Multaq Cardiovascular Deaths Overshadow Earlier Liver Injury Concerns For Drug Regulators

FDA Now Looking At Two-Fold Increase In CV Deaths, Strokes, And Heart Failure Hospitalizations From PALLAS Study Data

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 22, 2011; see http://bit.ly/pnheTF)

In mid-June 2011, soon after Sanofi-Aventis announced that it was discontinuing the late-stage PALLAS study, the European Medicines Agency (EMA) expanded its safety review of Multaq (dronedarone) to include cardiovascular side effects.

Previously, starting in January 2011, drug-induced liver injury had been the primary safety issue for Multaq.

Then, on July 21, 2011 the FDA issued this rather disturbing Safety Announcement about a two-fold increase in cardiovascular deaths associated with Multaq:

> The U.S. Food and Drug Administration (FDA) is reviewing data from a clinical trial [the Permanent Atrial fibriLLAtion Outcome Study Using Dronedarone on Top of Standard Therapy (PALLAS) study, sponsored by Sanofi Aventis (the maker of Multaq)]that was evaluating the effects of the antiarrhythmic drug Multaq (dronedarone) in patients with **permanent** atrial fibrillation. The study was stopped early after the data monitoring committee found a two-fold increase in death, as well as two-fold increases in stroke and hospitalization for heart failure in patients receiving Multaq compared to patients taking a placebo....
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> A critical question is whether and how the unfavorable results of the PALLAS study, obtained in patients with permanent atrial fibrillation, apply to patients who use Multaq for the approved indications (non-permanent atrial fibrillation, also known as paroxysmal or persistent atrial fibrillation)....
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> FDA has received and is currently reviewing preliminary results from the PALLAS study and will review the final results when they become available.

Source: "FDA Drug Safety Communication: Multaq (dronedarone) and increased risk of death and serious cardiovascular adverse events"

In its July 21, 2011 press release, "European Medicines Agency updates on ongoing benefit-risk review of Multaq", the EMA said that it aimed to conclude its safety review of Multaq by September 2011.

The FDA, however, has set no target date for completing its review of the just recently available safety data from this PALLAS Multaq study.

Likewise, Health Canada, which is reviewing the heart-related safety of Multaq, also, has not set any date by which it might make its safety determination.

Together with those patients who use or used Multaq and concerned cardiologists around the country. who are looking for some safety-issue guidance, we will watch to see what the EMA, FDA, and Health Canada decide about the fate 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