement. The vaccine will be placed in the Strategic National Stockpile and will be available for use in the event of a bioterror anthrax incident. "Together with an already substantial supply of antibiotics, which is the nation's first line of defense against an anthrax attack, the additional [anthrax] vaccine will further diversify the stockpile's medical countermeasures," according to the statement.

The HHS Office of Public Health Emergency Preparedness will manage the vaccine contract through Project BioShield. The 10 million doses will act as a bridge while another type of anthrax vaccine is developed, said HHS spokesman Bill Hall. If a physician suspects a case of anthrax, local and state public health departments should be contacted immediately, he said.

—Nancy Nickell

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