Sanofi Heart Medication Multaq Has Constantly Been On FDA's Radar During 2010 And 2011

Liver Failure, Renal Impairment, And Cardiovascular Problems Cited As Potential Signals Of Risk Involving Multaq

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 12, 2011; see http://bit.ly/r2eVlD)

We have reported previously here on some of the serious side effects that have been associated with Multaq (dronedarone):

Multaq Update: European Safety Review Expanded To Cardiovascular Side Effects Risk In July 2011

Sanofi-Aventis "Dear Doctor" Letter Will Warn Heart Drug Multaq Associated With Liver Failure

A July 18, 2011 article by Robert Lowes, "New FDA Watch List Has Drug Making Fifth Straight Appearance", published online by *Medscape* (free subscription required) points out that Multaq was on the FDA's Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) list for all four quarters in 2010:

- The AERS watch list for the first quarter of 2010 cited potential signals of congestive heart failure for the drug. On February 22, 2011, the FDA revised the warnings and precautions section of dronedarone's label regarding patients with new or worsening heart failure during treatment to state that postmarketing cases of such problems have been reported....
- In the second quarter, AERS identified potential signals of torsade de pointes, a rare kind of ventricular tachycardia.
- The list for the third quarter of 2010 listed a potential signal for an interaction with warfarin that increases its anticoagulant effect. On March 21, 2011, the drug interactions section of dronedarone's label was changed to mention postmarketing cases of higher internal normalized ratio (INR) clotting times with or without bleeding events in patients taking warfarin....
- Potential signals of liver failure for dronedarone appeared in the watch list for the last 3 months of 2010. On February 11, 2011, the FDA changed the warnings and precautions section of the label to mention postmarketing cases of hepatocellular liver injury and acute liver failure, and the need to promptly discontinue dronedarone if such an injury is suspected....

In addition, Multaq was on this so-called "FDA watch list" for the first quarter of 2011, when the FDA detected potential safety signals concerning renal impairment and kidney failure.

Just as the FDA is continuing to evaluate these issues to determine the need for any regulatory action, we will continue to monitor the safety profile of Multaq.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his

blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com